Copyright

Version: A03
No.: 046-00000135-00
Revision date: 2021/01
Product Name: Ventilator
Product Model: V3/V3A
Manufacturer: Shenzhen Comen Medical Instruments Co., Ltd.

Statement

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Warranty

Comen will be responsible for the safety, reliability and performance of the product within the warranty period, if all of the following conditions are satisfied:

- The product is used in accordance with this ***Manual***.
- The product is installed, maintained or upgraded by approved or authorized personnel by Comen.
- The storageand operating environments for the product shall comply with the recommended information and product specifications contained in this manual.
- The serial number label or manufacturing mark of the product is clearly legible.
- The damage is not caused by human factors.
- All replaceable components for maintaining, accessories, and consumables are originally supplied by Comen or recognized by Comen.

Products conforming to Comen’s warranty service policy can enjoy free services; for products not covered by the warranty scope, Comen will provide customer-paid services. If a product is transported to Comen for repair, the transportation expense (including customs fees) should be on the customer’s account.

Repair Services

The warranty period of the product you purchased is subject to the relevant sales contract.

Consumables are consumable materials that should be replaced after each use or vulnerable materials that require periodic replacement; consumables are not covered by the warranty.

The warranty period starts from the “Installation Date” shown on the *Equipment Warranty Card* provided attached to the product. *Equipment Warranty Card* is the only proof to calculate the warranty period. To protect

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your rights and interests, please fill in the *Equipment Warranty Card* after installation of the equipment, and hand over the second copy of the ("Comen Retained" Copy) *Equipment Warranty Card* to installer or send it back to the Customer Service Department of Shenzhen Comen Medical Instruments Co., Ltd.

Please note that the following circumstances will void the warranty:

1) The *Equipment Warranty Card*is not filled in and returned by the customer within30 days after installation and acceptance;
2) The equipment SN provided by the customer is incorrect (we confirm whether warranty service can be provided based on the equipment SN).

You are entitled to our free after-sales services within the warranty period of the product; however, please note that Shenzhen Comen Medical Instruments Co., Ltd. will only provide paid services and you are required to pay the repair charges and part costs if the product requires repair for any of the following reasons:

- Man-made damage
- Improper use
- Grid voltage beyond the range specified for the product
- Failures caused by force majeure natural disaster
- Replacement with or use of any parts or accessories not accepted by Comen or repair by any person not authorized by Comen
- Other failures not arising from the product itself

Any failure of the product caused by use of reagents or other consumables not accepted by Comen will not be covered by the scope of repair services provided by Comen.
Upon expiration of the warranty period, Comen can continue to provide paid repair services.
If you do not pay or delay the payment for any charges of our paid repair services, Comen will suspend the provision of repair services until you make the payment.

Return

If the products need to be returned to Comen, please contact Comen After-sales Service Department to acquire the right to return the goods. You must provide product serial number, which can be found on the product’s nameplate. If the serial number is illegible, your return request will be rejected. Please also present the manufacture date and briefly describe the reason for return.

After-sales Service Provider

Name: After-sales Service Department of Shenzhen Comen Medical Instruments Co., Ltd.
Address: Floor 10 of Building 1A, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen
Tel.: 0755-26431236
Fax: 0755-26431232
Customer Service Hotline: 4007009488
Postcode: 518000

Preface

This manual provides detailed descriptions of the performance, operation methods and other safety information about V3/V3Aventilator. Please read carefully and understand the content of this manual so as to ensure the safety of the patients and operator.
This manual introduces the product of the most complete configurations. Some configurations or functions may not be available on the product you have purchased. If you have any questions, please contact us.
Please keep this manual near the device for easy and prompt access when needed.

Applicable object

The user manual is applicable for professional clinical medical staffs, qualified after training, or authorized personnel.

Illustrations

All illustrations provided herein are for reference only. The menus, options, values and functions shown in the illustrations may be not exactly identical to those shown on the product.

Conventions

- →: Represents operating steps.
- [Character]: Represents character strings in the software.
- Bold and italic: Represents chapters quoted.

Password

Password to enter the related settings of the ventilator:

- User maintenance: 5188

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Chapter 1 Safety

This product does not involve any information about danger levels.

1.1 Safety Information

DANGER

- **Indicates an imminently hazardous situation, which, if not avoided, could result in death, serious injury or property damage.**

WARNING

- **Alerts you to situations that may result in serious consequences or adverse events or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of user or patient.**

CAUTION

- **Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.**

Note

- **Emphasizes important precautions and provides instructions or explanations for better use of the product.**

WARNING

- **This product can be used only by trained, qualified medical staff.Any unauthorized personnel or personnel without training shall not perform any operations. The equipment must be operated strictly in accordance with this manual.**
- **Prior to use, user must check the device and its accessories to ensure their normal and safe operation.**

- **The equipment cannot be used with inflammable anesthetic gas mixed with air, oxygen or nitrous oxide**
- **To prevent damage to the ventilator, the ventilator is only connected to clean and dry medical oxygen (≥99.5%).**
- **The ventilator cannot be connected to oxygen 93, the accuracy of the O_2monitoring is not maintained when used with Oxygen 93.It shall not be used with gas supplied from oxygen concentrators.**
- **Do not place the power plug used to disconnect the device from supply mains in a position not easily accessible by the operator.**
- **Do not place the ventilator near a barrier that will block cold air flow; otherwise the equipment will be overheated**
- **Do not cover the ventilator or place in aposition that affects proper operation, not block the gas intake port or emergency intake port, thereby interfering with patient ventilation..**
- **Do not open the housing of the device to avoid the potential risk of electric shock. The ventilator must be maintained and upgraded by service personnel having been trained and authorized by Comen.**
- **Alarm volume and upper and lower alarm limits should be set depending on the patient. Do not monitor the patient relying on the sound alarm system. If the alarm volume is set too low, it may further endanger the patient. The most reliable monitoring method is to pay close attention to the patient's actual clinical condition.**
- **The physiological waveforms, parameters, alarms and other information displayed on the screen of the equipment are only for reference by doctors, which shall not be used as a basis for clinical treatment.**
- **All personnel shall be aware that the risk of infection exists on some parts of the ventilator like reuse of disposal parts.**
- **The settings under maintenance menu can be modified only after disconnecting the patient from the equipment.**
- **Positive pressure breathing may be accompanied by the following side effects: barotrauma, hypoventilation, hyperventilation and other hazards.**
- **To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. If the power socket is not connected to protective earth conductor or there is any doubt about the integrity of protective earth connection, please use the rechargeable battery to supply voltage to the device. The supplementary insulation only achieved when qualified external DC power source is assured. .**
- **Please use external power supply (AC/DC power supply) in time before the battery runs out.**

- **Please observe the local regulations or the hospital's waste disposal policy when disposing of packaging materials. Keep the packaging materials out of the reach of pediatric.**
- **Use of the ventilator near a high-frequency electrosurgical unit, defibrillator or short wave therapeutic apparatus will affect normal working of the ventilator and cause hazards to the patient.**
- **To prevent electromagnetic interference from interrupting the operation of the ventilator, do not use other devices near or together with the ventilator. If it is necessary to use other devices near or together with the ventilator, please verify that the ventilator can work normally in the setting state when other devices are used.**
- **Use of an anti-static or conductive mask or breathing tube when a high-frequency surgical instrument is used could result in burn. Therefore, please do not use any anti-static or conductive mask or breathing tube.**
- **Please carefully place the power cord and the cables of various accessories to prevent the patient from getting wound or suffocated, entanglement of the cables, or electrical interference.**
- **If the monitoring system inside the equipment malfunctions, there must be an alternative scheme to ensure backup monitoring. Under all circumstances, the ventilator operator must be responsible for proper ventilation and safety of the patient.**
- **An alternative means of ventilation shall be available whenever the ventilator is in use. If a faultis detected in the ventilator, disconnect the patient from it and immediately start ventilation with such a device. For example, using a manual respirator.**
- **According to regulatory requirements, oxygen concentration monitoring is required when the equipment is applied to the patient. If the equipment you are using is not provided with this function or the function is disabled, please use a monitor complied with ISO 80601-2-55 to monitor oxygen concentration.**
- **The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.**
- **When oxygen is used, the ventilator should be kept away from sources of ignition.**
- **The ventilator shall not be used with nitricoxide. Such use might cause the ventilator to not function correctly, causing patient death orserious deterioration of health.**
- **When using nebulisation or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.**
- **The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebulizer.**
- **For non-invasive ventilation, the tidal volume actually exhaled by the patient will be different from the monitored value from the ventilator due to the leakage around the mask.**

- **The ventilator cannot be used in poisonous or contaminated environment, which is to avoid hazardous substances entering the patient circuit.**
- **All analog and digital devices connected with this system must have passed any required certifications in accordance with applicable standards (e.g., IEC 60950 Data processing equipment and IEC 60601-1 Medical electrical equipment), and all configurations should comply with the requirements as specified in the effective version of IEC 60601-1 Personnel responsible for connecting auxiliary devices to the signal input/output port should be equipped with the medical system and be liable to verify if the system complies with IEC 60601-1. If you have any questions, please contact us**
- **When the port is connected with patient or when replacing the O_2 sensor, do not touch the signal I/O port, otherwise the patient may get injured.**
- **Do not throw the O_2 sensor into fireto prevent explosions.**
- **When the patient cable port, network port and other signal ports connected to multiple equipment, the total leak current caused shall conform to IEC60601-1.**
- **This equipment cannot be used in a MRI environment.**
- **When the gas input system of the ventilator malfunctions or becomes abnormal, please contact the manufacturer to repair the system by designated personnel.**
- **When passing the ventilator through an obstacle (e.g., threshold), please carefully move the ventilator to avoid damage caused by toppling over.**
- **Before moving the ventilator, please remove the supporting arm to prevent the ventilator from toppling over.**
- **When stop moving the ventilator, please press down the brake pedal to avoid damage caused by accidental movement of the ventilator.**
- **To avoid personal injury or equipment damage, please ensure that the ventilator has been secured to a trolley or placed on a safe and steady platform.**
- **To prevent the patient from the harm caused by equipment, when the [** Technical Error] alarm is triggered, please remove the equipment immediately, record the failure code and contact our After-sales Service Department.**
- **To avoid malfunction of the ventilator, do not splash or spatter any liquid onto the ventilator.**
- **The blower fan will cause the gas being heated. Please ensure the pipe length from humidifier to the Y-joint greater than 1.2 m, so as to reduce the gas temperature in pipe and prevent the patient from being injured.**
- **When the buzzer alarms, please stop using the ventilator immediately and contact our After-sales Service Department.**
- **Do not modify this equipment without authorization of the manufacturer.**

- **Equipment and accessories s cannot be stored and used in extreme environments.**
- **Defibrillation energy has no effect on the applied parts of the ventilator.**
- **Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health.**
- **The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.**
- **It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flow rate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.**

CAUTION

- **The ventilator is suitable for use in patient environments.**
- **The ventilator must be maintained and checked regularly by specially trained personnel.**
- **When a mask is used for ventilation, avoid high airway pressure because this may cause gastrectasia.**
- **When P_{peak} is greater than 33cmH_2O, the risk of gaseous distention can be increased. At the moment, invasive ventilation shall be considered to use.**
- **Once the ventilator is connected to the patient, there should always be a appointed one to watch and monitor the operation status of the equipment.**
- **During the ventilator running, do not dismantle the inspiratory valve component and the expiratory valve component unless the ventilator is in standby.**
- **Electromagnetic field may affect the performance of the equipment. Therefore, other devices used near the equipment shall conform to the applicable EMC requirements. Mobile phones or X-ray are all potential sources of interference since they all transmit high-intensity electromagnetic radiation.**
- **This system can work normally under the anti-interference level identified in this User Manual. If the interference level is higher than this level, an alarm could be triggered, and mechanical ventilation may stop. Take care to avoid false alarms of the system caused by high-intensity electric field.**
- **To reduce the risk of fire, do not use any gas hose component that is worn or contaminated by combustible material (e.g., oil, grease).**
- **To reduce the risk of fire, only use hoses that are approved for medical purposesfor connecting the oxygen source to the ventilator.**

- **To reduce the risk of fire, please cut off the oxygen source when the ventilator is not in ventilation state.**
- **To reduce the risk of fire, please ensure good ventilation at the back of the ventilator.**
- **To avoid equipment damage and ensure patient safety, please use accessories specified in this User Manual.**
- **Clinicians are responsible for correct setting of ventilation.**
- **Before using the ventilator or when deviation exists in the measured value, please calibrate the flow sensor.**
- **A fan failure may cause an increase in the oxygen concentration inside the device, which may cause in a fireor explosive hazard.**
- **To reduce the risk of explosion, do not forcibly open the oxygen sensor or throw it into fire.**
- **To avoid the risk of fire, only use the specified fuses or fuses having the same type, rated voltage and rated current as the existing fuses. To replace fuses, please contact our After-Sales Service Department.**
- **To avoid patient injury, please select the correct patient type, set the ventilation parameters correctly and connect the proper breathing tube. Before the ventilator is applied to each patient, please ensure that the system self-test result is OK.**
- **To ensure the accuracy of oxygen concentration monitoring, please replace the damaged oxygen sensor in time, or use an external monitor conforming to the requirements of ISO 80601-2-55.**
- **Please properly install or relocate the equipment to avoid damage due to drop, collision, strong oscillation or other external mechanical forces.**
- **Before moving the ventilator, please ensure that the casters and brake pedals work normally and that the main unit of ventilator has been locked onto the trolley.**
- **Before powering on the device, please confirm that the supply voltage and frequency conform to the requirements specified on the device nameplate or in this manual.**
- **To achieve electrical isolation between the ventilator andAC/DC supply mains, please disconnect the power plug of the ventilator.**
- **Avoid long-term storage of the ventilator in an environment over 50℃. Such environment could damage the internal battery and oxygen sensor or reduce the battery life.**
- **When the expiry date of the equipment or its accessories or medical waste is due, please dispose of in accordance with the local regulations or the hospital's rules.**
- **Use the original package to transport the ventilator.**

Note

- **Please put the device in a place where observation, operation and maintenance are convenient.**
- **This manual introduces the product of the most complete configurations. Some configurations or functions may not be available on the product you have purchased.**
- **Please keep this manual near the device for easy and prompt access when needed.**
- **The device can be used for only one patient at a time.**
- **The software contained in this equipment has been developed in accordance with the requirements of IEC62034 to minimize the probability of risks caused by program error.**
- **Service life(25℃±5℃): 10 years (may shorten due to extreme environmental condition).**

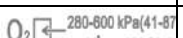
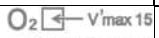
1.2 Contraindications

This product has no absolute contraindications. For some special diseases, however, necessary measures should be taken to proceed mechanical ventilation of the ventilator or a special ventilation mode should be used; otherwise the patient could be adversely affected.

1.3 Equipment Symbols

- **Device Symbols**

	Caution		Follow Instruction For Use[Note]
	Correct Disposal of This Product (Waste Electrical & Electronic Equipment)		Environment-friendly use period of electronic information products
	Manufacturer		Manufacturing date
	Serial number mark	IP21	protected against solid foreign objects of 12.5 mm and greater, and against vertically falling water drops
	Complies with medical device directive 93/42/EEC		European community representative
	Type CF applied parts, with the defibrillation-proof		Defibrillation-proof Type BF applied part
	AC/DC power indicator		Battery level indicator
	Equipotential symbol		Fuse

	DC-IN port		Class II devices, have double or reinforced insulation, as no provision for protective grounding(when connected with external DC power input only)
	High-pressure O2 port		Low-pressure O2 port
	Expiratory port		Inspiratory port
	Air outlet of the ventilator		WARNING: Gas Intake---DO NOT OBSTRUCT!
	Lock		Unlock
	Nebulizer port		Alarm audio paused
	Oxygen sensor compartment		O2 sensor port
	Power on/off key		Standby icon
	USB port		Network connection symbol
	Video output interface		Multi-function interface
	adult		pediatric
	Invasive ventilation		Non-invasive ventilation
	Wired network		Inspiratory trigger
	Alarm setup		Setup
	Tool		Historical data
	Recent alarm		Alarm off
	Oxygen enrichment		Freeze
	Nebulizer		Screenshot
	This side up		Stacking layer limit

	Fragile		Keep dry
	Temperature limit		Atmospheric pressure limit
	Humidity limit		Do Not Use if package is damaged
	Equipment weight		Safe working load
Note: Symbol maked adjacent to DC input connector, follow the required details concerning the power supply and specified DC power supply cord stated in this user manual.			

Chapter 2 Product Overview

2.1 Product Composition

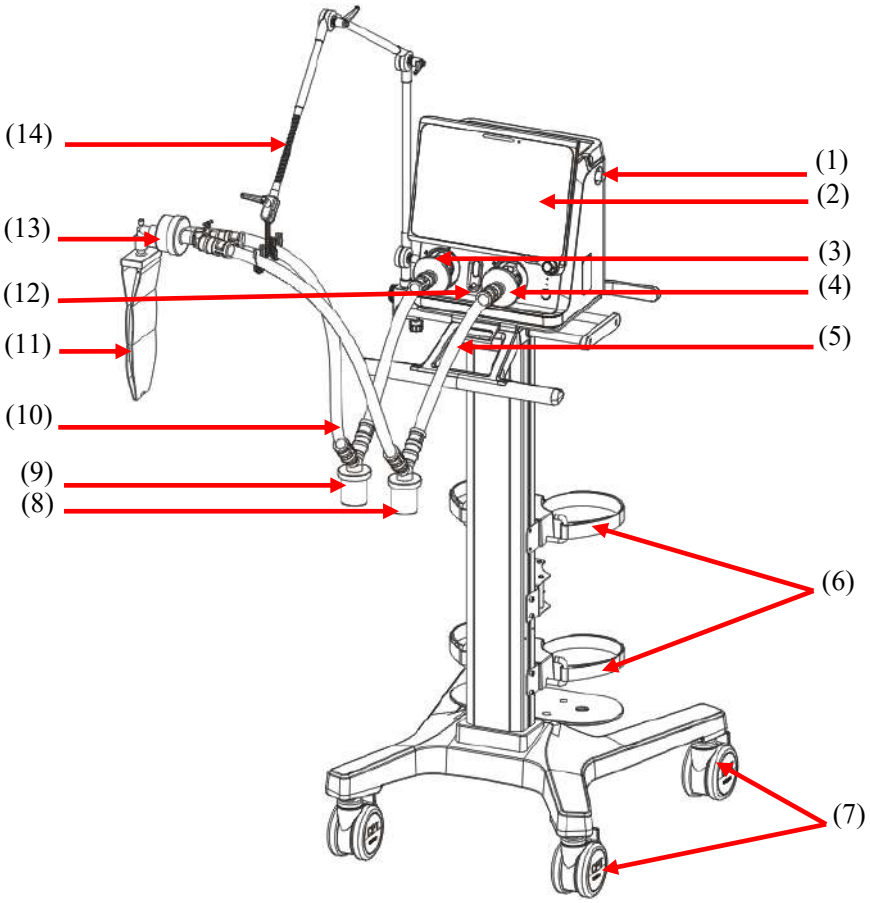
The product consists of a main unit (including gas circuit, electronic system, mechanical structure, display, CO_2 module and SpO_2 module), a trolley, a supporting arm, and accessories.

2.2 Intended Use

The product is intended for use in the ICU or internal transfer within the professional healthcare facilities. It provides assisted ventilation and respiratory support, SpO_2 and CO_2 monitoring for adult, pediatric and infant (＞3kg).

2.3 Product Appearance

2.3.1 Overall Appearance

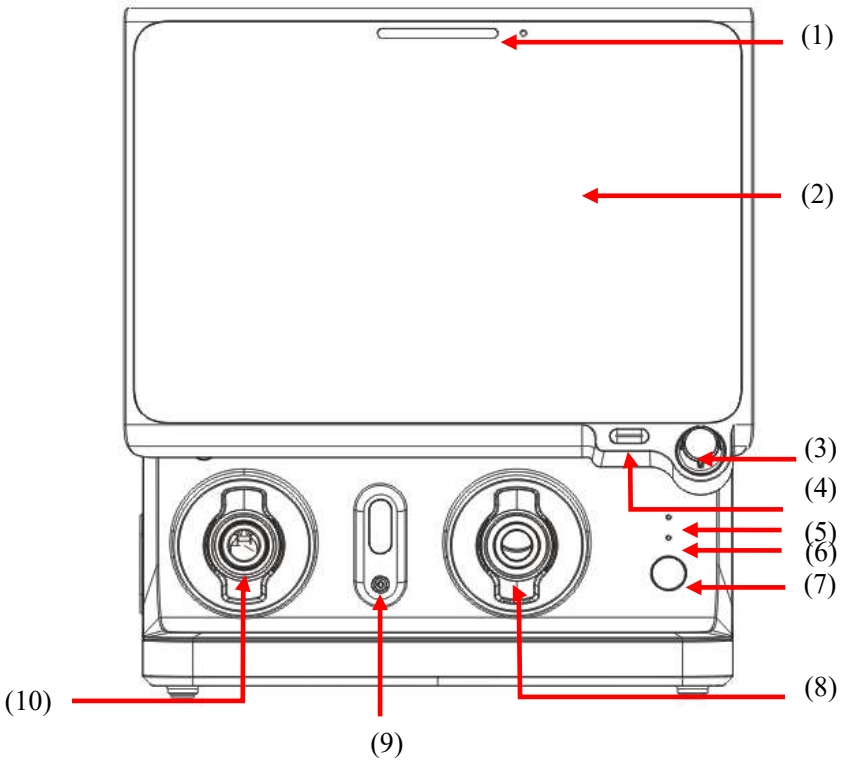


(1). Leak test plug
For system self-test or flow calibration.

(2). Main unit
(3). Expiratory filter
To prevent bacteria in the patient circuit from getting into the ventilator's internal airway.
(4). Inspiratory filter
To prevent bacteria in the patient circuit from getting into the ventilator's internal airway.
(5). Inspiratory pipe
(6). Spare cylinder fixing buckle
(7). Casters and brake pedal
The ventilator has four casters. Each of them has a brake pedal.
(8). Water collection cup of inspiratory limb
Collect the condensed water vapor in the suction line..
(9). Water collection cup of expiratory limb
Collect the condensed water vapor in the expiratorycircuit.
(10). Expiratory pipe
(11). Test lung
(12). Nebulizer port
To connect the nebulizer.
(13). The heat and moisture exchanger (HME)
(14). Supporting Arm
The patient's breathing circuit can be supported and suspended.

2.3.2 Main Unit Appearance

2.3.2.1 Front View



The control equipment consists of several operating elements. Main operating elements are:
(1) Alarm indicator light

When an alarm is generated, the alarm indicator lights will indicate different levels of alarm in different colors and blinking frequencies.

(2) Screen (Touch screen)

Software interfaces of ventilator system are displayed on the screen. Settings can be selected and changed by touching.

(3) Main control knob

Menu items can be selected or settings can be confirmed by pressing the main control knob. Menu items can be scrolled or settings can be changed by rotating it clockwise or counterclockwise.

(4) Alarm audio paused button

When this button is pressed, the system will enter the alarm audio paused state for 120 sec, and the alarm sound currently produced can be turned off. When 120 sec countdown is ended, the system will cancel the current alarm audio paused state and restore the sound alarm. When a new alarm is generated during the alarm audio paused state, the system will not restore the sound alarm. In alarm audio paused state, click the button again, the system will cancel the current alarm audio paused state.

(5) External power supply indicator

- ON: the ventilator is connected to external power supply (AC/DC).
- OFF: the ventilator isn’t connected to external power supply (AC/DC).

(6) Battery indicator light

- ON: battery is full. The ventilator is connected to external power supply (AC/DC), orthe ventilator isn’t connected to external power supply (AC/DC) and it is battery-powered.
- Blinking: the battery is charging.
- OFF: battery is not installed or battery is faulty,or the ventilator isn’t connected to external power supply (AC/DC) when it power off.

(7) Power switch (with indicator)

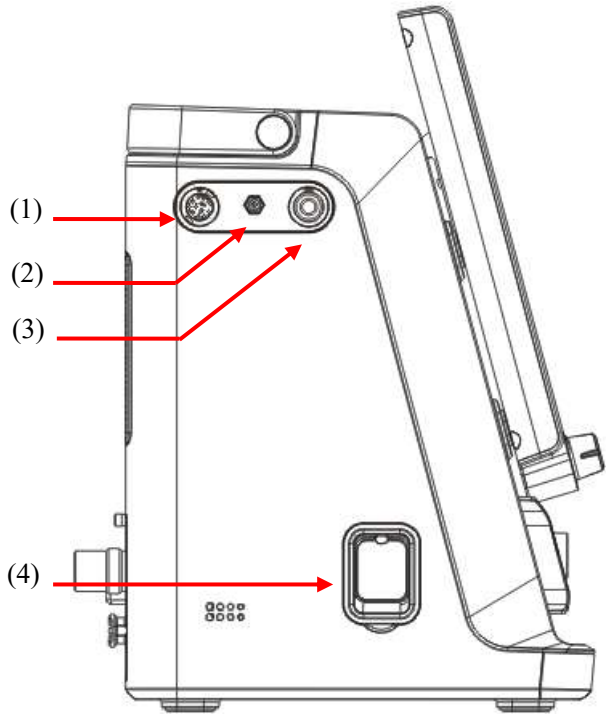
Press the button to turn on/off the system. The button light constanton when the system is turned on, goes off when the system is turned off.

(8) Inspiratory port: connected to inspiratory pipe

(9) Nebulizer port

(10) Expiratory port: connected to expiratory pipe

2.3.2.2 Left View



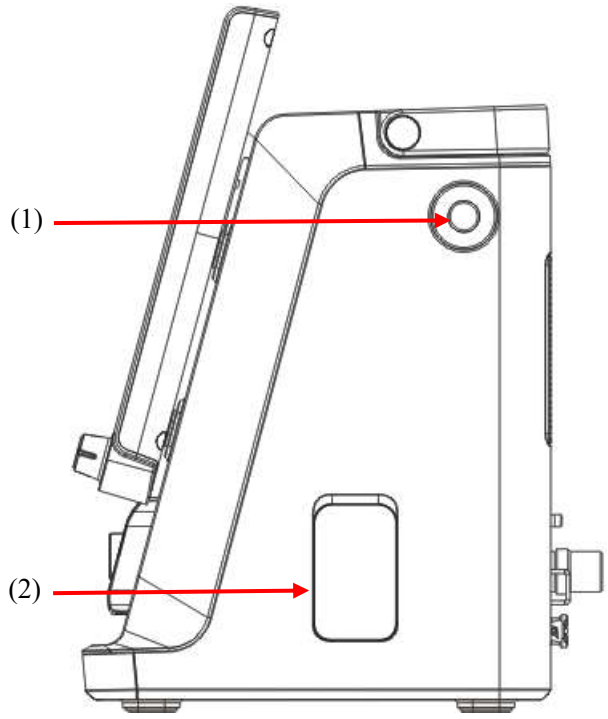
(1) SpO_2 cable connector

(2) Masimo Sidestream CO_2 outlet

(3) CO_2 cable connector (sampling line connector for Masimosidestream CO_2)

(4) Outlet for gas exhaled by the patient

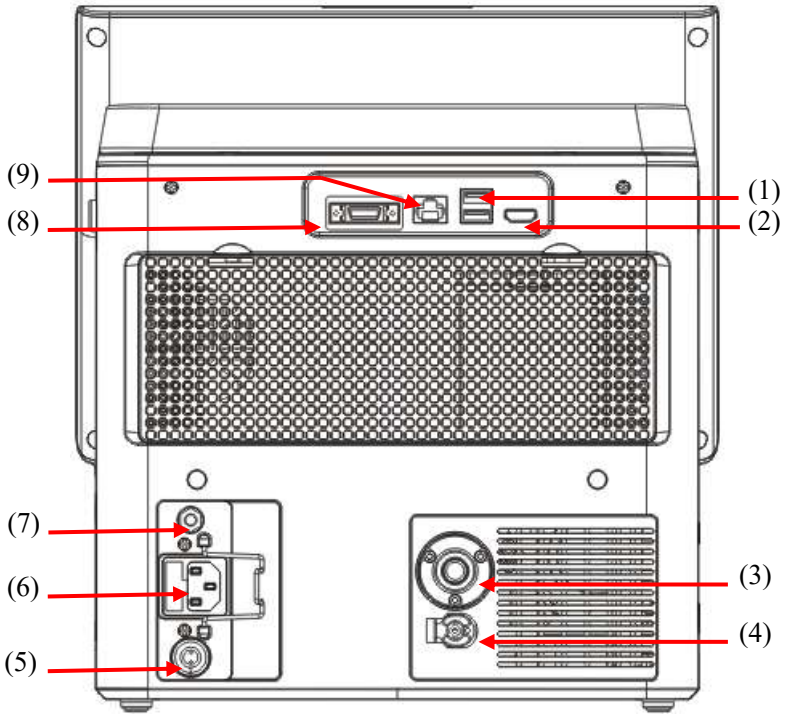
2.3.2.3 Right View



(1) Leak test plug

(2) O_2 sensor compartment

2.3.2.4 Rear View



(1) USB port: Export configuration information and historical data (e.g., patient data, alarm log, and calibration table);Connect ultrasonic Nebulizer.

(2) HDMI port: Connect an external display which can display pictures the same as those on the ventilator display. Connect an external display (display with 1280*800 pixel resolution is supported)

(3) High-pressure O_2 port

(4) Low-pressure O_2 port

(5) DC power port

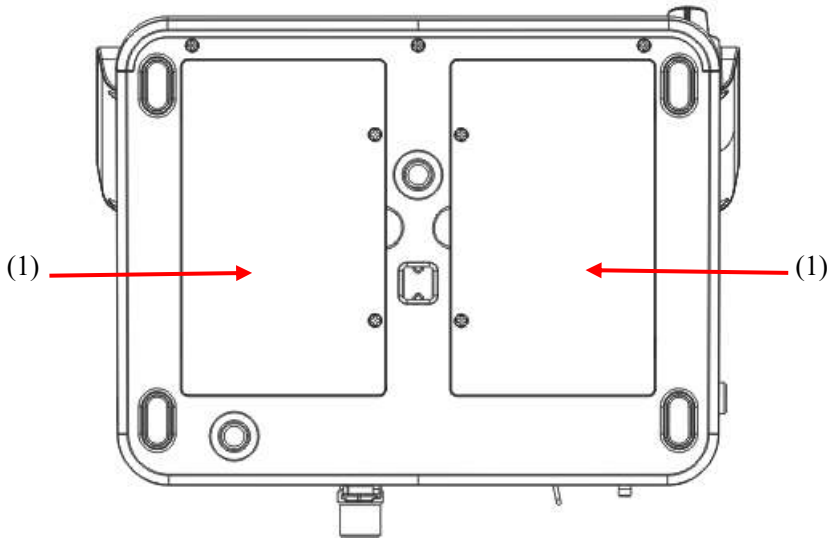
(6) AC appliance inlet

(7) Potential equalization conductor: when used other equipment with ventilator together, equipotential ends of other equipment and ventilator shall be connected by cables, to eliminate earth potential difference among different equipment and keep safe.

(8) Multi-function interface: 1) can be used as Nurse Call interface. When connected with calling system of hospital, if an alarm is triggered, nurse call message will be prompted.

(9) Network port: used for network communication.

2.3.2.5 Bottom View



(1) Battery compartment

Chapter 3 Installation & Connection

WARNING

- **When accessories or other components are added on the respiratory system of ventilator, expiratory/inspiratory resistance of the system might be increased.**
- **Use of an anti-static or conductive mask or breathing tube could result in burn. Therefore, do not use any anti-static or conductive mask or breathing tube.**
- **Each time a pipe, humidifier, breathing filter or other accessory or component is replaced, system self-test must be performed again.**
- **Components not specified in ventilator accessories shall not be installed in ventilator.**

3.1 Unpacking and Checking

Carefully take the ventilator and its accessories out of the packing box; properly keep the packaging materials for use in future transportation or storage. Check the accessories according to the Packing List. Check to see if there is any mechanical damage. In case of any problem, contact our Sales Department or agency immediately.

WARNING

- **If you find any damage, contact the related hospital staff or After-sales Service Department of Comen company.**

3.2 Environmental Requirements

Operating environment of this equipment must meet the environmental specifications in this manual. If the ambient temperature is beyond prescribed range, the accuracy of the device may be affected, and damage to components and circuits may be caused.

The equipment should be used in an environment that can reasonably avoid vibration, dust, corrosive or explosive gases, extreme temperature and humidity, etc.

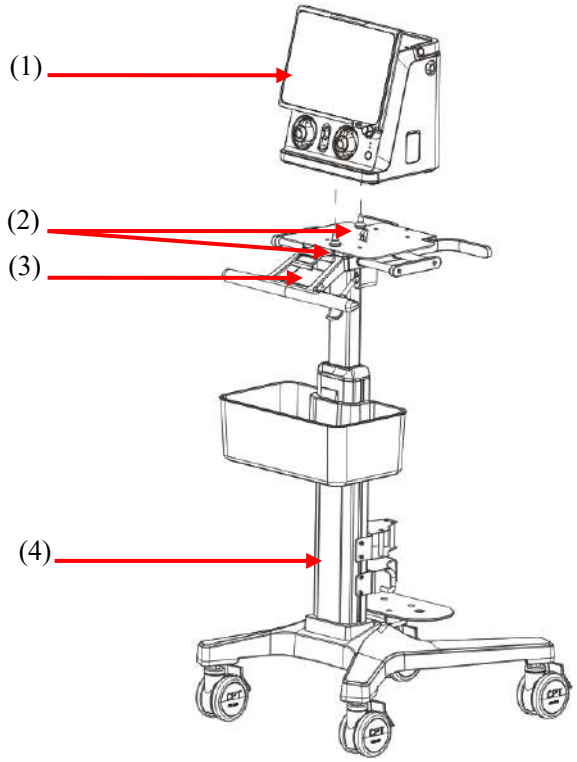
Please ensure that the device is free from condensation during operation. When the device is moved from one room to another, condensation may be formed. This is because the device is exposed to damp air and different temperatures. In order to avoid unnecessary troubles, use the device when it is dry if it is subjected to condensation.

Note

- **Condensation is formed when a gas or liquid touches a cold surface. For example, water vapor changes to water and water changes to ice when touching a cold surface. The lower**

the temperature is, the faster the condensation will be.

3.3 Install the Main Unit



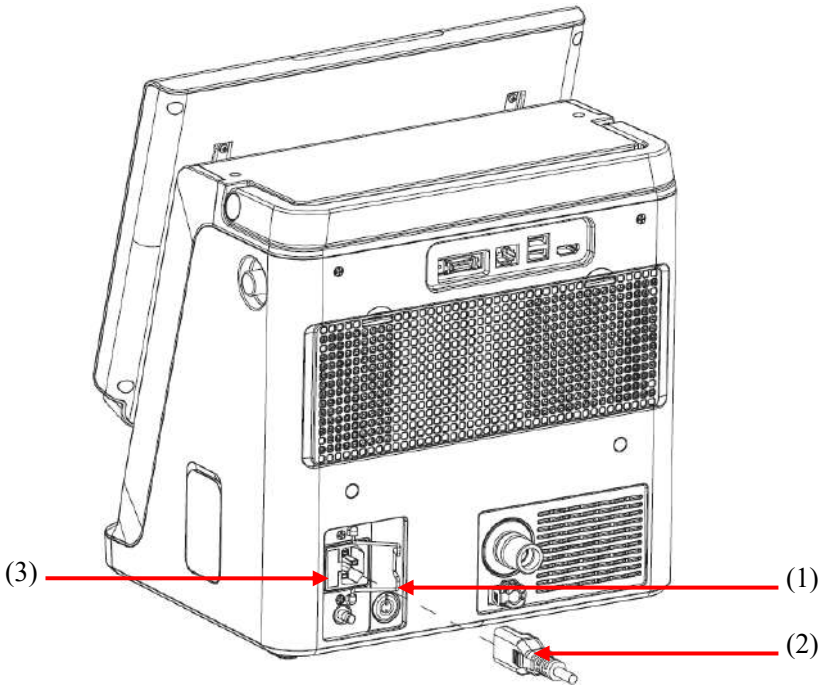
(1). Main unit (2). Pin (3). Trolley unlock button (4). Trolley

Align the main unit at 2 pins on the trolley and place it on the trolley.
If the main unit need to be removed from the trolley, press the trolley unlock button at first, then lift the main unit with both hands.

3.4 Connect Power Supply

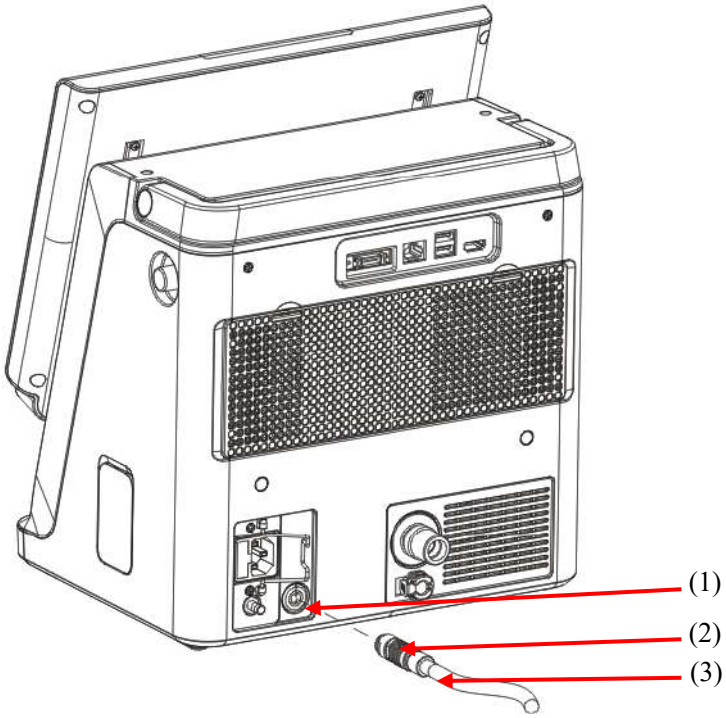
3.4.1 Connect AC Power Supply

As illustrated in following figure, plug the power cord into the power socket.



(1). Power cord bail latch (2). AC power cord (3). AC power socket

3.4.2 Connect DC Power Supply



(1). DC-IN port (2). Unlocking device (2). DC power cord

Align the red anchor point on the DC power cord at the red anchor point on the DC-IN port, then plug the DC power cord into the DC-IN port. You will hear a “snap” when it is installed in place.

When disconnecting the DC power supply, just pull the unlocking device axially, then the bail latch is unlocked, and remove the plug from the socket.

The DC input connection port is intended to receive by power from external d.c. power source. The usual configuration of ventilator V3/V3A has this port idle. This is just available for use when request by responsible organization, and after verified by professional service personnel. No reverse connection of the DC power cord is allowed, and the terminal interface shall be adequately secured.

Note

- **When connected to external DC power supply, the ventilator is classified as class II medical equipment without provision of protective earth.**
- **The external DC power supply connection with ventilator should include an additional safety precaution that prevent reverse of positive and negative polarity, prevent the accessible metal part from becoming live. It recommended to use a separate power source with floating output circuit.**
- **When connecting to the power source, please do use DC power cord provided by manufacturer only. The assembled DC power cord with special plug connection style shall be used to avoid incorrect attachment, reverse or short-circuit, This cable must only be assembled by manufacturer and authorized personnel.**
- **Only qualified technicians are allowed to configure the open end of DC power cable that is supplied for open contact. The field installation of the DC power supply connection shall be conducted by the professional service personnel and meet the installation requirement. The service technician will test and record the result before use.**
- **The external d.c. power source reverse protection does not relied on the ventilator itself, additional safety countermeasure shall be considered on field installation. Inspect the power cable for wear or damage. Replace if worn or damaged.**
- **Always check the reliability of the DC outlet. When DC power is connected, the DC symbol in the bottom righthand corner of the screen indicated.**
- **If the external DC power supply source has insufficient current capacity, or the supplied voltage falls outside the acceptable voltage range, the ventilator could automatically switchover to internal battery powered and trigger technical alarm condition. If the ventilator detects no external power supply condition but with cord connection, there may be a faulty on power supply source. Please stop using the external power supply.**

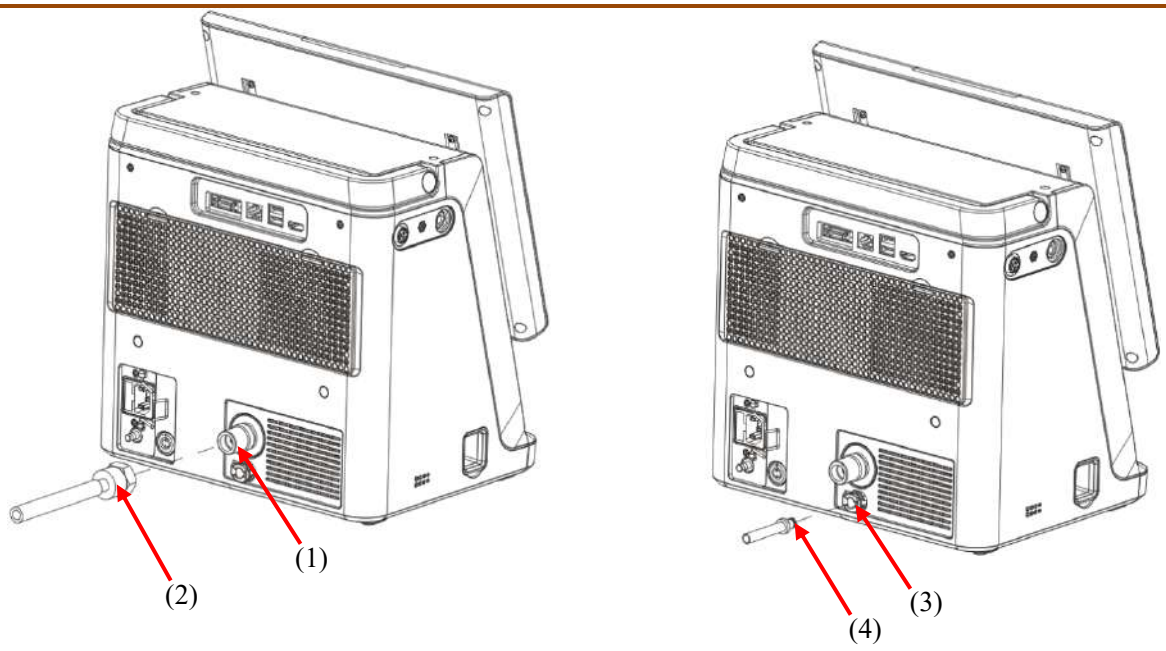
3.5 Connect the gas source

WARNING

- **Check the O_2 source port carefully to ensure there are no leaks. Too much leakage will lead to an oxygen concentration increase near the device, so there will be a potentially hazardous oxygen-enriched environment.**
- **Place the O_2 source hose carefully, to avoid exposing it to the environment where it may get cut, heated or damaged.**
- **To reduce the risk of fire, transport the Low-pressure O_2 with a flow no larger than 15 L/min.**

CAUTION

- **When Low-pressure O_2 is used, oxygen concentration setting of the ventilator is invalid. To prevent patient injury, ensure an abundant O_2 supply before using Low-pressure O_2.**
- **Before starting the ventilation, ensure the O_2 source is properly set. Set the Gas source type based on the actual situation. Refer to "Section *5.10 Set O_2 Source Type*" for setting method.**
- **To prevent patient injury, ensure the emergency O_2 source (e.g. oxygen cylinder) is available when a failure happens in Low-pressure O_2supply.**
- **Low-pressure O_2 hose should conform to the requirements of ISO 5359.**



(1). High-pressure O_2 port

(2). High-pressure O_2 hose and connector

(3). Low-pressure O_2 port

(4). Low-pressure O_2 hose and connector

The ventilator has 2 ports for gas source: High-pressure O_2 port and Low-pressure O_2 port.
When the ventilator is connected to High-pressure O_2, nominal Gas Source Pressure is 280~600 kPa. When Gas Source Pressure is less than 280kPa, the ventilator performance will be affected, even the ventilation will be stopped. When Gas Source Pressure is 600~1000 kPa, the ventilator performance will be affected, but no any harm will be caused due to high-pressure gas. Connecting steps of High-pressure O_2 are as follows:

1) Before connecting the gas source pipe, check whether the seal ring at the joints are in good condition. If the seal ring is damaged, the pipe cannot be used. Replacing the seal ring is a must to avoid leakage.
2) Align the joint and insert it into the High-pressure O_2 port on the back of the ventilator.
3) Ensure a correct connection between gas source hose and port, manually screw the hose nut tightly.

When the ventilator is connected to Low-pressure O_2, the flow rate of which shall not exceed 15 l/min. To reduce fire risks, do not use a Low-pressure O_2 which output at a flow rate exceeding 15 l/min. Connecting steps of Low-pressure O_2 are: align the Low-pressure O_2 hose and insert it into the Low-pressure O_2 port. You will hear a “snap” when gas source hose is installed in place. Before removing it, press the metal clip on the Low pressure-O_2 port, and pull the gas source hose out.

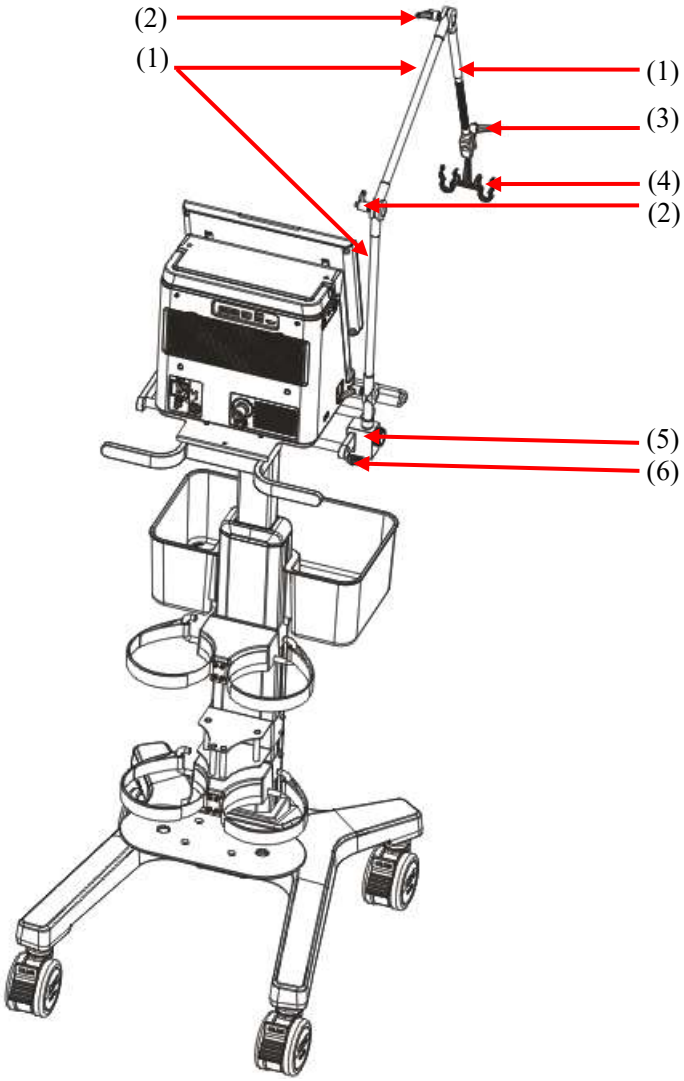
3.6 Install the Supporting Arm

WARNING

- **Before moving the ventilator, remove the supporting arm to prevent the ventilator from toppling over.**
- **Check whether the handle of supporting arm is tightly and safely connected as required to prevent the patient from accidental injury.**

Note

- **The maximum bearing capacity of the supporting arm does not exceed 0.8 kg.**
- **The supporting arm can be installed on the rail on the left or right side of the ventilator.**



(1). Supporting rod (2). Locking handle (3). Locking handle of pipe hook

(4). Pipe hook (5) Fixing block (6). Fixing block knob

1) Tighten the locking handle on the supporting arm.
2) Insert the supporting arm into the mounting hole on the fixing block.
3) Loosen the fixing block knob, and place the fixing block on the rail on the side of the ventilator.
4) Tighten the fixing block knob.
5) Adjust the supporting arm.

◆ If you need to adjust bending angle of supporting arm upward or downward, hold the supporting rod at the back-end of locking handle with one hand, while holding the supporting rod at the front-end of locking handle with the other hand at the same time, move it upward or downward to the required position.

6) Install the pipe hook on the supporting arm, screw up the locking handle of pipe hook.
7) Put the breathing tube on the pipe hook.

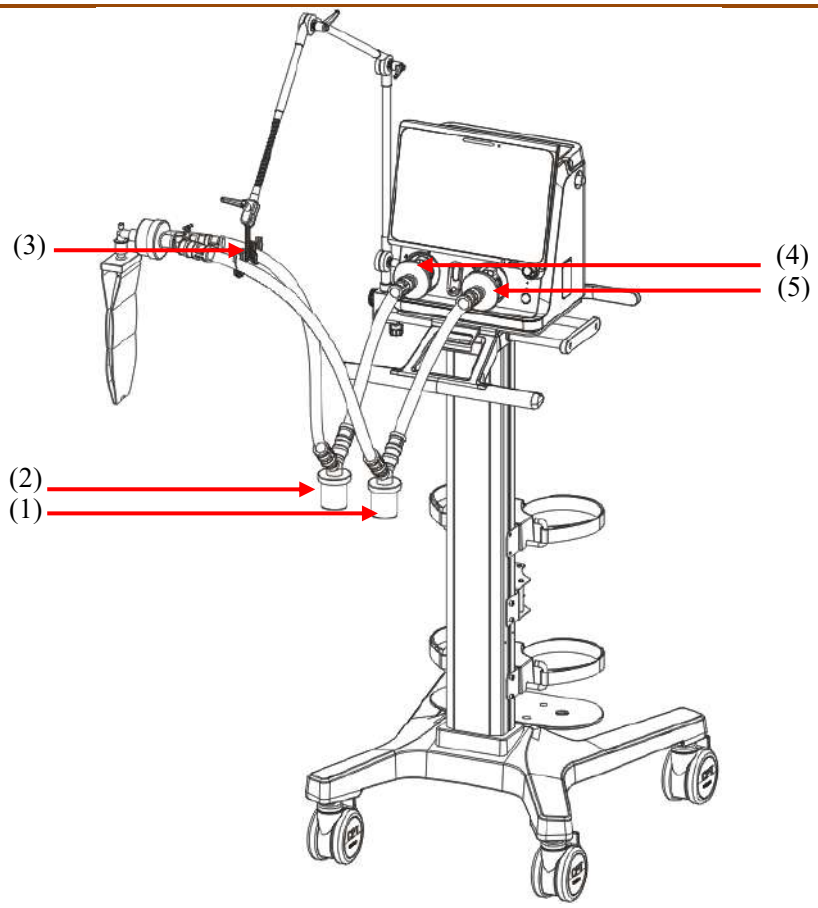
3.7 Install the breathing tube

WARNING

- **To minimize the risk of bacterial contamination or physical damage, carefully remove and install the bacterial filter.**
- **To prevent patient or ventilator contamination, a bacterial filter should always be used between the ventilator and the patient inspiratory limb.**

CAUTION

- **Use of the expiratory filter may result in dramatic increase of expiratory impedance. Excessive expiratory impedance may endanger ventilation and increase the patient's work of breathing and intrinsic PEEP.**
- **The breathing tube should conform to the requirements of ISO 5367.**
- **The bacterial filter should conform to the requirements of ISO 23328-1 and ISO 23328-2.**
- **A heat and moisture exchanger (HME) should conform to the requirements of ISO9360-1 and ISO9360-2.**



(1).Water collection cup of inspiratory limb

(2).Water collection cup of expiratory limb

(3).The pipe hook of the supporting arm

(4).Filter of expiratory limb

(5).Filter of inspiratory limb

1) Install the filters at the inspiratory and expiratory ports, respectively.
2) Connect the filter of inspiratory limb to the water collection cup via the pipe, and connect the other end of the pipe to the Y-joint.
3) Connect the filter of expiratory limb to the water collection cup via the pipe, and connect the other end of the pipe to the Y-joint.
4) Connect the patient end of Y-joint to the heat and moisture exchanger (HME), and connect HME to the patient.
5) Lastly, put the breathing tube on the pipe hook of the supporting arm.

3.8 Install the Humidifier

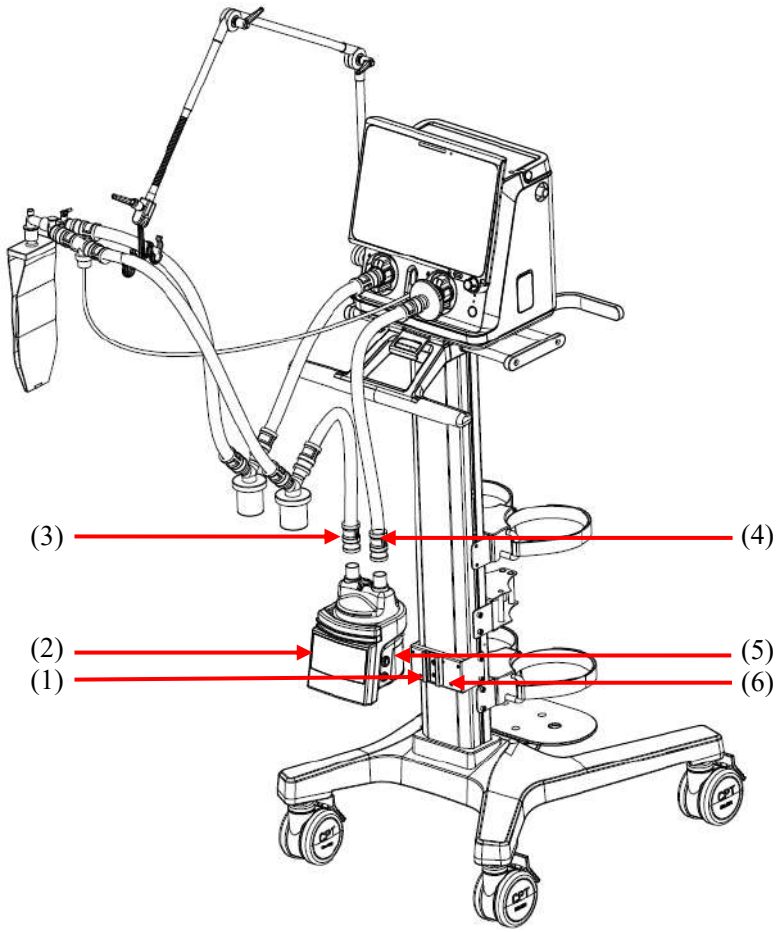
WARNING

- **To avoid patient injury and equipment damage, don't turn on the humidifier until the ventilator is calibrated and ventilated.**
- **To avoid patient injury and equipment damage, ensure that the humidifier is set to a proper temperature and humidity.Always use the humidifier within its rating and intended operation condition, otherwise it may reduce the performance of humidifier, which may lead to injury to patients, especially for invasive ventilation mode. For example, the elevated temperature of gas intake can cause the humidifier to reduce humidity output below the limited allowed by ISO 80601-2-74.**
- **To prevent possible patient injury or equipment damage, do not start the humidifier between the beginning and stabilization of the airflow. Start heating without airflow, or keeping it started for a longer period of time, may cause heat to build up, and hot air to be delivered to the patient. The breath tubing may melt in this case. Do turn off the humidifier before stop ventilation.**

CAUTION

- **The humidifier should conform to the requirements of ISO 80601-2-74. The humidifier components and installation steps described in this section are for reference only.**

3.8.1 Install the Humidifier to the Ventilator

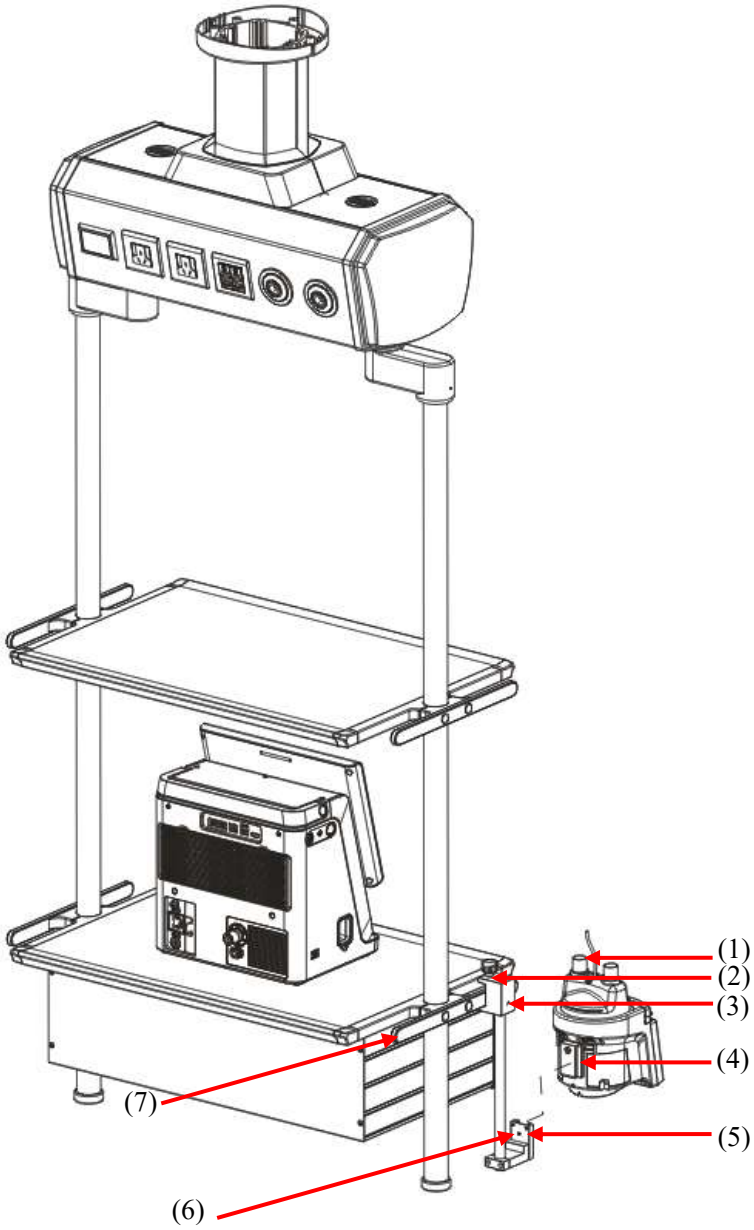


(1).Screw (2).Humidifier (3).The humidifier outlet

(4).The humidifier inlet (5).Humidifier pulley (6).Retaining bracket of humidifier holder

1) Align the humidifier pulley at the retaining bracket of humidifier holder, and slide in.
2) Tighten the screws.
3) Install the filters at the inspiratory and expiratory ports, respectively.
4) Connect the filter of inspiratory limb to the humidifier inlet via the pipe.
5) Connect the humidifier outlet to the water collection cup via the pipe, and connect the water collection cup to the Y-joint via the pipe.
6) Connect the filter of expiratory limb to the water collection cup via the pipe, and connect the water collection cup to the Y-joint via the pipe.
7) Put the breathing tube on the pipe hook of the supporting arm.

3.8.2 Install the Humidifier to the Hanging Tower



(1).Humidifier (2).Fixing block knob (3).Fixing block

(4).Humidifier pulley (5).Retaining bracket of humidifier holder (6).Screw

(7).Flat-tube beam

1) Loosen the fixing block knob and place the fixing block on the flat-tube beam of the hanging tower.
2) Tighten the fixing block knob.
3) Align the humidifier pulley at the humidifier holder, and slide in.
4) Tighten the screw F.
5) Install the pipes. See step 3 and step 7 in ***3.8.1*** for specific connecting method.

WARNING

- **When installing humidifier, ensure the humidifier port is lower than respiratory port of ventilator and patient.**

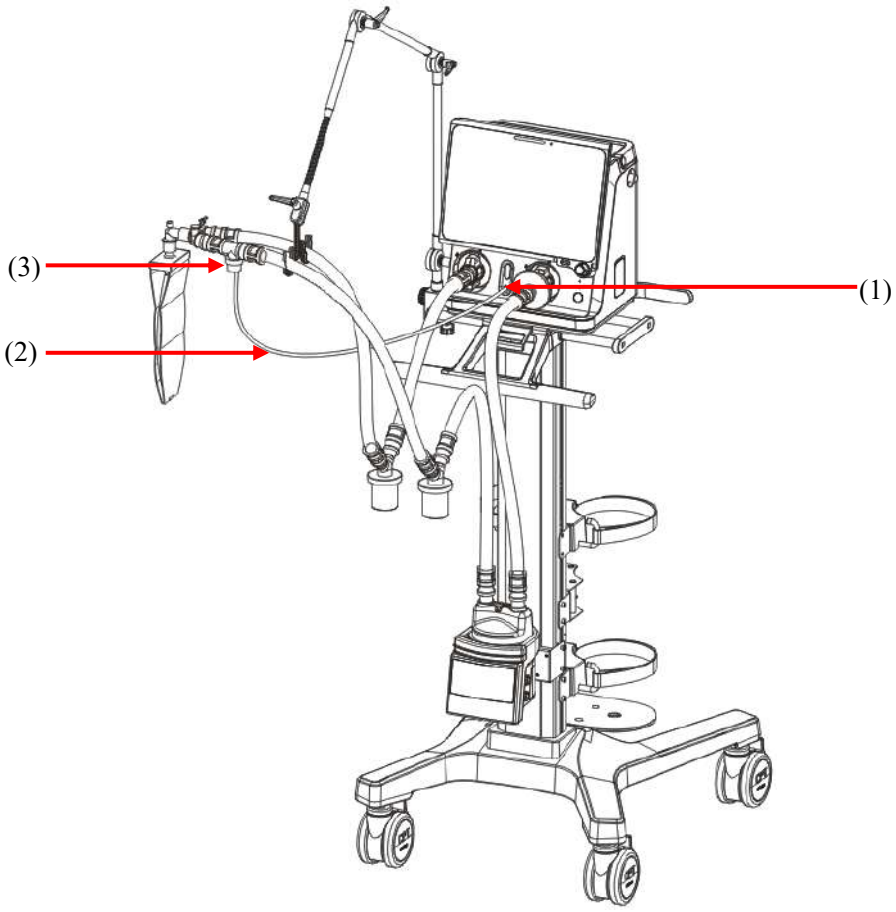
3.9 Install the Nebulizer

CAUTION

- **To prevent blockage of the expiratory valve caused by nebulization, only use drugs medically approved for nebulization, and regularly check, clean or replace the expiratory valve diaphragm.**
- **During nebulization, do notuse the expiratory filter or the heat and moisture exchanger (HME) in the breathing tube of the patient. Nebulization will cause filter blockage at the expiratory side, greatly increase the breathing resistance and adverse effect on ventilation.**
- **Please connectthe Nebulizer in the inspiratory limb. Connection of the Nebulizer between the patient connection port and the tracheal tube will increase the dead space volume.**

Note

- **Pleaseinstall a Nebulizer conforming to the specification requirements. The Nebulizer components and installation steps described in this section are for reference only. For installation and use of the Nebulizer, refer to the operating instructions supplied with the Nebulizer.**
- **The USB interface of the equipment supports the connection of USB electronic Nebulizer. For installation and use of the Nebulizer, refer to the operating instructions supplied with the Nebulizer.**



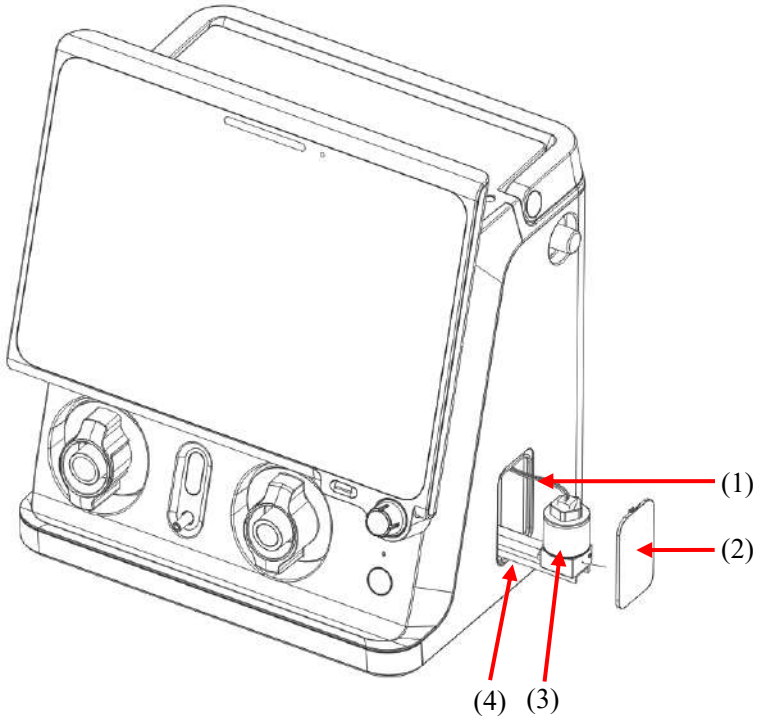
(1).Nebulizer port (2).Nebulizer intake pipe (3).Nebulizer

1) Install one end of the Nebulizer intake pipe to the Nebulizer port, and the other end to the Nebulizer.
2) Install the Nebulizer on the inspiratory limb of the breathing tube via the pipe.

3.10 Install the Oxygen Sensor

CAUTION

- **To reduce the risk of explosion, do not burn or forcibly open the oxygen sensor.**



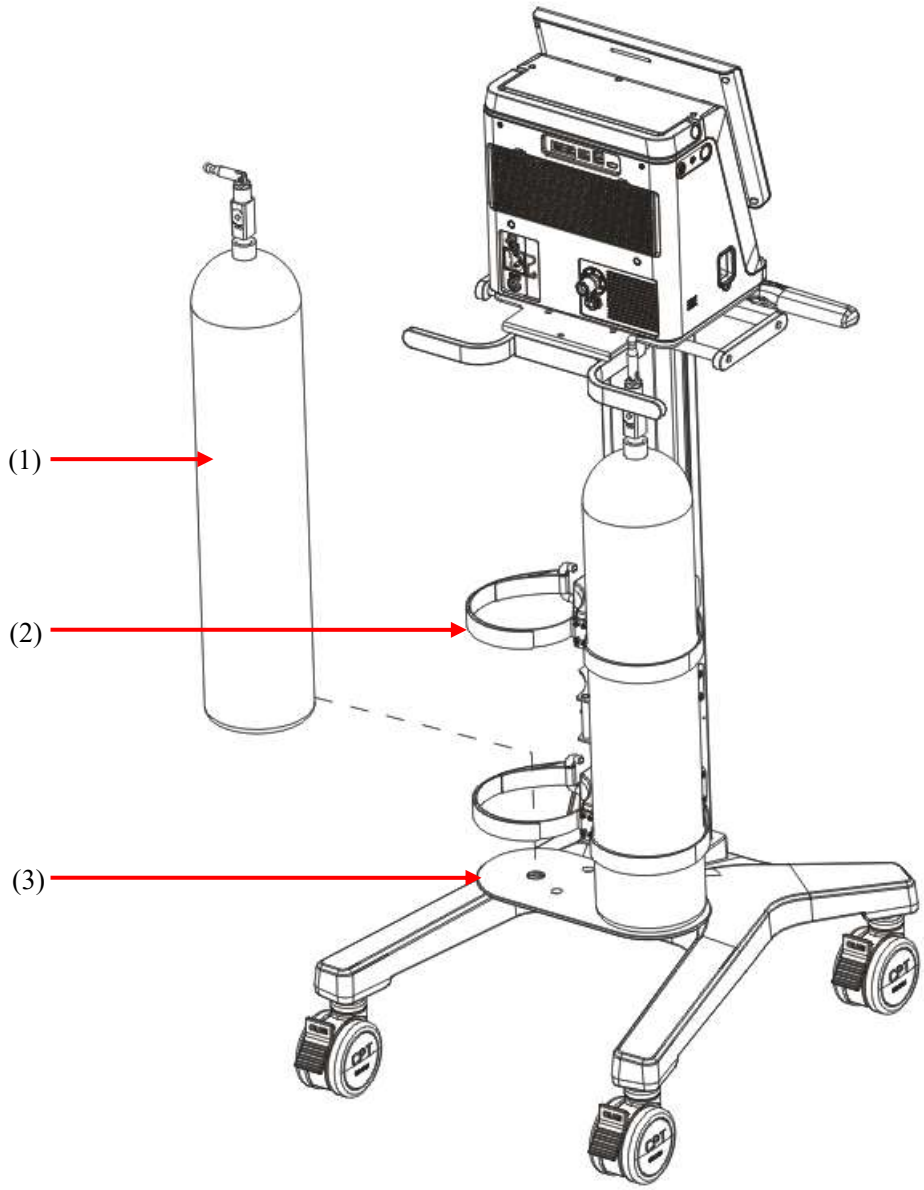
(1). Connecting cable of oxygen sensor
(2). Oxygen sensor cover
(3). Oxygen sensor
(4). Retaining bracket

1) Tighten the oxygen sensor clockwise;
2) Plug in the connecting cable of oxygen sensor;
3) Push the oxygen sensor and its retaining bracket into the ventilator;
4) Fasten the oxygen sensor cover.

3.11 Install the Spare Cylinder

CAUTION

- **Please ensure that the spare cylinder is equipped with a reducing valve.**



(1).Spare cylinder (2).Cylinder fixing buckle (3).Chassis of the trolley

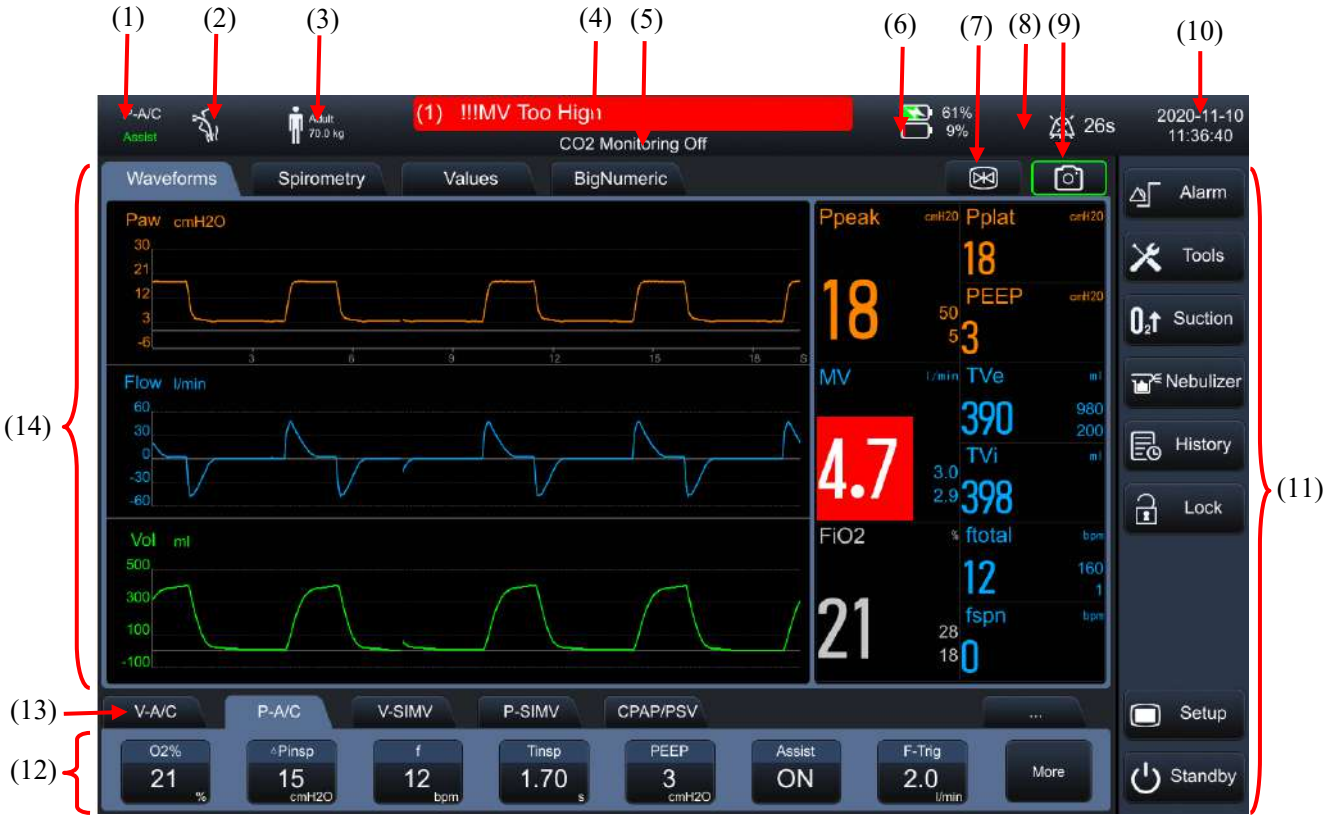
1) Put the spare cylinder in the chassis of the trolley.
2) Use the cylinder fixing buckle to fix the spare cylinder.

Chapter 4 Interfaces

4.1 Main interface

The screen of the ventilator displays Respiration parameters, Pressure, Flow, Volume, Waveform and Lung function loops, etc.

The figure below is a waveform interface in certain configuration. The interfaces displaying varies with different configuration.



(1) Ventilation mode area

Prompt on Ventilation Mode, Sigh and Ventilation Assistance in standby/current state is displayed.

(2) Ventilation type prompt area

Invasive or non-invasiveventilation type is displayed:

- When performing non-invasiveventilation, the non-invasivemask icon and NIV are displayed;
- When performing invasive ventilation with TRC function being disabled, the intubation icon is displayed;When performing invasive ventilation with TRC function being enabled, the intubation icon , TRC and Tube size are displayed.

(3) Patient information/Inspiratory triggering prompt area

◆ The current Patient type (Adult or Pediatric) is prompted. Inspiratory triggering icon is . The icon prompts for 1 s.

(4) Alarm message prompt area

◆ Current alarm message is displayed. When there are several alarm messages, the system will display the number of alarms. At this moment, if you click this alarm message prompt area, you can view the current alarm message, the time of alarm occurrence, the alarm duration, and alarm level in the interface opened.

(5) Prompt message area

◆ Current prompt message is displayed.

(6) Power status icon area

◆ Status of power used in the present system is displayed.

(7) Freeze button

(8) Inactive alarm prompt area

◆ When the icon is displayed, this suggests that an alarm existed recently but the alarm condition disappeared. Recent alarms (up to 10 alarms can be displayed) can be viewed in the interface opened after clicking the icon. Recent alarms can be cleared by selecting the [Reset] button.

(9) Screenshot button

(10) Alarm audio paused prompt area

◆ When the icon for 120 sec alarm audio paused countdown is displayed, this suggests that an alarm exists at the moment, and the alarm sound is in paused state.

(11) System time area

◆ The current system time is displayed.

(12) Hotkeys area

◆ Alarm setting, Tool, Oxygenation/Suction, Nebulizer, History, Lock screen, Mute, Main menu, Standby buttons is displayed.

(13) Parameter setting hotkeys area

◆ Ventilation set parameter corresponding to the ventilation mode is displayed.

(14) Ventilation mode setting area

◆ Buttons for Ventilation mode setting is displayed.

(15) Waveform/Loop/Monitoring Value area

◆ Waveform, Loop or Monitoring Value is displayed. When the measured value is invalid, there is no numerical display, and the horizontal line is displayed.

4.2 Waveform Interface

Select the [Waveform] button on the screen, and enter the interface as shown in the figure below.

4.3 Loop Interface

Select the [Spirometry] button on the screen, and enter the interface as shown in the figure below.

The Lung function loops can reflect the patient's pulmonary function and ventilation, including the pulmonary compliance, whether the lungs are over-inflated, whether there is any leakage in the respiratory system and whether the airway is occluded. It has a crucial clinical significance.

4.3.1 Set the Loop Type

3 Lung function loops provided by the system include: [P-V] (Pressure-Volume) loop, [F-V] (Flowrate-Volume) loop, and [F-P] (Flow rate-Pressure) loop. Data sources of [P-V]/ [F-V]/[F-P] loop are waveform data of pressure, flow rate and volume. When mainstream CO_2 module is configured, [V-CO2] curve will be displayed

Up to 2 types of loops can be displayed at the same time. You can select the loop required to be displayed by the following methods:

1) Select [Spirometry] on the main screen.
2) Select [Spirometry 1] or [Spirometry 2], and set the loop or EtCO2-t curve to be displayed as required.

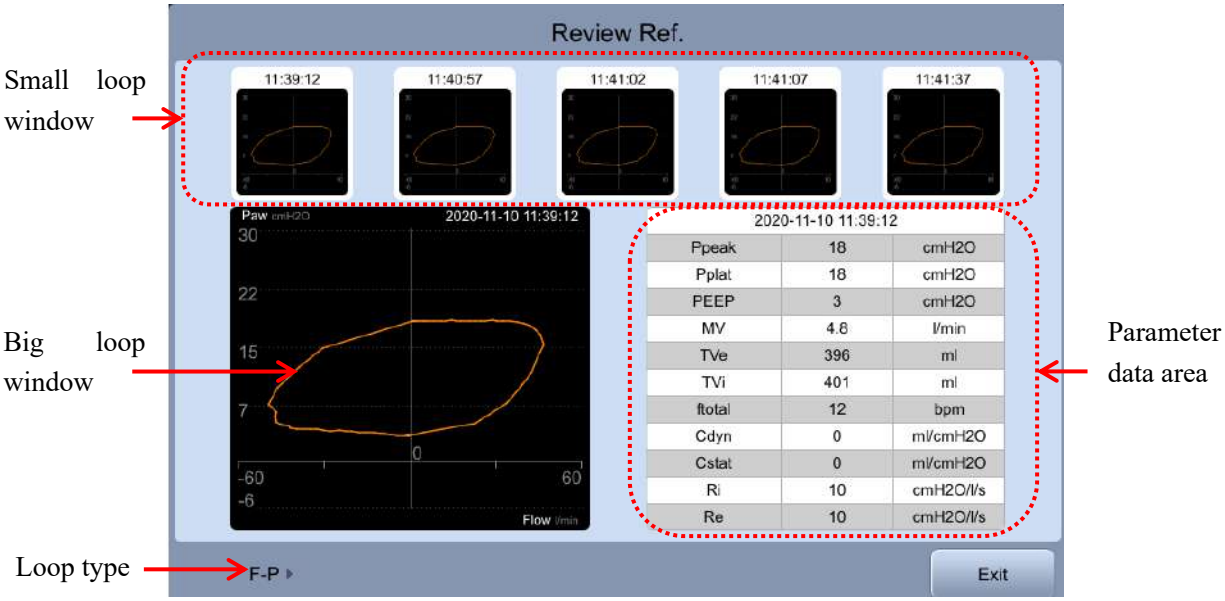
4.3.2 Set the Reference Loop

The ventilator is equipped with Reference Loop function. Below are the settings:

- Select [Save Ref.] button, the loop of current respiratory period can be saved as reference loop, and the saving time will be displayed.
- Select [Display Ref.] button, and select certain time, then the reference loop saved in the time.
- Select [Display Ref.] button, and select [Off], then the reference loop being displayed can be hidden.
- Select [Review Ref.] button to enter the Loop Review interface.

Reference loops of up to 5 times can be saved in the ventilator. When reference loops of 5 time have been saved, select [Save Ref.] button again, the system will clear the oldest reference loop and save the loop of current respiratory period as reference loop.

4.3.3 Reference Loop Review Interface



- Small loop window: these small graphic windows displays reference loop. Reference loops (5 at maximum) is displayed from the earliest (left) to the latest (right). Information on the selected reference loop will be highlighted in cyan.

- Big loop window: the graphic window displays the enlarged view of the selected reference loop.
- Loop type: used to select the loop type to be reviewed, including P-V, F-V, P-F and V-CO2. P-V is selected by default.
- Parameter data area: monitoring parameter data related to the reference loop saved is displayed.

4.4 Monitoring Value Interface

When configuring the CO_2 module or SpO_2 module, select the [Values] button on the screen, and enter the interface as shown in the figure below.

4.5 Big Font Interface

Select the [Big Font] button on the screen, and enter the interface as shown in the figure below.

You can perform the following operations on the interface:

4.5.1 Set display parameters

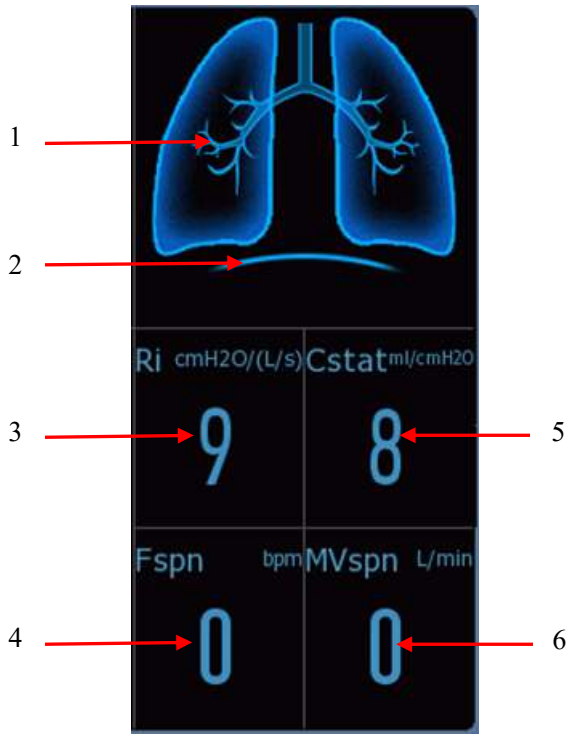
- Select a parameter name in certain parameter area, and select parameter displayed in this area in the parameter list popped up.

4.5.2 Setting the dynamic lung display function

The dynamic lung view is used to reflect the current state of the lungs, and the expansion and contraction of the lungs indicate the process of inhalation and exhalation. When inhaling, the lungs expand. When exhaling, the lungs contract. The characteristics of lung resistance, compliance, and tidal volume can be visually displayed according to the shape of the lung. Its detailed features are as follows:

- The compliance is too large, the alveolar contour becomes thinner;
- The compliance is small, and the alveolar outline becomes thicker;
- The impedance is too large, and the side line of Tiida becomes thicker;
- Excessive ventilation, the dotted line is within the alveolar outline;
- The ventilation is too small, and the dotted line is outside the alveolar outline;

The dynamic lung display is as follows:



1. Normal lung
2. Patient trigger (diaphragm)
3. Lung resistance (inspiratory resistance)
4. Percentage of spontaneous breathing rate
5. Lung compliance (static compliance)
6. Spontaneous minute ventilation

Select the button, set [Compliance Monitoring Value] and [Resistance Monitoring Value] in the menu opened. There are 3 parameter setting methods:

- ✧ Select the parameter setting area, and directly edit.
- ✧ After selecting [Reset to Default] button, the default value corresponding to current patient type will be loaded automatically by the system.
- ✧ Select [Use Current Value] button to use the Compliance Monitoring Value and Resistance Monitoring Value displayed in current interface.

4.6 Historical Data

Select [History] button on the screen to enter the Historical Data interface. In the interface, Tabular Trends, Graphic Trends, Tabular Trends Setting and Event log can be viewed.

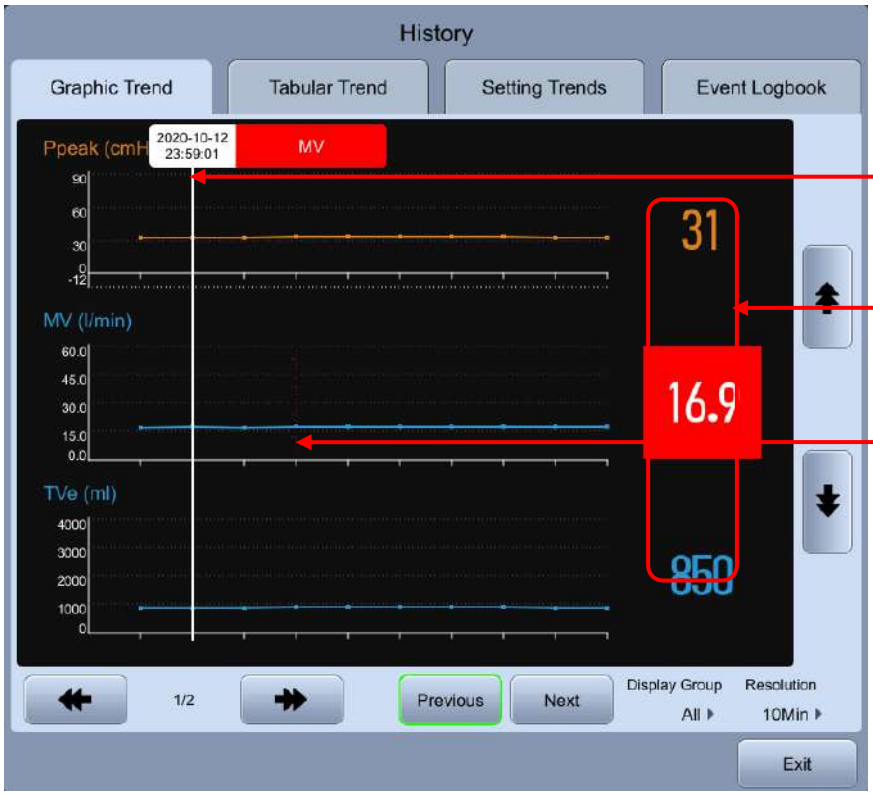
4.6.1 Icon Navigation

Button	Function
	The cursor moves across one record in the direction of the arrow.

	The cursor moves across one parameter in the direction of the arrow.
	The cursor moves to the beginning or ending of the records in the direction of the arrow.
	The cursor moves to the top or bottom of the parameters in the direction of the arrow.
Previous event	The cursor moves to previous event from the current event.
Next event	The cursor moves to next event from the current event.

4.6.2 Graphic Trends

The Graphic Trends is used to record the change trend of parameter values at the corresponding time. It uses a curve to describe changes in parameter measurement results, and each point on the curve corresponds to the value of physiological parameter at each time point. The Graphic trends can be used to record the parameter alarm event. If resolution is not set, trend data will be displayed at an interval of 1 minute by default.



(1) Current cursor. Relevant time is displayed above the cursor. If there is an alarm triggered at the time, relevant alarm information will be displayed above the cursor.

(2) Parameter data corresponding to the time suggested by the cursor.

(3) Event marking. The dotted line with color suggests a parameter alarm event occurs at this point in time. The parameter alarm event is marked with the color corresponding to relevant alarm level. The color corresponding to the highest alarm level will be used to mark when there are multiple events.

4.6.2.1 About Graphic Trends

- The horizontal axis of the Graphic trends displays the date/time.
- The vertical axis of the Graphic trends displays the parameter value.
- In the Graphic trends, the latest data is displayed at the right end.
- Trend data in standby status will not be saved by the system.
- Trend data during 72 consecutive hours can be recorded by the system
- If certain parameter triggered an alarm during the trend recording process and parameter record corresponding to the alarm can be founded, then the parameter data will be marked in the color corresponding to the alarm level. And it can be searched out quickly by clicking [Previous Event]/[Next Event].

4.6.2.2 Resolution

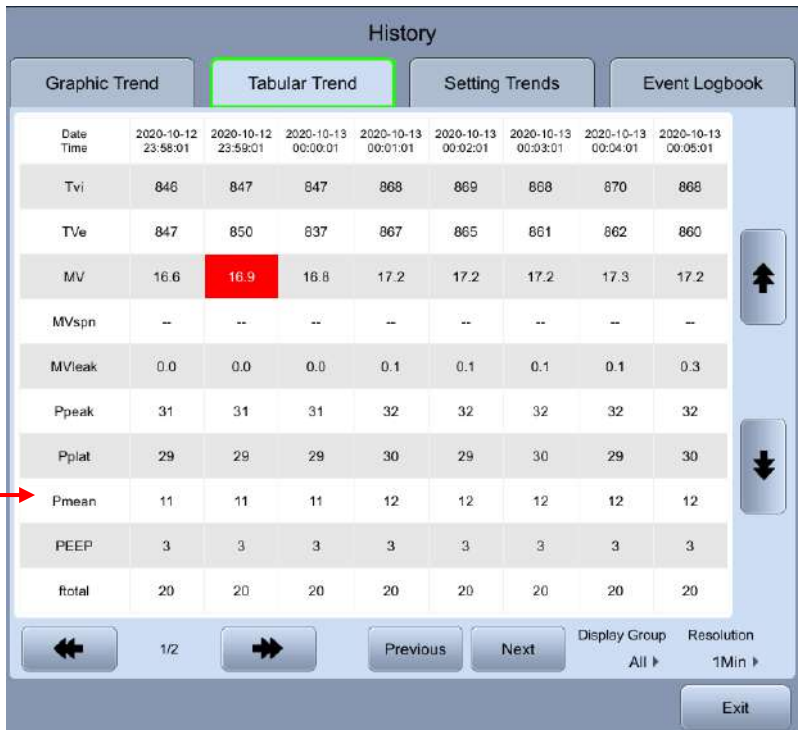
You can set the [Resolution] to[5min], [10min], [15min], [30min], [1Hour], and [2Hour] in Graphic Trends interface.

4.6.2.3 Display Group

In Graphic Trends interface, you can set [Display Group] to [Pressure], [Flow], [Volume], [Time], [Gas], [SpO_2], [Other] and [All].

4.6.3 Tabular Trends

In Tabular Trends interface, you can check the patient's monitoring parameter data and events. If the resolution is not set, the trend data will be displayed at an interval of 1 minute by default. The unit of each parameter is the same as the monitoring values setting.
The tabular trends could display the time of activating standby as well as the start of ventilation.



Parameter

4.6.3.1 About Tabular Trends

- The horizontal axis of the Tabular Trends displays the date/time.
- The vertical axis of the Tabular Trends displays the parameter value.
- In the Tabular Trends, the latest data is displayed at the right end.
- Trend data in standby status will not be saved by the system.
- Trend data during 72 consecutive hours can be displayed by the system.
- If certain parameter triggered an alarm during the trend recording process and parameter record

corresponding to the alarm can be founded, then the parameter will be marked in the color corresponding to the alarm level. And it can be searched out quickly by clicking [Previous Event]/[Next Event].

4.6.3.2 Resolution

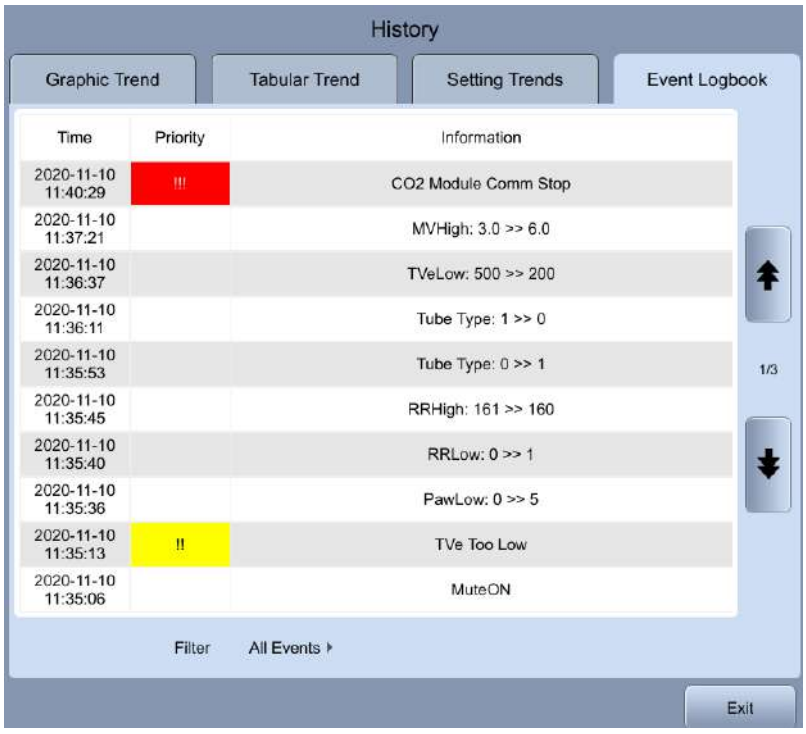
You can set the [Resolution] to [1min], [5min], [10min], [15min], [30min], [1Hour] and [2Hour] in Tabular Trends interface.

4.6.3.3 Display Group

In Tabular trends interface, you can set [Display Group] to [Pressure], [Flow], [Volume], [Time], [Gas], [SpO_2], [Other] and [All].

4.6.4 Event Logbook

Event log is used to record Startup/Shutdown, Ventilation Mode Setting, Ventilation Parameters Setting, Technical Alarms (alarm information, priority, the associated alarm limits and the date and time of the occurrence) , Physiological Alarms(alarm information, priority, the associated alarm limits and the date and time of the occurrence), Standby, Start Ventilation, New Patient, Special Function, Default Values Management, Calibration, System Self-test, VBS check, oxygen therapy event and Alarm Audio Paused Event.



4.6.4.1 About Event Log

- The latest record is displayed on top in Event log.
- Up to 8000 records can be stored in the system.

◆ The event log is maintained when the alarm system or the ventilator is powered down, or experienced a total loss of power.

Note

- **Up to 8000 records can be stored in the system. When exceeding 8000, the earliest record will be overwritten by the latest event.**
- **Do not permit the healthcare professional operator to erase or modify the contents of the alarm system log.**

4.6.4.2 Filter

In Event Log interface, you can set [Filter] to [High Alarms], [Med Alarms], [Low Alarms], [All alarms], [Operation Information] or [All Events].

4.7 Freeze

The Freeze function is used to suspend the real-time refresh of waveform/loop data on the screen. It allows short-time review of patient data so that you can carefully observe the patient's condition within this period. Data reviewed is the waveform/loop 2min before entering frozen state.

4.7.1 Enter Frozen State

In non-standby and non-frozen state, click the [Freeze] button "", the screen will prompt [It is frozen. Press the Freeze button again to unfreeze.]. When the system enters frozen state, the frozen cursor will appear in the area around the waveform/loop. All waveforms and loops are frozen, namely waveforms and loops will not be refreshed. Data in parameter area can be refreshed properly. In frozen state, the Save Reference Loop button is unavailable, so you can't save the reference loop, but you can view the reference loops that have been saved.

4.7.2 Waveform Review

In frozen state, the cursor appears around the waveform. You can move the cursor to review the waveform via the touchscreen or rotate the main control knob clockwise or counterclockwise.

4.7.3 View the Loop

In frozen state, the cursor appears around the loop. You can move the cursor to view the loop via the touchscreen or rotate the main control knob clockwise or counterclockwise.

4.7.4 Unfreeze

In frozen state, click the [Freeze] button " " to exit from frozen state. If no operation is performed on the ventilator within 3 minutes after entering frozen state, the system will exit from frozen state automatically.

4.8 Lock Screen

After clicking the [Lock Screen] button on the screen, the ventilator will enter locked state. [Lock screen] button becomes [Unlock] button, meanwhile, it will prompt [The screen is locked. Click the Unlock button to unlock!] in prompt message area. In locked state, only the [Mute] button on screen, [Mute] button on the panel , [O_2↑Suction] and [Unlock] button are valid, while the touchscreen, main control knob and other buttons are invalid. click the [Unlock] button to unlock.

Chapter 5 Basic Operations

5.1 Display Setting

5.1.1 Waveform Setting

1) Select [Setup] → [Setting] → [Waveform Interface].
2) Set [Waveform Count] as required by selecting the number of waveforms to be displayed.
3) Set [Waveform Curves Plotting] to On/Off as required:
   - ◆ OFF: waveform is drawn with curves.
   - ◆ ON: the area below the waveform is displayed with color filling.
4) Select [Color Setting] to set the color of waveform to be displayed.
5) Select the waveform area, and set the waveform to be displayed in the dialog box popped up.

5.1.2 Color Association Setting

The color of Waveform, Parameter, Loop and Parameter alarm limit are associated, in which the color of Waveform and Parameter are settable. As soon as the color of Waveform or Parameter is set, the color of the associated parameter, waveform or loop will change. The associated alarm limit will be displayed in dark color of the color set.
See the table below for Waveform, Parameter associated with waveform, Loop associated with waveform, and Alarm associated with waveform:

Waveform	**Parameter associated with waveform**	**Loop associated with waveform**	**Alarm limit associated with waveform**
Airway pressure	P_{peak}, P_{mean}, P_{plat}, PEEP	P-V loop, F-P loop	P_{peak}
Flow rate	MV, MV_{leak}, MV_{spn}, T_{Ve}, T_{Vi}, TV_{spn}, ftot, fmand, fspn, TVe/IBW	F-V loop	MV, TVe, ftot
Volume	/	/	/
/	FiO_2	/	FiO_2
CO_2	$EtCO_2$, Vdaw, VDaw/Tve, Vtalv, V'alv, $SlopeCO_2$, $V'CO_2$, $VeCO_2$, $ViCO_2$	V-CO_2 curve	$EtCO_2$

5.2 Set Ideal Weight/Height

1) Select [Setup] button → [Setting] → [System].
2) Set [IBW/Height]: [IBW] or [Height]. When the ventilator is applied to new patient, the default value of V_T (Tidal Volume), RR (Respiration Rate) and AF (Apnea Frequency) in ventilation mode will be figured out automatically by the system according to Ideal Weight/Height and Sex set.

5.3 Set Tidal Volume for Ideal Weight

1) Select [Setup] button → [Setting] → [System].
2) Set [TV/IBW] to appropriate ratio. The default value of V_T in ventilation mode will be set by the system according to [TV/IBW].

5.4 Set T_{insp}(Inspiratory Time) / I:E (Inspiratory Time : Expiratory Time Ratio)

1) Select [Setup] → [Setting] → [System].
2) Set [T_{insp}/I:E]: [T_{insp}] or [I:E]. According to [T_{insp}/I:E], the Ventilation set parameters associated with T_{insp} or I:E will be applied in V-A/C, P-A/C and PRVC ventilation mode.

5.5 Set DuoVent Time Parameter

1) Select [Setup] → [Setting] → [System].
2) Set [DuoLevel Setup]: [T_{high}] or [f]. If the item is set to High Pressure Time, time control parameters in DuoVent ventilation mode are [T_{high}] and [T_{low}]. If the item is set to [f], and [T_{insp}/I:E] is set to [T_{insp}], time control parameters in DuoVent ventilation mode are [f] and [T_{insp}]. If the item is set to [f], and [T_{insp}/I:E] is set to [I:E], time control parameters in DuoVent ventilation mode are [f] and [I:E].

5.6 Set Invasive Apnea Ventilation Mode

1) Select [Setup] → [Setting] → [System].
2) Set [IV Apnea Mode]: [Volume Control] or [Pressure Control]. While performing invasive ventilation, if the item is set to [Volume Control], the settable control parameter in Apnea ventilation mode is [TV_{apnea}]; if the item is set to Pressure Control, the settable control parameter in Apnea ventilation mode is [ΔP_{apnea}].

5.7 Set Oxygen Concentration Monitoring

1) Select [Setup] → [Sensor] → [O_2].

2) Set [Monitoring]: On or Off. When it is turned on, it indicates that the patient's inspired oxygen concentration can be monitored. If you do not need to use the oxygen concentration monitoring function you can turn off the oxygen concentration monitoring switch. At the moment, a prompt message saying [O_2 Monitoring Off] will appear on the screen.

CAUTION

- **Disabling the Oxygen Concentration Monitoring function is permissible. However, to prevent the patients from potential harm after disabling the monitoring and alarming function, we recommend that youdo not disable the Oxygen Concentration Monitoring function continuously.**

Note

- **Total system response time for the Oxygen Concentration Monitoring is 23s.**
- **It takes about 3 minutes from powering on the ventilator to performing the monitoring performance as specified of Oxygen Concentration Monitoring in Appendix of this manual.**

5.8 Set Language

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Settings] → [Language], and set the language as required.
3) Reboot the ventilator to put the language selected into effect.

5.9 Set Unit

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Settings] → set [Unit].
   - ◆ [Weight Unit]: kg or lb.
   - ◆ [Paw Unit]: cmH_2O, hPa or mbar.
   - ◆ [CO_2 Unit]: mmHg, kPa or %.

5.10 Set O_2 Source Type

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Settings] → [Module / Gas Source].
3) Set [Gas Supply]: high-pressure O_2 or low-pressure O_2. It's used to set the gas source type.

5.11 Set Screen Brightness

1) Select [Setup] → [Setting] → [Screen].
2) Select [Screen Mode] to [Day] or [Night], the default screen brightness will be adjusted accordingly.
3) If you are dissatisfied with screen brightness, you can also directly set [Screen Brightness]: 1～10. 1 is for the darkest level and 10 for the brightest. When using battery power supply, you can set the brightness at a lower level so as to save the battery's power.

5.12 Set Key Volume

1) Select [Setup] → [Setting] → [Brightness/Volume].
2) Set [Key Volume]: 0～10. Select 0 to mute the key volume, 10 to set the loudest level.

5.13 Set Time and Date

1) Select [Setup] →[Setting]→[Time / Date].
2) Set [Date Format]: [YYYY-MM-DD], [MM-DD-YYYY], or [DD-MM-YYYY].
3) Set [Time Format]: [24h] or [12h].
4) Set [Time] and [Date].

5.14 View System Information

5.14.1 Version Information

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Syst. Info] → [Version Information] to query software version information of the system.

5.14.2 Configuration Information

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Syst. Info] → [Config Info.] to query configuration information of the ventilator, e.g. ventilation mode.

5.14.3 Maintenance Information

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Syst. Info] → [Maintain] to query Total System Runtime, System Startup Time, Last O_2 Sensor Calibration Time, Last Flow Sensor Calibration Time, Time Remaining to Next Blower Maintaining and

Last Maintaining Time.

5.15 Default Values Management

The ventilator has the following set values:

- The factory default values, namely the set values preset by the factory. The default values can be divided into 2 groups (Adult and Pediatric) by patient type.The Pediatric mode is applied to both pediatric and infant.
- Current set values. Adjust the ventilator settings as per actual need, and save the setting as current set values. The set values can be divided into 2 groups (Adult and Pediatric) by patient type.
- The latest set values. The operator may change some settings in the practical application. Those changes could not necessarily be saved as current set values. The set values are saved in a real-time manner by the ventilator. The set values saved is the latest set values.

5.15.1 Save and Load Current Set Values

Adjust the ventilator settings as per actual need, and save the setting as current set values.

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Defaults] → [Use the Current Set Values] to save the current set values.

When applied to new patient after startup, the ventilator will load the set values saved automatically.

5.15.2 Restore Factory Default Settings

While the ventilator is in use, you can restore it to factory default settings manually.

1) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
2) [Defaults] → [Restore Factory Defaults] button, restore it to factory default settings.

When applied to new patient after startup, the ventilator will load the factory default values automatically.

5.15.3 Restore the Latest Set Values

When the ventilator is applied to the same patient after startup, the system will adopt the latest set values automatically.

Note

- **Records automatically saved by the system are as follows: Reference Loop, Monitoring Trends, Event Logbook (Including Alarm Log), Trends Setting, the Measured Value of Special Function (Including the Measured Value of PEEPi, NIF, P0.1 and P-V Tool), Patient Setting, Device Setting and Alarm Setting. The data changed will be stored in flash memory chip of motherboard. The data will be recovered automatically when restarting the device.**

5.16 Data Transfer

While the ventilator is in use, you can export/import the setting items.
Set Export:

1) Insert the U disk into USB port of the ventilator.
2) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
3) Select [Data Transfer] →[Setting] → [Export], save the current settings and default values in the ventilator to the U disk.
4) Set Import
5) Insert the U disk into USB port of the ventilator.
6) Select [Setup] → [Maintain] → input the User maintenance password to enter the [User] menu.
7) Select [Data Transfer] →[Setting] → [Import], load the settings in the U disk to the ventilator.

5.17 Data Export

Data export function means the ventilator exports some data to the U disk.

5.17.1 Screen Export

Screen export function means the ventilator exports screenshots saved recently. The file format exported is bmp.
Operating steps for Screen export are as follows:

1) Insert the U disk into USB port of the ventilator.
2) Select [Setup] → [Export] → [Export Screen], the system will check whether the U disk exists or not. If the U disk exists with enough free space, the system will export the interface saved by the device.
3) After the export is finished, select [Remove the U disk] button to remove the U disk.

5.17.2 Data Export

Data Export means the ventilator exports Patient information, Current Alarm Limit, Trend, etc.
Operating steps for data export are as follows:

1) Insert the U disk into USB port of the ventilator.
2) Select [Setup] → [Export] → [Export Data], the system will check whether the U disk exists or not. If the U disk exists with enough free space, the system will export patient information, current set parameter, current alarm limit, tabular trends, graphic trends, and the measured value of PEEPi/P0.1/Vtrap/NIF, etc. The file format exported is html.
3) In addition to exporting the data above, if you need to export Calibration data, Event log, Self-test log and more, select [Setup] → [Maintain]→ input the User maintenance password → [Data Transfer] → [Data] → select data type to be exported → [Export], the system will check whether the U disk exists or not. If the U disk exists with enough free space, the system will export the data. The file to be exported is encrypted, whose format is .blg.

4) After the export is finished, select [Remove the U disk] button to remove the U disk.

Note

- **If you need to view the file in .blg format, contact our After-sales Service Department.**
- **After power-down, the data could be stored no matter how long it is. The time of device power-down is also recorded.**

5.18 Power Failure Alarm

The ventilator provides Power failure alarm function. When the ventilator is in normal use, if the AC and DC power cord comes off accidentally or is unplugged from the ventilator, without battery installed or battery depletion, the device will provide an alarm sound through buzzer only and would last for at least 120s. Its feature: High level alarms: Di---.in this case, there are no alarm indicators nor LCD displayer.

Chapter 6 Alarms

An alarm is a prompt sent by the ventilator to medical workers in sound, light or other forms when the operator ventilator cannot smoothly use the ventilator due to abnormal changes of the patient's vital signs or failure of the ventilator.

6.1 Safety Precautions

WARNING

- **Users should set the alarm volume and the alarm limit according to the patent's actual condition. Do not monitor the patient only by relying on the sound alarm system. The patient may be put in a dangerous situation if the alarm volume is low. Set the minimum alarm volume should be higher than environmental noise. Users should pay close attention to the patient's actual clinical condition.**
- **The physiological waveforms, physiological parameters, alarms and other information displayed on the screen of the equipment are only for reference todoctors, which shall not be used as a basis for clinical treatment.**
- **A hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre. The operator should check that the current alarm presets is appropriate prior to use on each patient.**
- **No matter how long the power loss, after the restoration of supply mains, the equipment would restore to the last settings used. When start-up, the main menu is keep at the [New Patient] page, you could select [last patient] to retained alarm settings from previous use, or select the new patient type for new operation. Upon change of patient type, the ventilation parameter and alarm limit would restore to default pre-set.**

Note

- **The system will test whether the alarm sound and alarm light function normally at start-up. Normally, the equipment will sound one "beep" for alarming and the alarm light will blink yellow and red once respectively. If the alarm sound and alarm light function abnormally, do not use this equipment and contact us immediately.**
- **When several alarms of different levels are generated simultaneously, the equipment will give light and sound alarms according to the highest priorityalarm among all alarms.**

6.2 Alarm Type

Alarms generated by the ventilator are classified into physiological and technical alarms by the nature of alarm.

- Physiological alarm

  A physiological alarm is often generated when a certain physiological parameter of the patient is beyond the upper/lower alarm limit or the patient has physiological disorder. A physiological alarm message is displayed in the physiological alarm area in the upper part of the screen.

- Technical alarm

  A technical alarm is also known as a system error message, which is an alarm triggered when a system function cannot work normally or the monitoring result is distorted due to improper operation or system failure. A technical alarm message is displayed in the technical alarm area in the upper part of the screen.

Apart from physiological and technical alarms, the ventilator will show some messages related to system status. These messages generally do not involve vital signs of the patient, and are shown in the system prompt message area as prompt messages.

6.3 Alarm Level

- High-level alarm: The patient is in critical condition or the device has serious failure, and immediate response is necessary
- Medium-level alarm: The patient's physical signs are abnormal, the device has failure or is misoperated by the user, and timely response is necessary
- Low-level alarm: The patient feels unwell, the device has failure or is misoperated by the user, and the user is required to understand the current situation

6.4 Alarm Mode

6.4.1 Light Alarm

The alarm indicator lights will indicate different levels of alarms generated in different colors and blinking frequencies.

- High-level alarm: Red, flash frequency: 1.65 Hz.
- Medium-level alarm: Yellow, flash frequency: 0.55 Hz.
- Low-level alarm: Yellow, no blinking, light remaining on.

6.4.2 Sound Alarm

Sound alarms concerning for different levels of alarms generated by the ventilator with different sound characteristics.

- High-level alarm: beep-beep-beep--beep-beep----beep-beep-beep--beep-beep
- Medium-level alarm: beep-beep-beep
- Low-level alarm: beep

When supply mains and battery both loss, the ventilator will provide an alarm sound through buzzer only and would last for at least 120s, with sound characteristics:

- High level alarms: Di---

Sound alarm signal A weighted sound pressure level:

- Operator position: 1 m in front of the ventilator, and at the height of 1.5 m.
- A-weighted sound pressure level: not less than 45 dB, not greater than 85 dBwith adjustable alarm volume; at the manufacturerdefault alarm volume level, the alarm volume of high-priority alarm is not less than 60 dB.

6.4.3 Alarm Message

An alarm message is the message shown in the alarm area when an alarm is generated.

- The following signs are used in front of alarm messages to differentiate the levels of alarm messages:

  High-level alarm: ! ! !

  Medium-level alarm: ! !

  Low-level alarm: !

- Ground colors corresponding to different levels of alarm messages:

  High-level alarm: Red

  Medium-level alarm: Yellow

  Low-level alarm: Yellow

6.4.4 Alarm parameter form

- High-level alarm: red background, blinking, parameter constant (on)
- Medium-level alarm: yellow background, blinking, parameter constant (on)
- Low-level alarm: yellow background, blinking, parameter constant (on)

6.4.5 Alarm State Icons

: this suggests that an alarm existed recently but the alarm condition disappeared. Recent alarms (up to 10 alarms can be displayed) can be viewed in the interface opened after clicking the icon. Recent alarms can be cleared by selecting the [Reset] button.

: Indicates the alarm system is in audio paused state.

: Indicates the alarm is off.

: Indicates there are multiple alarm messages when the number of alarms is displayed before the alarm message. Red indicates the highest level of multiple alarm messages is high-priority. Yellow indicates the highest level of multiple alarm messages is medium-priority. Click the alarm message prompt area at the moment to view the current alarm.

6.5 Set Alarm Limit of Parameters

WARNING

- **When setting the upper/lower limit value of alarm limit of parameters, make sure they are appropriate for the patient type before use.**
- **After each change of ventilation parameters, please check the alarm limits are valid and appropriate for the patient's condition.**
- **When the alarm limit is enabled, after manually setting the upper/lower limit value of alarm limit, the device will display these upper/lower limit values set instead of displaying the initial alarm limit values preset by the system.**
- **After powering off accidentally while the device is in use, when the device is rebooted, settings before the power interruption will be auto loaded.**
- **When setting alarm limits to extreme values, the alarm system may be useless.**

CAUTION

- **If the high-pressure alarm limit needn't be set greater than 60cmH_2O as per clinical condition, it's recommended to set it to 60cmH_2O or lower to extend the service life of the blower and the battery life.**
- **When the airway pressure setting exceeding 60cmH2O, a deliberate action is needed, you would see prompt message of [ΔPinsp+int.PEEP+PEEP>60cmH2O? Press the control knob to confirm] before continuing your adjustment.**

Note

- **When a parameter value is greater than the upper alarm limit or less than the lower alarm limit, an alarm will be triggered.**
- **During use of the equipment, always pay attention to whether the alarm limits of each parameter are set to proper values.**

6.5.1 SetSpO_2 Limit

1) Select [Alarm] → [Limit 1] or [Limit 2].
2) Set the alarm s according to the patient's condition.

6.5.2 Set Auto Alarm Limit

The ventilator provides function of setting alarm limit automatically. It sets alarm limit automatically according to current patient type and parameter values measured.
Before using these alarm limits, ensure whether they are fit for current patient. If not, you need to set the alarm limit manually.

Alarm limit	**Formula**
Upper alarm limit of the airway pressure	Mean P_{peak} + 10cmH_2O or 35cmH_2O, whichever is larger.
Upper alarm limit of MV	1.5 × MV monitored value
Lower alarm limit of MV	0.6 × MV monitored value
Upper alarm limit of TVe	1.5 × TVe mean value
Lower alarm limit of TVe	0.5 × TVe mean value
Upper alarm limit of total frequency	1.4 × monitored value of total frequency
Apnea Ventilation Time	Default at15s

Mean value in formula: use the monitored value in the last 8 ventilation cycles or the monitored value in 1 minute as Mean value, whichever is smaller.
If the alarm limit figured out is greater than the high threshold of setting range, or less than low threshold, relevant threshold will be used as Auto alarm limit.
The steps to set the automatic alarm limit are as follows:

1) Select [Alarm] → [Limit 1].
2) Select [Auto Alarm Limits].

Note

- **When the factory configuration is used, relevant alarm limit of parameters will change. see "*Appendix IVDefault Settings*" for details.**
- **CO_2 and SpO_2 alarm limit don't have the function of setting auto alarm limit.**

6.6 Set Alarm Volume

6.6.1 Set Minimum Alarm Volume

Do not set the minimum alarm volume too low; otherwise you cannot hear the alarm sound. This may put the patient safety into danger. Follow the steps below to set the minimum alarm volume:

1) Select [Setup] →[Maintain], input user maintain password.
2) Select [Settings] →[Other].
3) Set [Setting minimum alarm volume].

Note

- **When the alarm volume is too low, the alarm sound may be hard to be heard. Set the minimum alarm volume should be higher than environmental noise.**

6.6.2 Set Alarm Volume

1) Select [Alarm] hotkey → [Volume].
2) Set [Alarm Volume]. The range of Alarm volume is 1～10. 1 is the lowest volume. If there is no alarm triggered, you can select [Test], the system will play the low-priority alarm sound once as per the volume you set.

Warning

- **In the process of using the equipment,do notonly rely on the sound alarm system. The patient may be put in a dangerous situation if the alarm volume is low. Do set the minimum alarm volume higher than environmental noise, otherwise, it could impede operator recognition of alarm conditions.Users should pay close attention to the patient's actual clinical condition.**

6.7 Alarm Audio Paused

In the alarm process, click alarm audio paused button on the panel to enter the [Alarm Audio Paused], the alarm sound currently produced can be turned off. After a countdown for 120 sec audio paused countdown, the sound alarm will be restored.

Alarm audio paused can be canceled in the following cases:

- When 120 sec audio paused countdown finished.
- When conditions for the alarm sound currently produced disappeared.
- In [Alarm Audio Paused], press the button on the panel.

WARNING

- **During alarm audio paused, pay close attention to the actual clinical condition of patient and the ventilator to ensure that no alarm message is ignored. If the alarm condition continuously exists without taking measures, harm can be caused to the patient or the equipment.**

Note

- **In [Alarm Audio Paused], all alarm signals except auditory alarm signals can work normally.**

6.8 Recent Alarm

When there are active alarms in the system, if the number of alarms is displayed before the alarm message, this indicates there are multiple alarm messages. At this moment, if you click this alarm message prompt area, you can view the current alarm message, the time of alarm occurrence, and the alarm priority in the Recent Alarm menu opened. Up to 10 alarms can be displayed.

After all active alarms are cleared, the icon will be displayed. Inactive recent alarms (up to 10 alarms can be displayed) can be viewed in the Recent Alarm menu opened after clicking the icon . Inactive recent alarms can be cleared by selecting the [Reset] button.

6.9 Turn off Alarm

When the lower alarm limit ofPaw, upper alarm limit of V_T, lower alarm limit of V_T, upper alarm limit of RR (Respiratory rate)or lower alarm limit of RR (Respiratory rate)are set to [OFF], the system will display the alarm off icon " " in the Alarm limit of parameters area, the relevant physiological alarms [Paw Too Low], [TVe Too High], [TVe Too Low], [f Too High] or[f Too Low] will be turned off. Namely, the sound, light, text display and alarm blinking on the alarm will be terminated.

WARNING

- **When the alarm is disabled, if an alarm is generated, the device cannot trigger an alarm condition. Therefore, operators shall use this function carefully.**

6.10 Set Nurse Call

Nurse Call function means when the alarms set by users are triggered, the ventilator can input signal to Nurse Call System to call a nurse. The ventilator provides Nurse call interface, which can realize "Nurse Call" function after connecting the ventilator with the Nurse call system of the hospital using the Nurse call cable supplied with the device.

Nurse Call function will be triggered when the ventilator meets the following conditions.

◆ Nurse call function is [On].

- There are alarms which meet user's settings generated.
- The system is not [Alarm Pause] or [Reset].

Setup steps for Nurse call:

1) Select [Setup] hotkey → [Maintain] → input the User maintenance password to enter the [User] menu.
2) Select [Interface Settings] tab → [Nurse Call] tab.
3) Switch on/off
4) Select [Signal Type] to set the signal type of Nurse call:
   - [Pulse]: Nurse call signal output is the pulse signal lasts 1s. When there are multiple alarms, only 1 pulse signal will be output; when a new alarm is generated with the current alarm being not removed, a pulse signal will be output again.
   - [Continuous]: The Nurse call signal output lasts as long as the time the alarm exists, namely lasts from the alarm happening to the alarm terminating.
5) Select [Contact Type] to set working mode for the relay of Nurse Call System to [Normally Closed] or [Normally Open].
6) Select [Alarm Level] to set the alarm level in which the nurse call can be triggered.
7) Select [Alarm Type] to set the alarm type which will trigger the Nurse call.

WARNING

- **Nurse call function shall not be used as main alarm messages source. Sound alarm and visual alarm must be combined with the patient's clinical presentation and symptoms.**
- **Use the nurse call cable supplied by us to connect the nurse call interface with the nurse call system of the hospital, otherwise this may lead to machine burnt and electric shock.**
- **When using Nurse Call function, regular check shall be performed on the ventilator's alarm signal.**
- **The Nurse Call System is required to meet the relevant IEC/ISO standard, with at least 2MOOP isolation from supply mains power supply. Under normal condition and single fault condition, the maximum voltage accessible shall not exceed the rating.**

6.11 Alarm System Check

The alarm system will perform a self-test on alarm light/sound at start-up.
Self-test phenomena:

- The alarm indicatorblinks in yellow-to-redsequence once and turns off.
- While the alarm indicatoris preforming self-test, the alarm system sound one "beep" of alarm sound to perform alarm sound self-test.

To perform further check on the alarm system, use the relevant simulator to measure and check. Adjust the alarm limit to check whether correct alarm response can be triggered.

6.11.1 Battery in Use Alarm

1) After the ventilator is connected to AC power supply, press ⊙/Ò On/Off button.
2) After the system is started, disconnect the AC power.
3) Verify whether the [Battery in Use] alarm is triggered, and the ventilator is powered by the battery.
4) Reconnect AC Power Supply
5) Verify whether the alarm is reset automatically, and the ventilator is powered by AC Power supply.

6.11.2 Power Failure Alarm

1) After the ventilator is connected to AC power, press ⊙/Ò On/Offbutton.
2) After the system is started, disconnect the external power supply when the battery is fully charged.
3) When the ventilator is connected to test lung, the ventilation is normal.
4) For the ventilator equipped with 1 battery, the ventilation time is about 2 hours (For the ventilator equipped with 2 batteries, the ventilation time is about 4 hours). When the battery capacity is running out, the Power failure alarm [System DOWM. Connect Ext. Power.] will be triggered.
5) Reconnect External Power Supply
6) Verify whether the alarm is reset automatically, and the ventilator is powered by external power supply.

6.11.3 Airway Pressure Too High Alarm

1) After the ventilator system is started normally, connect the ventilator to test lung and start ventilation.
2) Set the upper alarm limit of airway pressure to current P_{peak} + 5cmH_2O.
3) In the inspiratory phase, press hard on the test lung.
4) Verify whether the [Paw Too High] alarm is triggered, the respiratory cycle is in expiratory phase, and airway pressure is reduced to PEEP value.

6.11.4 Low airway pressure alarm test

1) After the ventilator system starts normally, connect the ventilator to the splint lung and start ventilation.
2) Set the lower limit of the airway pressure alarm to the current peak pressure + 5cmH2O.
3) Verify that the [airway pressure is too low] alarm is activated

6.11.5 Expiratory Tidal Volume Too Low Alarm

1) After the ventilator system is started normally, connect the ventilator to test lung and start ventilation.
2) Set the lower alarm limit of Tidal volume to greater than current expiratory tidal volume, and verify whether the [TVe Too Low] alarm is triggered.

6.11.6 Expiratory Tidal Volume Too High Alarm

1) After the ventilator system is started normally, connect the ventilator to test lung and start ventilation.
2) Set the upper alarm limit of Tidal volume to less than current Expiratory tidal volume, and verify whether the [TVe TooHigh] alarm is triggered.

6.11.7 Minute Volume Too Low Alarm

1) After the ventilator system is started normally, connect the ventilator to artificial lung and start ventilation.
2) Set the lower alarm limit of minute volume to greater than current minute volume, and verify whether the [MV Too Low] alarm is triggered.

6.11.8 Minute high ventilation alarm test

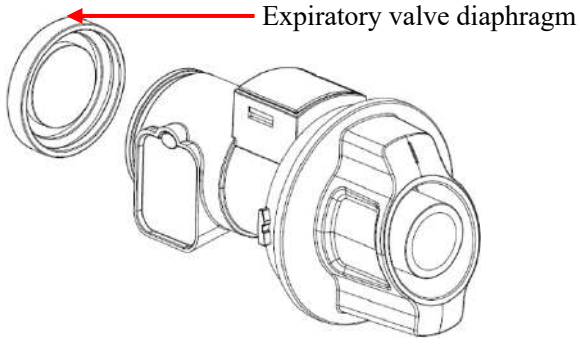
1) After the ventilator system is started normally, connect the ventilator to the splint lung and start ventilation.
2) Set the alarm high limit of minute ventilation to be less than the current minute ventilation, and verify that the alarm of [minute ventilation is too high] is activated.

6.11.9 Failure of O_2 Supply

1) Connect he ventilator to high-pressure O_2.
2) Turn off the high-pressure O_2, and verify whether the [O_2 Supply Failure] alarm is triggered.

6.11.10 PEEP Too Low Alarm

1) Dismantle the expiratory valve diaphragm of the ventilator, and install the expiratory valve.



2) After the ventilator system is started normally, connect the ventilator to test lung and start ventilation.
3) Set PEEP to 5cmH2O and verify whether the [PEEP Too Low] alarm is triggered.

6.11.11 Obstruction Alarm Condition

1) After the ventilator system is started normally, connect the ventilator to test lung and set to [Pressure] mode, and start ventilation.
2) Disconnect the connection between Y-shaped tube and test lung, use leakage-test plug to block Y-shaped tube.
3) After several respiratory cycles, verify whether the [Airway Obstructed?] alarm is triggered.
4) Connect Y-shaped tube with test lung, and verify whether the alarm is reset automatically.

Note

- **The maximum delay time of the technical alarm for the disconnection of the breathing circuit is two breathing cycles.**

6.11.12 FiO_2 Too High Alarm

1) Connect the ventilator to low-pressure O_2, and set the O_2 source type to low-pressure O_2.
2) Connect the ventilator to test lung, and start ventilation.
3) After ventilation is stable, set the upper alarm limit of FiO_2 to less than current monitored value of oxygen concentration.
4) Verify whether the [FiO_2 Too High] high-priority alarm is triggered.

6.11.13 FiO_2 Too Low Alarm

1) Connect the ventilator to high-pressure O_2, and set the O_2 source type to high-pressure O_2.
2) Connect the ventilator to test lung, and start ventilation.
3) After ventilation is stable, close the high-pressure O_2.
4) Verify whether the [FiO_2 Too Low] high-priority alarm is triggered.

6.11.14 $EtCO_2$ Too High Alarm

1) Connect he ventilator to test lung, and start ventilation.
2) Connect the CO_2 test module, and set it to working state.
3) After CO_2 is preheated, supply 3% ~ 7% CO_2 standard gas to the sampling port of sidestream CO_2 module or the airway adapter of mainstream CO_2 module, set the upper alarm limit of $EtCO_2$ to be less than the concentration of the standard gas.
4) Verify whether the [$EtCO_2$ Too High] medium-priority alarm is triggered.

6.11.15 EtCO2 Too Low Alarm

1) Connect the CO_2 test module, and set it to working state.
2) Connect he ventilator to test lung, and start ventilation.
3) After CO_2 is preheated, supply 3% ~ 7% CO_2 standard gas to the sampling port of sidestream CO_2 module or the airway adapter of mainstream CO_2 module, set the lower alarm limit of $EtCO_2$ to be greater than the concentration of the standard gas.
4) Verify whether the [$EtCO_2$ Too Low] medium-priority alarm is triggered.

6.11.16 Tube at Patient-End Disconnect Alarm

1) After the ventilator system is started normally, connect the ventilator to test lung and start ventilation.
2) Disconnect the test lung.
3) Verify whether the [Tubeat Patient-End Disconnect] alarm is triggered.

6.11.17 External Power Supply Loss

1) Connect the ventilator to AC power supply, press the Power button.
2) Disconnect the power cord.
3) Verify whether the [External Power Supply Lost] alarm is triggered, and the ventilator is powered by spare batteries.

6.11.18 Apnea Alarm

1) After the ventilator system is started normally, connect the ventilator to artificial lung and set the ventilator to Spontaneous Respiration mode. Ensure the Apnea spare ventilation is disabled.
2) Set [T_{apnea}] and wait.
3) Verify whether the [Apnea] alarm is triggered.
4) Press the artificial lung.
5) Verify whether the [Apnea] alarm is reset.

6.11.19 SpO2 Too high

1) Connect the ventilator and test lung, and start ventilation.
2) Connect the SpO_2 probe, and set the SpO2 monitoring function on
3) Connect the SpO_2 probe with finger, set the low SpO2 alarm limit at 20%, the high SpO2 alarm limit at 22%
4) Verify that the [SpO2 too high] alarm condition is activated.

6.11.20 SpO2 too low

1) Connect the ventilator and test lung, and start ventilation.
2) Connect the SpO2 probe, and set the SpO2 monitoring function on
3) Connect the SpO2 probe with finger, set the low SpO2 alarm limit at 98%, the high SpO2 alarm limit at 100%
4) Pinch the finger with SpO2 probe, when the % SpO2 is lower than 98%, verify that the [SpO2 too low] alarm condition is activated.

6.11.21 PRToo High

1) Connect the ventilator and test lung, and start ventilation.
2) Connect the SpO2 probe, and set the SpO2 monitoring function on
3) Connect the SpO2 probe with index finger, set the PR alarm upper limit at 30 bpm,
4) Verify that the [PRtoo high] alarm condition is activated.

6.11.22 PRToo Low

1) Connect the ventilator and test lung, and start ventilation.
2) Connect the SpO2 probe, and set the SpO2 monitoring function on
3) Connect the SpO2 probe with index finger, set the PR alarm upper limit at 240 bpm and the lower limits at 238 bpm. Verify that the [PR too low] alarm condition is activated.

6.12 Alarm Handling Measures

When the ventilator generates an alarm, take relevant measures according to the following steps:

1) Check the patient's condition.
2) Confirm the parameters or the type of alarm being happened.
3) Identify the cause of alarm.
4) Find the solution for discharging the alarm
5) Check whether the alarm is eliminated.

For detailed measures for handling each alarm, see "***Appendix V Alarm Messages***".

WARNING

- **To prevent patient injury, check whether patient ventilation is sufficient when an alarm is activated. Identify the cause of alarm and discharge the alarm. The alarm limit can be readjusted when the alarm limit setting is inappropriate for the circumstance.**

Note

- **If an alarm exists without any apparent cause, contact local After-sales Service Department of Comen.**

Chapter 7 Start Ventilation

7.1 Start System

1) Plug the power cord into a power outlet. Make sure the external power indicator is on.
2) Press the ⊙/Ò On/Off button.
3) The alarm indicator flashes once in the yellow-to-red sequence, and the speaker and buzzer beeps self-test tone once respectively. If the light and sound signals are not given, do not use this device and contact our after-sales service.
4) The screen displays the startup screen and a self-test progress bar, and then enters the system self-test interface.

Note

- **During the start-up process, the system detects whether the sound and light alarm functions are normal. If normal, the alarm indicator flashes once from red to yellow, and the speaker and buzzer give a self-test tone respectively. If the light and sound signals are not given, do not use this device and contact our after-sales service.**

7.2 System Self-test

WARNING

- **After each replacement of accessories/components such as a breathing tube, humidifier, or breathing filter, the system self-test must be performed again to ensure the ventilator works normally.**

CAUTION

- **Always run the self-test before using the ventilator on a patient. If any test fails, stop using the ventilator immediately. Do not use the ventilator until the necessary repairs have been completed and all tests are passed.**
- **Before performing the system self-test, disconnect the patient from the device and ensure that there is an alternative means of ventilation to support the patient ventilation.**

The path to the system self-test interface:

◆ After starting, the system automatically enters the system self-test interface.

- In a non-standby interface, select the [Standby] button and then confirm to enter the standby interface.
- In standby interface, select the [System Check] button to enter the system self-test interface.

In the system self-test interface, the time of the last system self-test is displayed.
Select the [Details] button to query the self-test information of the ventilator, including the items, results and time of self-tests.
Connect the gas sourceaccording to the prompt to close the Y-shaped tube and then select [Continue]. The system will start the self-checking procedure item by item.
The test items include:

- Blower test: test the rotation speed of the blower.
- O_2 flow sensor test: test the flow sensor in the O_2 limb.
- Inspiratory flow sensor test: test the inspiratory valve and flow sensor.
- Expiratory flow sensor test: test the expiratory flow sensor.
- Pressure sensor test: test the pressure sensors at the inspiratory end and expiratory end.
- Expiratory valve test
- Safety valve test
- Leakage amount test (ml/min)
- Compliance test (ml/cmH_2O)
- Tube resistance (cmH_2O/l/s)
- O_2 sensor test

The test results include:

- Passed: the test item has been completed and passed the self-check.
- Failed: the test item has been completed and failed to passed the self-check.
- Cancelled: the test item has been cancelled.
- Insufficient oxygen supply: the oxygen supply is insufficient during the O_2 sensor test or O_2 flow sensor test.
- The monitoring function is off: the sensor monitoring function may be turned off during the O_2 sensor test.

During self-test, the system prompts [Testing] to the right of the current self-check item.
If you select the [Skip] button to stop running this test item, with the self-test result displayed as [Cancel]. The next self-test item will start at the same time.
If you select the [Stop] button, the system will immediately stop running the current and all remaining test items, with the corresponding self-test results displayed as [Cancel].
When the O_2 sensor test fails, [O_2 Calibration] button is displayed. Press it to open the menu for performing O_2 concentration calibration.
After all self-test items are completed, you can select [Retry] to run the self-test procedure again.
Select [Exit] to exit the self-test mode and enter the standby interface.

7.3 Select Patient

Once the self-test is completed, select [Exit] to exit the self-test mode and enter the standby interface.
You need to select a patient:

- If you select [Last Patient], please set the ventilation type and ventilation mode in the current interface, and then select [Start Ventilation].

◆ If you select [New Adult] or [New Pediatric], set up [Gender], [Height] / [IBW], ventilation type and ventilation mode in the current interface, and then select [Start Ventilation].

Note

- **The Pediatric mode is applied to both pediatric and infant(not less than 3kg).**

7.4 Ventilation Type

This ventilator supports two types of ventilation: invasive and non-invasive.

WARNING

- **When switching from non-invasive ventilation to invasive ventilation, MAKE SURE to check the alarm limit settings.**

7.4.1 Invasive Ventilation

Invasive ventilation refers to the ventilation of patients through artificial airway (endotracheal intubation and tracheotomy).

Invasive ventilation modes include: V-A/C, P-A/C, V-SIMV, P-SIMV, CPAP/PSV, DuoVent, PRVC, APRV, PRVC-SIMV and VS ventilation mode.

Select the invasive ventilation icon or select

to open the setting interface, and select [Auto Tube Resistance Compensation] to finish the relevant settings. For details, refer to **"Section *10.13Tube Resistance Compensation (TRC)*"**.

WARNING

- **Wrong settings with the type, diameter or compensation of intubation may result in injury to the patient. MAKE SURE the settings are correct.**

CAUTION

- **NEVER select non-invasive ventilation for an intubated patient.**

7.4.2 Non-invasive Ventilation

Non-invasive ventilation refers to assist patient ventilation with a nasal mask or breathing mask, without endotracheal intubation and tracheotomy.

Non-invasive ventilation modes include: For Adult/Pediatric: P-A/C, P-SIMV, CPAP/PSV, DuoVent, APRV and PSV-S/T ventilation mode.

The unavailable ventilation modes are gray.

CAUTION

- **For patients without spontaneous breathing or with irregular spontaneous breathing, NEVER use non-invasive ventilation mode. Non-invasive ventilation is only intended for patient with spontaneous breathing.**
- **NEVER select non-invasive ventilation for an intubated patient.**

7.4.3 Set up Ventilation Type

Follow the steps below to set up ventilation type:

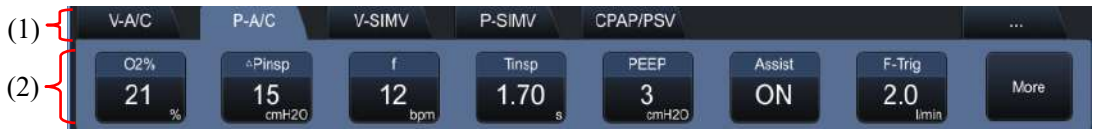
1) If the ventilator is not in standby mode, select the [Standby] button and then enter the standby interface after confirmation.
2) Select [Last Patient], [New Adult] or [New Pediatric] in the current interface.
3) Set the ventilation type to [Non-invasive] or [Invasive] in the current interface.

7.5 Ventilation Mode

Note

- **The ventilator does not produce negative pressure during expiratory phase.**
- **The maximum limited pressure is 95 cmH_2O.**
- **The maximum working pressure is Paw upper alarm limit. The user can adjust the high-pressure alarm limit. When the pressure reaches the set alarm limit, the high-level alarm "Paw too high" is triggered. The expiratory valve is opened to switch to the expiratory phase, until Paw drops to preset PEEP value. If the Paw value exceeds high-pressure alarm limit + 5 cmH_2O (adjustable pressure limit), the ventilator will open the safety valve to release pressure until 0.5s after Paw drops to 3 cmH_2O. For the sake of patient safety, set a reasonable high-pressure alarm limit for the patient.**
- **P-A/C or P-SIMV ventilation mode is recommended if the patient is using a closed suction catheter.**
- **The operator should set the ventilation parameters according to the actual situation of the patient.**

7.5.1 Ventilation Mode and Parameter Settings



(1). Ventilation Mode area

Only selected ventilation modes are displayed in this area.
Unselected modes are not displayed in the Ventilation Mode area.
The ventilating modes available on this ventilator are: V-A/C, P-A/C, V-SIMV, P-SIMV, CPAP/PSV, DuoVent, APRV, PRVC, PRVC-SIMV, VS and PSV-S/T. Your product may be equipped with different combinations of ventilation modes.

To set up ventilation modes to be displayed:

1) Select the "…"key in the Ventilation Mode area.
2) Under the [Mode Configuration], select ventilation modes you want to be displayed in this area.

(2). Shortcut key area for parameter settings.

Display the ventilation parameters corresponding to each ventilation mode. Select

to display other ventilation setting parameters. You can also set up parameters for the Sigh function and Tube Compensation function here.
Different ventilation modes have different parameters.

The general method to set up ventilation parameters is as follows:

1) In the Ventilation Mode area, select the button corresponding to a desired ventilation mode to open the menu, where you can set up the parameters for this ventilation mode.
2) Select the ventilation parameter button to be set.
3) If you are using the knob to select the parameter, press the main control knob, and turn the knob to set the parameter to a suitable value, and press the knob again to confirm the setting.
4) After all parameters are set as required, select the [OK] button.

The shortcut method to set up ventilation parameters is as follows:

1) In the hortcut key area for parameter settings, select a desired ventilation parameter.
2) If you are using the knob to select the parameter, press the main control knob, and turn the knob to set the parameter to a suitable value, and press the knob again to confirm the setting.
3) Set up other parameters in the same way.

7.5.2 Apnea Ventilation Mode

Apnea ventilation mode is an alternative mode enabled when patient apnea is detected in V-SIMV, P-SIMV, CPAP/PSV, DuoVent, APRV, PRVC-SIMV and VS mode.
The ventilator can exit apnea ventilation mode only when two consecutive spontaneous breaths are detected from the patient, or when you switch to another ventilation mode, or turn off the apnea ventilation switch.
Two apnea ventilation modes are provided: Volume-controlled Apnea Ventilation and Pressure-controlled Apnea Ventilation. Both modes are supported for invasive ventilation, and only Pressure-controlled Apnea Ventilation is supported for non-invasive ventilation.
Volume-controlled apnea ventilation allows you to set up tidal volume, respiratory rate and inspiratory time of the apnea ventilation cycle in the ventilation modes that support apnea ventilation. After entering apnea ventilation, the ventilator performs PRVC mode ventilation with the preset tidal volume, respiratory rate and inspiratory time of the apnea ventilation cycle (other parameter settings remain unchanged).
Pressure-controlled apnea ventilation allows you to set up inspiratory pressure, respiratory rate and inspiratory time of the apnea ventilation cycle in the ventilation modes that support apnea ventilation. After entering apnea

ventilation, the ventilator performs P-A/C mode ventilation with the preset inspiratory pressure, respiratory rate and inspiratory time of the apnea ventilation cycle (other parameter settings remain unchanged).

CAUTION

- **It is recommended to enable apnea ventilation mode under SIMV mode.**

7.5.3 Leak Compensation

Leakage in the breathing tube, breathing mask, etc. may cause the amount of gas delivered to the patient's lungs to fall below the preset value, false inspiratory triggering, or failure to switch between inhalation and exhalation. The ventilator has automatic leak compensation function, updating the leak volume according to the difference between the inspiratory and expiratory tidal volume after the end of each breathing cycle. The leak volume is used to calculate the real-time leak flow rate in the next breathing cycle. The real-time leakage flow rate is proportional to the airway pressure: the higher the airway pressure, the larger the leakage flow rate.

In the expiratory phase, in order to avoid the decrease in PEEP due to leakage, the ventilator automatically increases the basic flow rate to compensate for the leakage. To avoid false inspiratory triggering, the patient flow rate used for triggering judgment is also leakage-compensated. The maximum leak compensation flow rate is 65L/min for adults and 45 l/ min for pediatric.

In volume-controlled mode, the volume of gas delivered by the ventilator is the preset tidal volume + leakage, ensuring that the volume of gas delivered to the patient's lungs is equal to the preset value. The leakage compensation ininvasive ventilation, the maximum leakage compensation capacity is 80% of the preset tidal volume.

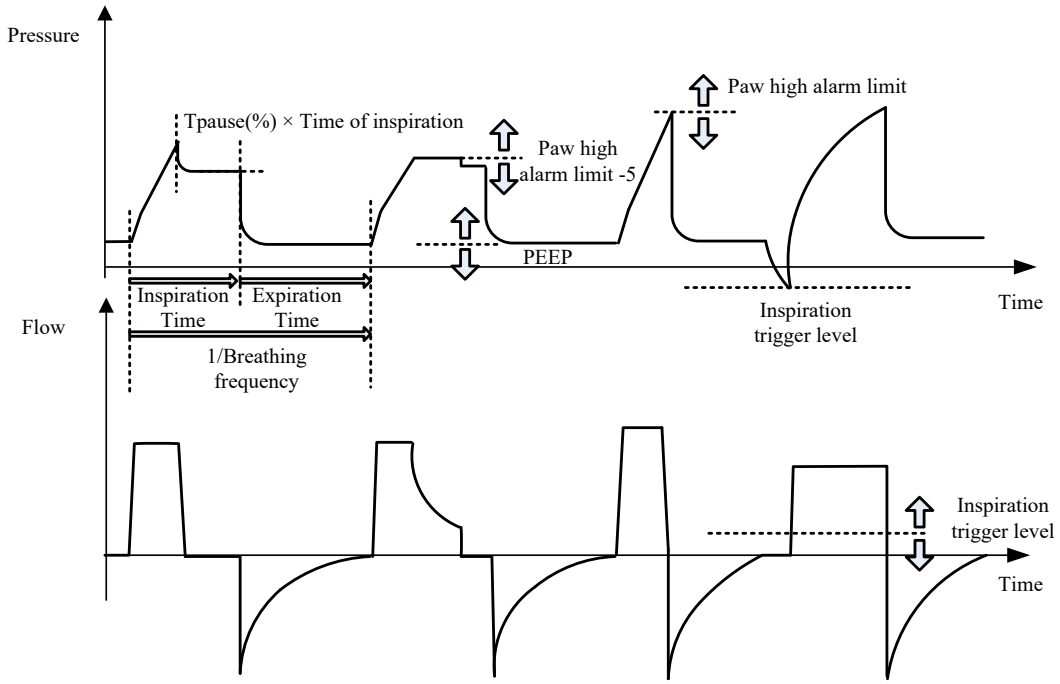
In the volume-controlled mode, as the primary purpose is to maintain the preset inspiratory pressure, the ventilator automatically increases the gas flow rate to compensate for leakage, until the maximum air supply capacity is reached. The maximum leakage compensation capacity is also limited by the upper limit of the TV alarm. When the [Volume Limit] alarm is given, if you need to reach the maximum compensation capacity, you can raise the upper limit of the TV alarm or turn off the alarm.

The flow rate waveform, volume waveform, TV monitoring parameters and MV monitoring parameters displayed by the ventilator are all leakage-compensated.

7.5.4 V-A/C Mode

In V-A/C mode, also called Volume-Controlled/Assist Ventilation mode, the ventilator delivers a certain tidal volume to the patient's lungs within a certain time. V-A/C mode supports synchronous triggering in the expiratory phase, that is, when the ventilator detects the patient's inhalation, it can start the next mechanical ventilation in advance.

The typical waveforms of V-A/C mode control are as follows:



The basic ventilation parameters required under V-A/C mode are:

1. [O_2%]: O_2 concentration
2. [TV]: Tidal volume
3. [T_{insp}] or [I:E]: Inspiratory time or ratio of inspiratory time to expiratory time
4. [f]: Respiratory rate
5. [PEEP]: Positive end-expiratory pressure
6. [Assist]: The switch to turn on assist triggering
7. [F-Trig] or [P-Trig]: Inspiratory triggering level
8. [T_{pause}]: The pause time as a percentage of the inspiratory time.

The optional parameters of Sigh function under V-A/C mode are:

1. [Sigh]: The switch to turn on the Sigh function
2. [Interval]: The interval between two signs
3. [Cycles Sigh]: The number of Sigh cycles
4. [Δint.PEEP]: End-expiratory pressure increased in Sigh cycle

In the V-A/C mode, the parameters of the Auto Tube Resistance Compensation function can be set as required (note that this function is applicable in all invasive modes):

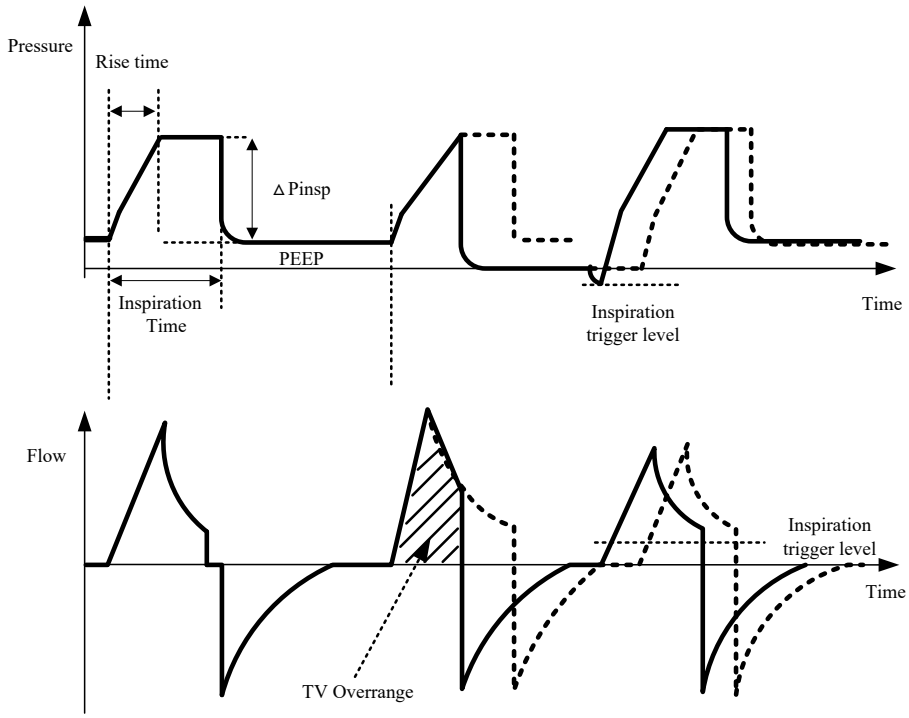
1. [Type of Intubation]: Select the type of intubation
2. [Tube I.D.]: Set up the tube diameter
3. [Compensate]: Set up the compensation proportion
4. [Expiration]: Turn on compensation switch for expiratory phase

7.5.5 P-A/C Mode

P-A/C mode is also called Pressure-Controlled/Assist Ventilation mode. This function enables the airway pressure (Paw) to rise to the preset level in the set rise time in the inspiratory phase, and maintains that pressure level until the end of inhalation, when exhalation phase starts.

In the pressure hold phase, the gas supply flow rate changes with the patient's lung resistance and compliance. In the inspiratory phase, the system switches to expiratory phase immediately when the delivered volume exceeds the preset upper limit of tidal volume alarm. In the expiratory phase, the ventilator supports synchronous triggering, that is, once patient inhalation is detected, the next mechanical ventilation is started in advance.

The typical waveforms of P-A/C mode control are as follows:



The basic ventilation parameters required under P-A/C mode are:

1. [O_2%]: O_2 concentration
2. [ΔP_{insp}]: Inspiratory pressure
3. [T_{insp}] or [I:E]: Inspiratory time or ratio of inspiratory time to expiratory time
4. [f]: Respiratory rate
5. [PEEP]: Positive end-expiratory pressure
6. [Assist]: The switch to turn on assist triggering
7. [F-Trig] or [P-Trig]: Inspiratory triggering level
8. [T_{slope}]: The time with which airway pressure builds toward a preset value.

The optional parameters of Sigh function under P-A/C mode are:

1. [Sigh]: The switch to turn on the Sigh function
2. [Interval]: The interval between two signs
3. [Cycles Sigh]: The number of sigh cycles

4. [∆int.PEEP]: End-expiratory pressure increased in Sigh cycle

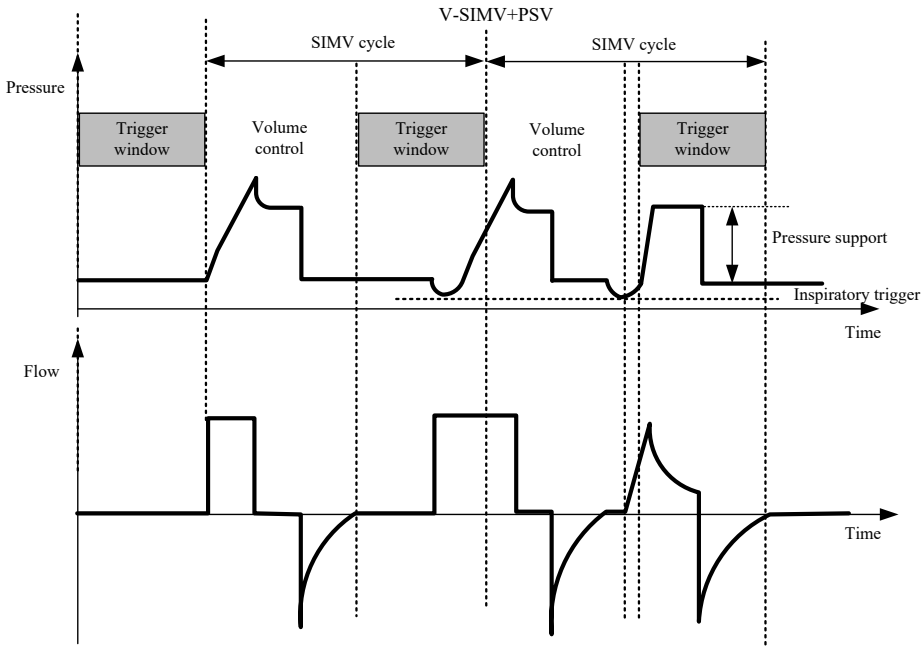
7.5.6 V-SIMV Mode

V-SIMV mode, or volume-controlled synchronized intermittent mandatory ventilation, guarantees the lowest preset ventilation frequency is realized. It provides a basic number of ventilations according to preset frequency of intermittent mandatory ventilation. The mechanical ventilation mode provided is Volume-Controlled/Assist Ventilation mode (V-A/C).

When SIMV is triggered in a trigger window, the ventilator delivers a volume-controlled ventilation. If SIMV is still not triggered at the end of a trigger window, a volume-controlled ventilation is also delivered.

Spontaneous breathing or pressure support breathing is conducted out of the trigger window.

The typical waveforms of V-SIMV+PSV mode control are as follows:



The basic ventilation parameters required under V-SIMV mode are:

1. [O_2%]: O_2 concentration
2. [TV]: Tidal volume
3. [T_{insp}]: Inspiratory time
4. [fsimv] Respiratory rate
5. [T_{pause}]: The pause time as a percentage of the inspiratory time.
6. [ΔP_{supp}]: Support pressure delivered by ventilator
7. [PEEP]: Positive end-expiratory pressure
8. [F-Trig] or [P-Trig]: Inspiratory trigger level
9. [Exp%]: Expiratory trigger
10. [T_{slope}]: The time with which airway pressure builds toward a presetvalue.
11. [Apnea Vent.]: The switch to turn on apnea ventilation
12. [TV_{apnea}] or [∆Apnea]: Tidal volume or inspiratory pressure in apnea ventilation cycle

13. [f_{apnea}]: Respiratory rate in apnea ventilation
14. [Apnea T_{insp}]: Inspiratory time in apnea ventilation

The optional parameters of Sigh function under V-SIMV mode are:

1. [Sigh]: The switch to turn on the Sigh function
2. [Interval]: The interval between two signs
3. [Cycles Sigh]: The number of sigh cycles
4. [∆int.PEEP]: End-expiratory pressure increased in Sigh cycle

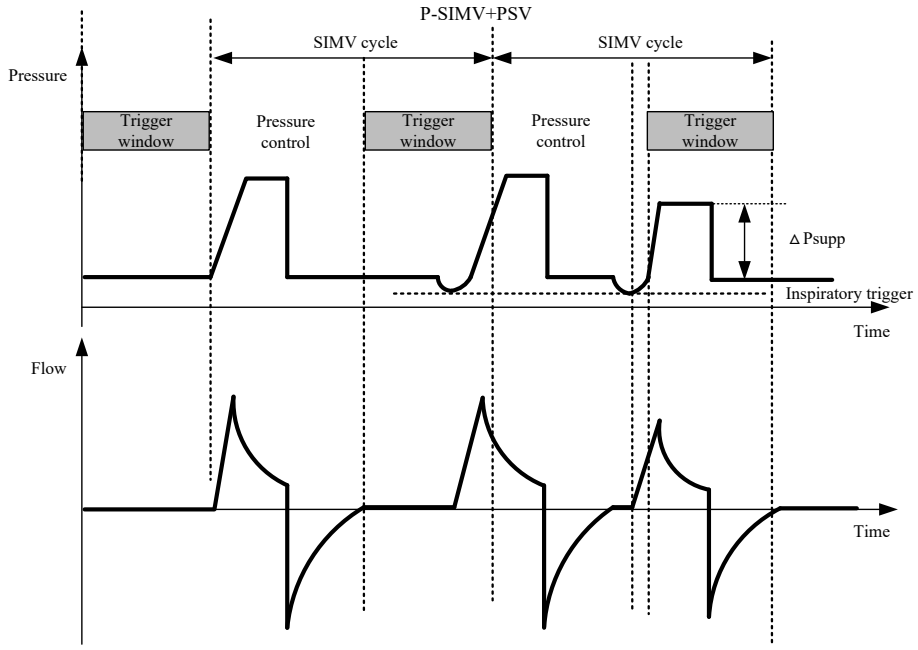
7.5.7 P-SIMV Mode

P-SIMV mode, or pressure-controlled synchronized intermittent mandatory ventilation, guarantees the lowest preset ventilation frequency is realized. It provides a basic number of ventilations according to preset frequency of intermittent mandatory ventilation. The mechanical ventilation mode provided is Pressure-Controlled/Assist Ventilation mode (P-A/C).

When SIMV is triggered in a trigger window, the ventilator delivers a pressure-controlled ventilation. If SIMV is still not triggered at the end of a trigger window, a pressure-controlled ventilation is also delivered.

Spontaneous breathing or pressure support breathing is conducted out of the trigger window.

The typical waveforms of P-SIMV+PSV mode control are as follows:



The basic ventilation parameters required under P-SIMV mode are:

1. [O_2%]: O_2 concentration
2. [ΔP_{insp}]: Inspiratory pressure
3. [T_{insp}]: Inspiratory time
4. [fsimv] Respiratory rate

5. [T_{slope}]:	The time with which airway pressure builds toward a preset value.
6. [PEEP]:	Positive end-expiratory pressure
7. [Exp%]:	Expiratory trigger
8. [ΔP_{supp}]:	Support pressure delivered by ventilator
9. [F-Trig] or [P-Trig]:	Inspiratory trigger level
10. [Apnea Vent.]:	The switch to turn on apnea ventilation
11. [TV_{apnea}] or [ΔApnea]:	Tidal volume or inspiratory pressure in apnea ventilation cycle
12. [f_{apnea}]:	Respiratory rate in apnea ventilation
13. [Apnea T_{insp}]:	Inspiratory time in apnea ventilation

The optional parameters of Sigh function under P-SIMV mode are:

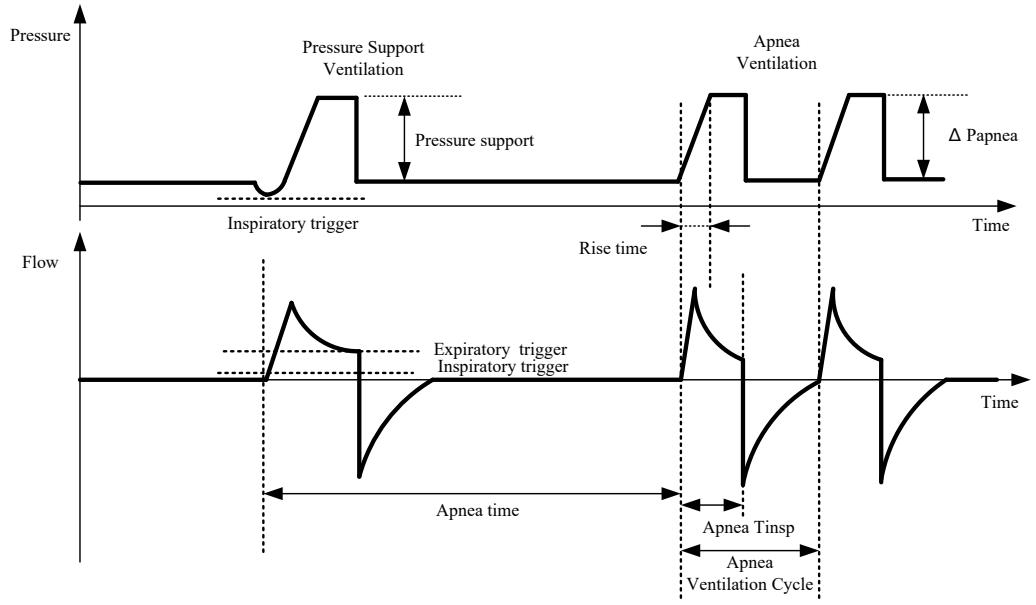
1. [Sigh]:	The switch to turn on the Sigh function
2. [Interval]:	The interval between two signs
3. [Cycles Sigh]:	The number of sigh cycles
4. [Δint.PEEP]:	End-expiratory pressure increased in Sigh cycle

7.5.8 CPAP/PSV Mode

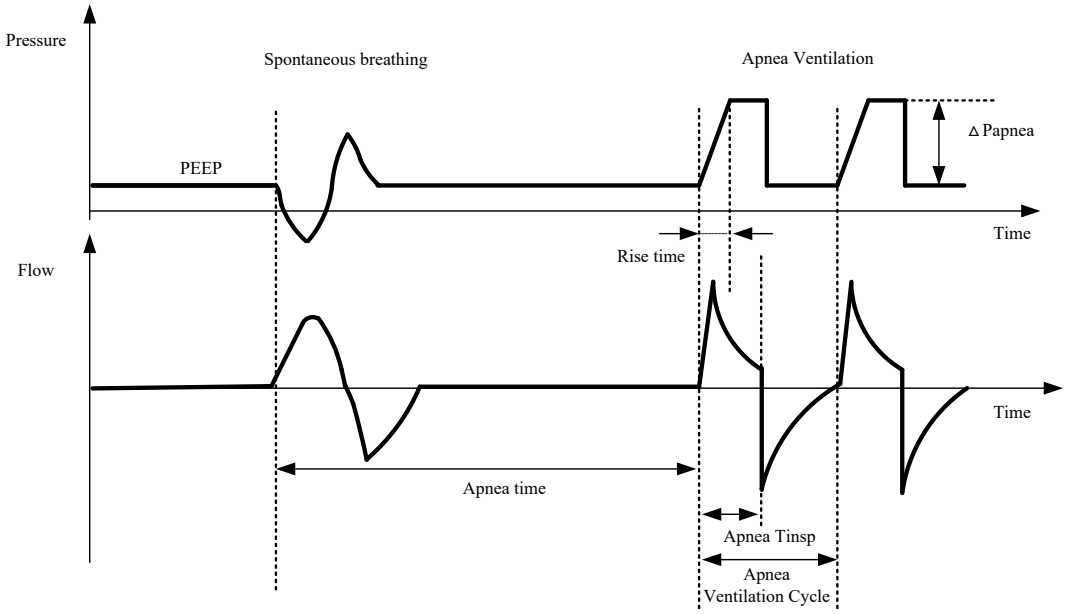
PSV mode is called the pressure support ventilation mode, which delivers a pressure support ventilation when the system detects the patient's inhalation effort reaches the preset inspiratory trigger level. In this mode, the pressure rise time and pressure support level are set by the user.

At the beginning of inspiratory phase, the ventilator increases the airway pressure to the preset level within the preset time of pressure rising (T_{slope}), and maintain this pressure level until the patient's inspiratory flow rate is detected to reach the expiratory trigger level.

The gas supply flow rate in the PSV pressure hold phase changes with the patient's lung resistance and compliance.



CPAP mode, which is also called continuous positive airway pressure ventilation mode, maintains the airway pressure at a preset positive pressure level throughout the ventilation cycle, but the patient should have spontaneous breathing so as to control the respiratory rate, timing and volume. When the system detects that the patient has no spontaneous breathing for a time period longer than the preset apnea limit, the backup apnea ventilation mode will be activated to continue ventilation.



The basic ventilation parameters required for invasive ventilation under CPAP/PSV mode are:

1. [O_2%]: O_2 concentration
2. [ΔP_{supp}]: Support pressure delivered by ventilator
3. [PEEP]: Positive end-expiratory pressure
4. [F-Trig] or [P-Trig] Inspiratory trigger level
5. [Exp%]: Expiratory trigger
6. [T_{slope}]: The time with which airway pressure builds toward a preset value.
7. [Exp%]: Tidal volume or inspiratory pressure in apnea ventilation cycle
8. [f_{apnea}]: Respiratory rate in apnea ventilation
9. [Apnea T_{insp}]: Inspiratory time in apnea ventilation

The basic ventilation parameters required for non-invasive ventilation (NIV) under CPAP/PSV mode are:

1. [O_2%]: O_2 concentration
2. [ΔP_{supp}]: Support pressure delivered by ventilator
3. [PEEP]: Positive end-expiratory pressure
4. [T_{imax}]: Maximum time of inspiratory phase
5. [F-Trig] or [P-Trig] Inspiratory trigger level
6. [Exp%] Expiratory trigger

7. [T_{slope}]	The time with which airway pressure builds toward a presetvalue.
8. [TV_{apnea}] or [ΔApnea]	Tidal volume or inspiratory pressure in apnea ventilation cycle
9. [f_{apnea}]	Respiratory rate in apnea ventilation
10. [Apnea T_{insp}]	Inspiratory time in apnea ventilation

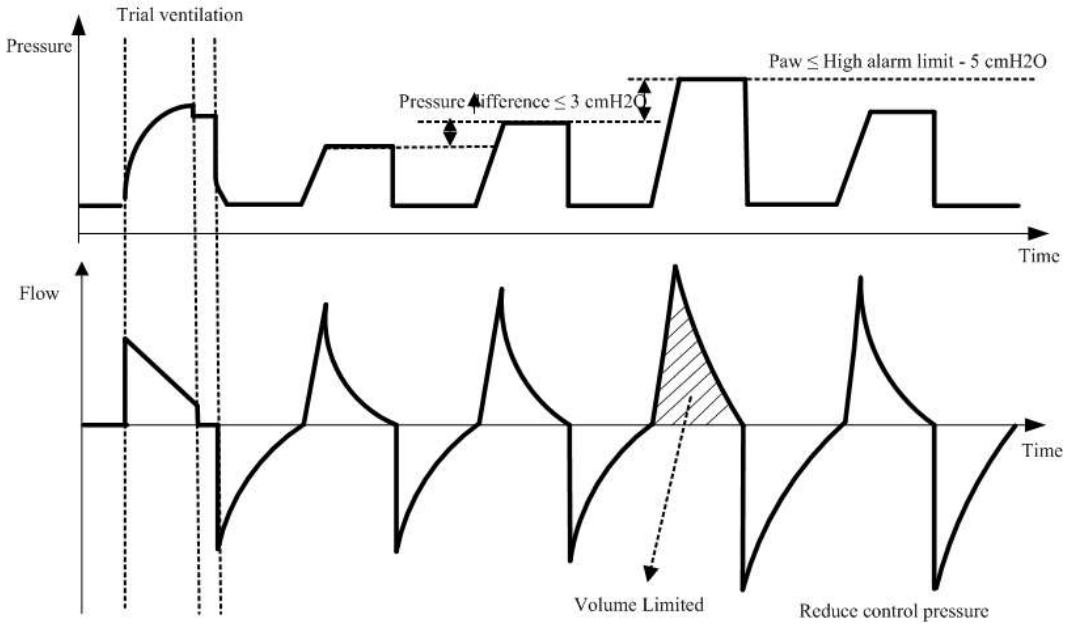
7.5.9 PRVC Mode

PRVC mode, or Pressure-regulated Volume Control mode, attempts to achieve set tidal volume at lowest possible airway pressure. The pressure control level varies with the tidal volume setting and the resistance and compliance of the patient's lungs.

In the first three cycles of ventilation, the pressure increasement does not exceed 10cm H_2O, and thereafter, the pressure increasement does not exceed 3cmH_2O each cycle. The maximum pressure does not exceed the upper pressure alarm limit -5cmH_2O.

The first PRVC ventilation cycle is experimental, delivering the gas at a pressure of 10cm H_2O + PEEP intended to calculate the compliance and resistance of the system and the patient 's lungs. The obtained results are used to calculate the pressure level suitable for the patient. In subsequent ventilation cycles, the system will use this pressure level as the adjustment target for tidal volume control.

The typical waveforms of PRVC mode control are as follows:



The basic ventilation parameters required under PRVC mode are:

1. [O_2%]:	O_2 concentration
2. [TV]:	Tidal volume
3. [T_{insp}] or [I:E]:	Inspiratory time or ratio of inspiratory time to expiratory time
4. [f]:	Respiratory rate
5. [PEEP]:	Positive end-expiratory pressure
6. [Assist]:	The switch to turn on assist triggering
7. [F-Trig] or [P-Trig]	Inspiratory trigger level
8. [T_{slope}]	The time with which airway pressure builds toward a preset value.

The optional parameters of Sigh function under PRVC mode are:

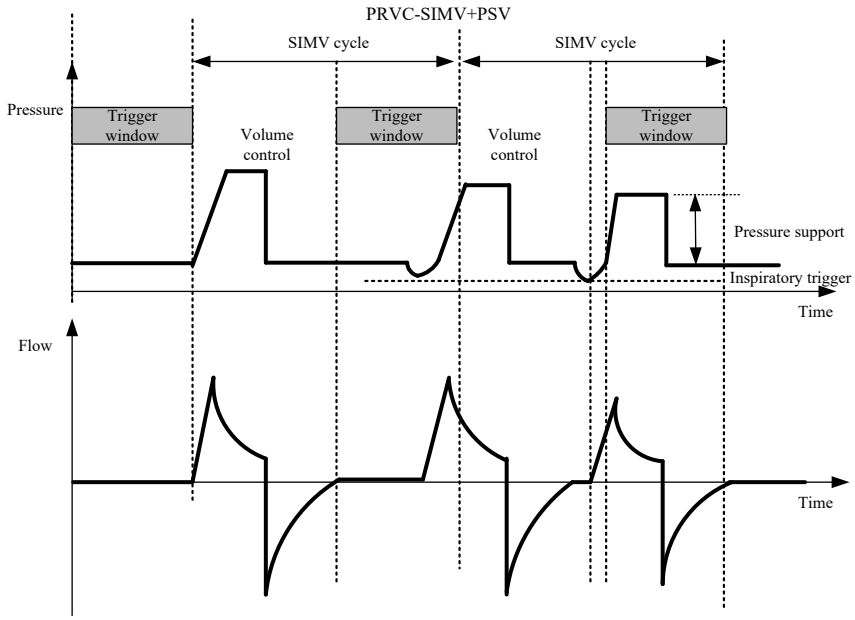
1. [Sigh]:	The switch to turn on the Sigh function
2. [Interval]:	The interval between two signs
3. [Cycles Sigh]:	The number of sigh cycles
4. [∆int.PEEP]:	End-expiratory pressure increased in Sigh cycle

7.5.10 PRVC-SIMV**Mode**

The PRVC-SIMV (Pressure Regulated Volume Control-Synchronized Intermittent Mandatory Ventilation) mode guarantees basic ventilation rate according to the preset intermittent mandatory ventilation frequency in volume-controlled mode (PRVC mode).

When SIMV is triggered in a trigger window, the ventilator delivers a volume-controlled ventilation. If SIMV is still not triggered at the end of a trigger window, a volume-controlled ventilation is also delivered. Spontaneous breathing or pressure support breathing is conducted out of the trigger window.

The typical waveforms of PRVC-SIMV+PSV mode control are as follows:



The basic ventilation parameters required under PRVC-SIMV mode are:

1. [O_2%]:	O_2 concentration
2. [TV]:	Tidal volume
3. [T_{insp}] or [I:E]:	Inspiratory time
4. [fsimv]:	Respiratory rate
5. [ΔP_{supp}]:	Support pressure delivered by ventilator
6. [PEEP]:	Positive end-expiratory pressure
7. [F-Trig] or [P-Trig]	Inspiratory trigger level
8. [Exp%]	Expiratory trigger
9. [T_{slope}]	The time with which airway pressure builds toward a preset value.

10. [Apnea Vent.] The switch to turn on apnea ventilation
11. [TV_{apnea}] or [ΔApnea] Tidal volume or inspiratory pressure in apnea ventilation cycle
12. [f_{apnea}] Respiratory rate in apnea ventilation
13. [Apnea T_{insp}] Inspiratory time in apnea ventilation

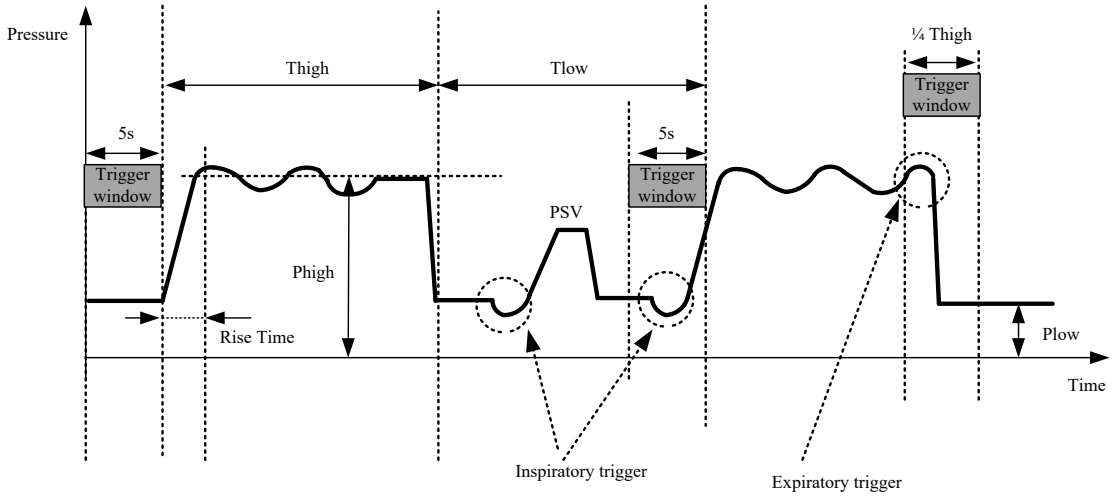
The optional parameters of Sigh function under PRVC-SIMV mode are:

1. [Sigh]: The switch to turn on the Sigh function
2. [Interval]: The interval between two signs
3. [Cycles Sigh]: The number of sigh cycles
4. [Δint.PEEP]: End-expiratory pressure increased in Sigh cycle.

7.5.11 DuoVent Mode

In DuoVent (Bi-level positive airway pressure ventilation) mode, the ventilator provides two different levels of positive airway pressure alternately for mechanical ventilation or spontaneous breathing. The patient can spontaneously breathe at both pressure levels, where pressure support can be set during the low-pressure phase. There are trigger windows in both high- and low-pressure stages: the trigger window in the low-pressure stage is 5 seconds after the low-pressure time, and the trigger window in the high-pressure stage is the last quarter at the end of the high-pressure time.

In the trigger window of the low-pressure phase, the inspiratory trigger will start high-pressure gas supply; and in the trigger window of the high-pressure phase, the expiratory trigger will start low-pressure gas supply. The typical pressure waveforms of DuoVent mode are as follows:



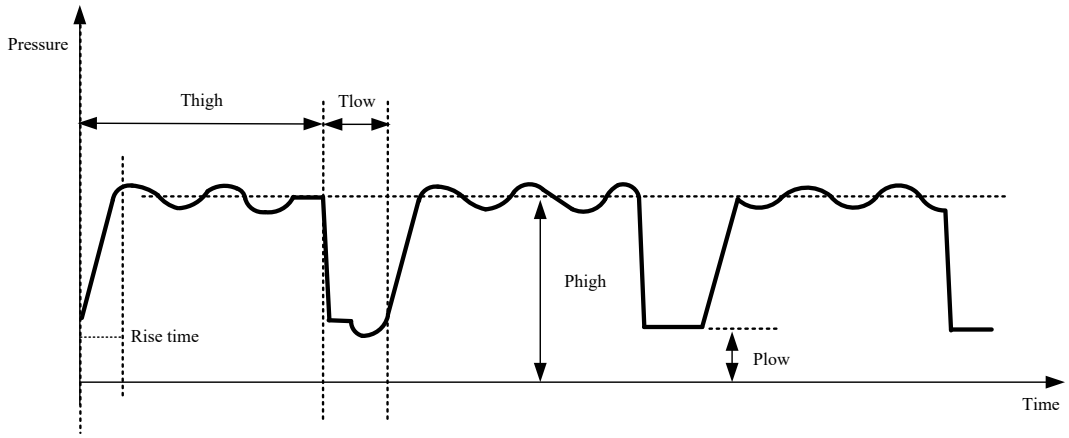
The basic ventilation parameters required under DuoVent mode are:

1. [O_2%]: O_2 concentration
2. [P_{high}]: High pressure
3. [T_{high}] or [f]: High pressure time or respiratory rate
4. [P_{low}]: Low pressure
5. [T_{high}] or [T_{insp}]: Low pressure time or inspiratory time
   or [I:E] or ratio of inspiratory time to expiratory time
6. [ΔP_{supp}]: Support pressure delivered by ventilator
7. [F-Trig] or [P-Trig]: Inspiratory trigger level

8. [Exp%]: Expiratory trigger
9. [T_{slope}]: The time with which airway pressure builds toward a preset value.
10. [TV_{apnea}] or [∆Apnea]: Tidal volume or inspiratory pressure in apnea ventilation cycle
11. [f_{apnea}]: Respiratory rate in apnea ventilation
12. [Apnea T_{insp}]: Inspiratory time in apnea ventilation

7.5.12 APRV Mode

The APRV (Airway Pressure Release Ventilation) mode can be regarded as CPAP mode integrated with periodic, short-term airway pressure release.
The typical pressure waveforms of APRV mode are as follows:



The basic ventilation parameters required under APRV mode are:

1. [O_2%]: O_2 concentration
2. [P_{high}]: High pressure
3. [T_{high}] : High pressure time
4. [P_{low}]: Low pressure
5. [T_{low}]: Low pressure time
6. [T_{slope}]: The time with which airway pressure builds toward a presetvalue.
7. [TV_{apnea}] or [∆Apnea]: Tidal volume or inspiratory pressure in apnea ventilation cycle
8. [f_{apnea}]: Respiratory rate in apnea ventilation
9. [Apnea T_{insp}]: Inspiratory time in apnea ventilation
10. [F-Trig] or [P-Trig]: Inspiratory trigger level

7.5.13 VS Mode

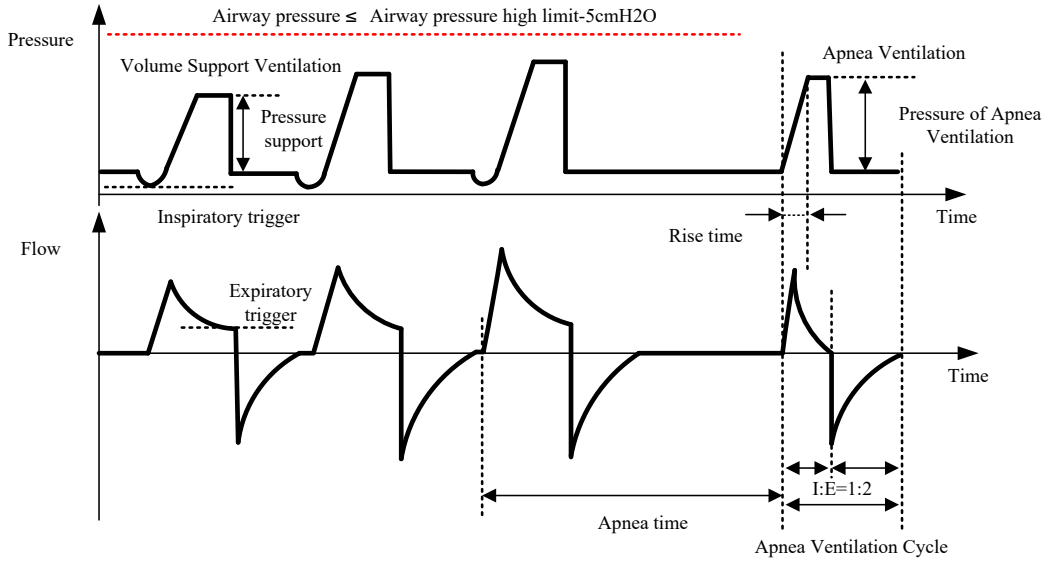
In VS (Volume Support) ventilation mode, the ventilator starts a volume support ventilation when the system detects the patient's inhalation effort has reached the preset inspiratory trigger level. This mode adjusts the pressure support level according to the resistance and compliance of the patient's lungs and breathing efforts, in order to ensure the patient is provided with preset tidal volume.

In this mode, the time period of the inspiratory phase and expiratory phase is controlled by the patient. When the system detects that the patient has no effective inspiratory triggering action in a time period longer than a preset apnea time, the system will enable the apnea ventilation mode to continue ventilation.

The first VS ventilation cycle is experimental in volume-controlled mode (V-A/C mode), intended to calculate the compliance and resistance of the system and the patient 's lungs. The obtained results are used to calculate the pressure support level suitable for the patient. In subsequent ventilation cycles, the ventilator will use this pressure level as the adjustment target for tidal volume control.

In the first three cycles of ventilation, the pressure increasement does not exceed 10cm H_2O, and thereafter, the pressure incensement does not exceed 3cmH_2O each cycle. The maximum pressure does not exceed the upper pressure alarm limit -5cm H_2O.

The typical waveforms of VS mode control are as follows:



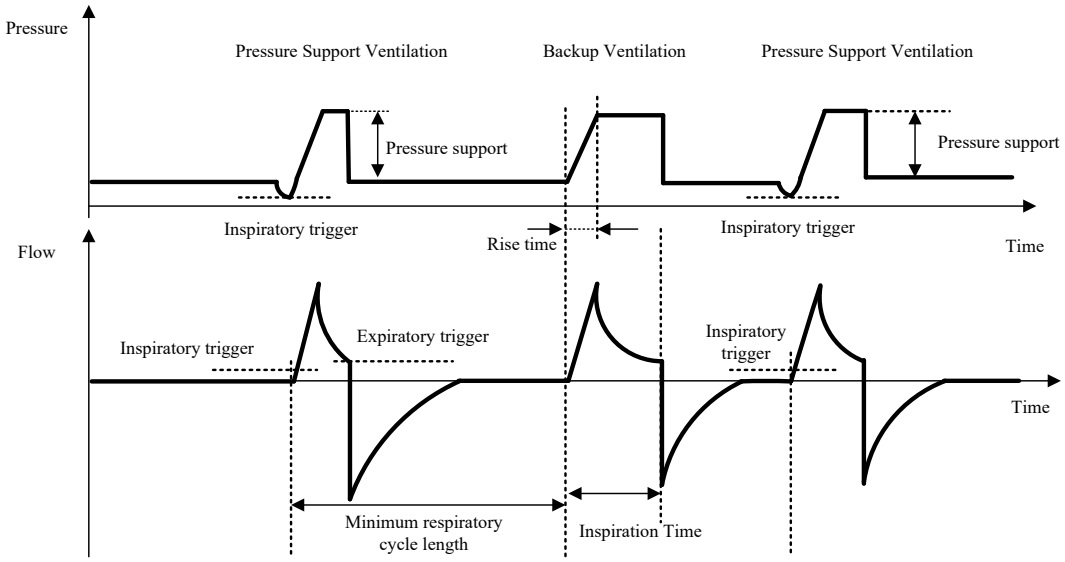
The basic ventilation parameters required under VS mode are:

1. [O_2%]: O_2 concentration
2. [TV]: Tidal volume
3. [PEEP]: Positive end-expiratory pressure
4. [F-Trig] or [P-Trig]: Inspiratory trigger level
5. [Exp%]: Expiratory trigger
6. [T_{slope}]: The time with which airway pressure builds toward a preset value.
7. [TV_{apnea}] or [ΔApnea]: Tidal volume or inspiratory pressure in apnea ventilation cycle
8. [f_{apnea}]: Respiratory rate in apnea ventilation
9. [Apnea T_{insp}]: Inspiratory time in apnea ventilation

7.5.14 PSV-S/T Mode

In PSV-S/T (Pressure Support Ventilation-Spontaneous/Timed) mode, the ventilator starts a pressure support ventilation when the system detects the patient's inhalation effort has reached the preset inspiratory trigger level. This mode adjusts the pressure support level according to the resistance and compliance of the patient's lungs

and breathing efforts, in order to ensure the patient is provided with preset tidal volume. Both the pressure rise time and the pressure support level are set by the user. At the beginning of inspiratory phase, the ventilator increases the airway pressure to the preset level within the preset time of pressure rising (T_{slope}), and maintain this pressure level until the patient's inspiratory flow rate is detected to reach the expiratory trigger level.
In PSV-S/T ventilation mode, when the system detects no patient trigger within the preset maximum breathing cycle (60s/RR), a mandatory ventilation is started automatically. The mandatory ventilation cycle is determined by the preset [f] And [T_{insp}]. When the system detects patient trigger within the preset maximum breathing cycle (60s/RR), the system starts a pressure ventilation.



The basic ventilation parameters required under PSV-S/T mode are:

1. [O_2%]:	O_2 concentration
2. [ΔP_{supp}]:	Support pressure delivered by ventilator
3. [PEEP]:	Positive end-expiratory pressure
4. [F-Trig] or [P-Trig]:	Inspiratory trigger level
5. [Exp%]:	Expiratory trigger
6. [T_{slope}]:	The time with which airway pressure builds toward a preset value.
7. [f]:	Respiratory rate in mandatory ventilation
8. [T_{insp}]:	Inspiratory time in mandatory ventilation
9. [Max. T_{insp}]:	Maximum time of inspiratory phase (only for pressure support ventilation cycle)

7.6 Alarm Limit Settings

Select the [Alarm] hotkey to open the alarm menu, select [Limit 1], and set the alarm limits for Paw, MV, VT, TVe, ftotal, and Apn Time as required.
You can also set the alarm limits of in [Limit 2].
If your ventilator is equipped with CO_2 module, you can also set the alarm limits of $EtCO_2$and FiO_2in [Limit 2].
If your ventilator is equipped with SpO_2 module, you can also set the alarm limits of SpO_2 and RR in [SpO2 Alarm].
You can also set volume for alarms in [Volume].

7.7 Start Ventilation

To start ventilation, select the [Start Ventilation] button on the interface in standby mode. The system will provide ventilation to the patient according to your settings.

WARNING

- **Before using, check whether the oxygen concentration of the delivered gas is consistent with the set value.**
- **If any problem occurs with the ventilator, do switch to manual ventilation immediately,otherwise it may cause death of the patient.**

7.8 Ventilation Parameter

WARNING

- **The ventilator is to be provided with O_2 monitoring equipment that conforms with ISO 80601-2-55:2018 before being put into service. If the equipment you are using is not equipped with O_2 concentration monitoring function, use with a respiratory gas monitor that meets the requirements of ISO80601-2-55 for oxygen concentration monitoring.**
- **The ventilator is to be provided with CO_2 monitoring equipment for the measurement of expiratory carbon dioxide concentration, (e.g. in the expiratory limb or at the patient connection port) in accordance with ISO 80601-2-55 before being put into service.**

Note

- **All parameters are calculated using real-time flow and pressure waveform. Low-pass filtering is used to measure the real-time flow rate and pressure, with the original sampling rate standing at 1kHz, and the cutoff frequency at 20Hz.**
- **Tidal volume, minute volume displayed on the ventilator associated the VBS and related calculationparameters are in the BTPS condition.**

Parameter	Description
TV (Tidal volume)	The volume inspired and expired with each breath of the patient at rest.
O_2 Concentration	The volume percentage of oxygen in the gas delivered to the patient.
I:E	Ratio of inspiratory time to expiratory time
PEEP	The measured circuit pressure at the end of the expiratory phase of a breath.

P_{high} (High pressure level)	The pressure level as an absolute value in the high-pressure phase, which allows the patient to breathe spontaneously during the high-pressure phase.
ΔP_{insp}	Inspiratory pressure in pressure-controlled mode, which is a value relative to PEEP.
P_{low} (Low pressure level)	The pressure level as an absolute value in the low-pressure phase, which allows the patient to breathe spontaneously during the low-pressure phase.
ΔP_{supp}	The inspiratory pressure level after the patient triggers the support pressure, which is a value relative to PEEP or P_{low}.
T_{slope}	The slope used to control pressure increasement.
T_{pause} (%)	The pause time as a percentage of the inspiratory time.
Respiratory Rate	The number of mandatory ventilation cycles in 1 minute.
fsimv	Respiratory rate set under SIMV mode.
T_{high} (Time of High Pressure)	The time length over which the high pressure is maintained.
T_{low} (Time of Low Pressure)	The time length over which the low pressure is maintained.
T_{insp} (Inspiratory Time)	The inspiratory time in a breathing cycle.
T_{imax}(Maximum Inspiratory Time)	The maximum length of inspiratory time in a breathing cycle.
F-Trig/ P-Trig	The inspiratory phase starts when the ventilator detects the trigger level of pressure trigger/flow trigger.
Exp%	At the end of inspiratory phase, when inspiratory flow drops to (peak flow * expiratory trigger), the expiratory phase starts.
Assist	Used to turn on / off the assist trigger function. When this function is turned on, the ventilator allows the patient to trigger mechanical ventilation at the end of expiratory phase.
Apnea Vent.	Used to turn on / off apnea ventilation function.
ΔP_{apnea}	When apnea ventilation is set to pressure-controlled mode, the inspiratory pressure of apnea ventilation is a value relative to PEEP or P_{low}.
f_{apnea}	Respiratory rate set under apnea ventilation mode.
TV_{apnea}	The tidal volume delivered in apnea ventilation when the apnea ventilation is set to volume- controlled mode.
Apnea T_{insp} (Apnea inspiratory time)	Inspiratory time set in apnea ventilation mode.
Sigh	Used to turn the on or off the sigh function.
Interval	Set the time interval between the two sigh ventilations.
Cycles Sigh	The number of sigh cycles set for each sigh ventilation.
Intermittent PEEP Δint.PEEP	Intermittent positive end-expiratory pressure, which is the increasement in PEEP over a number of sigh cycles.
Disable TRC (Tube compensation off)	You can turn off tube compensation, endotracheal intubation and tracheotomy.
ET Tube (Endotracheal intubation)	Used to turn on the automatic resistance compensation for endotracheal intubation.

Trach Tube (Tracheotomy)	Used to turn on the automatic intubation resistance compensation for tracheotomy.
Tube I.D. (Diameter)	The diameter of the tube.
Compensate	Percentage of compensation for automatic intubation resistance.
Expiration	Used to turn on/off automatic intubation resistance compensation in expiratory phase.

7.9 Enter Standby

Select the [Standby] button and confirm to enter the standby interface. Now ventilation will be stopped.

WARNING

- **Before entering standby state, MAKE SURE an alternative ventilation is available to prevent harm to patients due to lack of ventilation support. In addition, MAKE SURE that no patient is connected to the ventilator.**
- **In order to prevent the gas from overheating which may harm the patient or damage the breathing tube, the humidifier should be turned off when entering standby.**

7.10 Shut Down

In standby mode, press ON/OFF button until the ventilator is turned off.

In a non-standby state, if you select the ⊙/Ȯ n/Offbutton, the system prompts [Shut down the device in standby mode.]. Select [OK] to return to the previous non-standby state. Select the [Standby] button and then confirm to enter the standby interface. Now you can select the switch to turn off the ventilator.

Chapter 8 CO_2 Monitoring

8.1 Overview

The ventilator uses the CO_2 measurement to monitor the patient's breath state and control his/her ventilation. There are two methods of measuring the CO_2 in the patient's airway:

- Sidestream measurement method: take samples from the respiratory gas sensor in the patient's airway at a constant flow rate and use the built-in remote CO_2 sensor in the measurement system to analyze them.
- Mainstream measurement method: install the CO_2 sensor onto the airway connector of the respiratory system inserted directly into the patient.

In the above two cases, the measurement principle is IR emission. Use the optical detector to measure the intensity of the infrared rays penetrating the respiratory system. Such intensity depends on the CO_2 concentration as some infrared rays will be absorbed by CO_2 molecules.

CO_2 measurement is intended for adult and pediatric/Infant patients.

The CO2 measurement involves the following parameters.

- CO_2 waveform
- End-tidal CO2 ($EtCO_2$): the maximum partial pressure ofCO_2 at the end of a breath.

8.1.1 CO2 derived functions

For mainstream CO2 modules, in addition to providing CO2 waveform and EtCO2 monitoring parameters, it also provides:

1. V-CO2 curve
2. Monitoring parameters:

- Vtalv: Alveolar tidal volume
- MValv: Alveolar minute ventilation
- VDaw: dead space of airway
- VDaw/TVe: ratio of airway dead space to tidal volume
- slopeCO2: alveolar plateau slope
- MVCO2: Carbon dioxide emission rate
- ViCO2: Inhaled carbon dioxide volume
- VeCO2: the volume of exhaled carbon dioxide

WARNING

- **Please make sure that the patient's heart and lungs are in a stable state to obtain the most accurate CO2 measurement results.**
- **System leakage, respiratory rate higher than 35/min, and non-invasive ventilation types may affect the accuracy of mainstream CO2 monitoring parameters. The affected monitoring**

parameters include: VDaw, VDaw/TVe, Vtalv, MValv, slopeCO2, MVCO2, VeCO2, and $ViCO_2$.

- **The exhaled volume and exhaled CO2 of the patient can differ from the measured exhaled volume and exhaled CO2 due to leaks around the mask.**

8.2 Safety Information

WARNING

- **Place sampling line and other pipes well to prevent the patient from being entangled and thus suffering from apnea.**
- **Never use this device in an environment with inflammable anesthetic gases.**
- **Only the trained professionals familiar with this Manual are allowed to operate the device.**
- **Masimo CO_2 have the automatic atmospheric pressure compensation function.**
- **Respironics $CO_2$and Comen CO_2 sensors have no function of atmospheric pressure compensation, and have been set with a fixed value before delivery. If the value needs updated due to the altitude, contact the maintenance personnel.**
- **All parts or accessories except Respironics pathway adaptor did not contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic.**
- **Respironics pathway adaptor contains phthalates, such indication was marked on package.**
- **Take more care to treatment of children and treatment of pregnant and nursing women, who may allergy to such substance.**

CAUTION

- **When the patient is being treated with nebulized drugs, CO_2concentrationcannot be measured. After the Nebulizer function is activated, sampling and monitoring of CO_2 modules will be suspended.**
- **The $EtCO_2$ measured by CO_2 module may differ slightly from the partial pressure of carbon dioxide (PCO_2) measured by arterial blood gas analyzer.**
- **When the [CO_2 monitoring] is set at on, and if Nebulization is activated, [CO_2 monitoring Off] would be displayed as information signal, and set the [Monitoring] under [Sensor] to [OFF]. After 1 min upon completion of nebulization, the CO_2 monitoring is restarted, [CO_2 start] would be displayed as information signal.**

Note

- **The sampling gas of sidestream CO_2 module is the mix of air and oxygen only. The exhaust gas could be emitted to the environment for disposal.**

8.3 Adverse Effects on Performance

1) The following factors are known adverse effects on the specified performance:
   - Quantitative effects of RH or condensation;
   - Quantitative effects of barometric pressure;
   - Interfering gas or water vapor; and
   - Other interference sources.

2) Gas Measurement Unit

Use volume percentage as the gas concentration unit. The concentration calculation formula is:

$$\%gas = \frac{Partial\ pressure\ of\ gas\ component}{Total\ pressure\ of\ gas\ mixture} * 100$$

Use the cup-making pressure sensor of the ISA gas analyzer to measure the total pressure of the gas mixture. To convert into any other unit, use the actual barometric pressure sent from the ISA sidestream (IRMA mainstream).

CO_2 (mmHg) = (CO_2 Concentration) x (Barometric Pressure from ISA (kPa)) x (750 / 100).

Take 5.0 vol% CO_2 @ 101.3kPa as an example: 0.05 x 101.3 x 750 / 100 = 38 (mmHg).

3) Effects of RH

The partial pressure and volume percentage of the CO_2, N_2O, O_2 and anesthetic gas depend on the water vapor content in the measured gas. Calibrate the O_2 measurement, and the displayed value at the ambient temperature and RH level will be 20.8 vol%, not the actual partial pressure. The 20.8 vol% O_2 represents the actual O2 concentration of the room air (water concentration: 0.7 vol %) (for example, 25°C and 23% RH @ 1013hPa). The ventilator displays the actual partial pressure at the current RH level when measuring the CO2, N2O and anesthetic gas (like all gases measured by infrared cell).

In the patient's alveoli, the water vapor in the respiratory gas is saturated (BTPS) at the body temperature. Before the acquired respiratory gas in the sampling tube is transferred to the ISA sidestream gas analyzer, its temperature becomes approximate to the ambient temperature. No water enters the ISA gas analyzer after the Nomoline sampling tube removes all condensed water. The RH of the acquired gas is approximately 95%.

Use the following formula to calculate the CO_2 value at BTPS:

$$EtCO2(BTPS) = EtCO2 * \left(1 - \left(\frac{3.8}{Pamb}\right)\right)$$

In the above formula:

$EtCO_2$: $EtCO_2$ value [vol%] sent from ISA

Pamb: barometric pressure [kPa] sent from ISA

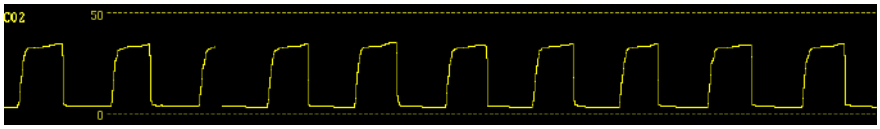
3.8 : typical partial pressure [kPa] of the water vapor condensed between the patient circuit and ISA

$EtCO_2$ (BTPS) = $EtCO_2$ concentration [vol%] at BTPS

It is assumed that the O_2 is calibrated by the room air at 0.7 vol% H_2O (RH).

Effects of Interfering Gases and Water Vapor		
Gas or water vapor	Gas Concentration	Quantitative effect[1)]
Nitrous oxide	60 vol%	±1 mmHg
Halothane	4 vol%	±1 mmHg
Enflurane, Isoflurane, Sevoflurane	5 vol%	±1 mmHg
Desflurane	15 vol%	±2 mmHg
Xenon	80 vol%	Reading-10%[3)]
Helium	50 vol%	Reading-6%[3)]
Metered dose inhaler propellants	--	Metered-dose inhaler
Ethanol	0.3 VOI%	_3)
Isopropanol	0.5 VOI%	_3)
Acetone	1 vol%	_3)
Methane	3 vol%	_3)
Note 1: means an extra error should be added in case of gas interference when CO2 measurements are performed between 0 to 40mmHg. Note 2: the above "Accuracy – all conditions" specifications include negligible interference and effect. Note 3: the interference at the indicated gas concentration. For example, 50 vol% He usually causes the CO2 reading to decrease by 6%. That is, if you measure the gas mixture containing 5.0 vol% CO2 and 50 vol% nitrogen, the measured CO2 concentration will be usually (1-0.06) × 5.0 vol% = 4.7 vol%.		

8.4 CO_2 Display



8.5 CO_2 Measure

WARNING

- **Check the airway adapter before use. Replace it if the airway adapter suffers from any exterior damage or breakage.**
- **Turn it off when the CO_2 module is idle, or it will remain in working state and its service life will be shortened.**
- **Hang the external CO_2 analyzer onto the CO_2 sensor holder on the back housing of the device reliably against falling and damage.**
- **MAKE SURE all connections are firm and reliable. Any leakage will cause the respiratory gas of**

the patient to include the ambient air, resulting in incorrect readings.

- **Check CO_2 sensor regularly for avoiding excessive humidity or secretion accumulation.**

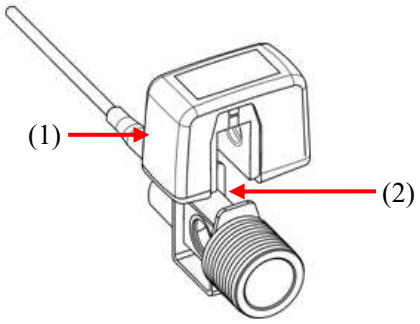
CAUTION

- **The Water Filter Assembly of Respironics sidestream CO_2 sensor will last up to 12 hours when used without the Dehumidification Tubing in a non-humidified environment.**
- **The Water Filter Assembly of Respironics sidestream CO_2 sensor will last up to 120 hours when used with the Dehumidification Tubing under conditions of ISO 80601-2-55 § 201.7.9.2.9.101b.**
- **The life of the water filter assembly of Respironics sidestream CO_2 sensor will be significantly reduced if used in a humidified circuit without dehumidification tubing.**

The Dehumidification Tubing is a replaceable part and is attached directly to the Water Filter Assembly. The Dehumidification tubing should be regularly examined for cracks or visual contaminates on its walls. If these conditions exist, the Dehumidification Tubing should be discarded in accordance with clinical protocol and replaced with a new part.

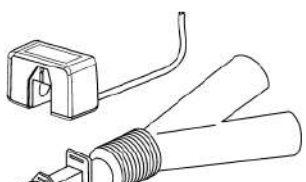
8.5.1 Preparations for Mainstream CO_2 Sensor Connection

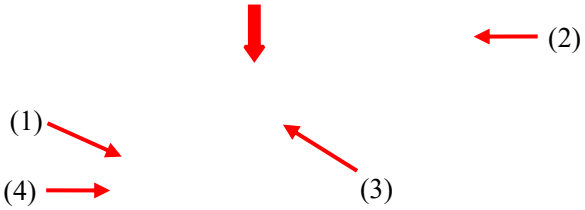
1) Connect the adapter cable with the CO_2 sensor cable (no need for Comen mainstream CO_2).
2) Insert the other end of the adapter cable into the CO_2 sensor interface on the device.
3) Wait for 10s (Masimo sensor) or 1min (Respironics and Comen sensor) until the sensor reaches its working temperature and a stable thermal state.
4) Fix the sensor to the airway adapter.



(1) Sensor (2) Airway adapter

5) Turn on CO_2 [Monitoring]. Refer to "**Section *8.7.1 CO_2 Monitoring Setting***".
6) For zero calibration of the sensor, refer to "**Section*8.6.1 Zero Mainstream CO_2 Sensors***".
7) Install the airway adapter onto one end of the breathing tube, between the Y-shaped tube (see figure below).





(1) Elbow tube (2) Y-shaped tube (3) Airway adapter (4) Breathing tube port

8) Make sure the airway is tight.

9) Set CO_2 parameters; please refer to **"Section*8.7 CO_2 Setting*"**for more information.

10) Start measurement.

8.5.2 Preparations for Sidestream CO_2 Sensor Connection

8.5.2.1 Preparations for Respironics Sidestream CO_2 Sensor

1) Plug the CO_2 sensor cable into the CO_2 sensor interface on the device.

2) Wait for 2min until the sensor reaches its working temperature and a stable thermal state.

3) Connect one end of the drying tube to the water filter component, and the other end with the sampling line, thus forming the sampling line component.

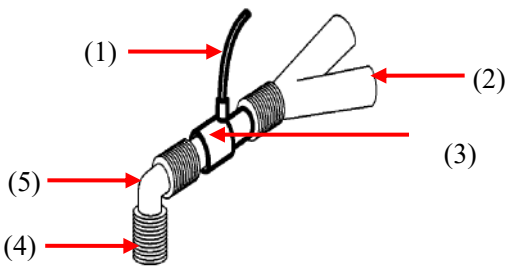
4) Insert the sampling line component into the CO_2 analyzer interface. A sound of "click" represents it is inserted correctly and locked in place.

5) Switch on CO_2 [Monitoring]. Refer to "**Section *8.7.1 CO_2 Monitoring Setting***".

6) Zero the sensor; please refer to "**Section*8.6.2 Zero Sidestream CO_2 Sensor***" for more information.

7) Set CO_2 parameters; please refer to "**Section *8.7 CO_2 Setting***" for more information.

8) For the patient with tracheal cannula: install the airway adapter of sampling line onto one end of the breathing tube, exactly speaking, between the elbow tube and the Y-shaped tube, shown as the figure below:



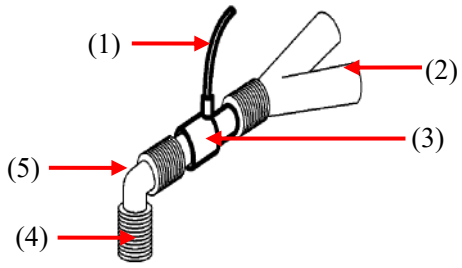
(1) Sampling line (2) Y-shaped tube (3) Airway adapter (4) Breathing tube port (5) Elbow tube

9) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O_2 cannula onto the patient's face, connect the O_2 supply tube to the O_2 supply system and set the O_2 flow as directed.

10) Start the measurement after confirming the airway tightness.

8.5.2.2 Preparations for Masimo Sidestream CO_2 Sensor

1) Insert sampling line into the interface of CO_2 sensor reliably until you hear a "click" sound.
2) Wait for 10s until the sensor reaches its working temperature and a stable thermal state.
3) Switch on CO_2 [Monitoring]. Refer to "**Section *8.7.1 CO_2 Monitoring Setting***".
4) Zero the sensor; please refer to "**Section*8.6.2 Zero Sidestream CO_2 Sensor***" for more information.
5) Check before its use; please refer to "**Section *8.5.2.2.1 Pre-use Checks***" for more information.
6) Set CO_2 parameters; please refer to "**Section *8.7 CO_2 Setting***" for more information.
7) For the patient with tracheal cannula: install the airway adapter onto one end of the breathing tube, exactly speaking, between the elbow tube and the Y-shaped tube, shown as the figure below:



(1) Sampling line (2) Y-shaped tube (3) Airway adapter (4) Breathing tube port (5) Elbow tube

8) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O_2 cannula onto the patient's face, connect the O_2 supply tube to the O_2 supply system and set the O_2 flow as directed.

8.5.2.2.1 Pre-use Checks

Perform the following operations before connecting the sampling line to the breathing tube:

1) Connect the sampling line to the CO_2 interface.
2) Check if the sensor interface LED remains green stably (an indication of normal system).
3) Expire into the sampling line and check if the ventilator displays the effective CO_2 waveform and value.
4) Block the sampling line with a fingertip and wait 10s.
5) Check if the prompt message “Sampling line clogged” appears and the sensor interface LED flashes in red.
6) Check the tightness of the patient circuit connected to the sampling line when appropriate.

WARNING

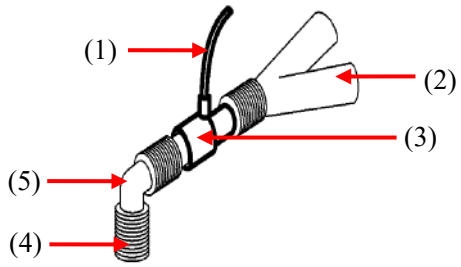
- **Place the IRMA sensor, if not protected by HME, with the status LED pointing up.**
- **Do not stretch the cable of the ISA sidestream gas analyzer.**
- **Operate the ISA sidestream gas analyzer in the specified working temperature environment only.**

Note

- **In order to prevent the condensed water dropping into the gas sampling line and blocking it, the gas sampling line connection end of the airway adapter should point up.**

8.5.2.3 Preparations for ComenSidestream CO_2 Sensor

1) Insert CO_2 cable to the ventilator's CO_2 interface.
2) Wait for 2min until the sensor reaches its working temperature and a stable thermal state.
3) Insert sampling line into the interface of CO_2 sensor reliably until you hear a click sound.
4) Switch on CO_2 [Monitoring]. Refer to "**Section *8.7.1 CO2 Monitoring Setting***".
5) Zero the sensor; please refer to "**Section*8.6.2 Zero Sidestream CO_2 Sensor***" for more information.
6) Set CO_2 parameters; please refer to "**Section *8.7 CO_2Setting***" for more information.
7) For the patient with tracheal cannula: install the airway adapter of sampling line onto one end of the breathing tube, exactly speaking, between the elbow tube and the Y-shaped tube, shown as the figure below:



(1) Sampling line (2) Y-shaped tube (3) Airway adapter (4) Breathing tube port (5) Elbow tube

8) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O_2 cannula onto the patient's face, connect the O_2 supply tube to the O_2 supply system and set the O_2 flow as directed.
9) Start the measurement after confirming the airway tightness.

8.6 Zero CO_2 Sensor

WARNING

- **If the alarm message "CO_2 Need Zero" appears directly after zeroing, please re-zero it.**

Note

- **For the best zeroing result, please zero Respironics CO_2 sensor after preheating for 5min.**

In order to eliminate the effect of baseline drift on measurement results and obtain accurate measurement results, please zero it before using CO_2 sensor to monitor the patient.

8.6.1 Zero Mainstream CO_2 Sensors

You can zero it manually when you consider it necessary by the following steps:

1) Connect the sensor to CO_2 module.

2) Select [Setup] → [Sensor] → Turn on CO_2 [Monitoring].
3) After preheating, connect the sensor to airway adapter.
4) Expose the sensor to room air and keep it away from all CO_2 sources, including ventilator, patient's breath and user's breath.
5) Select [Setup] → [Sensor] → [CO_2] → [Zero]; then [CO_2 Zero] will be prompted on the screen.
6) When zeroing is successful, [Zeroing Complete] is displayed as information signal.

8.6.2 Zero Respironics and ComenSidestreamCO_2 Sensors

You can zero it manually when you consider it necessary by the following steps:
1) Connect the sampling line to CO_2 sensor.
2) Select [Setup] key → [Sensor] → Turn on CO_2 [Monitoring].
3) After preheating, expose the sampling line to room air and keep it away from all CO_2 sources, including ventilator, patient's breath and user's breath.
4) Select [Setup] → [Sensor] → [CO_2] → [Zero]; then [CO_2 Zero] will be prompted on the screen.

8.6.3 Zero Masimo SidestreamCO_2 Sensors

For Masimosidestream CO_2 module, when you detach the sampling tube from the device, the module would start the zeroing procedure. When the zeroing is successfully, [Zeroing Complete] is displayed as information signal.

8.7 CO_2 Setting

8.7.1 CO_2 Monitoring Setting

1) Select [Setup] key → [Sensor] → [CO_2] tab.
2) Set [Monitoring].

◆ When [Monitoring] is switched to [On], CO_2 sensor will enter the running mode; CO_2 parameters and waveform will be displayed and physiological and technical alarms related to CO2 module will be provided by the device.

◆ When [Monitoring] is switched to [Off], CO_2 sensor will enter the sleeping mode; CO_2 parameters and waveform will not be displayed; physiological or technical alarms related to CO_2 module will not be provided by the device.

The sleeping mode of the CO_2 module is related to the standby mode of the device.

◆ If the device enters the standby mode, then the CO_2 module is switched to the sleeping mode.

◆ If the device exits the standby mode, then the CO_2 module returns to its previous mode before sleeping.

◆ Then ventilator is not be influenced by the running/sleeping mode switching of the CO_2 module.

In sleeping mode, the infrared source of CO_2 module is turned off by the system to reduce the power consumption and extend the module’s service life.

8.7.2 Set CO_2 Alarm

1) Select [Alarm] key → [Limit 2]
2) Set $EtCO_2$ alarm limit.

8.7.3 Set Gas Compensation

In some cases, such as ventilating with a ventilator, the patient's respiratory gas is mixed with other gases that interfere with CO_2 measurement, and then gas compensation is required to eliminate the interference of these gases in CO_2 measurement. The concentration of gas compensation should be set based on the actual concentration of interfering gases.

Set gas compensation for sidestream CO_2 modules as below:

1) Select [Setup] button → [Sensor] → [CO_2] tab.
2) Set [Gas Compensation] as below:

MASIMO CO_2 Module:

- [High]: The default O_2 Compensation is 85%.
- [Middle]: The default O_2 Compensation is 50%.
- [Low]: The default O_2 Compensation is 21%.

RESPIRONICS CO_2 Module:

- Choose the appropriate value according to the O_2 content in the measured gas.

COMEN CO_2 Module:

- Choose the appropriate value according to the O_2 content in the measured gas.

WARNING

- **Please set gas compensation based on the actual conditions, or the measurement results may differ greatly from the actual values to cause misdiagnosis.**

8.7.4 Set CO_2 Unit

1) Select [Setup] key → [Maintain] → Input the password → [Settings].
2) Select [Unit] tab.
3) Set [CO_2 Unit].

8.7.5 Set Elevation

For MASIMO CO_2 module, there is no need to set the elevation manually since it is set automatically.

For RESPIRONICS and COMEN CO_2 modules:

1) Select CO_2 parameter tile or waveform tile to enter [CO_2] menu.
2) Select [Setup] tab.
3) Set [Elevation Unit].
4) Set [Elevation] and [BaroPressure]: barometric pressure will be displayed automatically based on the elevation value set.

Elevation, Barometric Pressure & $ETCO_2$ Table

Altitude		**Barometric Pressure**	**5% CO2**
Feet	**Meters**	**mmHg**	**$EtCO_2$mmhg**
Sea Level (0)	Sea Level (0)	760	38
500	152.4	745	37
750	228.6	738	37
1,000	304.8	731	37
1,500	457.2	717	36
2,000	609.6	704	35
2,500	762	690	35
3,000	914.9	677	34
3,500	1066.8	665	33
4,000	1219.2	652	33
4,500	1371.6	640	32
5,000	1524	628	31
5,500	1676.4	616	31
6,000	1828.8	604	30
6,500	1981.2	593	30
7,000	2133.6	581	29
7,500	2286	570	29
8,000	2438.4	560	28
8,500	2590.8	549	27
9,000	2743.2	539	27
10,000	3048	518	26
10,500	3200.4	509	25
11,000	3352.8	499	25
11,500	3505.2	490	24
12,000	3657.6	480	24
12,500	3810	471	24

13,000	3962.4	462	23
13,500	4114.8	454	23
14,000	4267.2	445	22
14,500	4419.6	437	22
15,000	4572	428	21
15,500	4724.4	420	21
16,000	4876.8	412	21
16,500	5029.2	405	20
16,800	5120.6	400	20

Note: It is assumed that the sea level is of 760mmHg and 0℃, and that the ambient temperature is 0℃ when calculating barometric pressure based on elevation. For details, please refer to the table.

Warning

- **The RESPIRONICS and COMEN CO_2 module has no automatic air compensation function. Set the correct altitude before using the CO_2 measurement function for the first time. Incorrect altitude causes incorrect CO_2 reading (5% CO_2 error per 1,000m altitude difference).**

8.7.6 Set Waveform

Please refer to "***Section 5.1.1 Waveform Setting***".

8.8 Information on MASIMO Module

8.8.1 CO_2 Module LED

LEGI (Light Emitting Gas Inlet) LED indications (Sidestream module):

LED	**Indicted Status**
Remain green	Normal system
Flash in green	Zeroing…
Remain red	Sensor error
Flash in red	Please check the sampling line

Status LED on the IRMA probe:

LED	Indicted Status
Remain green	Normal system
Flash in green	Zeroing…
Remain red	Sensor error
Flash in red	Check adapter

8.8.2 Warning Information

8.8.2.1 ISA Sidestream Gas Analyzer Warning Information

⚠⚠Warning

- **The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only.**
- **Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.**
- **Do not lift the ISA gas analyzer by the sampling line as it could disconnect from the ISA, causing the ISA gas analyzer to fall on the patient.**
- **Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.**
- **Use only airway T-adapters with the sampling point in the center of the adapter.**
- **Do only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.**
- **Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.**
- **Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**
- **Since a successful zeroing requires the presence of ambient air, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.**
- **Never sterilize or immerse the ISA sidestream gas analyzer in liquid.**
- **The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.**
- **Replace the sampling line if the sampling line input connector starts flashing red, or the medical backboard equipment displays a "Check sampling line" message.**
- **No modification to the equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.**
- **The ISA sidestream gas analyzers are not designed for MRI environments.**
- **During MRI scanning, ISA must be placed outside the MRI suite.**
- **Use of high frequency electrosurgical equipment in the vicinity of the ISA/medical backboard equipment may produce interference and cause incorrect measurements.**

⚠⚠Caution

- **The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.**
- **Do not operate the ISA sidestream gas analyzer outside the specified operating environment.**
- **(US Only) Caution: Federal law restricts this equipment to sale by or on the order of a physician.**
- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

8.8.2.2 IRMA Mainstream Gas Analyzer Warning Information

⚠⚠Warning

- **The IRMA analyzers should be securely mounted in order to avoid the risk of damage to the IRMA.**
- **Do not operate the IRMA sidestream gas analyzer outside the specified operating environment.**
- **(US Only) Caution: Federal law restricts this equipment to sale by or on the order of a physician.**
- **For professional use. See the instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**
- **The IRMA probe is intended for use by qualified medical personnel only.**
- **The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.**
- **Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.**
- **Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
- **Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.**
- **Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.**
- **Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.**
- **The IRMA probe is not designed for MRI-environments.**
- **Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.**
- **To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.**
- **Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.**
- **Incorrect probe zeroing will result in false gas readings.**
- **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**
- **Use only Masimo manufactured IRMA airway adapters.**
- **The IRMA probe is not intended to be in patient contact.**
- **If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.**
- **No modification of this equipment is allowed.**

⚠⚠Caution

- **Never sterilize or immerse the IRMA probe in liquid.**
- **The IRMA airway adapters are non-sterile equipments. Do not autoclave the equipments as this will damage them.**
- **Do not apply tension to the probe cable.**
- **Do not operate the IRMA probe outside the specified operating temperature environment.**
- **(U.S. only) Caution: Federal law restricts this equipment to sale by or on the order of a**

physician.

- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

8.8.3 Airway Obstruction

When the sidestream module gas airway is obstructed, on the screen there will be such a prompt message as "Sampling Line Clogged"; under such a circumstance, replace the Nomoline sampling line.

⚠⚠Warning

- **Do not use the ISA gas analyzer together with a quantitative spraying agent or pulverization treatment; otherwise it may result in the clogging of the germ filter.**

8.8.4 Leakage Test

1) Connect a new Nomoline sampling line with male Luer lock to the ISA gas inlet connector and check that the gas inlet connector shows a steady green light.
2) Connect a short silicon tubing with an inner diameter of 3/32" (2.4 mm) to the Nomoline male Luer.
3) Exhale a long breath into the silicon tubing until the CO_2 concentration is greater than 4.5 vol% or 34 mmHg.
4) Quickly connect the silicon tubing tightly to the exhaust port.
5) Wait for 1 minute until the CO2 concentration has stabilized. Note the value.
6) Wait 1 minute and check that the CO2 concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.

8.8.5 Safety Symbols

Symbol	Text, Color Code and Text Format	Description
	Warning: additional information.	"Warning" indicates the hazardous conditions causing possible personal injuries or death. The warning symbol should comply with ISO 7010-W001.
	User's Manual	Refer to the User's Manual.
	Reference No.	
	Serial No.	
	Lot No.	
	Valid until [YYYY-MM-DD]	Do not use the equipmentafter such date.
	Temperature limit	

	Pressure limit	
	RH limit	
	No reuse	
	WEEE directive	Recycle this electrical and electronic equipment according to 2002/96/EC.
	Contain Pb	
IPX4	IP grade	The IP grade indicates the water ingress protection performance.
IP44	IP grade against water and solid object ingress	Protection against tools and short cable ends (>1mm). Protection against water sprays from all directions.
Rx ONLY	Sold on prescription only	Warning (U.S.): the equipmentshall be sold by medical practitioners or on prescription according to U.S. federal laws.
	CO2	The IRMA/ISA analyzer measures CO2 only.
	Multiple gases (AX+ or OR+)	The IRMA/ISA analyzer can measure multiple gases.
	Gas inlet	
	Gas (exhaust) outlet	
	Connect to patient circuit	Illustrate the connection between Nomoline and patient circuit.
	Connect to ISA	Illustrate the connection between Nomoline and ISA.
	Not sterile, latex free	The equipmentis latex free and not sterile.

8.8.6 Patents and Trademarks

(1) Patent Statement
Masimo Sweden AB owns the following patents for relevant products described in this operating instruction manual: SE519766; SE519779; SE523461; SE524086. Other patents are being applied.

(2) Trademark
Masimo IRMA™, Masimo ISA™, Masimo XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, Masimo GasMaster™ and ISA MaintenanceMaster™ are trademarks of Masimo Sweden AB.

8.8.7 Consumables

8.8.7.1 ISA Nomoline Family

ISA samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric and infant patients.
The Nomoline Family sampling lines incorporate a unique water separation (NO MOisture) section, which can remove the condensed water. The NOMO section is also fitted with a bacteria filter that protects the gas analyzer from water intrusion and cross contamination.
As long as no sampling line is connected, the ISA gas analyzer remains in a low-power sleep mode. Once the sampling lineis connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and reusableconfigurations.For instance, the disposable Nomoline Airway adapter Set or a combination of the reusable Nomoline Adapter and a disposable Nomoline Extension / T-adapter, is available for the intubated patient. For spontaneously breathing patients, similarly a disposable Nomoline Nasal CO_2 Cannula or a combination of the reusableNomoline Adapter and a disposable Nomoline Nasal CO_2 Cannula (with Luer Connector) can be applied.

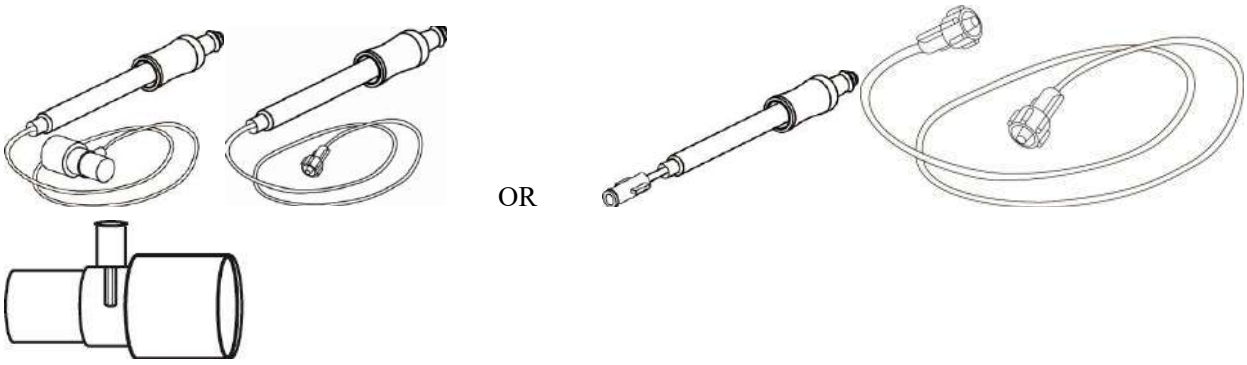


Fig 8-1 ISA Nomoline Family

Fig 8-2*The disposable Nomoline Airway Adapter Set is an alternative to the combination of the reusableNomoline Adapter and a disposable Nomoline Extension / T-adapter.*
The Nomoline Adapter may be used with other third-party sampling lines and cannulas. However, note that the Nomoline Family sampling lines are designed for optimal performance and measurement fidelity when used with the ISA gas analyzers. For instance, when connecting to a respiratory circuit, the Masimo T-adapter provides a central gas sampling point thereby minimizing the risk of sampling lineocclusion (see below)

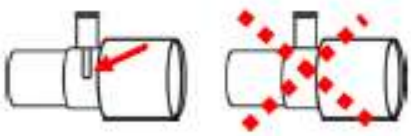


Fig 8-3T-adapters

Fig 8-4*For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.*

⚠ ⚠**Note**

- **Using sample tubes or cannulas with larger inner diameter than 1 mm will increase the response time of ISA system.**

Nomoline Family sampling line replacement

Nomoline Family sampling lines should be replaced according to good clinical practice or when the sampling line gets occluded. Occlusion occurs when water, secretion etc. is aspired from the respiratory circuit to such extent that ISA cannot maintain the normal 50 sml/min sample flow. This situation is indicated by a red flashing gas of inlet connector and an alarm message “Sampling Line Clogged”; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

8.8.7.2 IRMA Airway Adapter

The IRMA airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained through the XTP™ windows in the sides of the adapter. The XTP windows are transparent to light in the wavelength ranges of interest and they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

⚠⚠Warning

- **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**

The IRMA airway adapter is designed as a non-sterile single patient use disposable for Adult/Pediatric and Infant applications. The IRMA Infant airway adapter has specially designed connectors for minimizing the dead space and can be used even for very small patients.

IRMA airway adapters: Adult/Pediatric (REF: 106220) and Infant (REF: 106260)

⚠⚠Warning

- **Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
- **Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.**

8.8.8 Maintenance

The user should verify gas readings regularly; If any problem, contact an engineer of the manufacturer for maintenance.

Chapter 9 SpO_2 Monitoring (Available for V3 ONLY)

9.1 Overview

The SpO_2 plethysmography measures the arterial SpO_2, namely, the percentage of the oxyhemoglobin count. The SpO_2 is measured with the pulse oximetry; a continuous noninvasive method measuring how many of the lights emitted from the sensor (light source) can penetrate the patient's tissues (fingers or ears) and reach the receiver.

The ventilator measures the following parameters:

Arterial SpO_2: the ratio of the oxyhemoglobin to the sum of oxyhemoglobin and non-oxygenated hemoglobin (functional arterial SpO_2);

Pleth waveform: a visible indication of the patient's pulse;

PR (calculated from pleth waveform): The pulse rate is calculated and the display (beats per minute) and is updated at a frequency of once per second. The upper and lower alarm limits are also displayed next to the pulse rate measurement.

PI (perfusion index, not for Nellcor SpO_2): The Perfusion Index indicates numerically the percentage of pulsatile signal to non-pulsatile signal (pulse strength).

WARNING

- **If there is any carboxyhemoglobin (COHb),methemoglobin (MetHb) or dye dilution chemical, the SpO_2 value will have a deviation.**

9.1.1 Identification of SpO_2Sensor Type

The SpO2 sensor type is pre-configured before the ventilator is delivered. You can identify it based on the silkscreened logo beside the original SpO2 sensor below the left side sensor connector of the ventilator:

◆ Comen SpO_2 sensor:

Sensor connector: circular connector;
Silkscreened logo: SpO_2.

◆ Masimo SpO_2 sensor:

Sensor connector: circular connector;
Silkscreened logo: MasimoSET.

◆ NellcorSpO_2 sensor:

Sensor connector: circular connector;
Silkscreened logo:Nellcor.

The information about wavelength range and maximum optical output power of the sensor is useful to the clinician for some therapy, for example, photodynamic therapy.

◆ The Comen SpO_2 sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).

- The Masimo SpO_2 sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).
- The NellcorSpO_2 sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).
- The maximum optical output power of the sensor is lower than 15mW.

Warning

- **The ventilator can automatically recognize the SpO_2sensor type. However, the ventilator is configured with a specific internal SpO_2 hardware before delivery, the ventilator cannot measure SpO_2if using a incompatible sensor.**

Note

- **Functional test equipment or SpO_2 simulator cannot be used to verify the accuracy of SpO_2 monitor and pulse oximeter sensor. The accuracy of SpO_2 monitor and pulse oximeter sensor needs to be verified by clinical data.**
- **Functional test equipment or SpO_2 simulator can be used to evaluate the accuracy of PR.**
- **This ventilator and the specified SpO_2 sensor and cable extenders listed in this instruction for use have been tested for compliance with ISO 80601-2-61.**

9.2 Safety Instructions

Warning

- **The ventilator is compatible with the SpO_2 sensor designated by Comen only.Before monitoring the patient, check the sensor and extension cord are compatible with the ventilator. Incompatible accessories reduce the performance of the ventilator.**
- **Before monitoring the patient, check the sensor cable works properly. Remove the SpO_2sensor cable from the sensor interface and the ventilator displays the prompt message "SpO_2Finger off" and triggers the alarm sound.**
- **If the SpO_2 sensor or its package seems damaged, do not use it. Return the damaged product to the manufacturer.**
- **Long-time continuous monitoring increases the risk of undesired skin characteristic changes (extremely sensitive, turning red, blistered or pressure necrosis), especially for the patients with perfusion disorder or variable or immature skin morphology diagram. Align the sensor with the light path, adhere the sensors properly and check the sensors position regularly based on skin quality (change the sensor position whenthe skin quality decreases). Perform such check frequently if necessary (subject to the condition of the patient).**

- **Make sure the sensor cable and the electrosurgical equipment cable are not intertwined.**
- **Do not place the sensor on a limb with ductusarteriosus or intravenous tube.**
- **Setting the high SpO_2 alarm limit to 100% disables the high-limit alarm. Premature infants may get infected with crystalline posterior fibrous tissue diseases in case of high SpO_2. Please set the high SpO_2 alarm limit cautiously based on recognized clinical practices.**
- **The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.**
- **As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **Do not place the pulse oximeter or accessories in any position where it might fall on the patient.**
- **Do not start or operate the pulse oximeter unless the setup was verified to be correct.**
- **Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.**
- **Do not use the pulse oximeter if it appears or is suspected to be damaged.**
- **Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substances in combination with airor nitrous oxide or in oxygen-enriched environment.**
- **To ensure safety, avoid stacking multiple equipment or placing anything on the equipment during operation.**
- **To protect against injury, follow the directions below:**
  - **Do not soak or immerse the equipment in liquids.**
  - **Do not attempt to sterilize the equipment.**
  - **Use cleaning solutions only as instructed in this operator's manual.**
  - **Do not attempt to clean the equipment while monitoring a patient.**
- **To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.**
- **If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.**
- **Inaccurate SpO_2 readings may be caused by:**
  - **Improper sensor application and placement.**
  - **Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.**
  - **Elevated levels of bilirubin.**

- **Elevated levels of dyshemoglobin.**
- **Vasospastic disease, such as Raynaud's, and peripheral vascular disease.**
- **Hemoglobinopathies and synthesis disorders such as thalassemias, such as thalassemias, Hbs, Hbc, sickle cell, etc.**
- **Hypocapnic or hypercapnic conditions.**
- **Severe anemia**
- **Very low arterial perfusion.**
- **Extreme motion artifact.**
- **Abnormal venous pulsation or venous constriction.**
- **Severe vasoconstriction or hypothermia.**
- **Arterial catheters and intra-aortic balloon.**
- **Intravascular dyes, such as indocyanine green or methylene blue.**
- **Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.**
- **Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.**
- **Skin pigment disorders.**

- **Interfering Substances: Dyes or any coloring substance that can change usual blood pigmentation may cause erroneous readings.**
- **The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.**
- **The pulse oximeter is not an apnea monitor.**
- **The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.**
- **The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.**
- **The pulse oximeter should not be used for arrhythmia analysis.**
- **SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).**
- **Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for service if necessary.**
- **Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another part. Change the wearing part at least every four hours.**
- **During a technical alarm condition, the SpO_2 monitoring, both displayed values and waveform might not accurate, and the operator should additionally validate the values and the patient's**

status.

⚠ ⚠ **Cautions**

- **Do not place the pulse oximeter where the patient can control it.**
- **Electrical shock and flammability hazard: Before cleaning, always turn off the equipment and disconnect from any power supply.**
- **When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximeter may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.**
- **Do not place the pulse oximeter on electrical equipment that may affect the normal work of the oximeterequipment**
- **If SpO_2 values indicate the possibility of the hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.**
- **If using pulse oximeter during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the equipment might be zero for the duration of the active irradiation period.**
- **To ensure that alarm limits are appropriate for the patient monitored, check the limits each time the pulse oximeter is used.**
- **Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision made to completely understand the patient's condition.**
- **Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.**
- **Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.**
- **Disposal of product - Comply with local laws in the disposal of the equipment and/or its accessories.**
- **To minimize radio interference, other electrical equipment that emits radio frequency**

transmissions should not be in close proximity to the pulse oximeter.

⚠ ⚠ **Notes**

- **High-intensity extreme lights (such as pulsating strobe lights) directing on the sensormay not allow the pulse oximeter to provide vital sign readings.**
- **Pulse oximeter is calibrated to display functional blood oxygen saturation.**
- **The displayed SpO2 waveform is normalized.**

Masimo SpO_2 Specific Information

⚠ ⚠ **Cautions**

- **If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.**
- **Replace the cable or sensor if the instructions in the manual after firstlytried don't work when a low SIQ message is displayed in the process ofconsistently monitoring patients.after completing troubleshooting steps listed in this manual.**

⚠ ⚠ **Notes**

- **When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the equipment is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.**
- **Do not loop the patient cabling into a tight coil or wrap around the equipment, as this can damage the patient cabling.**
- **Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).**
- **Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.**

9.3 $SpO_2$and PRAccuracy Test

Assess the SpO_2 accuracy by comparing the readings respectively on the monitor and Index-2 SpO_2 simulator of FLUKE.

The reference method for the computation of pulse rate accuracy is electronic pulse simulator.

Warning

- **A functional tester cannot be used to assess the accuracy of the pulse oximeter.**

9.4 Measurement Restrictions

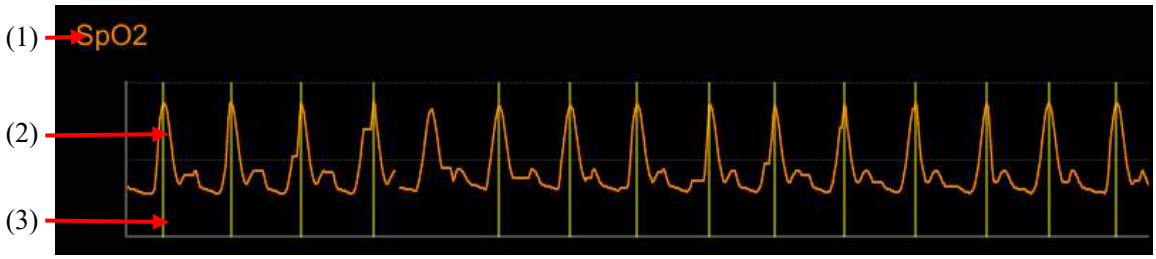
In operations, the following factors may affect the SpO_2 measurement accuracy:

1) High-frequency radio interference, whether from the ventilator or from the electrosurgical equipment connected to the ventilator. To minimize radio interference, other electrical equipment that emits high-frequency transmission should not be in close proximity to the ventilator.
2) Do not use the oximeteror SpO_2 sensor duringMRI scanning, or the induced current may cause burns.
3) Intravenous dyes.
4) The patient moves frequently.
5) Ambient ray radiation.
6) The sensor is fixed improperly or in an improper position on the patient.
7) Improper sensor temperature.
8) The sensor is placed on a limb with blood pressure cuff,ductusarteriosus or intravenous tube.
9) Concentration of the non-functional hemoglobin, like COHb or MetHb.
10) Low SpO_2.
11) Poor circulation perfusion at the tested part.
12) The shock, anemia, hypothermia and vasoconstrictors may reduce the arterial blood flow to a level that is not measureable.
13) The SpO_2 measurement accuracy depends also on the absorption of the lights with special wavelength by oxyhemoglobin and reduced hemoglobin. If any other substance also absorbs such lights, like COHb, MetHb, methylene blue or indigo carmine, you may obtain a false or low SpO_2 value.

9.5 SpO_2 Display

The waveform is show on the displayer while the monitoring values is under the [Monitoring Value Interface]. See *4.4 Monitoring Value Interface.*

Waveform display:

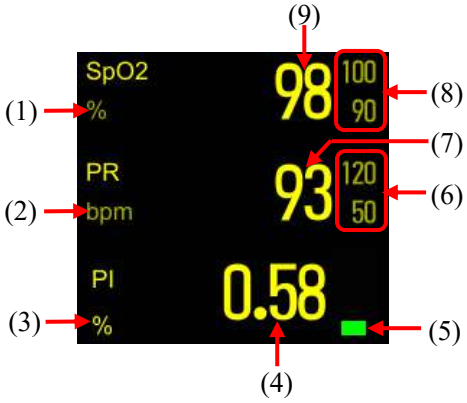


(1) Parameter Name

(2) SpO2 Waveform

(3) Bar graph (Signal Identification and Quality) (For Masimoand ComenSpO_2): Proportional to the pulse intensity. Bar graph can reflect the filling state of blood.
When the signal quality is low, the accuracy of SpO2 measurement maybe compromised. And "!SpO2 low signal" would be displayed.

Value display:



(1) SpO2 Unit

(2) PR Unit

(3) PI Unit

(4) PI Value

(5) Pulse Amplitude Indicator (blip bar) (For Nellcor SpO2): Indicates pulse beat and shows the relative pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.

(6) PR alarm limit

(7) PR value

(8) SpO2 alarm limit

(9) SpO2 value:The display will show dashed lines when the probes not connected or technical failure occurs.When the displayed SpO2 value is potentially incorrect (such as "!SpO2 low signal"), .a symbol? would appear next to the SpO_2 value.

Note: SatSeconds Indicator (For Nellcor SpO2): Fills in clockwise as the SatSeconds alarm management system detects a %SpO2 reading outside of the limit setting. Empties in counterclockwise direction when %SpO2 reading is within limits. When the indicator is full, a medium or high priority alarm sounds.

9.6 Monitoring Steps

Warning

- **Place the SpO_2 sensor properly based on the SpO_2sensor type.**
- **When changing application sites, or reattaching sensor, first disconnect sensor from the patient cable.**

9.6.1 Comen SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the patient type.
2) Fix the sensor to an appropriate position on the patient. Please refer to ***"Section9.7 Placement of SpO_2 Sensor"*** for more information.
3) Insert SpO_2 cable connector into the SpO_2 interface of the ventilator.
4) Set [Monitoring] to turn on, please refer to ***"Section9.8.1SpO2 Monitoring Setting"***.

9.6.2 Masimo SpO_2 &Nellcor SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the module type and patient type.
2) Fix the sensor to an appropriate position on the patient. Please refer to ***"Section 9.7 Placement of SpO_2 Sensor"*** for more information**.**
3) Connect SpO_2 patch cord to SpO_2 sensor.
4) Insert the other end of SpO_2 patch cord into the SpO_2 interface of the ventilator.
5) Set [Monitoring] to turn on, please refer to ***"Section9.8.1SpO2 Monitoring Setting"*.**

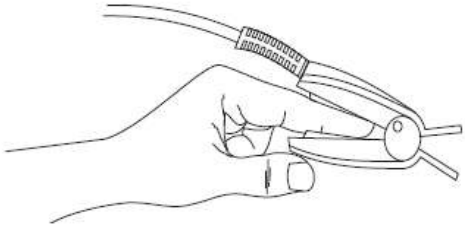
9.7 Placement of SpO_2 Sensor

Warning

- **Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another part. Change the wearing part at least every four hours.**

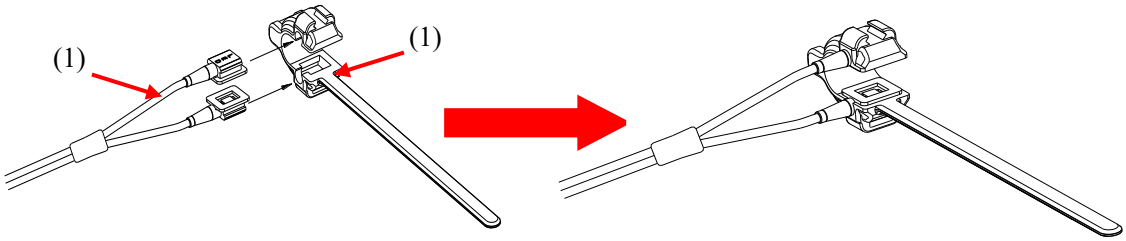
9.7.1 Placement of ADU SpO_2 Sensor

The location of ADU SpO_2 sensor is shown as the figure below:



9.7.2 Placement of PED SpO_2 Sensor

1) Assembly of NEO SpO_2 sensor: Embed the LED end and PD end of the Y-shaped SpO_2 sensor respectively in the upper and lower groove of the NEO SpO_2 sensor sheath, as shown in the figure below:



(1) Y-shaped SpO_2 Sensor (2) SpO_2 Sensor Sheath

2) Placement of SpO2 sensor: fix it on the finger of pediatric patient.

9.7.3 Placement of Disposable SpO2 Sensor

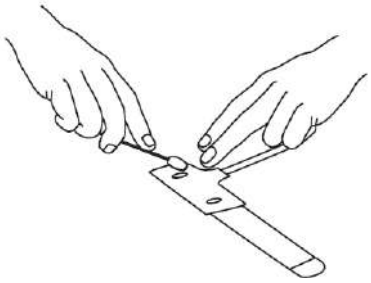


Fig. 1

Fig. 2

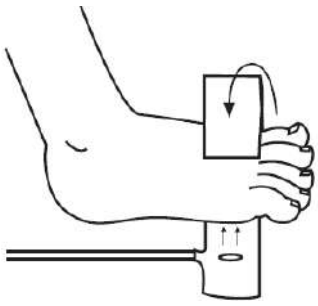


Fig. 3

Fig. 4

1) For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or with gauze (Refer to Fig. 1).
2) Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Apply the detector onto the fleshy part of the lateral aspect of the sole of the foot aligned with the fourth

toe. Alternatively, the detector may be applied to the top of the foot (not shown). Complete coverage of the detector window is needed to ensure accurate data (Refer to Fig. 2).

3) Wrap the adhesive/foam wrap around the foot and ensure that the emitter window (red star) aligns directly opposite of the detector (Refer to Fig. 3). Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive/foam wrap to secure the sensor.
4) Verify correct positioning and reposition if necessary (Refer to Fig. 4).

9.8 SpO_2Setup

9.8.1 SpO_2 Monitoring Setting

1) Select [Setup] key → [Sensor] → [SpO_2] tab.
2) Set [Monitoring] to turn on/off the SPO_2 monitoring function.

9.8.2 Open $SpO_2$and PR Alarm

1) Select [Alarm] key → [SpO_2]
2) Open SpO_2 and PR.

: Alarm open state.

: Alarm off state

9.8.3 Set SpO_2 Alarm Level

1) Select [Alarm] key → [SpO_2]
2) Select the drop-down box on the right of [SpO_2 High Level] to set the alarm level of SpO_2upper limit.
3) Select the drop-down box on the right of [SpO_2 low Level] to set the alarm level of SpO_2 lower limit.

9.8.4 Set PR Alarm Level

1) Select [Alarm] key → [SpO_2]
2) Select the drop-down box on the right of [PR High Level] to set the alarm level of PR upper limit.
3) Select the drop-down box on the right of [PRlow Level] to set the alarm level of PR lower limit

9.8.5 Set SpO_2 Alarm

1) Select [Alarm] key → [SpO_2]
2) Set SpO_2 alarm limits.

9.8.6 Set PR Alarm

1) Select [Alarm] key → [SpO_2]
2) Set PR alarm limits

9.8.7 Set Waveform Speed

1) Select [Setup] → [Sensor] → [SpO_2].
2) Set [Waveform Refresh Rate] to the appropriate value.

9.8.8 Set Pulse Volume

1) Select [Setup]→[Sensor]→[SpO_2].
2) Set [Smart Pulse Sound]. Volume characteristic:beep.

When there is a valid SpO_2 measurement value, the system will also adjust the pulse tone (Pitch Tone) according to the value of SpO_2.

9.8.9 Set Sensitivity (Available for Masimo SpO_2 Only)

[Sensitivity] can be set to [Normal], [High] or [APOD]. [High] represents the highest sensitivity. In typical monitoring conditions, please select [Normal]. If the sensor is likely to come off the patient due to wet skin, violent movements or other causes, please select [APOD]. If the patient's perfusion level is extremely low, please select [High] to increase the sensitivity.

Steps to set [Sensitivity]:

1) Select [Setup]→[Sensor]→[SpO_2].
2) Select an appropriate [Sensitivity] for Masimo SpO2: [Normal], [High] or [APOD].

9.8.10 Set Smart Tone (Available for Masimo SpO_2 Only)

You will / won't hear the PULSE tone in case of unstable signal or ambient noise if this function is enabled / disabled.

Set [Smart Tone]:

1) Select [Setup]→[Sensor]→[SpO_2].
2) Turn on or off [Smart Tone].

9.8.11 SetSatSeconds(Available for Nellcor SpO_2 Only)

1) Select [Setup]→[Sensor]→[SpO_2].
2) Set [SatSeconds] to the appropriate time.

The smart alarm is designed to reduce false alarms and keep the clinician informed of the SpO_2 changes more accurately and timely. For example, if you set [SatSeconds] to [50] and the upper and lower alarm limit of NELLCOR SpO_2 Respectively to 97% and 90%, maintain the measured SpO_2 value at 80% for 3s and then reduce it to 78% for 2s, the ventilator will trigger the alarm sound and indicator 5s after the SpO_2 value goes beyond the alarm limit and the circle beside the SpO_2 value will return to the origin.

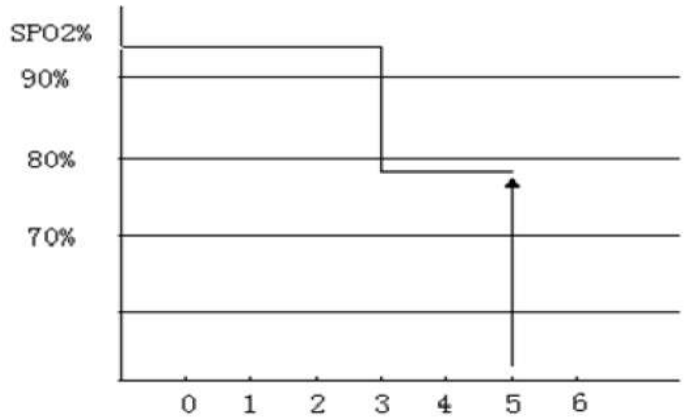
Calculation method:

Percentage points × seconds = SatSeconds (integer)

The calculated SatSeconds is displayed as follows:

%SpO_2	Seconds	SatSeconds
（90%-80%）×	3 =	30
（90%-78%）×	2 =	24

Total SatSeconds = 54



In the above SatSeconds example:

About 4.9s later, the ventilator will report a SatSeconds alarm because you've set [SatSeconds] to[50], smaller than 54.

The SpO_2 value may fluctuate in seconds rather than remain unchanged. The patient's SpO_2 value usually fluctuates within the alarm limit and sometimes goes beyond the alarm limit discontinuously. The ventilator will accumulate the positive and negative percentage points until the set value of [SatSeconds] is reached or the patient's SpO_2 value remains beyond the alarm limit.

9.8.12 Set Average Time

The SpO_2 value displayed on the ventilator is the average of the SpO2 values acquired in a given time. Shorter (longer) average time will lead to quicker (slower) response and lower (higher) measurement accuracy of the ventilator when the patient's SpO_2 value changes. For a critical patient, please set a short average time so as to analyze his/her condition timely. Set average time:

9.8.12.1 Set MasimoSpO_2Average Time

1) Select [Setup]→[Sensor]→[SpO_2]
2) Select an appropriate [Average Time]: [2-4s], [4-6s], [8s], [10s], [12s], [14s] or [16s].

9.8.12.2 Set Comen SpO_2Average Time

1) Select [Setup]→[Sensor]→[SpO_2]
2) Select an appropriate [Sensitivity]: [High] (4s), [Medium] (8s) or [Low] (16s).

9.8.13 Set Nellcor SpO_2Average Time

For Nellcor SpO2, the average time is not adjustable, default at 11 seconds.

9.8.14 Set Signal IQ(Unavailable for Nellcor SpO_2 Only)

The magnitude of the SpO_2 SIQ waveform provides an assessment of the confidence in the measurement displayed. A higher value indicates higher confidence in the measurement whereas a smaller value indicates lower confidence in the displayed measurement.

Movements usually affect the signal quality. When the arterial pulse reaches the peak, the ventilator marks its location on the vertical line (signal indicator). The smart tone volume (if enabled) remains consistent with the indication inthevertical line (the volume of the smart tone will increase or decrease accordingly when the SpO_2 value increases or decreases).

The height of the vertical line represents the quality of the measured signal (the higher line, the higher quality).
Set [Signal IQ] (Signal Identification and Quality):

1) Select [Setup]→[Sensor]→[SpO_2]
2) Select [Signal Indication] to switch between [ON] and [OFF].

9.9 Masimo Information

1) Masimo Patent Information

Masimo Patents: www.masimo.com/patents.htm

2) No Implied License Statement

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

3) Other Information

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RadNet, Radicalscreen, signal IQ, FastSat, fastStart and APOD are trademarks of Masimo Corporation.

Chapter 10 Other functions

10.1 Manual Respiration

Select [Tools] key → [Function] → [Manual Breath]; then the ventilator will perform gas supply once under the current ventilation mode.

Note

- **If press [Manual Breath] key during the inspiratory phase, the manual ventilation action will not be triggered.**
- **In CPAP ventilation mode, the manual ventilation function cannot be activated. If apnea ventilation occurs, the manual ventilation will be supported.**
- **In standby mode, the system cannot activate the manual ventilation function.**

10.2 Expiratory Hold

Expiratory hold is to stop the patient's inspiration within certain time in order to extend the patient's expiratory phase time.

1) Select [Tools] button → [Function];
2) Press and hold [Exp. Hold] key. The ventilator will activate the expiratory hold function and prompt the message of [Exp. Hold Active].
3) Release the [Exp. Hold] key. The corresponding function will be terminated.

The maximum duration of expiratory hold is 30s. When the [Exp. Hold] key is pressed and hold more than 30s or released, the ventilator will terminate the expiratory hold function automatically.

During the expiratory hold period, PEEPi will be automatically calculated displayed in the message dialog as in the picture.

Note

- **There is at least one inspiratory phase between two expiratory holds.**
- **Only in the non-standby mode, can the system respond to the action of pressing [Exp. Hold] key.**
- **In CPAP ventilation mode, the EXP. HOLD function cannot be activated. If apnea ventilation occurs, the expiratory hold will be supported.**

10.3 Inspiratory Hold

Inspiratory hold is to stop the patient's expiration within certain time in order to extend the patient's inspiratory phase time.

1) Select [Tools] key → [Function].
2) Press and hold [Insp. Hold] key. The ventilator will activate the inspiratoryhold function and prompt the message of [Insp. Hold Active].
3) Release the [Insp. Hold] key. The corresponding function will be terminated.

The maximum duration of inspiratory hold is 30s. When the [Insp. Hold] key is pressed and hold more than 30s or released, the ventilator will terminate the inspiratory hold function automatically.

During the inspiratory hold period, Cstat and P_{plat} will be automatically calculated displayed in the message dialog as in the picture.

Note:

- **There is at least one expiratory phase between two inspiratory holds.**
- **Inspiratory hold is disabled in standby and O_2 therapy status.**
- **In CPAP ventilation mode, the Insp. Hold function cannot be activated. If apnea ventilation occurs, the inspiratoryhold will be supported.**
- **The maximum "Inspiratory Pause (%)" is 6.0 s.**
- **The inspiratory pause can be used to synchronize radiographic imaging with lung inflation or used for a recruitment manoeuvre (a temporary increase in pressure intended to expand the lung).**

10.4 O_2↑ (Oxygen Enrichment)

O_2↑, also called oxygen enrichment, refers to the ventilation of higher O_2 concentration than normal in a specified period. When the patient type is ADU, O_2 concentration is set with 100% When the patient type is PED, O_2 concentration is set with 100% or current O_2 concentration times 1.25, whichever is smaller. Button 100% O2.

1) When [O_2↑ Suction] key is selected, the ventilator will activate the function of Oxygen enrichment.
2) The indicator corresponding to [O_2↑ Suction] button will be kept on, and the remaining time of this action will be displayed in the system prompt message area.
3) The maximum duration of oxygen enrichment is 2min. During the period of oxygen enrichment, the currently set O_2 concentration is displayed as the [O_2%] parameter value in the parameter setting hotkey area.

When oxygen enrichment is active for more than 2 min, or [O_2↑ Suction] key is selected again, the ventilator will terminate the function of Oxygen enrichment.

Note

- **In Standby mode, the system cannot activate the O_2↑ (oxygen enrichment) function.**
- **When O_2 source type is low-pressure O_2, O_2↑ will not be activated and the prompt "Fail to Start with low Pressure O2 Supply" will be displayed even if the [O_2↑ Suction] key is clicked.**
- **If the breathing tube is disconnected during oxygen enrichment, the Suction function will be activated. Refer to "Section *10.5Sputum Suction*" for more information.**

10.5 Sputum Suction

Sputum suction refers to the function that the ventilator assists the user by sucking sputum of the patient. The device automatically detects user's disconnection and connection of the patient circuit. Oxygen enrichment is applied before and after suction, and all physiological alarms are blocked during suction.

1) Click [O_2↑ Suction] button, and the system will perform oxygen enrichment function in ventilation of the patient, and will check whether the patient circuit is disconnected in the 120s ventilation. Then disconnect the patient circuit.
2) After the patient circuit is disconnected, the system will prompt [Patient tube disconnected. Reconnect the patient after completing sputum suction.] and terminate the ventilation. At this moment, manual suction can be performed against the patient.
3) After the operation towards the patient is completed, connect the patient circuit. The system will perform O_2↑ ventilation if detecting the circuit is connected.

During O_2↑ ventilation, press [O_2↑ Suction] key to terminate this operation.

Note

- **When suction is started, P0.1, PEEPi and NIF cannot be activated.**

10.6 Nebulizer

Nebulizer is used to nebulize medicine as aerosol which is inhaled by the patient to achieve the treatment purpose.

1) Select [Nebulizer] key.
2) Set [Time] (1min-60min) in the displayed menu with the knob. Press the knob to confirm and then click [Start], nebulizing function will be activated. When the nebulizing function is activated, the remaining time will be displayed in the system prompt message area.

When the nebulizing time is ended or [Nebulizer] key is pressed again, the ventilator will terminate this function.

Note

- **CO_2 cannot be measured in environments exposed to aerosols. After the nebulizing function is activated, sampling and monitoring of CO_2 modules will be suspended.**
- **In Standby mode, the system cannot activate the nebulizing function.**
- **When the patient type is Pediatric, in V-A/C, V-SIMV, PRVC-SIMV or PRVC mode, the Nebulizing function is invalid.**
- **When O_2 source type is low-pressure O_2, nebulizing will not be activated and the prompt "Fail to Start with low Pressure O_2 Supply" will be displayed even if the [Nebulizer] key is clicked.**
- **Nebulised drugs may block expiratory filters and the flow sensor within a short time, please carry out check and cleaning after nebulization.**
- **Nebulizing can result in fluctuation of the patient's FiO_2.**
- **If the inspiratory flow is less than 15 l/min, the nebulization flow of the ventilator is zero.**

10.7 P0.1

P0.1 refers to the pressure drop within the initial 100ms after the patient begins spontaneous respiration.

1) Select [Tools] key → [Diagnostics] → [P0.1].
2) Select [P0.1] button to enter the P0.1 measuring interface.
3) If [Start] button is selected in the opened interface, the system will perform the P0.1 measurement and prompt the message [Measurement in progress…].
4) After measurement, the system will display the measured result. The ventilator can display the last 3 measurement results.
5) The waveform and loop data will be frozen automatically after measurement is finished.

Note

- **When P0.1 is started, Suction, PEEPi and NIF cannot be activated.**
- **During P0.1 measurement, the system will not perform freezing after the "" [Freeze] button is clicked.**
- **In the P0.1 Measurement interface, if no operation is performed within 3 min, the system will automatically exit this interface.**

10.8 PEEPi

The PEEPi measurement function supports the measurement of PEEPi(Endogenous PEEPi) and Vtrap. PEEPi refers to the Intrinsic Positive End-Expiratory Pressure produced by trapped gas. Vtrap refers to the volume of trapped gas.

1) Select [Tools] key → [Diagnostics].
2) Select [PEEPi] button to enter the Intrinsic Positive End-Expiratory Pressure (PEEPi) measuring interface.
3) If [Start] button is selected in the opened interface, the system will perform the Intrinsic Positive End-Expiratory Pressure (PEEPi) measurement and prompt the message [Measurement in progress…].
4) After measurement, the system will display the measured result. The ventilator can display the last 3 measurement results.
5) The waveform and loop data will be frozen automatically after measurement is finished.

Note

- **When the PEEPi is being in measurement, the system will not perform freezing after the "" [Freeze] button is clicked.**
- **When the PEEPi is being in measurement, the functions of manual respiration, inspiratory hold and expiratory hold are disabled.**
- **In the PEEPi Measurement interface, if no operation is performed within 3 min, the system will automatically exit this interface.**

10.9 NIF

NIF refers to the maximum Negative Inspiratory Force produced by the patient's spontaneous breathing in a specified period.

1) Select [Tools] key → [Diagnosis].
2) Select [NIF] button to enter the NIF measuring interface.
3) Press and hold [Exp. Hold] button in the opened interface; the system will start NIF measurement.
4) Release the [Exp. Hold] button to finish the measurement; then the system will display the measured result. The ventilator can display the last 3 measurement results.

Note

- **In the NIF Measurement interface, if no operation is performed within 3 min, the system will automatically exit this interface.**
- **When the PEEP is set at Off, and the patient spontaneous breathing accompanying with subatmospheric pressure of -10cmH2O, the maximum negative pressure can be -10cmH2O.**

10.10 P-V Tool

Mechanical ventilation with the best PEEP setting can improve oxygenation and LMC and reduce lung injury. P-V tool is used to plot the static pressure-volume curve (static P-V loop) and then determine the best PEEP according to the feature points on the P-V loop. Doctors can use this function to determine the best PEEP for each patient.

Note

- **The P-V tool function is disabled in such cases: patient type being PED; in CPAS/PSV, non-invasive and apnea ventilation modes; in the O_2↑ (oxygen enrichment) process; in the P0.1 measuring being in progress, in the process of nebulizing or sputum suction or within 1min after the it is finished; within 1min after the last P-V loop test is finished.**
- **It is not suggested to use the P-V Tool function when there is large leakage or when the patient has spontaneous respiration. Feature points provided by the P-V Tool function are for reference only.**
- **In the P-V Tool interface, if no operation is performed within 3 min, the system will automatically exit this interface.**

1) Select [Tools] key → [PV Tool] tab to enter the P-V Tool interface.
2) Select [Prompt] button to view the Note message of P-V tool in the opened interface.
3) Select [Measure] button and set the parameters of [Pstart], [Flow], [Pmax] and [Vlimit] in the measurement interface. The system will use the equation to calculate the Tmax parameter value and display it on the menu interface.
   - ◆ Flow: The gas supply and expiratory flow of the static P-V loop.
   - ◆ Pstart: The initial pressure of the static P-V loop.
   - ◆ Pmax: The maximum pressure that the static P-V loop can reach.
   - ◆ Vlimit: The maximum volume that the static P-V loop can reach.
   - ◆ Tmax: The maximum measuring time needed to finish the static P-V loop measurement.
4) If [Start] button is selected, the system will perform the P-V tool measurement. If [Stop Breathing] button is pressed during the measurement, the system will immediately terminate the inspiratory limb measurement test, and start to conduct the inspiratory limb measurement. If [Abort Test] button is clicked during the measurement, the system will immediately suspend measurement.
5) The system will enter the result analysis interface automatically after the measurement is finished. The positions of [Cursor 1] and [Cursor 2] can be settled respectively as needed. When the [Cursor 1] button or [cursor 2] button is pressed, the corresponding cursor will turn green. You can move the cursor by rotating the main control knob to determine the feature points. The system also displays the volume and pressure and compliance of the inspiratory limb and expiratory limb corresponding to the cursor position respectively.
6) You can select [History] button and view the needed loop in the opened list. The system only displays the

loop you are viewing, whose measurement time is displayed on the right side of the [History] button.

7) You can select [Ref. Loop] button and view the needed loop in the opened list. The system only displays the loop you are viewing, whose measurement time is displayed on the right side of the [Ref. Loop] button.

10.11 Sustained Insufflation (SI)

WARNING

- **SI function is disabled in following situations:**
  - **The patient type is Neonate;**
  - **Sputum suction is in progress;**

Note

- **In SI process, pure oxygen or high oxygen concentration is used for ventilation;**
- **SI is not recommended for a patient with spontaneous breathing;**
- **It is recommended to stop SI when the patient's physiological state is abnormal.**

Sustained Insufflation is a tragedy for lung protective ventilation. A pressure higher than the conventional average airway pressure is provided and maintained for a specified period in the process of mechanical ventilation. It can make collapsed alveolar reopen, and prevent secondary atelectasis caused by small tidal ventilation.

SI function employs constant ventilation to fulfill a single cycle of lung recruitment.

1) Select [Tools] key → [SI] tab to enter the SI interface.
2) Select [Prompt] button to view the Note message of SI in the opened interface.
3) Select [Measure] button and set the parameters of [Pressure Hold] and [Hold Time] in the measurement interface. The system will use the equation to calculate parameter values of P_{peak}, P_{mean} and Peep, and display them on the menu interface.
4) If [Start] button is selected, the system will perform the SI tool measurement If the [Stop] button is clicked during measurement, the system will immediately stop measurement.

10.12 O2Therapy

The ventilator can be used with a legally marketed oxygen mask or nasal congestion catheter to continuously provide a certain concentration and flow rate of oxygen to the patient (commonly called as "oxygen inhalation" or "oxygen therapy" in clinic).

Oxygen therapy, also known as supplemental oxygen, refer to the method of increasing the oxygen concentration into the airway under a normal pressure through a simply connected pipeline. Oxygen therapy is also a clinical measure to relieve or correct organic hypoxia condition through increasing the oxygen

concentration of the inhaled gas, raising inhaled alveolar oxygen concentration, promoting oxygen diffusion, and thus adding the arterial PO_2 (Partial pressure of blood oxygen) and SpO_2 (blood oxygen saturation). Oxygen therapy is a method for preventing or curing hypoxia. The oxygen concentration provided is higher than that of air.

WARNING

- **Oxygen therapy can only be used for patients with regular spontaneous respiration.**
- **The ventilator can only provide oxygen therapy to patients under the supervision of professional medical staff. If there is a malfunction or the patient has difficulty in spontaneous breathing, a professional medical worker can immediately give help.**
- **During oxygen therapy, only the FiO_2 and oxygen flow rate are monitored.**
- **During oxygen therapy, all physiological alarms are shielded except the oxygen concentration physiological alarm.**
- **Airway pressure and parameters related to ventilation, such as flow rate, minute ventilation, asphyxia, were not monitored during oxygen therapy.**
- **For patients requiring increased oxygen concentration for treatment, SpO_2 monitoring equipment should be used to monitor SpO_2. Otherwise, the deterioration of the patient's condition may not be effectively recognized.**
- **Only oxygen mask or nasal congestion catheter can be used for oxygen therapy. Do not use NIV masks for oxygen therapy. Improper use of masks can be dangerous to patients.**
- **Insufficient pressure of the gas source may cause inaccurate control of oxygen concentration.**

10.12.1 Enter Oxygen Therapy Interface

1) In the standby interface, select [O_2 Therapy] button to enter the oxygen therapy interface.
2) Set [Flow] and [O_2%] with proper values as needed.

10.12.2 Oxygen Therapy Timer/Timing

In the oxygen therapy interface, select [O2 Therapy Timer]button to enter the [O_2 Therapy Timer] interface.
In the oxygen therapy timer interface, when the [Stop Timing] button is displayed, [Timer Reset] is locked (with dark background) and disabled. Click [Stop Timing] button, and the button will change to [Start Timing]. Then [Timer Reset] is unlocked (with light background). The displayed timer will be reset as ZERO when this button is clicked.
Click [Time] set iconbeside [Oxygen Therapy Timer]. Rotate the main control knob clockwise or counterclockwise to perform the oxygen therapy timing in the range of 0~600min. When the timer expires, the system will sound a reminder, but the oxygen supply will be without interruption.

10.12.3 Turn Off Oxygen Therapy

Select [Standby] key during the oxygen therapy. Click [Standby] to enter the standby interface. Then the oxygen therapy will be turned off.

10.13 Tube Resistance Compensation (TRC)

TRC stands for the automatic Tube Resistance Compensation. Select different size of endotracheal intubationor tracheotomy tube for the patient. The ventilator can automatically adjust the gas supply pressure so that the pressure at the tube end is consistent with the set pressure value on the ventilator as much as possible.
The TRC function can be set in the parameter settings interface of each mode.

1) Select ventilation mode and press [TRC] button to enter the automatic tube resistance compensation interface.
2) Set Type of Intubation, Diameter, Compensation Ratio and Expiratory Phase Compensation in the opened interface.
   - ◆ [Type of Intubation]: endotracheal intubationand tracheotomy tube
   - ◆ [Tube I.D.]: refer to the size of endotracheal intubation.
   - ◆ [Compensate]: refer to the percentage of automatic tube compensation.
   - ◆ [Expiration]: switch on/off the expiratory phase compensation function.
3) Select the [OK] button; the system will activate the TRC function automatically. When the TRC function is activated automatically, if you enter the [TRC] interface and set [Type of Intubation] to [Off], the system will immediately terminate the TRC function in the process of ventilation.

After turning ON the TRC function, the system will show the intratracheal pressure wave on the airway pressure waveform. The waveform is not influenced by the [Waveform Curves Plotting] settings. For more information of plethysmography waveform, refer to "Section ***5.1.1 Waveform Setting***". See the figure below:

WARNING

- **TRC can be triggered automatically. If it is triggered, check the patient, breathing circuit and other possible causes.**

CAUTION

- **Incorrect tube type or tube diameter can result in patient injury. Please set the tube size correctly.**

10.14 IntelliSyn Smart Sync Technology

The ventilator provides IntelliSyn intelligent synchronization technology, which can adjust the exhalation trigger through adaptive algorithm through the extraction and analysis of waveform characteristics.

10.15 Network settings

The network interface is only used by professional maintenance personnel authorized by Comen for software upgrade and data transmission.

Chapter 11 Battery

11.1 Overview

The device is equipped with a built-in rechargeable battery(This ventilator can be equipped with two built-in rechargeable batteries). When AC power supply is connected, the battery can be charged automatically till full no matter whether the device is turned on or not. When the battery is charging, the ventilator could operated normally. In the event of unexpected power outage, the system will automatically use the battery to supply voltage, thus to avoid interruption of device operation. After AC power supply is cut off, the battery indicator light blinks, indicating the battery is being used to supply voltage, and device operation will not be affected.
The Battery icon shown on the screen indicates the current battery status:

: Connect outer power supply. The ventilator is powered by external power supply. The battery is being charged.

: External power supply is not connected. The ventilator is powered by built-inpower supply.

: External power supply is not connected. The ventilator is powered by built-inpower supply.The battery power is low, the battery needs to be charged in time.

: External power supply is not connected. The ventilator is powered by built-inpower supply. The battery is too low. Charging is needed immediately.

: Battery is not installed or damaged.

Note

- **If the battery is to be left unused for a long period of time, please remove the battery and keep it properly.**
- **The device is provided with a built-in battery, the battery must be charged after each use to ensure sufficient battery reserve.**

WARNING

- **If the battery needs replaced, it only can be performed by the specified maintenance personnel, not by users. Improper replacement of the lithium battery will result in unacceptable risks.**
- **Battery electrolyte is hazardous. In case that battery electrolyte comes into contact with your skin or enters your eyes, please wash with clean water immediately and seek medical advice.**
- **Please keep the battery out of the reach of children.**
- **When the battery is used for operation, the device will power off automatically when the battery level is low.**
- **Only use this ventilator to charge the battery.**

- **To prolong the battery life, the battery should be used at least every month, and charged when the battery is to run out.**
- **Please check and replace the battery on a regular basis.**

11.2 Optimize and Check Battery Performance

11.2.1 Optimize Battery Performance

The battery must undergo at least two complete optimization cycles before first use. The battery's performance will gradually decrease as the time of use increases. It is recommended that you optimize the battery every sixmonths. If it is not optimized during a long time, the displayed battery voltage level may not be accurate.
When optimizing the battery, please ensure the following:

1) Completely disconnect the ventilator from the patient and stop all monitoring and measurement.
2) Put the battery for optimization in the battery case of the device.
3) Please ensure that the battery is charged uninterruptedly till it is fully charged.
4) Disconnect AC power supply, and use the battery to supply voltage to the ventilator till the ventilator shuts down automatically.
5) Battery optimization is finished.

11.2.2 Check Battery Performance

The battery life varies with the storage and operation environments, frequency of battery discharging and use time. The battery performance will degrade gradually even if the battery is not used.
A battery performance check must be performed every three months. When you suspect a battery fault, you will also need to perform a battery performance check.
For the battery performance check procedure, see steps 1 to 4 in **"Section *11.2.1 Optimize Battery Performance*"**. The length of discharge time reflects the performance of the battery. If the battery's power supply time is significantly lower than the time stated in the Specifications, the battery should be replaced.

Note

- **In order to prolong the service life of the rechargeable battery, if the battery is stored for a long period of time, it is suggested that the battery should be charged every three months to prevent excessive discharging.**
- **The voltage supply time of the battery depends on the configuration and operation of the device.**

11.3 Store the Battery

Please ensure that the battery electrode is not in contact with any metal object when storing the battery. For long-term storage, place the battery in a cool environment and maintain the battery capacity between 40% ~ 60%.

Storage of the battery in a cool environment can postpone the aging process of the battery. Ideally, the battery should be stored in a cool environment under the temperature of 15°C (60℉). Do not place the battery in an environment beyond the temperature range of -20°C (-4℉) ~ 60°C (140℉).

If the ventilator is to be left unused for a long period of time, the battery should be removed; otherwise the battery will discharge, thus significantly increasing the charging time. Maintain the battery capacity between 40% ~ 60%. Fully charge the battery before reuse.

Note

- **Storage of the battery in an environment over 38℃ (100℉) will greatly reduce its expected service life.**

11.4 Battery Recycling

If the battery is obviously damaged or runs out, it should be replaced. Waste batteries should be properly recycled in accordance with applicable laws and regulations or the rules of the hospital.

WARNING

- **Do not disassemble or short-circuit the battery or place it in fire; otherwise battery fire, explosion, leakage of hazardous gas or other hazards may be caused.**
- **WARNINGS: Disposing the device with the battery inserted presents a potential shock hazard. To avoid contaminating or infecting personnel, the environment, or other equipment, make sure you disinfect and decontaminate the device and any appropriate accessories prior to disposal**

Chapter 12 Cleaning, Disinfection and Sterilization

Only materials and methods listed in this chapter that are accepted by the Company can be used for cleaning or disinfection of the device. For any damage arising from use of unaccepted materials or methods, the Company will not provide any warranty.

The Company will not assume any liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital. Besides, please refer to local policies that apply to your hospital and country.

12.1 Overview

This chapter describes the cleaning and disinfection methods of the ventilator, parts and accessories. The cleaning and disinfection methods for other non-disposable accessories refer to the accessories' accompanying documents. The cleaning and disinfection or sterilization procedure, should refer to the instruction for use of the individual accessories.

Please keep the device and its accessories dustless. After cleaning, please check the device carefully. If there is any evidence of ageing or damage, please stop using it immediately. If it is necessary to send back the device to Comen for repair, first clean it.

WARNING

- **Please observe applicable safety protection regulations.**
- **Please carefully read the Material Safety Data Sheet of each detergent.**
- **Please carefully read all operation and maintenance instructions for the disinfection equipment.**
- **Only use detergents and disinfectants recommended in this Instruction Manual; use of other detergents and disinfectants will result in damage to the device or safety risks.**
- **Before cleaning the device, please power it off and disconnect it from the AC power supply.**
- **It is not allowed to use detergent mixture; otherwise hazardous gases will be generated.**
- **This chapter only introduces the methods for cleaning reusable accessories. Disposable accessories should not be reused after cleaning and disinfection to avoid cross infection.**
- **To protect the environment, disposable accessories must be recycled or dealt properly.**
- **Please wear safety gloves and goggles. Damage of the chemical oxygen sensor can cause leakage and result in combustion (containing potassium hydroxide).**
- **If a reusable accessory or component is reused without disinfection, cross-infection can be caused.**
- **To prevent system leakage, take care to avoid part damage during removal and re-installation,**

and ensure the installation correctness. During cleaning and disinfection, please ensure the applicability of cleaning and disinfection methods to the parts and also ensure their correct use.

- **Please carry out removal and assembly according to the instructions provided in this chapter. For further removal and assembly, please contact our After-sales Service Department.**
- **Improper removal and assembly can result in system leakage, affecting normal use of the equipment.**
- **Liquid ingress into the control component will damage the equipment or result in personal injury. When cleaning the housing, please ensure that no liquid flows into the control component, and always disconnect the equipment from AC power supply. AC power supply can be reconnected only after the cleaned parts are completely dry.**
- **To prevent adhesion, do not use talc, zinc stearate, calcium carbonate, corn starch or similar materials. These materials may enter the patient's lung or airway, resulting in irritation or injury.**
- **No modification of this equipment is allowed.**

CAUTION

- **If the device gets damped accidentally, put it in a ventilated place and then contact maintenance personnel or our company immediately.**

Note

- **This equipment should be cleaned and disinfected as per need before initial use. The gas pathways through the ventilator and its accessories that can become contaminated with body fluids or by contaminants carried by expired gases during normal condition or single fault condition, shall be subjected to cleaning and disinfection /sterilization. See this chapter for the cleaning and disinfection methods.**
- **To prevent equipment damage, if there is any doubt about the detergent, please see the data provided by the manufacturer.**
- **Do not use organic, halogenated or petroleum base solvents, glass cleaner, acetone or other irritant detergents.**
- **Do not use abrasive detergents (e.g., steel wool, silver polish or cleaner).**
- **Any liquid should be placed away from electronic components.**
- **Never allow any liquid to flow into the housing.**
- **Only parts claimedfor 134ºC allow sterilizationwith high-temperature steam.**

- **The pH value of cleaning solution must be between 7.0 ～ 10.5.**
- **After cleaning and disinfection, please perform system self-test before using this device again. The device can be used after passing self- test.**

12.2 Cleaning, Disinfection and Sterilization Methods

Parts of this ventilator can be cleaned and disinfected/Sterilization. The cleaning and disinfection methods vary with different parts. Select appropriate methods to timely and correctly clean and disinfect each part according to the actual situation, thus to prevent cross-infection of the ventilator user and the patient.

12.2.1 Cleaning, Disinfection and Sterilization of Main Unit and Patient's Circuit

The table below lists the part cleaning and disinfection methods recommended by our company, including those for initial use and reuse.

Part	**Recommended Time Interval**	**Cleaning**		**Disinfection**			**Sterilization**
		① Wiping	② Soaking	A Wiping	B Soaking	C Ultraviolet (UV) radiation	D Pressure Steam
Ventilator housing							
External surface of ventilator including housing, power cord, gas source hose)	Each patient	①		A or C			
Trolley and supporting arm	Each patient	①		A or C			
Touch screen	Each patient	①		A or C			
Fan Dust mesh	Every 4 weeks / As per need *	②		B			

Dust mesh at the air inlet of main unit	Every 4 weeks / As per need *	②	B
Inspiratory valve component of ventilator			
Inhalation valve component	As per need *	②	B or D
Expiratory valve component of ventilator (Including flow sensor - autoclavable)			
Expiratory valve diaphragm (Silicone rubber)	Each patient / Every week	②	B or D
Expiratory Valve Component (diaphragm excluded)	Each patient / Every week	②	B or D
Patient circuit of ventilator (reusable)			
Patient circuit (including water collection cup, Y-joint, and adapting part)	Each patient / Every week	Please refer to the cleaning and disinfection methods provided in the breathing circuit instructions.	
Others			
Nebulizer	Each patient / Every week	Please refer to the cleaning and disinfection methods provided in the Nebulizer instructions.	
Humidifier	Each patient / Every week	Please refer to the cleaning and disinfection methods provided in the humidifier instructions.	

Cleaning Methods: Wipe and Bath Immersion

① Wiping: Use a wet cloth having been soaked in alkalescent detergent (e.g., soapsuds) or alcohol solution to wipe the part, and use a dry lint-free cloth to wipe it dry.

② Soaking: Rinse with clear water; then soak in alkalescent detergent (e.g., soapsuds) solution (suggested

water temperature: 40ºC) for about 3 min; then wash with clear water and air-dry the part.

Disinfection Methods:

A. Wiping: Use a wet cloth having been soaked in intermediate or high-efficacy disinfectant (e.g., alcohol or isopropanol) solution to wipe the part, and use a dry lint-free cloth to wipe it dry.

B. Soaking: Soak in intermediate or high-efficacy disinfectant (e.g., alcohol or isopropanol) solution (recommended soaking time: >30 min); then wash with clear water and air-dry the part. (NOTE: The inspiratory valve and expiratory valve components can only be disinfected by high-efficacy disinfectant.)

C. UV: Disinfect the part through UV radiation; the recommended disinfection time is 30 ~ 60 min.

Sterilization methods:

D. Pressure steam: Sterilize the partwith high-temperature high-pressure steam (temperature: 134ºC); the recommended disinfection time is 4 min. An autoclave can be used to increase the steam pressure, and its temperature will also rise to rapidly solidify bacterial protein.

As per need*: If the equipment is used in a dusty environment, please reduce the cleaning and disinfection interval according to the circumstances, thus to ensure that the appearance is free from dust blockage. The inspiratory valve component needs cleaning and disinfection only when the gas exhaled by the patient may contaminate the inspiratory limb. For the removal and installation methods, see "**Section12.3.2 *Inspiratory Valve Component and Diaphragm***".

The table below lists the detergents, disinfectants and high-efficacy disinfection methods that can be used for the ventilator.

Name	**Type**
Alcohol (75%)	Intermediate-efficacy disinfectant
Isopropanol (70%)	Intermediate-efficacy disinfectant
Glutaraldehyde (2%)	High-efficacy disinfectant
o-Phthalaldehyde disinfectant (e.g., Cidex®OPA)	High-efficacy disinfectant
Soapsuds (pH value: 7.0 ~ 10.5)	Detergent
Clear water	Detergent
Disinfection with high-temperature high-pressure steam*	Sterilization

Remark: Sterilization with high-temperature high-pressure steam*: The recommended temperature for this method is 134ºC (273ºF).

Note

- **For reusable breath tubing, do follow the cleaning and sterilization method marked on its user manual and package label. The recommend number of procedure cycles during expected service life is 30 times.**

12.2.2 Cleaning and Disinfection of Physiological Module Accessories

Part	**Recommended Time Interval**	**Cleaning**		**Disinfection**			**Sterilization**
		① Wiping	② Soaking	A Wiping	B Soaking	C UV	D Pressure steam
CO_2 extended cable, CO_2 sensor, CO_2 analyzer	Each patient / Every week	①		A			
Respironics/Comen CO2 sampling line inlet	Each patient / Every week	①		A			
SpO_2 sensor and cable	Each patient / Every week	①		A			

Cleaning Methods (Wipe and Bath Immersion):

① Wiping: Use a wet cloth having been soaked in detergent solution to wipe the part, and use a dry lint-free cloth to wipe it dry.

② Soaking: Rinse with clear water; then soak in detergent solution (suggested water temperature: 40ºC) for about 3 min; then wash with clear water and air-dry the part.

Disinfection Methods

A. Wiping: Use a wet cloth having been soaked in disinfectant (e.g., alcohol or isopropanol) solution to wipe the part, and use a dry lint-free cloth to wipe it dry.

B. Soaking: Soak in disinfectant (e.g., alcohol or isopropanol) solution (recommended soaking time: >30 min); then wash with clear water and air-dry the part.

C. UV: Disinfect the part through UV radiation; the recommended disinfection time is 30 ~ 60 min.

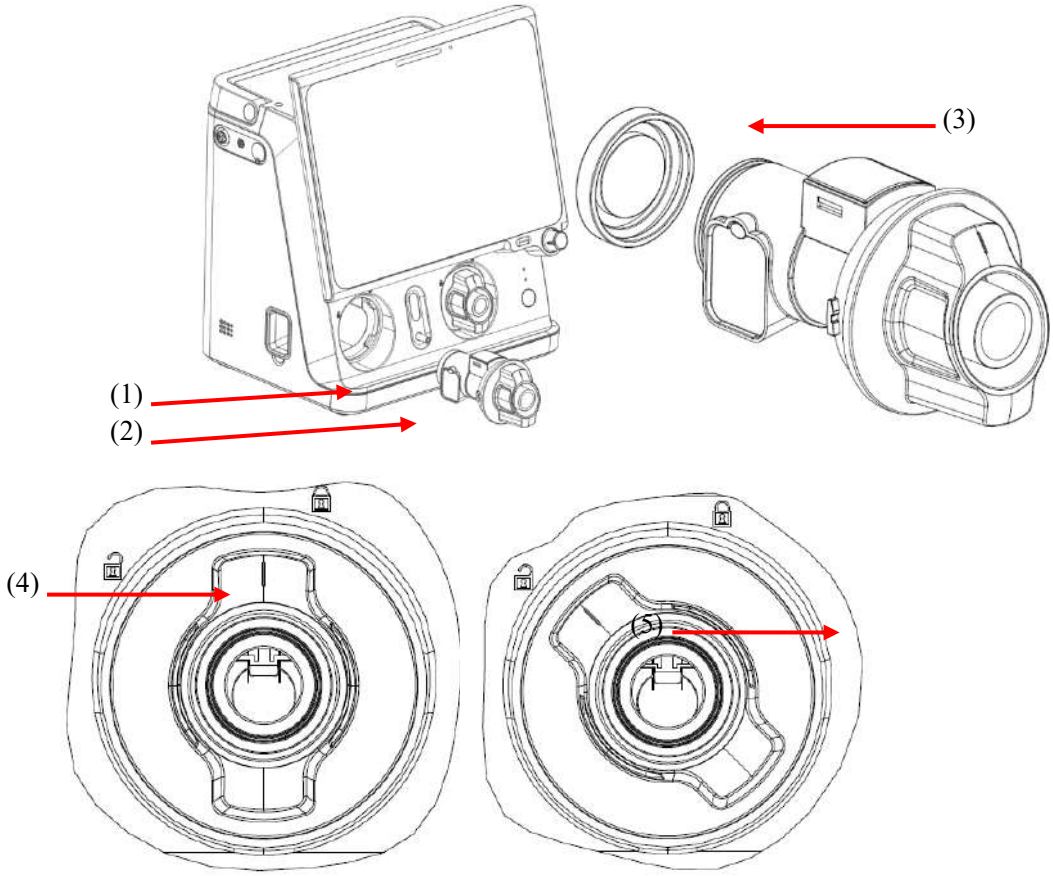
Sterilization methods:

D. Pressure steam: sterilize the part with high-temperature high-pressure steam (temperature: 134ºC); the recommended disinfection time is 4 min.

Parts for Disinfection	Detergent	Disinfectant
CO2 extended cable	Clean water, 75% alcohol	OPA (5.5g/l), 75% alcohol, 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution
Masimo mainstream CO2 analyzer component	Clean water, 75% alcohol	75% alcohol, 70% isopropanol
Respironics/Comen CO2 sampling line inlet	Clean water,75% alcohol	75% alcohol, 3% hydrogen peroxide, 0.6% or 2% sodium hypochlorite solution
Respironics/Comen mainstream CO2 analyzer component	Clean water, mild soap liquid	70% isopropanol
Respironics/ComenSidestream CO2 analyzer component	Clean water, 75% alcohol	OPA (5.5g/l), 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution
Masimo and Nellcor SpO2 sensor and cable	Water, neutral detergent, 70% isopropanol	0.5% sodium hypochlorite solution
Comen SpO2 sensor and cable	Clear water, 75% alcohol	OPA (5.5g/l), 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution
SpO2 sensor extended cable	Clear water, 75% alcohol	OPA (5.5g/l), 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution

12.3 Removal and Assembly of cleaning and sterilization parts of the Ventilator

12.3.1 Expiratory Valve Component and Diaphragm



Expiratory valve component　　Expiratory valve handwheel　　Expiratory valve diaphragm
Expiratory valve locked status　　Expiratory valve unlocked status

◆ Removal Method

1) Rotate the expiratory valve handwheel counterclockwise until the indicating arrow on the wheel is in line with ; then pull out the expiratory valve component laterally.

2) Remove the expiratory valve diaphragm.

◆ Installation Method

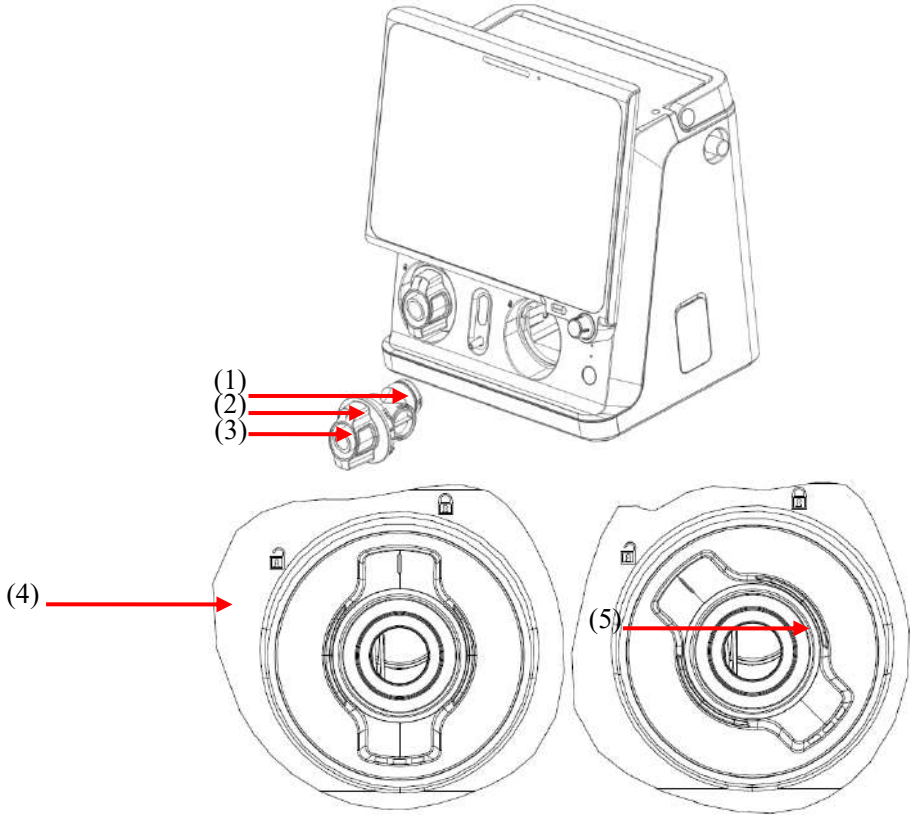
1) Install the expiratory valve diaphragm onto the expiratory valve component.

2) Push the expiratory valve component into the corresponding port on the ventilator to the end. Ensure that the indicating arrow on the handwheel is in line with , and then rotate the wheel clockwise (while

pressing the handwheel in its installing direction) until the indicating arrow on the handwheel is in line with .

12.3.2 Inspiratory Valve Component and Diaphragm

12.3.2.1 Inspiratory Valve Component



Seal ring | Safety valve component | Safety valve handwheel

Safety valve locked status | Safety valve unlocked status

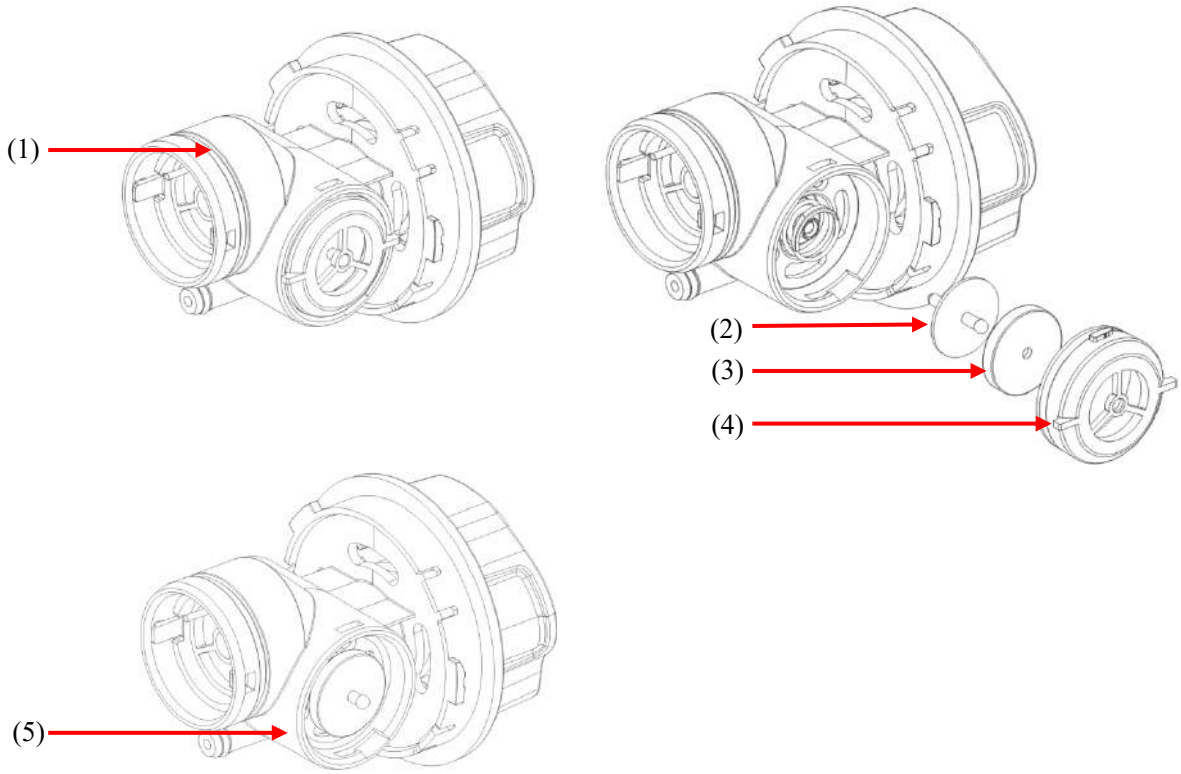
◆ Removal Method

Rotate the safety valve handwheel counterclockwise until the indicating arrow on the wheel is in line with ; then pull out the safety valve component laterally. Check if the seal ring on the end of safety valve comes adrift, and put it back if so.

◆ Installation Method

Push the safety valve component into the corresponding port on the ventilator to the end. Ensure that the indicating arrow on the handwheel is in line with , and then rotate the wheel clockwise (while pressing the handwheel in its installing direction) until the indicating arrow on the handwheel is in line with .

12.3.2.2 Inspiratory safety valve diaphragm



(1). The detachable body of the suction valve (2). The safety valve diaphragm gasket

(3). Safety valve diaphragm (4). Safety valve port (5). Suction valve body

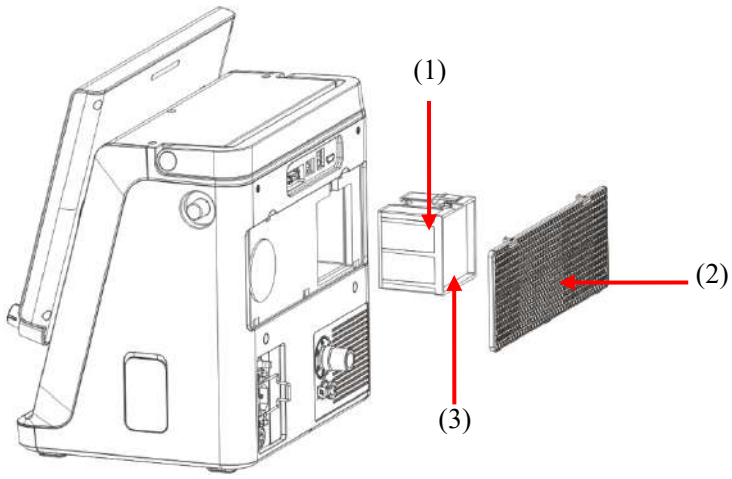
◆ Removal Method

1) Face the safety valve port; turn the safety valve port counterclockwise. When the safety valve port boss reaches the groove of the suction valve body, pull out the safety valve port.
2) Remove the Safety valve diaphragm.

◆ Installation Method

1) Assemble the safety valve diaphragm to the main body of the suction valve. The shaft of the safety valve diaphragm gasket matches the hole on the main body of the suction valve. Confirm that the safety valve diaphragm is completely assembled on the safety valve diaphragm gasket.
2) After aligning the valve port of the safety valve with the groove of the main body of the suction valve, insert it into the valve port of the safety valve, press it tightly and rotate it clockwise to the right limit position.

12.3.3 High-efficiency Particulate Air (HEPA) and Dust Mesh



HEPA high-efficiency filter　　Main unit air inlet baffle　　Air inlet dust mesh

◆ Removal Method

1) Grasp the two fasteners on the main unit air inlet baffle to remove the baffle.

2) Grasp the fastener on the HEPA high-efficiency filter to remove the filter. If the air inlet dust mesh needs disassembled, just hold it with two fingers and take it out.

◆ Installation Method

1) Push the HEPA high-efficiency filter in along the corresponding grooves; press it in the installing direction; then lock the fastener on it.

2) Check the fastener position on the HEPA high-efficiency filter and ensure that it is locked well.

3) Install the main unit air inlet baffle.

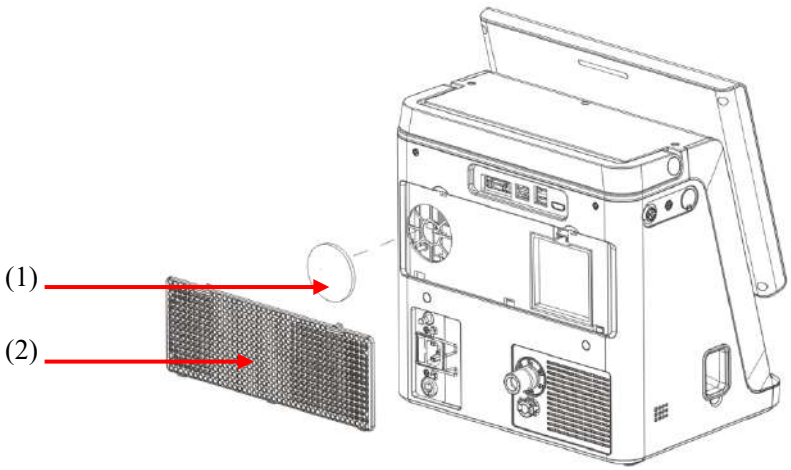
CAUTION

- **Do not operate the ventilator if a high-efficiency air filter (HEPA) is not installed. Otherwise the inspiratory side of the device and the patient circuit will be polluted.**

Note

- **Ensure the HEPA filter and air inlet air mesh installed conform with specification requirements.**

12.3.4 Fan dust Mesh



Fan Dust mesh Main unit air inlet baffle

◆ Removal Method:

1) Grasp the two fasteners on the main unit air inlet baffle to remove the baffle.
2) Remove the dust mesh.

◆ Installation Method:

1) Place the dust mesh on the corresponding position against the cooling fan.
2) Move the main unit air inlet baffle until the two convex points on it drop into the corresponding groove on the main unit; lock the fastener on the baffle in place.

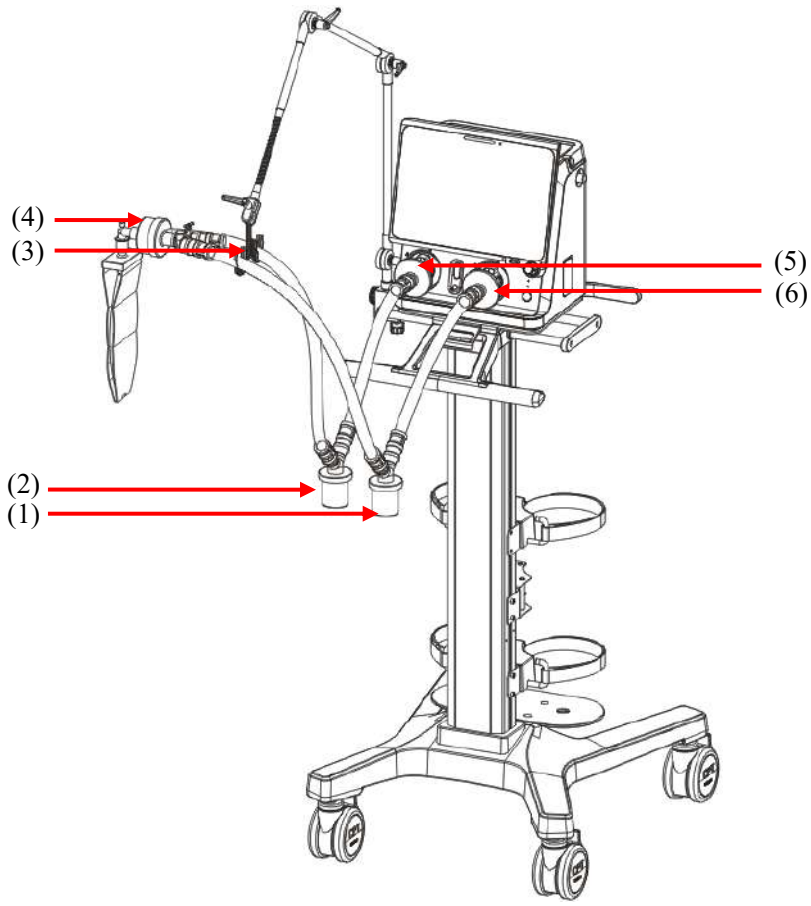
12.3.5 Breathing tube

WARNING

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

CAUTION

- **When removing a reusable patient circuit, do not pull the circuit. Please screw off the circuit from the connector position of the ventilator.**



(1).Water collection cup of inspiratory limb (2).Water collection cup of expiratory limb (3).The pipe hook of the supporting arm

(4).The heat and moisture exchanger (HME) (5).Filter of expiratory limb (6).Filter of inspiratory limb

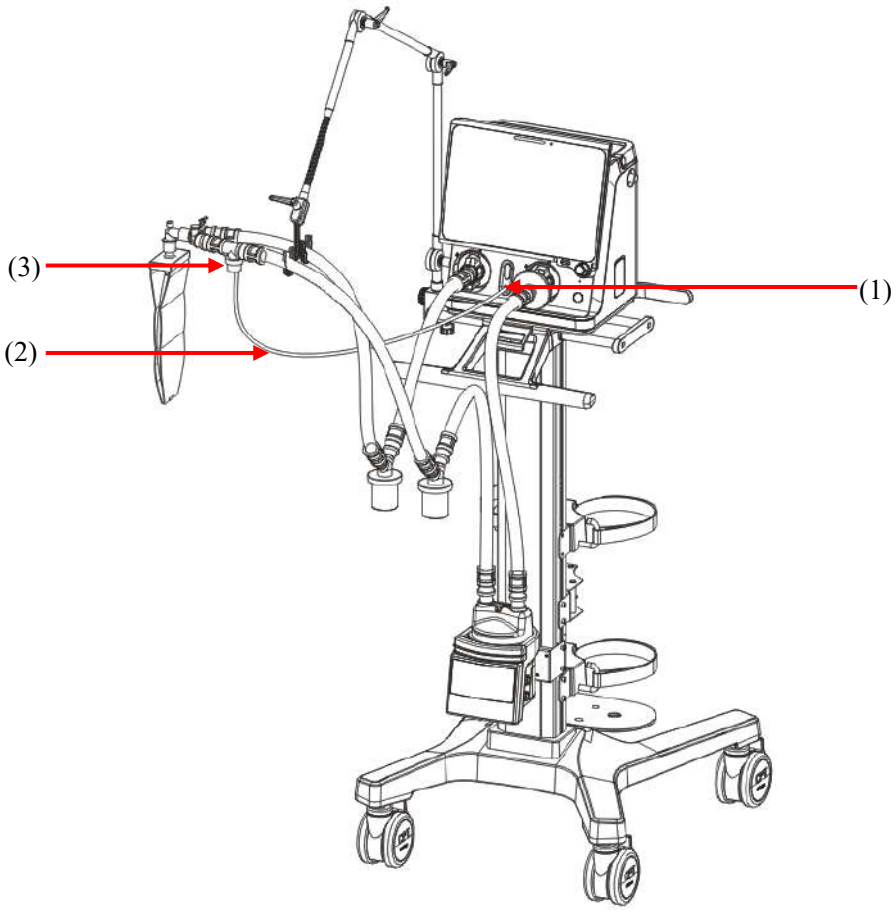
◆ Removal Method:

Simply disconnect each breathing tube.

◆ Installation Method:

1) Install the filters at the inspiratory and expiratory ports respectively.
2) Connect the filter of inspiratory limbto the water collection cup via the pipe, and connect the other end of the pipe to the Y-joint.
3) Connect the filter of expiratory limbto the water collection cup via the pipe, and connect the other end of the pipe to the Y-joint.
4) Use the patient end of the Y-connector to connect the HME, and then connect the patient and the HME.
5) Put the breathing tube on the supporting arm hook as the last step.

12.3.6 Nebulizer



(1).Nebulizer port (2).Nebulizer intake pipe (3).Nebulizer

◆ Removal Method:

1) Disconnect the Nebulizer intake pipe from its corresponding port.

2) Disconnect the pipes connected with the Nebulizer to take out the automizer.

◆ Installation Method:

1) Install one end of the Nebulizer intake pipe to the Nebulizer port, and the other end to the Nebulizer.

2) Install the Nebulizer on the inspiratory limbof the breathing tube via the pipe.

Note

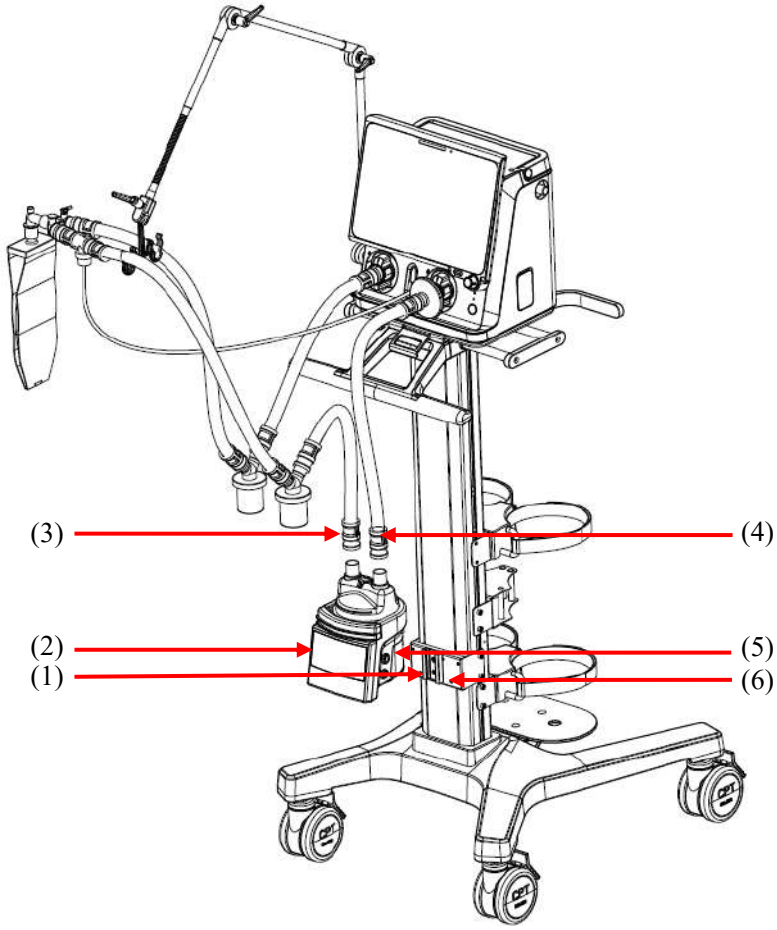
- **Please install a Nebulizer conforming to the specification requirements. The Nebulizer components and installation and removal methods described in this section are for reference only.**

12.3.7 Humidifier

Note

- **The humidifier should conform to the requirements of ISO 80601-2-74. The humidifier components and removal and installation methods described in this section are for reference only.**

12.3.7.1 Removal of Humidifier on the Ventilator



(1).Screw (2).Humidifier (3).The humidifier outlet

(4).The humidifier inlet (5).Humidifier pulley (6).Retaining bracket of humidifier holder

◆ Removal Method

1) Disconnect the pipe connected with the humidifier.

2) Unscrew the screw.

3) Carry the humidifier upward to move it out of the retaining bracket of humidifier holder.

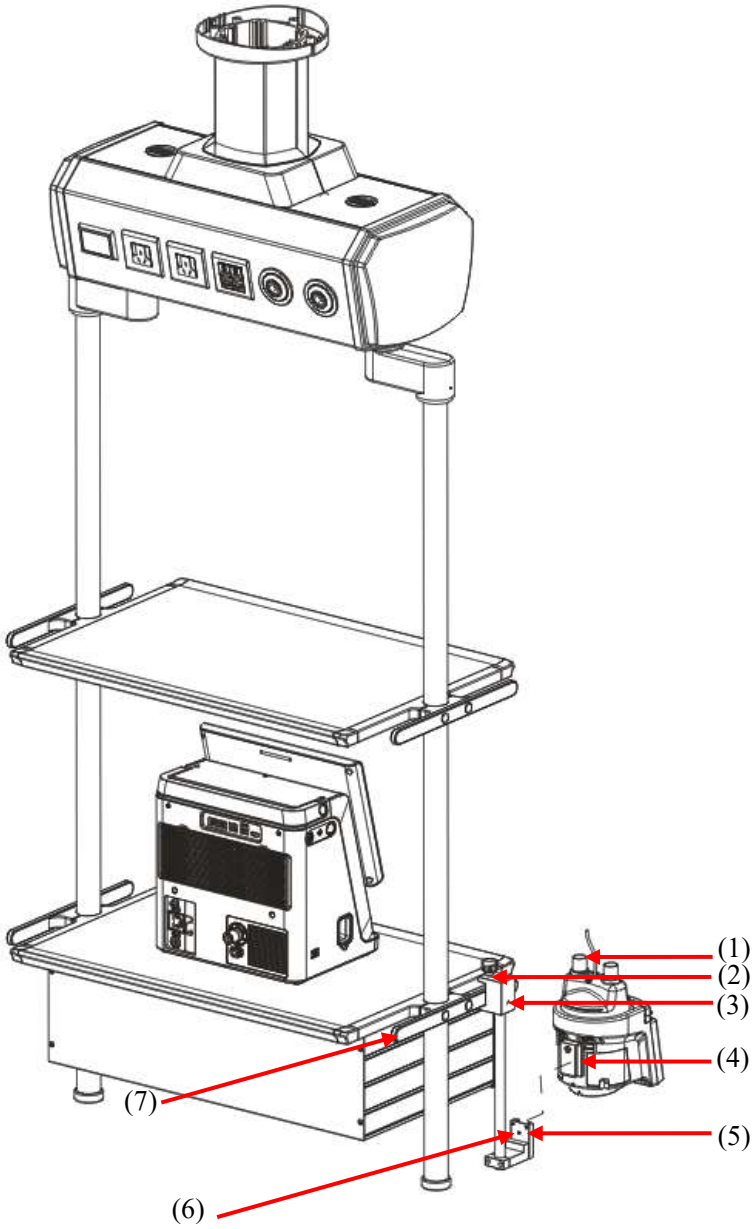
◆ Installation Method

1) Align the humidifier pulley with the humidifier frame fixing seat and slide it in.

2) Tighten the screw.

3) Install the filters at the inspiratory and expiratory ports respectively.
4) Connect the filter of inspiratory limb to the humidifier inlet via the pipe.
5) Connect the humidifier outlet with the water collection cup via the pipe; then connect the water collection cup with the Y-joint via the pipe.
6) Connect the expiratory limb filter with the water collection cup via the pipe; then connect the water collection cup with the Y-joint via the pipe.
7) Put the breathing tube on the pipe hook of the supporting arm.

12.3.7.2 Removal of Humidifier on the Tower



(1).Humidifier (2).Fixing block knob (3).Fixing block

(4).Humidifier pulley (5).Retaining bracket of humidifier holder (6).Screw

(7).Flat-tube beam

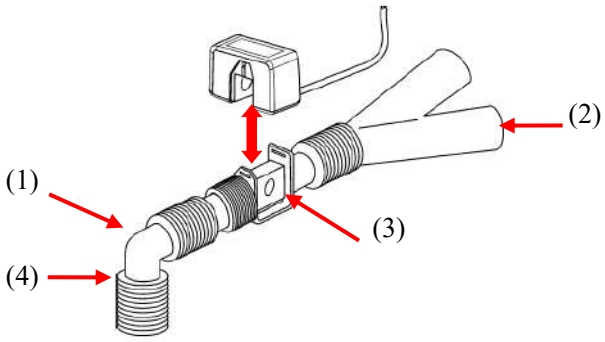
◆ Removal Method

1) Disconnect the pipe connected with the humidifier.
2) Unscrew the screw.
3) Carry the humidifier upward to move it out of the retaining bracket of humidifier holder.

◆ Installation Method

1) Loosen the fixing block knob; place the fixing block on the flat-tube beamon the tower.
2) Tighten the fixing block knob.
3) Align the humidifier pulley with the humidifier frame fixing seat and slide it in.
4) Tighten the screw.
5) Install the pipe for more connection details refer to Step 3 to Step 7 in "**Section*12.3.7.1 Installation Method***".

12.3.8 Mainstream CO_2 Sensor



(1) Elbow tube (2) Y-shaped tube (3) Airway adapter (4) Breathing tube port

◆ Removal Method

Pull out the CO_2 sensor in the vertically upward direction.

◆ Installation Method

Install the CO_2 sensor onto the CO_2 adapter in a vertically downward direction.

Chapter 13 Maintenance

13.1 Service Principles

All necessary service work should be done by service representatives authorized by our company whenever possible; replacement and maintenance of parts listed in this manual can also be done by qualified professionals. Upon request by the user, Comen will conditionally provide relevant circuit diagrams to help the user to repair user-serviceable components of the device by appropriate and qualified technicians.

WARNING

- **It is possible that used equipment is contaminated by blood or body fluid. Please observe the disinfection control and safety rules.**
- **Moving parts and removable parts have the risk of pinching hands or being crushed; be alert when moving or replacing system parts.**
- **Do not use lubricants containing oil or grease because such lubricants have the risk of combustion or explosion when certain O_2 concentration is reached.**
- **Service work should not be done by persons without experience in servicing this type of equipment.**
- **Damaged parts should be replaced by parts manufactured or sold by our company. Test should be performed after replacement to ensure that the equipment conforms to the manufacturer's specification requirements.**
- **When theventilator is in normal use, please do not repair or maintain.**

Note

- **For service support, please contact our After-sales Service Department.**

13.2 Maintenance Schedule

Time Interval	Part/Accessory	Maintenance
Each patient or as per need	Breathing tube (including mask, inspiratory filter, flow sensor, expiratory valve and diaphragm)	Carry out zero calibration of pressure and flow. Carry out system function check. Carry out flow sensor calibration. *(Refer to "**Section 13.5 Flow Calibration**".)* Replace parts with disinfected or new disposable parts.
	Inspiratory valve	When it is possible that the inspiratory valve component

As per need	component	is contaminated by the gas exhaled by the patient, it is necessary to replace the inspiratory safety valve and diaphragm with a disinfected one. (Refer to "**Section12.3.2** ***Inspiratory Valve Component and Diaphragm***".)
	Expiratory valve	Replace the expiratory valve component if it is damaged. (Refer to "**Section*12.3.1 Expiratory Valve Component and Diaphragm*")**
	CO_2 calibration	In case of large deviation of the measured value of CO_2, please calibrate the CO_2 module.
Several time a day or as per need	Breathing tube(single patient use or reusable)	Check the water accumulation condition in the breathing tube and the water collection cup, and empty them promptly. Check each part for damage; replace them where necessary.
During cleaning or installation	Ventilator	Check each part for damage; replace them where necessary.
Every day or as per need	Ventilator	Clean the external surface.
	O_2 sensor	Calibrate the O_2 sensor.
Before each use or after two weeks of continuous use	Whole machine	Perform system self-test; check the respiratory system for resistance and leakage.
Every year or as per need	Dust mesh at air inlet and the fan Dust mesh	Check dusts accumulated on the dust mesh, clean or replace it if needed (refer to "**Section*12.3.4 Fan Dust Mesh"***)
Check every six months, and replace every two years	Lithium battery	Check the charge and discharge condition of the lithium battery every six months. Replace the lithium battery every two years. Please contact our After-Sales Service Department for replacement.
Every year or every 5000 h, or as per need	O_2 sensor	Replace the O_2 sensor if it is damaged. (refer to "**Section*3.10 Install the Oxygen Sensor"***). [**Note**] The service life of the O_2 sensor is roughly

		estimated. The actual life depends on the working environment. Exposure to high temperature or high oxygen concentration will reduce its service life.
	Air inlet HEPA filter	Replace it (*refer to* "**Section*12.3.3High-efficiency Particulate Air (HEPA) and Dust Mesh***").
	Ventilator	Please contact our After-Sales Service Department for preventive maintenance.
	Check valve	Examine check valves of air source, spontaneous inspiration and expiratory limb. Where necessary, please contact our After-Sales Service Department for replacement.
	Backup Alarm System	Check the alarm duration of the backup alarm system (buzzer) If it is too short, Contact our After-sales Service Department.
	Gas source seal ring	Check the gas source seal ring. Where necessary, please contact our After-Sales Service Department for replacement.
	Expiratory valve diaphragm	Check the expiratory valve diaphragm. Where necessary, please contact our After-Sales Service Department for replacement.
Every six years or as per need	Battery of clock module	Replace the battery of the clock module.Contact our After-Sales Service Department.
Every 20,000 hours	Blower box	Please contact our After-Sales Service Department for replacement.
At least once every two years or when measurement out of accuracy range	Mainstream and sidestream CO_2 calibration and performance check	Please contact our After-Sales Service Department.

⚠ **Note**

- **When the turbine reaches the end of its service life, the ventilator prompts [Blower Needs**

Maintenance] in the prompt information area.

13.3 Zero Calibration of Pressure and Flow.

Zeroing should by calibrated in case of large error in the monitored pressure/flow value. It can be performed whether in standby condition or during ventilation.

1) Select [Setup] key → [Calibration].
2) Select [Zero] key → [Start Zero Calibration] key. Pressure/flow zeroing will be activated, and the system displays a prompt: [Sensor Zeroing].
3) If [Stop Zeroing] button is pressed, the process of zero calibration will be terminated. The system will display a prompt [Zeroing stops!] simultaneously. If [Re-zero] is pressed, the zero calibration will be restarted.
4) If the zero calibration is passed, the system will display a prompt: [Sensor Zeroing Completed]. Otherwise [Zeroing Failed!] will be prompted. In this condition a re-zero calibration is needed.

13.4 Flow Calibration

Note

- **Do not perform the flow calibration when the system is connected to a patient.**
- **Do not perform the flow calibration When O_2 source type is low-pressure O_2.**
- **Do not operate any gas circuit components of the device during the calibration, particularly moving or squeezing breathing tube.**
- **Ensure the system is in standby condition. Otherwise select [Standby] key and confirm it to enter the standby interface.**
- **It is recommended to disconnect the ventilator from the humidifier before calibration.**

Calibrate the flow sensor in case of large error in the sensor monitoring value or after replacement.
Perform the flow calibration as follows:

1) Connect a high-pressure O_2 source;
2) Connect the breathing tube and insert the Y-shaped connector into the leak detection plug, in order to close the breathing circuit.
3) Select [Setup] key → [Calibration] → [Flow], then select [Start] button. Flow zeroing will be activated, and the system displays a prompt: [Calibrating...].
4) If [Stop] button is pressed, the process of calibration will be terminated. The system will display a prompt [Calibration stopped!] simultaneously. If [Re-calibrate] is pressed, the calibration will be restarted.
5) If the calibration is passed, the system will display a prompt: [Calibration succeeded!]. Otherwise [Calibration Failed!] will be prompted. In this condition a re-calibration is needed.

Note

- **If the calibration is failed, check whether the corresponding alarm is generated; if it is still failed after removing the alarm, or if the measurement error after calibration is bigger than normal, replace the flow sensor; if the measurement error is still not be improved, contact the authorized after-sales service personnel in time.**

13.5 O_2 concentration calibration

Calibrate the oxygen concentration in case of (1) large error in monitoring value of O_2 concentration, (2) replacement of O_2 sensor.

Perform the O_2 concentration calibration as follows:

1) Connect a high-pressure O_2 source;
2) Select [Setup] key → [Calibration] → [O_2%]; then select [Start] button. The O_2 concentration calibration will be activated, and the system displays a prompt: [Calibrating...].
3) If [Stop] button is pressed, the process of calibration will be terminated. The system will display a prompt [Calibration stopped!] simultaneously. If [Re-calibrate] is pressed, the calibration will be restarted.
4) If the calibration is passed, the system will display a prompt: [Calibration Succeeded!]. Otherwise [Calibration Failed!] will be. In this condition a re-calibration is needed.

Note

- **If the O_2 calibration fails, please observe whether there is any technical failure alarm. If yes, eliminate the failure and perform an O_2 calibration again. If the repeated calibrations fail, replace the O_2 sensor and perform an O_2 calibration again. If the calibration still fails, contact the maintenance personnel or our company for help.**
- **The waste O_2 sensor should not be burnt but disposed of according to the applicable regulations on biological hazards.**
- **O_2 concentration monitoring has no function of atmospheric pressure compensation. If the ambient atmospheric pressure changes, a new O_2 concentration calibration should be performed.**
- **Since it is oxygen partial pressure that the O_2 sensor measures, it is affected by the pressure (absolute pressure) fluctuation. A 10% increase in pressure (absolute pressure) will cause a 10% increase in O_2 concentration; a 10% decrease in pressure (absolute pressure) will cause a 10% decrease in O_2 concentration. If the ambient atmospheric pressure changes, a new O_2 concentration calibration should be performed.**

13.6 Handle Water Accumulation Problem in Flow Sensor

13.6.1 Prevent Water Accumulation

Gas exhaled by the patient is warm and moist, and becomes condensed during flow along the expiratory pipe. The residual condensate water will be left on the pipe wall and finally flow into the water collection cup. When the exhaled gas arrives at the expiratory valve, condensate water can be produced at the expiratory valve (including expiratory flow sensor), affecting measurement of the expiratory flow sensor.

If it is found that the flow waveform is abnormal and the tidal volume fluctuation is unstable, please check whether there is accumulated water inside the expiratory valve. If accumulated water exists in the expiratory valve, please clear the accumulated water before reuse.

During use of the ventilator, please observe the water collection cup in the expiratory pipe on a regular basis. If there is plenty of accumulated water, please clear it in time. Use of a bacterial filter between the expiratory pipe and the expiratory valve can relieve the water accumulation problem in the expiratory valve.

13.6.2 Clear Accumulated Water

When there is accumulated water in the expiratory valve, remove the expiratory valve and clear accumulated water inside it; then reinstall the expiratory valve for reuse.

Note

- **Every time after cleaning and disinfection of the respiratory system, please ensure that all parts of the respiratory system are kept dry.**
- **If it is found that the flow waveform is abnormal and the tidal volume fluctuation is unstable, please check whether there is accumulated water inside the expiratory valve; clear the accumulated water if any.**

13.7 Electrical Safety Test

Note

- **Check the electrical safety after servicing or routine maintenance. Before electrical safety check and test, all covers, panels and screws should be correctly installed.**
- **It is suggested to perform an electrical safety test every year.**
- **Check the connection of external DC power supply conductor in prevention of reverse or short circuit.**

1) Perform the Protective Earth Resistance Test

   a） Connect the two earth resistance testing probes of the safety analyzer respectively to the screw and the protective earth terminal of AC power cord.

   b） Test the earth resistance using 25 A testing current.

   c） Verify that the resistance value does not exceed 0.1ohms (100mohms).

d） If the resistance value exceeds 0.1ohms (100mohms) but is less than 0.2ohms (200mohms), remove the AC power cord, and connect the probe that is previously connected to the protective earth terminal of AC power cord to the protective earth terminal of power outlet, and repeat Steps a to c.

2) Perform the earth leakage current test under the following conditions:

- Normal Polarity
- Reverse Polarity
- Open Neutral, Normal Polarity
- Open Neutral, Reverse Polarity

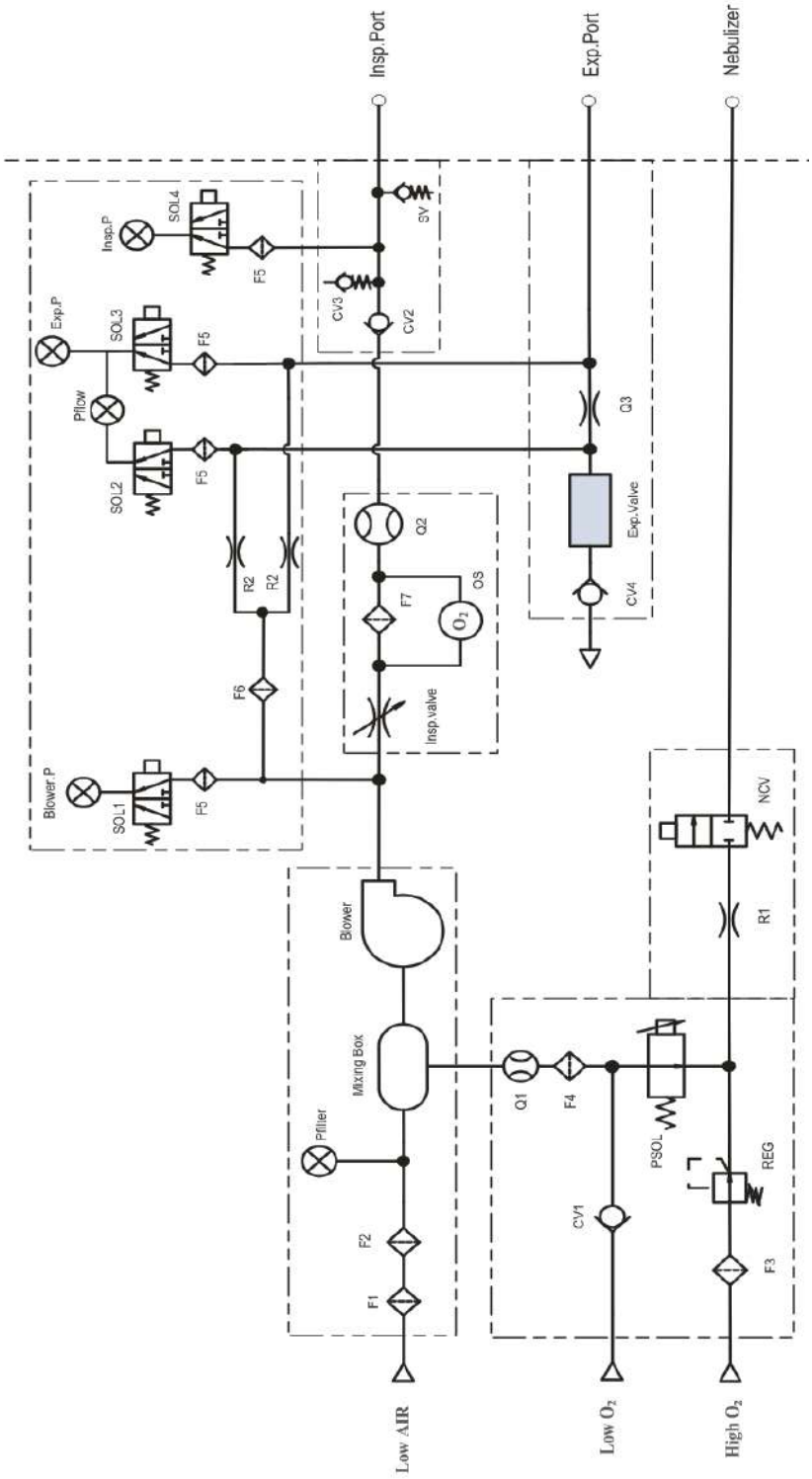
3) Verify that the maximum leakage current does not exceed 500μA (0.5 mA) under the first two conditions, and does not exceed 1000 μA (1 mA) under the last two conditions.

Note

- **Please use a certified safety analyzer (e.g., UL, CSA or AMAI), and perform tests according to the operation instructions.**

Appendix I Operating Principle

I.1)Schematic Diagram of Gas Circuit



I.2)PartList

Symbol	Name	Symbol	Name
Low AIR	Low-pressure air source	F5	Filter screen
F1	Dust filter screen	SOL0	Three-way valve
F2	HEPA filter	Blower P	Blower pressure sensor
Pfilter	Negative pressure sensor	Insp. valve	Inspiratory valve
Low O_2	Low-pressure O_2 source	OS	O_2 concentrationsensor
CV1	Check valve	F6	Filter screen
High O_2	High-pressure O_2 source	Q2	Flow sensor
F3	Filter	CV2	Check valve
REG	Pressure regulating valve	CV3	Check valve
PSOL	Proportional solenoid valve	SV	Safety valve
F4	Filter screen	CV2	Check valve
Q1	Flow sensor	SOL4	Three-way valve
Mixing Box	Class-I mixing noise-cancellation cavity	Insp.P	Inspiratory pressure sensor
Blower	Blower	CV4	Check valve
Q3	Expiratory flow sensor	SOL2	Three-way valve
Exp.Val	Expiratory valve	SOL3	Three-way valve
NCV	Atomizing valve	Pflow	Expiratory differential pressure sensor
R1	Nebulizingair resistance	Exp.P	Expiratory pressure sensor
R2	Air resistance	F6	Filter

I.3) Principle description

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 O2 concentration is formed in the upstream of inspiration valve after Air and O2 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 (F1) filters dust in the Air. Filter (F2) is an HEPA filter for filtering bacteria. After the machine is used or placedfor a period of time, dust or foreign substance absorbed on the surfaces of the two filters atthe Air inlet can occlude the Air inlet when the dust or foreign substance is accumulated to acertain extent. This may cause insufficient Air intake of the machine and compromise theventilation performance of the machine. Vacuum sensor (Pfilter) at the Air inlet monitors thevacuum at the Air inlet in real-time, effectively judges filter occlusion at the Air inlet, andgives the replacement prompt.

Check valve (CV1) ensures unidirectional flow of low-pressure O2. Filter (F3) filters foreignsubstance in the high-pressure O2 supply. Regulator (REG) regulates and stabilizes thepressure of high-pressure O2 supply to ensure the stability and repetitiveness of flowoutputted by the rear proportional solenoid valve (PSOL).

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

The gas supply part includes three parallel limbs: high-pressure O2, low-pressure O2, andlow-pressure Air. The high-pressure O2 and low-pressure O2 converge before mixing with Air.High-pressure O2 and low-pressure O2 cannot be used at the same time. Flow sensor (Q1) isplaced at the common outlet of low-pressure O2 and high-pressure O2 to monitor O2. Roomair enters the machine after passing through filter (F1) and HEPA filter (F2).

Turbine blower (Blower) inhales the room air and externally connected O2 and outputs themto the rear end of the inspiratory limb after compression. The turbine blower module containstwo levels of labyrinth, which are located in the upstream and downstream of the turbineblower respectively. Air and O2 are inhaled by the turbine blower after going through the firstlevel of labyrinth chamber (SD1). The mixed gas of Air and O2 is then compressed by theturbine blower and enters the second level of labyrinth chamber (SD2). These two levels oflabyrinth chamber mix Air and O2 and reduce noise. The turbine blower motor has a thermalconductive metal piece which conducts heat for heat dissipation via a cooling fan.

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

The outlet of large-diameter inspiration valve is connected to flow sensor (Q2) whichmonitors the flow in the inspiratory limb. Flow sensor (Q2) is a hot-wire mass flow sensorwhich does not require calibration. O2 sensor (OS) monitors O2 volume percentageconcentration in the inspiratory limb.

Check valve (CV2) prevents patient’s expired gas from polluting the components in theupstream of this valve under the single fault condition of expiratory limb being occluded.

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

The expiration valve assembly integrates the expiration valve (EV) and flow sensor (Q3). Q3is a diaphragm differential pressure flow sensor. It monitors the front and rear pressure andFlow Calibration processes for calibration via the differential pressure sensor PQ3. PE is anexpiratory pressure sensor which monitors the airway pressure. F9, F10 and F11 are filterswhich protect the upstream components from being polluted by the patient’s expired gas. R2and R3 are resistors which flush weak flow introduced to the expiration valve from the gassource, preventing water vapour condensation from occluding the pressure measurementtubes. V3 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 portwhen they are used by the ventilator. The nebulizer is pneumatic. The drive gas is introducedinto the nebulizer via the nebulizer connector on the front panel; and the liquid medicine isnebulized, enters the inspiratory tube, and reaches the patient’s lungs. The pneumaticnebulizer can be connected only when the machine is connected with high-pressure O2.

Appendix II Accessories

⚠ Warning

- **In order to avoid damage to the instrument and ensure the safety of the patient,please use accessories specified in this manual or conforming to relevant standards.**
- **Disposable accessories are for single use only; reuse of such accessories may result in performance degradation or cross-infection.**
- **If an accessory or its package shows any evidence of damage, pleasedo not use this accessory.**
- **All accessories that can come in contact with human body must comply with the requirements of ISO10993-1 on biocompatibility; no adverse reactions can be caused when such accessories contact human body.**
- **For other accessories necessary for realizing the functions of this equipment, please choose legal products on the market.**
  - **This ventilator and its supporting accessories have been tested for compliance with relevant standards.**
  - **Before monitoring the patient, check the accessories are compatible with the ventilator. Incompatible accessories reduce the performance of the ventilator.**
  - **The accessories provided in this manual are used in conjunction with this ventilator.**
- **Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health.**

1) SpO_2 accessories

Specifications	Models	Part of body applied	Intended patient population	Remarks
Comen SpO2 cable extender	SLZ122	/	/	Reusable
Comen SpO2 probe (Adult use, finger clip type)	SAL104	Finger	Adult	Reusable
Comen SpO2 probe (Adult use, finger clip type)	SAS104	Finger	Adult	Reusable
Comen SpO2 probe (Pediatric use, bandage type)	SES104	Foot /Toe/Finger	Pediatric	Reusable

Comen SpO2 probe (Adult use, finger clip type)	A0816-SA105PV	Finger	Adult	Reusable
Masimo SpO2 M-LNCS series patient cable extender	S-A1202026	/	/	Reusable
Masimo SpO2 probe (Adult use, finger clip type)	M-LNCS DCI	Toe/Finger	Adult/ Pediatric (>30 kg)	Reusable
Masimo SpO2 probe (Adult, pediatric and infant use, Y- type)	M-LNCS YI	Foot /Toe/Finger	Adult/ Pediatric or neonatal (>1 kg)	Reusable
Masimo SpO2 Y-shaped sheath	049-000256	/	/	/
Masimo SpO2 RD-SET series patient cable extender	CM12-RD-L	/	/	Reusable
Adult Reusable finger clip SpO2 sensor	RD SET DCI	Toe/Finger	Adult/ Pediatric (>30 kg)	Reusable
Padiatric/Slender digit Reusable finger clip SpO2 sensor	RD SET DCI-P	Toe/Finger	Adult/ Pediatric (10-50kg)	Reusable
Masimo SpO2 probe (Adult use, pediatric and infant use, Y- type)	RD SET YI	Foot /Toe/Finger	Adult/ Pediatric or neonatal (>1 kg)	Reusable
Neonatal/Adult pulse oximeter Adhesive sensor	RD SET Neo CS-2	Foot /Toe/Finger	Adult (>40 kg) or neonatal (<3 kg)	Single patient use
Neonatal/Adult pulse oximeter Adhesive sensor	RD SET Neo	Foot /Toe/Finger	Adult （>40 kg) or neonatal(<3 kg)	Single patient use
Nellcor SpO2 cable extender	SLZ068	/	/	Reusable
Nellcor SpO2 probe (Adult use, finger clip type)	DS100A	Finger	Adult/ Pediatric (>40kg)	Reusable
Nellcor SpO2 probe (Adult use, Y- type)	D-YS	Foot /Toe/Finger	Adult/ Pediatric	Reusable

2) CO_2 accessories

Specifications	Models	Remarks
Masimo mainstream CO2 module	CAT.NO.200101	Reusable
Masimo mainstream CO2 adaptor	CAT.NO.106220	Single patient use
Masimo CO2 module interface cable	98ME07GC968	Reusable
Masimo sidestream CO2 sampling linewith male connector (adult, padiatric and infant use)	CAT.NO.108210	Single patient use
CO2 sampling tube with airway adaptor set for Adult	REF 3827	Single patient use
CO2 sampling tube with airway adaptor set for Adult /Pediatric	REF 3828	Single patient use
Respironics mainstream CO2 module	1015928	Reusable
Respironics mainstream CO2 airway adaptor	6063-00	Single patient use
Respironics CO2 module interface cable	98ME07GC067	Reusable
Respironics CapnoTraksidestream CO2 module	F-01	Reusable
Respironics sidestream CO2 filtering tube	1103416	Single patient use
Respironics sidestream CO2 dehumidification tube	1103417	Single patient use
Respironics sidestream CO2 airway adapter set for Adult use	1103414	Single patient use
Respironics sidestream CO2 airway adapter for Pediatric use	1103415	Single patient use
COMEN sidestream CO_2 module	F-02	Reusable
COMEN mainstream CO_2 module	M-01	Reusable

3) Breathing circuit accessories

Specifications	Models	Remarks
VADI Reusable adult breathing tube (with and withoutheated wire)	G-328000	/
VADI Disposable adult breathing tube	G-316002	/
VADI Disposable adult breathing tube with heated wire	G-316003	/
VADI Reusable pediatric breathing tube (with and withoutheated wire)	G-330000	/
VADI Disposable pediatric breathing tube	G-316002-01	/
VADI Disposable pediatric breathing tube with heated wire	G-316003-01	/

VADI Reusable infant breathing tube (with heated wire)	G-329000	/
VADI Disposable infant breathing tube with heated wire	G-316003-00	/
Breathing system filter	800-51700	/
Disposal reservoir bag (2l)	504-012-50430600	/
Breathing reservoir bag -2l	G-118004	/
Breathing reservoir bag (test lung) -2l	800-21001	/
Breathing reservoir bag (test lung) -60 ml, type: infant	G-118000-0	/
Mask for infant	5312	/
Mask for adult	5315	/
Mask for pediatric	5313	/
Disposable nebulizer set	M-0801	/
Nasal cannula -small Adult use	OPT942	/
Nasal cannula -medium Adult use	OPT944	/
Nasal cannula -large Adult use	OPT946	/
Nasal cannula-small	RVL001S	/
Nasal cannula -medium	RVL001M	/
Nasal cannula -large	RVL001L	/
Headgear for CPAP mask S, Silicon	DCA100	/

Appendix III Product Specifications

Expiratory volume ventilator, pressure measurement unit and control unit have been integrated in the ventilator. Alarm system, O_2 ventilator and CO_2 ventilator are configured in the ventilator. Where:

- The expiratory volume ventilator, pressure measurement unit and pressure release unit conform to ISO 80601-2-12;
- The alarm system conforms to IEC60601-1-8;
- The O_2 ventilator conforms to ISO 80601-2-55
- The CO_2 ventilator conforms to ISO 80601-2-55;
- The SpO_2 ventilator conforms to ISO 86061-2-61

(1) Product classification

Item	Classification
Type of protection against electrical shock	Class I equipment (connected to a.c. supply mains), Class II equipment (connected to external d.c. power supply) configurated with internal power supply source
Classification of applied part	The breathing tubing & veil, mask and nasal cannula are classified as type BF applied part with defibrillation-proof. The CO_2 sampling tube is classified as type BF applied part with defibrillation-proof. The SpO_2 probe is classified as type CF applied part with defibrillation-proof.
Degree of safety for inflammable anesthetic gas	The equipment cannot be used with inflammable anesthetic gas mixed with air, oxygen or nitrous oxide.
Operating mode	Continuous operation
Rating of protection against ingress of water and particular matters	IP21 Enclosure protection class according to IEC 60529:
Mobility	Portable / Mobileequipment(mounted on trolley)

(2) Environmental Specification

Main unit			
Item	Temperature (ºC)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	5 ~ 40	5% - 95 %	62.0 ~ 106
Storage	–20～60 (O_2 sensor: –20～50)	5% - 95 %	50 ~ 106

Transportation conditions: applicable for land, air and sea transportation.

(3) Hardware specification

Overall specification	
Sound pressure level	Not greater than 45 dB (A) (under standard working condition)
Sound power level	52 dBA
Standard size	About 1365 mm × 526 mm × 544 mm (Height × Width × Depth) (including trolley); About 354 mm × 315 mm × 249 mm (Height × Width × Depth) (excluding trolley)
Weight	About 60kg (with all safe working load) About 10 kg (main unit)
Casters	4 pcs, each equipped with a brake pedal
Installation method	Trolley
Maximum load	Trolley: 23kg Retaining bracket of humidifier holder: 3kg Supporting Arm Fixing block: 2.5kg Support tray for V3/V3A: 25 kg Cylinder holder: 25kg
Display	
Display size	12.1 inch
Resolution	1280 × 800 pixels
Touch Screen	
Touch screen size	12.1 inch
Touch screen type	Capacitive screen
LED lights	
External power supply indicator	Green. The light turns on when external power is connected
Power switch indicator	Namely the backlight of the power switch button (Green. The light turns on when in power-on state, and turns off when in power-off state).
Battery status indicator	The green light remains on: the battery is fully charged or the ventilator is powered by the battery. The green light blinks: the battery is charging. The light turns off: No battery installed or the battery failure or the ventilator isn't connected to external power supply (AC/DC) when it power off.
Alarm indicator	Yellow and red. When high and medium-priority alarms are generated simultaneously, only the red light blinks.
Ports	
Port name	Function
HDMI port	When connected to external display, HDMI video signal with same display content as main display will be input via this port. (display with 1280*800 resolution is supported).
USB Type-A port	can export the configuration information and historical data (such as Patient data, Alarm log, Calibration table) via the USB port; and connect ultrasonic nebulizer.
Multi-function port	Used to connect the Nurse call system in the hospital. Contact Type: Normally closed or Normally open Contact rating: 1A@60V d.c (Vpeaka.c)

Requirement for breathing system bacteria filter	50 ml, bacteria filter efficiency: 99.99%； virus filter efficiency: 99.99%

(4) Power Specification

External AC power supply	
Input voltage	100 – 240 V~
Input frequency	50/60Hz
Input power	100-240V～, 1.2-0.5A
Fuse	T3AL/250V
External DC power supply	
Input voltage	12V
Input current	10A
Internal battery	
Number of battery(s)	1 or 2
Battery type	Lithium ion battery
Rated battery voltage	14.4VDC
Battery capacity	The capacity of single battery is 6700 mAh
Voltage supply time	≥140 min (when a new fully charged battery is used in standard operating mode) ≥280 min (when two new fully charged batteries are used in standard operating mode)

Note: Standard operating mode of the ventilator:

- Respiration mode: V-A/C volume control/assisted ventilation mode;
- Tidal volume: 500 ml;
- Respiratory rate: 10 bpm;
- Inspiratory time: 2.00s;
- O_2 concentration: 40 vol.%;
- PEEP: 3cmH_2O;
- Rated operating pressure of gas source: 400 ± 100kPa.
- CO_2 monitoring is off.
- SpO_2monitoring is off.

(5) Data review

Name	**Specification**
Trends data	The graphic/tabular trends data of the latest 72-hours working parameter for a single patient can be saved.
Event logs	Up to 8000 event logs can be saved, including alarm logs and operation logs. The alarm log includes parameter alarm events, parameter waveforms related to the alarm time and alarm inactivation action.

Freeze the waveform review	Freeze the waveform of the interface at the current time, and use the knob to review the data. When freezing, 30 most recent historical waveforms can be reviewed by sliding the screen or rotating the knob.
Freeze the loop review	Up to 5 reference loops can be saved.

(6) Ventilator specification

Ventilator control parameter specification		
Parameter	**Range**	**Step**
Oxygen concentration (O_2%)	21vol.%~100vol.%	1 vol.%
Tidal volume (TV)	Adult: 100~2200 ml Pediatric: 20~300 ml	Adult: 10 ml Pediatric: 1 ml
Inspiratory Time (T_{insp})	0~10.00 s	0.05 s
Max inspiratory Time (T_{imax})	0 ~ 15.0 s	0.1 s
Inspiratory Time : Expiratory Time Ratio (I:E)	1:10~4:1	0.5
Inspiratory Pause (%) (T_{pause} (%))	OFF, 5 ~ 60%	5%
Pressure Rise Time (T_{slope})	0.00~2.00 s	0.05 s
Respiratory Frequency (f)	0~100 bpm	1 bpm
SIMV frequency (F_{simv})	1~60 bpm	1 bpm
Δ Inspiratory pressure (ΔP_{insp})	0～80 cmH_2O	1 cmH_2O
Δ Support pressure (ΔP_{supp})	0～85 cmH_2O	1 cmH_2O
Positive End-Expiratory Pressure (PEEP)	OFF, 0~50 cmH_2O	1 cmH_2O
Inspiratory Pressure Trigger (P-trig) Sensitivity	-10.0～-0.5 cmH_2O	0.5 cmH_2O
Expiration Trigger (Exp%) Sensitivity	10～85%, Auto	5%
InspiratoryFlow Trigger Sensitivity	0.5 l/min～15.0 l/min	0.1 l/min
High Pressure Level (P_{high})	Low Pressure Level (P_{low})～80 cmH_2O	1cmH_2O
High Pressure Time (T_{high})	0.2~30.0 s	0.1 s
Low Pressure Level (P_{low})	0～50 cmH_2O	1 cmH_2O
Low Pressure Time (T_{low})	0. 2~30.0 s	0.1 s
Intermittent PEEP (Δint.PEEP)	OFF, 0~45 cmH_2O	1 cmH_2O
Tube Diameter (Tube I.D.)	Adult: 5.0 ~ 12.0 mm Pediatric: 2.5 ~ 8.0 mm	0.5 mm
Compensation Ratio (Compensate)	1 ~100 %	1%
HFNC Therapy Flow (Flow)	2~60 l/min	1 l/min

Apnea ventilation	Apnea Tidal Volume (VT_{apnea})	Adult: 100~2200 ml Pediatric:20~300 ml	Adult: 10 ml Pediatric: 1 ml
	ΔApnea Pressure (ΔP_{apnea})	5～80cmH_2O	1 cmH_2O
	Apnea Respiratory Rate (RR_{apnea})	1~80 bpm	1 bpm
	Apnea Inspiratory Time (Apnea T_{insp})	0.20~10.00 s	0.05 s
	Note: (1) Apnea ventilation setting parameter contains: ON/OFF; (2) Use PRVC mode when performing volume control ventilation; (3) Volume control mode and Pressure control mode can be customized by user. Volume control mode is selected by default.		

Ventilator monitoring parameter specification			
Parameter		**Range**	**Step**
Airway pressure	Peak Pressure (P_{peak})	-20～120 cmH_2O	1 cmH_2O
	Plat Pressure (P_{plat})		
	Mean Pressure (P_{mean})		
Positive End-Expiratory Pressure (PEEP)		0～120 cmH_2O	1 cmH_2O
Tidal volume	Inspiratory Tidal Volume (V_{ti})	0～4000 ml	1 ml
	Expiratory Tidal Volume (V_{te})		
	Spontaneous Expiratory Tidal Volume (V_{tespn})		
Minute volume	Minute Volume (MV)	0.0～100.0l/min	0.1 l/min
	Spontaneous Minute Ventilation (MV_{spn})		
	Leakage Volume per Minute (MV_{leak})		
Respiratory Frequency	Total Frequency (F_{total})	0~200 bpm	1 bpm
	Spontaneous Frequency (F_{spn})		
	Mandatory Frequency (F_{mand})		
Oxygen Concentration Monitoring	Fraction of Inspired Oxygen (FiO_2)	15%～100 vol.%	1 vol.%
O2 Therapy (BTPS)	Flow Rate (Flow)	0～100 l/min	0.1 l/min
Other parameters	AirwayResistance (InspiratoryResistance (Ri), ExpiratoryResistance (Re))	0~600 cmH_2O/l/s	1 cmH_2O/(l/s)
	Compliance C (Static Compliance (C_{stat}), Dynamic Compliance (C_{dyn}))	0~300 ml/ cmH_2O	1ml/ cmH_2O

	Rapid Shallow Breathing Index (RSBI)	0~999 (Min·l)	1 /(Min·l)
	Tinsp (Inspiratory time)	0 - 10 s	0.05
	Oral Closure Pressure (P0.1)	-20.0～0.0 cmH_2O	0.1 cmH_2O
	Maximum Negative Inspiratory Pressure (NIF)	-45.0～0.0 cmH_2O	0.1 cmH_2O
	Expiratory Time Constant (TC_{exp})	0.0～10.0 s	0.1 s
	Work of Breathing (WOB)	0.0～100.0 J/min	0.1 J/min
	Inspiratory Time : Expiratory Time Ratio (I:E)	1:10~4:1	0.5

(7) Ventilator Accuracy

Control accuracy	
Parameter	Accuracy (in standard state)
O_2 Concentration	± (3 vol.% + 1% of the set value)
Tidal Volume	± (10 ml+ 10% of the set value)
Δ Inspiratory pressure (ΔPinsp)	± (2 cmH2O + 5% of the set value)
Δ[P_{supp}](Support pressure)	± (2 cmH2O + 5% of the set value)
PEEP	Within the range of1cmH_2O~2cmH2O: ±1 cmH_2O Within the range of2cmH2O～50cmH2O (exclude2cmH2O) : ± (2 cmH_2O + 5% of the set value)
Respiratory Frequency	±1 bpm
SIMV Frequency	±1 bpm
Inspiratory Time	±0.1s or ± 10% of the set value, whichever is larger
Rising Time	± (0.2s + 20% of the set value)
I:E	1:4~2:1: ± 10% of the set value; Other range (1:10~4:1): ± 15% of the set value.
High Pressure Level	± (2 cmH_2O + 5% of the set value)
Low Pressure Level	Within the range of 1cmH_2O~2cmH2O: ±1 cmH_2O Within the range of2cmH2O～50cmH2O (exclude2cmH2O) : ± (2 cmH_2O + 5% of the set value)
High Pressure Time	±0.2s or ± 10% of the set value, whichever is larger
Low Pressure Time	±0.2s or ± 10% of the set value, whichever is larger
Inspiratory Trigger	Flow Rate Trigger: ± (1 l/min + 10% of the set value) Pressure Trigger: ± (1 cmH_2O + ± 10% of the set value)
Expiratory Trigger	±10% (absolute error)
Oxygen Therapy Flow	± (1.5l/min + 10% of the set value)
Apnea Frequency	±1bpm
∆Apnea Pressure	± (2 cmH_2O + 5% of the set value)
Apnea Tidal Volume	± (10 ml + 10% of the set value)
Apnea Inspiratory Time	±0.1s or ± 10% of the set value, whichever is larger
Intermittent PEEP	Within the range of 1cmH_2O~2cmH2O: ±1 cmH_2O

∆int.PEEP	Within the range of2cmH2O～45cmH2O (exclude2cmH2O) :± (2 cmH_2O + 5% of the set value)

Monitoring accuracy	
Parameter	**Accuracy**
Tidal Volume	Within the range of 0 ml～100 ml, ± (10 ml + 3% of the actual reading); Within the range of 100 ml～4000 ml (not include 100 ml), ± (3 ml + 10% of the actual reading)
Airway Pressure	Within the range of -20 cmH_2O～120 cmH_2O, ± (2 cmH_2O + 4% of the actual reading)
PEEP	Within the range of 0 cmH_2O～2cmH_2O:±1 cmH2O Within the range of 2 cmH_2O～120cmH_2O (exclude 2cmH_2O): ± (2 cmH_2O + 4% of the actual reading)
Minute volume	Within the range of 0.0 l/min～100.0 l/min, ± (0.2 l/min + 10% of the actual reading)
Respiratory Frequency	Within the range of 0 bpm～200 bpm, ±1 bpm or ±5% of the actual reading, whichever is larger
O_2 Concentration*	Within the range of 15 vol.%～100 vol.%, ± (2.5 vol. % + 2.5% of the actual reading).
Resistance	Within the range of 0 cmH_2O/(l/s) ～5 cmH_2O/(l/s) and 500 cmH_2O/(l/s) ～600cmH_2O/(l/s) : the measurement accuracy is not defined. Within the range of 5 cmH_2O/(l/s)~20 cmH_2O/(l/s): ±10 cmH_2O/(l/s); Within the range of 20 cmH_2O/(l/s) ～500 cmH_2O/(l/s) (exclude 20cmH_2O), ±50% of the actual reading).
Compliance	Within the range of 0 ml/ cmH_2O～300 ml/ cmH_2O, ± (2 ml/ cmH_2O + 20% of the actual reading).
Rapid Shallow Breathing Index	Within the range of 0 /(min·l)～999 /(min·l) , ± (3 /(min·l)+15% of the actual reading).
Maximum negative inspiratory pressure	Within the range of -45.0 cmH_2O～0.0 cmH_2O, ± (2 cmH_2O + 4% of the actual reading)
Oral Closure Pressure	Within the range of -20.0 cmH_2O～0.0 cmH_2O, ± (2 cmH_2O + 4% of the actual reading).
Work of Breathing	Within the range of 0.0 J/min～100.0 J/min, ± (1 J/min + 15% of the actual reading).
Expiratory Time Constant	Within the range of 0.0s～10.0s, ± (0.2s + 20 % of the actual reading).
Oxygen Therapy Flow	Within the range of 0.0 l/min～100.0 l/min: ± (1.5l/min +10% of the actual reading).
The response of the ventilator to oxygen concentration	The time required for the oxygen concentration in the delivery ventilation to change from 21% to the maximum settable 90%: When TV=500ml, f=10/min, I:E=1:2, ≤50s When TV=150ml, f=20/min, I:E=1:2, ≤100s When TV=30ml, f=30/min, I:E=1:2, ≤100s

O_2 Concentration *: According to the drift test method for measurement accuracy as specified in ISO 80601-2-55, the measurement accuracy can be ensured to meet the requirement in this table.

(8) CO_2 module specification

Sidestream CO_2 module	
Range of measurement	Comen sidestream: 0 mmHg～150 mmHg, 0%～19.7%, 0 kPa～20 kPa (at 760 mmHg)
	Respironics Capnosidestream: 0 mmHg～99 mmHg, 0.0 %～13.0 %, 0 kPa～13.2 kPa (at 760 mmHg)
	Masimo ISA Capnosidestream: 0 mmHg～190 mmHg, 0 % ～ 25 % (at 760 mmHg)
Accuracy	Comensidestream: a) Within the range of 0 mmHg～40 mmHg, ± 2 mmHg; b) Within the range of 41 mmHg～70 mmHg, ± 5% of the reading; c) Within the range of 71 mmHg～100 mmHg, ± 8% of the reading; d) Within the range of 101 mmHg～150 mmHg, ± 10% of the reading.
	Respironics Capnosidestream: 0 mmHg～38 mmHg: ± 2 mmHg, 39 mmHg～99 mmHg: ± 10% of the actual reading.
	Masimo ISA Capnosidestream: a) Within the range of 0 mmHg ～114 mmHg, ± (2.25 mmHg + 4% of the reading). b) Within the range of 115 mmHg ～190 mmHg, the accuracy is not defined.
Sampling Rate and Rate Control Accuracy	Comensidestream: sampling rate: 50 ml/min; sampling rate control accuracy: ± 10ml/min;
	Respironics Capnosidestream: sampling rate: 50 ml/min; sampling rate control accuracy: ± 10 ml/min.
	Masimo ISA Capnosidestream: sampling rate: 50ml/min; sampling rate control accuracy: ± 10 ml/min.
Total system response time	**Masimo ISA Capnosidestream:** < 3s **Respironics Capno CO_2**: Less than 3 seconds(with dehumidification and extension tubing). **Comensidestream CO_2**: Less than 3 seconds(with dehumidification and extension tubing).
10% to 90% Rise time	**Masimo ISA Capnosidestream:**Typical rise time at 50 ml/min sample flow: ≤200ms **Respironics Capno CO_2:** Less than 410 ms(with dehumidification and extension tubing) **Comensidestream CO_2**: Less than 410 ms (with dehumidification and extension tubing)
ETCO2 Calculation	**Masimo ISA Capnosidestream:** ET CO2 are displayed after one breath and have a continuously updated breath average; **Respironics CapnoCO_2:** Range: 0, 5 to 99 mmHg Method: Peak of the expired CO2 waveform over selected time period. Minimum of 5 mmHg between peak and valley of waveform required. Time Period Selections: 10 second, 20 second

	Comensidestream CO_2: Method: Peak of the expired CO2 waveform. Selections: 1 breath, 10 second, 20 second.
CO2 Stability	**Masimo ISA Capnosidestream:**No drift **Respironics CapnoCO₂:**Short Term Drift: Drift over 6 hours shall not exceed 0.80 mmHg maximum. Long Term Drift: Accuracy specification will be maintained over a 120 hour period. **Comensidestream CO_2:** Short Term Drift: Drift over four hours shall not exceed 0.8 mmHgmaximum. Long Term Drift: Accuracy specification will be maintainedover a 120 hour period.

Sidestream CO_2 alarm specification			
Item	**Range**	**Step**	**Note**
Upper $EtCO_2$ alarm limit	Comensidestream: 2 mmHg ～ 150 mmHg	1 mmHg	Set the upper alarm limit to be greater than the lower alarm limit
	Respironics Capnosidestream: 2 mmHg～99 mmHg		
	Masimo ISA Capnosidestream: 2 mmHg～190 mmHg		
Lower $EtCO_2$ alarm limit	Comen sidestream: 0 mmHg ～ 148 mmHg		
	Respironics Capno sidestream: 0 mmHg～97 mmHg		
	Masimo ISA Capno sidestream: 0 mmHg～188 mmHg		

Sidestream CO_2sensor environment specification			
Item	**Temperature (ºC)**	**Relative humidity (non-condensing)**	**Atmospheric pressure (kPa)**
Operation	Respironics: 0~55 Comen: 0～45	Respironics:10~95% Comen: 10~95%	Respironics:53.3~106.6 Comen: 53.3 ～106.6
Storage	Respironics:-40~＋70 Comen: -40~＋70	Respironics:10~95% Comen: 10~95%	Respironics: 50~106 Comen: 50～106

Mainstream CO_2 module specification	
Item	**Range**
Range of measurement	Comen mainstream: 0 mmHg～150 mmHg,0%～19.7%,0 kPa～20 kPa (at 760 mmHg);
	Respironics CAPNOSTAT 5: 0 mmHg～150 mmHg, 0%～19.7%, 0 kPa～20 kPa (at 760 mmHg);
	Masimo IRMA™ mainstream: 0 mmHg～190 mmHg, 0 % ～ 25% (at 760 mmHg);
Accuracy	Comen mainstream:

	a) Within the range of 0mmHg～40mmHg, ± 2 mmHg; b) Within the range of 41mmHg～70mmHg, ± 5% of the reading; c) Within the range of 71mmHg～100mmHg, ± 8% of the reading; d) Within the range of 101mmHg～150mmHg, ± 10% of the reading.
	Respironics CAPNOSTAT 5 mainstream: a) Within the range of 0 mmHg～40 mmHg, ± 2 mmHg; b) Within the range of 41 mmHg～70 mmHg, ± 5% of the reading; c) Within the range of 71 mmHg～100 mmHg, ± 8% of the reading; d) Within the range of 101 mmHg～150 mmHg, ± 10% of the reading.
	Masimo IRMA™ mainstream: a) Within the range of 0 mmHg ～114 mmHg, ± (2.25 mmHg + 4% of the reading); b) Within the range of 114 mmHg ～190 mmHg, the accuracy is not defined;
Total System Response Time	Masimo IRMAmainstream:<1s Respironics CAPNOSTAT 5 and COMEN CO2:<1s
CO2 Stability	Masimo IRMA™ mainstream: No drift Respironics CAPNOSTAT 5 and COMEN CO2:Short Term Drift: Drift over four hours shall not exceed 0.8 mmHgmaximum; Long Term Drift: Accuracy specification will be maintained over a 120 hourperiod.
ETCO2 Calculation	Masimo IRMA™ mainstream:ETCO2is displayed after one breath and have a continually updated breath average.The following methods are used to calculate end-tidal (ET) values:The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle.ETCO2 will be within specification for all respiratory rates up to 150 bpm. Respironics CAPNOSTAT 5 and COMEN CO2: Method: Peak of the expired CO2 waveform Selections: 1 breath, 10 second, 20 second Note: the minimum reported differential value between the baseline and the CO2 value shall be 5 mmHg.
Sampling Rate	Masimo IRMAmainstream: sample rate 20 Hz / channel Respironics CAPNOSTAT 5 and COMEN CO2: 100 Hz

Mainstream CO_2 alarm specification			
Name	**Range**	**Step**	**Note**
Upper $EtCO_2$ alarm limit	Comen mainstream: 2 mmHg ～150 mmHg	1mmHg	Set the upper alarm limit to be greater than the lower alarm limit
	Respironics CAPNOSTAT 5 mainstream: 2mmHg ～150 mmHg		
	Masimo IRMA2 mmHg ～190 mmHg		
Lower $EtCO_2$ alarm limit	Comen mainstream: 0 mmHg ～ 148 mmHg		
	Respironics CAPNOSTAT 5 mainstream: 0 mmHg～148 mmHg		

	Masimo IRMAmainstream: 0 mmHg～188mmHg		
Mainstream CO_2sensorenvironment specification			
Item	Temperature (ºC)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	Comen/Respironics: 0~45 Masimo: 0~40	Comen/Respironics:10~90% Masimo:＜95%	Comen/Respironics: 53.3～106.6 Masimo: 52.5~120
Storage	Comen/Respironics: -40～70 Masimo:-40~＋75	Comen/Respironics:＜90% Masimo: 5～100%	Comen/Respironics: 50~106 Masimo:50~120

(9) SpO_2module specification (only applicable for V3)

SpO_2module	
Display	Pulse rate (PR) waveform/parameter, SpO_2
SpO_2 measurement range	Nellcor SpO_2: 0%～100%
	Masimo SpO_2: 1%～100%
	Comen SpO_2: 0%～100%
SpO_2 accuracy	Nellcor SpO_2: Within the range of 70%～100%, Adult/Pediatric measurement accuracy is ±3% (during non-motion state); Within the range of 0%～69%, measurement accuracy is not defined.
	Masimo SpO_2: Within the range of 70%～100%, Adult/Pediatric measurement accuracy is ±3% (during non-motion state),; Within the range of 1%～69%, the measurement accuracy is not defined.
	Comen SpO_2: Within the range of 70%～100%, Adult/ Pediatric measurement accuracy is ±3% (during non-motion state); Within the range of 0%～69%, the measurement accuracy is not defined.
PR measurement range	Nellcor SpO_2: 20 bpm～300 bpm
	Masimo SpO_2: 25 bpm～240 bpm
	Comen SpO_2: 20 bpm～254bpm
PR measurement resolution	Nellcor SpO_2: resolution: 1 bpm
	Masimo SpO_2: resolution: 1 bpm
	Comen SpO_2: resolution: 1 bpm
PR measurement accuracy (during non-motion state)	Nellcor SpO_2: 20 bpm～250 bpm: the measurement error should be ±3 bpm; 251～300 bpm: measurement accuracy is not defined.
	Masimo SpO_2: 25 bpm～240 bpm: the measurement error should be ±3 bpm
	Comen SpO_2: 20 bpm～254 bpm : the measurement error should be ±2 bpm
Perfusion index	Nellcor SpO_2: / (Note: Nellcor SpO_2 module has no perfusion index.)
	Masimo SpO_2: Measurement range: 0.02%～20%, accuracy: not defined Resolution: 0.02%~9.99%, resolution: 0.01%.

	10.0%~20.0%, resolution: 0.1%.
	Comen SpO_2: 0.05~20%; accuracy: not defined. Resolution: 0.05%~9.99%, resolution: 0.01%, 10.0%~20.0%, resolution: 0.1%.
Data update period	1 s
Signal Quality Index (SIQ) indication function	Masimo SpO_2 and Comen SpO_2 are configured with SIQ indication function
Regulatory compliance	should conform to the requirements of ISO 80601-2-61

SpO_2 alarm limit specification	**Range**	**Step**	**Note**
Upper SpO_2 alarm limit	Nellcor SpO_2: lower +1 %～100 %	1%	Set the upper alarm limit to be greater than the lower alarm limit
	Masimo SpO_2: lower +1 %～100 %		
	Comen SpO_2: lower +1 %～100 %		
Lower SpO_2 alarm limit	Nellcor SpO_2: 0 %～upper-1 %		
	Masimo SpO_2: 1 %～upper-1%		
	Comen SpO_2: 0 %～upper-1%		
Upper PR alarm limit	Nellcor SpO_2: 21 bpm～300 bpm	1 bpm	
	Masimo SpO_2: 26 bpm～240 bpm		
	Comen SpO_2: 21 bpm～254 bpm		
Lower PR alarm limit	Nellcor SpO_2: 20 bpm～299 bpm		
	Masimo SpO_2: 25 bpm～239 bpm		
	Comen SpO_2: 20 bpm～253 bpm		

(10) O2 sensor specifications

Name	Specifications
Expected operation life	1.5 x 106 % measurement time at 20°C 0.8 x 106 % measurement time at 40°C
Thermal compensation	Fluctuation of ±2% within the range 0-40°C
Barometric pressurecompensation	Automatic barometric pressure compensation configured
Pressure range	50~200 kPa
Total system response time of O2 sensor	<15s

(11) Pneumatic system specification

Gas source	
Gas type	O_2
Gas source requirement	Compressed medical gas oxygen
High-pressure O_2 source	
Gas source pressure range	280～600 kPa
Flow	120 l/min (STPD)
Input connector	NIST (ISO 5356-1) or DISS (CGA 1240)
Hose compliance standard	EN ISO5359
Low-pressure O_2 source	
Input pressure range	< 100 kPa
Maximum flow rate	15 l/min
Input connector	CPC quick coupling
Inspiratory module	
Peak flow rate	≥ 210 l/min
Nebulizer connector	Flow rate: 5l/min～8l/min
Safety pressure of respiration	≤ 12.5 kPa
Inspiratory-side external connector	Coaxial 22 mm/15 mm conical connector
Removable, sterilizable	Detachable for clean and sterile and be installed.
Connector compliance standard	EN ISO5356-1
Expiratory module	
Expiratory-side external connector	Coaxial 22 mm/15 mm conical connector
Removable, sterilizable	Detachable for clean and sterile and be installed.
Regulatory compliance	EN ISO5356-1
System compliance and resistance	
Compliance	VBS compliance: 0 to 5 mL/cmH2O. VBS when configured with Adult disposable circuit: ≤ 4 ml/cmH2O; VBS when configured with Adult reusable circuit: ≤ 2 ml/cmH2O; VBS when configured with Pediatric disposable circuit: ≤ 2 ml/cmH2O; VBS when configured with Pediatric reusable circuit: ≤ 2 ml/cmH2O; VBS when configured with Infant reusable circuit: ≤ 1 ml/cmH2O.
Inspiratory resistance	≤ 6 cmH_2O at the flow rate of 60 l/min (with adult breathing tube); ≤ 6 cmH_2O at the flow rate of 30 l/min (with pediatric breathing tube); ≤ 6 cmH_2O at the flow rate of 5 l/min (with infant breathing tube).
Expiratory resistance	≤ 6 cmH_2O at the flow rate of 60 l/min (with adult breathing tube); ≤ 6 cmH_2O at the flow rate of 30 l/min (with pediatric breathing tube); ≤ 6 cmH_2O at the flow rate of 5 l/min (with infant breathing tube).
Biocompatibility of breathing gas pathwaye	
Gas compatibility	Meet the requirements of ISO18562

(12) Adjustable parameter alarm

Parameter		Range	Step	Note
Tidal volume	Upper alarm limit	Adult: 110~4000 ml, OFF Pediatric: 25~600 ml, OFF	5 ml	Set the upper alarm limit to be greater than the lower alarm limit
	Lower alarm limit	Adult: OFF, 50~3995 ml Pediatric: OFF, 10~595 ml	5 ml	
Minute volume	Upper alarm limit	Adult: 0.2~100.0 l/min Pediatric: 0.2~60.0 l/min	0.1 l/min	
	Lower alarm limit	Adult: 0.1~50.0 l/min Pediatric: 0.1~30.0 l/min	0.1 l/min	
Fraction of Inspired Oxygen (in low pressure O_2mode)	Upper alarm limit	20 vol.%～100 vol.%	1 vol.%	
	Lower alarm limit	18 vol.%～ 98 vol.%	1 vol.%	
Fraction of Inspired Oxygen (in high pressure O_2mode)	Upper alarm limit	Min(Oxygen concentration setting value + max (7 vol.%, oxygen concentration setting value x 10%), 100 vol.%) (rounded)	/	
	Lower alarm limit	Max(18 vol.%, oxygen concentration setting value-max (7 vol.%, oxygen concentration setting value x 10%)) (rounded)	/	
Airway pressure	Upper alarm limit	10~90 cmH_2O.	1 cmH_2O	
	Lower alarm limit	OFF,5~ upper -5 cmH_2O	1 cmH_2O	
Respiratory Rate	Upper alarm limit	2~160 bpm, OFF	1 bpm	
	Lower alarm limit	OFF,1~159 bpm	1 bpm	
Apnea alarm		5~60s	1s	Error: ±3s
Other alarms		High PIP High/Low/Missing PEEP Disconnected respiratory circui		

Appendix IV Default Settings

(1) Interface setting

Display setting	Factory default settings
Setting - Waveform Interface`- Number of Waveforms	3
Setting -Waveform Interface - Waveform Drawing	Curve

(2) Setting

Setting	Factory default values
Brightness/Volume - Key Volume	2
Brightness/Volume - Screen Brightness	5
System Setting - Inspiratory Time / I:E	Inspiratory time
System Setting -Height/Ideal body weight	Height
System Setting - DuoVent Time Parameter	Time of High Pressure
System Setting - Invasive Apnea Mode	Pressure Control
System Setting - Ideal body weight tidal volume	7 ml/kg
Sensor-O_2-Monitoring Switch	ON
Time Setting -Date Format	YYYY-MM-DD
Time Setting - Time Format	24-hour

(3) CO_2 Module

Name	Default settings
CO_2 monitoring	On

$EtCO_2$	Alarm Switch	ON
	Alarm Limit (mmHg)	Adult: 15~50 Pediatric: 20~50
	Alarm Level	Medium
Gas Compensation (Respironics, Comen)	16%	
Gas Compensation (Masimo)	High	

(4) SpO_2 Module (only applicable in V3)

Name	**Factory default settings**
Monitoring Switch	ON
SpO_2 Alarm Switch	ON
SpO_2 Alarm Level	Medium
Sensitivity	Masimo SpO_2: APOD; Comen SpO_2: High
Waveform Scanning Speed	25 mm/s
Signal Indication	ON
Smart Pulse Sound	ON
Average Time	8 s
FastSat	OFF
PR Alarm Switch	ON
PR Alarm Level	Medium

(5) Ventilation mode

Setting parameter for each ventilation mode	Factory default settings
Tidal Volume	Adult: 500 ml; Pediatric: 100 ml
O_2 Concentration	21 vol.%
I:E	1:2
PEEP	3 cmH_2O
P_{high}	15 cmH_2O
ΔInspiratory Pressure	15 cmH_2O
P_{low}	3 cmH_2O
ΔSupport Pressure	0 cmH_2O
Rise Time	0.20s
Inspiratory Pause (%)	OFF
Respiratory Rate	Adult: 12 bpm; Pediatric: 20 bpm;
SIMV Frequency	Adult: 5 bpm; Pediatric: 15 bpm
Time of High Pressure	Adult: 1.70 s; Pediatric: 1.00 s
Time of Low Pressure	Adult: 3.3 s; Pediatric: 2.0 s
Inspiratory Time	Adult: 1.70 s; Pediatric: 1.00 s;
Flow Rate Trigger / Pressure Trigger	Default Flow Rate Trigger: Adult: 2.0 l/min; Pediatric: 1.0 l/min
Expiratory Trigger	Auto
Auxiliary Trigger	ON
Apnea Ventilation	ON

ΔApnea pressure	15 cmH_2O
Apnea Respiratory Rate	Adult: 12 bpm; Pediatric: 20 bpm
Apnea Tidal Volume	Adult: 500 ml; Pediatric: 100 ml
Apnea Inspiratory Time	Adult: 1.70 s; Pediatric: 1.00 s
Sigh	OFF
Sigh Interval	1 min
Sigh Times	3
∆int.PEEP	5 cmH2O
Type of Intubation	Turn Off Tube Compensation
Diameter	Adult: 8.0 mm; Pediatric: 5.0 mm
Compensation Ratio	80%
Expiratory Phase Compensation	ON

(6) Alarm

Alarm	**Factory default settings**	**Auto Alarm Limit (based on the measured value)**
Upper Paw Alarm Limit	50 cmH_2O	Mean P_{peak}+ 10 cmH_2O or 35 cmH_2O, whichever is greater
Lower Paw Alarm Limit	OFF	PEEP + 4cmH_2O
Upper MV Alarm Limit	Adult: 7.4 l/min, Pediatric: 3.2 l/min;	1.5 × MVe monitoring value
Lower MV Alarm Limit	Adult: 2.9 l/min, Pediatric: 1.3 l/min;	0.5 × MVe monitoring value
Upper TVe Alarm Limit	Adult: 980 ml, Pediatric: 210 ml;	1.5 × TVe mean value

Lower TVe Alarm limit	Adult: 245 ml, Pediatric: 55 ml;	0.5×TVe mean value
Upper FiO_2 Alarm Limit	100%	/
Lower FiO_2 Alarm limit	21%	/
Lower $EtCO_2$ alarm limit	Adult: 15 mmHg; Pediatric: 20 mmHg;	/
Upper $EtCO_2$ Alarm Limit	Adult/Pediatric: 50 mmHg;	/
Upper SpO_2 Alarm Limit	100%	/
Lower SpO_2 Alarm Limit	90%	/
Upper PR Alarm Limit	Adult: 120 bpm; Pediatric: 160 bpm;	/
Lower PR Alarm Limit	Adult: 50 bpm; Pediatric: 75 bpm;	/
Upper RR Alarm Limit	OFF	1.4 × the monitoring value of total frequency, less than 160 breaths/min
Respiratory Rate is too low	OFF	0.6 × the monitoring value of total frequency
T_{apnea}	15s	15 s
Alarm Volume	5	/

Note: Auto Alarm Limit:

- Auto Alarm Limit uses an algorithm based on measured values;
- Mean value in the formula: Use the monitoring value of the last eight ventilation cycles or the monitoring value within one minute as the mean value, whichever is smaller.
- If the calculated alarm limit is greater than the high threshold of the set range, or less than the low threshold, the corresponding threshold will be used as the Auto Alarm Limit.

(7) Historical Data

Trend log	Factory default settings
Graphic Trends - Show Grouping	All
Graphic Trends - Resolution	10 min
Tabular Trends - Show Grouping	All
Tabular Trends - Time step	1 min
Event Log - Filter	All events

(8) Special functions

Special functions	Factory default settings
Nebulizing Time	30 min
P-V tool -Pstart	3 cmH_2O
P-V tool -Pmax	15 cmH_2O
P-V tool -Flow	6 l/min
P-V tool -Vlimit	770 ml
Lung recruitment tool	Pressure Hold = 30 cmH_2O, Hold Time = 30 s

(9) User Maintenance

System setting	Factory default values
Setting -Gas Source - O_2 Source Type	High-pressure O_2 source
Port Setting - Nurse Call - Call Switch	ON
Port Setting - Nurse Call - Signal Type	Continuous
Port Setting - Nurse Call - Trigger Type	Normally Closed

Port Setting - Nurse Call – Alarm Type	Physiological Alarm, Technical Alarm
Port Setting - Nurse Call- Alarm Level	High, Medium
Setting -Unit - CO_2 Unit	mmHg
Setting - Unit -Pressure Unit	cmH_2O
Setting - Unit – Body Weight Unit	kg

(10) Other

Patient settings	**Factory default settings**
Body weight	Adult: 70 kg; Pediatric: 15.1 kg
Sex	Male
Height	Adult: 174 cm; Pediatric: 99 cm
Ventilation type	Invasive Ventilation

Appendix V Alarm Messages

All alarm levels of the ventilator have been set in factory and cannot be changed by the user.
For each alarm message, the corresponding countermeasures are listed. If the alarm still persists after following the countermeasures, please contact the maintenance personnel.

1) Physiological Alarm

Source	Alarm messages	Alarm level	Causes and solutions
Ventilator parameter	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. When alarm condition activated, the ventilator inflation changes to expiratory phase to reduce the airway pressure. If Paw further increase to pressure high alarm limit+5 $cmH2_O$, the alarm condition remained but the safety valve open and reduce the airway pressure.
	Paw too Low	H	Airway pressure setting is lower than the low limit of pressure alarm.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. 4. Check if the patient tubing are leaked or disconnected.
	FiO2 Too High	H	The inspired O2 concentration is greater than the FiO2 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 O2 sensor.
	FiO2 Too Low	H	The inspired O2 concentration has been lower than the FiO2 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 O2 supply. 4. Calibrate the O2 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.

Source	Alarm messages	Alarm level	Causes and solutions
	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.
	MV Too High	H	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.
	MV Too Low	H	MV is less than MV 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.
	ftotal Too High	M	ftotal is greater than ftotal high alarm limit.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
	ftotal Too Low	M	ftotal is lower than the ftot low alarm limit.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
	Apnea Ventilation Ended	L	This alarm is given when apnea ventilation ends. There is no need to process this alarm.
CO_2	EtCO2 Too High	M	The monitored parameter value exceeds the alarm limit.
			1. Check the patient type. 2. Check the alarm limits.
	EtCO2 Too Low	M	The monitored parameter value exceeds the alarm limit.
			1. Check the patient type. 2. Check the alarm limits.

Source	Alarm messages	Alarm level	Causes and solutions
			1. Check the patient. 2. Check apnea time setup. 3. Check the connections of CO2 module sampling device.
SpO_2	SpO2 Too High	H or M	SpO2 value is greater than the high alarm limit.
			1. Check the patient's condition and ventilator settings. 2. Check the patient's inspiratory O2%. 3. Check the alarm limits.
	SpO2 Too Low	H or M	SpO2 value is lower than the low alarm limit.
			1. Check the patient's condition and ventilator settings. 2. Check the patient's inspiratory O2%. 3. Check the alarm limits.
	PR Too High	H or M	PR value exceeds the high alarm limit.
			1. Check the patient's condition. 2. Check ventilator settings. 3. Check the alarm limits.
	PR Too Low	H, M or L	PR value is lower than the low alarm limit.
			1. Check the patient's condition. 2. Check ventilator settings. 3. Check the alarm limits.

2) Technical Alarm

Source	Alarm messages	Alarm level	Causes and solutions
Power board	Battery1 Failure 01	H	The temperature of battery 1 is higher than expected.
			Contact your service personnel.
	Battery1 Failure 02	H	Battery 1 Charge Failure
			Contact your service personnel.
	Battery1 Failure 03	H	Battery 1 Aging
			Contact your service personnel.
	Battery1 Failure 04	H	Battery 1 Comm Error
			Contact your service personnel.
		H	Battery 1 Failure

Source	Alarm messages	Alarm level	Causes and solutions
	Battery1 Failure 05		Contact your service personnel.
	Battery2 Failure 01	H	The temperature of battery 2 is higher than expected.
			Contact your service personnel.
	Battery2 Failure 02	H	Battery 2 Charge Failure
			Contact your service personnel.
	Battery2 Failure 03	H	Battery 2 Aging
			Contact your service personnel.
	Battery2 Failure 04	H	Battery 2 Comm Error
			Contact your service personnel.
	Battery2 Failure 05	H	Battery 2 Failure
			Contact your service personnel.
	Battery Temp. High.Connect Ext.Power	M	Battery temperature is a bit high during discharge.
			Connect to the external power supply.
	Battery Temp High. System Maybe Down	H	Battery temperature is too high during discharge. The system may be down.
			Connect to the external power supply.
	Battery in Use	L	The current system is powered by battery.
			Connect to the external power supply.
	Low Battery.Connect Ext.Power.	M	The remaining battery power is lower than a threshold.
			Connect to the external power supply.
	System DOWN Connect Ext.Power.	H	Battery power is depleted. The system will shut down in a few minutes.
			Connect to the external power supply immediately.
	Battery Undetected	H	Battery is not available in the current system.
			Contact your service personnel
	Technical Error 21	M	Buzzer Failure.
			Contact your service personnel.
	Fan Failure	M	Fan speed error.

Source	Alarm messages	Alarm level	Causes and solutions
			Restart the machine if the error cannot be corrected. Contact your service personnel. Warning of explore hazard due to oxygen-enrich
	Device Failure 70	H	PowerBoard Charging Voltage Error.
			Contact your service personnel.
	Device Failure 71	H	AC Power Supply Voltage Error.
			Contact your service personnel.
	Device Failure 72	H	DC Power Supply Voltage Error.
			Contact your service personnel.
	Device Failure 73	H	System total Power Supply Voltage Error.
			Contact your service personnel.
	Device Failure 74	H	Power Supply Voltage Error.
			Contact your service personnel.
	Comm Error 75	H	Communication error between power board and main control board
			Contact your service personnel.
Monitoring board（VCM）	Blower Failure 01	H	Blower Temperature too High
			Contact your service personnel.
	Blower Failure 02	M	Turbine blower Temp Sensor Failure.
			Contact your service personnel.
	Blower Failure 03	H	HEPA Pressure Sensor Failure.
			Contact your service personnel.
	Blower Failure 04	H	Blower hardware failure
			Contact your service personnel.
	Blower Failure 05	H	Blower failed.
			Contact your service personnel.
	Insp. Limb Failure 06	H	Inspiratory flow sensor malfunctin.
			Contact your service personnel.
	Insp. Limb Failure 07	H	Insp. Pressure sensor failure
			Contact your service personnel.

Source	Alarm messages	Alarm level	Causes and solutions
	Insp. Limb Failure 08	H	The suction valve falls off.
			Contact your service personnel.
	Exp. Limb Failure 10	H	Expflow sensor failure
			Contact your service personnel.
	Exp. Limb Failure 11	H	ExpPressure sensor failure
			Contact your service personnel.
	Exp. Limb Failure 12	M	Exhalation valve failure
			Contact your service personnel.
	O2 Limb Failure 15	H	O2 flow sensor failure
			Contact your service personnel.
	O2 Limb Failure 16	H	O2 proportional valve failure
			Contact your service personnel.
	Device Failure 20	H	Abnormal power supply of protection module
			Contact your service personnel.
	Device Failure 21	H	Safety valve failure
			Contact your service personnel.
	Comm Error 23	H	The communication between the monitoring board and the main control board is abnormal.
			Contact your service personnel.
	Comm Error 24	H	The communication between the monitoring board and the backup CPU is abnormal.
			Contact your service personnel.
	Technical Error 01	M	HEPA filter pressure sensor failure.
			Contact your service personnel.
	Technical Error 02	M	Atmospheric pressure sensor failure..
			Contact your service personnel.
	Technical Error 03	M	Insp. Temp Sensor Failure.
			Contact your service personnel.
	Technical Error 05	M	Nebulizer Valve Failure.
			Contact your service personnel.

Source	Alarm messages	Alarm level	Causes and solutions
	Technical Error 06	M	Insp.pressure three-way valve failure
			Contact your service personnel.
	Technical Error 07	M	Blower pressure three-way valve failure
			Contact your service personnel.
	Technical Error 08	M	Exp.pressure three-way valve failure
			Contact your service personnel.
	Technical Error 09	M	Exp. flow three-way valve failure
			Contact your service personnel.
	Blower Temp. Too High	H	Blower Temperature exceeds a certain threshold.
			1. Check whether the working environment temperature of the machine exceeds the maximum working temperature claimed by the manufacturer. 2. Check whether the fan inlet and outlet are blocked. If it is blocked, clean up foreign objects and dust.
	Replace the HEPA Filter	L	HEPA filter occluded, resistance increased.
			Contact your service personnel.
	Device Temp. Too High	H	Device Temp Too High
			Contact your service personnel.
	Insp. Gas Temp. Too High	H	The gas temperature exceeds 55℃.
			1. Disconnect the patient. 2.Restart the machine. Contact the specified service personnel if the issue persists.
	Air Flow Sensor TypeError	H	Installation error with air flow sensor.
			Contact your service personnel.
	O2 Flow Sensor TypeError	H	Installation error with O2 flow sensor.
			Contact your service personnel.
	O2 Sensor Unconnected	L	The O2 sensor is not connected.
			Connect the O2 sensor.
	Calibrate Flow Sensor	H	Calibrate the flow sensor.
			Please perform flow calibration.
		H	Calibrate the pressure sensor.

Source	Alarm messages	Alarm level	Causes and solutions
	Calibrate Pressure Sensor		Contact your service personnel.
	Replace O2 Sensor.	M	The chemical O2 sensor is expired.
			Please replace the O2 sensor.
	Calibrate O2 Sensor	L	Please calibrate the O2 sensor.
			Please calibrate O2 concentration.
	Calibrate O2 Valve	H	Calibrate the O2 proportional valve
			Please perform O2valve calibration.
	Calibrate Insp. Valve	H	Calibrate the Insp. valve
			Please calibrate the Insp. valve
	Calibrate Exp. Valve	H	Calibrate the Exp. valve
			Please calibrate the Exp. valve
	Watchdog Failure	H	Watchdog error.
			Contact your service personnel.
	O2 Supply Failure	H	O2 pressure is low or high-pressure O2 is not connected.
			1. Check connection with O2 supply. 2. Check O supply pressure.
	Airway Obstructed?	H	Tube is occluded.
			1. Check and clean the patient tubing. 2. Check and clean the expiration valve.
	Tube Disconnected?	H	Tube is disconnected.
			Re-connect the patient tubing.
	Airway Leak?	L	Tube is leakage.
			1. Check the patient tubing for leakage. 2. Perform System Check to test the leakage
	Disconnection on patient side?	H	High priority. VTe< 1/8 delivered VTi, and delivered VTi>50 ml.
			1.Check the patient. 2. Check the breathing circuit for a disconnection between the patient and the Flow Sensor, or for other large leaks(for example, ET tube, bronchopleural fistula).

Source	Alarm messages	Alarm level	Causes and solutions
	Pressure Limited	L	In volume mode, the pressure reaches Paw high alarm limit-5 cmH_2O.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check pressure high alarm limit. The ventilator changes the inflation type to pressure control under a pressure of [Paw high alarm limit-5 cmH_2O].
	Volume Limited	L	In pressure mode, delivered gas volume exceeds the set TV high limit.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. The ventilator continues ventilation under a safe manner.
	Pinsp Not Achieved	L	Pinsp is lower than the pressure setting value by 3 cmH2O or 1/3 of the pressure setting value, whichever is less.
			1. Check the patient. 2. Check TV alarm limits. 3. Check the O2 supply. 4. Check the patient tubing for leakage. 5. Check the HEPA filter for occlusion.
	Pressure Limited in Sigh Cycle	L	The pressure reaches Paw high alarm limit-5 in sigh cycle.
			1. Check the patient. 2. Check pressure high alarm limit. 3. Check the patient tubing for occlusion. 4. Consider to turn off sigh.
	TV Not Achieved	L	TVi is less than the TV setting value by more than 10 mL + 10 % of the setting value.
			1. Check the patient. 2. Check pressure high alarm limit. 3. Check the high-pressure gas supply or the HEPA filter for occlusion. 4. Check the O2 supply. 5. Check the patient tubing for leakage or occlusion.
	Tinsp Too Long	L	In PSV mode, Tinsp exceeds 4s for adult, 1.5s for pediatric, and the maximum inspiration time set by the user for neonates for continuous 3 cycles.

Source	Alarm messages	Alarm level	Causes and solutions
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the patient tubing for leakage.
	PEEP Too High	H	Monitored PEEP exceeds PEEP + 5 cmH2O 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
	Sustained Airway Pressure	H	The airway pressure measured by any pressure sensor is greater than the setting PEEP + 15 cmH2O for 15 s consecutively.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the patient tubing for occlusion.
Main control board	Please Reset Date and Time	L	Button cell is available in the system. But the clock is powered down and reset.
			Re-set the date and time.
	Comm Error 30	M	The button board communication is stopped, and the button is faulty.
			Contact your service personnel.
	Comm Error 31	H	The monitoring module communication is stopped.
			Contact your service personnel.
	Comm Error 32	H	The power board communication stops.
			Contact your service personnel.
VPM	Device Failure 50	H	The 7490 reference voltage is abnormal.
			Contact your service personnel.
	Device Failure 51	H	The analog 10V voltage is abnormal.
			Contact your service personnel.
	Device Failure 52	H	The analog 5V voltage is abnormal.
			Contact your service personnel.

Source	Alarm messages	Alarm level	Causes and solutions
	Device Failure 53	H	The 3.3V voltage of the main controller is abnormal.
			Contact your service personnel.
	Device Failure 54	H	The backup 5V voltage is abnormal.
			Contact your service personnel.
	Device Failure 55	H	The 7V voltage of the exhalation valve is abnormal.
			Contact your service personnel.
	Device Failure 56	H	The core 4.2V voltage is abnormal.
			Contact your service personnel.
	Device Failure 57	H	The core 1.8V voltage is abnormal.
			Contact your service personnel.
	Device Failure 58	H	The power 12V voltage is abnormal.
			Contact your service personnel.
	Device Failure 59	H	The safety valve 12V voltage is abnormal.
			Contact your service personnel.
	Device Failure 60	H	The 5V voltage of the monitoring board system is abnormal.
			Contact your service personnel.
	Device Failure 61	H	The turbine 22V voltage is abnormal.
			Contact your service personnel.
	Device Failure 62	H	The 7V/5V voltage of the voice coil motor is abnormal.
			Contact your service personnel.
	Device Failure 63	H	The 3.3V voltage of the monitoring board is abnormal.
			Contact your service personnel.
	Device Failure 64	H	The 12V/5V voltage of the hyperbaric oxygen proportional valve is abnormal.
			Contact your service personnel.
	Device Failure 65	H	The 5V voltage of the hot wire sensor is abnormal.
			Contact your service personnel.
	Comm Error 66	H	The communication between the VPM and the MCM is abnormal.

Source	Alarm messages	Alarm level	Causes and solutions
			Contact your service personnel.
	Comm Error 67	H	The communication between the VPM and the VCM is abnormal.
			Contact your service personnel.
KBM	Key Error	L	Hardkey is depressed continuously for more than 35s.
			Contact your service personnel.
	Rotary Encoder Error	L	Rotary encoder is depressed continuously for more than 35s.
			Contact your service personnel.
	Comm Error 80	H	The communication between the KBM and the MCM is abnormal.
			Contact your service personnel.
CO2	CO2 Comm Err	H	CO2module cannot communicate normally with the main system. Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
	CO2 Comm Stop	H	
	CO2 Span Calibrating... (Masimo)	L	CO2 Span Calibrating. Contact the manufacturer for maintenance.
	CO2 Span Cal Error (Masimo)	L	Module Failure. contact the manufacturer formaintenance.
	CO2 Line Blocked	L	CO2 Line Blocked. Check and replace the sampling line; if the error still exists, contact the manufacturer formaintenance.
	Replace CO2 Adapter (Masimo)	L	The adapter Failure.Check and replace the adapter; if the error still exists, contact the manufacturer for maintenance.
	CO2 No Sampling Line	L	The sampling line is not or poorly connected. Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
	CO2 No Adapter (Masimo)	L	The adapter is not or poorly connected. Check and replace the adapter; if the error still exists, contact the manufacturer for maintenance.
	CO2 Out Of Accuracy Range	L	The measured value exceeds the nominal accuracy range.Follow the nominal accuracy range specified by the manufacturer.
	CO2 Temp Out Of Range	L	Module Failure. Contact the manufacturer for maintenance.

Source	Alarm messages	Alarm level	Causes and solutions
	CO2 Need Zero	L	Need Zero is prompted.
	CO2 Software Error (Masimo)	L	An error occurs in the software.Reboot the device.
	CO2 Hardware Error (Masimo)	L	An error occurs in the hardware.Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
	CO2 Speed Out Of Bounds (Masimo)	L	The module Failure. Contact the manufacturer for maintenance.
	CO2 Factory Calibration Lost (Masimo)	L	The module Failure. Contact the manufacturer for maintenance.
	CO2 Pressure Overrange (Masimo)	L	The module Failure. Contact the manufacturer for maintenance.
	CO2 ID unmatched (Respironics,)	L	CO_2 ID unmatched. Reinsert the module.
	CO2 Need Calibrate (Comen)	L	Need Calibrate is prompted.
SpO2	SpO2 Finger Off	M	The SpO2 Sensor is disconnected with the finger. Check the condition of SpO2 sensor.
	SpO2 No Sensor	L	The RRA sensor is not connected Check the sensor and replace it with a proper one if needed.Check or reinsert the sensor; if the error still exists, contact the manufacturer for maintenance.
	SpO2 Low Signal (Masimo,Comen)	L	The SpO2 sensor is connected unreliably.Check if the SpO2 sensor is connected properly.
	Search Pulse	L	The SpO2 sensor is connected unreliably or the patient moves his/her arm.Check the patient's condition and if the SpO2 sensor is connected properly.
	SpO2 Low Perfusion (Masimo)	L	Unsmooth peripheral circulation. Use another finger; or examine whether the limb is compressed.
	SpO2 Sensor Fault (Masimo)	L	The sensor is fault.Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.

Source	Alarm messages	Alarm level	Causes and solutions
	SpO2 Interference (Masimo)	L	Strong external interference. Check the connection of SpO2 lead wire; check the patient's condition and whether a big body movement is made.
	SPO2 Too Much Light (Masimo)	L	The patient (sensor) receives too much light. The sensor is covered by a fabric.Check the SpO2 sensor is fixed well; block or reduce the light; Shield the sensor from light; relocate the sensor.
	SpO2 Unknown Sensor (Masimo)	L	SpO2 module cannot recognize the sensor.Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
	SpO2 No Cable (Masimo)	L	SpO2 cable is not connected. Check the RRA cable and replace it with a proper one if needed.
	SpO2 No Adhesive Sensor (Masimo)	L	The SpO2 adhesive sensor is not connected.Check the SpO2 adhesive sensor and replace it with a proper one if needed.
	SpO2 Module Error (Masimo,Comen)	L	The module fails.Contact the manufacturer for maintenance.
	SpO2 Comm Stop	H	SpO2module cannot communicate with the main system. Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
	SpO2 Comm Err	H	SpO2module cannot communicate normally with the main system.Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
	Nellcor Error, Resetting	L	There is a NELLCOR module error. The system is resetting.If system resetting failsor the error still exists after you restart the Monitor, contact the manufacturer for maintenance.
	SpO2 Sensor Fault (Comen)	L	The sensor is fault.Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.

Appendix VI EMC

This equipment meets the requirements of EMC standard IEC 60601-1-2: 2014 standards. Under the test conditions specified in standard IEC 60601-1-2: 2014clause 8, the following basic performances were checked:

- Inhaled tidal volume control accuracy
- Inhaled tidal volume monitoring accuracy
- CO_2 monitoring accuracy
- O_2 concentration control accuracy
- O_2 concentration monitoring accuracy
- PEEP control accuracy and PEEP monitoring accuracy
- SpO_2 monitoring accuracy

Note

- **The V3/V3A Ventilator complies with the applicable EMC requirements in IEC 60601-1-2.**
- **Please follow the EMC instructions in the User's Manual to install and use the V3/V3A Ventilator.**
- **Portable and mobile RF communication equipment may affect the performance of the V3/V3A Ventilator. To protect the V3/V3A Ventilator against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.**
- **Refer to the attached guide and manufacturer's statement.**

WARNING

- **Do notstack this product on/under or get it close to any other equipment. If you have to use it this way, observe and verify whether it works properly in such condition first.**
- **Using any accessory or cable other than sold by the manufacturer as spare parts may cause higher electromagnetic emission or lower electromagnetic immunity.**
- **Operation of the equipment or system below the minimum amplitude or minimum value stated in the manual may lead to inaccurate results.**

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Clause 5

declaration - electromagnetic immunity		
Immunity test	IEC 60601test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycleAt 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycleand 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycleAt 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycleand 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

declaration - electromagnetic immunity		
Immunity test	IEC 60601test level	Compliance level
Conducted RF IEC 61000-4-6	3V 0.15 MHz to 80MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3V 0.15 MHz to 80 MHz 6 V in ISM bandsbetween 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m
declaration - IMMUNITY to proximity fields from RF wireless communications equipment		

Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

Appendix VII Abbreviations

Parameter	Description
AMV	AMV Adaptive Minute Ventilation
APRV	APRV Airway Pressure Release Ventilation
ATPD	ATPD Ambient Temperature and Pressure Dry
BTPS	Body Temperature and Pressure Saturated
Cdyn	Dynamic Compliance
CPAP/PSV	Continuous Positive Airway Pressure/ Pressure Support Ventilation
Cstat	Static Compliance
DuoLevel	Duo Level Ventilation
Et CO_2	End-tidal Carbon Dioxide
FiO_2	Inspired Oxygen Concentration
Flow	Flow
f	Breathing Frequency
fapnea	Frequency of Apnea Ventilation
fmand	Mandatory Frequency
fspn	Spontaneous Frequency
fsimv	Frequency of SIMV
ftotal	Total Breathing Frequency
I:E	Inspiratory Time : Expiratory Time Ratio
MV	Minute Volume
MV%	Percentage of Minute Volume
MVspn	Spontaneous Minute Volume
MVleak	Leakage Minute Volume
NIF	Negative Inspiratory Force
NIV	Non-Invasive Ventilation
O_2	Oxygen
P0.1	100ms Occlusion Pressure
P-A/C	Pressure - Assist/Control Ventilation
Paw	Airway Pressure
PEEP	Positive End-Expiratory Pressure
PEEPi	Intrinsic PEEP
ΔPinsp	Pressure Control Level of Inspiration
Pmean	Mean Pressure
Ppeak	Peak Pressure
Pplat	Plateau Pressure
PR	Pulse Rate
PRVC	Pressure Regulated Volume Control Ventilation
PRVC-SIMV	Pressure Regulated Volume Controlled - Synchronized Intermittent Mandatory Ventilation

P-SIMV	Pressure - Synchronized Intermittent Mandatory Ventilation
int.PEEP	Intermittent Positive End-Expiratory Pressure
Papnea	Pressure of Apnea Ventilation
Psupp	Pressure Support Level
ΔintPEEP	Intermittent Positive End-Expiratory Pressure (relative to PEEP)
ΔPapnea	Pressure of Apnea Ventilation (relative to PEEP/Plow)
ΔPsupp	Pressure Support Level(relative to PEEP/Plow)
ΔPinsp	Pressure Control Level of Inspiration (relative to PEEP/Plow)
Ri	Inspiration Resistance
Re	Expiration Resistance
Sigh	Sigh
SIMV	Synchronized Intermittent Mandatory Ventilation
slopeCO_2	CO_2 rising slope.
SpO_2	Arterial oxygen saturation from pulse oximetry
STPD	Standard temperature and pressure dry
Texp	Expiration Time
Thigh	Time of High Pressure
Tinsp	Inspiration Time
Tlow	Time of Low Pressure
Tpause(%)	Percent of Inspiratory Pause Time
Tpause(s)	Pause Time
Tplat	Time of Plat In Inspiratory Period
Tslope	Time of Pressure Rising
TV	Tidal Volume
TVe	Expired Tidal Volume
TVespn	Spontaneous Expired Tidal Volume
TVi	Inspired tidal Volume
TV/IBW	Tidal Volume Per Ideal Body Weight
Volume	Gas Volume
Vtrap	Volume of Trap Gas
V-A/C	Volume - Assist/Control Ventilation
V-SIMV	Volume - Synchronized Intermittent Mandatory Ventilation
RSBI	Rapid Shallow Breath Index
WOB	Work of Breath
Vdaw	Airway dead space.
VDaw/TVe	Ratio of airway dead space to tidal volume.
$VeCO_2$	Exhaled CO2 volume.
$ViCO_2$	Inspired CO2 volume.
Vtalv	Alveolar tidal ventilation.
V'alv	Alveolar minute ventilation.
V'CO2	CO2 elimination.

In which,

- NIF, P0.1, PEEPi, V_{trap} are special parameters monitored and displayed under Tool menu when tools are used.

- SpO_2, PR are parameters monitored and displayed when SpO_2 module is used with the ventilator.
- V_{daw}, VDaw/Tve, Vtalv, V'alv, SlopeCO_2, V'CO_2, VeCO_2, ViCO_2 are parameters monitored and displayed when CO_2 module is used with the ventilator.

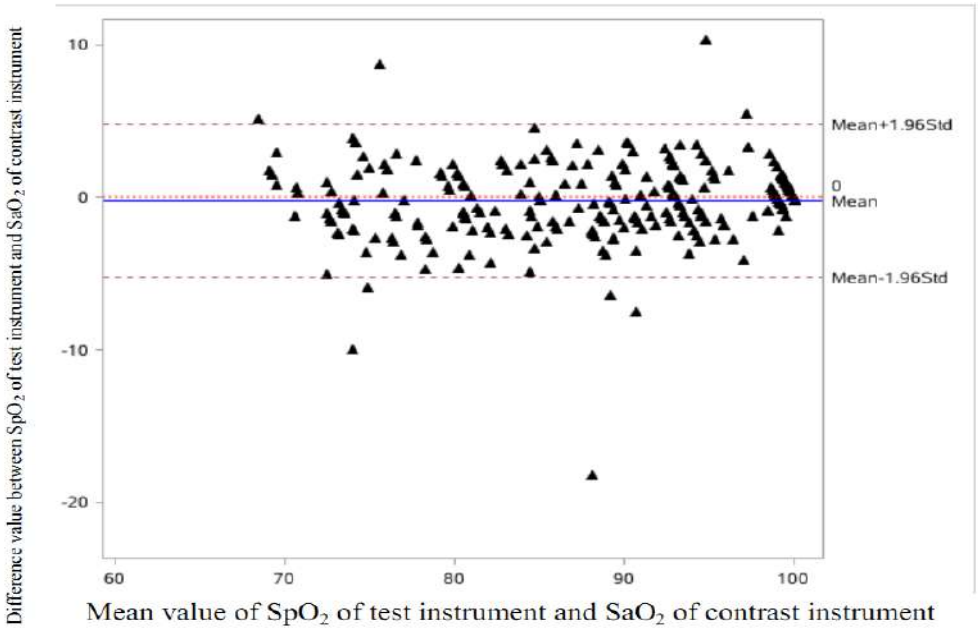
Appendix VIII The accuracy of SpO_2

The accuracy of COMEN SpO_2:

Twenty-four adult subjects are included in clinical trial aged from 24 years old to 44 years old (7 males and 17 females, 20 yellows and 4 blacks), with 6 neonates included aged from 1 day to 24 days (5 males and 1 female), there are 30 subjects in total were included in the tests. The table below show SpO2 accuracy for Comen SpO2 module vs Co-Oximeters(Arms) in a clinical study.

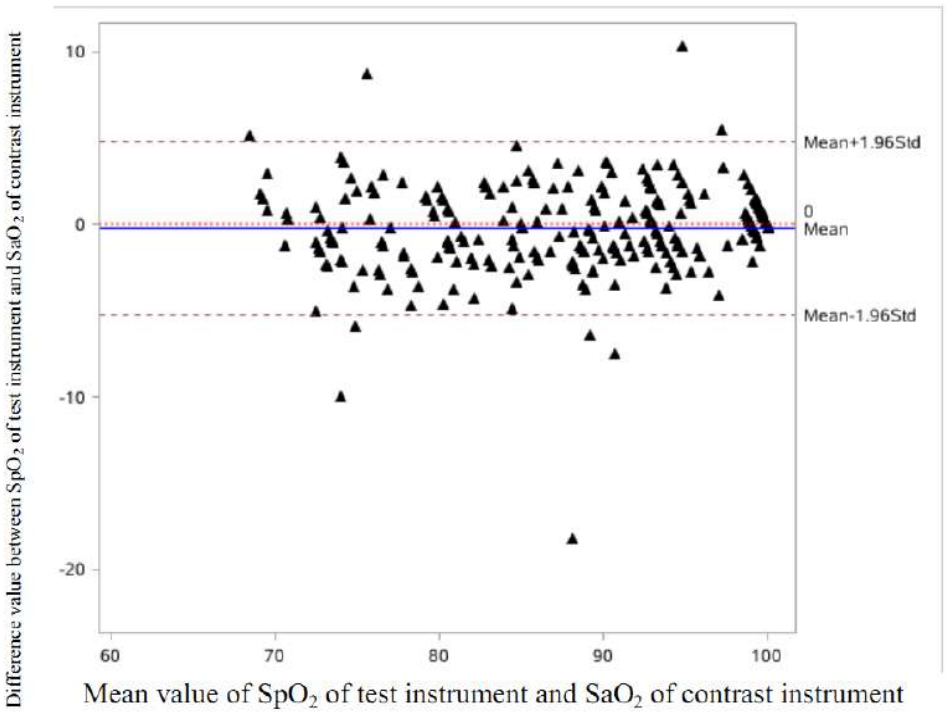
For SAL104 COMEN SpO_2:

SpO2 sensor	model	70%-100%	90%-100%	80%-90%	70%-80%
040-000312-00	SAL104	2.562%	2.486%	2.482%	2.855%



For SES104 COMEN SpO_2:

SpO2 sensor	model	70%-100%	90%-100%	80%-90%	70%-80%
040-000730-00	SES104	2.157%	2.329%	2.015%	1.908%



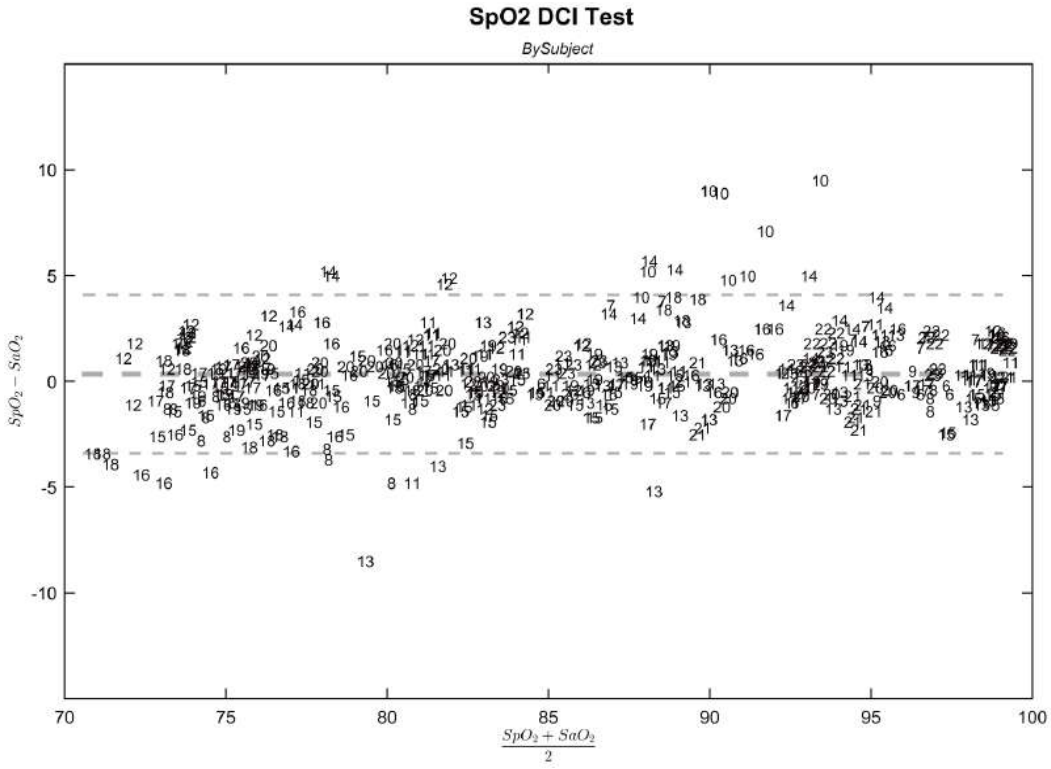
⚠Note

- The two sensors that have been tested in the clinical trial are considered as the representative of other Comen SpO2 sensors. So the accuracy claimed applies to all Comen SpO2 sensors.

The accuracy of Masimo SpO2:

For M-LNCS DCI MASIMO SpO2

SpO2 sensor	model	70%-100%	90%-100%	80%-90%	70%-80%
040-000203-00	M-LNCS DCI	1.90%	1.44%	2.30%	1.84%



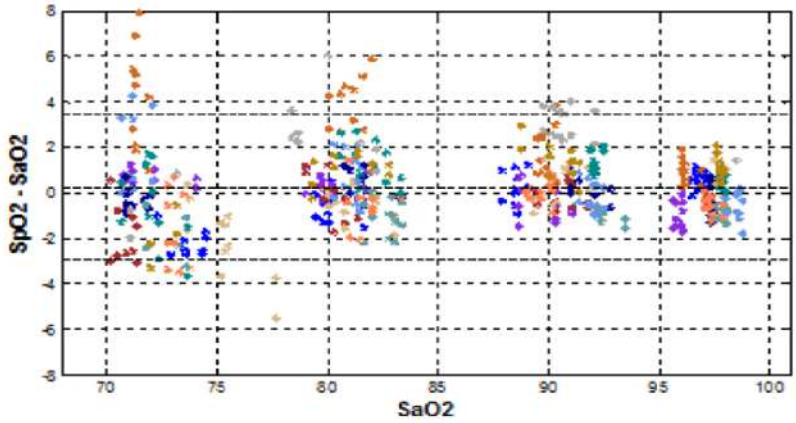
⚠Note

- The data above about the accuracy of Masimo SpO2 originated from Masimo's IFU. Please visit www.masimo.com for more details.

The accuracy of Nellcor SpO2:

For DS-100A NELLCOR SpO2

SpO2 sensor	model	70%-100%	90%-100%	80%-90%	70%-80%
040-000010-00	DS-100A	1.64%	1.16%	1.67%	2.25%



⚠Note

- The data above about the accuracy of Nellcor SpO2 originated from Nellcor's IFU. Please visit www.nellcor.com for more details.