Copyright

Version: B00

No.: 046-00000005-01

Revision Date: 11/2021

Product Name: Emergency and Transport Ventilator

Product Model: V1/V1A

Manufacturer: Shenzhen Comen Medical Instruments Co., Ltd.

Service Life: 10 years

Statement

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 storage and operation 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.

The product will be repaired or replaced free of charge within the warranty period. After the warranty period, Comen will charge for the service and replacement parts. If the products need to be returned to Comen for service, the freight charges (including the customs duty) shall be on the customer's account.

Return Procedure

If the products need to be returned to Comen, please contact Comen After-sales Service Department to acquire the right to return. You must provide the product serial number, which can be found on the product's

nameplate. If the serial number of an instrument is not clear and legible, the product return may not be accepted. Please present the manufacture date and briefly describe the reason for return.

After-sales Service

Name: After-sales Service Department of Shenzhen Comen Medical Instrument Co., Ltd

Address: Floor 10 of Building 1A, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

Tel.: +86-755-26431236, +86-755-86545386, +86-755-26074134

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Customer Service Hotline: 0086-755-4007009488

Postcode: 518000

Preface

This manual provides detailed descriptions of the performance, operation methods and other safety information about the V1/V1A Emergency and Transport Ventilator (hereinafter referred to as the "ventilator").

Intended Readers

This manual is intended for trained professionals and personnel who are experienced in medical procedures, practices and terminology as required for monitoring patients.

Illustrations

All illustrations provided herein are for reference only. The menus, options, values and functions shown in the illustrations may not exactly match what you see on the device's interface.

Conventions:

- —>: This symbol is used to indicate operating steps.
- [**Character**]: This is used to represent character strings in the software.
- Bold and italic: This is used to represent chapters quoted.

Password

Password to enter the related settings of the ventilator:

- User maintenance: 5188

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Contents

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Chapter 1 Safety

1.1 Safety Information

⚠ 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 or maintenance. The equipment must be operated strictly in accordance with this manual. Professionals who use the ventilator must have basic clinical application knowledge and emergency application knowledge, and be proficient in the use of equipment.**
- **Prior to use, the 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.**
- **The ventilator cannot be connected to Oxygen 93, the accuracy of the O_2 monitoring is not maintained when using with Oxygen 93, and it shall not be used with gas supplied from oxygen concentrators.**
- **Do not place the power plug/appliance coupler 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 overheat.**
- **Do not touch the conductive components (e.g. USB port) and the patient simultaneously, and do not touch the conductive parts of the ventilator housing and the patient simultaneously.**

- **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 alarm limits should be set depending on the patient state. Do not monitor the patient only by relying on the audio alarm system. If the alarm volume is set too low or is completely turned off, alarm failure may be caused, which will further endanger the patient. The most reliable monitoring method is to pay close attention to the patient's actual clinical condition.**
- **Do not turn off the audio alarm when the patient is unattended.**
- **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.**
- **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 supply is assured.**
- **The ME EQUIPMENT installation, including a correct protective earth connection, must only be carried out by qualified service personnel. After each installation, do verify the integrity of the external protective earthing system, and ensure that the ME equipment is correctly and properly connected to the external protective earthing system.**
- **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 children.**
- **This ventilator cannot be used in any MRI environment.**
- **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 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.**
- **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, X-ray or MRI devices are all potential sources of interference since they all transmit high-intensity electromagnetic radiation.**
- **Always assure that there is an alternative means of providing mechanical ventilation. A bag-valve resuscitator and an appropriate mask for the patient being ventilated should be immediately available.**

- **The intended patients' height is within the range from 30 cm (ideal body weight: 3kg) to 250cm (ideal body weight: 139kg). The minimum tidal volume should be equal to or greater than 20 ml (for adults/pediatric patients/infants).**
- **An additional independent monitoring device is recommended to use during the mechanical ventilation. The operator should be completely responsible for the normal ventilation and patient's safety under any circumstances. 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.**
- **Using the device on an ambulance may increase the risk of spurious triggering. Adjust the flow trigger if necessary.**
- **Do not place a vessel filled with liquid on the ventilator. It may cause a fire or electric shock if any liquid flows into the device.**
- **To avoid hazardous substances entering the patient circuit, the ventilator cannot be used in a poisonous or contaminated environment.**
- **Do not use the ventilator together with equipment contaminated by oil or oil stain. When the compressed oxygen meeting flammable substance (grease, oil, alcohol lamp), there may be an explosion hazard.**
- **To ensure the safe operation of the ventilator, perform a pre-operational check before use. A ventilator which fails any test cannot be used for clinical use. Only after completing the repair needed and passing all tests, the ventilator can be used.**
- **No modification of this equipment is allowed.**
- **Isolate the equipment from supply mainly by disconnection of power supply cord / plug. Do not place the equipment in such a way that hard to operate the plug.**
- **If you question the functionality of the AC/DC power cord, disconnect the cord from the device and operate on battery power. Replace the cord before reconnecting to AC/DC power.**
- **The ventilator shall not be covered or positioned in such a way that the operation or performance of the ventilator is adversely affected.**
- **In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death.**
- **When a technical alarm condition occurs on the monitoring parameter module (e.g. SpO_2, CO_2 and O_2), the measured value will be displayed as "—". It is suggested that the operator take more attention to the patient's status and aware the alarm conditions.**
- **The effects of degraded sensors can degrade performance or cause other problems.**
- **The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebulizer.**
- **When using nebulization or humidification, the breathing system filters can require more frequent replacement to prevent increased resistance and blockage.**
- **The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly causing patient death or additional serious deterioration of health.**
- **When the ventilator is used on an ambulance, it must be fixedly installed.**

⚠ CAUTION

- **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 Ppeak is greater than 33 cmH_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 special person to watch and monitor the operation of the equipment.**
- **Under the worst case that the ventilator operating in an environment of 50℃, caution that the maximum temperature at patient end is 51℃.**
- **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 purposes for connecting the oxygen supply to the ventilator.**
- **To reduce the risk of fire, please cut off the oxygen supply when the ventilator is not in ventilation state.**
- **In order to avoid the damage of instruments and ensure the safety of patients, please use accessories specified in this User Manual.**
- **Please properly install or relocate the equipment to avoid damage due to drop, collision, strong oscillation or other external mechanical forces.**
- **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.**
- **Avoid long-term storage of the ventilator in an environment over 50℃or below 18℃. Such environment could damage the internal battery, SpO_2 sensor, CO_2 sensor and oxygen sensor or reduce the battery life.**
- **When the service life of the equipment or its accessories are about to expire, please dispose of them and the medical waste in accordance with the local regulations or the hospital's rules.**
- **When disposing of discarded oxygen sensor, please comply with relevant regulations on biological hazards and do not burn them.**
- **Do not throw the O_2 sensor into fire to prevent explosions.**
- **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 configure the medical system and be liable to verify if the system complies with IEC 60601-1. If you have any questions, please contact us.**
- **To prevent the patient's leak current from exceeding the safety limit, do not contact the patient**

while connecting a peripheral device via the signal input/output port or replacing the oxygen sensor.

- **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.**
- **Since silicone/rubber parts are easy to burn in and become brittle, please prevent them from exposure to ultraviolet radiation and direct sunlight for a long time.**
- **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 check result is [Passed].**
- **When not in use, store the device within a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.**
- **This equipment needs to be installed and put into service in accordance with the information provided in the manual and keep the minimum safe distance from wireless equipment or high-power instrument.**
- **Do not use the device or sensors if it is damaged/degraded/loosen in any way. The continuous use of a damaged one may cause injury, improper results, or serious danger.**
- **In order to prevent the error resulting from software, do follow the instruction of power on/off.**

NOTE

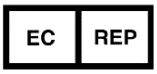
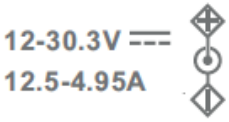
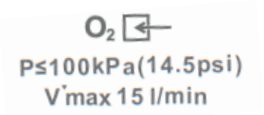
- **Please put the device in a place where observation, operation and maintenance are convenient.**
- **This manual introduces the product of the most complete configurations. Some configurations or functions may not be available on the product you have purchased.**
- **Please keep this manual near the device for easy and prompt access when needed.**
- **This device is not intended for home use.**
- **When this ventilator is used for emergency transportation on road ambulances, the applicable road ambulance types are type A, type B and type C, according to EN 1789.**
- **The device can be used for only one patient at a time.**
- **To prevent any damage to the device, keep it away from dust, lint, sunlight and dirt, sources of heat or moisture.**
- **Working in a high temperature or high oxygen environment will shorten the life of the oxygen sensor.**
- **Service life(25℃±5℃): 10 years (may shorten due to extreme environmental condition).**
- **The applied parts of ventilator are defibrillation-proof and is unaffected by defibrillation voltage.**

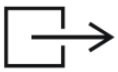
1.2 Contraindications

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

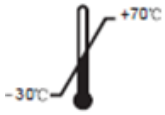
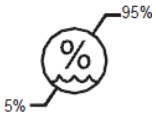
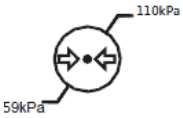
1.3 Equipment Symbols

1) Device Symbols

	Caution		Emergency AIR inlet (general warning symbol)
	Manufacturer		Date of manufacture
	Serial number		Reference number
	Complies with medical device directive 93/42/EEC		Authorized Representative in the European Community
IP24	Protection against ingress of particular matter and liquid		Refer to instruction manual/ booklet Follow instructions for use[Note]
	AC/DC power indicator		Battery level indicator
	Class II devices, have double or reinforced insulation, as no provision for protective grounding (when connected with external DC power input only)		DC power indicator
	Low-pressure O_2 port		High-pressure O_2 port
	Power/Standby key		Standby icon
	Defibrillation-proof Type CF applied part		Defibrillation-proof Type BF applied part

	Equipotentiality		Protective earth
	Oxygen Enrichment/Suction key		Manual ventilation/inspiration hold key
	Air Intake-Do not obstruct		Audio paused
	Expiratory port		Inspiratory port
	Nebulizer port		Flow sensor port
	Gas exhaust port		Screen Lock/ Unlock
	Network connection symbol		USB port
	Correct Disposal of This Product (Waste Electrical & Electronic Equipment) Statement: Contact the local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories		Environment-friendly use period of electronic product is 20 years
	Storage temperature limit		Patient weight limit
	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.			

2) Package Symbols

	This way up		Stacking limit by number
	Fragile; handle with care		Keep away from rain
	Temperature limit		Humidity limit
	Atmospheric pressure limit		Do not use if package is damaged
	General symbol for recovery/recyclable		"Single Use Only" “Do Not Reuse”
	Non-sterilize		Use by date
	Lot number		Latex free

Chapter 2 Product Overview

2.1 Product Composition

The emergency and transport ventilator is composed of host device (including battery and SpO_2 module), CO_2 module, trolley, support arm, vehicle mount and accessories.

2.2 Intended Use

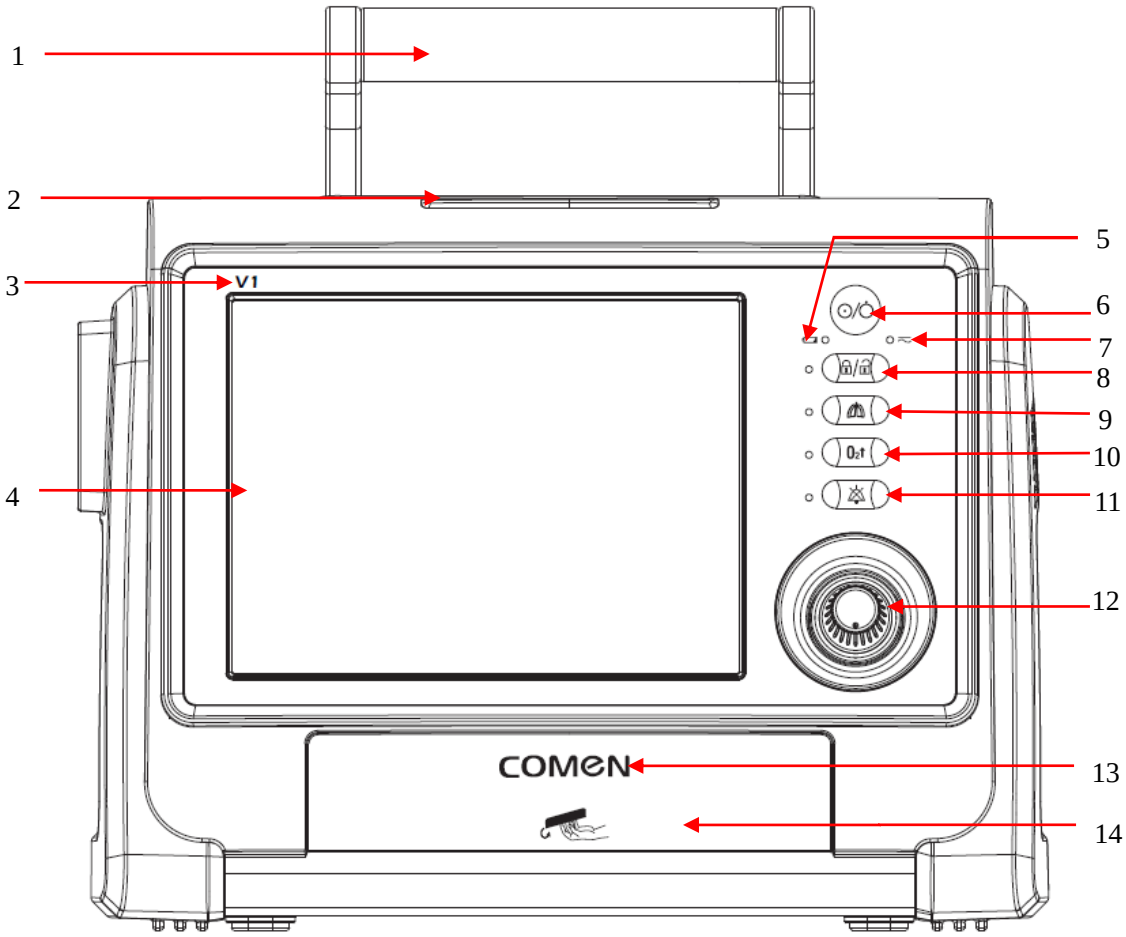
The emergency and transport ventilator V1/V1A provides positive pressure ventilation, SpO_2 and CO_2 monitoring for adults, pediatric patients and infants (from 3kg-139 kg).

The ventilator is appropriate for use in intensive care unit or post-operative resuscitation room, emergency medical care or primary care and emergency medical services environment. The ventilator is transit-operable during transport inside and outside the healthcare facility. When used inside the healthcare facility, it's intended to be used by the skilled care providers with knowledge of mechanical ventilation. When used outside the healthcare facility, V1/V1A should be fixed on the road vehicle and operated by authorized personnel.

NOTE

- **The weight limit is the range of ideal body weight (IBW) setting range when applied to a new patient. If an IBW is set, the default value of TV (Tidal Volume), f (Respiration Rate) and fapnea (Apnea Frequency) in ventilation mode will be figured out automatically by the system. It's convenient for the operator to conduct ventilation in an emergency situation.**
- **If a patient weighted over the 139kg, the operator can adjust the TV, f and fapnea himself according to the patients' situations.**

2.3 Front View

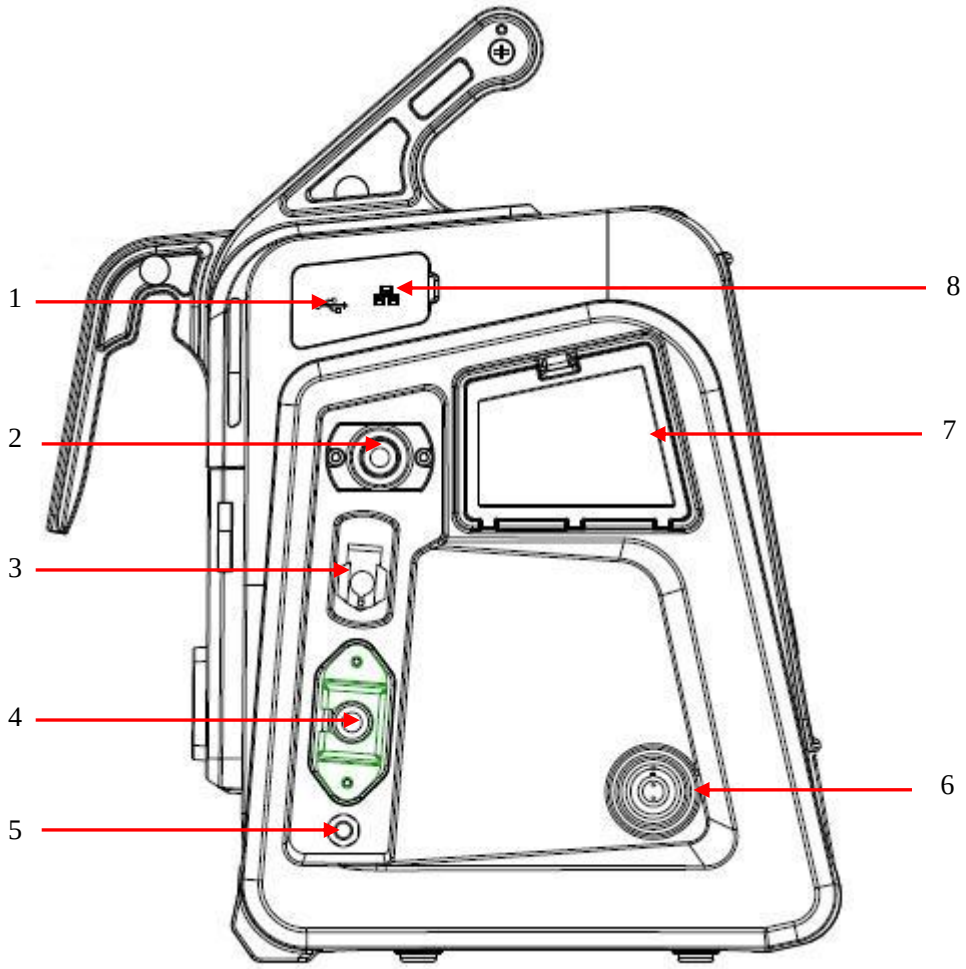


1. Handle
2. Alarm indicator light
   - When an alarm is generated, the alarm indicator lights indicate different alarm priorities in different colors and blinking frequencies.
3. Product model
4. Screen (touch screen)
   - Software interfaces of ventilator system are displayed on the screen. Settings can be selected and changed by touching.
5. Battery indicator light
   - Blinking: indicates that the battery is being charged and the ventilator is powered by an external power supply (AC or DC).
   - ON: indicates that the battery has been fully charged or is powered by batteries.
   - OFF: indicates that no battery is installed, or the ventilator is not connected to the external power supply or the battery fails after shutdown.
6. Power/Standby key
7. 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).
8. Screen Lock/Unlock key
   - Press this key to lock or unlock the screen. When screen-lock activated, the green light lights up.
9. Manual Ventilation/Inspiration Hold key

- If the user presses and releases this key during expiration, the ventilator provides manual ventilation.

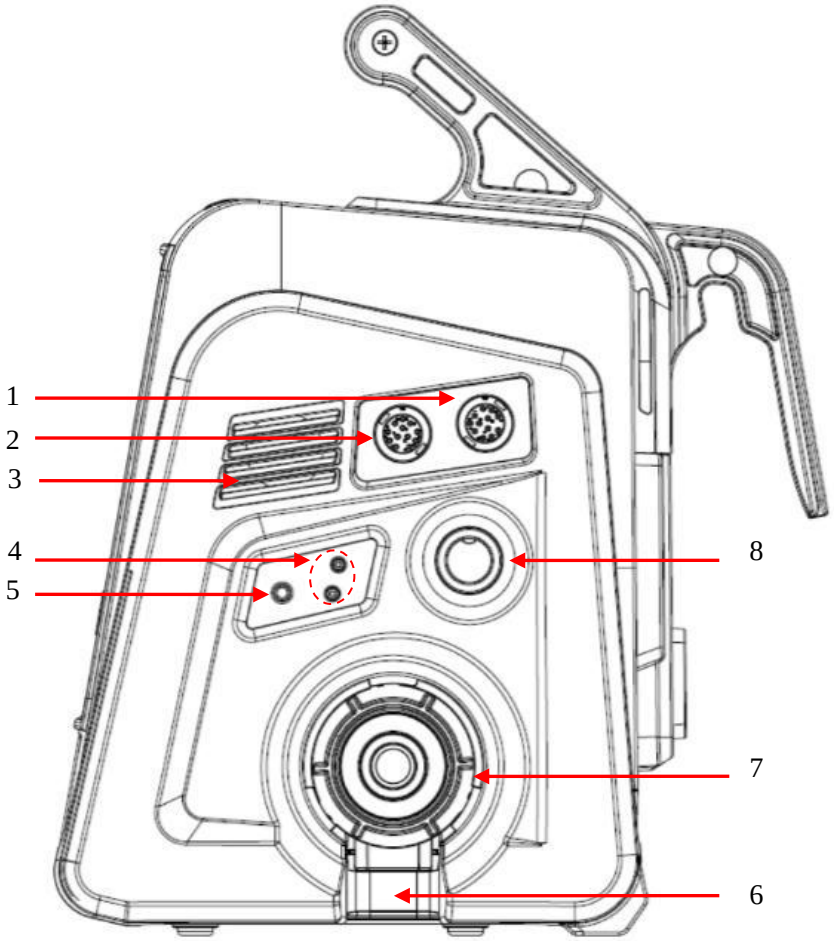
10. Oxygen Enrichment /Suction key
    - When the user presses the key in the expiratory phase, the ventilator provides mandatory respiration and then hold the respiration until the key is released; it can extend maximum 15s at the end of the set inspiratory time. When the user presses the key in the inspiratory phase, the ventilator holds the respiration at the end of the inspiratory phase until the key is released; it can extend maximum 15s again.
11. Alarm Audio Paused key
    - When the user presses this key, the system enters the alarm audio paused mode for 120 seconds, and the alarm audio is temporarily turned off. When a 120 second countdown ends, the system restores the alarm audio. When a new alarm is activated during the alarm audio pause, the system does not restore the alarm audio. In the alarm audio paused mode, when the key is pressed again, the system cancels the current alarm audio pause.
12. Rotary knob
    - Menu items can be selected or settings can be confirmed by pressing the rotary knob. Menu items can be scrolled or settings can be changed by rotating it clockwise or counterclockwise.
13. Company logo: COMEN
14. Battery compartment

2.4 Left View



1. USB port: the ventilator software can be upgraded through the USB port, and configuration information, trend data, screenshots, log and calibration forms can also be exported through the USB port.
2. High-pressure O_2 port
3. Low-pressure O_2 port
4. AC power port
5. Potential equalization conductor: when other equipment is used with the ventilator together, equipotential ends of other equipment and the ventilator shall be connected by cables so as to eliminate earth potential difference among different equipments and ensure the safety of both users and patients.
6. DC power port
7. Air inlet of fan
8. Network port: used for device calibration (For manufacturer maintenance use only).

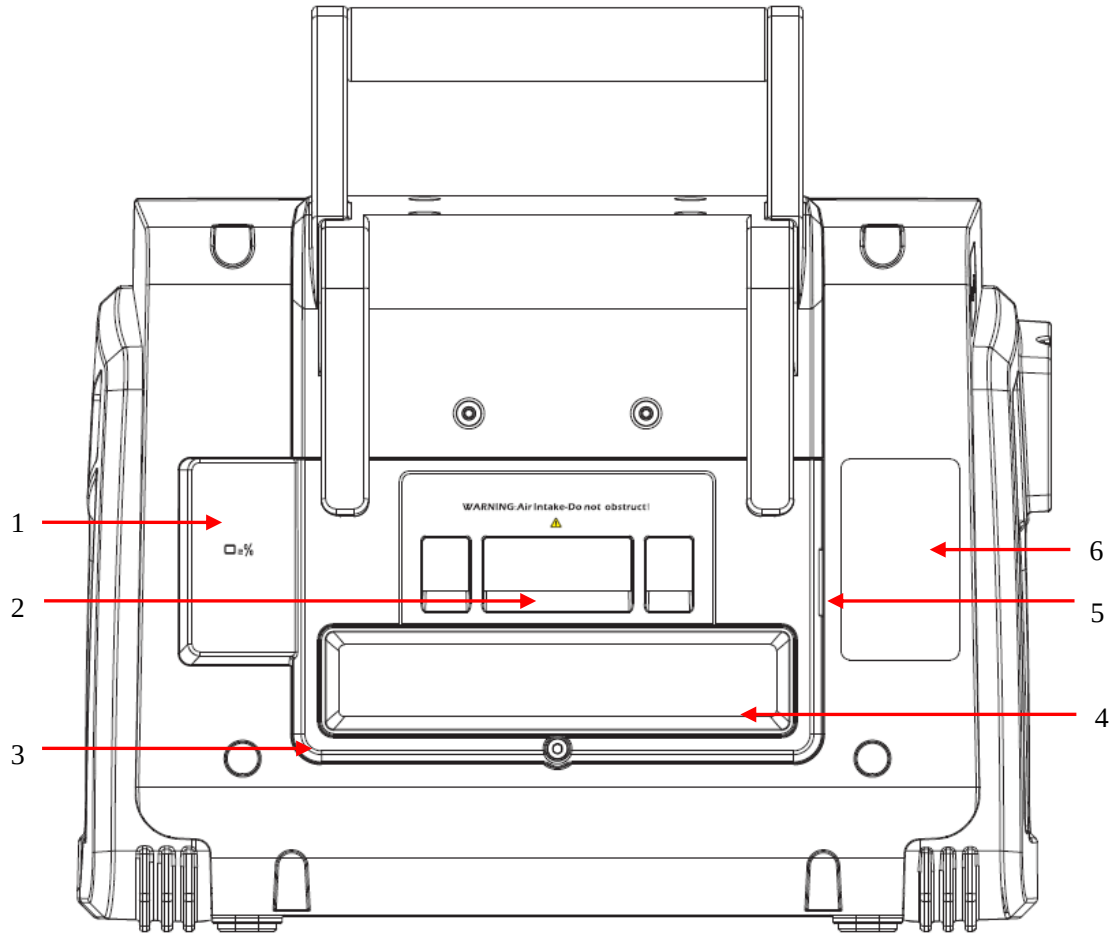
2.5 Right View



1. SpO_2 cable connector
2. CO_2 cable connector
3. Loudspeaker
4. Flow sensor port
5. Nebulizer interface
6. Expiratory outlet
7. Expiratory port: connected to expiratory tube.

8. Inspiratory port: connected to inspiratory tube.

2.6 Rear View



1. O_2 sensor
2. Air inlet and dust filter: do not block
3. Back cover: If need to replace the HEPA filter or O_2 sensor, remove the back cover with use of tool
4. HEPA filter: located under plastic cover
5. Emergency air inlet
6. Nameplate

Chapter 3 Installation & Connection

3.1 Safety Information

⚠ 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.**
- **Do not use the ventilator in a hyperbaric oxygen chamber.**
- **Before starting ventilation, make sure that O_2 sensor is installed.**
- **The ventilator installation, including a correct protective earth connection, must only be carried out by personnel designated by our company.**
- **When the ventilator is installed beside the bed, after the hook is hung, it needs to be fixed with a strap. The dimension of side rail shall well match the hook so as to ensure the whole stability.**
- **The parts supporting the ventilator shall have safe working load of 35 kg with tensile safety factor of 4. After the ventilator is hung, the recommended tilt angle is within 10 °.**
- **When the ventilator is used for patient transfer within hospital, the ventilator can be hand-held or fixed on the transfer bed or fixed on the trolley.**
- **When the ventilator is used for emergency situations, it needs to be fixed on the road vehicle.**
- **No matter how long the power loss, the equipment will retain the last patient setting and alarm setting. Default setting is always ready for selection by operator.**

⚠ CAUTION

- **To prevent patient injury, do not block the holes in the back and side of the ventilator (cooling fan). These holes are vents for fresh air and cooling fan.**
- **Please make sure that all accessories are fully waterproof during transportation.**
- **Use the original package to transport the ventilator.**

3.2 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.**

3.3 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. When the device is exposed to excessive vibration and/or is mounted in a vehicle or shipped in a manner that increases its exposure to vibration, false alarm maybe triggered.

- When operating the ventilator at high extreme temperature or low extreme temperature, please pay more attention to the alarm conditions associated with battery performance, blower temperature or the inlet gas temperature. Time required for the equipment to warm from the minimum storage temperature, or cool from the maximum storage temperature between uses, to status of ready for intended use is two hours.

- When using the device in high altitude, please note that the tidal volume might increases as altitude increases, therefore take good care to prevent over-pressurization of the lung when the altitude increases to 4500m.

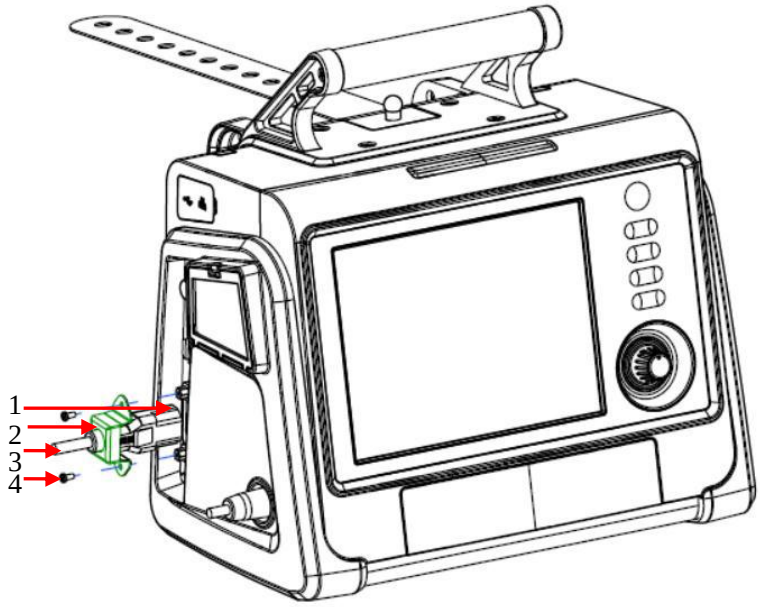
- The device is not intended for hyperbaric operation. Use in a hyperbaric chamber can result in harm to the patient and/or damage to the device.

- When using the device for professional transport to a professional healthcare facility or between professional healthcare facilities, please do set the audio alarm volume higher than the background.

- When the ventilator is used in extreme ambient temperatures exceeding the normal range of 0-40 ℃, accompanying safety hazards may not be immediately apparent. (O_2 monitoring function is disabled under 5 ℃) However, the O_2 sensor and flow sensor should be properly calibrated before use to prevent the accuracy tolerance from exceeding specified ranges during monitoring.

3.4 Power Supply Connection

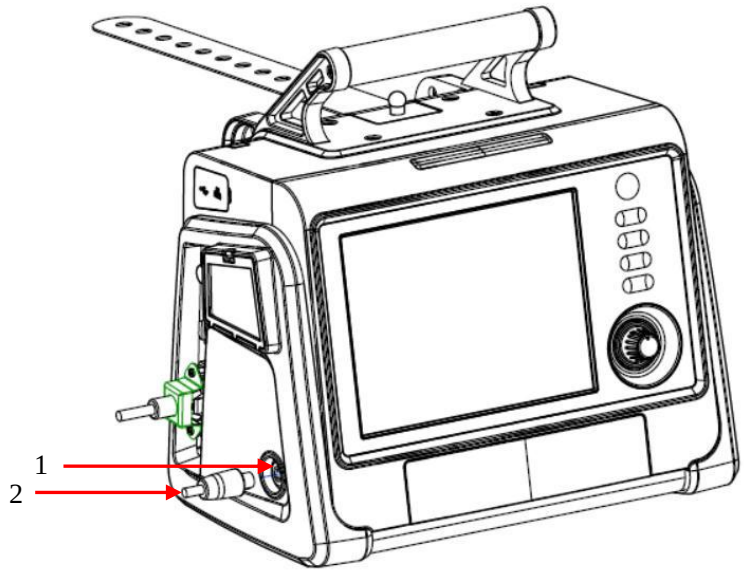
3.4.1 AC Power Supply Connection



1. AC power socket 2. Socket limiting base 3. AC power cord 4. Screws

1) Plug the power cord into the power socket.
2) Fix the socket limiting base with screws to lock the power cord. When the ventilator is used in EMS environments, the power cord shall be fixed with protective means to avoid accidental detachment.

3.4.2 DC Power Supply Connection



1. DC-IN port 2. DC power cord

Plug the DC power cord into the DC-IN port.

The ventilator is available for use only after it's requested by responsible organization and verified by professional service personnel. The DC power cord shall not be connected reversely and the terminal interface shall be firmly 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 using a separate power supply with floating output circuit.**
- **When connecting to the power supply, 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 reverse protection of external DC power supply does not rely 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 right and corner of the screen indicated.**
- **If the external DC power supply has insufficient current capacity, or the supplied voltage falls outside the acceptable voltage range, the ventilator could automatically switchover to internal battery powered and triggers technical alarm condition. If the ventilator detects no external power supply condition but with cord connection, there may be a faulty on power supply. Please stop using the external power supply.**
- **When using the standard vehicle DC outlet, do not jump start the vehicle during operation of the ventilator.**

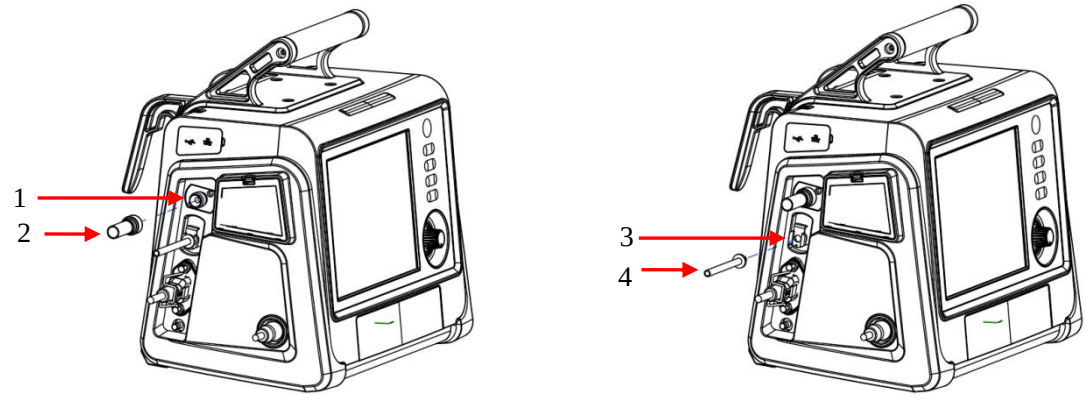
3.5 Gas Supply Connection

WARNING

- **O_2 sensor must be installed for O_2 monitoring before putting the device into service.**
- **Check the O_2 supply port carefully to ensure there are no leakages. Too much leakage will lead to an oxygen concentration increase near the device, so there will be a potential hazardous oxygen-enriched environment.**
- **Please place the O_2 supply hose carefully, to avoid exposing it to the environment where it may get cut, heated or damaged.**
- **Make sure oxygen cylinders are equipped with pressure-reducing valves.**
- **To reduce the risk of fire, transport the low-pressure O_2 with a flow no larger than 15 l/min.**
- **When using low-pressure O_2 supply, the oxygen concentration control function is not activated. It is the operator's responsibility to control the oxygen setting.**
- **After the ventilator is connected to the oxygen supply, if there is an abnormal sound, stop using the ventilator.**

⚠ CAUTION

- **To prevent damage to the ventilator, connect only clean, dry medical-grade oxygen.**
- **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 supply is properly set. Set the Gas supply type based on the actual situation. Refer to *"Section 6.13 O_2 Supply Type Setting"* for instructions.**
- **Always check the status of the oxygen cylinders or other supply before using the ventilator during professional transport. To prevent patient injury, ensure the emergency O_2 supply (e.g. oxygen cylinder) is available when a failure happens in low-pressure O_2.**
- **Low-pressure O_2 hose should conform to the requirements of ISO5359.**
- **To protect the oxygen control system, do not connect the device to high-pressure O_2 and low-pressure O_2 supply at the same time.**



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

The ventilator has 2 ports for gas supply: high-pressure O_2 port and low-pressure O_2 port.

◆ The external gas supply of high pressure connects to the device with the high-pressure O_2 port. This supply can be from a medical gas supply system or oxygen cylinder. When the ventilator is used in road ambulance, the gas supply may be but not limited to the following types: gas in cylinders; Cryogenic Oxygen in cylinder stationary vessels.

The nominal high-pressure O_2 inlet pressure is 280~600kPa. When gas supply pressure is less than 280kPa, the ventilator performance will be affected, even the ventilation will be stopped. When gas supply pressure is up to 1000kPa, the ventilator performance will be affected, but no safety hazard caused to patients. Connecting steps of high-pressure O_2 are as follows:

1) Before connecting the gas supply pipe, check whether the seal ring at the joints is 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 left of the ventilator.
3) Ensure a correct connection between gas supply 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. This gas supply may be from an oxygen bag or oxygen concentrator source.

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 clicking sound when the gas supply hose is installed in place. Before removing it, press

the metal clip on the low pressure-O_2 port, and pull the gas supply hose out.

3.6 Breathing Tube Installation

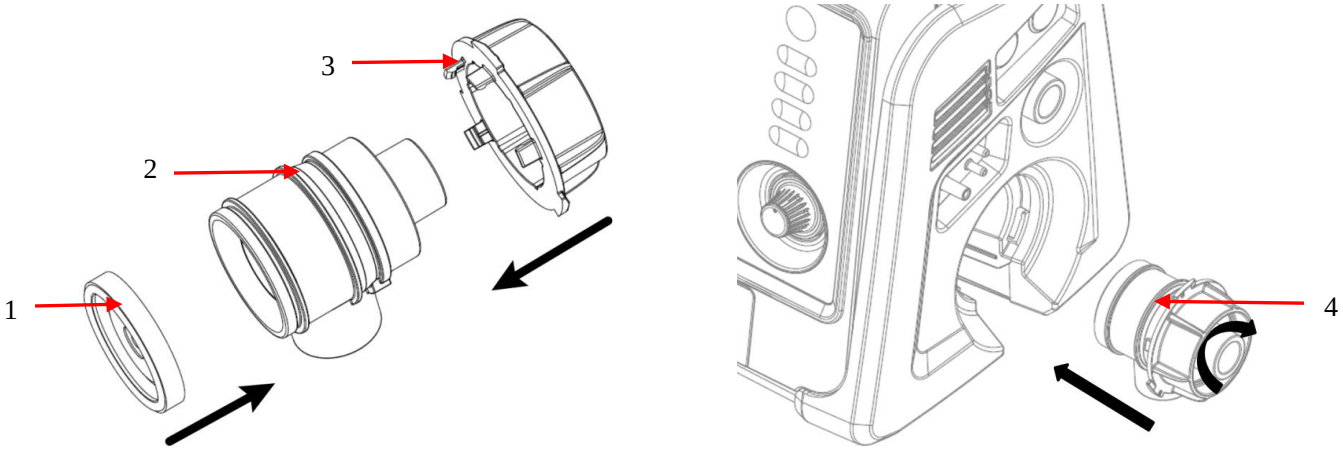
⚠ WARNING

- **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.**
- **Make sure the HEPA filter is installed. Removal of HEPA may cause contamination to the breathing gas.**

⚠ 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/HMEF) should conform to the requirements of ISO9360-1 and ISO9360-2.**

3.6.1 Expiratory Valve Installation



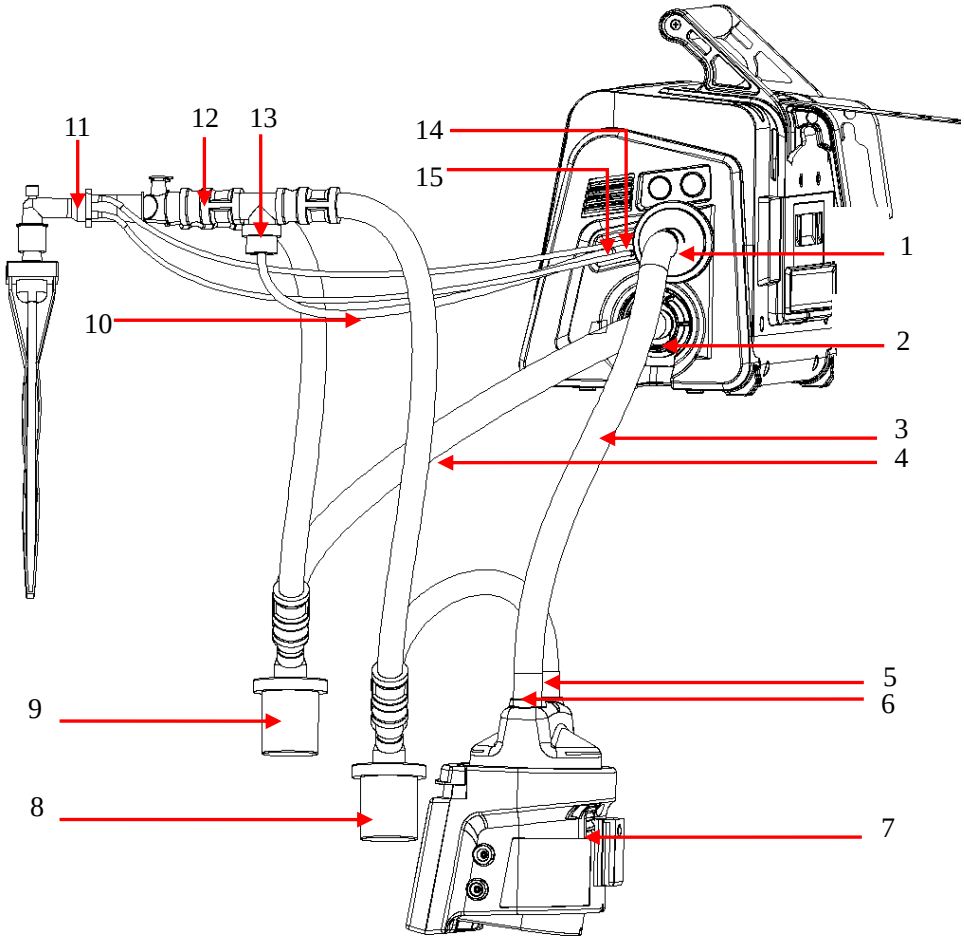
1. Expiratory valve diaphragm
2. Expiratory valve core
3. Expiratory valve knob
4. Detachable assembly of expiratory valve

Installation steps:

1) As shown in the figure, install expiratory valve diaphragm, the expiratory valve core and the expiratory valve knob into the detachable assembly of expiratory valve.
2) Align the detachable assembly of expiratory valve at the breathing tube port on the right side of the ventilator, and turn the expiratory valve knob clockwise and fix it.

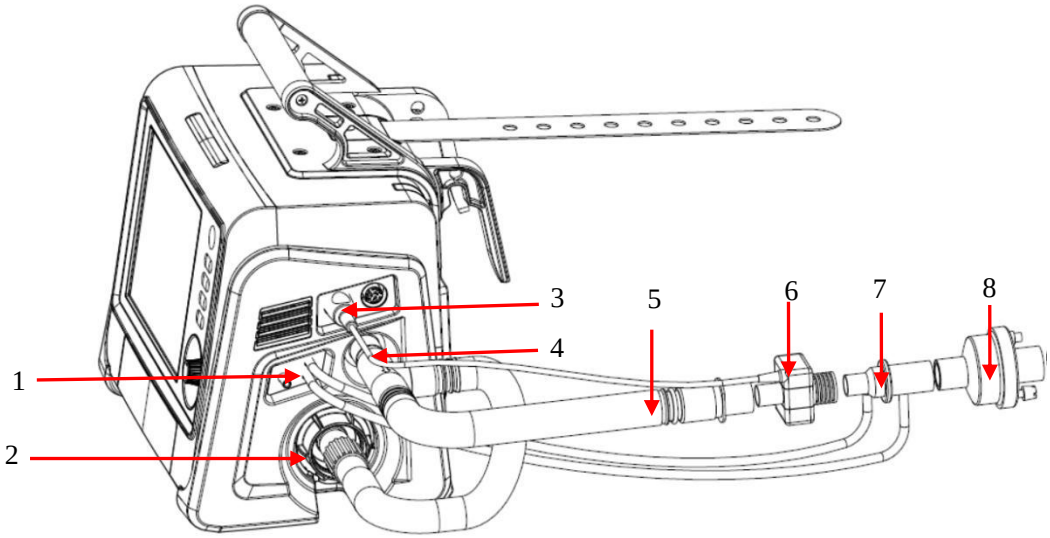
3.6.2 Breathing Tube Connection

1. For adults/pediatric patients: dual limb with humidifier



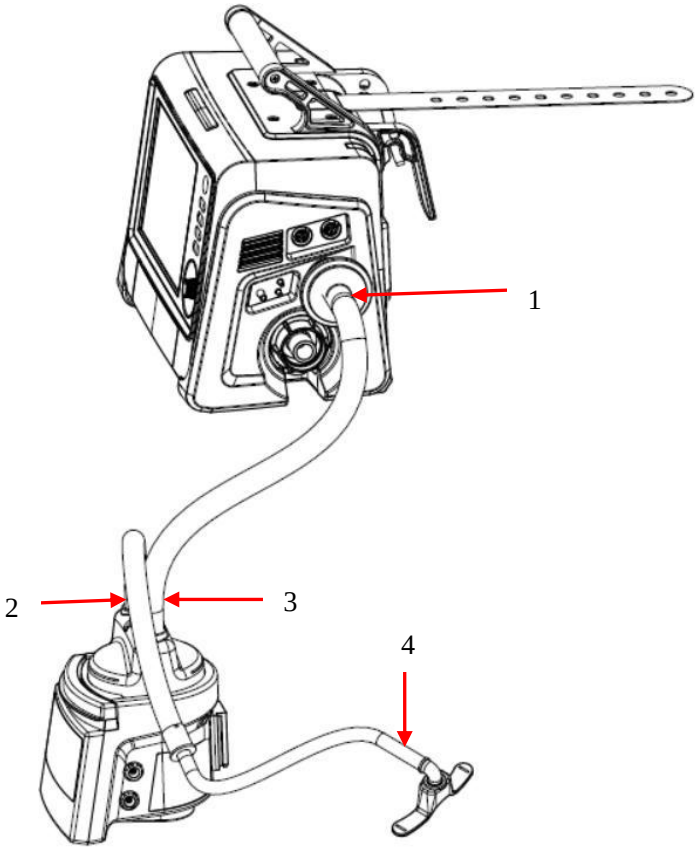
1. Inspiratory port
2. Expiratory port
3. Inspiratory limb
4. Expiratory limb
5. The humidifier outlet
6. The humidifier inlet
7. Humidifier
8. Inspiratory water trap
9. Expiratory water trap
10. Nebulizer intake pipe
11. Flow sensor
12. Y-piece
13. Nebulizer
14. Flow sensor port
15. Nebulizer port

2. For adults/pediatric patients: coaxial with HMEF



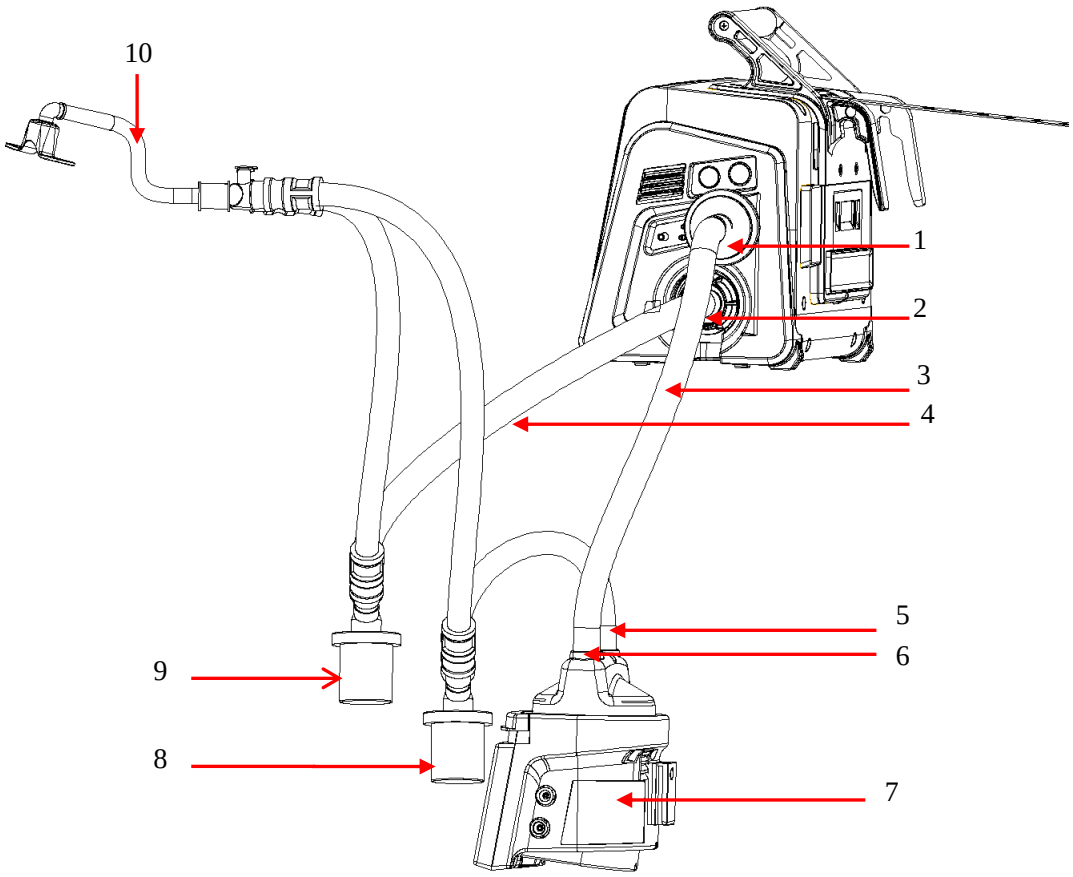
1.Flow sensor port
2.Expiratory port
3.CO_2 sensor port
4.Inspiratory port
5.Coaxial inspiratory/expiratory limb
6.CO_2 sensor/adaptor
7.Flow sensor
8.HMEF

3. For adults/pediatric patients: single limb in high flow oxygen therapy.



1.Inspiratory port
2.The humidifier outlet
3.The humidifier inlet
4.Nasal cannula

4. Dual limbs in high flow oxygen therapy



1.Inspiratory port
2.Expiratory port
3. Inspiratory limb
4. Expiratory limb
5. The humidifier outlet
6.The humidifier inlet
7. Humidifier
8. Inspiratory water trap
9. Expiratory water trap
10. Nasal cannula

NOTE

- **Adult patients should only be ventilated with Pediatric/Adult circuits. Infant patients should only be ventilated with Infant/Pediatric circuits. Refer to "*Appendix II*" for applicable breathing tubes intended tidal volume.**
- **When the operator admits one new patient based on the ideal body weight, do select the correct ventilator circuit for the patient group and pay more attention to young adults and pediatric patients. If necessary, always correct TV for the intended delivered minute ventilation.**

3.7 Humidifier Installation

WARNING

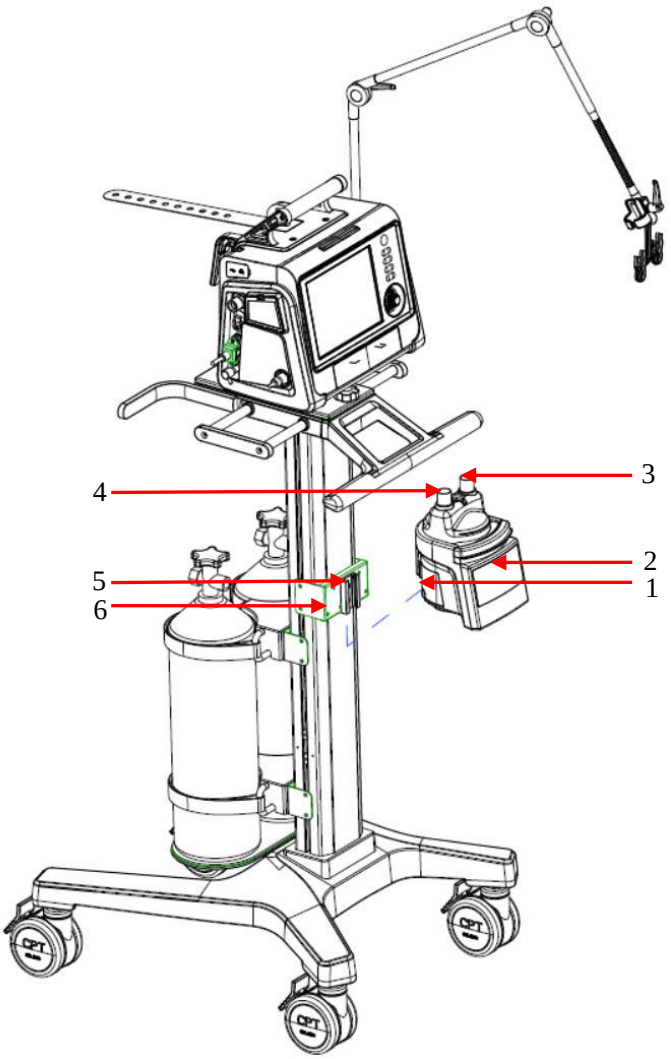
- **To avoid patient injury and equipment damage, don't turn on the humidifier until the ventilator is calibrated and ventilated.**
- **To avoid patient injury and equipment damage, ensure that the humidifier is set to a proper**

temperature and humidity.

- **The proximal flow sensor of the ventilator and the internal TSI flow sensor are sensitive to the direction of airflow and need to be installed correctly.**

⚠ 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.**
- **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.**



1. Humidifier pulley 2. Humidifier 3.The humidifier inlet
4. The humidifier outlet 5.Screw 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 trap via the pipe, and connect the water trap to the Y-joint via

the pipe.

6) Connect the filter of expiratory limb to the water trap via the pipe, and connect the water trapto the Y-joint via the pipe.

7) Put the breathing tube on the tube hook of the supporting arm.

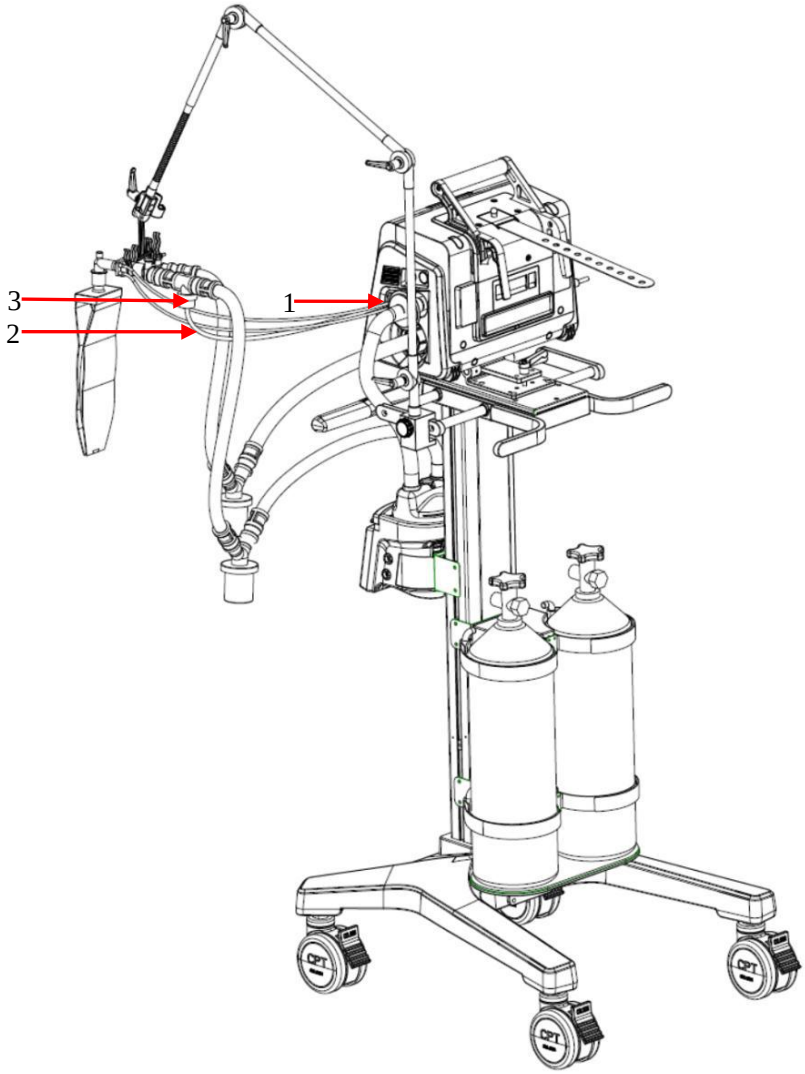
3.8 Nebulizer Installation

⚠ WARNING

- **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 not use the expiratory filter or the heat and moisture exchanger (HME) in the the patient circuit. Nebulization will cause filter blockage at the expiratory side, greatly increase the air resistance and impede ventilation.**
- **Please connect the 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

- **The pneumatic nebulizer kit connected should conform to the requirements of ISO 27427/EN 13544-1, with CE approved.**
- **Before connecting a pneumatic nebulizer with V1/V1A, the user should ensure that the flow rate meets the requirements of nebulizer when the pneumatic nebulizer connected with V1/V1A.**
- **Please install 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.**



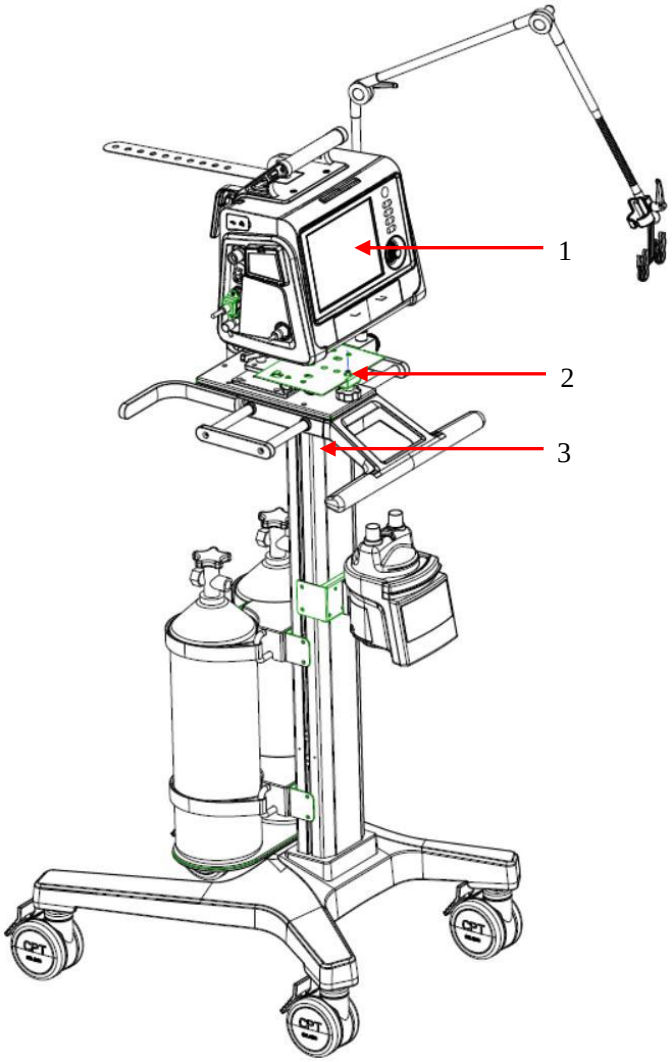
1.Nebulizer port 2.Nebulizer tube 3.Nebulizer

1) Install one end of the nebulizer tube 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 tube.

3.9 Trolley for Intrahospital Transport

WARNING

- **To prevent personal injury and device damage, make sure the ventilator is properly mounted on the trolley.**
- **To prevent tilting of the trolley and damage to the device:**
  - **Lock the trolley wheels when parking the ventilator.**
  - **Be careful when you cross thresholds.**
- **The ventilator must be fastened to the trolley with locking bolts, make sure the device is fixed tightly before use.**
- **The trolley supports the ventilator to be transported between hospital rooms and departments, between hospital and / or other sites.**
- **The required atmospheric pressure of trolley during transportation is 50.0kpa-110.0kpa.**



1. Main unit 2. Screw 3. Trolley

Put the main unit on the trolley, then align the fasteners and push backward, then tighten the screws.

If you want to remove the main unit from the trolley, please unscrew it first, then pull it out with both hands

and lift it up.

If a trolley is to be used for in-hospital transport, the ventilator, components and trolley must be configured and adjusted according to the following requirements:

- The ventilator must be firmly mounted on the trolley.
- The oxygen cylinder must be firmly mounted on the trolley.
- During the transfer, only the following components are allowed to be connected: breathing circuit, flow sensor, CO_2 sensor, SpO_2 sensor, oxygen cylinder

NOTE

- **The above requirements only apply to the ventilator transport installed on a trolley. They do not apply to other installation methods.**

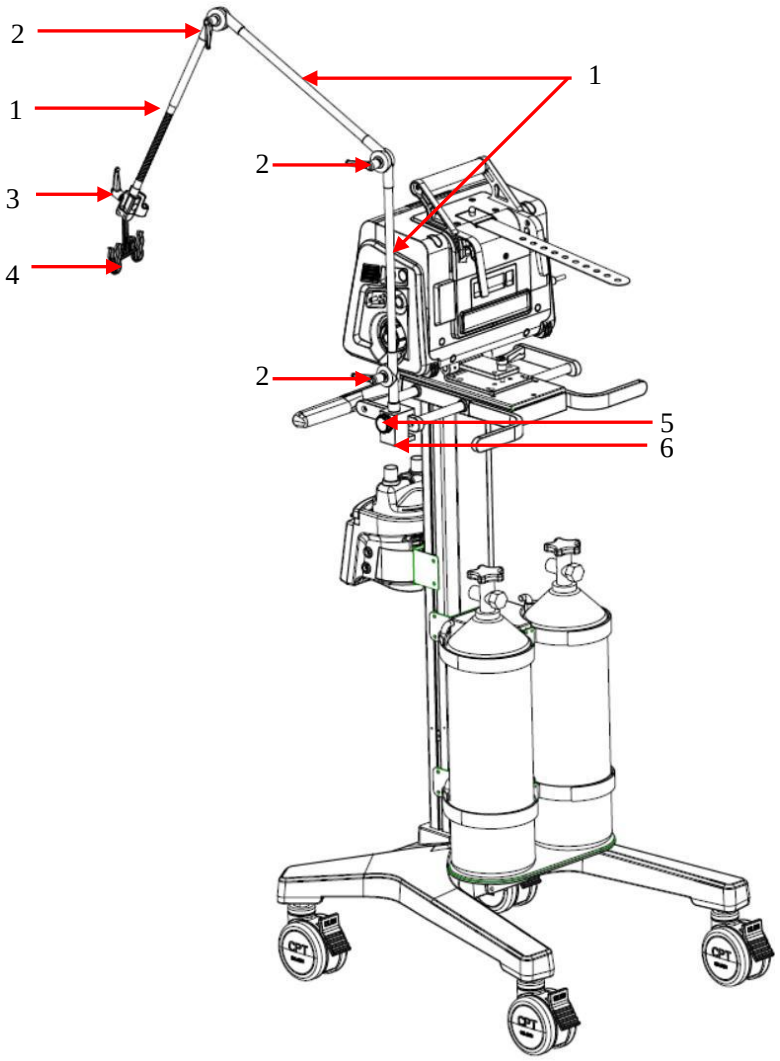
3.10 Supporting Arm Installation

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 2.5 kg.**
- **The supporting arm can be installed on the rail on the left or right side of the ventilator.**



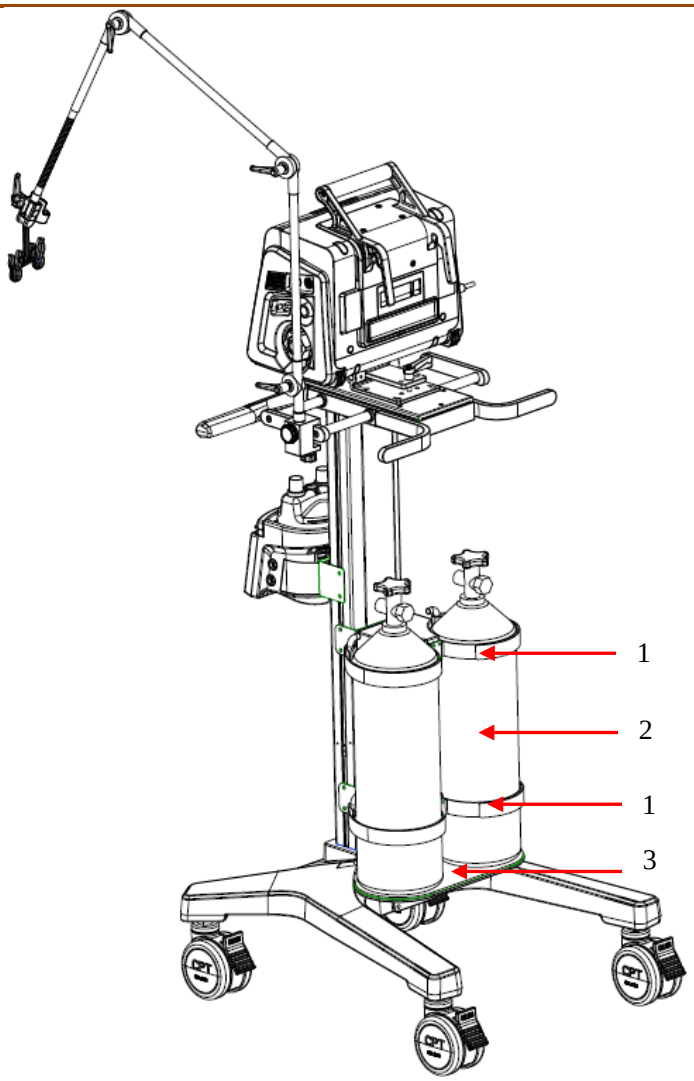
1. Supporting arm 2. Locking handle 3. Locking handle of tube hook
4. Tube hook 5.Fixing block 6. Fixing block knob

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

3.11 Spare Cylinder Installation

CAUTION

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



1. Cylinder fixing buckle 2. Cylinder 3. Chassis of the trolley

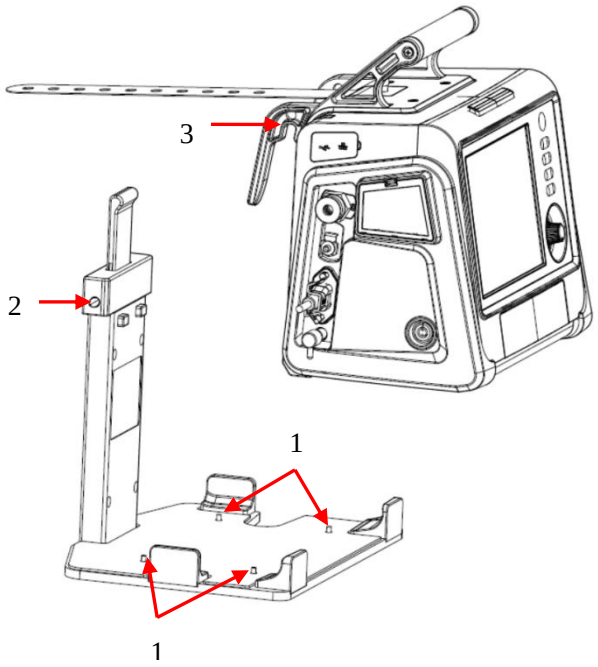
1) Put the spare cylinder on the chassis of the trolley.
2) Use the cylinder fixing buckle to fix the spare cylinder.

3.12 Installing the Ventilator on the Road Ambulance

NOTE

- **When the ventilator is installed on an ambulance, if the sidestream CO_2 module is configured, it needs to be tied to the handle of the ventilator fixed on the ambulance platform with straps or tape.**

When the EMS ventilator is intended for emergency situation and/or long-distance planned transport, it shall be properly installed on the vehicle mount on road vehicle, through a fixed base, as shown in the figure below:



1.Screw 2. Bullet needle 3. Hole

1) Lock the four screws on the fixed base bracket into the nuts on the four-foot pads at the bottom of the ventilator.
2) Clip the bullet into the hole in the handle of the device.

Remove the ventilator from the fixed base:

1) Remove the four screws that connect the ventilator to the fixed base.
2) Press the handle of the bracket and take the ventilator out of the fixed base.

Chapter 4 Test and Calibration

⚠ WARNING

- **Before connecting the patient to the ventilator, it is important to perform a complete pre-operation inspection to ensure that the breathing circuit is properly attached and appropriate for the patient, and the primary patient safety alarms are functioning properly.**
- **If the ventilator does not pass any test, it should not be continued for clinical use. The ventilator should be used only after the necessary repairs have been completed and all tests have been passed.**

4.1 Overview

The test and calibration information illustrated in this section is helpful to verify the safety and reliability of the ventilator, if the test failed, please troubleshoot the ventilator and repair the ventilator according to the instructions, make sure the ventilator passes the test before returning to the clinic use.

The situations where testing and calibration are required are as follows:

When to perform	Test or calibration
Before applying to a new patient on a ventilator	Pre-operation inspection
After installing new/disinfected breathing tubes or components (including flow sensors or pressure monitoring tubes).	System check, flow sensor calibration and circuit test
After a new O_2 sensor is installed or when there is a relevant alarm generating	O_2% calibration
Must be performed when installing a new CO_2 sensor or when there is a relevant alarm generating, and it is suggested to perform the operation after switching to different types of airway ports	CO_2 sensor/port calibration

4.2 Check Before Operation

⚠ CAUTION

- **To prevent injury to the patient, disconnect the patient from the ventilator before running this test, make sure other ventilation support is available**

Checking process：

To operate or observe	To confirm
1. Connect the ventilator to an AC or DC power supply and O_2 supply. Assemble the patient's breathing circuit.	The patient's breathing circuit has been properly assembled.
2. Turn on the power.	During power on self-test, the red and yellow alarm lights flashes in turn, and the buzzer sounds.
3. Make Sure the ventilator is in Standby mode, select the [**System Check**] key to enter the system check interface, and perform system check.	Every system check is passed.
4. Make sure that the ventilator is in Standby mode, then select the [**Circuit Test**] key on the Standby interface to enter the interface and perform circuit test.	Each circuit test is passed. If the system check has been passed, there is no need to perform a circuit test.
5. Run O_2 sensor calibration if required.	The calibration is passed.
6. Generate an alarm	Display corresponding alarm information in the information column. See ***"Chapter 7.10 Turning off Alarm at Extreme Limits"*** for details.
7. Resolve the alarm status	Alarm has been reset.

4.3 System Check

WARNING

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

CAUTION

- **Always run the self check 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 check, 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 check interface:

- In a non-standby interface, select the ⊙/Ó key and then confirm to enter the Standby interface. In the Standby interface, select the [**System Check**] key to enter the system check interface.

The system check interface displays the total system check results, time and detailed information of last system self check, including each test item and the corresponding result.

Connect the Gas Supply according to the prompt to close the Y-shaped tube and then select the [**Continue**] key. The system will start the self check 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 flow sensor in the inspiratory limb.
- Pressure sensor test: test the pressure sensors at the inspiratory end and expiratory end.
- Expiratory valve test
- Safety valve test
- Leakage (ml/min)
- Compliance (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 pass 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.

After the completion of all the items, the total self-check results are as follows:

- Passed: all the test items have been completed and passed the self check.
- Partially Passed: some test items are not passed but the mechanical ventilation is allowed.
- Mechanical Ventilation Disabled: some test items are not passed and the mechanical ventilation is not allowed.
- Large Leakage, Mechanical Ventilation Disabled. Failed: the tests of pressure sensor, Exp. valve and safety valve are all failed and the mechanical ventilation is not allowed.
- Cancelled: some self check items are cancelled but others are passed successfully.

During self check, the system prompts [**Testing**] to the right of the current self check item.

When the user selects the [**Skip**] key to stop running this test item, with the self check result displayed as [**Cancelled**]. The next self check item starts at the same time.

When the user selects the [**Stop**] key, the system immediately stops running the current and all remaining test items, with the corresponding self check results displayed as [**Cancelled**].

When the O_2 sensor test fails, the [**O_2 Calibration**] key is displayed. Press it to open the menu for performing O_2 concentration calibration.

When the result of system self check is [**Mechanical Ventilation Disabled. Failed**] or [**Big Leakage. Ventilation Disabled. Failed**], the [**Factory Maintainance**] key is displayed. Touch the key and input the password to enter the factory maintainance interface, in which the reason for system check failure can be found.

After all self check items are completed and the results are [**Passed**], you can select the [**Retry**] key to run the self check procedure again.

Select the [**Standby**] key to exit the self check mode and enter the Standby interface.

4.4 Circuit Test

WARNING

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

CAUTION

- **Before performing the circuit test, disconnect the patient from the device and ensure that there is an alternative means of ventilation to support the patient ventilation.**

NOTE

- **If the system self check has been passed, there is no need to perform a circuit test.**

The path to the circuit test interface:

In a non-standby interface, select the ⊙/Ò key and then confirm to enter the Standby interface. In the Standby interface, select the [**Circuit Test**] key to enter the circuit test interface.

The circuit test interface displays the last test time, the total test results and the last system test information, including each test item and the corresponding result.

Connect the Gas Supply according to the prompt to close the Y-shaped tube and then select the [**Continue**] key. The system will start the circuit test procedure item by item.

The test items include:

- Leakage (ml/min)
- Compliance (ml/cmH_2O)
- Circuit resistance (cmH_2O/(l/s))

The test results include:

- Passed: the test item has been completed and passed.
- Failed: the test item has been completed but not passed.
- Cancelled: the test item has been cancelled.

After the completion of all the items, the total circuit test results are as follows:

- Passed: all the test items have been completed and passed.
- Partially Passed: some test items are not passed.
- Failed: all the test items have been completed but not passed.
- Cancelled: some items are cancelled but others are passed successfully.

During the circuit test, the system prompts [**Testing**] on the right of the current circuit test item.

When the user selects the [**Skip**] key to stop running this test item, with the circuit test result displayed as [**Cancelled**]. The next circuit test item will start at the same time.

When the user selects the [**Stop**] key, the system immediately stops running the current and all remaining test items, with the corresponding circuit test results displayed as [**Cancelled**].

After all circuit test items are completed; you can select the [**Retry**] key to run the circuit test again.

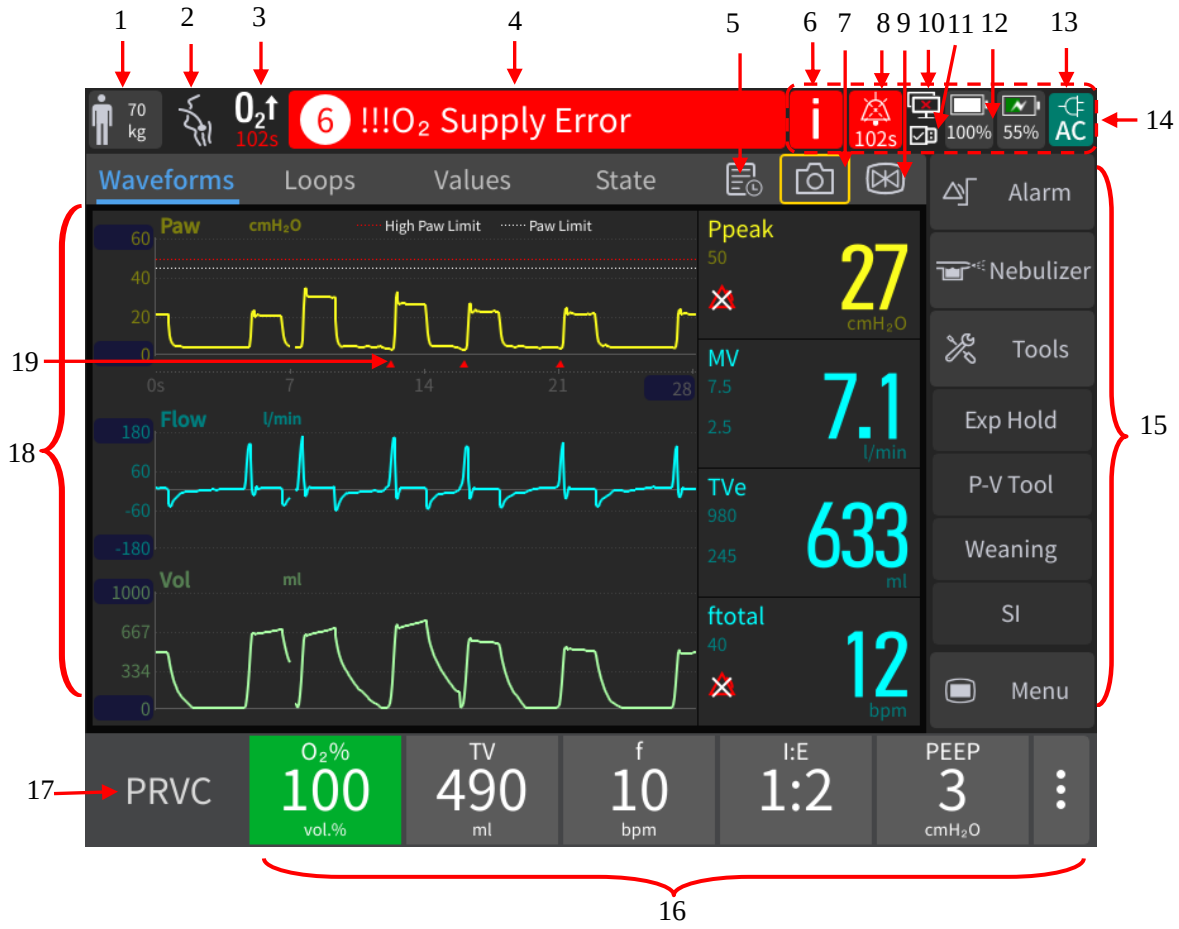
Select the [**Standby**] key to exit the circuit test mode and enter the Standby interface.

Chapter 5 Interface

5.1 Main Interface

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

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



1. Patient type/Inspiratory trigger prompt area
   - The current Patient type (Adult, Pediatric Patient or Infant) is prompted. Inspiratory trigger icon is  .The icon prompts for 1s.
2. Ventilation type prompt area

   Invasive or non-invasive ventilation type is displayed:
   - When performing non-invasive ventilation, the non-invasive mask icon  is displayed.
   - When performing invasive ventilation, the invasive mask icon  is displayed.
3. Oxygen enrichment/Sputum suction prompt area
   - When the [O_2 Enrichment/Suction] key  is pressed, the O_2 enrichment icon and countdown will be displayed.
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 touch this alarm prompt area, you can view the current alarm message, the alarm occurrence time, alarm durations and priority.

5. History data prompt area
   Select the [**History**] key on the screen to view the history data in the opened interface. In the interface, [**Table**] (Tabular Trends), [**Graph**] (Graphic Trends), [**Settings**] and [**Event Log**] can be viewed.
6. Inactive alarm prompt area
   When the icon  is displayed, it indicates that there are most recent alarms but the alarm conditions disappear. Touch this icon, and you can view the most recent alarms (up to 10 alarm messages are displayed) on the accessed window. You can also clear the most recent inactive alarms with the [**Reset**] key.
7. Screenshot icon area
   - Select the icon, capture the screen and save it as a picture.
8. Alarm audio paused prompt area
   - When the countdown icon  for 120-second alarm audio pause is displayed, it indicates at least one existing alarm and the alarm audio is paused.
9. Freeze icon area
   - Select the icon, enter the frozen state, the system temporarily suspends the real-time refresh of waveforms and spirometry loop data on the screen, and the short-term patient data can be reviewed.
10. Network connection icon
    - When the wired network function is turned on and the wired network is available: the icon of wired network available  is displayed;
    - When the wired network function is turned on and the wired network is unavailable: the icon of wired network unavailable  is displayed;
11. USB icon area
    - When the system is connected to a recognizable USB device, the USB connection success icon  is displayed; when the system is not connected to a USB device, the USB icon is not displayed.
12. Battery state icon area
13. The state icon area of external power supply
    The state of the external power supply currently connected to the system is displayed:
    - When only AC power supply is connected, the AC icon  is displayed.
    - When only DC power supply is connected, the DC icon  is displayed.
    - When AC and DC power supplies are connected at the same time, the AC icon  is displayed.
    - When the external power supply is not connected, the external power connection icon is not displayed and the gray background color switches to the battery icon area on the left.
14. Prompt message area
    - Current prompt message is displayed.
15. Function keys area
    - Display Alarm, Nebulizer Tools, menu keys and so on.
16. Parameter setting keys area
    - Ventilation parameter settings corresponding to the ventilation mode are displayed.
17. Ventilation mode setting area
    - Keys for ventilation mode setting is displayed.
18. Waveforms/Loops/Values/State area

- Display waveforms, Loops, Values and State Diagram.

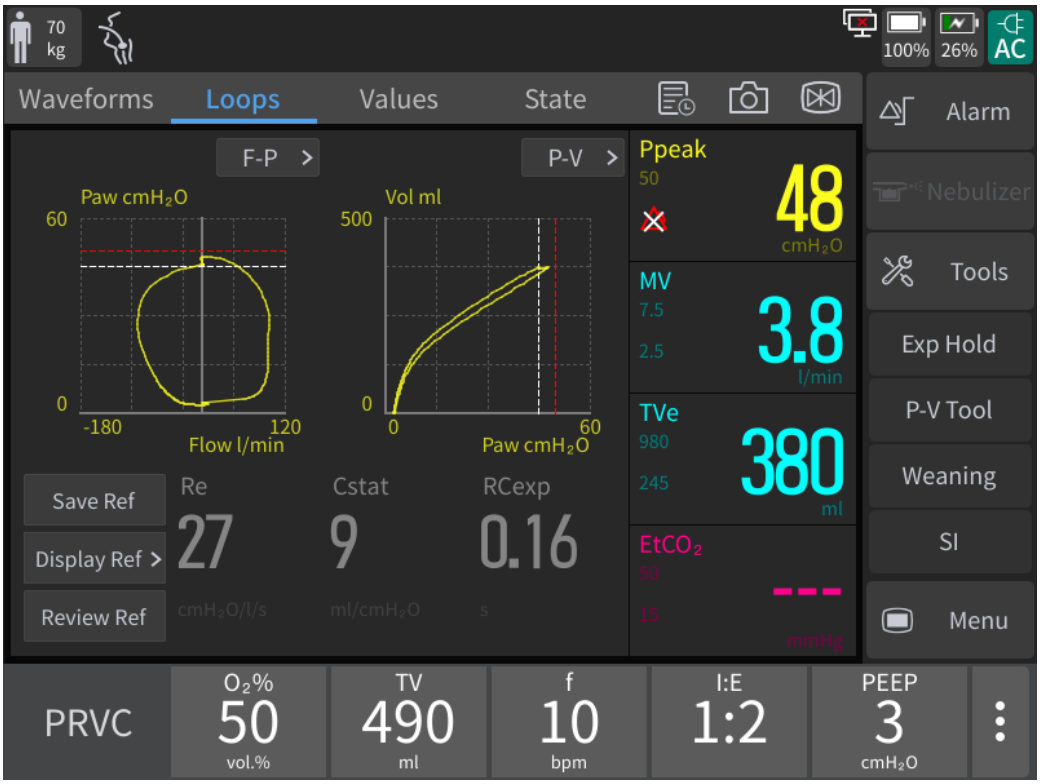
19. Spontaneous inspiration trigger icon
    - When the patient triggers spontaneous inspiration, the icon is displayed.

5.2 Waveform Interface

Select the [**Waveforms**] key on the screen to enter the interface as shown in the picture of ***"Section 5.1 Main Interface"***.

5.3 Loop Interface

Select the [**Loops**] (Spirometry loop) key on the screen to enter the interface as shown in the figure below.



Spirometry loops can reflect the patient's pulmonary function and ventilation, including the pulmonary compliance, over-inflation, leakage in the respiratory system and occlusion in the airway. It has a crucial clinical significance.

5.3.1 Loop Type Setting

Spirometry loops provided by the system include: [**P-V**] (Pressure-Volume) loop, [**F-V**] (Flow Rate-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-CO_2**] curve will be displayed as shown in the figure below.

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 the [**Loops**] key on the main screen.
2) Set the loops or V-CO_2 curve to be displayed as required.

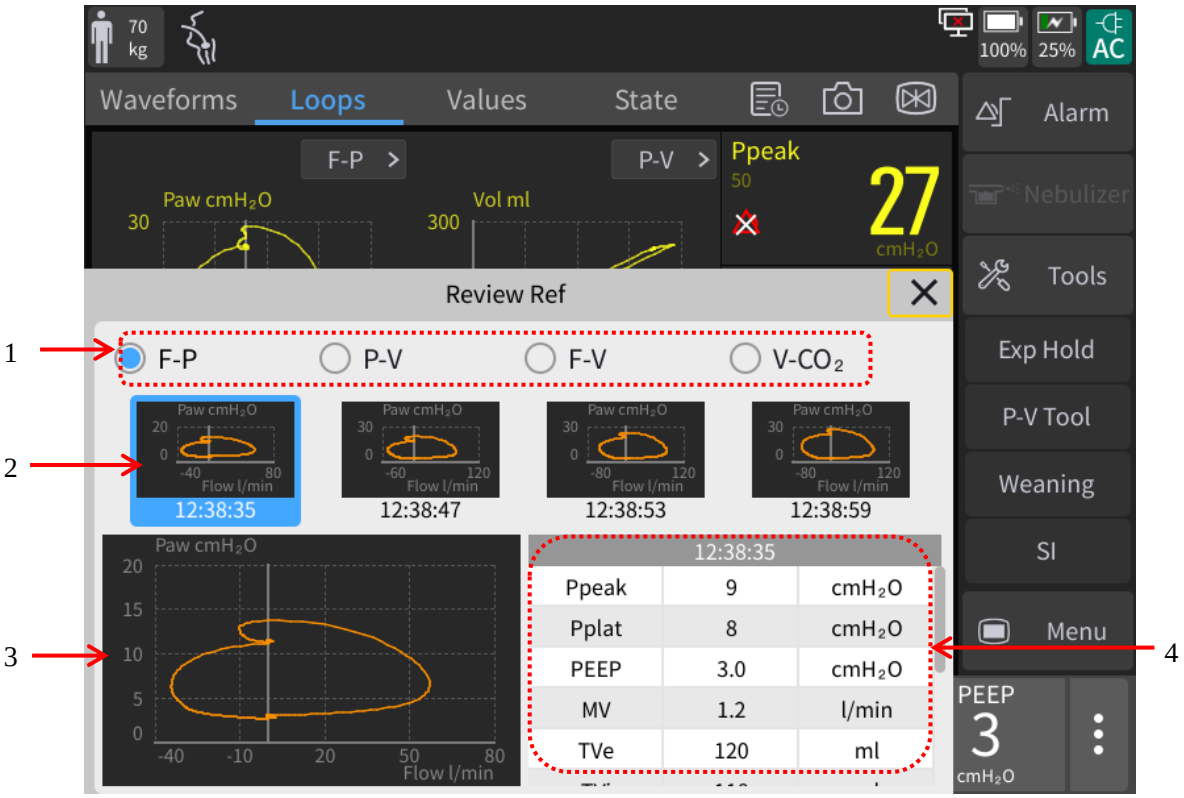
5.3.2 Reference Loop Setting

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

- Select the [**Save Ref**] (Save Reference Loop) key, the loop of current respiratory period can be saved as reference loop, and the saving time will be displayed.
- Select the [**Display Ref**] (Display Reference Loop) key, and select certain time, then the reference loop saved in that time can be viewed.
- Select the [**Display Ref**] (Display Reference Loop) key, and select the [**Close**] key, then the reference loop being displayed can be hidden.
- Select the [**Review Ref**] (Review Reference Loop) key to enter the Loop Review interface.

Up to 10 reference loops can be saved in the ventilator. When 10 reference loops have been saved, selecting the [**Save Loop**] key again will clear the oldest reference loop in memory to save the loop for the current respiratory period.

5.3.3 Reference Loop Review Interface

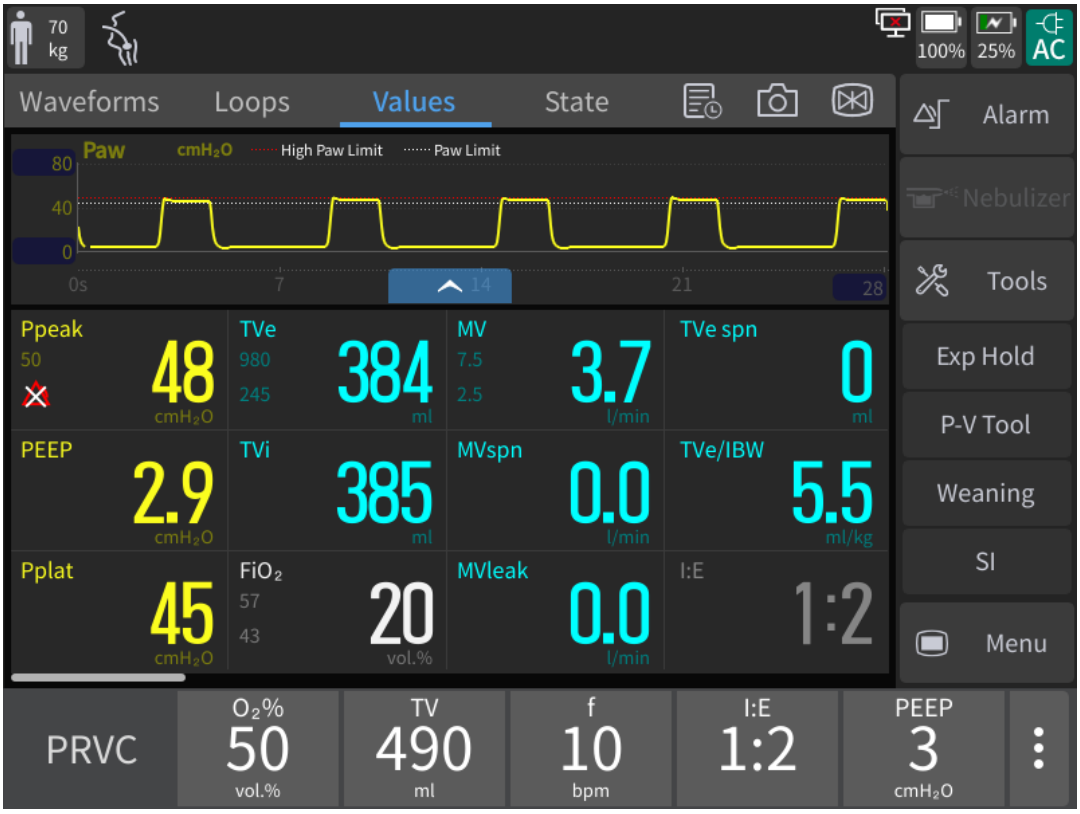


1. Loop type
2. Small loop window
3. Big loop window
4. Parameter data area

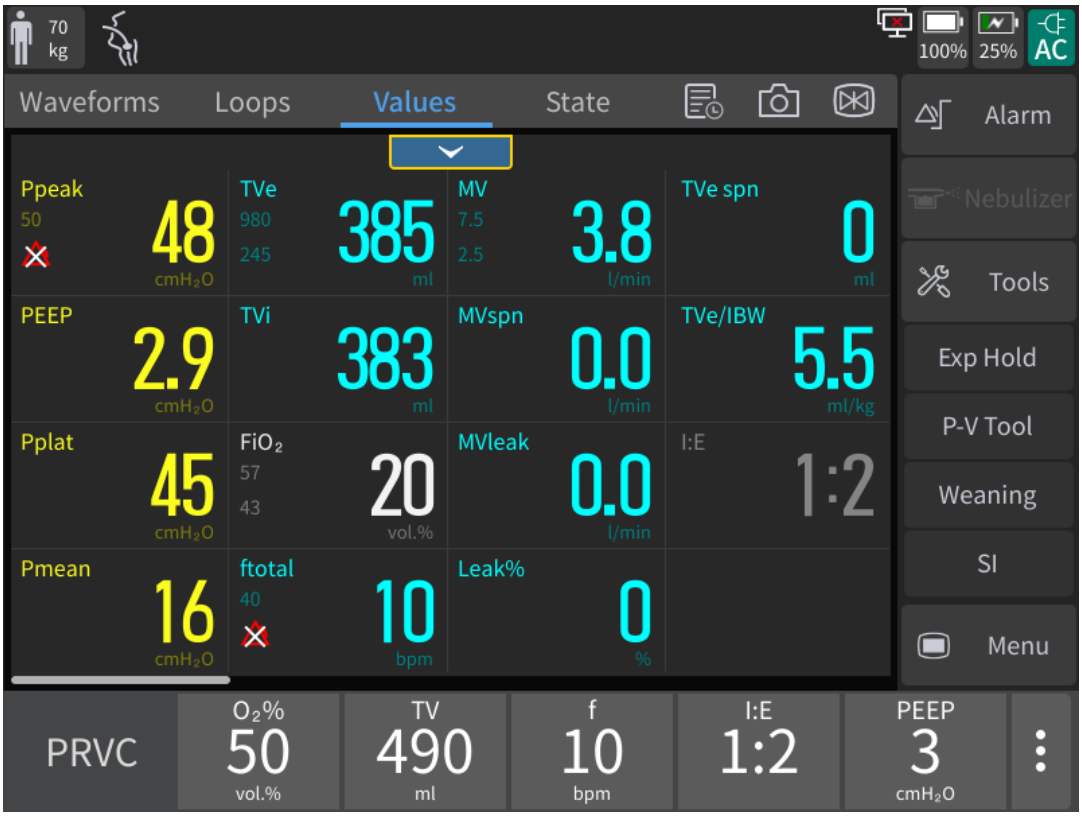
- Loop type: used to select the loop type to be reviewed, including P-V, F-V, F-P and V-CO_2. P-V is selected by default.
- Small loop window: these small graphic windows displays reference loop. Reference loops (4 at maximum) are displayed from the earliest (left) to the latest (right). Information on the selected reference loop will be highlighted in blue.
- Big loop window: the graphic window displays the enlarged view of the selected reference loop.
- Parameter data area: monitoring parameter data related to the reference loop saved is displayed.

5.4 Monitoring Values Interface

Select the [**Values**] key on the screen, and enter the interface as shown in the figure below.

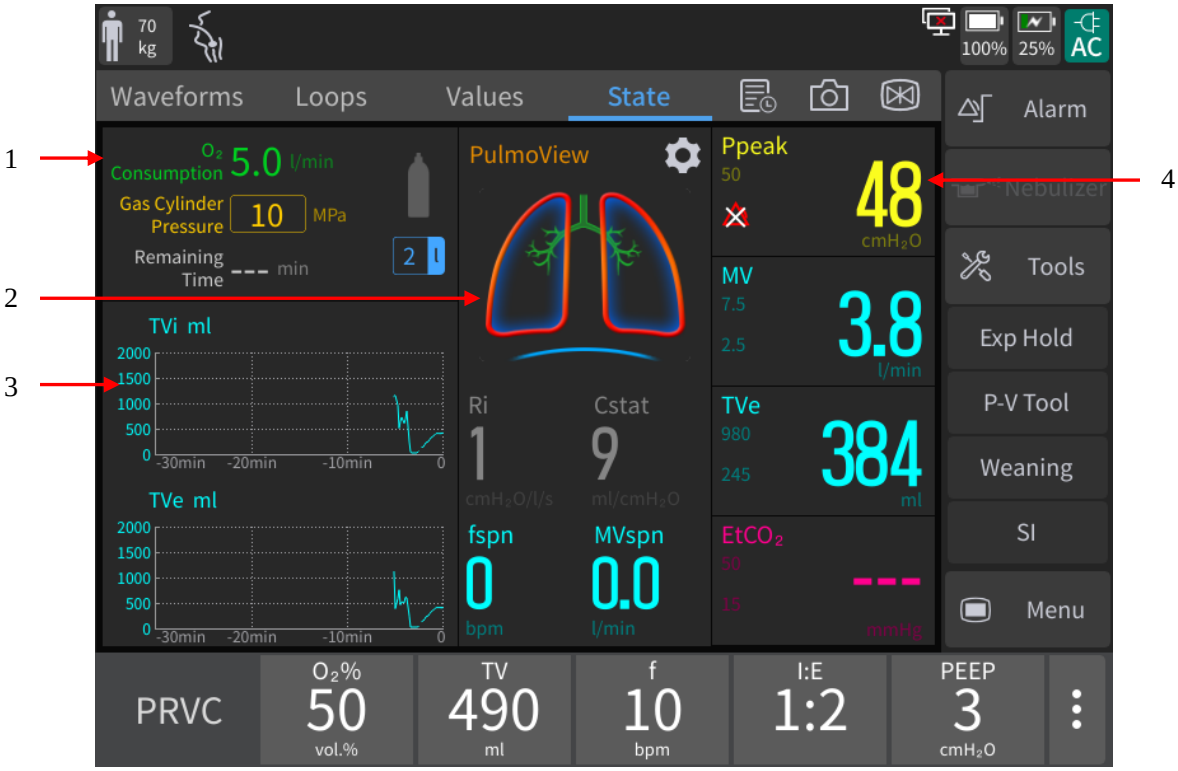


Select the  key on the screen, and enter the interface as shown in the figure below.



5.5 State Figure

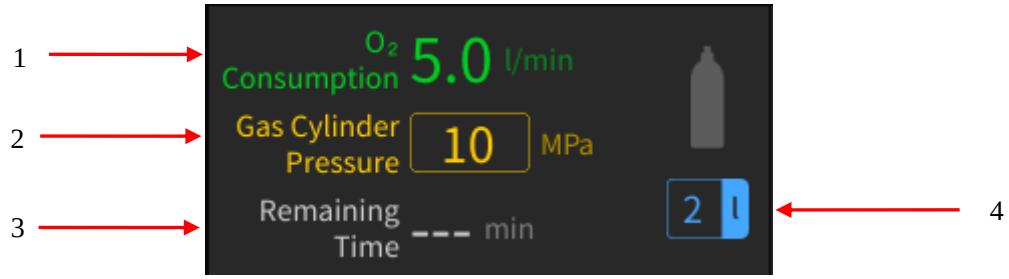
Select the [**State**] (State Graph) key on the screen to open the interface as shown in the following figure:



1. Oxygen consumption calculator 2. PulmoView
3. Short-time graphic trend 4. Monitoring values

5.5.1 Oxygen Consumption Calculator

The oxygen consumption calculator area displays the current oxygen consumption and the estimated time available for the remaining oxygen. The cylinder volume and pressure can be set as shown below:



1. Oxygen consumption 2. Cylinder pressure set by the user
3. The estimated time available for the remaining oxygen 4. Cylinder volume set by the user

5.5.2 Short-time Graphic Trend

The short-time graphic trend is applied to record the monitoring parameter value changes at the corresponding time. It uses a curve to describe the parameter measurement result changes. Each point on the line corresponds to a monitoring parameter value at each time. The monitoring parameter values in up to 30 minutes can be displayed in the short-time graphic trend.

Select the parameter name area of the short-time graphic trend and set the monitored parameters to be

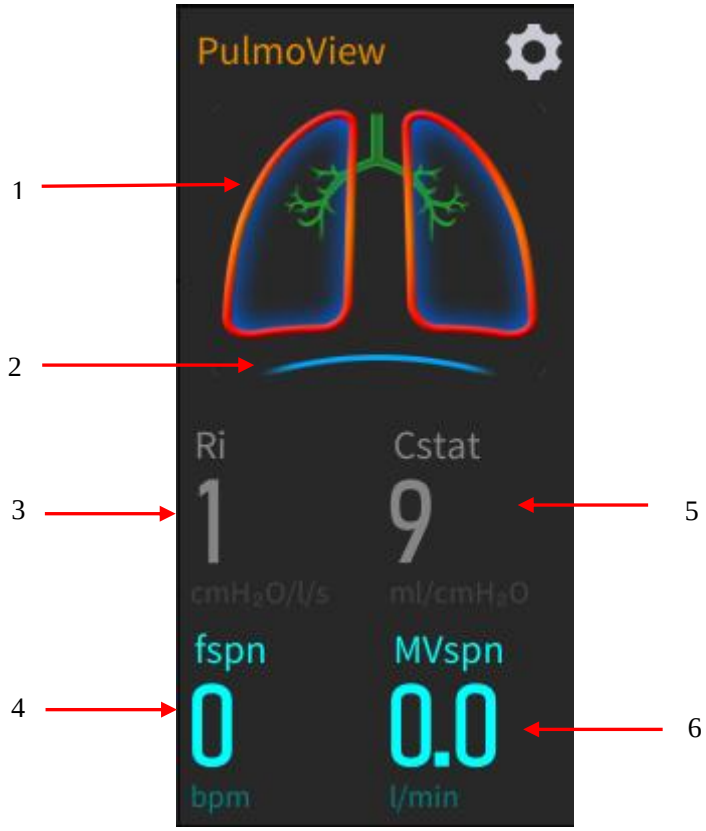
displayed in the setting interface. The cursor position can be adjusted by selecting the trend area or turning the rotary knob after selecting the trend area.

5.5.3 PulmoView Setting

The PulmoView 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:

- When the compliance is too large, the alveolar outline becomes thinner;
- When the compliance is too small, the alveolar outline becomes thicker;
- When the resistance is too large, the lines representing bronchial branches become thicker;
- When the ventilation volume is too much, the dotted line is within the alveolar outline;
- When the ventilation volume is too small, and the dotted line is outside the alveolar outline;

The PulmoView display is as follows:



1. Normal lung
2. Patient trigger (Diaphragm)
3. Resistance (Inspiration Resistance)
4. Spontaneous Frequency
5. Compliance (Static Compliance)
6. Spontaneous Minute Volume

Select the  key, set the [**Compliance Benchmark**] and [**Resistance Benchmark**] key respectively in the menu. There are three parameter setting methods:

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

5.6 History Data

Select key on the screen to enter the History Data interface. In the interface, [**Table**] (Tabular Trends), [**Graph**] (Graphic Trends), [**Settings**] and [**Event Log**] can be viewed.

5.6.1 Icon Navigation

Key	**Function**
Last event	Select the [**Last Event**] key, the cursor moves to last event from the current event.
Next event	Select the [**Next Event**] key, the cursor moves to next event from the current event.

5.6.2 Graph (Graphic Trends)

Graphic trend is used to review 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. Graphic trend can be used to record the parameter alarm event. If the interval time is not set, trend data will be displayed at an interval of 1 minute by default. The Graphic Trends can be viewed by sliding the interface up and down to select different parameters and sliding left and right to select the parameters of different time.

(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. When an event occurs, the parameters will be marked with different background colors corresponding to relevant event priority.

(3) Event mark. 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 priority. The color corresponding to the highest alarm priority will be used to mark when there are multiple events.

5.6.2.1 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 the parameter record corresponding to the alarm can be founded, then the parameter data will be marked in the color corresponding to the alarm priority.
- Select the [**Last event**] key, the cursor moves to last event from the current event.
- Select the [**Next event**] key, the cursor moves to next event from the current event.

5.6.2.2 Interval

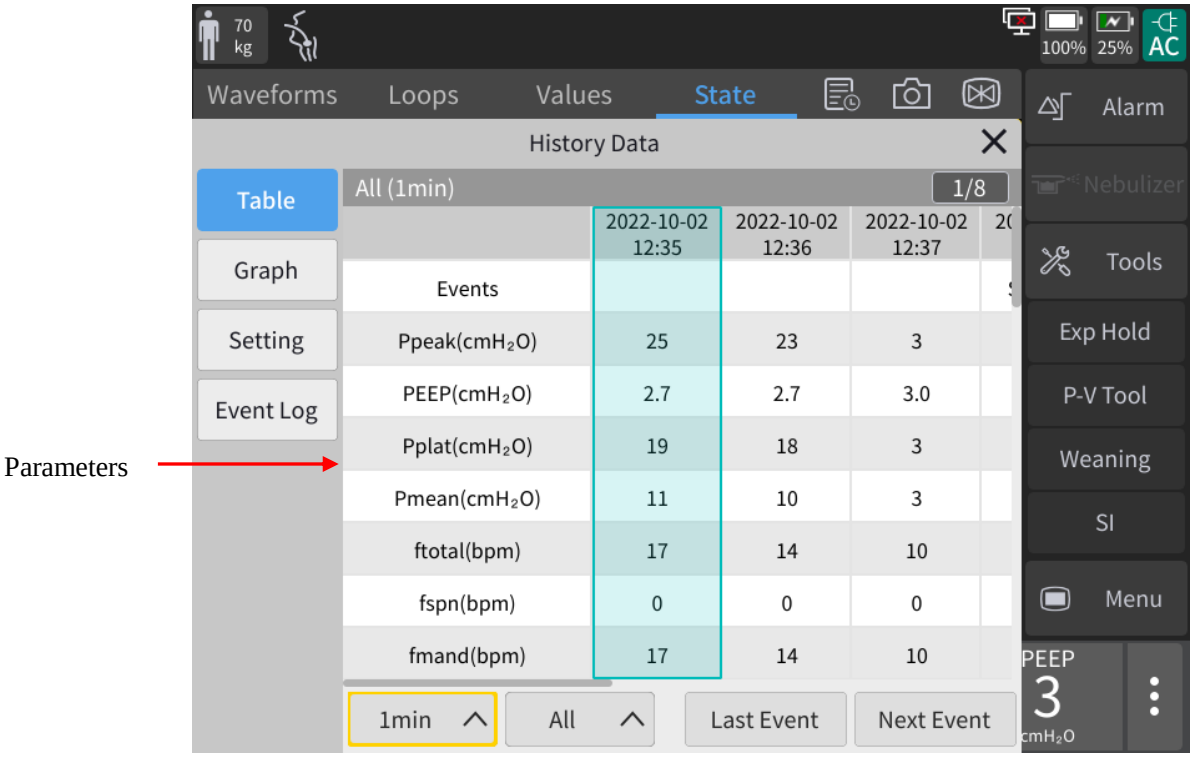
You can set time interval to [**5min**], [**10min**], [**15min**], [**30min**], [**1h**], and [**2h**] in Graphic Trends interface.

5.6.2.3 Group Display

In Graphic Trends interface, you can set group display to [**Pressure**], [**Volume**], [**Time**], [**Gas**], [**SpO$_2$**], [**Other**] and [**All**].

5.6.3 Table (Tabular Trends)

In the [**Table**] (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 tabular trends can be viewed by sliding the interface up and down to select different parameters or sliding left and right to select the parameters at different time.



5.6.3.1 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 on the right.
- 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 priority.
- Select the [**Last Event**] key, the cursor moves to last event from the current event.
- Select the [**Next Event**] key, the cursor moves to next event from the current event.

5.6.3.2 Interval

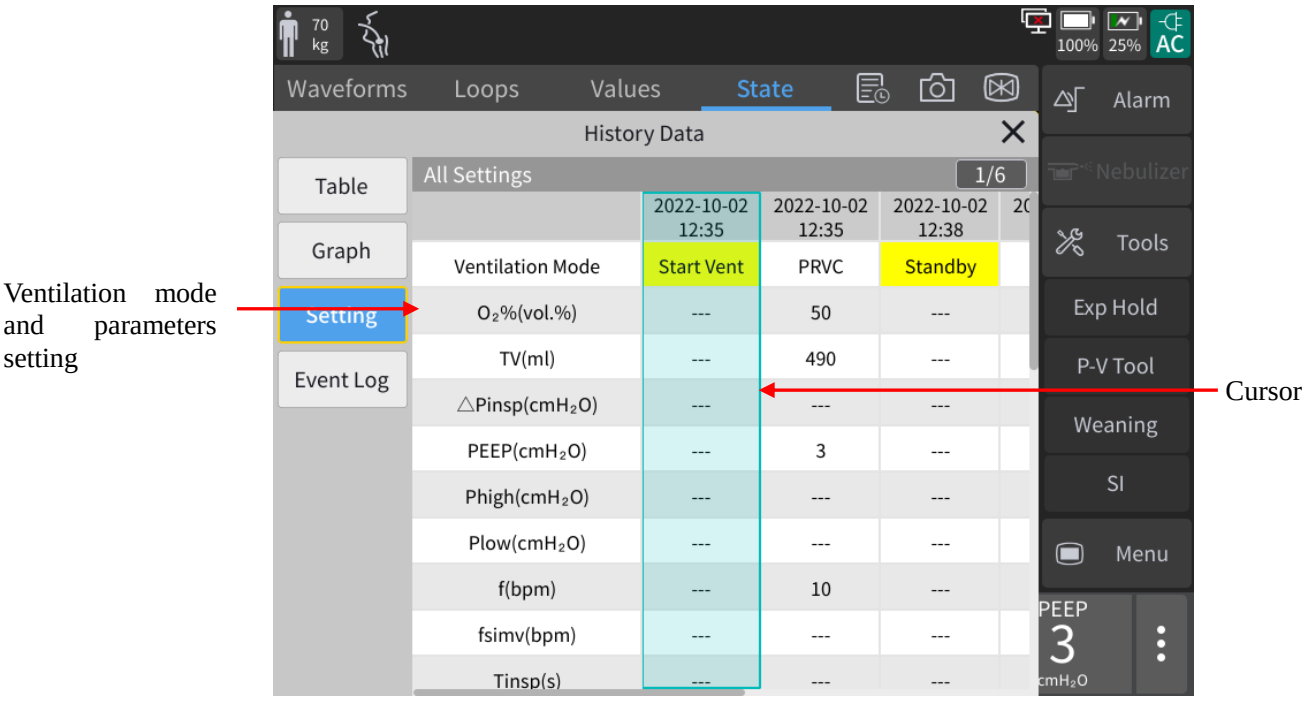
You can set the [**Interval**] to **[1min**], [**5min**], [**10min**], [**15min**], [**30min**], [**1h**] and [**2h**] in [**Table**] (Tabular Trends) interface.

5.6.3.3 Display Group

In the [**Table**] (Tabular Trends) interface, you can set the [**Display Group**] to [**Pressure**], [**Volume**], [**Time**], [**Gas**], [**SpO$_2$**], [**Other**] and [**All**].

5.6.4 Tabular Trends Setting

Tabular Trends Setting is used to record ventilation mode settings and parameter settings. The tabular trends setting can be viewed by sliding the interface up and down to select different parameters or sliding left and right to select parameters at different moments.



5.6.4.1 About Tabular Trends Setting

- The horizontal coordinate of the tabular trends displays date/time.
- The vertical coordinate of the tabular trends displays ventilation modes and setting parameters.
- The latest data of the tabular trends is displayed on the far right.

5.7 Event Log

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, Same Patient, Special Function, Default Values Management, Calibration, SystemCheck, Circuit Test, PulmoView Setting, oxygen therapy event and Alarm Audio Paused Event.

5.7.1 About Event Log

- The latest record is displayed on the top in Event log.
- Up to 5000 records can be stored in the system.
- Select the [**Event Log**] key, the parameters corresponding to the selected events can be viewed.
- Select the [**Last Event**] key, the cursor moves to last event from the current event.
- Select the [**Next Event**] key, the cursor moves to next event from the current event.

NOTE

- **Up to 5000 records (not less than 1000 alarm event) can be stored in the system. When the records exceed 5000, the earliest record will be overwritten by the latest event.**
- **The system will save the logs before the power is cut off normally. When the power is cut off abnormally, ensure that the logs are saved 3s before the power cut.**
- **The time of normally power off is captured in the log, but the time of sudden powering down is not captured in the log.**
- **No matter how long the power loss, the log would be saved.**
- **The contents of the alarm system log cannot be erased or modified by a healthcare professional operator.**

5.7.1.1 Filter

In the [**Event Log**] interface, you can set [**Filter**] to [**High Prio. Alarms**] ("Prio." is the short form of "priority"), [**Med Prio. Alarms**], [**Low Prio. Alarms**], [**All alarms**], [**Operation**] or [**All Events**].

5.8 Freeze

The Freeze function is used to suspend the real-time refresh of waveform and spirometry 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 displayed on the screen 2 minutes before entering the frozen state and the spirometry loop of last breathing cycle.

5.8.1 Entering Frozen Mode

In non-standby and non-frozen mode, touch the [**Freeze**] key  , the screen prompts [**Frozen! Touch the Freeze key to unfreeze.**]. When the system enters the frozen mode, the frozen cursor appears in the area around the waveform. All waveforms and spirometry loops are frozen, namely waveforms and spirometry loops will not be refreshed. Data in parameter area can be refreshed properly. In the frozen mode, the [**Save Ref.**] key is unavailable, so you can't save the reference loop, but you can view the reference loops that have been saved.

5.8.2 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 rotary knob clockwise or counterclockwise.

5.8.3 Loop Viewing

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

5.8.4 Unfreeze

In frozen state, touch the [**Freeze**] key "  " to exit from frozen state. If no operation is performed on the ventilator within 3 minutes after entering frozen state, the system exits from frozen state automatically.

5.9 Screenshot

When the user touches the  key on the main interface, the system will capture the current interface automatically and save the screenshot as a picture in bmp format. When a USB disk is not installed to the ventilator, up to 50 pictures can be stored in the ventilator and the earliest captured will be overwritten when the number is exceeded. When a USB disk is installed to the ventilator, the captured screenshots will be directly stored in the USB disk rather than the ventilator. Up to 2000 screenshots can be stored in the USB disk.

5.10 Screen Lock

After pressing the soft key  on the front panel, the indicator next to the key turns green, and the ventilator enters the lock state. At the same time, the message area l prompts [**Screen locked. Press the Lock key to unlock!**]. Only keyss as  ,  and  works during the lock state. Touch screens, rotary knobs and other keys do not work. Press the key again to unlock.

Chapter 6 Basic Operation

6.1 Display Setting

6.1.1 Waveform Setting PV Measurement

1) Select the [**Menu**] key → [**Screen**] → [**Screen Setting**].
2) Select the corresponding icon to set the displayed waveform number and type.
3) To adjust the specific waveform and monitoring value displayed at each position, please set the [**Layout Setting Switch**] to  (indicating ON). Then select the name area of waveforms or monitoring parameters in the main interface and set the required waveforms and monitoring values in the displayed interface. To turn off this function, please set the [**Param Selection**] to  (indicating OFF).
4) Set [**Line Width**]: [**Thin**], [**Med**] or [**Thick**].

6.1.2 Color Setting

1) Select the [**Menu**] key → [**Screen**]→[**Color**].
2) The colors of Waveform, Parameter, Loop and Parameter alarm limit are related. As soon as the color of a certain parameter is set, the color of the related parameterswill change. The related alarm limit will be displayed in the color set.

See the table below for waveforms, related parameters, related loops and related alarms:

Waveforms	**Waveform Related Parameters**	**Waveform Related Spirometry Loops**	**Waveform Related Alarm Limits**
Airway Pressure	Ppeak, Pmean, Pplat, PEEP	P-V loop, F-P loop	Ppeak
Flow	MV, MVleak, MVspn, TVe, TVi, TVespn, ftotal, fmand, fspn, TVe/IBW	F-V loop	MV, TVe, ftotal
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 loop	$EtCO_2$
Pleth	SpO_2, PR, PI	/	SpO_2, PR

6.2 Ideal Height/IBW Setting

1) Select the [**Menu**] key → [**Settings**] → [**Ventilation**].
2) Set [**Ideal Height/IBW**] (Ideal Body Weight): [**Ideal Height**] or [**IBW**]. In Standby mode, the default value of TV (Tidal Volume), f (Breathing Frequency) and fapnea (Apnea Frequency) in ventilation mode will be figured out automatically by the system according to Ideal Weight/IBW and gender set.

6.3 Apnea Inspiratory Time/I:E Setting

1) Select the [**Menu**] key → [**Settings**] → [**Ventilation**].
2) Select the [**Apnea Tinsp**] (Apnea Inspiratory Time) key or the [**Apnea I:E**] key: according to the apnea parameters set in the ventilation mode, [**Apnea Tinsp**] or [**Apnea I:E**] is displayed.

6.4 Inspiratory Time/I:E Setting

1) Select the [**Menu**] key → [**Settings**] → [**Ventilation**].
2) Select the [**Tinsp/I:E**] key: [**Tinsp**]: (Inspiratory Time)or [**I:E**] (Inspiratory Time : Expiratory Time). According to the parameters set in the ventilation mode, is displayed as [**Tinsp**] or [**I:E**] in Duovent ventilation mode (When the time parameter for DuoVent is [**f**]), P-A/C ventilation mode and PRVC ventilation mode.

6.5 DuoVent Setting

1) Select the [**Menu**] key→[**Settings**]→[**Ventilation**].
2) Set [**DuoVent Setting**]: [**Thigh**] or [**f**].
   - If the item is set to [**Thigh**], time control parameters in DuoVent ventilation mode are [**Thigh**] and [**Tlow**].
   - If the item is set to [**f**], and [**Tinsp/I:E**] is set to [**Tinsp**], time control parameters in DuoVent ventilation mode are [**f**] and [**Tinsp**].
   - If the item is set to [**f**], and [**Tinsp/I:E**] is set to [**I:E**], time control parameters in DuoVent ventilation mode are [**f**] and [**I:E**].

6.6 Invasive Apnea Mode Setting

1) Select the [**Menu**] key→ [**Settings**] → [**Ventilation**].
2) Set [**Invasive Apnea Mode**]: [**Volume Ctrl**] (Volume Control) or [**Pressure Ctrl**] (Pressure Control). While performing invasive ventilation in P-SIMV, CPAP/PSV, DuoVent and APRV ventilation mode, if the item is set to [**Volume Ctrl**], the settable control parameter in Apnea ventilation mode is [**TVapnea**]; if the item is set to [**Pressure Ctrl**], the settable control parameter in Apnea ventilation mode is [**ΔPapnea**].

6.7 O_2% Increment Setting During Oxygen Enrichment

1) Select the [**Menu**] key→ [**Settings**] → [**Ventilation**].
2) O_2% increment setting during Oxygen Enrichment (O_2 ↑): set O_2 ↑ amplitude under different patient types respectively. When O_2 ↑ is started, the system compares "current oxygen concentration + O_2 ↑ amplitude" and "100vol.%", then ventilates with the smaller of the comparison.

6.8 O_2 ↑ Duration Setting

1) Select the [**Menu**] key→ [**Settings**] → [**Ventilation**].
2) Set [**O_2 ↑ Duration(s)**]: [**30**], [**60**], [**90**], [**120**].

6.9 Sputum Suction Duration Setting

1) Select [**Menu**] → [**Settings**] → [**Ventilation**].

2) Set [**Sputum Suction Duration(s)**]: [**30**], [**60**], [**90**], [**120**].

6.10 Language Setting

1) Select the [**Menu**] key → [**System**] →input the System Password → [**Settings**].
2) Set the [**Language/Unit**] key→ [**Language**], and select the language as needed.
3) Reboot the ventilator to put the language selected into effect.

6.11 Unit Setting

1) Select the [**Menu**] key → [**System**] →input the System Password → [**Settings**].
2) Set [**Language/Unit**] → [**Unit**]:
   - [**Pressure Unit**]: [**cmH_2O**], [**hPa**] or [**mbar**].
   - [**CO_2 Unit**]: [**mmHg**], [**kPa**] or [**%**].
   - [**Height Unit**]: [**cm**] or [**inch**].
   - [**Weight Unit**]: [**kg**] or [**lb**].

6.12 TV/IBW Setting

1) Select the [**Menu**] key→ [**Settings**] → [**Ventilation**].
2) Select the [**TV/IBW**] key and set it to appropriate ratio. The adjustable range of TV/IBW is 6 ml/kg-12 ml/kg. The default value of TV in ventilation mode will be set according to [**TV/IBW**].

6.13 O_2 Supply Type Setting

1) Select the [**Menu**] key → [**Settings**] → [**O_2 Type**]
2) Select the [**O_2 Type**] key: [High-press O_2] (High-pressure O_2) or [**Low-press O_2**] (Low Pressure O_2). It's used to set the O_2 supply type.
   - When [**Low-press O_2**] (Low Pressure O_2) is selected, O_2% alarm limit can only be set manually. O_2% parameter turns gray and unadjustable.

NOTE

- **Please set correct O_2 supply type based on the connected O_2 supply before ventilation.**
- **When the ventilator is connected to high-pressure oxygen but [O_2 Type] is set to [Low-press O_2], O_2% parameter will be displayed as [OFF] in gray and setting is disabled. Under such condition, if [OFF] is selected, a prompt [O_2% Setting Disabled in Low-press O_2] will be displayed and the user is required to modify O_2 supply type.**

6.14 O_2 Sensor Monitoring Setting

1) Select the [**Menu**] key→ [**Settings**] → [**O_2 Sensor**].
2) Select the [**Monitoring Switch**] key:  (indicating ON) or  (indicating 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 that comes with the ventilator, 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

- **Oxygen Concentration monitoring function can be disabled. However, to prevent the patients from potential harm, we strongly recommend that you DO NOT disable the function for extended periods of time.**

NOTE

- **The total system response time of the oxygen sensor is less than 15s.**
- **O_2 sensor has the automatic barometric pressure compensation function.**
- **It takes about 3 minutes from powering on the ventilator to performing the monitoring performance as specified of Oxygen Concentration Monitoring in Appendix III of this manual.**
- **When the [Monitoring Switch] is turned off, monitoring parameters related to oxygen cannot be displayed, and alarms related to oxygen will not be triggered. O_2 control functions are not affected.**
- **After turning off the [Monitoring Switch], [O_2%] on the interface displays [OFF], and the [O_2%] alarm limit setting displays gray and cannot be adjusted.**
- **When the ambient is below 5℃, the monitoring FiO_2 maybe incorrect, please turn off the O_2 sensor monitoring. And the ventilator shall be provided stand-alone O_2 monitoring equipment that conforms with ISO 80601-2-55:2018 before being put into service.**

6.15 Time and Date Setting

1) Select the [**Menu**] key→[**System**]→input the System Password→[**Settings**] → [**Date/Time**].
2) Set [**Date**] and [**Time**]: Set date and time in the opened window after touching.
3) Set [**Date Format**] to [**YYYY-MM-DD**], [**DD-MM-YYYY**] or [**MM-DD-YYYY**].
4) Set [**Time Format**]: [24 h].

   (indicating ON): the ventilator uses 24-hour system.

   (indicating OFF): the ventilator uses 24-hour system and the AM/PM key are displayed in the pop-up time setting interface.

6.16 Screen Brightness Setting

1) Select the [**Menu**] key→ [**Screen**]→[**Brightness/Volume**].
2) Select or , the default screen brightness will be adjusted accordingly.
3) If you are dissatisfied with screen brightness, you can also directly set [**Brightness**]（slide the brightness bar or touch the icon on the left side to lower brightness and the icon on the right side to increase brightness）: 1～15. 1 is for the darkest level and 15 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.

6.17 Key Volume Setting

1) Select the [**Menu**] key → [**Screen**] → [**Brightness/Volume**].
2) Select  or  , the default key volume will be adjusted accordingly.
3) Set [**Key Volume**] (slide the key volume bar or touch the icon on the left side  to lower the key volume and the icon on the right side  to increase the key volume): level 0 ~ 10. 0 indicates turning off the key sound and 10 is the maximum volume.

6.18 Pulse Volume Setting

1) Select the [**Menu**] key → [**Screen**] → [**Brightness/Volume**].
2) Select  or  to adjust the corresponding default pulse volume.
3) Set [**Pulse Volume**] (slide the pulse volume bar or touch the icon on the left  to lower the volume and the icon on the right  to increase the volume): 0 ~ 10. 0 indicates turning off the key sound and 10 is the maximum volume.

6.19 System Information Viewing

6.19.1 Version Information

Select the [**Menu**] key→[**System**]→input the System Password→ [**System Info**] (System information) → [**Software Version**] to query software version information of the system.

6.19.2 Configuration Information

Select the [**Menu**] key→[**System**]→input the System Password→ [**System Info**] (System information) → [**Config Info**] (Configuration information) to query ventilator configuration information (ventilation mode).

6.19.3 Maintenance Information

Select the [**Menu**] key→[**System**]→input the System Password→ [**System Info**] (system information) → [**Maintenance Info**] (Maintenance information) to query system Total Running Time, Total Ventilation Time, Current Running Time, Current Ventilation Time, O_2 Sensor Last Calibration Time, Flow Sensor Last Calibration Time, Time Left for Next Blower Maintenance, Last Maintenance Time.

6.19.4 System Check Result

When the device is turned on, it conducts system check. The system check results of the ventilator can be viewed in the following steps:

1) Select the [**Menu**] key → [**Syst Check**] (System Check Result).
2) In the [**Syst Check**] (System Check Result) interface, the results of system check on [**VCM**], [**VPM**] and [**Power Board**] can be viewed. Slide up and down to scroll the system check result of each item. The item that passes will display green [**Passed**] in the result column and the item that fails will display red [**Failed**] in the result column.

6.20 Defaults Management

The ventilator concludes the following set values:

- The Factory Defaults: namely the values preset by the factory, including patient information, mode, defaults and alarm limit defaults. The default values can be divided into 6 groups (Adult Invasive, Adult Non-invasive, Pediatric Patient Invasive, Pediatric Patient Non-invasive, Infant Invasive and Infant Non-invasive) by the patient type.
- User Defaults: adjust the ventilator settings as required and save them as the user defaults, including patient information, mode, default values and alarm limit defaults. The user defaults can be divided into six groups (Adult Invasive, Adult Non-invasive, Pediatric Patient Invasive, Pediatric Patient Non-invasive, Infant Invasive and Infant Non-invasive) by the patient type.
- Latest Setting Values: in practice, some settings may be modified by the operator. The ventilator stores the settings values in real time and those are the latest settings values.
- Current Setting Values: the current setting values of the ventilator.

6.20.1 Loading and Saving Current Settings

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

1) Select the [**Menu**] key → [**System**] →input the System Password → [**Defaults**].
2) Select the [**Use Current**] key to save the current set values.

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

6.20.2 Factory Defaults Restoration

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

1) Select the [**Menu**] key →[**System**]→input the System Password →[**Defaults**].
2) Select the [**Restore Defaults**] key, restore it to factory default settings.

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

6.20.3 Defaults Application

When the ventilator is applied to a new patient, the ventilator will automatically load the corresponding user defaults based on the set patient type. When the ventilator is applied to the same patient, the ventilator will automatically load the latest setting values.

6.20.4 Restoring the Latest Setting Values Automatically

When the ventilator is turned on and applied to the same patient, the system automatically adopts the latest setting values.

NOTE

- **The system saves the following records automatically: reference loops, monitoring trends, event logs (including alarm logs), trend settings, patient settings, device settings and alarm settings. When the above data changes, the system automatically saves the changed data in the flash chip of the mainboard. When the device is restarted, the data is automatically restored.**

6.21 Data Export

The data export function means that the ventilator exports some data to a USB disk.

NOTE

- **The connection of equipment or transmission networks other than as specified in the user instructions can result in an electric shock hazard or equipment malfunction. Substitute or alternate equipment and connections require verification of compatibility and conformity to IEC/EN 60601-1 by the installer. Equipment modifications, possible resulting malfunctions and electromagnetic interference, these risks should be identified, analyzed, evaluated and controlled by responsible organization.**
- **It is user's responsibility to ensure the USB disk is virus-free. Improper use of a USB disk may cause the virus infections of system and eventually malfunction may occur.**

6.21.1 Screen Export

Screen export refers to the latest saved screenshot exported by the ventilator. The export file format is bmp. Up to 50 screenshots can be stored by the ventilator.

The steps of screen export are as follows:

1) Insert a USB disk into the USB interface of the ventilator and the icon  is displayed in the interface.
2) Select the [**Menu**] key →[**Transfer**]→ [**Screenshot Export**], the system checks the USB disk availability. If the USB disk is available and has sufficient space, the system exports the last captured screenshot.
3) After the export is completed, select the [**Uninstall USB**] key to remove the USB disk.

6.21.2 Data Export

Data Export means the ventilator exports Patient Information, Current Alarm Limit, Trends, etc.

Operating steps for data export are as follows:

1) Insert a USB disk into the USB port of the ventilator and the icon  is displayed in the interface.
2) Select the [**Menu**] key →[**Transfer**]→ [**Data Export**] → [**User Data Export**], the system checks the USB disk availability. If the USB disk is available and has sufficient space, the system exports patient information, current set parameter, current alarm limit, tabular trends and graphic trends. The file format exported is html.
3) In addition to exporting the data above, if you need to export Calibration Data, Event log, System Check log and more, select the [**Factory Data Export**] key→input the password; the system checks the USB disk availability. If the USB disk is available and has sufficient space, the system exports these data. The exported data is encrypted in the blg format.
4) After the export is completed, select the [**Uninstall USB**] key to remove the USB disk.

6.21.3 Settings Transfer

During the ventilator application, the user default settings can be exported or imported.

Export settings:

1) Ensure that the ventilator is in Standby mode.
2) Insert the USB disk into the USB port of the ventilator. The icon  is displayed on the main interface.

3) Select the [**Menu**] key→[**Transfer**]→[**Settings Transfer**]→[**Export**], and the system will check whether the storage space of the USB disk is enough. If the space is enough, the system saves the current settings and defaults of the ventilator to the USB device.
4) After the export is completed, select the [**Uninstall USB**] key to remove the USB disk.

Import settings:

1) Ensure that the ventilator is in Standby mode.
2) Insert a USB disk into the USB port of the ventilator. The icon  is displayed on the main interface.
3) Select the [**Menu**] key→[**Data Transfer**]→[**Settings Transfer**]→[**Import**] to load the settings from the USB device to the ventilator.
4) After the import is completed, select the [**Uninstall USB**] key to remove the USB disk.

6.22 Password Modification

1) Select the [**Menu**] key→[**System**]→enter the System Password→[**Settings**].
2) Select the [**Password Modification**] key.]
3) Enter the current password and new password respectively, and confirm new password.
4) Touch the [**Save Password**] key to save the new password.

6.23 Shortcut Tools Setting

1) Select the [**Tools**] key→[**Shortcut**].
2) Select shortcut keys in the interface. The system adds the shortcut keys in corresponding sequence.

6.24 Factory Service

Only maintenance personnel authorized by the company can access the [**Service**] (Factory Service) menu. If you need help, please contact our After-sales Service.

6.25 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 the batteryfails to support normal function of the ventilator, the device will provide an alarm audio through buzzer only and would last for at least 120s. Its feature: High priority alarms: Di---. In this case, there are no alarm indicators or LCD displayer.

Chapter 7 Alarms

7.1 Overview

The ventilator continuously monitors the patient, device, and environment to ensure that all of the systems are functioning as intended. An alarm is a prompt sent by the ventilator to medical workers in audio, light or other forms when the device detects a problem.

7.2 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 audio alarm system. The patient may be put in a dangerous situation if the alarm volume is low. Set the minimum alarm volume higher than environmental noise.**
- **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.**
- **The physiological waveforms, physiological parameters, alarms and other information displayed on the screen are only for reference by doctors, which shall not be used as a basis for clinical treatment.**

⚠ NOTE

- **The system will test whether the alarm audio 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 alternately. If the alarm audio and alarm light function abnormally, do not use this equipment and contact us immediately.**
- **When several alarms of different priorities are generated simultaneously, the equipment will generate light and audio alarms according to the highest alarm priority among all alarms.**
- **Upon each startup,**

  - When the [Last Patient] key is selected, the ventilator will retain the alarm setting from previous setting;

  - When the [New Patient] key is selected, the default alarm preset will be automatically loaded;

  - When the [Quick Vent] key is selected, if restarted within 180s after powering off, the set parameters and the alarm limit before losing power will be loaded; if restarted after 210s, the default configurations will be loaded; if restarted within 180s~210s, the data before power loss or the default configurations would be loaded.

7.3 Alarm Types

Alarms generated by the monitor are classified into physiological alarm, technical alarms and prompt messages according to the alarm type.

1. Physiological alarm
   A physiological alarm is often generated when a certain physiological parameter of the patient is beyond the high/low 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.
2. 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.
3. Prompt messages
   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.

7.4 Alarm Priority

High priority alarm: the patient is in critical condition or the device has serious failure, and immediate response is necessary.
Medium priority alarm: the patient's physical signs are abnormal, the device has failure or is misoperated, and timely response is necessary.
Low priority alarm: the patient feels unwell, the device has failure or is misoperated, and the user is required to be aware of the current situation.
Prompt messages: information on the patient and system status is provided.

7.5 Alarm Signals

7.5.1 Alarm Indicator Light

The alarm indicator light indicates different alarm priorities generated in different colors and blinking frequencies.

High priority alarm: red, fast blinking frequency

Medium priority alarm: yellow, slow blinking frequency

Low priority alarm: yellow, no blinking, light remaining on

7.5.2 Audio Alarm

Audio alarms of different priorities are generated by the ventilator with different audio characteristics.
High priority alarm: beep-beep-beep—beep-beep----beep-beep-beep—beep-beep
Medium priority alarm: beep-beep-beep
Low priority alarm: beep

A-weighting sound pressure level:

- Operator position: 1 m in front of the ventilator, and at the height of 1.5 m.
- A-weighting sound pressure level: not less than 45 dB, not greater than 85 db with adjustable alarm volume; in the manufacturer default, the alarm volume of high priority alarm is not less than 60 dB(A).

7.5.3 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 alarm priorities:

High priority alarm: !!!

Medium priority alarm: !!

Low priority alarm:!
Background colors corresponding to different alarm priorities:

High priority alarm: red

Medium priority alarm: yellow

Low priority alarm: yellow

7.5.4 Alarm Parameter Form

- High priority alarm: red background, background blinking
- Medium priority alarm: yellow background, background blinking
- Low priority alarm: yellow background, background blinking

NOTE

- When multiple alarms of different priorities occur at the same time, the alarm indicator light and auditory alarm are the same as highest priority, and each alarm message is displayed in turn.
- If there are multiple alarms in the same priority, each alarm message in the same priority is displayed in turn.

7.5.5 Alarm State Icons

 : Indicates that there is an inactive alarm whose alarm condition has disappeared. Touch the icon to view the most recent inactive alarm (up to 10 alarms can be displayed) in the opened interface, or you can select the [**Clear**] key to clear the most recent inactive alarm.

: Indicates the alarm system is in audio paused state.

 : Indicates the alarm is off or the alarm limit is disabled.

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

7.6 Alarm Limits Setting

WARNING

- **When the alarm limit is enabled, after manually setting the high/low value of alarm limit, the device will display these high/low limit values continuously.**
- **Do not set the alarm limit to an extreme value; otherwise the alarm system will fail.**
- **The delay time of the [FiO_2 Too High] alarm and [FiO_2 Too Low] alarm exceed 10 seconds.**

CAUTION

- **It's recommended to set the high-pressure alarm limit up to 60 cmH_2O as per clinical condition, except for special need.**

NOTE

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

7.6.1 Adjusting the Alarm Limit Manually

1) Select the [**Alarm**] key→ [**Alm Limit**] (Alarm Limit), [**CO_2 Alm**] (CO_2 Alarm) or [**SpO_2 Alm**] (SpO_2 Alarm).
2) Set ventilation parameters, CO_2 and SpO_2 alarm limits as needed.

7.6.2 Auto Alarm Limit Setting

The ventilator provides function of setting alarm limit automatically. It sets alarm limit automatically according to current patient type and parameter values measured. When not entering the ventilation interface, the automatic alarm limit setting is not allowed.

Before using these alarm limits, confirm whether they are fit for current patient. If not, you need to set the alarm limit manually.

Alarm Limit	Formula
High Expiratory Tidal Volume Limit	1.5*TVe ml
Low Expiratory Tidal Volume Limit	0.5* TVe ml
High Minute Ventilation Limit	1.5*MVe monitoring value
Low Minute Ventilation Limit	0.6*MVe monitoring value
High Airway Pressure Limit	Mean Ppeak+10 cmH_2O or 35 cmH_2O, whichever is larger
Low Airway Pressure Limit	PEEP monitoring value
High Total Frequency Limit	1.4* monitoring value of total frequency, not exceeding 160bpm
Low Total Frequency Limit	0.6* monitoring value of total frequency
Apnea Ventilation Time	Default at 15s

Mean value in the formula: the mean monitoring value in last eight ventilation cycles or the monitoring value in 1 minute, whichever is smaller.

When the calculated alarm limit is larger than the high threshold of the set range, or less than the low threshold, the corresponding threshold will be used as the automatic alarm limit.

Steps to set the automatic alarm limit:

1) Select the [**Alarm**] key→ [**Alm Limit**] (**Alarm Limit**).
2) Select the [**Auto Alarm Limit**] key.

NOTE

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

7.7 Alarm Volume Setting

7.7.1 Alarm Volume Setting

1) Select the [**Alarm**] key → [**Alm Volume**] (Alarm Volume).

2) Set [**Alm Volume**]: Touch the icon on the left to lower the volume, and the icon on the right to increase the volume). The alarm volume ranges from X to 10, where X is the minimum alarm volume and 10 is the maximum volume. If there is no alarm, when you adjust the volume, the system will play a low priority alarm tone according to the alarm volume you set. For Minimum Alarm Volume setting, see ***"Chapter 7.7.2* Minimum Alarm Volume Setting"** for details.

WARNING

- **In the process of using the device, do not only rely on the audio alarm system. The patient may be put in a dangerous situation if the alarm volume is low. Users should pay close attention to the patient's actual clinical condition.**
- **Adjusting the audio alarm volume to less than the ambient noise will hinder the operator from identifying the alarm state.**

7.7.2 Minimum Alarm Volume Setting

1) Select the [**Menu**] key→[**System**]→Enter the System Passport →[**Settings**]→ [**System Setting**].

2) Set [**Minimum Alarm Volume**]: Slide the volume bar or touch the icon on the left to lower the volume and the icon on the right to increase the volume). Modifying the [**Minimum Alarm Volume**] may change the alarm loudness.

7.8 Alarm Audio Paused

In the alarm process, touch the [**Alarm Audio Paused**] key on the panel to enter the [**Alarm Audio Paused**] mode, the alarm audio currently produced can be turned off. After an audio paused countdown for 120 seconds, the audio alarm will be restored.

Alarm audio pause can be cancelled in the following cases:

- When 120 sec audio paused countdown finished.
- In Alarm Audio Paused state, press the key on the panel.

WARNING

- **During the alarm audio paused state, 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 state, the alarm system except the alarm audio is activated.**

7.9 Current 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 touch 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.

When there is an inactive alarm whose alarm condition has disappeared, the icon  will be displayed. Inactive recent alarms (up to 10 alarms can be displayed) can be viewed in the [**Recent Alm**] menu opened after touching the icon  . Inactive recent alarms can be cleared by selecting the [**Clear**] key.

7.10 Turning off Alarm at Extreme Limits

When the low Paw alarm limit, high/low TV alarm limit and low ftotal alarm limit are set to [**OFF**], the system will display the alarm off icon "  " in the Parameter Alarm Limit area and the corresponding physiological alarm of [**Paw Too Low**], [**TVe Too High**], [**TVe Too Low**] or [**ftotal Too Low**] will be turned off. Namely, the text messages, lighting and audio of the physiological alarm are turned off.

WARNING

- **When the alarm is turned off, if an alarm is generated, the device cannot trigger an alarm. Caution is advised when using this function, and careful consideration should be taken before turning off any alarm.**

7.11 Alarm System Check

7.11.1 Airway Pressure Too High

1) After the ventilator system is started normally, connect the ventilator to test lung and start ventilation.
2) Set the high alarm limit of airway pressure to current Ppeak + 5 cmH_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.

7.11.2 Airway Pressure Too Low

1) After the ventilator system starts normally, connect the ventilator to the test lung and start ventilation.
2) Set the low limit of the airway pressure alarm to the current peak pressure + 5 cmH_2O.
3) Verify whether the [**Paw Too Low**] alarm is activated.

7.11.3 Expiratory Tidal Volume Too Low

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

7.11.4 Expiratory Tidal Volume Too High

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

7.11.5 Minute Volume Too Low

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

7.11.6 Minute Volume Too High

1) After the ventilator system is started normally, connect the ventilator to test lung and start ventilation.
2) Set the high alarm limit of minute ventilation to less than the current minute ventilation, and verify whether the [**MV Too High**] alarm is activated.

7.11.7 FiO_2 Too High

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

7.11.8 FiO_2 Too Low

1) The ventilator is connected to the high-pressure O_2 supply, and the type of O_2 supply of the ventilator is set as high-pressure O_2.
2) The ventilator is connected to the test lung to start ventilation.

3) Set the O_2 concentration control parameter to 50%.
4) Turn off the high-pressure O_2 supply after ventilation is stable.
5) Verify whether the [**FiO_2 Too Low**] alarm is activated.

7.11.9 $EtCO_2$ Too High

1) Connect the 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 and starts functioning, 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 high alarm limit of $EtCO_2$ to be less than the concentration of the standard gas.
4) Verify whether the medium priority alarm [**$EtCO_2$ Too High**] is triggered.

7.11.10 $EtCO_2$ Too Low

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 and starts functioning, 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 low alarm limit of $EtCO_2$ to be greater than the concentration of the standard gas.
4) Verify whether the medium priority alarm [**$EtCO_2$ Too Low**] is triggered.

7.11.11 Tube Blocked

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) Verify whether the [**Tube Blocked**] alarm is triggered.

7.11.12 Apnea Alarm

1) After the ventilator system is started normally, connect the ventilator to test lung and set the ventilator to Spontaneous Respiration mode. Ensure the Apnea Backup Ventilation is disabled.
2) Set [**Tapnea**] and wait.
3) Verify whether the [**Apnea**] alarm is triggered.
4) Press the test lung.
5) Verify whether the [**Apnea**] alarm is reset.

7.11.13 SpO_2 Too High

1) Connect the ventilator to test lung and start ventilation.
2) Connect SpO_2 sensor, turn on the [**SpO_2 Module**].
3) Connect SpO_2 sensor to the index finger, set the low SpO_2 alarm limit to 20% and the high alarm limit to

22%.

4) Verify whether the [**SpO_2 Too High**] alarm is triggered.

7.11.14 SpO_2 Too Low

1) Connect the ventilator to test lung and start ventilation.
2) Connect SpO_2 sensor, turn on the [**SpO_2 Module**].
3) Connect SpO_2 sensor to the index finger, set the SpO_2 high alarm limit to 100% and the low alarm limit to 98%.
4) Put another finger on the finger with SpO_2 sensor. When the monitored value of SpO_2 is less than 98%, verify whether the [**SpO_2 Too Low**] alarm is triggered.

7.11.15 PR Too High

1) Connect the ventilator to test lung and start ventilation.
2) Connect SpO_2 sensor, turn on [**SpO_2 Module**].
3) Connect SpO_2 sensor to the index finger, set the PR high alarm limit to 30 bpm.
4) Verify whether the [**PR Too High**] alarm is triggered.

7.11.16 PR Too Low

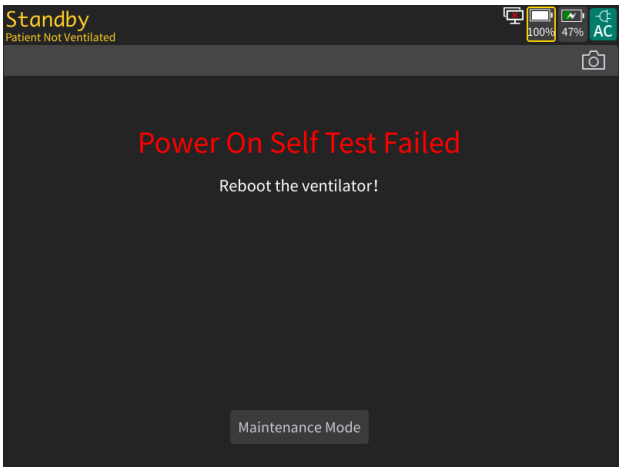
1) Connect the ventilator to test lung and start ventilation.
2) Connect SpO_2 sensor, turn on the [**SpO_2 Module**].
3) Connect SpO_2 sensor to the index finger, set the high PR alarm limit to 240 bpm and low PR alarm limit to 238 bpm.
4) Verify whether the [**PR Too Low**] alarm is triggered.

7.12 Safety Ventilation/Ambient State

When a certain technical error occurs, the ventilator switches to Safety Ventilation. This gives you time to arrange for corrective actions, including organizing a replacement ventilator.

During the Safety ventilation, the function of the sensor on the patient end is disabled. While the blower continues to operate and generates inspiration pressure, the expiration valve switches systematic pressure level between PEEP and inspiratory pressure. If the respiratory mode is set to PRVC or PRVC-SIMV before entering the safety ventilation, the safety ventilation parameters will be automatically set according to the following table. If the respiratory mode is set to P-A/C, DuoVent, APRV, CPAP/PSV, P-SIMV or PSV-ST pressure controlled mode before entering the safety ventilation, the safe ventilation continues according to the parameters set in this mode. When the ventilator detects that the corresponding fault is eliminated, it can automatically resume normal ventilation.

If the technical fault alarm is serious enough to possibly compromise safety ventilation (the failure of power on self test as the following picture shows is an example), the ventilator enters the Ambient State, in which the safety valve and expiration valve are opened to meet the patient's spontaneous breathing needs and avoid apnea. When the technical fault is eliminated, the ventilator must be shut down and restarted to exit the ambient state.



Safety mode setting is shown as below:

IBW(kg)	ΔPinsp(cmH_2O)	f	I:E	PEEP[1]	O_2%[2]
＜3	15	＜35	1:3		＞21%
3 to 5	15	30	1:4		＞21%
6 to 8	15	25	1:4		＞21%
9 to 20	15	20	1:4		＞21%
21 to 29	15	15	1:4		＞21%
30 to 39	15	14	1:4		＞21%
40 to 59	15	12	1:4		＞21%
60 to 89	15	10	1:4		＞21%
90 to 99	15	10	1:4		＞21%
≥99	15	10	1:4		＞21%

1: PEEP is the preset PEEP of the previous mode 2. O_2% is the preset O_2% of the previous mode

7.13 Alarm Handling Measure

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 generated.
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 System 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 only 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 8 Starting Ventilation

8.1 Starting the Ventilator

1) Press the [**Power/Standby**] key ⊙/Ò on the ventilator
2) The system conducts startup system self check. The ventilator enters the Standby interface after the system check is completed.

> ⚠ **NOTE**
>
> - **Press the [Power/Standby] key ⊙/Ò of the ventilator and the ventilator will enter the Standby interface. At this time, the ventilator can be operated normally.**

8.2 System Check

See ***"Chapter 4.3 System Check"*** for details.

8.3 Circuit Test

See ***"Chapter 4.4 Circuit Test"*** for details.

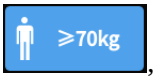
8.4 Patient Setting

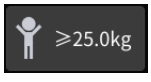
> ⚠ **WARNING**
>
> - **Specifying an obviously incorrect patient height results in incorrect IBW input and errors in the respiratory rate setting. Please examine carefully the values you specify in the Standby window.**
> - **Default settings are intended to provide basic support and prevent unintended injury. Particular care should be taken to adjust the ventilator appropriately before ventilating infants and pediatric patients. The ventilation parameters should always be adjusted before connecting the patient.**

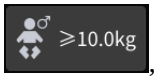
The ventilator support ventilation with a patient group of Adult/Pediatric Patient/Infant, varying from Height: 30 to 250 cm, IBW: 3 to 139 kg.

Select a patient in Standby mode:

The ventilator supports the operator's selection between new patient and last patient upon each startup. Select the [**Quick Vent**], [**New Patient**] or [**Last Patient**] key to admit one new patient:

- [**Quick Vent**] (Quick Ventilation): select 

, 

or 

, then select the [**Start Ventilation**] key. The specified ventilation mode is PRVC, which is recommended for use in emergency situations. When the PRVC mode is selected, the prompt [**To select other modes, click New Patient**] is displayed.
  This part provides operator a quick access to three pre-set emergency ventilation settings.
  The default setting refers to ***"Appendix IV Default Setting"***
- [**New Patient**]: Set the parameters of the patient such as Ventilation Mode, Patient Type, Gender, Height/

IBW (Ideal Body Weight), and then select the [**Start Ventilation**] key.

The interface supports the patients' height input by typing, then the device automatically calculates patients' IBW, varies on male and female. Then the ventilation starts according to the corresponding settings.

- Set the parameters of the patient such as Ventilation Mode, Gender, Height/ IBW, and then select the [**Start Vent**] (Start Ventilation) key.
- When [**Gender**], [**Height**] or [**IBW**] is changed, the setting values of [**TV**], [**TVapnea**], [**f**] and [**fapnea**] change accordingly, so do the high/low alarm limits of both tidal volume and minute ventilation.

Open the patient information setting menu and set the patient information in ventilation state:

- Select the [**Same Patient**] key and set [**Gender**], [**Height**] / [**IBW**] in the [**Same Patient**] menu.
- The [**New Patient**] menu cannot be selected or opened.

After changing [**Gender**], [**Height**]/[**IBW**], the setting values of [**TV**], [**TVapnea**], [**f**] and [**fapnea**] remain unchanged, so do the high/low alarm limit of both tidal volume and minute ventilation.

The table below shows an informative reference between patient weight verse nominal patient groups well as the recommended breathing tubing.

Nominal patient group	Weight range	Recommended breathing tubing
Adult	10 kg-139kg	Adult breathing tubing
Pediatric Patient	3 kg-35 kg	Adult breathing tubing, pediatric breathing tubing, infant breathing tubing
Infant	3 kg-15 kg	Pediatric breathing tubing, infant breathing tubing

When a new patient is admitted, the default alarm limit and start-up settings are recalculated according to the rules below:

IBW (kg)	f/fapnea (bpm)	Thigh (Duovent)/ Ti / Apnea Ti (s)	IBW (kg)	Thigh (APRV) (s)	Tlow (APRV) (s)
3≤IBW＜6	35	0.57	3≤IBW≤5	1.7	0.3
6≤IBW＜9	25	0.8	5＜IBW≤8	2.1	0.3
9≤IBW＜20	20	1.0	8＜IBW≤20	2.6	0.4
20≤IBW＜30	15	1.3	20＜IBW＜40	3.5	0.5
30≤IBW＜40	14	1.4	40≤IBW＜60	4.4	0.6
40≤IBW＜60	12	1.7	60≤IBW≤139	5.4	0.6
60≤IBW≤139	10	2.0	--	--	--
IBW (kg)	Exp %	--	IBW (kg)	Phigh(cmH_2O)	--
3≤IBW＜9	10%	--	3≤IBW＜90	20	--
9≤IBW＜15	15%	--	90≤IBW＜100	23	--
15≤IBW≤30	20%	--	100≤IBW≤139	25	--
30＜IBW≤139	25%	--	--	--	--
IBW (kg)	TV/TV apnea (ml)	High TVe Limit (ml)	Low TVe Limit (ml)	--	--
3≤IBW≤139	IBW * TV/IBW	TV*2	TV/2	--	--

NOTE

- Setting the weight properly is critical for ensuring that the tidal volume and minute volume alarms are correctly set.

8.5 Ventilation Type

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

WARNING

- **When switching from non-invasive ventilation to invasive ventilation, please check the alarm limit settings.**
- **The device you have might not have all the ventilation modes configurated, the actual mode is selected by the user configuration decisions.**
- **In the [Quick Vent] mode, only PRVC ventilation is supported.**

8.5.1 Invasive Ventilation

Invasive ventilation means the ventilation of patients through artificial airway (endotracheal intubation).

Invasive ventilation modes include:

Adult/Pediatric Patient/Infant: P-A/C, P-SIMV, DuoVent, APRV, CPAP/PSV, PRVC and PRVC-SIMV.

8.5.2 Non-invasive Ventilation

Non-invasive ventilation means assist patient ventilation with a nasal mask or breathing mask, without endotracheal intubation.

Non-invasive ventilation modes include:

Adult/Pediatric Patient/Infant: P-A/C, P-SIMV, CPAP/PSV, DuoVent, APRV and PSV-S/T.

CAUTION

- **For patients without spontaneous breathing or with irregular spontaneous breathing, never use non-invasive ventilation. Non-invasive ventilation is only intended for patient with spontaneous breathing.**
- **Never select non-invasive ventilation for an intubated patient.**
- **When using non-invasive ventilation, please note that the exhaled volume and exhaled CO_2 of the patient can differ from the measured exhaled volume and exhaled CO_2 due to leaks around the mask.**
- **The ventilator is to be provided with CO_2 monitoring equipment in the expiratory limb or at the patient connection port in accordance with ISO 80601-2-55 before being put into service.**

8.5.3 Ventilation Type Setting

When first starting to ventilate a patient, a default mode is preselected. You can change it, if needed.

You can set the ventilation type by following steps:

1) Select the [**Same Patient**] key or [**New Patient**] key in the Standby mode.

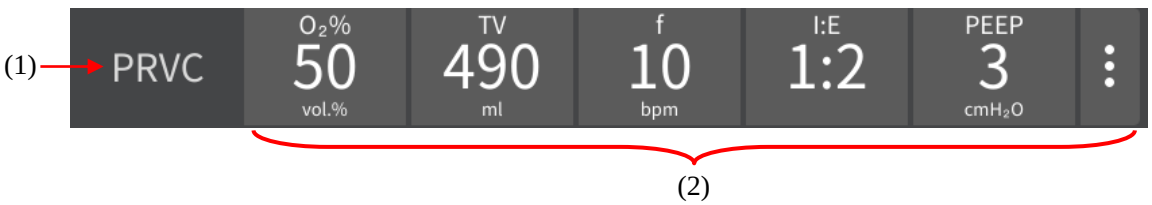
2) Set the ventilation type as  (indicating Invasive) or  (indicating Non-invasive)

8.6 Ventilation Mode

NOTE

- **The maximum limited pressure is 80 cmH_2O.**
- **The maximum minute volume is 60 l/min.**
- **The operator should set the ventilation parameters according to the actual situation of the patient.**
- **If you set ΔPinsp or high Paw alarm limit higher than 60 cmH_2O (this may cause potential danger to patients), the ventilator will prompt [Press the rotary knob to confirm before continuing your adjustment.].**
- **Normally, the delivered tidal or minute volumes and oxygen concentrations are not affected by pressure at the patient connection port. Only when alarm conditions [Pressure Limited] and [Volume Limited] are activated then the TV/MV is limited. The maximum deviations from stated settings at mean pressures of 0.5kPa, 1.5kPa, 3kPa and 6kPa is within the control accuracy.**
- **The maximum working pressure is high Paw alarm limit. The user can set the high-pressure alarm limit for inspiratory phase. When the pressure reaches the alarm limit, the High priority 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, make sure to set up a reasonable high-pressure alarm limit.**
- **The ventilator does not produce negative pressure during expiratory phase.**
- **P-A/C or P-SIMV ventilation mode is recommended if the patient is using a closed suction catheter.**

8.6.1 Ventilation Mode and Parameter Setting



(1). Ventilation Mode

Only selected ventilation modes are displayed in this area. Not selected modes are not displayed in the ventilation mode area.

The ventilating modes available on this ventilator are: P-A/C, P-SIMV, DuoVent, APRV, CPAP/PSV, PRVC, PRVC-SIMV and PSV-S/T. Your ventilator may be equipped with different combinations of ventilation modes.

Set ventilation mode of display:

1) Select the PRVC key to enter the [**Ventilation Mode Setting**] interface.
2) Select the ventilation mode required.

(2). Shortcut key area of parameter settings

Display the ventilation parameters corresponding to each ventilation mode. Select the [**Basic Param**] key  to display other ventilation setting parameters. You can also set parameters for the Sigh function here. Different ventilation modes require different parameters.

The general setting method of ventilation parameters is as follows:

1) Select the PRVC key to enter the [**Ventilation Mode Setting**] interface, select the required ventilation mode and touch the [**OK**] key to display the menu, where ventilation parameters that can be set in the ventilation mode are displayed.
2) Select the desired ventilation parameter key. Press the rotary knob at this time if the knob is used to select parameters.
3) Rotate the knob to set the parameters to the appropriate value, and press the rotary knob to confirm.
4) Select the [**Close**] key after all parameters was set as required.

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

1) In the shortcut key area for parameter settings, select a desired ventilation parameter.
2) If you are using the knob to select the parameter, press the rotary 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.

8.6.2 Apnea Ventilation Mode

Apnea ventilation mode refers to an alternative ventilation mode activated by the ventilator when the patient apnea is detected in Duovent, APRV, P-SIMV, PRVC-SIMV and CPAP/PSV mode, which is a mechanism to minimize patient injury caused by apnea or breathing interruptions. The ventilator exits apnea ventilation only when two consecutive spontaneous breaths are detected, ventilation mode is switched, or apnea ventilation is switched off.

Two apnea ventilation modes are provided: Volume Controlled mode and Pressure Controlled mode. Invasive ventilation supports Volume Controlled mode while non-invasive ventilation supports Pressure Controlled mode.

Volume controlled apnea ventilation allows you to set up tidal volume, respiratory rate and I:E 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 I:E of the apnea ventilation cycle (other parameter settings remain unchanged).

Pressure controlled apnea ventilation allows you to set up inspiratory pressure, respiratory rate and I:E 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 I:E of the apnea ventilation cycle (other parameter settings remain unchanged).

8.6.3 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 pre-set 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.

Under pressure regulated volume mode (PRVC), the ventilator shall ensure that the average value of monitored inspiratory and expiratory tidal volume is equal to the preset tidal volume. This definition can be adaptive to compensate for the compliance and leakage of the breathing circuit.

In the pressure-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 high limit of the TV alarm. When the [**Volume Limited**] alarm is generated, if you need to reach the maximum compensation capacity, you can raise the high 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-compensate.

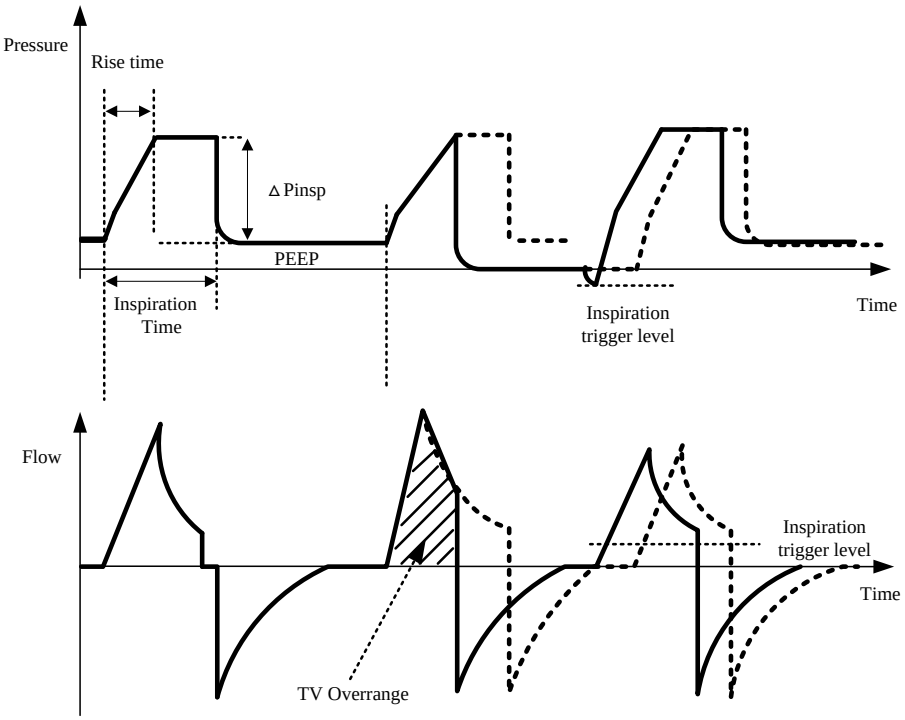
8.6.4 P-A/C Mode

P-A/C mode is also called Pressure-Controlled/Assist Ventilation mode. This function enables the airway pressure (Paw) to rise to the pre-set 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 high 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.

In the inspiratory phase, when the airway pressure exceeds the pressure limit (high Paw alarm limit-10 cmH_2O), the inspiratory pressure is controlled according to the value of the pressure limit instead of going up further.

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. [**ΔPinsp**] Inspiratory pressure
3. [**f**] Respiratory frequency
4. [**Tinsp**] or [**I:E**] Inspiratory time or Ratio of inspiratory time to expiratory time
5. [**PEEP**] Positive end-expiratory pressure
6. [**Assist Trig**] Assist Trigger
7. [**F-Trig**] Inspiration trigger level
8. [**Tslope**] The time with which airway pressure builds toward a preset value.

The optional parameter of Sigh function under P-A/C mode is:

1. [**Sigh**]: The switch to turn on the Sigh function

8.6.5 P-SIMV Mode

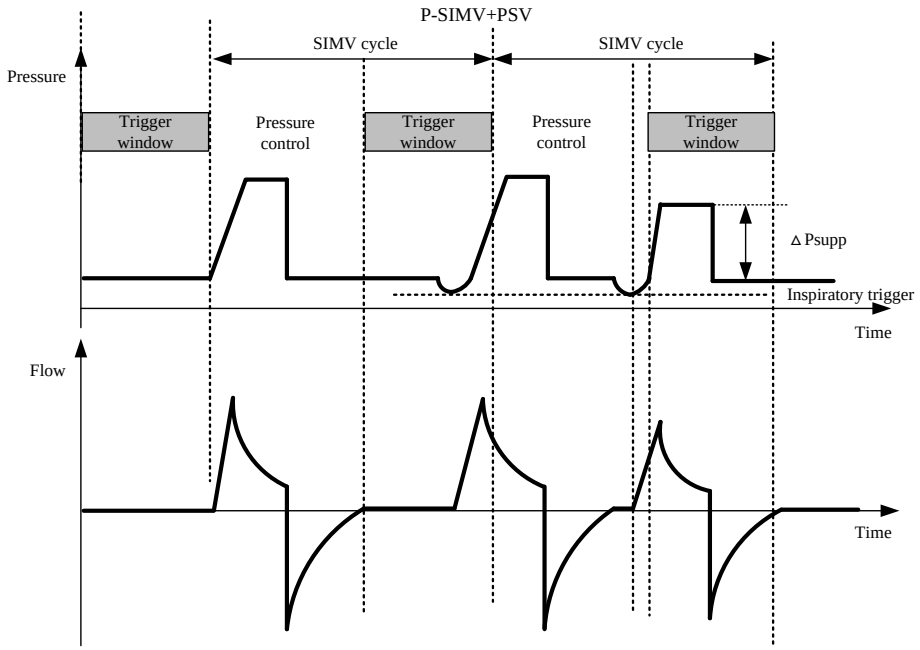
P-SIMV mode, or pressure-controlled synchronized intermittent mandatory ventilation, guarantees the lowest preset ventilation frequency is realized. It provides a basic number of ventilations according to preset frequency of intermittent mandatory ventilation. The mechanical ventilation mode provided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

When SIMV is triggered in a trigger window, the ventilator delivers 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.

In the inspiratory stage, when the airway pressure exceeds the pressure limit (high Paw alarm limit-10 cmH_2O), the inspiratory pressure is controlled according to the value of the pressure limit instead of going up further. The trigger window is 5 seconds for adults and 1.5 seconds for pediatric patients and infants. If the expiratory time is shorter than the trigger window, the whole expiratory phase is a 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. [**ΔPinsp**] Inspiratory pressure
3. [**SIMV f**] Respiratory frequency
4. [**Tinsp**] Inspiratory time
5. [**ΔPsupp**] Support pressure delivered by ventilator
6. [**PEEP**] Positive end-expiratory pressure
7. [**F-Trig**] Inspiration trigger level
8. [**Exp%**] Percentage of Expiratory trigger
9. [**Tslope**] The time with which airway pressure builds toward a preset value.
10. [**Apnea Vent**] The switch for apnea ventilation
11. [**TVapnea**] (available only in invasive mode) or [**ΔPapnea**] Tidal volume during apnea ventilation cycle or inspiratory pressure during apnea ventilation cycle
12. [**fapnea**] Respiration frequency of apnea ventilation
13. [**Apnea Tinsp**] or [**Apnea I:E**] Inspiratory time or ratio of inspiratory time to expiratory time during apnea ventilation

The optional parameter of Sigh function under P-SIMV mode is:

1. [**Sigh**]: The switch to turn on the Sigh function

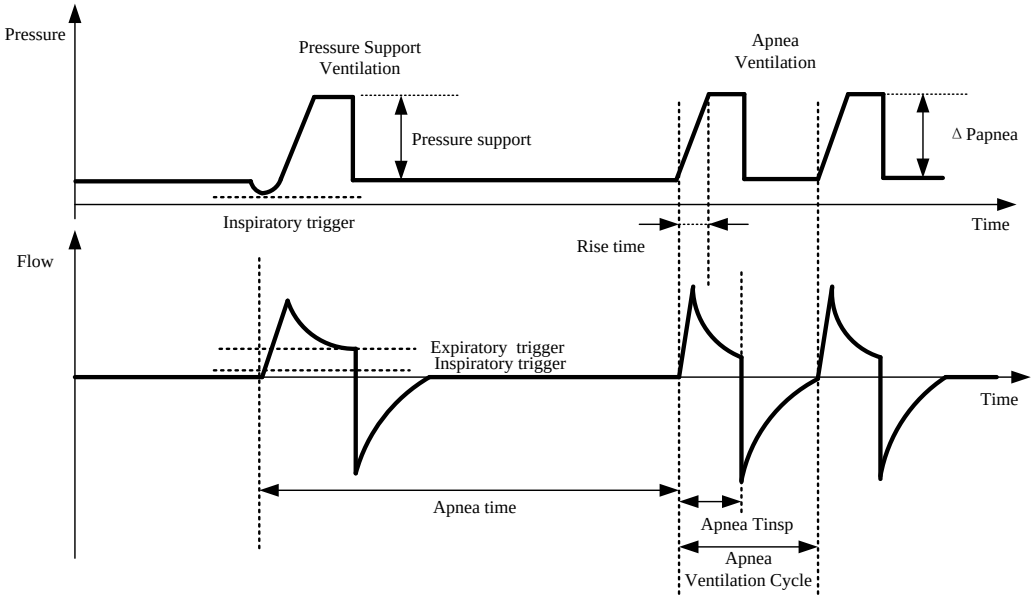
8.6.6 CPAP/PSV Mode

PSV mode is called the pressure support ventilation mode, which delivers pressure support ventilation when the system detects that 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.

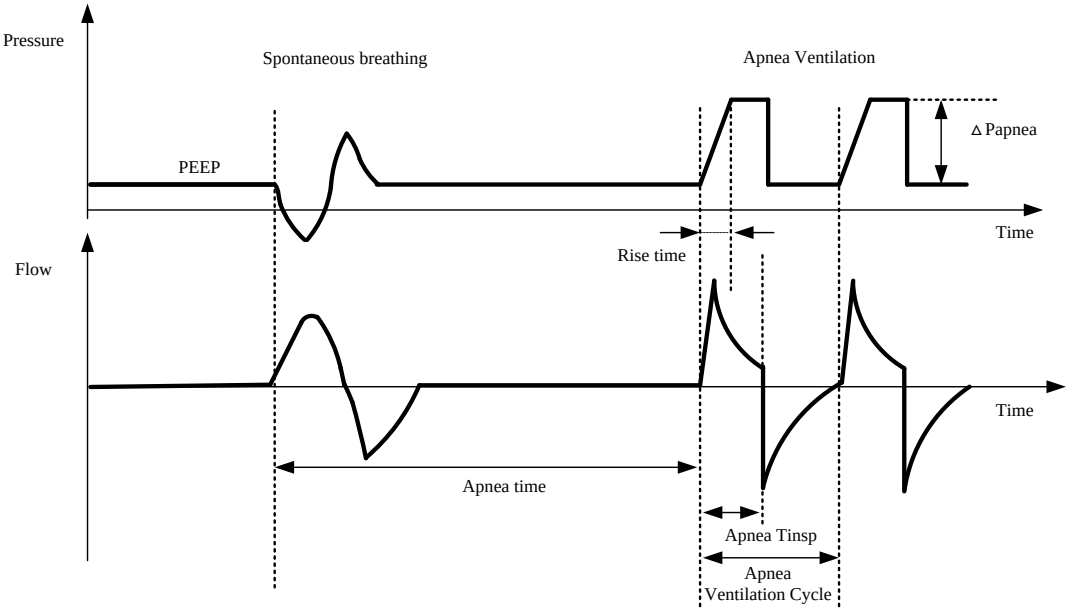
At the beginning of inspiratory phase, the ventilator increases the airway pressure to the pre-set level within the preset time of pressure rising (Tslope), and maintains this pressure level until the patient's inspiratory flow

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. The patient has 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. [**PEEP**] Positive end-expiratory pressure
3. [**ΔPsupp**] Support pressure delivered by ventilator
4. [**F-Trig**] Inspiration trigger level

5. [**Exp%**]	Percentage of Expiratory Trigger
6. [**Tslope**]	The time with which airway pressure builds toward a preset value
7. [**TVapnea**] or [**ΔPapnea**]	Tidal volume during apnea ventilation cycle or inspiratory pressure during apnea ventilation cycle
8. [**fapnea**]	Respiratory rate of apnea ventilation
9. [**ApneaTinsp**] or [**Apnea I:E**]	Inspiratory time or ratio of inspiratory time to expiratory time during apnea ventilation

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

1. [**O_2%**]	O_2 concentration
2. [**PEEP**]	Positive end-expiratory pressure
3. [**ΔPsupp**]	Support pressure delivered by ventilator
4. [**Ti max**]	Maximum time of inspiratory phase
5. [**F-Trig**]	Inspiration trigger level
6. [**Exp%**]	Percentage of Expiratory Trigger
7. [**Tslope**]	The time with which airway pressure builds toward a preset value
8. [**ΔPapnea**]	Inspiratory pressure during apnea ventilation cycle
9. [**fapnea**]	Respiratory rate of apnea ventilation
10. [**ApneaTinsp**] or [**Apnea I:E**]	Inspiratory time or ratio of inspiratory time to expiratory during apnea ventilation

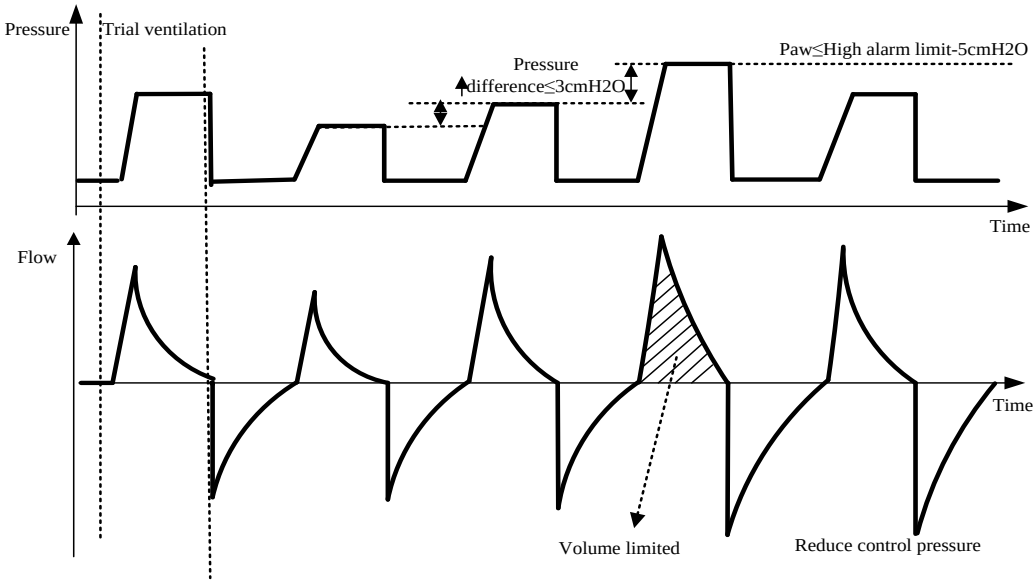
8.6.7 PRVC Mode

PRVC mode, or Pressure-regulated Volume Control mode, attempts to achieve set tidal volume at lowest possible airway pressure, while ensuring that the average value of the tidal volume supplied and exhaled is equal to the preset tidal volume. 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 increase does not exceed 10cm H_2O, and thereafter, the pressure increase does not exceed 3 cmH_2O each cycle. The maximum pressure does not exceed high pressure alarm limit -10 cmH_2O.

The first PRVC ventilation cycle is experimental; delivering the gas at a pressure of 5cm 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%**]	Oxygen concentration
2. [**TV**]	Tidal volume
3. [**f**]	Respiratory frequency
4. [**Tinsp**] or [**I: E**]	Inspiratory time or ratio of inspiratory time to expiratory time
5. [**PEEP**]	Positive end-expiratory pressure
6.[**Assist Trig**]	Assist Trigger
7. [**F-Trig**]	Inspiratory trigger level
8. [**Tslope**]	The time with which airway pressure builds toward a preset value.

Switch of sighing function can be set as required in PRVC

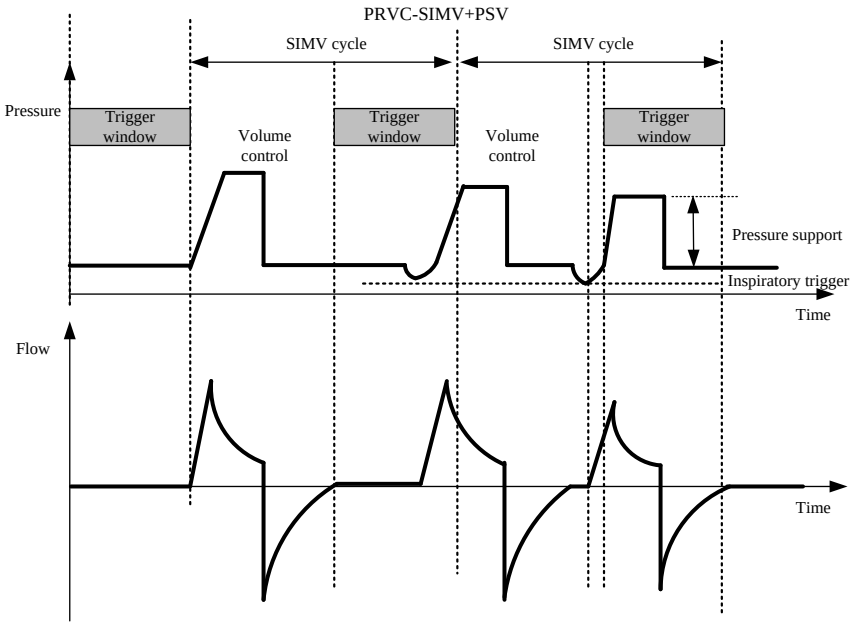
1. [**Sigh**]:	The switch to turn on the Sigh function

8.6.8 PRVC-SIMV Mode

The PRVC-SIMV (Pressure Regulated Volume Control-Synchronized Intermittent Mandatory Ventilation) mode guarantees basic ventilation frequency 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 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 trigger window is 5 seconds for adults and 1.5 seconds for pediatric patients and infants. If the expiratory time is shorter than the trigger window, the whole expiratory phase is a 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. [**SIMV f**] Respiratory frequency
4. [**Tinsp**] Inspiratory time
5. [**ΔPsupp**] Support pressure delivered by ventilator
6. [**PEEP**] Positive end-expiratory pressure
7. [**F-Trig**] Inspiratory trigger level
8. [**Exp%**] Percentage of Expiratory Trigger
9. [**Tslope**] The time with which airway pressure builds toward a preset value.
10. [**Apnea Vent**] The switch to turn on apnea ventilation
11. [**TVapnea**] (available only in invasive mode) or [**ΔPapnea**] Tidal volume during apnea ventilation cycle or inspiratory pressure during apnea ventilation cycle.
12. [**fapnea**] Respiratory frequency during apnea ventilation
13. [**Apnea Tinsp**] or [**Apnea I:E**] Inspiratory time or ratio of inspiratory time to expiratory time during apnea ventilation

Switch of sighing function can be set as required in PRVC-SIMV.

1. [**Sigh**]: The switch to turn on the Sigh function

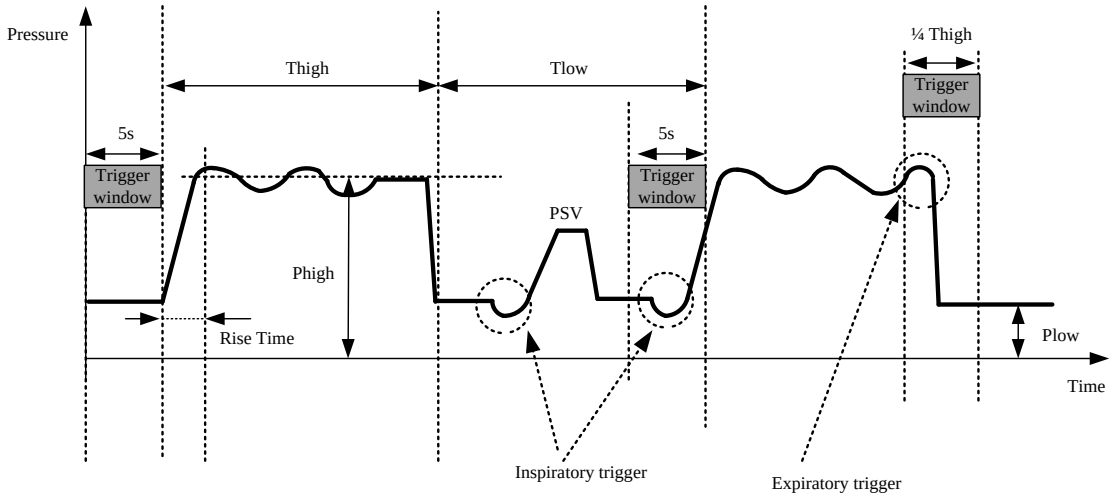
8.6.9 DuoVent Mode

In DuoVent (Duo-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 breathe at both pressure levels, where pressure support can be set during the low-pressure phase. There are trigger windows in both high and lowpressure 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 switch to high-pressure gas supply; and in the trigger window of the high-pressure phase, the expiratory trigger will switch to low-pressure gas supply. In the inspiratory phase, when the airway pressure exceeds the pressure limit (high Paw alarm limit -10 cmH_2O), the inspiratory pressure is controlled according to the value of the pressure limit instead of going up further.

The typical pressure waveforms of DuoVent mode are as follows:



The basic ventilation parameters required under DuoVent mode are:

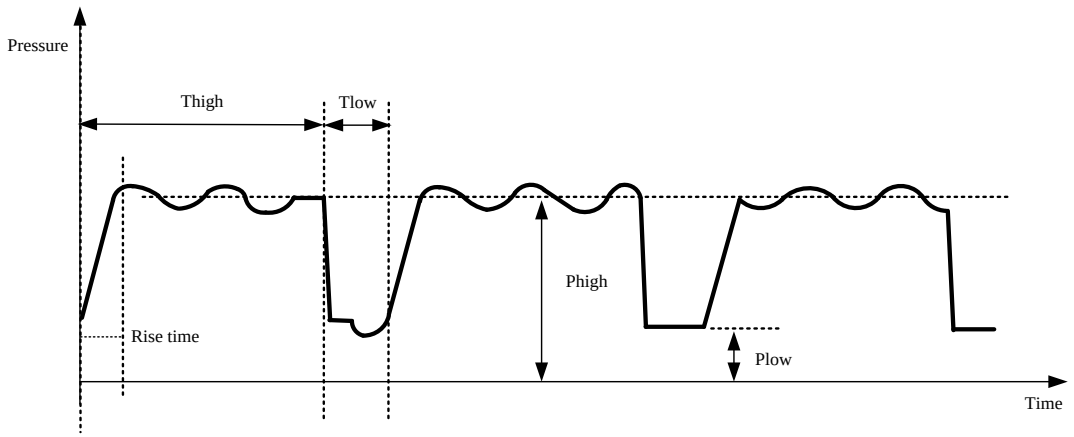
1. [**O_2%**]	O_2 concentration
2. [**Phigh**]	High pressure
3. [**Plow**]	Low pressure
4. [**Thigh**] or [**f**]	High pressure time or respiratory frequency.
5. [**Tlow**] or [**Tinsp**] or [**I:E**]	Low pressure time or inspiratory time or ratio of inspiratory time to expiratory time.
6. [**ΔPsupp**]	Support pressure delivered by ventilator
7. [**F-Trig**]	Inspiratory trigger level
8. [**Exp%**]	Percentage of Expiratory Trigger
9. [**Tslope**]	The time with which airway pressure builds toward a preset value.
10. [**TVapnea**] (available only in invasive mode) or [**ΔPapnea**]	Tidal volume during apnea ventilation cycle or inspiratory pressure during apnea ventilation cycle.
11.[**fapnea**]	Respiratory frequency during apnea ventilation
12. [**ApneaTinsp**] or [**Apnea I:E**]	Inspiratory time ratio of inspiratory time to expiratory time during apnea ventilation

8.6.10 APRV Mode

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

In the inspiratory phase, when the airway pressure exceeds the pressure limit (high Paw alarm limit -10 cmH_2O), the inspiratory pressure is controlled according to the value of the pressure limit instead of going up further.

The typical pressure waveforms of APRV mode are as follows:



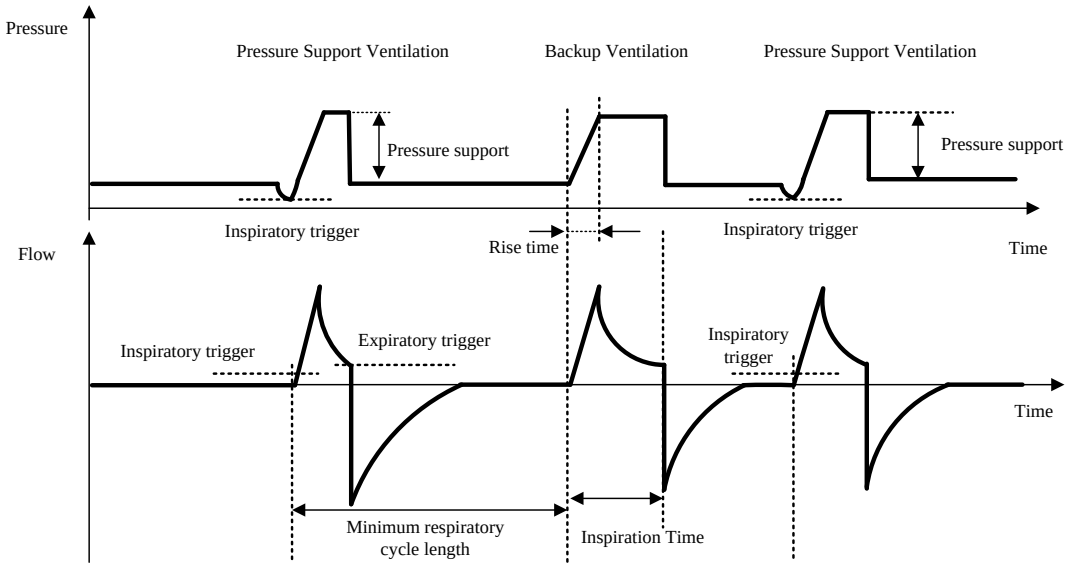
The basic ventilation parameters required under APRV mode are:

1. [**O_2%**]	O_2 concentration
2. [**Phigh**]	High pressure
3. [**Plow**]	Low pressure
4. [**Thigh**]	High pressure time
5. [**Tlow**]	Low pressure time
6. [**Tslope**]	The time with which airway pressure builds toward a preset value.
7. [**F-Trig**]	Inspiratory trigger level
8.[**TV apnea**] (available only in invasive mode) or [Δ**Papnea**]	Tidal volume during apnea ventilation cycle or inspiratory pressure during apnea ventilation cycle.
9.[**fapnea**]	Respiratory frequency during apnea ventilation
10. [**ApneaTinsp**] or [**Apnea I:E**]	Inspiratory time or ratio of inspiratory time to expiratory time during apnea ventilation

8.6.11 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 rising 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 present level within the preset time of pressure rising (Tslope), and maintains 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), mandatory ventilation is started automatically. The mandatory ventilation cycle is determined by the preset [f] And [Tinsp]. When the system detects patient trigger within the preset maximum breathing cycle (60s/RR), the system starts pressure ventilation.



The basic ventilation parameters required under APRV mode are:

1. [**O_2%**] O_2 concentration
2. [**ΔPsupp**] Support pressure delivered by ventilator
3. [**f**] Respiratory frequency
4. [**Tinsp**] Inspiratory time
5. [**PEEP**] Positive end-expiratory pressure
6. [**Ti max**] Maximum time of inspiratory phase (only for ventilation cycle)
7. [**F-Trig**] Trigger level
8. [**Exp%**] Percentage of Expiratory Trigger
9. [**Tslope**] The time with which airway pressure builds toward a preset value.

8.7 O_2 Therapy

O_2 therapy (oxygen therapy), also known as supplemental oxygen, refers to the method of increasing the oxygen concentration into the airway under a normal pressure through a simply connected pipeline. O_2 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). O_2 therapy is a method for preventing or curing hypoxia. The oxygen concentration provided is higher than that of air.

⚠ WARNING

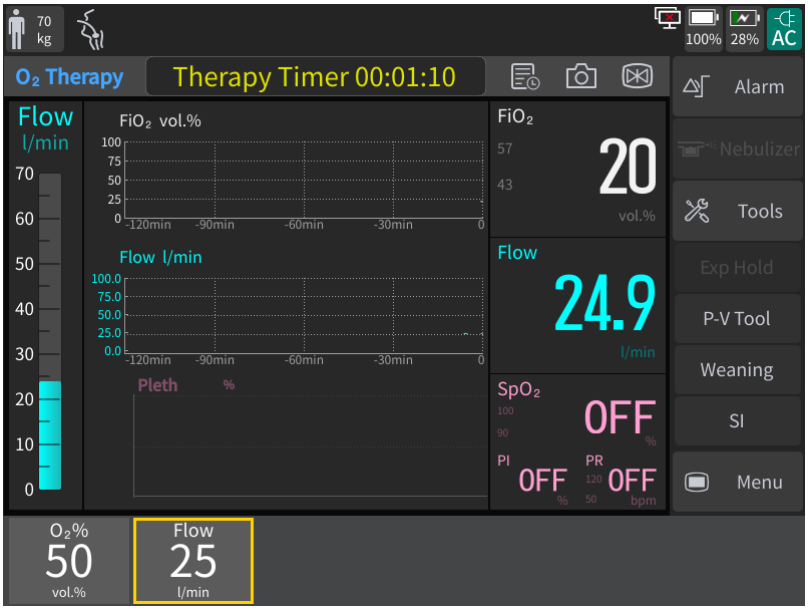
- **When connected to low-pressure O_2 supply, O_2 therapy is disabled.**
- **O_2 therapy can only be used for patients with regular spontaneous respiration.**
- **During oxygen therapy, only the inhaled oxygen concentration and oxygen flow rate are monitored.**
- **During oxygen therapy, all physiological 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 monitered during O_2 therapy.**
- **For patients requiring increased oxygen concentration for treatment, SpO_2 monitoring equipment should be used. Otherwise, the deterioration of the patient's condition may not be**

effectively recognized.

- **Only oxygen mask or nasal cannula 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 supply may cause inaccurate control of oxygen concentration.**

8.7.1 Entering O_2 Therapy Interface

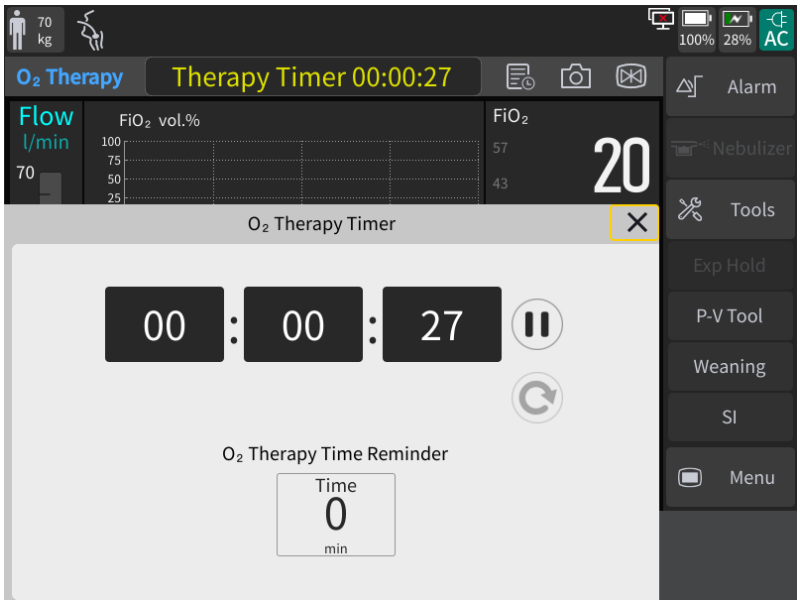
1) In the Standby interface, touch the ventilation mode setting area and select the [**O_2 Therapy**] key in the ventilation mode setting interface, a prompt message is displayed on the screen [**Start O_2 Therapy for spontaneous breathing patient with an oxygen mask or a nasal cannular.**]. Touch the [**Start**] key to enter the oxygen therapy interface. After entering the interface, the system prompt area in the upper right corner displays [**In O_2 Therapy, click Standby to exit!**].
2) Set [**Flow**] and [**O_2%**] with proper values as needed.



8.7.2 O_2 Therapy Timer

In the O_2 therapy interface, select 

to enter the [**O_2 Therapy Timer**] interface.



Touch or key to stop or start the timer. Touch the key to reset the displayed time to zero. Set the remaining time in [**O_2 Therapy Time Reminder**]. When the scheduled time is up, a prompt tone will be issued by the system and the oxygen supply will not be interrupted at this time.

8.7.3 Turning Off the O_2 Therapy Function

During O_2 therapy, press the key and enter the Standby interface after confirmation, the O_2 therapy function will be turned off.

8.8 Alarm Limit Setting

Select the [**Alarm**] key to open the alarm menu, then select the [**Alm Limit**] key and set the alarm limits of [**Paw**], [**MV**], [**ftotal**], [**TV**] and [**Tapnea**] as required.

If your ventilator is equipped with CO_2 module and SpO_2 module, you can also set the alarm limits of $FiCO_2$, $EtCO_2$, SpO_2 and PR in [**SpO_2 Alm**] and [**CO_2 Alm**].

You can also set volume for alarms in [**Alm Volume**].

8.9 Starting Ventilation

To start ventilation, select the [**Start Ventilation**] key 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, switch to use manual ventilation immediately.**

8.10 Ventilation Parameters

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. Integral O_2 monitoring unit is provided and it is suggested to turn the O_2 monitoring on during ventilation.**

NOTE

- **All parameters are calculated using real-time flow and pressure waveform data. 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 and related calculation parameters displayed on the ventilator are in the BTPS condition.**

Ventilator Control Parameters	Introduction
TV (Tidal Volume)	The volume inspired or expired with each breath of the patient at rest.
O_2% (O_2 Concentration)	The volume percentage of oxygen in the gas delivered to the patient, not activated when using low-pressure oxygen.
ΔPinsp (Inspiratory Pressure)	Inspiratory pressure in pressure-controlled mode, which is an absolute value relative to PEEP.
Δ Psupp (Support Pressure)	The value relative to positive end-expiratory pressure in the pressure support ventilation mode.
PEEP (Positive End-Expiratory Pressure)	The measured circuit pressure at the end of the expiratory phase of a breath, which is the baseline pressure for expiratory phase.
Tinsp (Inspiratory Time)	The inhaling time within a breathing cycle.
I:E	Ratio of inspiratory time to expiratory time.
f (Respiratory Frequency)	Number of breaths per minute.
Phigh (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.
Plow (Low Pressure Level)	The pressure level in the low-pressure phase, which allows the patient to breathe spontaneously during the low-pressure phase.
Thigh (Time of High Pressure)	The time length over which the high pressure is maintained.
Tlow (Time of Low Pressure)	The time length over which the low pressure is maintained.
Tslope (Rise Time)	The time required for the inspiratory pressure to rise to the set (target)

	pressure.
Assist Trig	Assist Trigger
F-Trig (Flow Trigger)	When the ventilator detects the trigger level, it enters the inspiratory phase.
Exp% (Expiratory Trigger Sensitivity)	At the end of inspiratory level, when the inspiratory flow drops to (peak flow * Exp%), the ventilator switches to expiratory phase.
Timax (Maximum Inspiratory Time)	Maximum inspiratory time of flow-switching ventilation in non-invasive mode.
TVapnea (Tidal Volume of Apnea Ventilation)	When apnea ventilation is volume-controlled, the tidal volume delivered in apnea ventilation.
ΔPapnea (Inspiratory Pressure of Apnea Ventilation)	When apnea ventilation is pressure-controlled, the inspiratory pressure of apnea ventilation, which is an absolute value.
fapnea (Frequency of Apnea Ventilation)	Respiration frequency set in apnea ventilation mode.
Apnea I:E (Inspiratory Time : Expiratory Time in apnea ventilation mode)	I:E in apnea ventilation mode.
Apnea Tinsp (Apnea Inspiratory Time)	Inspiratory time set in apnea ventilation mode.
Flow (Oxygen Therapy Flow)	Flow rate set in oxygen therapy mode.
Sigh	Used to turn on or off the sigh function. Under pressure alarm limit, ventilation 10 cmH_2O higher than sigh-free ventilation is delivered at every 50 breathing cycles, to increase the tidal volume. During sigh ventilation, Duovent and APRV mode are not applicable.
Apnea Vent (Apnea Ventilation)	Used to turn on or off apnea ventilation function.

Ventilator Monitoring Parameters	Introduction
FiO_2 (Fraction of Inspired Oxygen)	Fraction of Inspired Oxygen
Ppeak (Peak Pressure)	Peak airway pressure. The highest pressure during the previous breath cycle. It is influenced by airway resistance and compliance. Ppeak may differ noticeably from alveolar pressure if airway resistance is high. This value is always displayed.
Pplat (Plateau Pressure)	Plateau or end-inspiratory pressure. The pressure measured at the end of inspiration when flow is at or close to zero. Used as a rough representation of alveolar pressure. Pplat is displayed for mandatory and time-cycle breaths.
Pmean (Mean Pressure)	Mean airway pressure. The absolute pressure, averaged over the breath cycle. Pmean is an important indicator of the possible impact of applied positive pressure on hemodynamics and surrounding organs.
PEEP (Positive End-Expiratory Pressure)	The measured circuit pressure at the end of the expiratory phase of a breath, which is the baseline pressure for expiratory phase.
TVi (Inspired Tidal Volume)	Inspired tidal volume, the volume delivered to the patient, determined from the flow sensor measurement. If there is a gas leak on the patient side, the displayed TVi may be larger than the displayed TVe.
TVe (Expired Tidal Volume)	Expired tidal volume, the volume exhaled by the patient. It is determined from the flow sensor measurement, so it does not show any volume added due to compression or lost due to leaks in the breathing circuit. If there is a gas leak on the patient side, the displayed TVe may be less than the tidal volume the patient actually receives.
TVe spn (Spontaneous Expired Tidal Volume)	Spontaneous expired tidal volume, the volume exhaled by the patient. If there is a gas leak on the patient side, the displayed TVe spn may be less than the tidal volume the patient actually receives. Only displayed for spontaneous breaths.
MV (Minute Volume)	The moving average of the monitored expiratory volume per minute for spontaneous breaths, over the last 6 mandatory and spontaneous breaths.
MVspn (Spontaneous Minute Volume)	Accumulated spontaneous expired tidal volume in one minute.
MVleak (Leakage Minute Volume)	Accumulated leakage in one minute.
Vleak% (Percentage of Leakage)	Percentage of Leakage

TVe/IBW (Tidal Volume Per Ideal Body Weight)	Tidal volume is calculated according to ideal body weight (IBW) for adult/pediatric patients and according to the actual body weight for infant patients.
I:E (Inspiratory Time : Expiratory Time)	Ratio of inspiratory time to expiratory time.
Tinsp (Inspiratory Time)	In mandatory breaths, Tinsp is measured from the start of breath delivery until the set time has elapsed for switch to exhalation. In spontaneous breaths, Tinsp is measured from patient trigger until the flow falls to Exp% setting for the switch to exhalation. Tinsp may differ from the set inspiratory time if the patient breaths spontaneously.
Texp (Expiratory Time)	In mandatory breaths, Texp is measured from the start of exhalation until the set time has elapsed for switch to inspiration. In spontaneous breaths, Texp is measured from the start of exhalation, as dictated by the Exp% setting, until the patient triggers the next inspiration. Tinsp may differ from the set expiratory time if the patient breaths spontaneously.
ftotal (Total Breathing Frequency)	The moving average of the patient's total breathing frequency per minute over the last 8 breaths, including both mandatory and spontaneous breaths. When the patient triggers a breath or the operator initiates a breath, ftotal may be higher than the rate setting.
fspn (Spontaneous Frequency)	The moving average of spontaneous breaths per minute over the last 8 total breaths.
fmand (Mandatory Frequency)	The moving average of mandatory breaths per minute over the last 8 total breaths.
fspn% (Spontaneous Breath Percentage)	Spontaneous Breath Percentage
Rinsp (Inspiratory Resistance)	Resistance to inspiratory flow caused by the endotracheal tube and the patient's airways during inspiration. Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements.
Rexp (Expiratory Resistance)	Resistance to inspiratory flow caused by the endotracheal tube and the patient's airways during expiratory.
PIF (Peak Inspiratory Flow)	Peak inspiratory flow, spontaneous or mandatory. Measured every breath.
PEF (Peak Expiratory Flow)	Peak Expiratory Flow
Cstat (Static Compliance)	Static compliance of the respiratory system, including lung and chest wall compliances, calculated using the LSF method. Cstat can help diagnose changes in elastic characteristics of the patient's lungs. Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements.
Cdyn (Dynamic Compliance)	The ease of filling the patient's lungs in mandatory breath, calculated

	during expiration.
RSBI (Rapid Shallow Breathing Index)	Rapid shallow breathing index. The total breathing frequency divided by the exhaled tidal volume. Because patients with dyspnea breathe faster and shallower, they have higher RSBI; those without dyspnea have lower RSBI. RSBI is commonly used clinically as an indicator of whether ventilator patients can be weaned. RSBI is important only for patients who breathe autonomously, and is therefore shown only when 80% of the past 25 breaths are spontaneous.
PTP (Pressure-time Product)	The product of measured pressure decrease required to trigger the breath and the time interval from the beginning of inspiration until the PEEP/CPAP level is reached. PTP is valid for patient-initiated breaths only, and indicates work by the patient to trigger the breath. PTP does not indicate total patient work but is a good indicator of how well the ventilator is adjusted for the patient.
RCexp (Expiratory Time Constant)	RCexp is calculated as the ratio between TVe and flow at 75% of the TVe.
PEEPi (Intrinsic PEEP)	Intrinsic PEEP
P0.1 (100ms Occlusion Pressure)	It's the pressure decrease during the first 100ms when a breath is trigged. P0.1 indicates the patient's respiratory drive and patient inspiration effort.
RSS	The product of oxygen concentration and the average pressure.
$EtCO_2$ (End-tidal Carbon Dioxide)	End-tidal Carbon Dioxide
$FiCO_2$ (Inspired Carbon Dioxide)	Inspired Carbon Dioxide
VDaw (Airway Dead Space)	Gives an effective, in-vivo measure of volume lost in the conducting airways. A relative increase in dead space points to a rise in respiratory insufficiency and can be regarded as an indicator of the current patient situation. Patients with high dead space values are at particular risk if the muscles also show fatigue.
VDaw/TVe (Ratio of Airway Dead Space to Tidal Volume)	Airway dead space fraction at the airway opening.
VCO_2 (CO_2 Elimination)	Net exhaled volume of CO_2 in a single breath. Permits assessment of metabolic rate and treatment progress.
Vtalv (Alveolar Tidal Ventilation)	Alveolar tidal ventilation
MValv (Alveolar Minute Ventilation)	Permits assessment of actual alveolar ventilation (as opposed to minute ventilation)
$MVCO_2$	Minute volume of expired CO_2
$VeCO_2$ (Exhaled CO_2 volume)	Exhaled CO_2 volume, updated breath by breath.

$ViCO_2$ (Inspired CO_2 volume)	Inspired CO_2 volume, updated breath by breath.
$slopeCO_2$ (CO_2 Rising Slope)	Slope of the alveolar plateau in the $EtCO_2$ curve, indicating the volume/flow status of the lungs.
SpO_2 (Arterial Oxygen Saturation from Pulse Oximetry)	Arterial oxygen saturation from pulse oximetry
PR (Pulse Rate)	Pulse Rate
PI (Perfusion Index)	Perfusion Index
SpO_2/FiO_2	Arterial oxygen saturation from pulse oximetry/Fraction of Inspired Oxygen
OSI	Oxygen Saturation Index
ROX	ROX Index

8.11 Standby Mode

WARNING

- **Before entering the Standby mode, make sure 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 the Standby mode.**

Press the hard key ⊙/Ó, a prompt message [**Enter the Standby Mode?**] is displayed on the screen. Select the [**OK**] key, and the ventilator enters the Standby interface and stop ventilation at this time.

8.12 Power Off the Ventilator

NOTE

- **The ventilator is still powered even when the system has been shut down, so as to continue recharging the battery. To completely disconnect the ventilator from power supply, remove the AC and DC power.**

In the Standby state, press and hold the hard key ⊙/Ó, the screen will prompt [**Power Off?**]. Touch the [**OK**] key and turn off the ventilator.

In the non-standby state, press the hard key ⊙/Ó, the screen will prompt [**Enter the Standby Mode?**]. Touch the [**OK**] key and the ventilator enters the Standby interface. Then press and hold the hard key ⊙/Ó, the screen will display [**Power Off?**]. Touch the [**OK**] key and turn off the ventilator.

Chapter 9 CO_2 Monitoring (Only for V1)

9.1 Overview

The Monitor 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 applies IR emission by using 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.

9.2 Safety Information

⚠ WARNING

- **Place sampling line and other tubes 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 has the automatic barometric pressure compensation function.**
- **Respironics and Comen CO_2 sensors have no function of barometric pressure compensation, and have been set with a fixed value before delivery. If the value needs updating due to altitude, contact the maintenance personnel.**
- **All parts or accessories except Respironics pathway adaptor do not contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic and mutagenic.**
- **Respironics pathway adaptor contains phthalates, such indication was marked on package.**
- **Take more care to the treatment of children and pregnant and nursing women, who may be allergy to such substance.**

⚠ CAUTION

- **When the patient is being treated with nebulized drugs, CO_2 cannot be measured. After the nebulization function is activated, sampling and monitoring of CO_2 modules will be suspended, the entire CO_2 module enters theStandby state. When the CO_2 module function is not turned on, the CO_2 module is in thestandby state. When the ventilator does not start the ventilation mode, the CO_2 module is in working state.**
- **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.**

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.**

9.3 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;
   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 O_2 concentration of the room air (water concentration: 0.7 vol%) (for example, 25℃ and 23% RH @ 1013hPa). The monitor displays the actual partial pressure at the current RH level when measuring the CO_2, N_2O 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 line 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 line 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

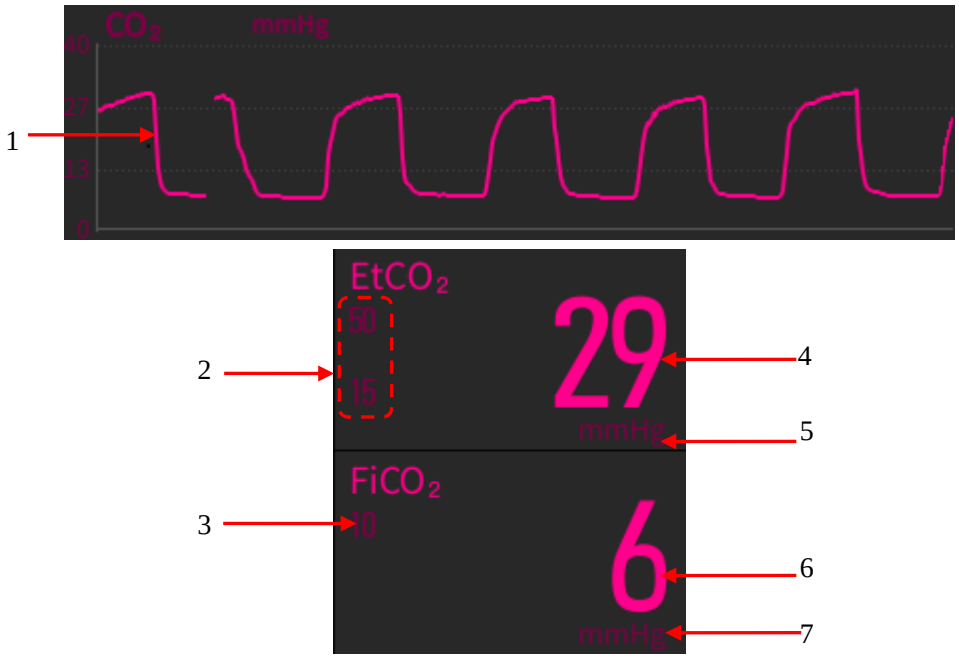
3.8: typical partial pressure [**kPa**] of the water vapor condensed between the patient circuit and ISA

$EtCO_2$ (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%	±1mmHg
Halothane	4 vol%	±1mmHg
Enflurane, Isoflurane, Sevoflurane	5 vol%	±1mmHg
Desflurane	15 vol%	±2mmHg
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 CO_2 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 CO_2 reading to decrease by 6%. That is, if you measure the gas mixture containing 5.0 vol% CO_2 and 50 vol% nitrogen, the measured CO_2 concentration will be usually (1-0.06) × 5.0 vol% = 4.7 vol%.		

9.4 CO_2 Display



1. CO_2 Waveform
2. $EtCO_2$ alarm limit
3. $FiCO_2$ alarm limit
4. $EtCO_2$ value
5. $EtCO_2$ unit: mmHg, kPa or %.
6. $FiCO_2$ value
7. $FiCO_2$ unit: mmHg, kPa or %.

9.5 CO_2 Measurement

⚠ WARNING

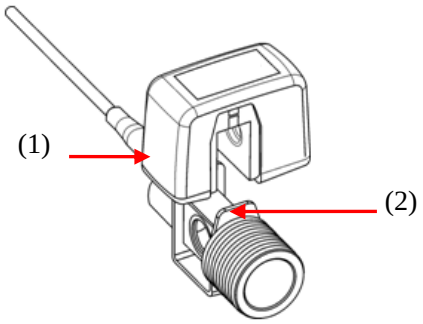
- **Check the airway adapter before use. Replace it if the airway adapter suffers from any exterior damage or breakage.**
- **Hang the external CO_2 analyzer onto the CO_2 sensor holder on the back housing of the device reliably against falling and damage.**
- **Make sure all connections are firm and reliable. Any leakage will cause the respiratory gas of the patient mixed with 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.**

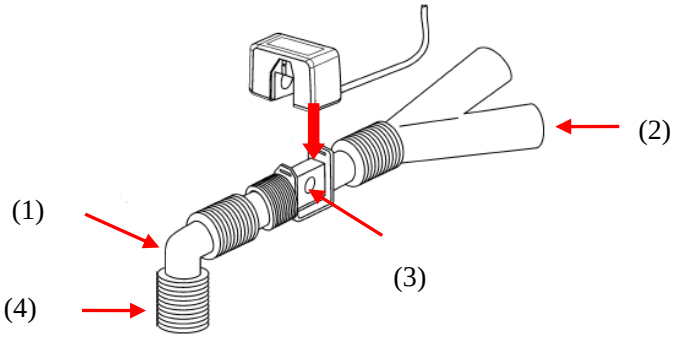
9.5.1 Preparation for Mainstream CO_2 Sensor Connection

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 2min (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 the [**Monitoring Switch**]. Refer to ***"Section 9.7.1 CO_2 Monitoring Setting"***.
6) For zeroing the sensor, refer to ***"Section 9.6.1 Zeroing Mainstream CO_2 Sensors"***.
7) Install the airway adapter onto one end of the breathing tube, between the breathing tube and the Y-shaped tube (see figure below).



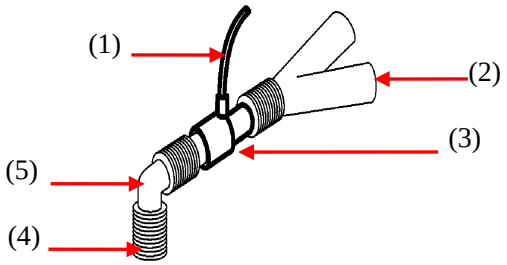
(1) Elbow tube (2) Y-shaped tube (3) Airway adapter (4) Breathing tube port

8) Make sure the airway is tight.
9) Set CO_2 parameters; please refer to ***"Section 9.7 CO_2 Setting"*** for more information.
10) Start measurement.

9.5.2 Preparations for Sidestream CO_2 Sensor Connection

9.5.2.1 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 clicking sound represents it is inserted correctly and locked in place.
5) Turn on the [**Monitoring Switch**]. Refer to **"*Section 9.7.1 CO_2 Monitoring Setting*"**.
6) Zero the sensor; please refer to ***"Section 9.6.2 Zeroing Respironics and Comen Sidestream CO_2 Sensors"*** for more information.
7) Set CO_2 parameters; please refer to ***"Section 9.7 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

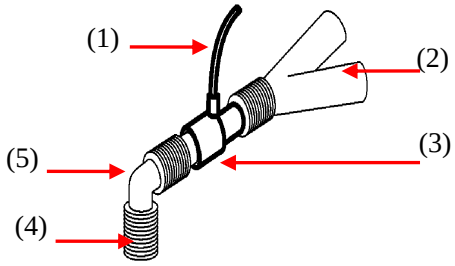
9) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O_2 cannula onto the patient's face, connect the O_2 supply tube to the O_2 supply system and set the O_2 flow as directed.
10) Start the measurement after confirming the airway tightness.

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.

9.5.2.2 Preparations for Masimo Sidestream CO_2 Sensor

1) Insert sampling line into the interface of CO_2 sensor reliably until you hear a clicking sound.
2) Wait for 10s until the sensor reaches its working temperature and a stable thermal state.
3) Turn on the [**Monitoring Switch**]. Refer to ***"Section 9.7.1 CO_2 Monitoring Setting"***.
4) Zero the sensor; please refer to ***"Section 9.6.2 Zeroing Respironics and Comen Sidestream CO_2 Sensors"*** for more information.
5) Check before its use; please refer to ***"Section 9.5.2.3 Pre-use Checks"*** for more information.
6) Set CO_2 parameters; please refer to ***"Section 9.7 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.

9.5.2.3 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 [**CO_2 Sampleline Blocked**] 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

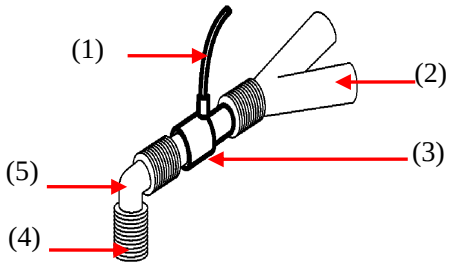
- **Place the IRMA sensor, if not protected by HME, with the status LED pointing up.**
- **Do not stretch the cable of the ISA sidestream gas analyzer.**
- **Operate the ISA sidestream gas analyzer in the specified working temperature environment only.**

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.**

9.5.2.4 Preparations for Comen Sidestream CO_2 Sensor

1) Insert CO_2 cable to the monitor's CO_2 interface.
2) Wait for 2min until the sensor reaches its working temperature and a stable thermal state.
3) Insert the sampling line into the interface of CO_2 sensor reliably until you hear a clicking sound.
4) Turn on the [**Monitoring Switch**]. Refer to ***"Section 9.7.1 CO_2 Monitoring Setting"***.
5) Zero the sensor; please refer to ***"Section 9.6.2 Zeroing Respironics and Comen Sidestream CO_2 Sensors"*** for more information.
6) Set CO_2 parameters; please refer to ***"Section 9.7 CO_2 Setting"*** 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

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) Start the measurement after confirming the airway tightness.

9.6 Zeroing CO_2 Sensor

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.

9.6.1 Zeroing 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 the [**Menu**] key→[**Settings**]→ [**CO_2**] → Turn on the [**Monitoring Switch**].
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 the [**Menu**] key→[**Settings**]→ [**CO_2**] →[**Zeroing**], then a prompt [**CO_2 Zeroing…**] will be displayed.

9.6.2 Zeroing Respironics and Comen Sidestream CO_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 the [**Menu**] key→[**Settings**] → [**CO_2**] →Turn on the [**Monitoring Switch**].
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 the [**Menu**] key→[**Settings**]→ [**CO_2**] → [**Zeroing**], then a prompt [**CO_2 Zeroing…**] will be displayed.

NOTE

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

9.6.3 Zeroing Masimo Sidestream CO_2 Sensors

For Masimo sidestream CO_2 module, when you detach the sampling line from the device, the module would start the zeroing procedure. When the zeroing is successfully completed, a prompt [**Zeroing Succeeded**] is displayed.

9.7 CO_2 Setting

9.7.1 CO_2 Monitoring Setting

1) Select the [**Menu**] key → [**Settings**] → [**CO_2**].
2) Select the [**Monitoring Switch**] key.

◆ When the [**Monitoring Switch**] is set to ONHEPA Filter, CO_2 module will enter the working mode, CO_2 parameters and waveform will be displayed and physiological and technical alarms related to CO_2 module will be provided by the device.

◆ When the [**Monitoring Switch**] is set to OFF, CO_2 module will enter Standby Mode, physiological alarms related to CO_2 module will not be provided by the device.

The standby 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 standby mode.

■ If the device exits the Standby mode, then the CO_2 module returns to its previous mode before the device enters the standby mode.

■ The ventilator is not influenced when the CO_2 module enters or exits the standby mode.

In Standby 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.

9.7.2 CO_2 Alarm Setting

1) Select the [**Alarm**] key → [**CO_2 Alm**]
2) Set $EtCO_2$ and $FiCO_2$ alarm limit.

9.7.3 Gas Compensation Setting

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 the [**Menu**] key → [**Settings**] → [**CO_2**].
2) Set [**O_2 Compensation**]:

◆ **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.**

9.7.4 CO_2 Unit Setting

1) Select the [**Menu**] key → [**System**] →input the System Password → [**Settings**].
2) Set [CO_2 Unit]: mmHg, kPa or %.

9.7.5 Altitude Setting

For MASIMO CO_2 module, there is no need to set the altitude manually since it is set automatically.
For RESPIRONICS and COMEN CO_2 modules:

1) Select the [**Menu**] key→[**Settings**]→ [**CO_2**].
2) Set [**Altitude Unit**].
3) Set [**Altitude**] and [**Baro Press**]: barometric pressure will be displayed automatically based on the altitude value set.

Altitude, Barometric Pressure & $ETCO_2$ Table

Altitude		**Barometric Pressure**	**5% CO_2**
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 barometric pressure and temperature of the sea level is 760mmHg and 0℃, and that the ambient temperature is 0℃ when calculating barometric pressure based on altitude. 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).**

9.8 Information on MASIMO Module

9.8.1 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

9.8.2 Safety Information

9.8.2.1 Sidestream Gas Module

⚠ 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 tubes 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 block the bacteria filter.**
- **Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), 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 [CO_2 Tube Blocked] 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.**

9.8.2.2 Mainstream Gas Module

⚠ 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 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 biohazards 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.**

9.8.3 Airway Blockage

When the sidestream module gas airway is blocked, a prompt [**CO_2 Tube Blocked**] will be displayed; under such a circumstance, replace the Nomoline sampling line.

9.8.4 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 tube 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 tube tightly to the exhaust port.
5) Wait 1 minute until the CO_2 concentration has stabilized. Note the value.
6) Wait 1 minute and check whether the CO_2 concentration has 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.

9.8.5 Safety Symbols

Symbol	Text, Color Code and Text Format	Description
	Warning: additional information.	"Warning" indicates the hazardous conditions causing possible personal injuries or deaths. 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 monitor after the 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 monitor shall be sold by medical practitioners or on prescription according to U.S. federal laws.
CO_2	CO_2	The IRMA/ISA analyzer measures CO_2 only.
CO_2	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.
NON-STERILE LATEX FREE	Not sterile, latex free	The monitor is latex free and not sterile.

9.8.6 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.

9.8.7 Consumables

9.8.7.1 ISA Nomoline Family

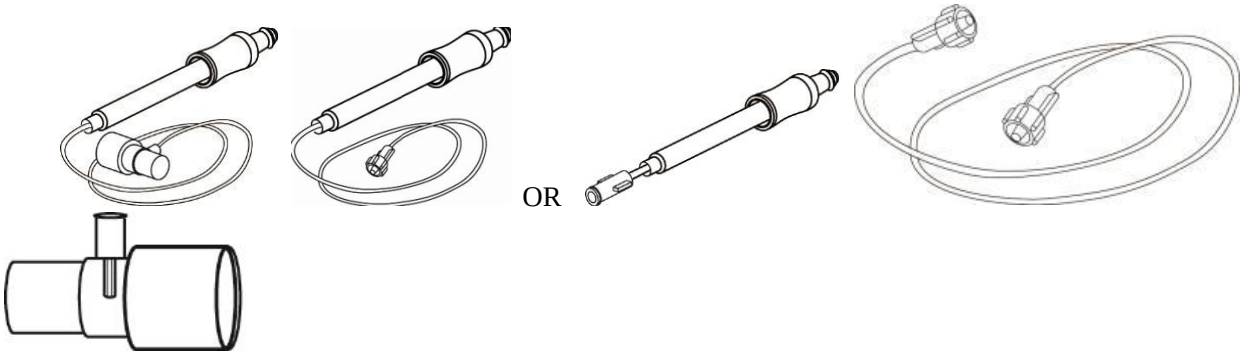
ISA samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric and infant patients.

The Nomoline Family sampling linesincorporate 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 line is 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 reusable configurations. 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 reusable Nomoline Adapter and a disposable Nomoline Nasal CO_2 Cannula (with Luer Connector) can be applied.



The disposable Nomoline Airway Adapter Set is an alternative to the combination of the reusable Nomoline 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 line bloakage (see below)

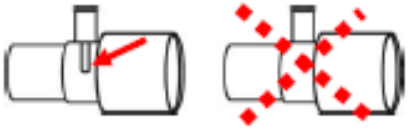


Fig 9-7T-adapters

Fig 9-1*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 an inner diameter larger 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 blocked. Blockage occurs when water, secretion etc. is aspired from the respiratory circuit to such extent that ISA cannot maintain the normal 50 ml/min sample flow. This situation is indicated by a red flashing gas inlet connector and an alarm message [**Samplingline Blocked**]; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

9.8.7.2 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 adults/pediatric

patients and infants. 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: Adults/Pediatric Patients (REF: 106220) and Infants (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.**

9.8.8 Maintenance

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

Chapter 10 SpO_2 Monitoring

10.1 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 patient's pulse count per minute;

PI (perfusion index, not for Nellcor SpO_2): pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal.

⚠ WARNING

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

10.1.1 Identification of SpO_2 Sensor Type

The SpO_2 sensor type is pre-configured before the ventilator is delivered. You can identify it based on the silkscreened logo beside the original SpO_2 sensor below the right 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.

◆ Nellcor SpO_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 Nellcor SpO_2 sensor can measure a wavelength of 660nm (red LED) or 900nm (IR LED).
◆ The maximum optical output power of the sensor is lower than 15mW.

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 monitor and its supporting SpO_2 sensor and sensor extension cord have been tested for compliance with ISO 80601-2-61.**

10.2 Safety Instructions

WARNING

- **The ventilator is only compatible with the SpO_2 sensor designated by Comen.**
- **Before monitoring the patient, check that sensor and extension cord are compatible with the ventilator. Incompatible accessories reduce the performance of the ventilator.**
- **Before monitoring the patient, check that sensor cable works properly. Remove the SpO_2 sensor cable from the sensor interface and the monitor displays the prompt message [SpO_2 Sensor Off Finger] and triggers the alarm audio.**
- **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 and 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 when the skin quality decreases). Perform such check frequently if necessary (subject to the condition of the patient).**
- **Make sure that sensor cable and the electrosurgical equipment cable are not intertwined.**
- **Do not place the sensor on a limb with ducts arteriosus 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** setting **has been 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 air or 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:**
  - **Avoid placing the device on surfaces with visible liquid spills.**
  - **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 thalassemia, Hb s, Hb c, 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 electro cautery, 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.**
- **Do not apply a catheter or sensor cable on the position incurring tangle or compression.**
- **It is recommended to perform SpO_2 monitoring in the temperature of 0-40℃, otherwise the accuracy of SpO_2 measurement may be inaccurate.**
- **Don't clip oxygen saturation probe on the same position for long period.**
- **The patients who are allergic to the rubber materials shall not use it.**

⚠ CAUTION

- **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 oximetry 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 oximeter equipment.**
- **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.**
- **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.**

NOTE

- **High-intensity extreme lights (such as pulsating strobe lights) directing on the sensor, may not allow the pulse oximeter to provide vital sign readings.**
- **Make sure your nails block the light inside the probe. The probe cable should be placed on the back of the hand.**
- **Do not place the blood oxygen probe and blood pressure cuff blood pressure measurement on the same limb, because blood flow occlusion during blood pressure measurement will affect the blood oxygen saturation reading.**
- **The displayed SpO_2 waveform is normalized.**
- **The pulse oximeter device is calibrated to display functional blood oxygen saturation.**
- **Confirmation of the accuracy of blood oxygen measurement: The accuracy of Masimo SpO_2 has been confirmed in comparison with the reference value of arterial blood samples measured by CO-oxygen manometers in human experiments. The pulsation oximeter measurement results conform to the statistical distribution. Compared with the CO-oximeter measurement results, it is expected that about two-thirds of the measurement results will fall within the specified accuracy range.**
- **Masimo blood oxygenation has induced a hypoxic state in human blood with a SpO_2 of 70% to 100% in healthy adult volunteers. By comparing with the laboratory combined photoelectric oximeter and high flow respiratory humidification therapy device, it passed no exercise Verification of accuracy. This difference is equivalent to adding or subtracting one standard deviation. Adding or subtracting one standard deviation will include 68% of the sample.**
- **Masimo blood oxygenation has been verified by exercise accuracy in human blood studies in which healthy adult volunteers perform friction or light buckle exercise at a frequency of 2 to 4 Hz to induce hypoxia. With an amplitude of 1 to 2 cm and a non-repetitive motion of 1 to 5 Hz. Compared with laboratory combined photoelectric oximeter and high-flow respiratory humidification therapy device, the induction of low (SpO_2 range of 70% to 100%) is 2 to 3 cm. This difference is equivalent to adding or subtracting one standard deviation. Adding or subtracting one standard deviation will include 68% of the sample.**

10.3 Masimo SpO_2 Specific Information

CAUTION

- **If the Low Perfusion message is frequently displayed, find a better perfusion 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 firstly tried don't work when a low SIQ message is displayed in the process of consistently monitoring patients, after completing troubleshooting steps listed in this manual.**

NOTE

- **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 may 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.**

10.4 SpO_2 and PR Accuracy Test

Functional test equipment or SpO_2 simulator cannot be used to verify the accuracy of SpO_2 monitor and pulse oximeter sensor. Assess the SpO_2 measurement functionality 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.**

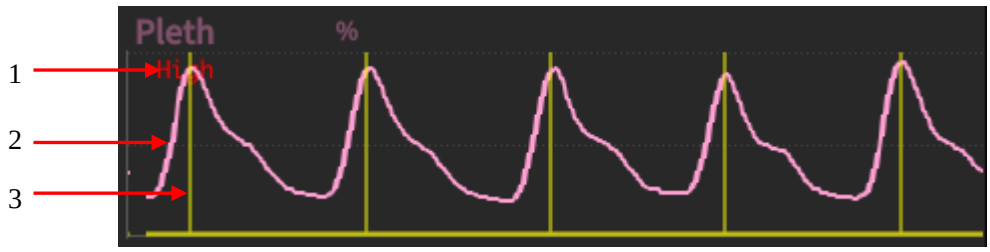
10.5 Measurement Restriction

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

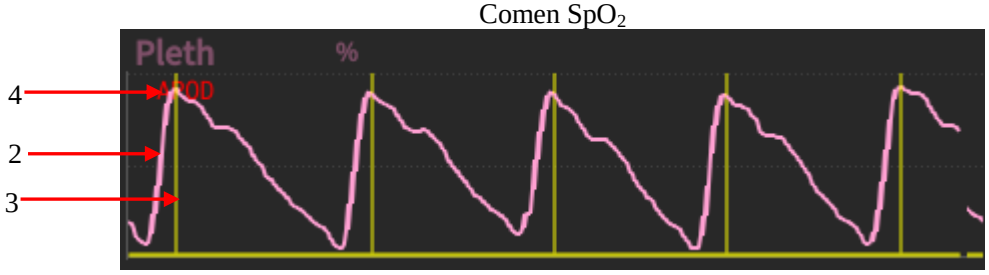
1) High-frequency radio interference, whether from the ventilator or the electrosurgical equipment connected to the ventilator. To minimize radio interference, other electrical equipment that emits high-frequency transmission should not be in close proximity to the ventilator.
2) Do not use the oximeter or SpO_2 sensor during MRI 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 (optimum temperature: 28℃~42℃).
8) The sensor is placed on a limb with blood pressure cuff, ductus arteriosus 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.

10.6 SpO_2 Display

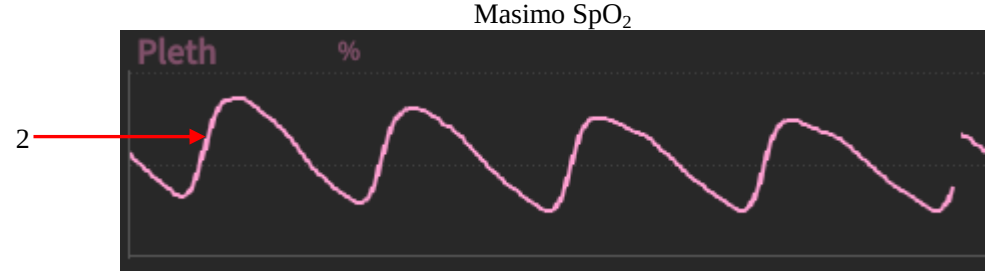
1) Waveform display:



Comen SpO_2



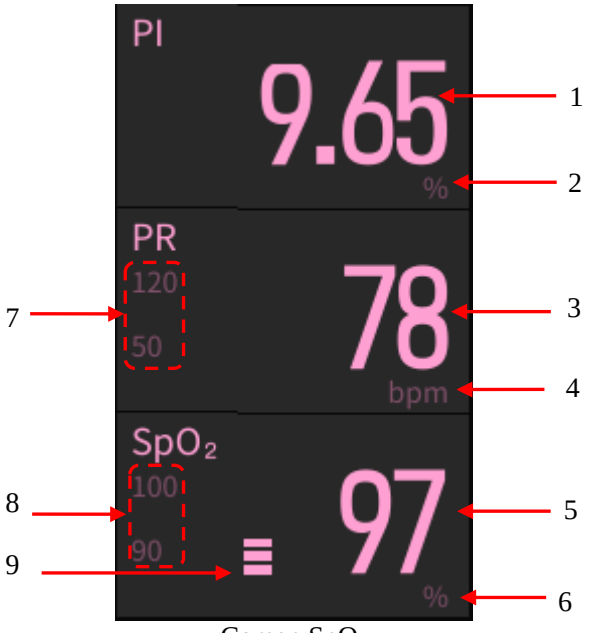
Masimo SpO_2



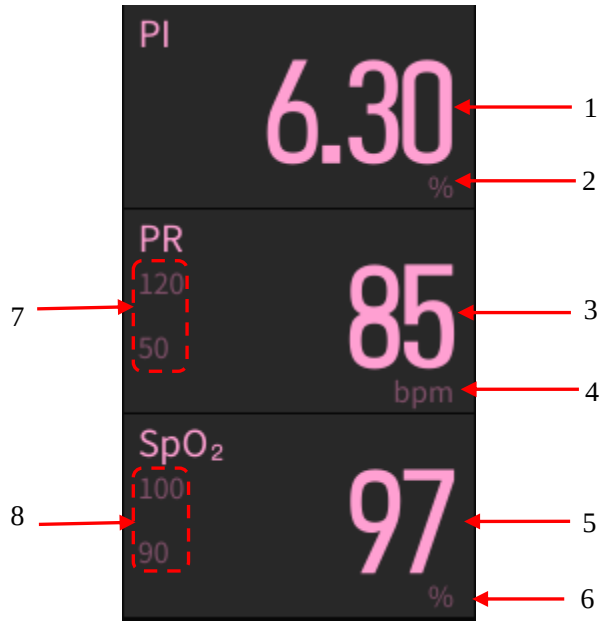
Nellcor SpO_2

1. Comen SpO_2 average time
2. SpO_2 waveform
3. Bar graph (Signal Identification and Quality) (For Masimo and Comen SpO_2): proportional to the pulse adequacy.
4. Masimo SpO_2 sensitivity

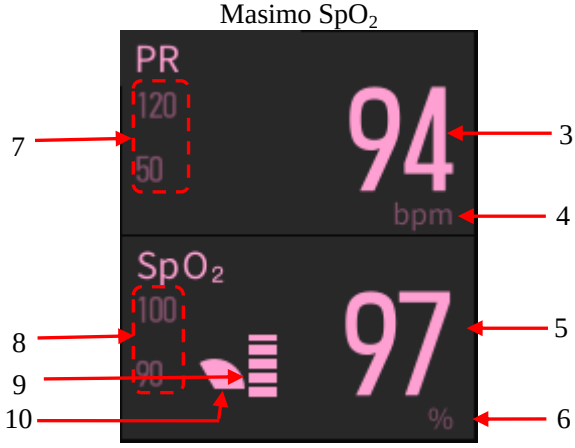
2) Value display:



Comen SpO_2



Masimo SpO_2



Nellcor SpO_2

1. PI value
2. PI unit
3. PR value
4. PR unit
5. SpO_2 value: The display will show dashed lines when the probes are not connected or technical failure occurs. When the displayed SpO_2 value is potentially incorrect (such as [**Weak SpO_2 Signal**]), a symbol ? would appear next to the SpO_2 value.
6. SpO_2 unit
7. PR alrm limit
8. SpO_2 alarm limit
9. Pulse amplitude indicator (blip bar) (For Comen and Nellcor SpO_2): Indicates pulse beat and shows the relative pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.
10. SatSeconds Indicator or (For Nellcor SpO_2): Fills in clockwise as the SatSeconds alarm management system detects a $\%SpO_2$ reading outside of the limit setting. Empties in counterclockwise direction when $\%SpO_2$ reading is within limits. When the indicator is full, a medium or high priority alarm is triggered.

10.7 Monitoring Steps

WARNING

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

10.7.1 Comen SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the patient type.
2) Insert SpO_2 cable connector into the SpO_2 interface of the ventilator.
3) Fix the sensor to an appropriate position on the patient. Please refer to **"*Section 10.8 Placement of SpO_2 Sensor*"** for more information.

10.7.2 Masimo SpO_2 &Nellcor SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the module type and patient type.
2) Connect SpO_2 patch cord to SpO_2 sensor.
3) Insert the other end of SpO_2 patch cord into the SpO_2 interface of the ventilator.
4) Fix the sensor to an appropriate position on the patient. Please refer to **"*Section 10.8 Placement of SpO_2 Sensor*"** for more information**.**

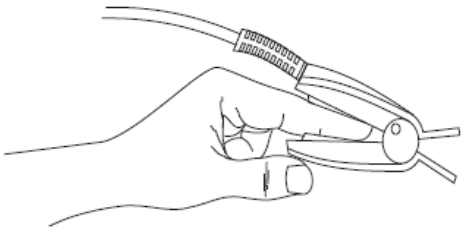
10.8 Placement of SpO_2 Sensor

WARNING

- **Check the patient's skin approximately 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.**

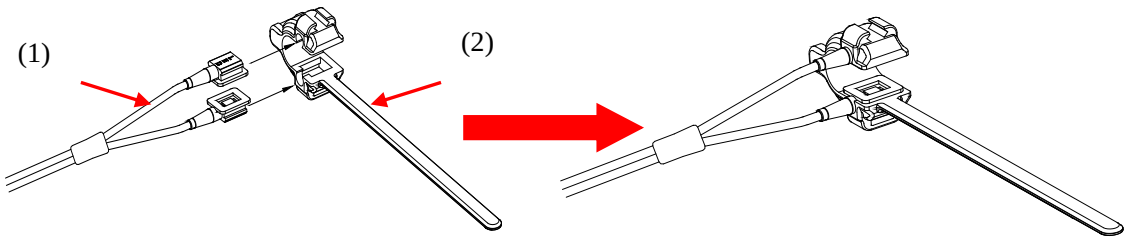
10.8.1 Placement of ADU SpO_2 Sensor

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



10.8.2 Placement of PED SpO_2 Sensor

1) Assembly of 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 SpO_2 sensor sheath, as shown in the figure below:



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

2) Placement of SpO_2 sensor: fix it on the finger of a pediatric patient.

10.8.3 Placement of Disposable SpO_2 Sensor

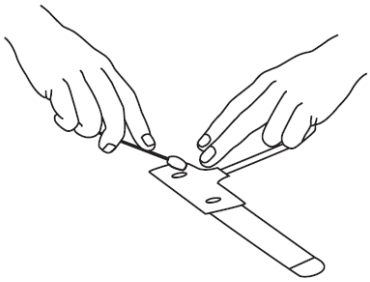


Fig. 1

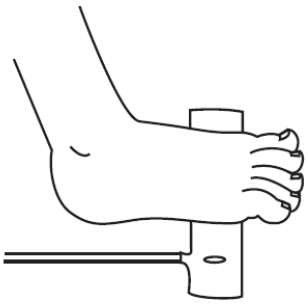


Fig. 2

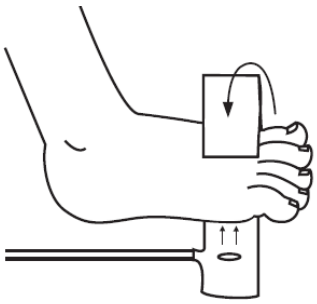


Fig. 3

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).

10.9 SpO_2 Setting

10.9.1 Turning on the SpO_2 and PR Alarm

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

: Alarm on.
: Alarm off.

10.9.2 SpO_2 Alarm Priority Setting

1) Select the [**Alarm**] key → [**SpO_2 Alarm**].
2) Set the SpO_2 alarm priority.

10.9.3 PR Alarm Priority Setting

1) Select the [**Alarm**] key → [**SpO_2 Alarm**].
2) Set the PR alarm priority.

10.9.4 SpO_2 Alarm Limits Setting

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

10.9.5 PR Alarm Limits Setting

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

10.9.6 Waveform Speed Setting (Only for Masimo SpO_2)

1) Select the [**Menu**] key→ [**Settings**] → [**SpO_2**].
2) Turn on the [**Monitoring Switch**] and set [**Speed**] to the appropriate value.

10.9.7 Sensitivity Setting (Only for Masimo SpO_2)

[**Sensitivity**] can be set to [**Normal**], [**High**] or [**APOD**] (Adaptive Probe Off Detection). [**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**].

Set [**Sensitivity**]:

1) Select the [**Menu**] key→[**Settings**]→[**SpO_2**]
2) Select an appropriate [**Sensitivity**]: [**Normal**], [**High**] or [**APOD**].

10.9.8 Intelli Pulse Tone Setting (Only for Masimo SpO_2)

You will (will not) hear the pulse tone in case of unstable signal or ambient noise if this function is enabled (disabled).

Set [**Intelli Pulse Tone**]:

1) Select the [**Menu**] key→[**Settings**]→[**SpO_2**].
2) Switch on or off [**Intelli Pulse Tone**].

10.9.9 SatSeconds Alarm Setting (Only for Nellcor SpO_2)

1) Select the [**Menu**] key→[**Settings**]→[**SpO_2**].
2) Set the [**SatSeconds Alarm**]: [**10s**], [**25s**], [**50s**], [**100s**] or [**OFF**].

SatSeconds 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 the [**SatSeconds Alarm**] to [**50**] and the high/low 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 audio 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.

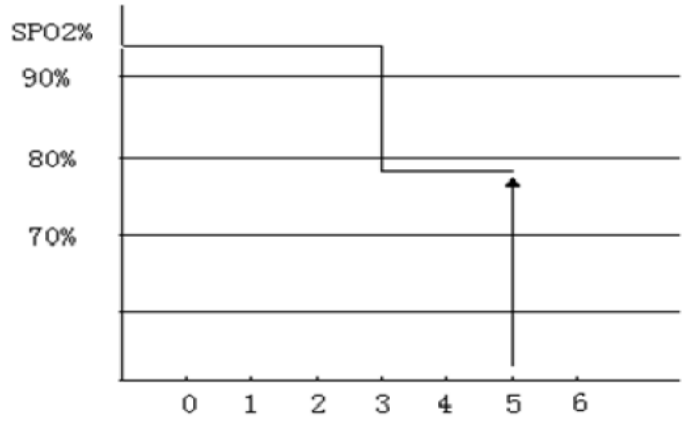
Calculation method:

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 the [**SatSeconds Alarm**] 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 SatSeconds limit is reached or the patient's SpO_2 value remains beyond the alarm limit.

10.9.9.1 Average Time Setting

The SpO_2 value displayed on the ventilator is the average of the SpO_2 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.

10.9.9.2 Masimo SpO_2 Average Time Setting

1) Select the [**Menu**] key→[**Settings**]→[**SpO_2**].
2) Set [**Average Time**]: [**2-4s**], [**4-6s**], [**8s**], [**10s**], [**12s**], [**14s**] or [**16s**].

10.9.9.3 Comen SpO_2 Average Time Setting

1) Select the [**Menu**] key→[**Settings**]→[**SpO_2**].
2) Set [**Sensitivity**]: [**High**], [**Medium**] or [**Low**].

10.9.9.4 Nellcor SpO_2 Average Time Setting

Nellcor SpO_2 average time is not adjustable, fixed at 11s.

10.9.10 Signal IQ Setting（Only for Comen SpO_2 and Masimo SpO_2）

The magnitude of the SpO_2 Signal IQ 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 will mark its location on the vertical line (signal indicator). The volume of the smart tone (if enabled) remains consistent with the vertical 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 the [**Menu**] key→[**Settings**]→[**SpO_2**].
2) Switch on or off [**Signal IQ**].

10.9.11 Fast Sat Setting（Only for Masimo SpO_2）

Fast Sat enables rapid response to and display of fast changes in SpO_2 by giving priority to the most recent data. This aids the clinician in clinical settings requiring fast response time such as those seen with induction, intubation, sleep studies and resuscitation.

1) Select the [**Menu**] key→[**Settings**]→[**SpO_2**].
2) Switch on or off the [**Fast Sat**].

10.10 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

10.11 Nellcor Information

1) Nellcor Patents

This device maybe covered by one or more of the following US Patents:

5,485,847; 5,676,141; 5,743,263; 6,035,223; 6,226,539; 6,411,833; 6,463,310; 6,591,123; 6,708,049; 7,016,715; 7,039,538; 7,120,479; 7,120,480; 7,142,142; 7,162,288; 7,190,985; 7,194,293; 7,209,774; 7,212,847; 7,400,919.

2) No Implied License Statement

Purchase of this instrument confers no express or implied license under any Covidien patentto use the

instrument with any pulse oximeter that is not manufactured or licensed by Covidien.

Chapter 11 Other Functions

11.1 Manual Ventilation

The ventilator provides manual ventilation function if you press and then release the Manual Ventilation/Inspiration hold  key during expiratory phase.

NOTE

- **If press Manual Ventilation/ Inspiration hold 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.**

11.2 Expiratory Hold

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

1) Select the [**Tools**] key → [**Basic**] → [**Exp Hold**].
2) Touch and hold the [**Exp Hold**] (Expiratory Hold) key. The ventilator will activate the expiratory hold function and prompts [**Exp Holding...**] (Expiratory Holding...).
3) Release the [**Exp Hold**] (Expiratory Hold) key. The corresponding function will be terminated.

The maximum duration of expiratory hold is 30s. When the [**Exp Hold**] (Expiratory Hold) key is touched and held for more than 30s or released, the ventilator will terminate the expiratory hold function automatically. During the expiratory hold period, PEEPi will be automatically calculated and displayed.

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 touching the [Exp Hold] (Expiratory Hold) key.**
- **In CPAP ventilation mode, the Exp Hold function cannot be activated. If apnea ventilation occurs, the expiratory hold will be supported.**

11.3 Inspiration hold

Inspiration hold refers to manually extending the patient's inspiratory phase to prevent the patient from expiration for a certain period of time.

1) Press and hold the  key, the inspiration hold function will be activated and the prompt [**Insp Holding…**] will be displayed.

2) Release the  key, the inspiration hold function.

The maximum time for inspiration hold is 15 seconds. If you hold down the key  for longer than the

maximum time, the ventilator will automatically terminate the inspiration hold.
During the inspiration hold, the ventilator automatically calculates the static compliance [**Cstat**] and platform pressure [**Pplat**], and the calculation results are displayed in the prompt box of the figure.

NOTE

- **There is at least one expiratory phase between two inspiration holds.**
- **Operation on the Inspiration Hold key is not responded in Standby mode or O_2 Therapy mode.**
- **The inspiration hold function is disabled in CPAP mode and available in Apnea ventilation.**

11.4 Nebulization

WARNING

- **Remove the main CO_2 module adapter from the patient's respiratory circuit before starting nebulization. CO_2 cannot be measured in the aerosol drug environment. After nebulization is started, the sampling and monitoring of CO_2 module are suspended.**
- **Check and clean up the expiratory valve and flow sensor after nebulization because they may be blocked by drugs during nebulization.**

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

1) Select the [**Nebulizer**] key.
2) Set [**Neb Time**] (Nebulization Time) in the menu. The time range is 1 min~60 min and the nebulization time is adjustable by rotating the rotary knob. After touching the [**Start**] key, the ventilator starts nebulizing. Remaining time of nebulization is displayed under the [**Nebulizer**] key. When nebulization time is up or the [**Nebulizer**] key is touched again, the ventilator will terminate this function.

NOTE

- **In the Standby or O_2 Therapy mode, the system cannot activate the nebulization function.**
- **During nebulization, if the [O_2 Supply Error] or [FiO_2 Too Low] alarm is triggered, the nebulization terminates and the system prompts [O_2 Sup Err, Neb Disabled.].**
- **When O_2 supply is low-pressure, nebulization will not be activated and the prompt [Nebulization Disabled in Low-pressure O_2] will be displayed even if the [Nebulizer](Nebulization) key is touched. Refer to *"Section 6.13 O_2 Supply Type Setting"* to set the oxygen supply to high-pressure oxygen and then start the nebulization function.**
- **Nebulization can result in fluctuation of the patient's FiO_2.**

11.5 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. The O_2↑ range and duration can be set in the following order: [**Menu**]→[**Settings**]→[**Ventilation**]. For adults and pediatric patients, the default O_2↑ range is 60%. For infant patients, the default

O_2↑ range is 40%. The O_2↑ duration can be set to 30s, 60s, 90, or 120s.

- After selecting the Oxygen Enrichment 

/Sputum Suction key, the ventilator starts performing oxygen enrichment function.
- The indicator light corresponding to the key (

) turns green and the oxygen enrichment icon and the remaining time of the function are displayed on the menu bar top.
- [**O_2%**] in the shortcut key area is displayed as 100% during the oxygen enrichment period.

When oxygen enrichment reaches the set O_2↑ duration, or Oxygen Enrichment/Sputum Suction key 

is selected again, the ventilator will terminate the function of Oxygen enrichment.

NOTE

- **O_2 ↑ function cannot be activated in Standby mode or O_2 therapy mode.**
- **O_2 ↑ function cannot be activated during the P-V test.**
- **O_2 ↑ terminates if the alarm [O_2 Supply Failure] is triggered during the process.**
- **When O_2 supply is low-pressure O_2, O_2↑ will not be activated and the prompt [Disabled in Low-pressure O_2] will be displayed in system prompt area even if the [Oxygenate/Sputum Suction] key is pressed.**
- **If the breathing tube is disconnected during oxygen enrichment, the Sputum Suction function will be activated. Refer to *"Section 11.6 Sputum Suction"* for more information.**

11.6 Sputum Suction

Sputum suction refers to the function in which the user performs negative pressure sputum suction for the patient. The ventilator does not perform the negative pressure suctioning, and related equipment such as a sputum suction device should be prepared in advance by the user prior to sputum suction. The ventilator automatically detects user's disconnection and connection of the patient circuit. Oxygen enrichment is applied before and after suction, and related alarms are blocked during suction. The duration of sputum suction can be set in the following order: [**Menu**]→[**Settings**]→[**Ventilation**]. Sputum suction duration can be set to [**30s**], [**60s**], [**90s**], or [**120s**].

- Press the [**Oxygen Enrichment/ Sputum Suction**] key 

, the system conducts O_2↑ ventilation for the patient. The ventilator judges whether the patient tube is disconnected during the set O_2 ↑ ventilation duration . Disconnect patient tube at this time.
- After disconnecting the patient tube, the system prompts [**Patient circuit disconnected, please reconnect after Sputum Suction completed**] and stop ventilation for the patient while you can perform artificial sputum suction on the patient at the time.
- Connect the patient tube after the completion of the operation on the patient. When the circuit connection is detected, the system will start the O_2 ↑ ventilation for the patient according to the set O_2 ↑ duration.
- Press the [**Oxygen Enrichment/Sputum Suction**] key 

to terminate the operation at the O_2↑ ventilation stage.

NOTE

- **In the Standby or O_2 Therapy mode, the system cannot activate the O_2↑suction function.**

11.7 P0.1

P0.1 refers to the pressure drop within the initial 100ms after the patient begins spontaneous respiration.
You can check the measured value of P0.1 in the [**Values**] interface.

11.8 PEEPi

PEEPi is an informative parameter when it comes to determining dynamic hyperinflation in patient lungs. It is determined by the pressure caused by remaining air in a patient's lungs after exhalation. In the presence of dynamic hyperinflation, PEEPi is the abnormal pressure generated by "trapped" air in the alveoli due to incomplete lung evacuation. Ideally, this value should be zero. When PEEPi is present, it may cause volutrauma or barotrauma. For patients with active breathing, PEEPi may impose an additional workload on them.
PEEPi may be produced by short expiratory phase under the following conditions:

- The tidal volume provided is too high
- The inspiratory time too short or the respiratory rate too high
- Excessive tube resistance or obstruction of the expiratory airway
- Expiratory peak flow is too low

You can check the measured value of PEEPi in the [**Values**] interface.

11.9 Weaning Auxiliary Tools

WARNING

- **The ventilator only provides parameter trends and changes to assist doctors in weaning screening and spontaneous breathing trials. There is no suggestion or prompt on whether to wean patients off ventilators or whether it is successful. Medical staff are required to rely on their own judgements and operate based on the clinical situations of each individual patient.**

Patients on ventilators get better after a period of treatment and can be weaned off ventilators and resume spontaneous breathing. Before weaning, daily weaning screening and spontaneous breathing trials should be performed according to patients' conditions. During this process, the patient's breathing and vital signs need to be closely monitored to determine whether weaning can be performed and whether weaning is successful.
Dynamic trends and changes of the following parameters can be displayed by the ventilator: TVe/IBW, fspn, MVe, RSBI, $EtCO_2$, SpO_2 and PR. Users can set the normal range of TVe/IBW, fspn, RSBI, $EtCO_2$, SpO_2, PR and observe the parameter changes. During the weaning process, the user can observe the parameter trend changes and assess the patient's vital signs and breathing conditions to help judge whether the weaning is successful.

NOTE

- **The SBT function is disabled in Standby mode, O_2 ↑ therapy, non-invasive ventilation or when**

an apnea alarm is triggered.

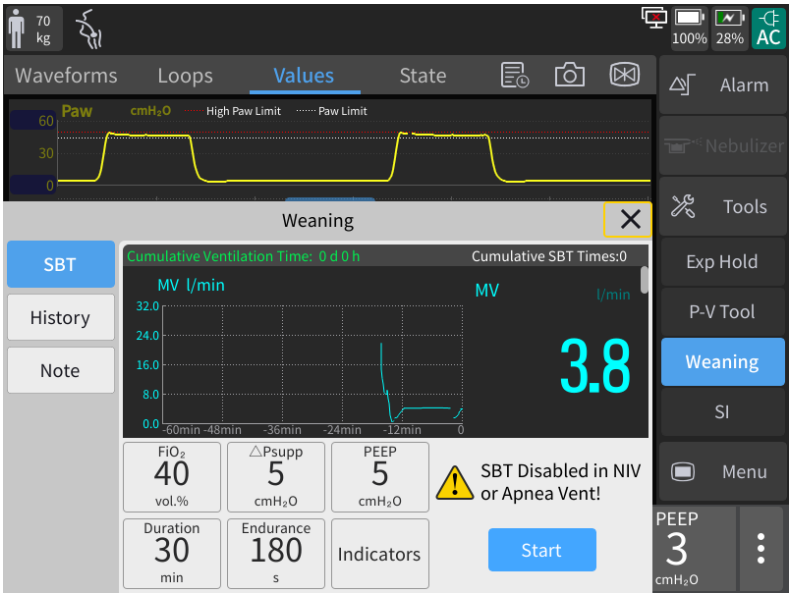
11.9.1 Viewing Help Information

1) Select the [**Tools**] key→ [**Advanced**]→[**Weaning**] to enter the interface of weaning auxiliary tools.
2) Select the [**Help**] key to view the basic principles and precautions of weaning auxiliary tools.

11.9.2 Spontaneous Breathing Trial (SBT)

Spontaneous breathing trial (SBT): the user can set and start SBT and the ventilator will perform PSV ventilation according to preset parameters while presenting the real-time values and trends of weaning indicators. If the indicators exceed the preset ranges, PSV ventilation will be automatically terminated and the previous ventilation mode will be restored.

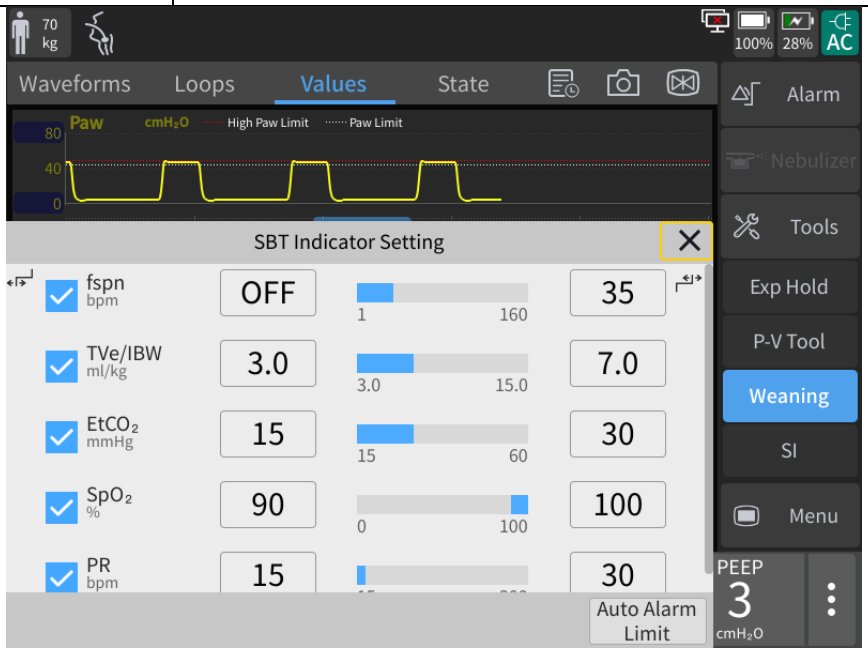
1) Select the [**Tools**] key→ [**Advanced**]→[**Weaning**] to enter the interface of weaning auxiliary tools.



2) Set [**PEEP**], [**ΔPsupp**], [**O_2%**], [**Duration**] (setting range: 20min to 240min) and [**Endurance**] (setting range: 100s to 300s).
3) Select the [**Indicators**] key to enter the [**SBT Indicators Setting**] interface and return to the SBT interface after setting. You can also choose [**Auto Alarm Limit**] (Automatic Alarm Limit). The ventilator will automatically change the indicator parameters according to the algorithm. The algorithm is as follows:

Alarm Limit	**Formula**
High fspn limit	1.5 ×fspn monitoring value, not exceeding160/min
Low fspn limit	0.5 ×fspn monitoring value
High TVe/IBW limit	15 ml/kg
Low TVe/IBW limit	4 ml/kg
RSBI	105 1/(L•min)
High $EtCO_2$ limit	$EtCO_2$ average+10mmHg
Low $EtCO_2$ limit	Adult: 15mmHg； Pediatric Patient: 20mmHg
High SpO_2 limit	100%
Low SpO_2 limit	90%

High PR limit	1.2×PR monitoring value, not exceeding 300/min
Low PR limit	0.8×PR monitoring value, no less than 15/min



4) After selecting the [**Start**] key, the system will start SBT and the ventilation mode area will display [**SBT Active**] and the remaining time countdown. If the [**Stop**] key is touched during the SBT process, the system will stop the SBT and return to the previous ventilation mode. If the countdown is over, the system will automatically stop the SBT and return to the original ventilation mode. During the SBT process, if any weaning indicators exceeds the preset range and the duration exceeds the endurance time, the system will automatically stop the SBT and return to the original ventilation mode. If an apnea or apnea ventilation alarm is triggered, the system will automatically stop the SBT and return to the previous ventilation mode.

11.9.3 Viewing History Data

1) Select the [**Tools**] key→[**Advanced**]→[**Weaning**] to enter the interface of weaning auxiliary tools.
2) Select the [**History**] interface to view all history weaning information of the current patient.

11.10 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: in Standby mode, patient type being Pediatric Patient or Infant; in CPAS/PSV, non-invasive and apnea ventilation modes; in the O_2↑ (oxygen enrichment) process; in the process of nebulization 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**

is breathing spontaneously. Feature points provided by the P-V Tool function are for reference only.

1) Select the [**Tools**] key → [**Advanced**] →[**P-V**] to enter the P-V interface.
2) Select the [**Note**] key to view the note of P-V tool in the opened interface.
3) Select the [**Measure**] key 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 the [**Start**] key is selected, the system will perform the P-V measurement. If the [**Stop Insp**] key is pressed during the measurement, the system will immediately terminate the inspiratory limb measurement test, and start to conduct the inspiratory limb measurement. If the [**Stop Meas.**] (Stop Measuring) key is touched during the measurement, the system will immediately stop measuring.
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 [**Cursor 1**] or [**Cursor 2**] is touched, the cursor will turn green. You can move the cursor by rotating the rotary 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 the [**History Loop**] key 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 Loop**] key.
7) You can select the [**Ref Loop**] (Reference Loop) key 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**] (Reference Loop) key.

11.11 Sustained Insufflation (SI)

WARNING

- **SI function is disabled if:**
  - **Patient type is Infant;**
  - **Undergoing Sputum Suction;**
  - **Undergoing Oxygen therapy.**

NOTE

- **100% O_2 or high O_2 concentration is required.**
- **SI is not recommended for a spontaneously breathing patient.**
- **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 the [**Tools**] key →[**Advanced**] → [**SI**] to enter the SI interface.
2) Select the [**Note**] key to view the Note message of SI in the opened interface.
3) Select the [**Measure**] key and set the parameters of [**Pressure Hold**] and [**Hold Time**] in the measurement interface.
   Parameters of SI setting:
   - [**Pressure Hold**]: the pressure maintained during SI.
   - [**Hold Time**]: the duration time of SI.
4) Select the [**Start**] key, the system will perform the SI tool measurement. SI ventilation ends automatically when the hold time is reached. If the [**Stop**] key is touched during measurement, the system will immediately stop measuring.

11.12 Display of CO_2 Derived Parameters

For mainstream CO_2 modules, this ventilator can monitor 9 CO_2 derived parameters, which are as follows:
VDaw: dead space of airway
VDaw/Tve: ratio of airway dead space to tidal volume
Vtalv: alveolar ventilation
MValv: alveolar minute ventilation.
slope CO_2: rising slope of carbon dioxide
VCO_2: carbon dioxide output per breath
$VeCO_2$: volume of exhaled CO_2
$ViCO_2$: volume of inhaled CO_2
$MVCO_2$: minute volume of expired CO_2

For sidestream CO_2 modules, this ventilator can monitor two CO_2 derived parameters, which are as follows:
VCO_2: carbon dioxide output per breath
$MVCO_2$: minute volume of expired CO_2

WARNING

- **Please ensure the patient's cardiorespiratory state is stabilized to attain the most accurate CO_2 measurement results. The accuracy of mainstream CO_2 monitoring parameters may be affected by system leakage, respiratory frequency higher than 35bmp and non-invasive ventilation. The affected monitoring parameters include VDaw, VDaw/TVe, Vtalv, MValv, slope CO_2, VCO_2, $VeCO_2$ and $ViCO_2$.**
- **A patient's expired gas volume and expired CO_2 volume may differ from the measured volumes due to leakage around the mask.**

11.13 IntelliSyn Technology

IntelliSyn Technology refers to the function that the ventilator can set [**Exp%**] to [**Auto**] in the modes of CPAP/PSV, P-SIMV, PRVC-SIMV and DuoVent. Then through extracting and analyzing the waveform features, the system will optimize [**Exp%**] with adaptive algorithm dynamically according to the patient's

lung characteristics. In this way, patient-ventilator synchrony can be improved, thereby allowing for more comfortable ventilation, reduced ventilator setting adjustments during treatment and lower workload of the medical workers while providing the same excellent synchrony performance.

Chapter 12 Battery

12.1 Overview

The ventilator is equipped with one or two built-in rechargeable battery packs. When the ventilator is connected to the external power supply, the battery can be charged whether or not it is turned on until it is fully charged. In the case of a sudden external power supply failure, the system will automatically use the battery to power the device without causing the interruption of the device's work. When an acceptable external power supply is present, the ventilator automatically charges the internal battery while the device operates.

If the ventilator is equipped with an optional battery (battery B) and it is fully charged, the ventilator will be switched to optional battery first. The ventilator will be switched to the standard battery (battery A) when the optional battery is drained or not installed. The standard battery will power the ventilator until the main power supply is restored or the battery runs out. When the battery is not installed, the battery uninstallation symbol is displayed in the battery status area of the screen.

The ventilator is powered by batteries. When one battery is installed with a level of 11%-19% or two batteries are installed with one level of 0-10% and another 11-19%, or both are 11-19%, a medium priority alarm [**Low Battery**] is activated. At this time, the device could run under maximum configuration for about 10 minutes, and the user shall connect the device to a supply main or have backup ventilation prepared.

The ventilator under battery powered with its capacity is less than 11%, a high priority alarm condition [**Battery Running Out**] is activated. This means the device might run for about 5 min., reserved electrical power supply is in urgent need so as to maintain the intended function.
The battery symbol on the screen indicates the current power state:

 : the external power supply is connected. The ventilator is powered by an external power supply. The battery is charging. The percentage below the battery icon represents the battery level.

 : the external power supply is not connected. The ventilator is powered by a built-in battery.

 : the external power supply is not connected. The ventilator is powered by a built-in battery. The battery is low and needs to be charged in time.

 : No battery is installed in the ventilator.

 : The ventilator battery is damaged.

Touch the battery icon and the battery information interface is displayed. On this interface, the following

information of battery A and B can be viewed: serial number, designed capacity, full battery capacity, remaining battery capacity, battery temperature and the number of battery charge cycles.

⚠ WARNING

- **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.**
- **Battery can only be maintained for some time, when the battery is too low, the ventilator will generate technical alarm [Low Battery], the external power supply of ventilator should be connected. Total loss of power would cause serious injuries to patient, therefore do connect to external electrical power supply before the batteries exhaust.**
- **The expected service life of lithium-ion batteries is 300 cycles of charge and discharge. When the battery pack reaches the end of its life, replace it.**
- **When the ventilator battery is running out, the ventilator activated high priority alarm condition [Battery Running Out]. And the ventilator would automatically switch off in a safety manner.**

⚠ NOTE

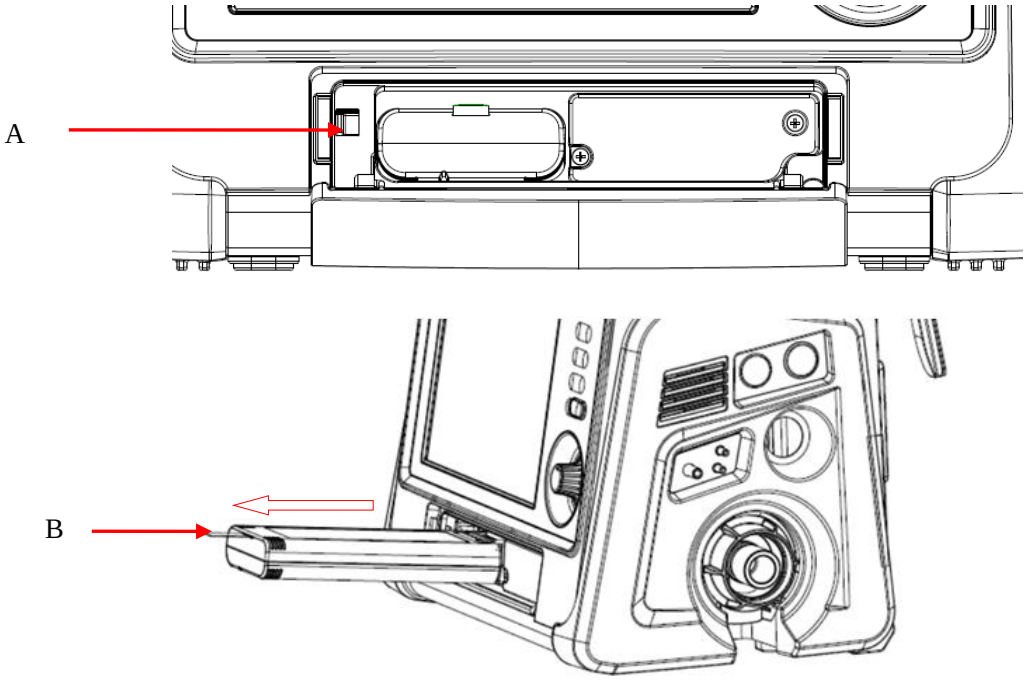
- **If the battery is to be left unused for a long period of time, please remove the battery and keep it properly. The battery must be charged after each use to ensure sufficient battery reserve.**
- **Do not use or store the battery where is exposed to extremely hot, direct sunlight. Otherwise, the battery may be overheated. This can also reduce battery performance and/or shorten service life.**
- **Under extreme operating temperature range: -18℃-5℃/45-50℃, it is suggested not to charge the battery pack and used battery as power supply.**
- **The battery life can be delayed by reducing the brightness of the LCD screen, reducing the inspiratory pressure and tidal volume, and reducing set value of the respiratory rate.**

12.2 Battery Installation

The steps to install and replace the battery are as follows:

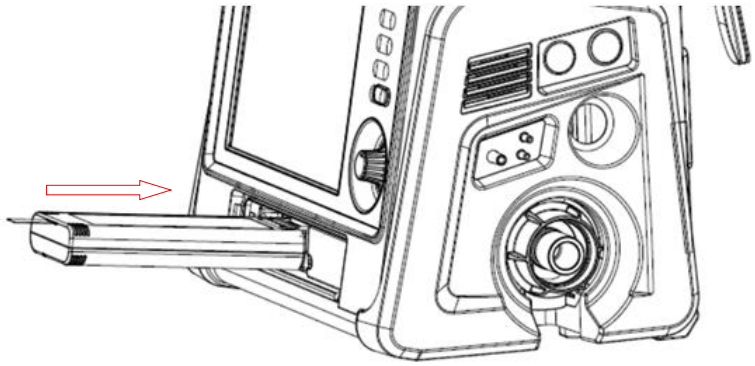
1) Turn off the ventilator, and disconnect the power cord and other connecting wires.
2) Open the battery cover of the panel according to the illustration on the battery compartment cover's silk screen on the front panel.

3) The user can replace the battery on the left side of the the battery compartment. Shift the lock latch to the left, and pull the old battery out of the battery compartment by pulling the handle on the battery as shown in the figure below. The battery on the right side of the battery compartment is not installed in the ventilator before delivery and must be installed by the engineer designated by the manufacturer. When installing the battery, the battery fixing cover must be fixed firmly on the battery with screws.



A. Battery lock B. Battery handle

4) Put the battery into the empty battery compartment by holding the battery handle.



5) Close the battery compartment.

⚠ WARNING

- **Use only the battery specified by the manufacturer.**

- **Do not disassemble the battery when the device is working.**

12.3 Battery Performance Optimization and Check

12.3.1 Battery Performance Optimization

When the battery is used for the first time, it should be ensured that the battery does at least two complete optimization cycles. A complete optimization cycle is: uninterruptedly charge the battery, and then discharge until the ventilator is turned off, and then uninterruptedly charge the battery. The performance of the battery will gradually decrease with the increase of use time. It is recommended that you optimize the battery every three months. If you do not optimize the battery for a long time, it may cause inaccurate display of the battery power.

1) Disconnect all connections of ventilator from the patient and turn off the ventilator.
2) Ensure that the battery is installed in the battery compartment.
3) Connect the ventilator to an external power supply and continuously charge the battery until the battery is fully charged.
4) Disconnect the external power supply and use the battery to power the ventilator until the battery is discharged and the ventilator will automatically power off.
5) Reconnect the ventilator to external power and charge the battery continuously until the battery is fully charged.
6) The battery optimization is completed.

12.3.2 Battery Performance Check

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 6 in **"*Section 12.3.1 Battery Performance Optimization*"**. The 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.**

12.4 Battery Storage

Please ensure that the battery pack 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℃ (60℉). Do not place the battery in an environment beyond the temperature range of -20℃ (-4℉) ~ 60℃ (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

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

12.5 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.**
- **Do not store the ventilator with batteries in a discharged condition.**
- **Follow local governing ordinances and recycling instructions regarding disposal or recycling of the batteries.**

Chapter 13 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.

13.1 Overview

This chapter describes the cleaning, disinfection and sterilization methods of the Ventilator and reusable accessories. 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 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. After cleaning, thoroughly dry the unit with a lint-free cloth. Make sure that all exposed surfaces are cleaned and dried.**
- **It is not allowed to use detergent mixture; otherwise hazardous gases will be generated.**
- **Disposable accessories should not be reused 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 reusable accessories or components are 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.**

- **Please carry out removal and assembly according to the instructions provided in this chapter.**
- **Improper removal and assembly can result in system leakage, affecting normal use of the equipment. After re-installation, please perform the Check before ventilation.**
- **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.**

⚠ 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.**
- **The pH value of cleaning solution must be between 7.0 ～ 10.5.**
- **After cleaning, disinfection or sterilization, please perform system check before using this device again. The device can be used after passing the system check.**

13.2 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.

13.2.1 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 O3	E Pressure steam
Ventilator housing								
External surface of ventilator including housing, gas supply hose, power cord, Touch screen	Each patient	①		A or C				
Inspiratory valve	As per need[1]	①		D				
Trolley and supporting arm	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				
Expiratory valve component of ventilator								
Expiratory valve detachable diaphragm (Silicone rubber)	Each patient / Every week	②		B or E				
Expiratory Valve Component (diaphragm excluded)	Each patient / Every week	②		B or E				
Patient circuit of ventilator (reusable)								
Patient circuit (including water collection cup, Y-joint, and adaptor)	Each patient / Every week	Please refer to the cleaning and disinfection methods provided in the breathing circuit instructions.						
Others								

Humidifier	Each patient / Every week	Please refer to the cleaning and disinfection methods provided in the humidifier instructions.

Cleaning Methods:

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: 40℃) 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 expiratory Valve Component (diaphragm excluded) can only be disinfected by high-efficacy disinfectant.).

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

D. O3：Connect the ozone generator interface with the gas outlet of the main unit, press the ozone generator to start disinfection, the recommended ozone concentration is 100mg/m^3 and the recommended disinfection time is 35 minutes. After this procedure, disconnect the ozone generator and place the equipment in a ventilated and cool environment for more than 30 minutes to complete disinfection.

Sterilization Methods:

E. Pressure steam: Sterilize the part with high-temperature high-pressure steam (temperature: 134℃); the recommended sterilization 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[1]：A bacterial filter should always be used between the ventilator and the inspiratory limb. If not, the ventilator might expose to large amounts of contaminants, then the cleaning/disinfection/sterilization procedure shall be performed on inspiratory valve and expiratory valve assembly before use.

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

Item	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
Sterilization with high-temperature high-pressure steam *	Sterilization

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

NOTE

- **For reusable breath tubing, do follow the cleaning and sterilization method marked on its user manual and package label. The expected number of procedure cycles is 30 times.**
- **The exhalation valve can be cleaned and disinfected or sterilized under high pressure and temperature. The recommended maximum frequency for moist heat sterilization is 56 times. Perform system check for the exhalation valve before each use, if the test before ventilation passes, the valve could be further used. If it fails two consecutive system checks, it must be replaced.**

13.2.2 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
Physiological Module							
CO_2 extended cable, CO_2 sensor, CO_2 analyzer	Each patient / Every week	①		A			
Masimo/Respironics/Comen CO_2 sampling line inlet	Each patient / Every week	①		A			
SpO_2 sensor and cable	Each patient / Every week	①		A			

Cleaning Methods:

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: 40℃) 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 and high-pressure steam (temperature: 134℃); the recommended sterilization time is 10 ~ 20 min.

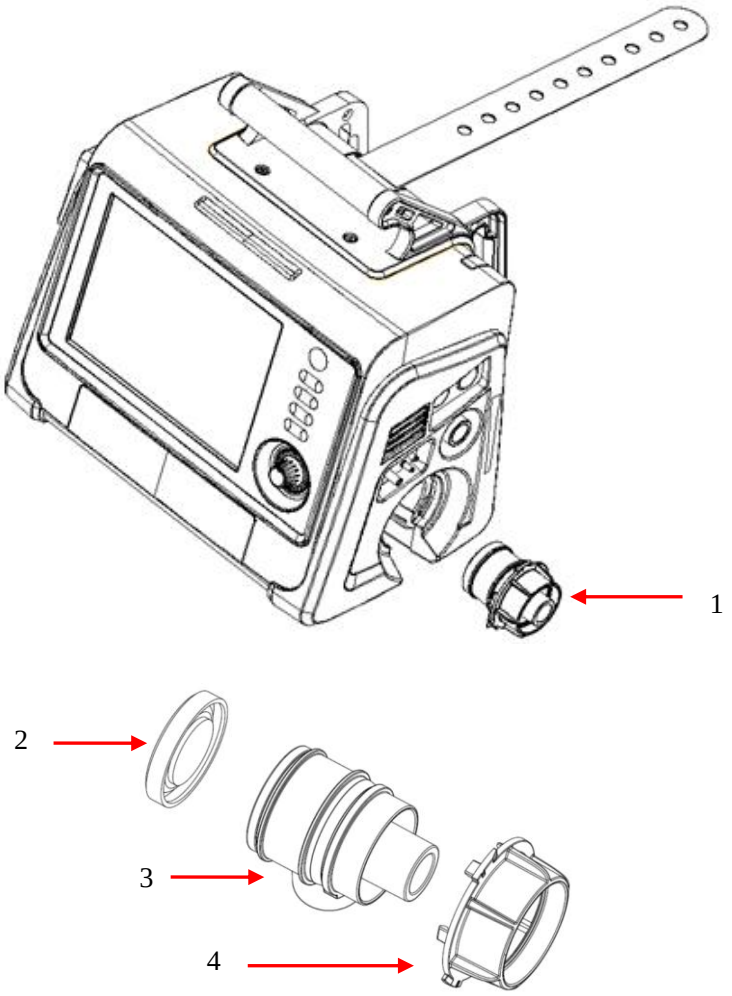
Parts for Disinfection	**Detergent**	**Disinfectant**
CO_2 extended cable	Clean water, 75% alcohol	OPA (5.5g/l), 75% alcohol, 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution
Masimo mainstream CO_2 analyzer component	Clean water,75% alcohol	75% alcohol, 70% isopropanol
Masimo SidestreamCO_2 analyzer componentand sampling line inlet	Clean water,75% alcohol	75% alcohol
Respironics/Comen CO_2 sampling line inlet	Clean water,75% alcohol	75% alcohol, 3% hydrogen peroxide,0.6% or 2% sodium hypochlorite solution
Respironics/Comen mainstream CO_2 analyzer component	Clean water, mild soap liquid	70% isopropanol
Respironics/Comen Sidestream CO_2 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 SpO_2 sensor and cable extender	Water, neutral detergent, 70% isopropanol	0.5% sodium hypochlorite solution
Comen SpO_2 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
SpO_2 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

13.3 Removing and Installing Ventilator Parts for Cleaning, Disinfection or Sterilization

NOTE

- **After re-installing the parts for maintenance, please do perform the functional check before ventilation, so as to ensure the safe use of the device. See "Chapter 4 Test and Calibration" for details.**

13.3.1 Detachable Component and Diaphragm of the Expiratory Valve

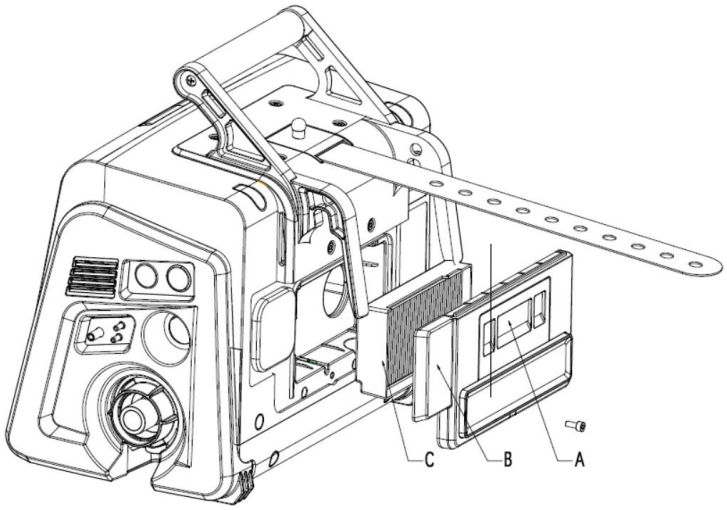


1. Expiratory valve detachable component
2. Expiratory valve diaphragm
3. Expiratory valve spool
4. Expiratory valve knob

■ Removal method:

1) Turn the expiratory valve knob counterclockwise, and then pull out the expiratory valve detachable component horizontally.
2) Remove the expiratory valve diaphragm.

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



A. Air inlet dust filter B. High-efficiency filter cover C. HEPA high-efficiency filter

■ Removal method

1) Use a cross screwdriver to unscrew the fixing screw which is used to fix the high-efficiency filter cover and remove the high-efficiency filter cover.
2) If you need to remove the air inlet filter, you can use two fingers to pinch it and take it out.
3) Pick the HEPA high-efficiency filter and take it out of the installation slot.

■ Installation method

1) Push the HEPA high-efficiency filter into the corresponding slot, and press in the direction that the HEPA high-efficiency filter is installed.
2) Check the HEPA high-efficiency filter and confirm whether it is installed in place.
3) Install the high-efficiency filter cover.

⚠ WARNING

- **When replacing HEPA, only the HEPA designated by Comen can be used.**

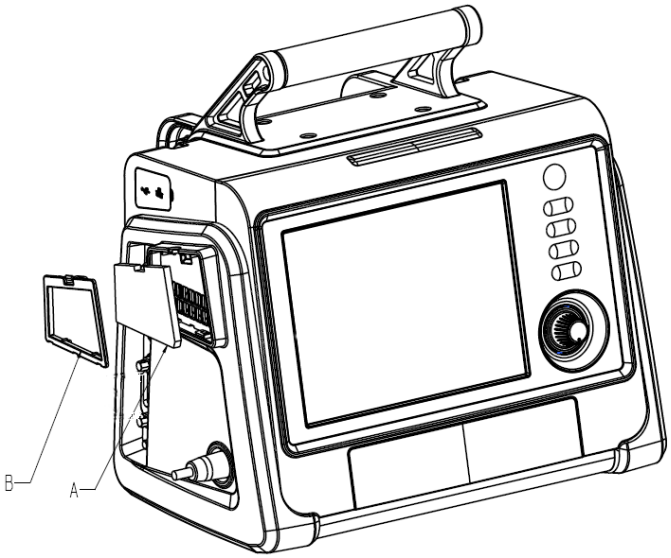
⚠ CAUTION

- **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 the air inlet air mesh installed conforms to specification requirements.**

13.3.3 Fan Dust Mesh



A. Fan dust mesh B. Fan dust cover

■ Removal Method

1) Press a buckle on dust cover of the fan, and take down the dust cover.

2) Remove the dust mesh.

■ Installation Method:

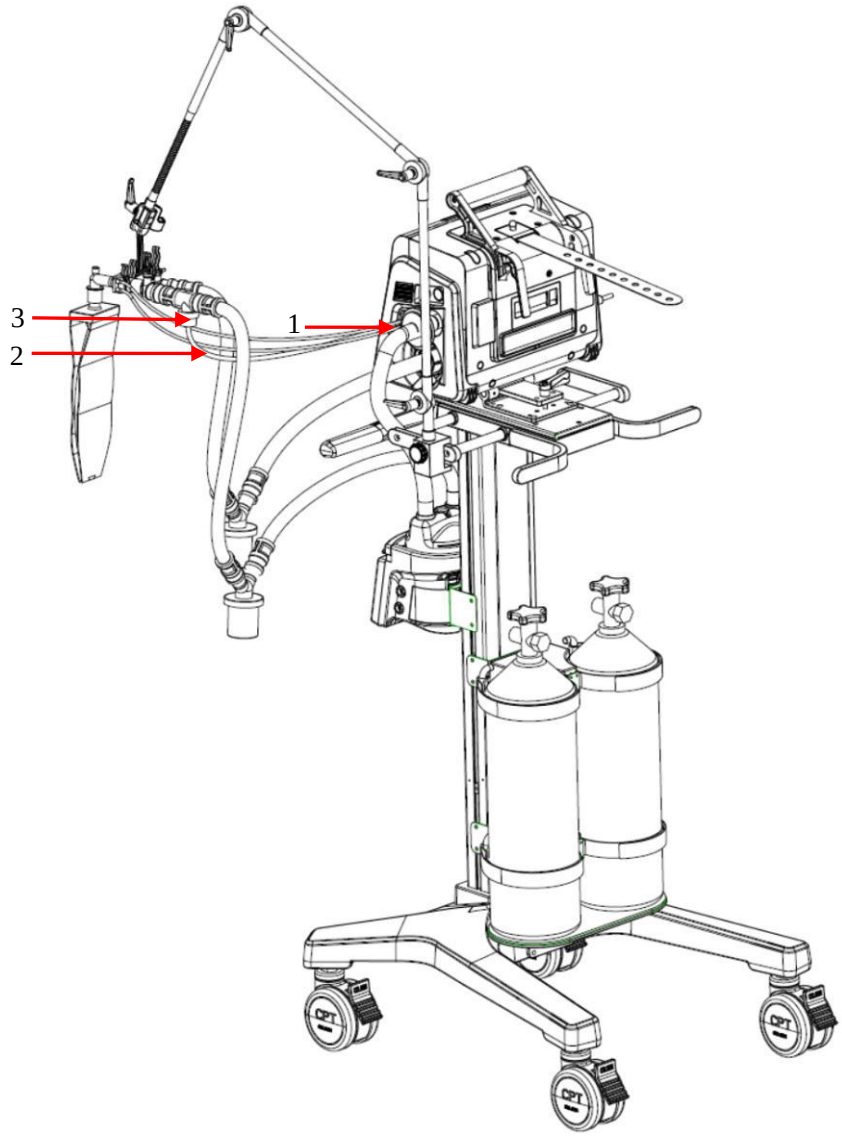
1) Place the dust mesh on the corresponding position against the cooling fan.

2) Snap the 2 pins under the dust cover of the main fan into the corresponding slots, and lock the buckle

NOTE

- **When used in dusty environments, you should inspect and replace this part more frequently.**

13.3.4 Nebulizer



1. Nebulizer port 2. Nebulizer intake tube 3.Nebulizer

■ Removal Method:

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

2) Disconnect the tubes connected with the Nebulizer to take out the nebulizer.

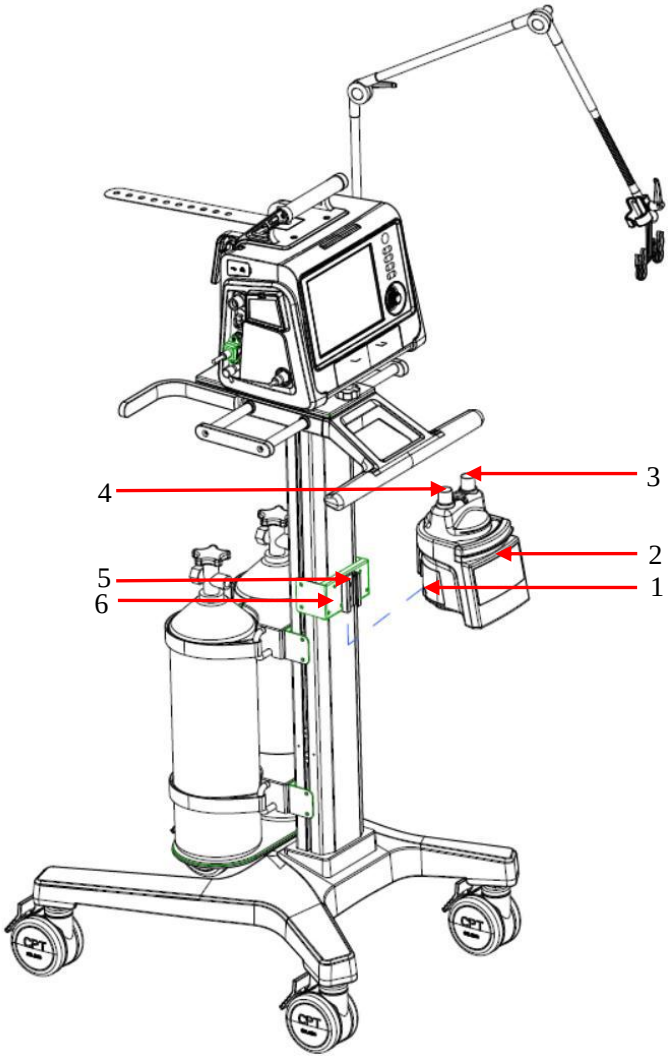
⚠ NOTE

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

13.3.5 Removing Humidifier from the Ventilator

NOTE

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

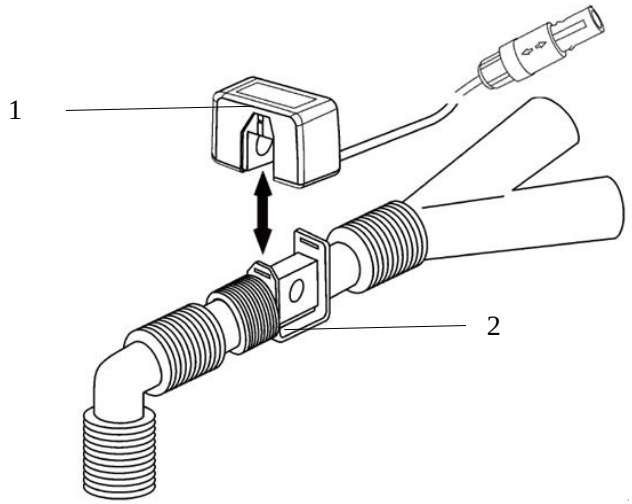


1. Humidifier pulley
2. Humidifier
3. Humidifier inlet
4. Humidifier outlet
5. Screw
6. Retaining bracket of humidifier holder

■ 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.

13.3.6 Mainstream CO_2 Sensor



1. CO_2 sensor 2. CO_2 adapter

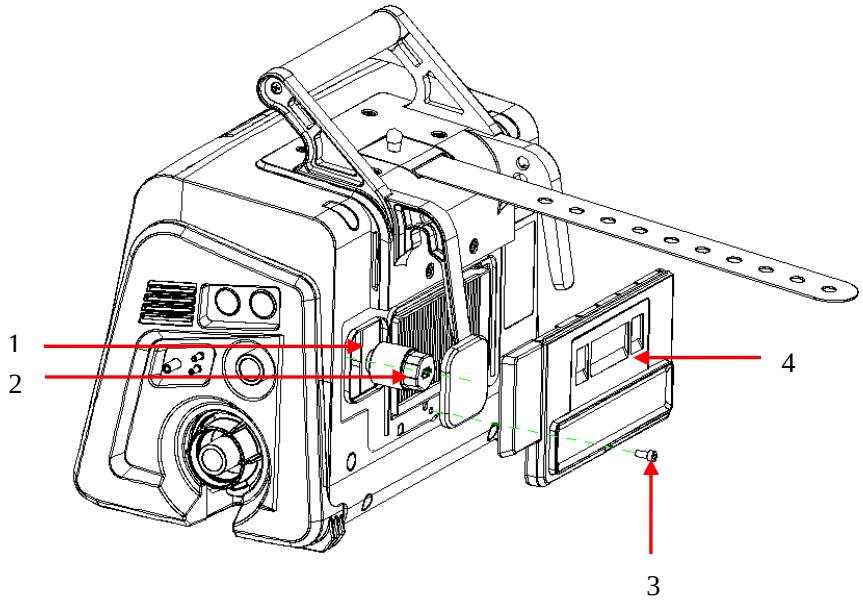
■ Removal Method

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.

13.3.7 Replacing O_2 Sensor



1. O_2 Sensor compartment 2. O_2 Sensor 3.Screws 4. Back cover

Replacement Method:

1) Screw out the fixing screw of back cover and remove the back cover.
2) Unplug the old O_2 sensor, turn the O_2 sensor counterclockwise, and then take out the O_2 sensor.
3) Insert a new O_2 sensor into the O_2 sensor compartment, and turn it clockwise to fix it, and plug in the O_2 sensor cable.
4) Reinstall the back cover.

Chapter 14 Maintenance

14.1 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. Only qualified biomedical equipment technicians should service the device.
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.**
- **No parts of the device can be serviced or maintained while the ventilator is in use with the patient. If you have any problems with this device, such as setting up, maintaining or using, please contact with service personnel. Don't open or repair the device by yourself.**
- **Inspect the circuit every day to ensure that there is no damage or wear that could affect its performance.**
- **No modification of this equipment is allowed.**

NOTE

- **For service support, please contact our After-sales Service Department.**
- **If you want to know more about product information and related technical materials, please co ntact our After-sales Services Department. We can provide documents of some parts according to specific conditions.**

14.2 Maintenance Schedule

Time Interval	Part/Accessory	Maintenance
Each patient or as per need	Breathing tube, mask, inspiratory filter, flow sensor, expiratory valve assembly and diaphragm	Perform pressure and flow zeroing (Refer to ***"Section 14.4 Pressure and Flow Zeroing"***); Perform flow sensor calibration. (Refer to ***"Section 14.5 Flow Calibration"***) Replace parts with a disinfected or new one.
As per need	CO_2 calibration	In case of large deviation of the measured value of CO_2,

		please calibrate the CO_2 module.
	Expiratory valve	Replace the expiratory valve component if it is damaged. (Refer to ***"Section 13.3.1 Detachable Component and Diaphragm of the Expiratory Valve"*** and ***"Section 13.2.1 Cleaning, Disinfection and Sterilization of Main Unit and Patient's Circuit")***
Every year or every 5000 h, or as per need	Expiratory valve diaphragm	Check the expiratory valve diaphragm. Where necessary, please contact our After-Sales Service Department for replacement.
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.
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 check; check the respiratory system for resistance and leakage.
Everymonth or as per need	Dust mesh at air inlet and the fan	Check dusts accumulated on the dust mesh, clean or replace it if needed (refer to ***"Section 13.3.3 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 13.3.7 Replacing 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	Inspect the ventilation operation time and check for damage or deterioration; replace it when necessary. (*refer to* **"*Section 13.3.2 High-efficiency Particulate Air (HEPA) and Dust Mesh*"**).
	Backup Alarm System	Check the alarm keeping time of the backup alarm system (buzzer) If it is too short, Contact our After-sales Service Department.
	Gas supply seal ring	Check the gas supply seal ring. Where necessary, please contact our After-Sales Service Department for replacement.
Every 20,000 hours	Blower box	Please contact our After-Sales Service Department for replacement.

At least once every two years or when measurement inaccuracy is suspected of.	Mainstream and sidestream CO_2 calibration and performance check	Please contact our After-Sales Service Department.

NOTE

- **Lithium battery, O_2 sensor and Air inlet HEPA filter is maintained by the maintenance personnel appointed by the hospital.**

14.3 Term of Validity of Reusable Accessories

Item	Term of Validity
Comen SpO_2 sensor	2 years
Masimo/Nellcor SpO_2 sensor	6 months
Comen/ Masimo/NellcorSpO_2 cable extender	2 years
CO_2 module	5 years
CO_2 module interface cable	2 years

14.4 Pressure and Flow Zeroing

If the monitoring value error of pressure or flow is big, please carry out pressure and flow zeroing. Zeroing can be carried out in Standby mode or during ventilation.

1) Touch the [**Menu**] key→[**Calibration**]
2) Touch the [**Zeroing**] key and then select the corresponding [**Start**] key below [**Pressure and Flow Zeroing**]. Start pressure and flow zeroing and a prompt message [**Zeroing…**] is displayed.
3) During zeroing, press the [**Stop**] key, the ongoing zeroing will be stopped. At the same time, the system will prompt [**Zeroing Stopped!**] Pressing [**Start**] can restart zeroing.

If the zeroing passes, the system will display the message [**Passed**]. Otherwise, a message is displayed indicating that zeroing fails. In this case, restarting zeroing is required.

14.5 Flow Calibration

NOTE

- **Do not carry out flow calibration while the system is connected to the patient.**
- **Do not carry out flow calibration when the oxygen supply is low-pressure oxygen.**
- **During a calibration process, do not operate the pneumatic parts of the ventilator, especially by moving or squeezing the respiratory circuit.**
- **Ensure that the system is in Standby mode, otherwise press the [Standby] key to enter the Standby interface after confirming.**
- **It is recommended to disconnect the ventilator from the humidifier before calibration.**

If the flow monitoring value error is big or the flow sensor is replaced, please carry out flow calibration.
Flow calibration can be performed in the following steps:

1) Disconnect the respiratory circuit from patient.
2) Connect high-pressure oxygen supply.
3) Connect the respiratory circuit and insert the Y-shaped joint into the leakage detection plug to obturate the breathing circuit.
4) Select the [**Menu**] key→[**Calibration**]→[**Flow Calibration**], and then select the [**Start**] key. Start flow calibration, the system displays a prompt message: [**Calibrating…**] and the interface displays a blue calibration progress bar. In the calibration process, first connect the flow sensor reversely. If not, a prompt is displayed: [**Please connect the flow sensor reversely**], and there is a flow sensor connection diagram on the right. After the reverse calibration is completed, the calibration progress reaches 50% and the forward calibration starts. The prompt [**Please connect the flow sensor reversely**] is displayed again. At the same time, there is the connection diagram of the flow sensor on the right. If the forward connection is not completed within the specified time (15s), the prompt [**Calibration Stopped Uncompleted!**] is displayed.
5) During the calibration process, touch the [**Stop**] key to stop the ongoing calibration process and the blue calibration progress bar stops and turns red. At the same time, the system will prompt [**Calibration Stopped!**]. Touch the [**Start**] key to restart the calibration.
6) If the calibration passes, the system will prompt [**Passed**]. Otherwise, a message indicating calibration failure is displayed. In this case, you need to recalibrate.

NOTE

- **If the calibration fails, check whether there is a fault alarm. If it still fails after the alarm fault elimination, or the measurement error after calibration is found to be large, please replace the flow sensor and repeat the above operations; if the measurement error is still large, please contact authorized after-sales service personnel in time.**

14.6 Oxygen Concentration Calibration

NOTE

- **When the system is connected to the patient, please do not calibrate the oxygen concentration.**
- **Ensure that the system is in Standby mode, otherwise press the [Standby] key to enter the Standby mode after confirming.**

If the ventilator uses a chemical oxygen sensor, calibrate the oxygen concentration when the error of the oxygen concentration monitoring value is large or the oxygen sensor is replaced.

Follow these steps to calibrate the oxygen concentration:

1) Disconnect respiratory circuit from patient.
2) Connect high-pressure oxygen supply.
3) Select the [**Menu**] key→[**Calibration**] →[**O_2% Calibration**], and then touch the [**Start**] key to start oxygen concentration calibration. The system prompts [**Calibrating…**] and the interface displays a blue calibration progress bar.
4) During the calibration process, touch the [**Stop**] key to stop the ongoing calibration process and the blue calibration progress bar stops and turns red. At the same time, the system will prompt [**Calibration Stopped!**]. Touch the [**Start**] key to restart the calibration.
5) If the calibration result is passed, the system will prompt [**Passed**]. Otherwise, information on calibration failure is displayed. In this case, you need to recalibrate.

NOTE

- **If calibration fails, check whether there is a technical fault alarm and recalibrate after troubleshooting. If multiple calibrations fail, replace the chemical oxygen sensor and recalibrate. If calibration still fails, please contact the equipment maintenance personnel or Comen in time.**
- **When disposing of a discarded chemical oxygen sensor, please stick to the rules for biohazards and don't burn it out.**
- **Oxygen concentration monitoring does not generate automatic atmospheric pressure compensation, so please pay attention to recalibrate oxygen concentration after the ambient atmospheric pressure changes.**
- **The periodic pressure rising to 10kPa (100 cmH_2O) does not affect the monitoring accuracy of oxygen concentration.**
- **A chemical oxygen sensor measures the oxygen partial pressure, which is affected by either pressure (the absolute pressure) increasing or decreasing. A 10% increase/decrease in pressure (absolute pressure) lead to a 10% increase/decrease in oxygen concentration correspondingly. After the ambient atmospheric pressure changes, attention should be paid to the oxygen concentration calibration.**

14.7 Handling Water Accumulation Problem in Expiration Valve

14.7.1 Water Accumulation Prevention

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 trap. When the exhaled gas arrives at the expiratory valve, condensate water can be produced at the expiratory valve.

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 trap 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.

14.7.2 Accumulated Water Cleaning

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.**

14.8 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. Or any of the following occurs:**
  -Installation;
  -Re-installation;
  -Replace critical component or repair
- **When the ventilator is installed on a road ambulance, the protective grounding impedance should not exceed 0.1ohms (without power supply cord)/0.2 ohms (with power supply cord). Test the earth resistance with a current of 25 A. The apparent resistance of supply mains shall be less than 0.3Ω·m-1 and being regularly checked for proper PE connection.**
- **When the ventilator is installed on a road ambulance, the connected power supply needs to meet the power supply specifications in Appendix III.**
- **When the ventilator is fixedly installed on a road ambulance, it is connected to the AC/DC supply mains. It cannot be plugged or unplugged directly. You need to use a tool to remove the AC power cord fixing clip, unplug the power cord. Accident detachment should be avoided.**

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

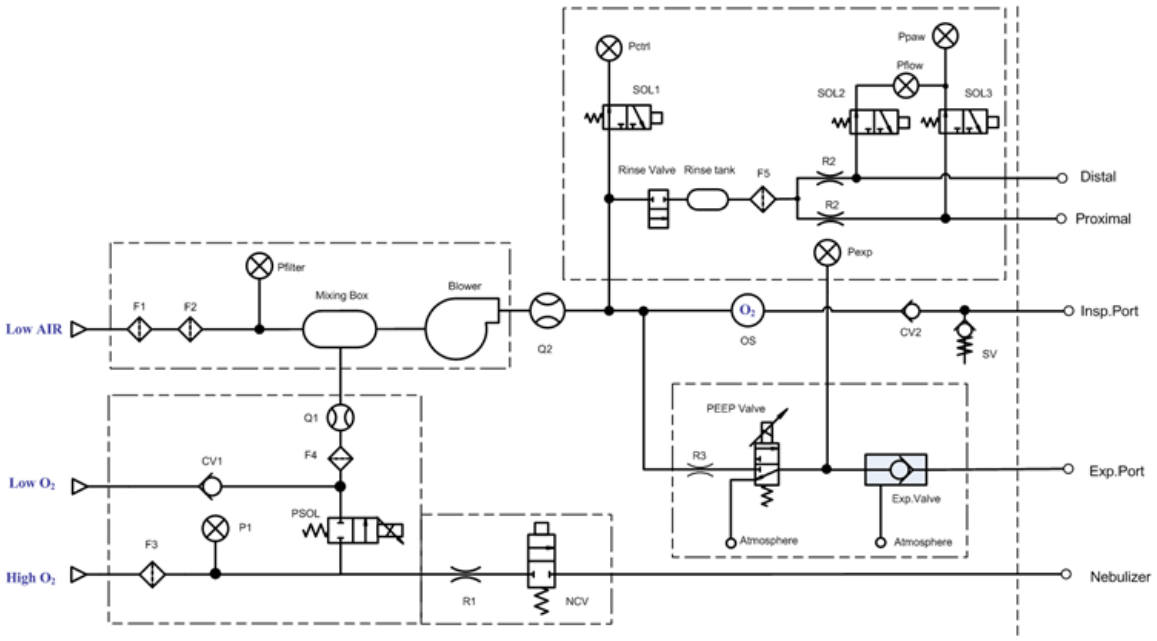
3. Verify that the maximum leakage current does not exceed 500μA (0.5 mA) under the first two conditions, and does not exceed 1000 μA (1 mA) under the last two conditions.

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

1. Schematic Diagram of Gas Circuit



2. Parts List

Symbol	Name	Symbol	Name
Low AIR	Low-pressure air source	Rinse tank	Rinse gas volume
Low O_2	Low-pressure O_2 supply	F5	Rinse filter
High O_2	High-pressure O_2 supply	R2	Rinse air resistance
F1	Dust filter screen	SOL2	Zeroing valve
F2	HEPA filter	SOL3	Zeroing valve
Pfilter	Filter pressure sensor	Pflow	Flow monitoring sensor
CV1	Check valve (Low-pressure O_2 input)	Ppaw	Airway pressure sensor
F3	Filter	Pctrl	Inspiratory pressure control sensor
P1	Gas supply pressure sensor	Pexp	Expiratory pressure sensor
PSOL	Proportional solenoid valve	OS	O_2 sensor
F4	Filter mesh	Proximal	Proximal end
Q1	O_2 flow sensor	Distal	Distal end
R1	Atomization air resistance	CV2	Check valve
NCV	Nebulizing valve	SV	Safety valve
Nebulizer	Nebulizer	Insp.Port	Inspiratory port
Mixing Box	Mixing Box	R3	Expiratory valve air resistance
Blower	Blower motor	PEEP Valve	Expiratory proportional valve
Q2	Total flow sensor	Exp.Valve	Expiratory valve

SOL1	Zeroing valve	Atmosphere	Atmosphere
Rinse Valve	Rinse switch valve	Exp.Port	Expiratory port

3. Principle Description

This ventilator is an electronically controlled ventilator. Oxygen can be supplied by high-pressure oxygen supply (High O_2) or low-pressure oxygen supply (Low O_2). The air is sucked in from ambient by a turbine (blower motor). A complete breathing cycle is divided into inspiratory and expiratory phases: In the inspiratory stage: The expiratory valve is closed. The air and oxygen are mixed by the blower upstream to form a gas mixture, which is regulated to intended O_2 concentration, specified flow rate or pressure, and then delivered to patient lungs through inspiratory limb. In the expiratory stage: the expiratory valve opens and the inspiratory valve closes, discharging the exhaust gas from patient lungs that return to the expiratory valve through expiratory limb.

The gas supply part includes three parallel limbs: high-pressure oxygen, low-pressure oxygen and low-pressure air. high-pressure oxygen and low-pressure oxygen supply will mix before they are mixed with air, but high-pressure oxygen and low-pressure oxygen cannot be used at the same time. An O_2 flow sensor Q1 is placed at the common outlet of low-pressure oxygen and high-pressure oxygen to monitor the oxygen flow. Indoor air passes through the dust filter mesh (F1) and HEPA filter (F2) to enter the blower box.

The low-pressure oxygen-side check valve (CV1) prevent return flow of low-pressure oxygen; the filter (F3) is used to filter impurities in the high-pressure oxygen supply; Gas supply pressure sensor（P1）moniters the gas supply pressure in real time and can trigger an alarm when the gas supply pressure is out of range; the O_2 proportional solenoid valve (PSOL) is used to adjust the input high-pressure oxygen flow. The filter (F4) is placed in front of the O_2 flow sensor to stabilize the air flow, so that the sensor can measure the oxygen flow accurately; the flow sensor (Q1) is a hot-wire air flow sensor which does not require calibration.

When the blower sucks in air from the surrounding, the dust filter mesh (F1) filters dust in the air, and the HEPA filter (F2) is used to filter bacteria. As a result, if the ventilator is used or left for a certain period of time, dust or impurities get accumulated on the surface of the two-layer filters, which will cause a certain degree of blockage of the air inlet. At this time, the air flow into the ventilator may be insufficient, affecting the ventilation performance.

The filter pressure sensor (Pfilter) of the air inlet monitors the pressure in real time, making effective judgment whether the gas intake port is blocked. After the air and oxygen are fully mixed in the Mixing Box which is located in front of the blower inlet, the gas mixture is compressed by the blower and delivery to the inspiratory limb.

The inspiratory limb assembly supports monitoring the blower output gas flow rate and oxygen concentration, providing a sampling port for pressure monitoring, which also serves as a gas supply for flushing air flow and expiratory proportional valve, and is equipped with safety valves and gas output port to patient. The total flow sensor (Q2) monitors the flow of air-oxygen mixture at the blower outlet. It adopts mainstream O_2% monitoring, using an oxygen sensor (OS) with a short total system responding time. The one-way valve (CV2) prevents the exhalation gas return to inspiratory limb. The safety valve (SV) is operated to reduce the Paw to PEEP when the airway pressure exceeds the maximum limited pressure.
The gas from gas output port could be divided: one is for inspiratory pressure control sensor (Pvent ctrl) through zeroing valve(SOL1), the others go through the Rinse Valve, Rinse tank, filter screen (F5), flushing gas resistor (R2) to form two flushing air flows and for proximal-end flow sensor. One flushing air flow goes

through zeroing valve (SOL2) for flow monitoring sensor(Pflow), this pressure is named flow sensor distal-end pressure; the other one flushing gas flow goes through zeroing valve (SOL3) for flow monitoring sensor (Pflow) and Airway pressure sensor(Ppaw), this pressure is named flow sensor proximal-end pressure.

The expiratory valve assembly is mainly used to control pressure of the patient expiratory phase. The expiratory valve driving gas flow through the expiratory valve air resistor (R3) for flow-limiting, and then enters the expiratory proportional valve (PEEP Valve) to control the valve diaphragm opening, thereby changing the inner pressure of valve chamber of the expiratory valve (Exp. Valve). This pressure, which is monitored by the expiratory valve pressure sensor (Pexp), works with the blower control output gas to achieve the target airway pressure. The gas exhaled by the patient is discharged from the expiratory valve and exhaust from the expiratory port (Exp Port) to atmosphere.

From the high-pressure O_2 supply after a check valve, there is one branch taken from inlet of the oxygen proportional valve. The gas flows through the nebulizer gas resistor (R1) and generates a continuous flow. The nebulizer on-off valve (NCV) controls the on/off state of the nebulizer gas flow, for driving the pneumatic nebulizer kit. With the nebulizer connected in the inspiratory limb of breathing tube, the driving gas is introduced into the Nebulizer through the nebulizer port on the side panel of the ventilator.

Appendix II Accessories

The following accessories are recommended by the manufacturer when using the ventilator.

⚠ 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, please do 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 with human body.**
- **Ventilator breathing systems, their parts and accessories listed in this manual are validated for use with V1/V1A ventilators.**
- **Before monitoring the patient, check that accessories are compatible with the ventilator. Incompatible accessories reduce the performance of the 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.**

⚠ NOTE

- **The listed parts are only applicable for this ventilator. The hospital is responsible for the compatibility of ventilator and accessories to keep its performance. The responsible organization is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use.**

1. Breathing Circuit Accessories

Description	Models	Remark
Breathing system filter	800-51700	/
VADI Reusable adult breathing tube[1]	G-328000	/
VADI Reusable pediatric breathing tube[2]	G-33000	/
VADI Reusable infant breathing tube[3]	G-329000	/
Disposable adult/pediatric breathing tube[4]	Q112218P	/
Disposable reservoir bag -2l	504-012-50430600	/

[1]Recommended tidal volume range for the tube:100 ml~2200 ml
[2]Recommended tidal volume range for the tube:20 ml ~300 ml
[3]Recommended tidal volume range for the tube:20 ml ~300 ml
[4]Recommended tidal volume range for the tube:20 ml ~2200 ml

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	/
HMEF (Heat and Moisture Exchanger/Bacterial Viral filter combined)	800-51800	/
Mask for infant	5312	/
Mask for pediatric patient	5313	/
Mask for adult	5315	/
Disposable differential pressure flow sensor	CM0212FLOW	/
Disposable differential pressure flow sensor	007-00006	/
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 L, Silicon	DCA100, REF 0011	/
Headgear for CPAP mask S, Silicon	DCA100, REF 0012	/

2. SpO_2 Accessories

Description	**Models**	**Application site**	**Applicable people**	**Remark**
Comen SpO_2 probe (finger clip type)	A0816-SA105PV	Finger	Adult	Reusable
Comen SpO_2 probe (finger clip type)	SAL104	Finger	Adult	Reusable
Comen SpO_2 probe (finger clip type)	SAS104	Finger	Adult	Reusable
Comen SpO_2 probe (bandage type)	SES104	Foot/Toe/ Finger	Pediatric Patient	Reusable
Comen SpO_2 cable extender	SLZ122	/	/	Reusable
Nellcor SpO_2 probe (finger clip type)	DS100A	Finger	Adult/Pediatric Patient (>40 kg)	Reusable
Nellcor SpO_2 probe (Y- type)	D-YS	Foot/Toe/ Finger	Adult/Pediatric Patient/Infant(>1kg)	Reusable
Nellcor SpO_2 cable extender	SLZ068	/	/	Reusable
Masimo SpO_2 Y-shaped sheath	/	/	/	Reusable

Masimo SpO_2 probe (finger clip type)	M-LNCS DCI	Toe/Finger	Adult/Pediatric Patient (>30 kg)	Reusable
Masimo SpO_2 probe (Y- type)	M-LNCS YI	Foot/Toe/ Finger	Adult/Pediatric Patient/Infant(>1kg)	Reusable
Masimo SpO_2 M-LNCS series patient cable extender	S-A1202026	/	/	Reusable
Masimo SpO_2 RD-SET series patient cable extender	CM12-RD-L	/	/	Reusable
Adult Reusable finger clip SpO_2 sensor	RD SET DCI	Toe/Finger	Adult/Pediatric Patient (>30 kg)	Reusable
Padiatric/Slender digit Reusable finger clip SpO_2 sensor	RD SET DCI-P	Toe/Finger	Adult/Pediatric Patient (10-50 kg)	Reusable
Masimo SpO_2 probe (Y- type)	RD SET YI	Foot/Toe/ Finger	Adult/Pediatric Patient/Infant(>1kg)	Reusable
Infant/Adult pulse oximeter Adhesive sensor	RD SET Neo	Foot/Toe/ Finger	Adult(>40kg) /Infant(<3 kg)	Disposable
Infant/Adult pulse oximeter Adhesive sensor	RD SET Neo CS-2	Foot/Toe/ Finger	Adult(>40kg) /Infant(<3 kg)	Disposable

3. CO_2 Accessories

Description	**Models**	**Remark**
Masimo mainstream CO_2 module	CAT.NO.200101	Reusable
Masimo mainstream CO_2 airway adaptor	CAT.NO.106220	Single patient use
Masiimo mainstream airway adaptor for infant	CAT.NO.106260	Single patient use
Masimo CO_2 module interface cable	98ME07GC968	Reusable
Masimo sidestream NomoLine ISA CO_2 module	NomoLine ISA CO_2	Reusable
Masimo sidestream CO_2 sampling line with male connector (adult, pediatric and infant use)	CAT.NO.108210	Single patient use
CO_2 sampling line with airway adapter for Adult use	REF 3827	Single patient use
CO_2 sampling line airway adapter for Adult /Pediatric use	REF 3828	Single patient use
Respironics mainstream CO_2 module	1015928	Reusable
Respironics mainstream CO_2 airway adaptor	6063-00	Single patient use
Respironics CO_2 module interface cable	98ME07GC067	Reusable
Respironics CapnoTrak sidestream CO_2 module	F-01	Reusable
Respironics sidestream CO_2 filtering tube	1103416	Single patient use
Respironics sidestream CO_2 dehumidification tube	1103417	Single patient use
Respironics sidestream CO_2 sampling line with airway adapter set for Adult use	1103414	Single patient use
Respironics sidestream CO_2 sampling line with airway for Pediatric use	1103415	Single patient use
Comen sidestream CO_2 module	F-02	Reusable
Comen mainstream CO_2 module	M-01	Reusable

Appendix III Product Specification

(1) Safety Classification

Item	Classification
Type of protection against electrical shock	Class I equipment (connected to AC supply mains), Class II equipment (connected to external DC 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 line 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 liquid ingress	IP24
Standard compliance	IEC60601-1:2005+A1:2012, IEC60601-1-2:2014, IEC 60601-1-6:2010+A1:1013, IEC60601-1-8:2006+A1:2012, IEC60601-1-12:2014, ISO 80601-2-55:2018, ISO 80601-2-61:2017, EN 794-3:1998+A2:2009, ISO 80601-2-12:2011, ISO 18562-1:2017, EN 1789:2007+A2:2014

(2) Environmental Specification

Main Unit

Item	Temperature (℃)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	-18~50(transit operation) 0~40(continuous operation)	5%～95 %R.H	59.0 ～110.0
Transport & Storage	-30 ～ 70(except chemical O_2 sensor: -20~50)	5 %～95 %R.H	59.0 ～110.0

Comen Mainstream CO_2 Module

Item	Temperature (℃)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	0～45	10 %～90 %R.H	53.3～113.3
Transport & Storage	-40～70	＜90%R.H	50~106

Comen Sidestream CO_2 Module

Item	Temperature (℃)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	0～55	10 %～95 %R.H	53.3~106.6
Transport & Storage	-40～70	10 %～95 %R.H	50~106.6

Masimo IRMA™ Mainstream CO_2 Module

Item	Temperature (℃)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	0～40	＜95%R.H	52.5~120
Transport & Storage	-40～75	5%～100% R.H	50~120

Masimo Nomoline ISA Sidestream CO_2 Module

Item	Temperature (℃)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	0～50	10 %～95 %R.H	52.5~120
Transport & Storage	-40～70	5 %～100 %R.H,(100% RH at 40℃)	20~120

Respironics CAPNOSTAT^5 Mainstream CO_2 Module

Item	Temperature (℃)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	0～45	10 %～90 %R.H	53.3～113.3
Transport & Storage	-40～70	＜90%R.H	50~106

Respironics Capno Trak Sidestream CO_2 Module

Item	Temperature (℃)	Relative humidity (non-condensing)	Atmospheric pressure (kPa)
Operation	0～55	10 %～95 %R.H	53.3~106.6
Transport & Storage	-40～70	10 %～95 %R.H	50~106.6

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

Note: The ventilator supports transit operation within environmental condition -18℃~5℃, 5%~95%R.H., 59.0~110.0kPa, for up to 1 hour, and within environmental condition 40℃ ~50℃, 5%~95%R.H., 59.0~110.0kPa for up to 25 minutes.

(3) Power Specification

External AC power supply		
Input voltage	100～240V~	
Input frequency	50Hz/60Hz	
Input current	1.8～0.75A	
Power consumption	50 VA typical, 180VA maximum	
External DC power supply		
Input voltage	12～30.3Vd.c.	
Input current	12.5~4.95A	
Power consumption	50 VA typical, 180VA maximum	
Internal battery		
Number of battery(s)	1 or 2	
Battery type	Lithium-ion battery pack	
Dimension	About 154mm×62mm×23mm	
Rated battery voltage	10.8Vd.c.	
Battery capacity	The capacity of single battery pack is 6600mAh	
Current	Max. 20A	
OperatingTemperature	Charge	10℃~+45℃
	Discharge	-20℃~+60℃
StorageTemperature	Lessthan1month	-20 ℃~50 ℃
	Lessthan 3 months	-20 ℃~40 ℃
	Lessthan 6 months	-20 ℃~20 ℃
Expected Number of charge and discharge cycles	300 times	
Minimum operation time	280min (when a new fully charged battery is used in typical operating mode) 560min (when two new fully charged batteries are used in typical operating mode)	

Standard operating condition of the ventilator:
Test lung settings: R=20 $cmH_2O/(l/s)$ ±10%, C=50 ml/cmH_2O ±5%
Gas supply type: medical gas pipeline system;
Rated working pressure of gas supplysource: 400±100kPa;
Ventilation parameter settings of the ventilator:
Respiratory mode: P-A/C
Waveform displayed: 3 curves
Inspiratory pressure: 10 cmH_2O
Respiratory rate: 10 bpm
I:E: 1: 4
PEEP: 5 cmH_2O
Flow trigger: 5 l/min
O_2 concentration: 21%
Screen brightness: 4(20%)

(4) Physical Specification

Overall Dimension	
Dimension	About 330mm×314mm×215mm (with handle) About 330mm×247mm×215mm (without handle)
Weight	About 6.5kg (with 1 battery) About 60kg (trolley with safe working load)
Casters	4 pcs, each equipped with a brake pedal
Installation method	Trolley/Bed rail/Fixed base
Noise	Not more than 45dB(A)
Display	
Type	TFT display
Size	8.4 inch
Resolution	800×600
Adjustable angle	None
Brightness	Clear waveforms and important parameters can be seen under strong and weak light, and the viewing angel is not less than 160°.
Touch Screen	
Size	8.4 inch
Type	Resistive screen
LED Indicator	
External power supply light	1 pc (green. ON: external power supply is connected)
ON/OFF light	1 pc; also called power switch key backlight (white. ON: the device is powered on; OFF: the device is powered off).
Battery indicator	1 pc (green) Device powered off and with AC/DC current: FLASHING - charging; CONSTANT ON - fully charged Device powered off and without AC/DC current: OFF Device powered on and with AC/DC current: FLASHING - charging; CONSTANT ON - fully charged Device powered on and without AC/DC current: ON
Alarm light	1 pc (red/yellow. When high priority and medium priority alarms are generated simultaneously, only the red light blinks.)
Screen lock/unlock indicator	1 pc (green)
Manual ventilation/ inspiration hold key indicator	1 pc (green)
Oxygen enrichment/Sputum suction light	1 pc (green)
Alarm Audio Paused light	1 pc
Audio indicator	
Speaker	For generating alarm audio, key tone; multiple volume levels supported; alarm audio complying with the requirements of IEC60601-1-8.
Buzzer	Technical error and total power failure occur, buzzer alarming
Ports	
RJ45 network port	Calibration use (for manufacturer maintenance only)
USB port	For the ventilator software update, as well as export of configuration files,

	trend data, screenshots, logs, calibration tables, etc.
DC power port	DC power inlet
AC power port	AC power inlet
Earthing rod	Equipotentiality
CO_2 connector	CO_2 module connector
SpO_2 connector	SpO_2 cable connector
Requirement for breathing system bacteria filter	50 ml, bacteria filter efficiency: 99.99%； virus filter efficiency: 99.99%
Filter cotton	Filter efficiency: ≥99.99%, Filter accuracy≤0.3μm
Dead space of nasal cannula	≤50 ml

(5) Data Review

Item	Specification
Screenshot	When a USB disk is not inserted, up to 50 screenshots can be stored in the ventilator. When a USB disk is inserted, up to 2000 screenshots can be stored in the USB disk.
Graphic Trend	Up to 72 hours Graphic Trend data can be stored.
Tabular Trend	Up to 72 hours Tabular Trend data can be stored.
Event Log	Up to 5000 events can be stored.

(6) Pneumatic System Specification

High Pressure O_2 Supply	
Pressure range	280kPa~600kPa
Flow	Maximum of 200 l/min (STPD)
Input connector	NIST or DISS
Low Pressure O_2 Supply	
Pressure range	<100kPa
Maximum flow rate	15 l/min
Input connector	Quick connector system compatible with CPC (PMC series)
Inspiratory Module	
Peak flow	260 l/min
Nebulizer port	Flow rate: 4 l/min~9 l/min
Inspiratory-side external connector	Coaxial 22mm/15mm conical connector
VBS Connector compliance	ISO 5356-1
Expiratory Module	
Expiratory-side external connector	Coaxial 22mm/15mm conical connector
Removability and	Could be disassembled, cleaned, disinfection or sterilization.

sterilizability	
System Compliance and Resistance	
Compliance	Two-limb circuit; with reusable adult circuit breathing tube: ≤2 ml/cmH_2O
	Two-limb circuit, with reusable pediatric breathing tube: ≤2 ml/cmH_2O
	Two-limb circuit, with reusable infant breathing tube: ≤2 ml/cmH_2O
	Coaxial circuit, with adult/pediatric disposable breathing tube: ≤2 ml/cmH_2O
Inspiratory resistance	≤ 6 cmH_2O at the flow rate of 60 l/min (Adult breathing tube) ≤ 6 cmH_2O at the flow rate of 30 l/min (Pediatric breathing tube) ≤ 6 cmH2O at the flow rate of 5 l/min (Infant breathing tube)
Expiratory resistance	≤ 6 cmH_2O at the flow rate of 60 l/min (Adult breathing tube) ≤ 6 cmH_2O at the flow rate of 30 l/min (Pediatric breathing tube) ≤ 6 cmH_2O at the flow rate of 5 l/min (Infant breathing tube)
System Leakage	
System leakage	＜200 ml/min@50 cmH_2O(BTPS) ＜100 ml/min@40 cmH_2O(BTPS) ＜50 ml/min@20 cmH_2O(BTPS)
Gas Compatibility	
Gas compatibility	Meet the requirements of ISO18562-1, ISO18562-2, ISO18562-3, ISO18562-4

(7) Ventilator Specification

Control Parameter Specification			
Parameter	**Set Range**	**Step**	**Ventilation mode**
Tidal volume (TV)[5]	20 ml～2200 ml	5 ml in the range of 20 ml~100 ml; 10 ml in the range of 100 ml~1000 ml; 50 ml in the range of 1000 ml~2200 ml;	PRVC, PRVC-SIMV
Inspiratory Pressure (ΔPinsp)	3 cmH_2O～65 cmH_2O	1 cmH_2O	P-A/C, P-SIMV, PSV-S/T
O_2 concentration (O_2%)	21 vol.%～100 vol.%	1 vol.%	P-A/C, P-SIMV, CPAP/PSV, PRVC, DuoVent, APRV, PRVC-SIMV, PSV-S/T
Pressure support (ΔPsupp)	0 cmH_2O～65 cmH_2O	1 cmH_2O	CPAP/PSV, P-SIMV, PRVC-SIMV, DuoVent
Positive End-expiratory Pressure (PEEP)	0 cmH_2O～40 cmH_2O	1 cmH_2O	P-A/C, P-SIMV, CPAP/PSV, PRVC, DuoVent, PRVC-SIMV, PSV-S/T

[5]Recommended set Tidal volume (TV): for Adult: 100 ml ~2200 ml; for Pediatric Patient/Infant: 20 ml~300 ml.

Inspiratory Time (Tinsp)	0.10s～12.00s	0.01s in the range of 0.10s~1.00s; 0.05s in the range of 1.00s~3.00s: 0.1s in the range of 3.00s~12.00s	P-SIMV, PRVC-SIMV, PSV-S/T
Inspiratory Time: Expiratory Time (I:E)	1:10～4:1	1 in the range of 1:10~1:4; 0.1 in the range of 1:4~4:1;	P-A/C, PRVC
Respiratory Rate (f)	1 bpm～80 bpm	1bpm	P-A/C, P-SIMV, DuoVent, PRVC, PRVC-SIMV, PSV-S/T
Rise Time (Tslope)	0 ms～2000 ms	50ms	P-A/C, P-SIMV, CPAP/PSV, PRVC, DuoVent, APRV, PRVC-SIMV, PSV-S/T
High Pressure Level (Phigh)	0 cmH_2O～65 cmH_2O	1 cmH_2O	DuoVent, APRV
Low Pressure Level (Plow)	0 cmH_2O～40 cmH_2O	1 cmH_2O	APRV
High Pressure Time (Thigh)	0.10 s～40.00 s	0.01s in the range of 0.10s~1.00s; 0.05s in the range of 1.00s~3.00s; 0.10s in the range of 3.00s~40.00s	DuoVent, APRV
Low Pressure Time (Tlow)	0.20 s～40.00 s	0.01s in the range of 0.20s~1.00s; 0.05s in the range of 1.00s~3.00s; 0.10s in the range of 3.00s~40.00s	APRV
Flow Trigger Level(F-Trig)	OFF, 1.0 l/min ～ 20.0 l/min	0.1 l/min in the range of 1.0 l/min~2.0 l/min; 0.5 l/min in the range of 2.0 l/min~20.0 l/min	P-A/C, P-SIMV, CPAP/PSV, PRVC, DuoVent, APRV, PRVC-SIMV, PSV-S/T
Expiratory Trigger Sensitivity (Exp%)	Auto, 5%～80%	5%	CPAP/PSV, PRVC-SIMV, PSV-S/T, P-SIMV, DuoVent

Maximum Inspiratory Time (Timax)	1.00s～3.00s	0.05s	CPAP/PSV, PSV-S/T
Apnea Tidal Volume (TVapnea)	20 ml～2200 ml	5 ml in the range of 20 ml~100 ml; 10 ml in the range of 100 ml~1000 ml; 50 ml in the range of 1000 ml~2200 ml;	DuoVent, APRV, CPAP/PSV, PRVC-SIMV
Apnea pressure (ΔPapnea)	3 cmH_2O～65 cmH_2O	1 cmH_2O	CPAP/PSV
Apnea frequency (fapnea)	1 bpm～80 bpm	1 bpm	DuoVent, APRV, CPAP/PSV, PRVC-SIMV
Apnea I:E	1:10～4:1	1 in the range of 1:10~1:4; 0.1 in the range of 1:4~4:1	DuoVent, APRV, CPAP/PSV, PRVC-SIMV
Apnea Inspiratory Tim (Apnea Tinsp)	0.10 s～12.00 s	0.01s in the range of 0.10s~1.00s; 0.05s in the range of 1.00s~3.00s: 0.10s in the range of 3.00s~12.00s	DuoVent, APRV, CPAP/PSV, PRVC-SIMV
Oxygen therapy flow (Flow)	2 l/min～60 l/min	1 l/min	HNFC
Sigh	ON, OFF	/	P-A/C, P-SIMV, CPAP/PSV, PRVC, PRVC-SIMV, PSV-S/T
Apnea Ventilation (Apnea Vent)	ON, OFF	/	DuoVent, APRV, CPAP/PSV, PRVC-SIMV

Monitoring Parameter Specification		
Parameter		**Monitoring Range**
Tidal volume (TV)	Inspiratory Tidal Volume (TVi)	0 ml～9999 ml
	Expiratory Tidal Volume (TVe)	
	Spontaneous expiratory tidal volume (TVe spn)	
Airway Pressure	Peak Pressure (Ppeak)	-20 cmH_2O～85 cmH_2O
	Plat Pressure (Pplat)	

(Paw)	Mean Pressure (Pmean)	
FiO_2		0 vol.%～100 vol.%
Positive End-expiratory Pressure (PEEP)		0.0 cmH_2O～85.0 cmH_2O
Minute ventilation (MV)	Minute ventilation (MV)	0.0 l/min～100.0 l/min
	Spontaneous minute ventilation (MVspn)	
	Leakage per Minute (MVleak)	
Respiratory Rate(f)	Total respiratory rate (ftotal)	0 bpm～200 bpm
	Spontaneous respiratory rate (fspn)	
	Mandatory respiratory frequency (fmand)	
Oxygen therapy flow (Flow)		0.0 l/min～100.0 l/min
Inspiratory peak flow (PIF)		0.0 l/min～260.0 l/min
Expiratory peak flow (PEF)		0.0 l/min～260.0 l/min
Inspiratory Time: Expiratory Time (I:E)		9.9:1~1:99
Inspiratory Time (Tinsp)		0.00s～60.00s
Expiratory Time (Texp)		0.00s～60.00s
Resistance	Inspiratory resistance (Rinsp)	0 cmH_2O/(l/s)～600 cmH_2O/(l/s)
	Expiratory resistance (Rexp)	
Compliance	Static Compliance (Cstat)	0 ml/cmH_2O～300 ml/cmH_2O
	Dynamic Compliance (Cdyn)	
Rapid shallow breathing index (RSBI)		0 (min Ł)～999/(min Ł)
100ms Occlusion Pressure (P0.1)		-20.0 cmH_2O～0.0 cmH_2O
Expiratory Time Constant (RCexp)		0.00 s～99.90s
Intrinsic PEEPi (PEEPi)		0.0 cmH_2O～85.0 cmH_2O
Pressure-time integral (PTP)		0.0 cmH_2O*s～100 .0 cmH_2O*s
TVe/IBW		2.0 ml/kg～20.0 ml/kg
Spontaneous respiratory rate% (fspn%)		0%～100%
Pneumatic Leak% (Vleak%)		0%～100%

(8) Ventilator Parameter Accuracy

Control Parameter Accuracy	
Control Parameter	**Accuracy**
TV	±(10 ml+10% of the set value)
ΔPinsp	±(2 cmH_2O + 5% of the set value)
O_2%	±(3 vol.% + 1% of the set value)
ΔPsupp	±(2 cmH_2O + 5% of the set value)
PEEP	±(2 cmH_2O + 5% of the set value)
Tinsp	±0.1s or ±10% of the set value, whichever is larger
I:E	1:4~2:1: ±10% of the set value; other ranges: ±15% of the set value.

f	±1 bpm
Tslope	± (200 ms + 20% of the set value)
Phigh	± (2 cmH_2O + 5% of the set value)
Plow	± (2 cmH_2O + 5% of the set value)
Thigh	±0.1s or ± 10% of the set value, whichever is larger
Tlow	±0.1s or ± 10% of the set value, whichever is larger
F-Trig	± (1 l/min + 10% of the set value)
Exp%	± 10% (absolute error)
Timax	±0.1s or ± 10% of the set value, whichever is larger
TVapnea	± (10 ml+10% of the set value)
ΔPapnea	± (2 cmH_2O + 5% of the set value)
fapnea	±1 bpm
Apnea I:E	1:4~2:1: ±10% of the set value; other ranges: ±15% of the set value.
Apnea Tinsp	±0.1s or ± 10% of the set value, whichever is larger
Flow	± (2 l/min + 10% of the set value)

Monitoring Parameter Accuracy	
Monitoring Parameter	**Accuracy**
TV	±10 ml or ± 10% of the actual reading, whichever is larger in the range of 0 ml～9999 ml
Paw	±(2 cm H_2O + 4% of the actual reading) in the range of -20 cmH_2O～85 cmH_2O
FiO_2	± (3 vol.%+1% of the set value) in the range of 0 vol.%～100 vol.%
PEEP	±(2 cmH_2O + 4% of the actual reading) in the range of 0 cmH_2O～85 cmH_2O
MV	±10% of the actual reading or ±0.3 l/min, whichever is larger in the range of 0.0 l/min～100.0 l/min
f	±1bpm in the range of 0 bpm~200 bpm
Flow	±1 l/min or ± 10% of the actual reading, whichever is larger in the range of 0.0 l/min～100.0 l/min
PIF	±1.2 l/min or ± 10% of the actual reading, whichever is larger in the range of 0.0 l/min～260.0 l/min
PEF	±1.2 l/min or ± 10% of the actual reading, whichever is larger in the range of 0.0 l/min～260.0 l/min

Resistance	±10 cmH_2O/(l/s) in the range of 5 cmH_2O/(l/s) ~ 20 cmH_2O/(l/s) ±50% of the actual reading in the range of 20 cmH_2O/(l/s) ~ 500 cmH_2O/(l/s) (not including 20 cmH_2O/(l/s)) In the range of 0 cmH_2O/(l/s)～5 cmH_2O/(l/s) and 500 cmH_2O/(l/s)～600 cmH_2O /(l/s), the accuracy is not defined.
Compliance	± (2 ml/cmH_2O+20% of the actual reading) in the range of 0 ml/cmH_2O~300 ml/cmH_2O
RSBI	± (3/(min Ł) +15% of the actual reading) in the range of 0/(min Ł) ~999 /(min Ł)
P0.1	± (2 cmH_2O + 4% of the actual reading) in the range of -20.0 cmH_2O～0.0 cmH_2O
RCexp	± (0.2s+20 % of the actual reading) in the range of 0.00s~10.00s
The response of the ventilator to oxygen concentration	The time required for the oxygen concentration in the delivery ventilation to change from 21% to 90% of the maximum settable value: When TV=500 ml, f=10/min, I:E=1:2, ≤45s When TV=150 ml, f=20/min, I:E=1:2, ≤120s When TV=30 ml, f=30/min, I:E=1:2, ≤250s

(9) Alarm

Parameter Name		Set Range	Step	Remark
Tidal volume (TV)	High Limit	10 ml～3000 ml, OFF	5 ml in the range of 10 ml～500 ml; 10 ml in the range of 500 ml～1000 ml; 50 ml in the range of 1000 ml～3000 ml;	The high limit shall be set larger than the low limit.
	Low Limit	OFF, 10 ml~3000 ml		
Minute ventilation (MV)	High Limit	0.2 l/min ~50.0 l/min	0.1 l/min in the range of 0.1 l/min～1.0 l/min; 0.5 l/min in the range of 1.0 l/min～10.0 l/min; 1 l/min in the range of 10.0 l/min～50.0 l/min;	
	Low Limit	0.1 l/min ~49.0 l/min		
O_2%	High Limit	22 vol.%~100 vol.%	1 vol.%	
	Low Limit	18 vol.%~ 99 vol.%		

O_2% (in high pressure O_2 supply and O_2 therapy)	High Limit	Min [O_2 concentration set value + Max. (7 vol.%, set O_2 concentration set value ×10%), 100 vol.%]	/	
	Low Limit	Max [18 vol%, O_2 concentration set value - max (7 vol.%, O_2 concentration set value ×10%)]	/	
Airway Pressure (Paw)	High Limit	5 cmH_2O~75 cmH_2O	1 cmH_2O	The high limit should not be set lower than set ΔPinsp + 5 cmH_2O
	Low Limit	OFF, 1 cmH_2O~74 cmH_2O		
Respiratory Rate (ftotal)	High Limit	1 bpm~100 bpm	1 bpm	The high limit should be set larger than the low limit.
	Low Limit	OFF, 1 bpm ~99 bpm		
Apnea		15s~60s	5s	/

(10) O_2 Sensor Specification

Item	Specifications
Expected service life	0.94 x 10^6 % O_2 hours at 20 ℃ 0.6 x 10^6 % O_2 hours at 40 ℃
Thermal compensation	Fluctuation of ±2% within the range 0-40 ℃
Barometric pressure compensation	Automatic barometric pressure compensation configured
Pressure range	0.5-2.0 Bar
Total system response time of O_2 sensor	<15s

(11) SpO_2 Specifications

Item	Specifications
Regulatory compliance	ISO80601-2-61.
Displayed parameters	Pulse waveform; %SpO_2 and PR
Display resolution	1% SpO_2
Measurement range and accuracy of pulse SpO_2	a) Comen SpO_2 module: Measurement range: 0%~100%. 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. b) Masimo SpO_2 module: Measurement range: 1%~100%. 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. c) Nellcor SpO_2 module: Measurement range: 1%~100%. 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.
Measurement range and accuracy of PI	Comen SpO_2 module: 0.05%~20%; accuracy: not defined; Masimo SpO_2 module: 0.02%~20%; accuracy: not defined;
PI index resolution	Masimo SpO_2 module: 0.02%~9.99%: 0.01%. 10.0%~20.0%: 0.1%. Comen SpO_2 module: 0.05%~9.99%: 0.01%. 10.0%~20.0%: 0.1%.
Data update period	1 s
Signal IQ (SIQ) indicator	Masimo SpO_2 module and Comen SpO_2 module have the feature of SIQ.
SpO_2 alarm limit and accuracy	a) Comen SpO_2 module: 0%～100%; High limit: (low limit + 1%) ~100%; Low limit: 0%~ (high limit - 1%). b) Masimo SpO_2 module: 1%～100%; High limit: (low limit + 1%) ~100%; Low limit: 1%~ (high limit - 1%). c) Nellcor SpO_2 module: 20%～100%; High limit: (low limit + 1%) ~100%; Low limit: 20%~ (high limit - 1%). d) Adjusting step: ±1%
Measurement range, resolution and error of pulse rate (PR)	a) Comen SpO_2 module Measurement range: 20 bpm~254 bpm; resolution: 1 bpm; Measurement error: ±2 bpm. b) Masimo SpO_2 module Measurement range: 25 bpm~240 bpm; resolution: 1 bpm; Measurement error: ±3 bpm (during non-motion state). c) Nellcor SpO_2 module Measurement range: 20 bpm~300 bpm; resolution: 1 bpm; Measurement error: ±3 bpm in 20 bpm~250 bpm range, not defined in 251 bpm~300 bpm range.
PR alarm limit and error	a) Comen SpO_2 module Alarm limit range: 20 bpm~254 bpm; High limit: 21 bpm~254 bpm; Low limit: 20 bpm~253 bpm. b) Masimo SpO_2 module Alarm limit range: 25 bpm~240 bpm; High limit: 26 bpm~240 bpm; Low limit: 25 bpm~239 bpm. c) Nellcor SpO_2 module Alarm limit range: 20 bpm~300 bpm; High r limit: 21 bpm~300 bpm;

	Low limit: 20 bpm~299 bpm. d) Adjusting step:1 bpm

(12) CO_2 Module Specifications (only applicable to V1)

Name	Specifications
CO_2 module meets the requirements of ISO80601-2-55.	
Sidestream CO_2 Module	
Measurement range of CO_2	Comen sidestream: 0 mmHg~150 mmHg, 0%~19.7%, 0 kPa~20 kPa (at 760 mmHg)
	Respironics CapnoTrak sidestream:0 mmHg～99 mmHg， 0%～13.03%，0 kPa～13.20 kPa(at 760 mmHg)
	Masimo Nomoline ISA sidestream: 0 mmHg~190 mmHg, 0%~25% (at 760 mmHg)
Measurement accuracy of CO_2	Comen sidestream: a) In the range of 0 mmHg ~40 mmHg: ±2 mmHg; b) In the range of 41 mmHg ~70 mmHg: ±5%×reading; c) In the range of 71 mmHg ~100 mmHg: ±8%×reading; d) In the range of 101 mmHg~150 mmHg: ±10%×reading.
	Respironics CapnoTrak sidestream: CO_2 accuracy: a) In the range of 0 mmHg ~38 mmHg: ±2 mmHg; b) In the range of 38.01 mmHg ~99 mmHg: ±10%×reading; Additional effects of respiration rate on $ETCO_2$ (0～99 mmHg): 0 rpm -40 rpm: -2 mmHg~+0.5 mmHg 41 rpm -70 rpm: 6%×reading～+0.5 mmHg 71 rpm ～100 rpm: 14%×reading～+0.5 mmHg
	Masimo Nomoline ISA sidestream: CO_2 accuracy (under all conditions): a) ±(2.25 mmHg+4%×reading) in the range of 0 mmHg~114 mmHg; b) not defined in the range of 114 mmHg~190 mmHg.
Sampling Rate and Rate Control Accuracy	Comen sidestream: Sampling rate: 50 ml/min; Sampling rate control accuracy: ±10 ml/min
	Respironics CapnoTrak sidestream: Sampling rate: 50 ml/min; Sampling rate control accuracy: ±10 ml/min
	Masimo Nomoline ISA sidestream: Sampling rate: 50 ml/min; Sampling rate control accuracy: ±10 ml/min
Total system response time	Masimo Nomoline ISA sidestream: <3s Respironics CapnoTrak sidestream: Less than 3 seconds (with dehumidification and extension tubing). Comen sidestream: Less than 3 seconds (with dehumidification and extension tubing).
10% to 90% Rise time	Masimo Nomoline ISA sidestream: Typical rise time at 50 ml/min sample flow: ≤200ms Respironics CapnoTrak sidestream: Less than 410 ms (with

	dehumidification and extension tubing) Comen sidestream: Less than 410 ms (with dehumidification and extension tubing)
$ETCO_2$ Calculation	Masimo Nomoline ISA sidestream: $ETCO_2$ are displayed after one breath and have a continuously updated breath average； Respironics CapnoTrak sidestream: Range: 0, 5 to 99 mmHg Method: Peak of the expired CO_2 waveform over selected time period. Minimum of 5 mmHg between peak and valley of waveform required. Time Period Selections: 10 second, 20 second Comen sidestream: Method: Peak of the expired CO_2 waveform. Selections: 1 breath, 10 second, 20 second.
CO_2 Stability	Masimo Nomoline ISA sidestream: No drift Respironics CapnoTrak sidestream: 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. Comen sidestream: Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg Max. Long Term Drift: Accuracy specification will be maintainedover a 120-hour period.
Respiratory Rate	Masimo Nomoline ISA sidestream: 0 to 150±1 breaths/min. Measured at I/E ratio 1:1 using breath simulator according to ISO80601-2-55 fig.201.101
$ETCO_2$ and Respiratory rate accuracy method	Respironics CapnoTrak/ Comen sidestream: $ETCO_2$ and Respiration Rate accuracy is verified by using a solenoid test setting to deliver a square wave of known CO_2 concentration to the device. 5% and 10% CO_2 concentrations were used and respiration rate was varied over the range of the device. Pass/Fail criteria was a comparison of the respiratory rate output from the sensor to the frequency of the square wave. $EtCO_2$ measurements at those rates were compared to the CO_2 readings under static flow conditions.
Respiratory Rate Calculation	Respironics CapnoTrak sidestream: Range: 0, 2 to 100 mmHg breaths per minute(br/m) Accuracy: ±1 breath per minute Method: 8 breath averaging
Alarm specifications	Comen sidestream: Alarm range: 0mmHg ~150 mmHg $EtCO_2$ High Limit: (low limit+2mmHg) ~150mmHg; low limit: 0mmHg~ (high limit-2mmHg). $FiCO_2$ High Limit:0 mmHg～76mmHg; low limit: N/A
	Respironics CapnoTrak sidestream: Alarm range: 0mmHg ~99 mmHg $EtCO_2$ High Limit: (low limit+2mmHg) ~99 mmHg; low limit: 0mmHg~ (high limit-2mmHg). $FiCO_2$ High Limit:0 mmHg～76mmHg; low limit: N/A
	Masimo Nomoline ISA sidestream:

	Alarm range: 0mmHg~190 mmHg $EtCO_2$ High Limit: (low limit + 2mmHg) ~190mmHg; low limit: 0mmHg~ (high limit - 2mmHg). $FiCO_2$ High Limit: 0 mmHg～99mmHg; low limit: N/A
	Adjusting step: ±0.1kPa or ±1mmHg.
Mainstream CO_2 Module	
Measurement range of CO_2 module	Comen mainstream: 0mmHg~150 mmHg, 0%~19.7%, 0kPa~20kPa (at 760mmHg)
	Respironics CAPNOSTAT 5 mainstream: 0mmHg~150 mmHg, 0%~19.7%, 0kPa~20kPa (at 760mmHg)
	Masimo IRMA mianstream: 0mmHg~190mmHg, 0%~25% (at 760mmHg)
Measurement accuracy of CO_2	Comen mainstream: a) In the range of 0 mmHg ~ 40mmHg: ±2mmHg; b) In the range of 41mmHg ～70mmHg: ±5%×reading; c) In the range of 71mmHg ～100mmHg: ±8%×reading; d) In the range of 101mmHg~150 mmHg: ±10%×reading
	Respironics CAPNOSTAT 5 mainstream: a) In the range of 0 mmHg ~ 40mmHg: ±2mmHg; b) In the range of 41mmHg ～70mmHg: ±5%×reading; c) In the range of 71mmHg ～100mmHg: ±8%×reading; d) In the range of 101mmHg~150 mmHg: ±10%×reading
	Masimo IRMA mainstream: CO_2 accuracy (under all conditions): a) ±(2.25mmHg+4%×reading) in the range of 0mmHg~114mmHg; b) not defined in the range of 114 mmHg~190 mmHg.
Total system response time (for all CO_2 module)	<1s
CO_2 Stability	Masimo IRMA mainstream: No drift Respironics CAPNOSTAT 5 and COMEN CO_2: Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg maximum; Long Term Drift: Accuracy specification will be maintained over a 120 hour period.
$ETCO_2$ Calculation	Masimo IRMA mainstream: $ETCO_2$ is 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 CO_2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. $ETCO_2$ within specification for all respiratory rates up to 150 bpm. Respironics CAPNOSTAT 5 and COMEN CO_2: Method: Peak of the expired CO_2 waveform Selections: 1 breath, 10 second, 20 second Note: the minimum reported differential value between the baseline and the CO_2 value shall be 5 mmHg.
Sampling Rate	Masimo IRMA mainstream: sample rate 20 Hz / channel Respironics CAPNOSTAT 5 and COMEN CO_2: 100 Hz
Respiratory rate	Masimo IRMA mainstream: 0 to 150±1bpm. The respiration rate is

	displayed after three breaths and the average value is updated every breath. Measured at I/E ratio 1:1 using breath simulator according to ISO80601-2-55 fig.201.101 Respironics CAPNOSTAT 5 mainstream: Range: 0 to 150 breaths per minute (BPM) Accuracy: ± 1 breath
Alarm specifications	Comen mainstream: Alarm range: 0mmHg ~150 mmHg $EtCO_2$ High Limit: (low limit+2mmHg) ~150mmHg; Low Limit: 0mmHg~ (high limit-2mmHg). $FiCO_2$ High Limit:： 0 mmHg～76mmHg; low limit: N/A
	Respironics CAPNOSTAT 5 mainstream: Alarm Range: 0mmHg ~150 mmHg $EtCO_2$ High Limit: (low limit+2 mmHg) ~150mmHg; Low Limit: 0mmHg~ (high limit-2mmHg). $FiCO_2$ High Limit:： 0 mmHg～76mmHg; Low Limit: N/A
	Masimo IRMA mainstream: Alarm Range: 0mmHg~190 mmHg $EtCO_2$ High Limit: (low limit + 2mmHg) ~190mmHg; Low Limit: 0mmHg~ (high limit - 2mmHg). $FiCO_2$ High Limit:： 0 mmHg～99mmHg; Low Limit: N/A
	Adjusting step: ±0.1kPa or ±1mmHg.

Appendix IV Default Setting

(1) Standby Interface

[**Quick Vent**], default gender: male

Preset ventilation group	Default Control Parameters
IBW1: 70 kg @TVe/IBW=7 ml/kg	Ventilation mode: PRVC TV: 490 ml f: 10 bpm PEEP: 3 cmH_2O I:E: 1:2 O_2%: 50%
IBW2: 25 kg @TVe/IBW=7 ml/kg	Ventilation mode: PRVC TV: 180 ml f: 15 bpm PEEP: 3 cmH_2O I:E: 1:2 O_2%: 50%
IBW3: 10 kg @TVe/IBW=7 ml/kg	Ventilation mode: PRVC TV: 70 ml f: 20 bpm PEEP: 3 cmH_2O I:E: 1:2 O_2%: 50%

Default: [**New Patient**]

Default patient information	Default Control Parameters
Gender: Male Height (Weight): 174cm (70 kg) @TVe/IBW=7 ml/kg	Ventilation mode: P-A/C ∆Pinsp: 15 cmH_2O f: 10 bpm PEEP: 3 cmH_2O I:E: 1:2 O_2%: 50%
Default patient information	Default Control Parameters
Gender: Female Height (Weight): 174cm (70 kg) @TVe/IBW=7 ml/kg	Ventilation mode: P-A/C ∆Pinsp: 15 cmH_2O f: 10 bpm PEEP: 3 cmH_2O I:E: 1:2 O_2%: 50%

(2) Operating Interface

Display Settings	**Factory Settings**
Waveform	Wave 2 (Flow) Wave 3 (Volume) (can't be restored by restoring factory defaults)
Loop	Graph 1: (P-V) Graph 2 (F-V) (can't be restored by restoring factory defaults)

Loop: Display Reference Loop: OFF

Graphic Trends: Interval: not saved Classification: not saved
Tabular Trends: Interval: not saved Classification: not saved
O2 Threapy Time Reminder: 0

(3) Settings

Settings	Factory Defaults
Menu-Settings-Ventilation	Tinsp/ I:E: I:E
	DuoVent Setting: Thigh
	IBW/Height: IBW
	Invasive Apnea Mode: Volume Control
	TVe/IBW: 7 ml/kg
	Apnea Tinsp/ Apnea I:E: Apnea Tinsp
	Sputum Suction Duration: 120s
	O_2 ↑ Duration: 120s
	Adult O_2 ↑ Increment：60vol.%
	Pediatric O_2 ↑ Increment：60vol.%
	Infant O_2 ↑ Increment：40vol.%
Menu-Settings-O_2 Sensor	Monitoring Switch: ON
(Masimo) Menu-Settings-CO_2 Settings	Monitoring Switch: ON
	O_2 Compensation: Low
Menu-Settings-CO_2 Settings(Respironics、Comen)	Monitoring Switch: ON
	O_2 Compensation: 16%
	Balance Gas: Indoor Gas
	Altitude: 0.0
	Unit: m
	Baro Pres: 760mmHg
Menu-Settings-SpO_2 Settings (Masimo)	Monitoring Switch: ON
	Sensitivity: APOD
	Waveform Speed: 25mm/s
	Signal Strength Switch: ON
	Intelligent Alarm Tone Switch: ON
	Average Time: 8s
	Fast Sat.Switch: OFF
Menu-Settings-SpO_2 Settings (Nellcor)	Monitoring Switch: ON
	Waveform Speed: 25mm/s
	Intelligent Alarm: OFF
Menu-Settings-SpO_2 Settings (Comen)	Monitoring Switch: ON
	Sensitivity: High
	Waveform Speed: 25mm/s
	Signal Strength Switch: ON
Menu-Settings- O_2 Type	HPO
Menu-Screen-Brightness/Volume	Day/Light: Day
	Screen Brightness: 11
	Key Volume: 3
	Pulse Volume: 2
Menu-Screen-Interface Settings	Waveform Num: 3
	Waveform Type: Line
	Layout Setting Switch: ON
	Waveform Thickness: Med

Menu-Screen-Color	Pressure: Yellow
	Flow: Blue
	Volume: Green
	O_2: White
	SpO_2: Pink
	CO_2: Fuchsia
	Others: Gray
System-Settings-Language/Unit	Lanugage: English
	Pressure Unit: cmH_2O
	CO_2 Unit: mmHg
	Height Unit: cm
	Weight Unit: kg
	Frequency Unit: bpm
System-Settings-Date/Time Setting	24h Switch: ON
	Date Format: yyyy-MM-dd
System-Settings-Password Modification	Current Password: 5188
System-Settings-System Setting	Minimum Alarm Volume: 6

(4) Ventilation Mode

Parameters Setting (New Patient)	**Factory Defaults**
Mode	P-A/C
O_2%	50 vol.%
ΔPinsp	15 cmH_2O
f	10 bpm
I:E	1:2
PEEP	3 cmH_2O
Assist Trig	ON
F-Trig	5.0 l/min
Tslope	0.20s
Sigh	OFF
Parameters Setting (Quick Vent)	**Factory Defaults**
Mode	PRVC
O_2%	50 vol.%
TV	490 ml
f	10 bpm
I:E	1:2
PEEP	3 cmH_2O
Assist Trig	ON
F-Trig	5.0 l/min
Tslope	0.20s
Sigh	OFF

(5) Alarm Settings

Parameters	Default Settings	Auto Alarm Limits (based on monitoring value)
High TVe limit	TV*2 ml	1.5*TVe monitoring value
Low TVe limit	TV/2 ml	0.5*TVe monitoring value
High MV limit	Default TV*Default f*3/2 (round up and keep 1 decimal place)	1.5*MV monitoring value
Low MV limit	Default TV*Default f*1/2 (round up and keep 1 decimal place)	0.6*MV monitoring value
High Paw limit	50 cmH_2O	Mean Ppeak+10 cmH_2O or 35 cmH_2O, whichever is larger
Low Paw limit	OFF	PEEP monitoring value
High ftotal limit	Adult/Pediatric Patient: 40bpm Infant: 70bpm	1.4* monitoring value of total frequency, not exceeding 160bpm.
Low ftotal limit	OFF	0.6* monitoring value of total frequency
High O_2% limit (with low pressure O_2 supply)	100%	-
Low O_2% limit (with low pressure O_2 supply)	21%	-
High O_2% limit (O_2 Therapy)	57%	
Low O_2% limit (O_2 Therapy)	43%	
High $FiCO_2$ limit	4mmHg	-
Low $FiCO_2$ limit	-	-
High $EtCO_2$ limit	Adult/Pediatric Patient: 50mmHg Infant: 45mmHg	-
Low $EtCO_2$ limit	Adult: 15mmHg Pediatric Patient: 20mmHg Infant: 30mmHg	-
High SpO_2 alarm limit	100%	-
Low SpO_2 alarm limit	90%	-
High PR alarm limit	Adult: 120 bpm Pediatric Patient: 160 bpm Infant: 200 bpm	-
Low PR alarm limit	Adult: 50 bpm Pediatric Patient: 75 bpm Infant: 100 bpm	-
Tapnea	15s	15s
Alarm volume	6	-

Note: About the auto alarm limit

(1) This function uses an algorithm based on recent values of a monitored variable.

(2) Mean value in the formula: use the mean value of the monitoring values in the last 8 ventilation cycles or the monitoring value in 1 minute as Mean value, whichever is smaller.

(3) If the calculated alarm limit is greater than the high limit of the set range, or less than the low limit of it, the corresponding limit will be used as the auto alarm limit.

(4) Monitoring value in the formula: use the mean value of the monitoring values in last eight ventilation cycles.

Appendix V System Alarms

For each alarm, the corresponding countermeasures are listed. If the alarm still persists after following the countermeasures, please contact the maintenance personnel.

1) Physiological Alarms

Ventilator Parameters		
Alarms	**Alarm Priority**	**Causes and Solutions**
Paw Too High	H	The airway pressure exceeds the set high pressure alarm limit. 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits. 4. Check the respiratory circuit for occlusion.
Paw Too Low	H	The airway pressure setting is lower than the low limit of pressure alarm for two breathing cycles. 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits. 4. Check if the patient circuit is leaky or disconnected.
FiO_2 Too High	H	FiO_2 exceeds the high O_2 concentration alarm limit at least 30 seconds. 1. Check the ventilation parameter settings. 2. Check the alarm limits. 3. Check the HEPA filter for occlusion. 4. Calibrate the O_2 sensor.
FiO_2 Too Low	H	FiO_2 is less than the low O_2 concentration alarm limit at least 30s or less than 18% immediately. 1. Check the ventilation parameter settings. 2. Check the alarm limits. 3. Check the O_2 supply. 4. Calibrate the O_2 sensor.
TVe Too High	M	The TVe monitoring value is greater than high TVe alarm limit for 3 consecutive mechanical ventilation cycles. 1. Check the ventilation parameter settings. 2. Check the alarm limits.
TVe Too Low	M	The TVe monitoring value is less than low TVe alarm limit for 3 consecutive mechanical ventilation cycles. 1. Check the patient. 2. Check the ventilation parameter settings. 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	MV exceeds the high MV alarm limit. 1. Check the ventilation parameter settings.

		2. Check the alarm limits.
MV Too Low	H	MV is less than the low MV alarm limit.
		1. Check the ventilation parameter settings. 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 duration of not detecting breathing exceeds the set Tapnea.
		1. Check the patient. 2. Apply Manual ventilation. 3. Check apnea time setting. 4. Check if the patient tubing is disconnected.
Apnea Ventilation	H	The duration of not detecting breathing exceeds the set Tapnea. Start apnea ventilation mode.
		Check apnea ventilation parameter settings.
Apnea Vent Ended	L	Apnea Ventilation Ended
		Check apnea ventilation parameter settings.
ftotal Too High	M	ftotal is greater than the high ftotal alarm limit for 3 consecutive mechanical ventilation cycles.
		1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits.
ftotal Too Low	M	ftotal is less than the low ftotal alarm limit for 3 consecutive mechanical ventilation cycles.
		1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits.
PEEP Too High	M	Monitoring PEEP> (set PEEP+5), lasts for two consecutive breathing cycles.
		1. Check the ventilation parameter settings. 2. Check the patient tubing for occlusion. Alarm delay is within two breathing cycles.
PEEP Too Low	M	The PEEP is less than (set PEEP -3 cmH_2O), lasts two consecutive breathing cycles.
		1. Check the ventilation parameter settings. 2. Check the patient tubing for occlusion.
Inverse Ratio Vent	L	The set I:E is greater than 1:1, resulting in inverse breathing.
		1. Check the patient. 2. Check the ventilation parameter settings.
CO_2 Module		
$EtCO_2$ Too High	H/M	Monitoring parameter value exceeds the alarm limit.
		1. Check the patient type. 2. Check the alarm limits.

$EtCO_2$ Too Low	H/M	Monitoring parameter value exceeds the alarm limit. 1. Check the patient type. 2. Check the alarm limits.
$FiCO_2$ Too High	H/M/L	Monitoring parameter value exceeds the alarm limit. 1. Check the patient type. 2. Check the alarm limits.
SpO_2 Module		
SpO_2 Too High	H or M	SpO_2 value exceeds the high alarm limit. 1. Check the patient status and ventilator settings. 2. Check the patient's oxygen inhalation. 3. Check the alarm limits.
SpO_2 Too Low	H or M	SpO_2 is less than the low alarm limit. 1. Check the patient status and ventilator settings. 2. Check the patient's oxygen inhalation. 3. Check the alarm limits.
PR Too High	H or M	PR value exceeds the high alarm limit. 1. Check the patient status. 2. Check ventilator settings. 3. Check the alarm limits.
PR Too Low	H or M	PR value is less than the low alarm limit. 1. Check the patient status. 2. Check ventilator settings. 3. Check the alarm limits.

2) Technical Alarms

Key Board		
Alarm Messages	**Alarm Priority**	**Causes and Solutions**
Comm Error 202#	H	The main control board crashes or the uart connection fails. Restart the ventilator. If it reoccurs, please contact the designated maintenance service provider.
Comm Error 203#	H	The key board cannot be connected to the power board. The power board crashes or the uart connection fails. Restart the ventilator. If it reoccurs, please contact the designated maintenance service provider.
Power Error 266#	H	The +3V3_TOUCH Voltage is abnormal. Contact the designated maintenance service provider.
Key Error 201#	L	Foreign object continuously pressing the knob is detected. Check whether the knob is continuously pressed. If it reoccurs, please contact the designated maintenance service provider.
Key Error 202#	L	Foreign object continuously pressing the Alarm Audio Pause key is detected. Check whether the Alarm Audio Paused key is continuously

		pressed. If it reoccurs, please contact the designated maintenance service provider.
Key Error 203#	L	Foreign object continuously pressing the Screen Lock key is detected.
		Check whether the Screen Lock key is continuously pressed. If it reoccurs, please contact the designated maintenance service provider.
Key Error 204#	L	Foreign object continuously pressing the Oxygen Enrichment key is detected.
		Check whether the Oxygen Enrichment key is continuously pressed. If it reoccurs, please contact the designated maintenance service provider.
Key Error 205#	L	Foreign object continuously pressing the Manual Inspiration key is detected.
		Check whether the Manual Ventilation key is continuously pressed. If it reoccurs, please contact the designated maintenance service provider.
Power Supply Board		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
Comm Error 201#	H	The power board cannot be connected to the main board. The main control board crashes or the uart connection fails.
		Restart the ventilator. If it reoccurs, please contact the designated maintenance service provider.
Power Error 201#	H	The voltage of AC switch power is abnormal.
		Please contact the designated maintenance service provider.
Power Error 202#	H	The voltage of external DC power VAUXB is abnormal.
		Please contact the designated maintenance service provider.
Power Error 203#	H	The voltage of external DC boost power is abnormal.
		Please contact the designated maintenance service provider.
Power Error 204#	H	The voltage of external main power VADP is abnormal.
		Please contact the designated maintenance service provider.
Power Error 206#	H	The voltage of system main power VPWR（VBUS）is abnormal.
		Please contact the designated maintenance service provider.
Power Error 207#	H	The voltage of 5V power is abnormal.
		Please contact the designated maintenance service provider.
Power Error 209#	H	The voltage of 10V power is abnormal.
		Please contact the designated maintenance service provider.
Power Error 210#	H	The voltage of 12V power is abnormal.
		Please contact the designated maintenance service provider.
Power Error 211#	H	The voltage of blower 32V power is abnormal.
		Please contact the designated maintenance service provider.
Power Error 221#	H	Dual battery management circuit mulfunctions.

		Please contact the designated maintenance service provider.
Technical Error 201#	M	The buzzer malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 202#	H	The hardware watchdog malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 203#	H	The single chip microcomputer on the power board resets abnormally during operation.
		Please contact the designated maintenance service provider.
Bat A Temp High 201#	H	The temperature of battery A is too high during charging.
		Keep the ventilator away from sunlight or other heat sources. If it occurs many times at room temperature, please contact the designated maintenance service provider.
Battery A Error 202#	H	Battery A fails to charge.
		Please contact the designated maintenance service provider.
Replace Bat A	H	The battery has been used for a long time so that power supply time becomes shorter after it is fully charged. As a result, the battery is insufficient to maintain effective operation of the ventilator.
		Please contact the supplier to purchase new batteries.
Battery A Error 204#	H	Battery A fails to communicate.
		Check whether battery A is properly installed. If the error still appears after battery insertion and removal, please contact the designated maintenance service provider.
Battery A Error 205#	H	The voltage of battery A is abnormal.
		Please contact the designated maintenance service provider.
Bat B Temp High 201#	H	The temperature of battery B is too high during charging.
		If it occurs many times at room temperature, please contact the designated maintenance service provider.
Battery B Error 202#	H	Battery B fails to charge.
		Please contact the designated maintenance service provider.
Replace Bat B	H	The battery has been used for a long time so that power supply time becomes shorter after it is fully charged. As a result, the battery is insufficient to maintain effective operation of the ventilator.
		Please contact the supplier to purchase new batteries.
Battery B Error 204#	H	Battery B fails to communicate.
		Check whether battery B is properly installed. If the error still appears after battery insertion and removal, please contact the designated maintenance service provider.
Battery B Error 205#	H	The voltage of battery A is abnormal.
		Please contact the designated maintenance service provider.
Bat Temp High 206#	L	The battery temperature is too high during discharging.
		Keep the ventilator away from sunlight or other heat sources.

		If it occurs many times at room temperature, please contact the designated maintenance service provider.
Bat Temp Too High, May Power Off.	H	The battery temperature is too high during discharging. The system may power off.
		Keep the ventilator away from sunlight or other heat sources. If it occurs many times at room temperature, please contact the designated maintenance service provider.
Battery in Use	L	The current system is powered by battery.
		Pay attention to power usage and connect to external power supply in time.
Main Control Board		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
VCM Uart Comm Err	H	The VCM sends data falsely. The VCM is faulty
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
Comm Error 300#	H	The main control board fails to connect the VCM. The VCM crashes or the uart connection is abnormal.
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
VCM Uart Comm Error	H	TheVPM sends data falsely. The VPM is faulty
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
Comm Error 301#	H	The main control board fails to connect the VPM. The VPM crashes or the uart connection is abnormal.
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
Key Board Comm Error	H	The communication check between the main control board and the key board fails.
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
KYBD Uart Comm Stop	H	The main board cannot be connected to the key board. The KYBD (key board) crashes or the uart connection fails.
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
Power Board Comm Error	H	The communication check between the main control board and the power board fails.
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
PSB Uart Comm Stop	H	The main control board fails to connect the PSB (power supply board). The power crashes or the uart connection is abnormal.
		Restart the ventilator. If it occurs many times, please contact the designated maintenance service provider.
No Battery	H	The ventilator has no battery installed.
		Install the battery.
Low Battery	M	The ventilator is powered by batteries. When a battery is

		installed, the battery level is 11%-19%. When two batteries are installed, one battery level is 0-10% and another 11-19%, or both are 11-19%. About 10 minutes it could continue to run for (depending on the battery and operating conditions)
		Connect it to the DC or AC power supply immediately.
Low Battery	L	The ventilator is not powered by batteries and the level of each installed battery is less than 20%.
		None
Battery Running Out	H	The ventilator is powered by batteries and the level of each installed battery is less than 11%. The system will shut down after 300 seconds.
		Connect it to the DC or AC power supply immediately.
Monitoring Board		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
Technical Error 001#	M	The zeroing valve of blower pressure malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 002#	M	The zeroing valve of proximal pressure malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 003#	M	The zeroing valve of proximal flow malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 006#	M	The nebulization valve malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 008#	H	The safety valve malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 011#	M	The total flush valve malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 016#	H	The electric circuit of oxygen valve malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 019#	H	The electric circuit of expiratory valve malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 020#	H	The EEPROM on the sensor board malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 021#	H	The flow sensor type is faulty. (in power on self test)
		Please contact the designated maintenance service provider.
Technical Error 022#	H	The inspiratory flow sensor malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 024#	H	Proximal flow sensor malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 025#	H	The oxygen flow sensor malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 031#	H	The proximal pressure sensor malfunctions.
		Please contact the designated maintenance service provider.
Technical Error 033#	H	The oxygen supply pressure sensor malfunctions.
		Please contact the designated maintenance service provider.

Technical Error 034#	H	The blower pressure sensor malfunctions. Please contact the designated maintenance service provider.
Technical Error 035#	H	The PEEP pressure sensor malfunctions. Please contact the designated maintenance service provider.
Technical Error 036#	M	The pressure sensor of blower filter fails to communicate. Please contact the designated maintenance service provider.
Technical Error 037#	M	The barometric pressure sensor fails to communicate. Please contact the designated maintenance service provider.
Technical Error 038#	M	The value of blower filter pressure sensor is abnormal. Please contact the designated maintenance service provider.
Technical Error 039#	H	The VCM watchdog malfunctions. Please contact the designated maintenance service provider.
Technical Error 041#	M	The data of of barometric pressure sensor is abnormal. Please contact the designated maintenance service provider.
Technical Error 042#	H	The EEPROM on the monitoring board malfunctions. Please contact the designated maintenance service provider.
Technical Error 043#	H	The external ADC fails to communicate. Please contact the designated maintenance service provider.
Technical Error 044#	H	The VCM system resets abnormally. Please contact the designated maintenance service provider.
Technical Error 104#	H	The VPM watchdog malfunctions. Please contact the designated maintenance service provider.
Technical Error 105#	H	The VPM system resets abnormally. 1. Restart the ventilator. 2. Please contact the designated maintenance service provider.
Calib Prox Flow Sensor	H	Please calibrate proximal flow sensor. Please contact the designated maintenance service provider.
Calib Press Sensor	H	Please calibrate pressure sensor. Please contact the designated maintenance service provider.
Calib O_2 Sensor	H	Please calibrate O_2 sensor. Please contact the designated maintenance service provider.
Calib Air-O_2 Coefficient	H	Please calibrate Air-O_2 coefficient. Please contact the designated maintenance service provider.
Calib O_2 Valve	H	Please calibrate O_2 valve. Please contact the designated maintenance service provider.
Calib PEEP Valve	H	Please calibrate PEEP valve. Please contact the designated maintenance service provider.
Calib O_2 Sup Press	H	Please calibrate O_2 supply pressure sensor. Please contact the designated maintenance service provider.
O_2 Sensor Disconnected	L	The O_2 sensor is disconnected. Please connect the O_2 sensor.
Replace O_2 Sensor	M	The chemical electricity of the O_2 sensor has run out.

		Replace the O_2 sensor.
Exp Valve Type Error	M	The patient type doesn't match the expiratory valve type.
		Replace the expiratory valve.
No Flow Sensor	H	The single tube or dual tubes of the proximal flow sensor are disconnected.
		Connect the proximal flow sensor.
Prox Flow Sensor Type Err	H	The patient type doesn't match the proximal flow sensor type.
		Replace the proximal flow sensor.
Reverse Flow Sensor	H	The proximal flow sensor is connected reversely.
		Please reverse the flow sensor.
Proximal Tube Off	H	The proximal tube is not connected to the patient.
		Connect the proximal tube to the patient.
Tube Blocked	H	End expiratory pressure is too high and the end expiratory flow is too low.
		1. Check the patient. 2. Check and clean the expiratory valve. 3. Check the diaphragm and cap of the expiratory valve.
Insp Limb Blocked	H	The tube in the patient end is bent or blocked during oxygen therapy.
		Check if the tube in the patient end is bent or blocked. If so, please deal with it or unblock it.
Tube Disconnected	H	Tube Disconnected
		Reconnect the respiratory circuit.
Tube Leak	H	Tube Leak
		1. Check if the respiratory circuit is leaky. 2. Perform system check to test the leak volume.
Insp Gas Temp Too High	H	The gas temperature exceeds 55℃.
		1. Disconnect the patient. 2. Restart the ventilator.
Device Temp Too High	H	The internal temperature of the ventilator is higher than expected; the monitoring temperature of PCB barometric pressure is above 70℃ or the monitoring temperature of the blower gas inlet is above 65℃.
		1. Keep the ventilator away from sunlight. 2. Check the cooling fan. 3. Maintain the ventilator.
Function Limited at High Altitude	M	Altitude exceeding the ventilator limits, the airway pressure needed by the patient can't be reached and then the Function Limited at High Altitude alarm is triggered.
		Check the patient. Perform backup ventilation if needed.
Power Error 000#	H	VPM3.3V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 001#	H	The Power board VDD12V malfunctions.

		Please contact the designated maintenance service provider.
Power Error 002#	H	The valve power V12VAL malfunctions.
		Please contact the designated maintenance service provider.
Power Error 003#	H	The valve power V10VAL malfunctions.
		Please contact the designated maintenance service provider.
Power Error 005#	H	The flow sensor voltage is abnormal.
		Please contact the designated maintenance service provider.
Power Error 006#	H	The power board analog 10V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 007#	H	The Analog V5A malfunctions.
		Please contact the designated maintenance service provider.
Power Error 008#	H	REF2V5 malfunctions.
		Please contact the designated maintenance service provider.
Power Error 011#	H	The power board VDD10V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 012#	H	VCM1.8V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 100#	H	The voltage of blower power VM malfunctions.
		Please contact the designated maintenance service provider.
Power Error 101#	H	The system VDD5V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 102#	H	VCM power V3C malfunctions.
		Please contact the designated maintenance service provider.
Power Error 103#	H	The power voltage 32V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 104#	H	The main board 4.2V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 105#	H	The main board 3.3V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 106#	H	The main board 1.8V malfunctions.
		Please contact the designated maintenance service provider.
Power Error 107#	H	Large capacitance 32VB malfunctions.
		Please contact the designated maintenance service provider.
Comm Error 000#	H	Communication between VCM and the main control board fails.
		Restart the ventilator or contact the designated maintenance service provider.
Comm Error 001#	H	Communication between VCM and VPM fails.
		Restart the ventilator or contact the designated maintenance service provider.
Comm Error 100#	H	Communication between VPM and the main control board

		fails.
		Restart the ventilator or contact the designated maintenance service provider.
Comm Error 101#	H	Communication between VPM and VCM fails.
		Restart the ventilator or contact the designated maintenance service provider.
Comm Error 300#	H	Communication between the main control board and VCM fails.
		Please contact the designated maintenance service provider.
Comm Error 301#	H	Communication between the main control board and VPM fails.
		Please contact the designated maintenance service provider.
Pressure Limited	M	When the ATRC function is activated in Volume mode or Pressure mode, the pressure reaches the high Paw alarm limit -5.
		Adjust the airway pressure high limit.
Press Limited in Sigh Cycle	H	In sigh cycle, the pressure is higher than the Paw alarm high limit -5.
		Adjust the airway pressure high limit.
Pinsp Too Low	L	In pressure control mode: inspiratory pressure value (platform pressure) < (the smaller of the set pressure value -3 or its 2/3) for 3 breathing cycles.
		Check if the respiratory circuit is disconnected or leaky.
Sustained Paw Too High (Sustained Airway Pressure Too High)	H	In non-oxygen therapy mode: inspiratory pressure or expiratory pressure >= set PEEP+15 cmH_2O for 15s.
		1. Check the patient. 2. Check ventilation parameter settings. 3. Check the respiratory valve for blockage.
Press Not Released	L	The airway pressure exceeds the pressure high limit and the pressure isn't released through the expiratory valve after 5s.
		1. Check the patient. 2. Check ventilation parameter settings. 3. Check the respiratory valve for blockage.
Tinsp Too Long	L	In PSV mode: for three consecutive circles, inspiratory time > the high limit of the set value (adult 4s, pediactric 1.5s).
		1. Check the patient. 2. Check the respiratory circuit for blockage. 3. Check ventilation parameter settings. 4. Check the respiratory valve for blockage.
Set TV Not Reached	L	In non-standby mode: expiratory tidal volume < set tidal volume - (set tidal volume /10+10), lasting 9 breathing cycles.
		1. Check the respiratory circuit for leakage. 2. Perform system check for leakage.
Volume Limited	M	The inspiratory tidal volume is larger than 1.5 times the high alarm limit of the set tidal volume.
		1. Adjust the volume high limit;

		2. Adjust the set value of tidal volume;
Set Flow Not Reached	H	In high flow oxygen therapy mode, the monitoring flow is 1LPM less than the set flow, continuing for 120S.
		1. Check if the HEPA filter is blocked; if so, replace the filter. 2. Check the respiratory circuit for blockage.
Replace HEPA Filter	L	When the difference between barometric pressure and blower filter pressure is greater than the set value, an alarm will be trigged.
		1. Check if the HEPA filter is blocked; if so, replace the filter. 2. Check the respiratory circuit for blockage.
Blower Error 100#	H	The blower drive configuration is faulty.
		Please contact the designated maintenance service provider.
Blower Error 101#	H	The Hall signal of the blower is abnormal.
		Please contact the designated maintenance service provider.
Blower Error 102#	H	The blower malfunctions.
		Please contact the designated maintenance service provider.
Blower Error 103#	H	The blower speed is abnormal.
		Please contact the designated maintenance service provider.
Blower Error 104#	H	The blower temperature is abnormal.
		Please contact the designated maintenance service provider.
Blower Error 105#	H	The blower temperature is high and its internal temperature is above 80℃.
		1. Check the fan for blockage. 2. Check ventilation parameter settings. 3. Check the blower HEPA filter for blockage. 4. Please contact the designated maintenance service provider.
Blower Error 106#	H	The blower temperature is too high and its internal temperature is above 85℃.
		1. Check the fan for blockage. 2. Check ventilation parameter settings. 3. Check the blower HEPA filter for blockage. 4. Please contact the designated maintenance service provider.
Blower Error 107#	H	The drive electric circuit of the blower malfunctions.
		Please contact the designated maintenance service provider.
Cooling Fan Error	M	The cooling fan speed is abnormal.
		Please contact the designated maintenance service provider.
O_2 Supply Error	H	The air supply pressure is below 170kPa.
		1. Check whether the pressure of HPO supply is below 170kPa. 2. Please contact the designated maintenance service provider.
O_2 Supply Press Too	H	The air supply pressure is above 680kPa.

High		1. Check whether the pressure of HPO supply is above 680kPa. 2. Please contact the designated maintenance service provider.
Masimo CO_2 Module		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
CO_2 Comm Stopped	H	The CO_2 sensor data is not received. Please check the CO_2 sensor connection. If the error reoccurs, contact the manufacturer for maintenance.
CO_2 Comm Error	H	The communication check with the CO_2 sensor fails. Please check the CO_2 sensor type. If the error still exists, please contact the manufacturer for maintenance.
CO_2 Software Error	L	The CO_2 sensor software is faulty. Reconnect the CO_2 sensor.
CO_2 Hardware Error	L	The CO_2 sensor hardware is faulty. Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
CO_2 Speed Out of Range	L	The CO_2 sensor malfunctions. Contact the manufacturer for maintenance.
CO_2 Factory Calib Lost	L	The CO_2 sensor malfunctions. Contact the manufacturer for maintenance.
CO_2 Sampleline Blocked	L	The CO_2 sampling line is blocked. Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
No CO_2 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.
CO_2 Accu. Out of Range	L	The measured value exceeds the nominal accuracy range. Follow the nominal accuracy range specified by the manufacturer.
CO_2 Sensor Overtemp	L	The CO_2 sensor malfunctions. Contact the manufacturer for maintenance.
CO_2 Press Out of Range	L	The CO_2 sensor malfunctions. Contact the manufacturer for maintenance.
Zero Calib CO_2	L	CO_2 Zeroing is required. Perform CO_2 Zeroing in the CO_2 setting interface. Under this option zeroing is equal to zero calibration.
CO_2 Span Calib Error	L	The module malfunctions. Contact the manufacturer for maintenance.
CO_2 Span Calibrating...	L	CO_2 Span is being calibrated. Contact the manufacturer for maintenance.
No CO_2 Adapter	L	The adapter is not or poorly connected. Check and replace the adapter; if the error still exists, contact the manufacturer for maintenance.
Replace CO_2	L	The adapter malfunctions.

Adapter		Check and replace the adapter; if the error still exists, contact the manufacturer for maintenance.
Respironics CO_2 Module		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
CO_2 Comm Stopped	H	The CO_2 sensor data is not received. Please check the CO_2 sensor connection. If the error reoccurs, contact the manufacturer for maintenance.
CO_2 Comm Error	H	The communication check with the CO_2 sensor fails. Please check the CO_2 sensor type. If the error still exists, please contact the manufacturer for maintenance.
CO_2 Sampleline Blocked	L	The CO_2 sampling line is blocked. Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
No CO_2 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.
CO_2 Accu. Out of Range	L	The measured value exceeds the nominal accuracy range. Follow the nominal accuracy range specified by the manufacturer.
CO_2 Sensor Overtemp	L	The CO_2 sensor malfunctions. Contact the manufacturer for maintenance.
Zero Calib CO_2	L	CO_2 Zeroing is required. Perform CO_2 Zeroing in the CO_2 setting interface. Under this option zeroing is equal to zero calibration.
CO_2 ID Unmatched	L	CO_2 ID unmatched Reinsert the module.
Comen CO_2 Module		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
CO_2 Comm Stopped	H	The CO_2 sensor data is not received. Please check the CO_2 sensor connection. If the error reoccurs, contact the manufacturer for maintenance.
CO_2 Comm Error	H	The communication check with the CO_2 sensor fails. Please check the CO_2 sensor type. If the error still exists, please contact the manufacturer for maintenance.
CO_2 Sampleline Blocked	L	The CO_2 sampling line is blocked. Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
No CO_2 Sampling line	L	The sampling line is not connected. Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
CO_2 Accu. Out of Range	L	The measured value exceeds the nominal accuracy range. Follow the nominal accuracy range specified by the manufacturer.
CO_2 Temp Out of Range	L	The CO_2 sensor malfunctions. Contact the manufacturer for maintenance.

Zero Calib CO_2	L	CO_2 Zeroing is required.
		Perform CO_2 Zeroing in the CO_2 setting interface. Under this option zeroing is equal to zero calibration.
CO_2 ID Unmatched	L	CO_2 ID unmatched
		Reinsert the module.
Calibrate CO_2	L	CO_2 Zeroing is required.
		Perform the CO_2 Zeroing in the CO_2 setting interface. Under this option zeroing is equal to zero calibration.
Masimo SpO_2 Module		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
SpO_2 Sensor Off	M	The SpO_2 Sensor is disconnected with the finger.
		Check the connection of SpO_2 sensor.
No SpO_2 Sensor	L	The SpO_2 sensor is poorly connected.
		Check the connection of SpO_2 sensor.
Weak SpO_2 Signal	L	The SpO_2 sensor is poorly connected.
		Check the condition of SpO_2 sensor.
No Pulse	H	No pulse is detected by the SpO_2 Module.
		Check the patient's vital signs and confirm that the patient has a pulse. If the fault reoccurs, please replace the sensor or contact the manufacturer for maintenance.
Search Pulse	L	The SpO_2 sensor is poorly connected, or the patient moves his/her arm excessively.
		Check the SpO_2 sensor condition; check the patient's condition.
SpO_2 Low Perfusion	L	The poor peripheral circulation is detected by the Sp sensor.
		Use another finger; or examine whether the limb is compressed.
SpO_2 Sensor Error	L	The SpO_2 sensor malfunctions.
		Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
SpO_2 Interference	L	Strong external interference
		Check the connection of SpO_2 lead cable; check the patient's condition and whether a big body movement is made.
SpO_2 Too Much Light	L	The patient (sensor) receives too much light. The sensor is covered by a fabric.
		Check whether the SpO_2 sensor is fixed well; block or reduce the light; shield the sensor from light; relocate the sensor.
Unknown SpO_2 Sensor	L	The SpO_2 module cannot recognize the sensor.
		Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
No SpO_2 Cable	L	The SpO_2 sensor is disconnected to the main cable.
		Check the SpO_2 module cable connection.
No Adhesive SpO_2 Sensor	L	The SpO_2 module cannot recognize the sensor.
		Check and replace the sensor; if the error still exists, contact

		the manufacturer for maintenance.
SpO_2 Module Error	L	The SpO_2 sensor malfunctions.
		Contact the manufacturer for maintenance.
SpO_2 Comm Stopped	H	The SpO_2 sensor malfunctions.
		Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
SpO_2 Comm Error	H	The SpO_2 sensor type is not consistent with the setting or the sensor malfunctions.
		Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
Nellcor SpO_2 Module		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
SpO_2 Sensor Off	M	The SpO_2 Sensor is disconnected with the finger.
		Check the SpO_2 sensor connection.
No SpO_2 Sensor	L	The SpO_2 sensor is poorly connected.
		Check the SpO_2 sensor connection.
Weak SpO_2 Signal	L	The SpO_2 sensor is poorly connected.
		Check the condition of SpO_2 sensor.
Search Pulse	L	The SpO_2 sensor is poorly connected, or the patient moves his/her arm excessively.
		Check the condition of SpO_2 sensor; check the patient's condition.
No Pulse	H	No pulse is detected by the SpO_2 Module.
		Check the patient's vital signs and confirm that the patient has a pulse. If the fault reoccurs, please replace the sensor or contact the manufacturer for maintenance.
Nellc Error, Resetting	L	The system is resetting.
		The system cannot be reset or if the error persists after restarting the ventilator, please contact the manufacturer for maintenance.
SpO_2 Comm Stopped	H	The SpO_2 sensor malfunctions.
		Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
SpO_2 Comm Error	H	The SpO_2 sensor type is not consistent with the setting or the sensor malfunctions.
		Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
Comen SpO_2 Module		
Alarm Messages	**Alarm Priority**	**Causes & Solutions**
SpO_2 Sensor Off	M	The SpO_2 Sensor is disconnected with the finger.
		Check theSpO_2 sensor connection.
Weak SpO_2 Signal	L	The SpO_2 sensor is poorly connected.
		Check the SpO_2 sensor.
Search Pulse	L	The SpO_2 sensor is poorly connected, or the patient moves

		his/her arm excessively.
		Check the condition of SpO_2 sensor; check the patient's condition.
No Pulse	H	No pulse is detected by the SpO_2 Module.
		Check the patient's vital signs and confirm that the patient has a pulse. If the fault reoccurs, please replace the sensor or contact the manufacturer for maintenance.
SpO_2 Sensor Error	L	The SpO_2 sensor malfunctions.
		Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
SpO_2 Module Error	L	The SpO_2 sensor malfunctions.
		Contact the manufacturer for maintenance.
SpO_2 Comm Stopped	H	The SpO_2 sensor malfunctions.
		Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.
SpO_2 Comm Error	H	The SpO_2 sensor type is not consistent with the setting or the sensor malfunctions.
		Reboot the system. If the error reoccurs, contact the manufacturer for maintenance.

Appendix VI EMC

NOTE

- **The V1/V1A ventilator complies with the applicable EMC requirements in IEC60601-1-2.**
- **Please follow the EMC instructions in the User's Manual to install and use the ventilator.**
- **Portable and mobile RF communication equipment may affect the performance of the V1/V1A ventilator. To protect the 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

- **This device is intended for use in professional healthcare facility and emergency medical environment. If it is used in a special environment, such as a magnetic resonance imaging environment, or near active HF surgical equipment, the equipment may be disrupted by the operation of nearby equipment.**
- **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the V1/V1A ventilator or shielding the location. During this time, the user should stop using the ventilator and contact the service personnel.**
- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the V1/V1A ventilator could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the V1/V1A ventilator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could be caused.**

Table 1

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

Table 2

Declaration - electromagnetic immunity		
Immunity test	**IEC 60601 test 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 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0 ° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % UT; 1 cycle and 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.		

Table 3

Declaration - electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	10V/m

Table 4

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 IEC 61000-4-3	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
P-A/C	Pressure - Assist/Control Ventilation
P-SIMV	Pressure - Synchronized Intermittent Mandatory Ventilation
DuoVent	Duo Level Ventilation
APRV	Airway Pressure Release Ventilation
CPAP/PSV	Continuous Positive Airway Pressure/ Pressure Support Ventilation
PRVC	Pressure Regulated Volume Control Ventilation
PRVC-SIMV	Pressure Regulated Volume Controlled - Synchronized Intermittent Mandatory Ventilation
PSV-S/T	Pressure Support Ventilation-Spontaneous/Timed
ATPD	Ambient Temperature and Pressure Dry
BTPS	Body Temperature and Pressure Saturated
TV	Tidal Volume
O_2%	O_2 Concentration
ΔPinsp	Inspiratory Pressure
ΔPsupp	Pressure Support Level
PEEP	Positive End-expiratory Pressure
Tinsp	Inspiratory Time
I:E	Ratio of Inspiratory Time to Expiratory Time
f	Breathing Frequency
Phigh	High Pressure Level
Plow	Low Pressure Level
Thigh	High Pressure Time
Tlow	Low Pressure Time
Tslope	Rise Time
F-Trig	Flow Trigger Level
Exp%	Expiratory Trigger Sensitivity
Timax	Maximum Inspiratory Time
TVapnea	Tidal Volume of Apnea Ventilation
Papnea	Inspiratory Pressure of Apnea Ventilation
fapnea	Frequency of Apnea Ventilation
Apnea I:E	Inspiratory Time: Expiratory Time in Apnea Ventilation Mode
Apnea Tinsp	Apnea Inspiratory Time
Flow	Oxygen Therapy Flow
Apnea Vent	Apnea Ventilation
FiO_2	Fraction of Inspired Oxygen

Ppeak	Peak Pressure
Pplat	Plateau Pressure
Pmean	Mean Pressure
TVi	Inspiratory Tidal Volume
TVe	Expiratory Tidal Volume
TVe spn	Spontaneous Expired Tidal Volume
MV	Minute Volume
MVspn	Spontaneous Minute Volume
MVleak	Leakage Minute Volume
Vleak%	Percentage of Leakage
TVe/IBW	Tidal Volume Per Ideal Body Weight
Texp	Expiration Time
ftotal	Total Breathing Frequency
fmand	Mandatory Frequency
fspn	Spontaneous Frequency
fspn%	Spontaneous Breath Percentage
Rinsp	Inspiratory Resistance
Rexp	Expiratory Resistance
PIF	Peak Inspiratory Flow
PEF	Peak Expiratory Flow
Cstat	Static Compliance
Cdyn	Dynamic Compliance
RSBI	Rapid Shallow Breath Index
PTP	Pressure-time Product
RCexp	Expiratory Time Constant
PEEPi	Intrinsic PEEP
P0.1	100ms Occlusion Pressure
RSS	The Product of Oxygen Concentration Times the Average Pressure
$EtCO_2$	End-tidal Carbon Dioxide
$FiCO_2$	Inspired Carbon Dioxide
VDaw	Airway Dead Space
VDaw/Tve	Ratio of Airway Dead Space to Tidal Volume
VCO_2	CO_2 Elimination
Vtalv	Alveolar Tidal Ventilation

MValv	Alveolar Minute Ventilation
$MVCO_2$	Minute Volume of Expired CO_2
$VeCO_2$	Exhaled CO_2 Volume
$ViCO_2$	Inspired CO_2 Volume
$slopeCO_2$	CO_2 Rising Slope
SpO_2	Arterial Oxygen Saturation from Pulse Oximetry
PR	Pulse Rate
PI	Perfusion Index
SpO_2/FiO_2	Arterial Oxygen Saturation from Pulse Oximetry/Inspired Oxygen Concentration
OSI	Oxygen Saturation Index
ROX	ROX Index

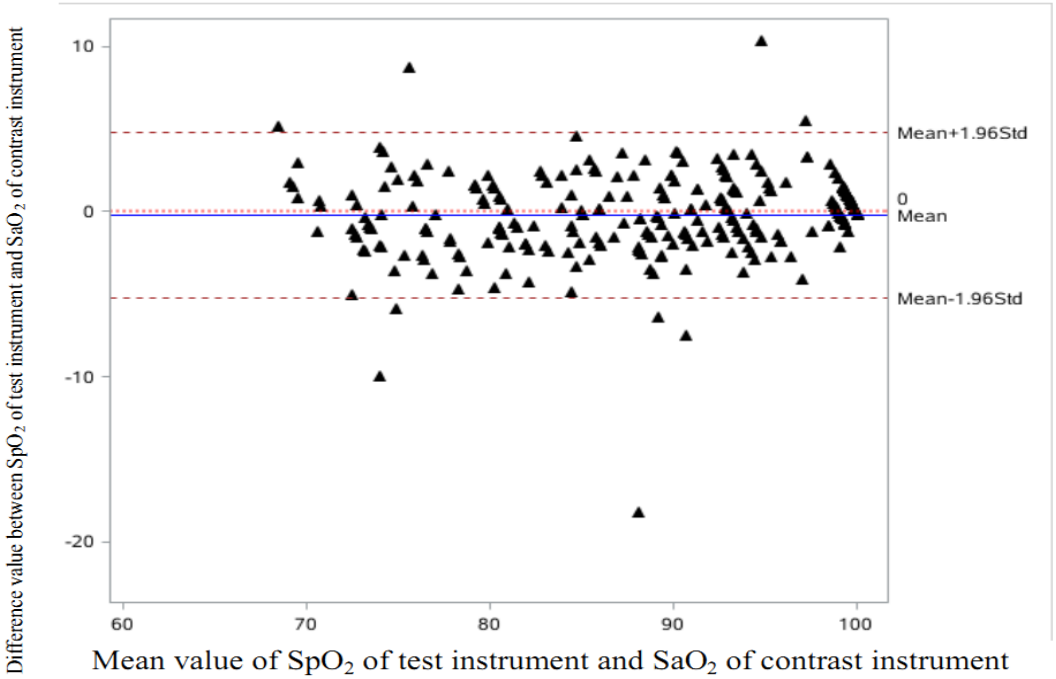
Appendix VIII The Accuracy of SpO_2

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 SpO_2 accuracy for Comen SpO_2 module vs Co-Oximeters (Arms) in a clinical study.

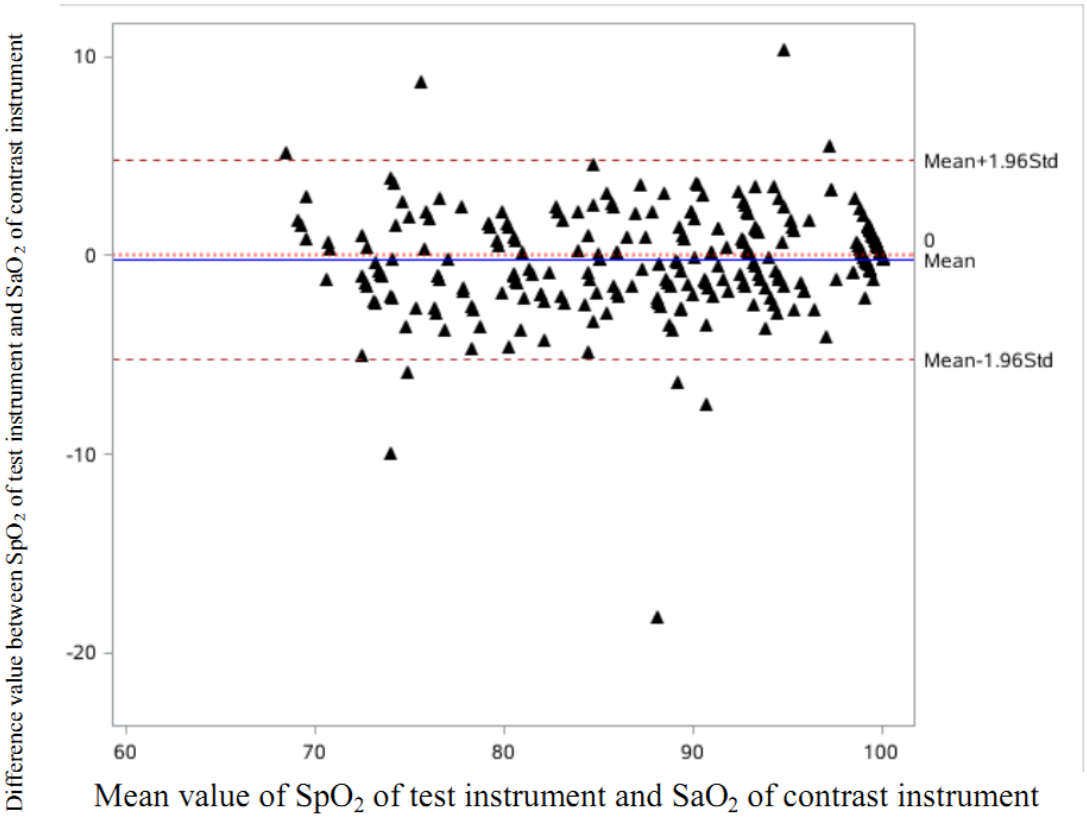
For SAL104 COMEN SpO_2:

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:

SpO_2 Sensor	Model	70%-100%	90%-100%	80%-90%	70%-80%
040-000730-00	SES104	2.157%	2.329%	2.015%	1.908%



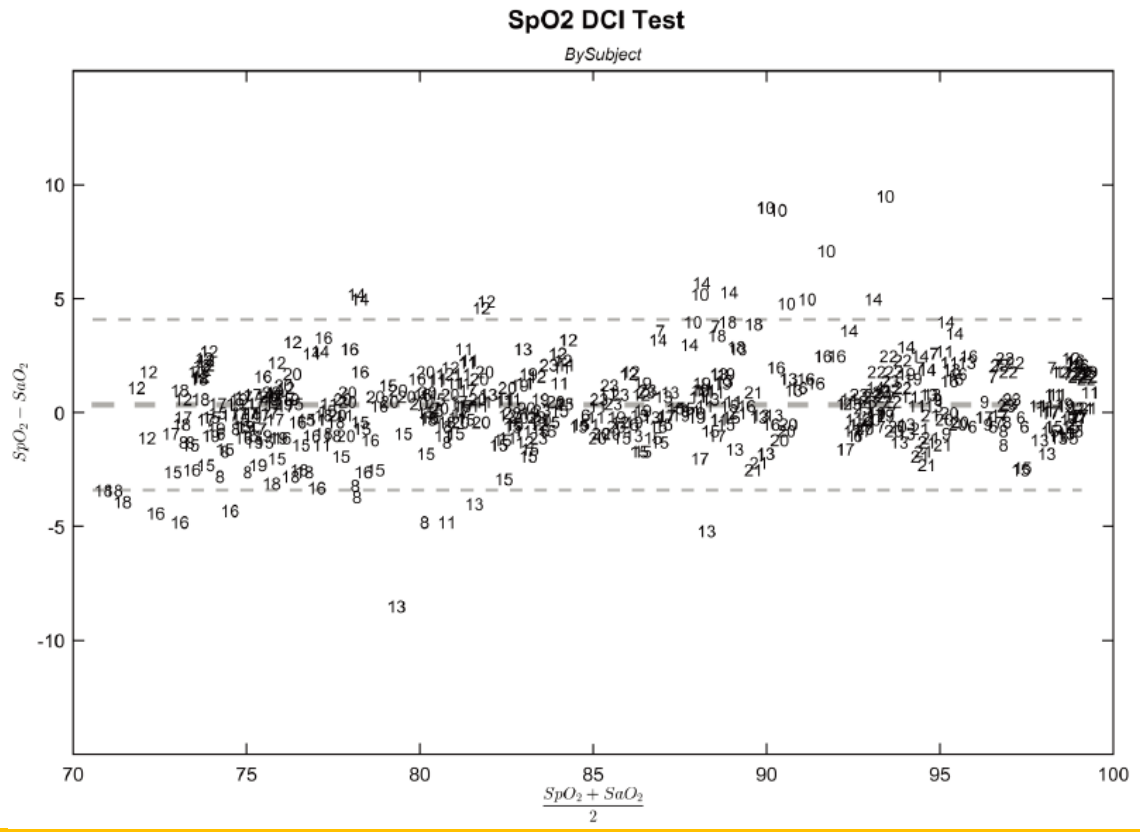
⚠NOTE

- **The two sensors that have been tested in the clinical trial are considered as the representative of other Comen SpO_2 sensors. The accuracy claimed applies to all Comen SpO_2 sensors.**

The Accuracy of Masimo SpO_2

For M-LNCS DCI MASIMO SpO_2

SpO_2 Sensor	**Model**	**70%-100%**	**90%-100%**	**80%-90%**	**70%-80%**
040-000203-00	M-LNCS DCI	1.90%	1.44%	2.30%	1.84%



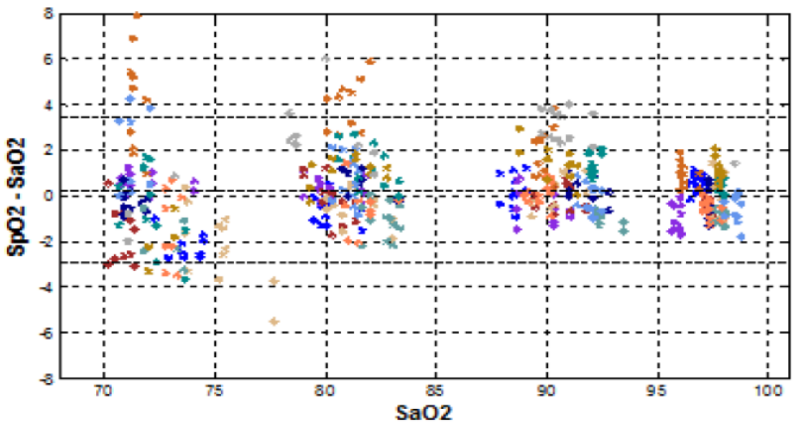
⚠NOTE

- **The data above about the accuracy of Masimo SpO_2 originated from Masimo's IFU. Please visit www.masimo.com for more details.**

The Accuracy of Nellcor SpO_2

For DS-100A NELLCOR SpO_2

SpO_2 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 SpO_2 originated from Nellcor's IFU. Please visit www.nellcor.com for more details.**