axcent medical

LYRA x1

Instructions for Use

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Applicable Model Description

This manual is based on aXcent LYRA x1 Intensive Care Ventilator.

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Contents

Chapter 1

1. Safety Information

Before using the ventilator on a patient, familiarize yourself with this user manual, particularly the safety considerations listed. Be aware, however, that this manual is a reference only. It is not intended to supersede your institution's protocol regarding the safe use of assisted ventilation devices.

Warnings and cautions that apply to the use of the ventilator under all circumstances are included in this section. Additional warnings and cautions are also inserted within the manual where they are most meaningful.

Notes are also located throughout the manual to provide additional information related to specific features.

1.1 Safety Information

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury or equipment damage.

NOTE

Emphasizes information of particular importance.

1.1.1 WARNING

- The ventilator must only be operated and used by authorized medical personnel well trained in the use of this product. It must be operated strictly following the user manual.

- An alternative means of ventilation shall be available whenever the ventilator is in use. If a fault is detected in the ventilator, disconnect the patient from it and immediately start ventilation with such a device. For example, using a manual respirator.
- Before use, the ventilator, cables and accessories must be inspected to ensure that they can work normally and safely.
- Users should set alarm volume and alarm limits based on patients' actual condition. Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.
- All staff should be aware that disassembling or cleaning some parts of the ventilator can cause risk of infection.
- Using the ventilator in the vicinity of high frequency electrosurgery equipment, defibrillators or short-wave therapy equipment may impair correct functioning of the ventilator and endanger the patient.
- Do not place the ventilator adjacent to any barrier, which can prevent cold air from flowing, resulting in equipment overheat.
- If the equipment internal monitoring system malfunctions, an alternative plan must be available to ensure adequate level of monitoring. The operator of the ventilator must be responsible for patient's proper ventilation and safety under all circumstances.
- Do not touch the patient when connecting the peripheral equipment via the I/O signal ports or replacing the O_2 cell, to prevent patient leakage current from exceeding the requirements specified by the standard.
- The maximum pressure of hose is 1.4MPa@21℃

and please check whether gas supply pressure meets hose requirements before usage.

- Hose connectors adopt standardized gas terminal connector with gas nature.
- Different types of gas and gas with different pressures shall not be exchanged with each other.
- Hose may be aging quickly by long-term exposure to acidity, alkalinity or ultraviolet rays.
- Don't cascade two or more hose assemblies together.
- The ventilator arm could bear 1kg maximally and don't hang over 1kg goods.
- After the ventilator is installed or changes main control board, please perform flow calibration again.
- When disconnecting fast connectors, please operate by two hands to prevent potential injury caused by sudden pressure release.
- Do not block the air intake on the rear side of the ventilator.
- To prevent interrupted operation of the ventilator due to electromagnetic interference, avoid using the ventilator adjacent to or stack with other device. If adjacent or stacked use is necessary, verify the ventilator's normal operation in the configuration in which it will be used.
- Avoid the use of polluted air. When the equipment uses air as gas source for ventilation, if the air is polluted, harmful substance may enter the patient tubing.
- Check if the alarm limit settings are appropriate before taking measurement.
- When operating the unit with the power supply unit, always connect the unit to an easily accessible outlet so that it can be unplugged quickly in the event of a malfunction.

- System leakage, such as leakage caused by an uncuffed endotracheal tube, may influence airflow readings, including airflow parameters, pressure, dead space, and CO_2 production.
- Do not open the equipment housings. All servicing and future upgrades must be carried out by qualified service personnel only.
- Modification of the ventilator and associated equipment is not permitted and may compromise ventilator operation and patient safety. Servicing should only be done by qualified service personnel.
- To ensure the correct performance of the ventilator and the accuracy of patient data, use only specified accessories with the ventilator.
- To reduce the risk of electric shock from liquid entering the device, do not put a container filled with a liquid on the ventilator.
- To reduce the risk of fire, use the ventilator in well-ventilated areas away from flammable anesthetics. Do not use in a hyperbaric chamber or other similarly oxygen-enriched environments. Do not use near an open flame.
- Do not use the ventilator with helium or mixtures with helium.
- To reduce the risk of strangulation from patient tubing, use a tubing support arm and secure the proximal pressure line with clips to position the sensor cables and tubing appropriately.
- Manufacturer default settings are not appropriate for all patients. Prior to using the ventilator, verify that the current alarm settings or defaults are appropriate for each particular patient.
- Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.

- The physiological parameters and alarm messages displayed on the screen of the ventilator are for doctor's reference only and cannot be directly used as the basis for clinical treatment.
- To reduce the risk of fire, use only patient circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.
- Be sure to set the high inspiratory pressure alarm appropriately to minimize patient risk from overpressurization or early breath termination.
- To minimize patient risk from aspiration of condensate, use either a circuit with water traps or a heated wire circuit.
- The patient's exhaled volume can differ from the measured exhaled volume due to leaks around the mask during noninvasive ventilation. We recommend that you set the leak alarm to detect and notify when a clinically significant leak occurs.
- To prevent unintentional disconnection of the power cord, always use the correct specified power cord and lock it into place with the power cord retainer before use. The plug is used as disconnect device to the mains supply, do not to position the equipment so that it is difficult to operate the disconnection device.
- To reduce the risk of electric shock, connect the ventilator to an AC supply mains with protective earth only.
- A ventilator shutdown due to a total loss of power during ventilation poses serious risks to the patient. Always have a backup battery built-in and fully charged.
- The backup battery must be fitted in the ventilator. Periodically check and replace the battery as needed. Refer servicing to qualified service personnel.

- The battery is intended for backup or transport use only. Battery operation time can be affected by discharge and recharge cycles, time, and ambient temperature. Using the battery as primary power source increases patient risk resulting from a ventilator shutdown due to total power loss.
- Use external power source before the batteries are depleted.
- It is the responsibility of the end user to validate the compatibility and use of information transmitted from the ventilator to the device to be connected to the ventilator.
- Do not use this equipment in an MRI environment.
- To dispose of the package material, observing the applicable waste control regulations and keeping it out of children's reach.
- To prevent possible patient injury, maintenance mode can only be used when the ventilator is disconnected from the patient.
- Nebulization or humidification can increase the resistance of breathing system filters and that you need to monitor the breathing system filters frequently for increased resistance and blockage.
- The ventilation accuracy can be affected by the gas added by use of a nebulizer.
- As required by the relevant rules and regulations, oxygen concentration should be monitored when the equipment is used on the patient. If your ventilator is not configured thewith such monitoring function or this functionon your ventilator is turned off, use a monitor which complies with the requirements of ISO 80601-2-55 for oxygen concentration monitoring.
- Do not move the ventilator before removing the support arm from it, in order to avoid the ventilator getting tilted during the movement.

- To prevent possible device damage, avoid tipping over the ventilator when crossing thresholds.
- To prevent possible device damage, step down the brake when parking the ventilator.
- A turbofan can cause gas to be heated. To reduce the temperature of gas inside the tube and prevent patient injury accordingly, make sure that the length of patient tube from the humidifier to Y piece is greater than 1.2m.
- To reduce the risk that the patient will aspirate condensed water from the breathing circuit, position any humidifier lower than both the ventilator and the patient.
- The ventilator shall not be used with nitric oxide.
- It is recommended to connect this equipment to equipotential system. Use yellow and green equipotential grounding cables, one end is connected to position with symbol, and other end is connected to equipotential system. Use of potential equalization conductor together with a reference to requirements in clause 16 of IEC 60601-1 for Medical Electrical System.
- Additional equipment connected to medical electrical equipment through the network/data coupling must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3.1Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configurations a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service

department.

- A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area.

1.1.2 CAUTION

- The ventilator is intended for use by healthcare professionals only.
- At the end of the ventilator service life, the equipment and its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products.
- Grounding reliability can only be achieved when equipment is connected to an appropriate voltage receptacle marked “hospital only” or “hospital grade.”
- To prevent possible damage to the ventilator, use only those cleaning agents listed in this manual.
- To prevent possible damage to the ventilator, do not drip or spray any liquids directly onto any surface.
- Do not attempt to sterilize or autoclave the ventilator.
- To reduce the risk of electrical shock, disconnect electrical power from the ventilator before cleaning.
- To reduce the risk of fire, do not use a high-pressure oxygen hose that is worn or contaminated with combustible materials like grease or oil.
- To prevent possible damage to the ventilator, always secure it to its stand or securely place it on a flat, stable surface that is free of dirt and debris. Do not use the ventilator adjacent to, or stack it with, other equipment.
- Magnetic and electrical fields are capable of interfering with the proper performance of

the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

- Before moving the ventilator, make sure its casters and brakes are in good condition.

1.1.3 NOTE

- If you detect any unexplained changes in the performance or visual displays of the ventilator, discontinue ventilator use and contact your service representative .
- Keep this manual close to the ventilator so that it can be obtained conveniently when needed.
- The software of ventilator was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.
- This user manual describes all features and options. Your ventilator may not have all of them.
- The ventilator is not made with natural rubber latex.
- The user can set high pressure alarm limit in the inspiratory phase. If the pressure reaches the high pressure alarm limit, the “High Pressure” high-level alarm is triggered. The ventilator opens the expiration valve and switches to expiratory phase until the airway pressure reaches the preset PEEP value. Make sure to set high pressure alarm limit properly to ensure patient safety.
- In addition, all breathing tubing is treated as the applied part.
- Position of the operator is on the front of the ventilator.

- Dispose of all parts removed from the device according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, oxygen cell, batteries).
- If you must ship the ventilator, to prevent possible damage to the ventilator, use the original packing materials. If these materials are not available, contact your sales representative for replacement materials.
- The buzzer of the ventilator alarm 120s and the exhalation valve is open, if the AC power supply and battery are not in place.

1.2 Symbols

Refer to these tables to interpret symbols used on the ventilator and battery labels, and on the ventilator screen. To interpret symbols pertaining to accessories, refer to their instructions for use.

Table 1-1.Symbols

Symbol	Definition
	Manufacturer.
	Date of Manufacture.
	Serial number.
	DC Power.
	Temperature limitations at transport and storage.
	Humidity limitations at transport and storage.
	Atmospheric pressure at transport and storage.
	Follow instruction for use. This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.
	European Authorized Representative.
	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment).

Symbol	Definition
IP21	Indicates the degree of protection provided by enclosure according to IEC 60601-1.
	Type BF Applied part (classification of medical electrical equipment, type BF, as specified by IEC 60601-1).
	The device is not suitable for use in MRI environment.
	This way up at transport and storage.
	Fragile, handle with care.
	Keep dry at transport and storage.
	Do not roll.
	Stacking limitations.
	Recyclable materials.
	Attention, consult accompanying section in the operator's manual.
	Equipotentiality
	Fuse
	Power switch
	Battery
$O_2\%$	Oxygen sensor connector
	Oxygen supply connector

Symbol	Definition
RS232	RS-232 connector
HDMI	HDMI connector.
	USB connector
	Inspiration connector
	Expiration connector
	Lock
	Unlock
	Nebulizer connector
	Proximal pressure port
	Alarm Audio pause

(For your note.)

Chapter 2

2. General Information

2.1 Intended Use

The ventilator is a mechanical ventilator designed to provide invasive and non-invasive, continuous or intermittent, respiratory support for pediatric and adult patients weighting.

Intended areas of use:

- In the intensive care ward or in the recovery room.
- During transfer of ventilated patients within the hospital.

The ventilator is intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

2.2 Contraindications

The contraindications listed below is only for noninvasive ventilation.

- Lack of spontaneous respiratory or inability to trigger breath
- Moderate or severe facial or brain damage
- Recent upper airway or esophageal surgery
- Hemodynamic instability
- Diseases such as gastric dilatation that cause reflux mistaken aspiration
- Inability to maintain a patent airway or adequately clear secretions

2.3 Potential Side Effects

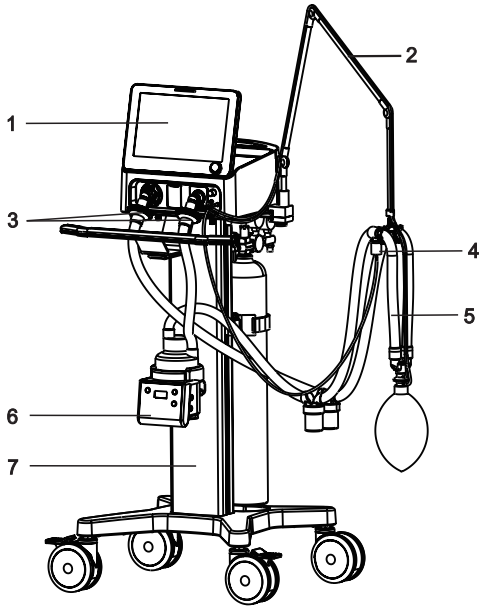
Noninvasive ventilation may be accompanied by some side effects.

Advise the patient to immediately report any unusual chest discomfort, shortness of breath, or severe headache. Other potential side effects of noninvasive positive pressure ventilation include: ear discomfort, conjunctivitis, skin abrasions due to mask/patient interface, and gastric distention (aerophagia). If skin irritation or breakdown develops from the use of the mask, refer to the accompanying mask instructions for appropriate action.

2.4 Physical Description

2.4.1 Front View with Circuit

The below picture shows the ventilator with its breathing circuit and accessories. Contact your sales representative for details on breathing circuits and accessories specified.



1	Display Screen
2	Circuit support arm
3	Inspiratory bacteria filter
4	Nebulizer device
5	Patient circuit(dual-limb)
6	Trolley
7	Humidifier

Figure 2-1.Ventilator with accessories

Table lists recommended patient circuits, masks/patient interfaces, and other accessories for use with the ventilator. Appendix B provides more information for parts and accessories.

Table 2-1.Compatible parts and accessories

Part	Description
Patient circuit, dual-limb	Intended for invasive ventilation. To minimize turbulence, we recommend that you use smooth-inner wall tubing. Use a circuit listed in Appendix B or equivalent.
Patient interface (noninvasive or invasive)	Masks listed in Appendix B Invasive interface (tracheostomy or endotracheal (ET) tube)
Inspiratory bacteria filter	Inspiratory bacteria filter listed in AppendixB
Expiratory bacteria filter	Expiratory bacteria filter listed in Appendix B
Humidifier	Humidifier isted in Appendix B
Heat and Moisture Exchangers (HME)	HMEs listed in Appendix B or equivalent.
Oxygen sensor	Oxygen sensor listed in Appendix B
Nebulizer	VADI M-0801-EN

2.4.2 Main Unit

Figure 2-2 through Figure 2-4 show the controls, indicators, and other important parts of the ventilator unit.

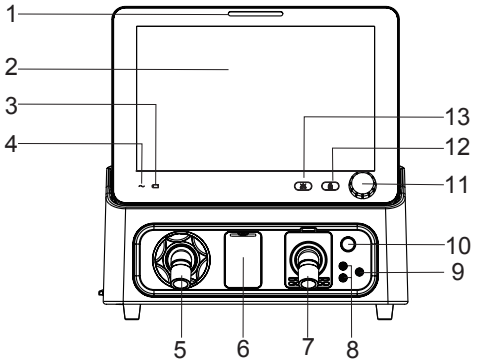


Figure 2-2.Front view of main unit

Table 2-2.Description of front view of main unit

No.	Description
1	**Alarm indicator light** The alarm indicator light indicates the priority of an active alarm by flashing different colors at different frequencies.
2	**Display (touch screen)** The display shows the software screen of the ventilator system. You can select and change settings by touching the screen.
3	**External power indicator light** **Lit**: when the ventilator is connected to an external power supply. **Not lit**: when the ventilator is not connected to an external power supply.

No.	Description
4	**Battery indicator light** **Lit**: indicates that the battery is being charged when the ventilator is power off, or the ventilator is operating on battery power or external power. **Not lit**: indicates that the ventilator is not connected to an external power supply, or that the ventilator does not have a battery installed, or that there is a fault with the battery.
5	**Inspiration patient connector**
6	**Oxygen Sensor**
7	**Expiratory valve**
8	**Nebulizer connector**
9	**Flow sensor connectors**
10	**Leak test plug**
11	**Control knob** Press the control knob to select menu items or confirm settings. Rotate clockwise or counter clockwise to scroll through menu items or change settings.
12	**Lock Screen key** Press to enter locked status.During the period of screen locked, all keys on the main screen are disabled. Touch screen, control knob, and other keys are disabled. Press this key again to unlock the screen.
13	**Alarm AUDIO PAUSED key** Press to initiate the AUDIO PAUSED for 120 seconds, so that audible alarm tones of the active alarms are switched off. If AUDIO PAUSED exceeds 120 seconds, the AUDIO PAUSED status terminates automatically and audible alarm tones are restored. If a new alarm is triggered under AUDIO PAUSED status, the AUDIO PAUSED status terminates automatically and audible alarm tones are restored. Under AUDIO PAUSED status, press this key a second time to terminate AUDIO PAUSED status.

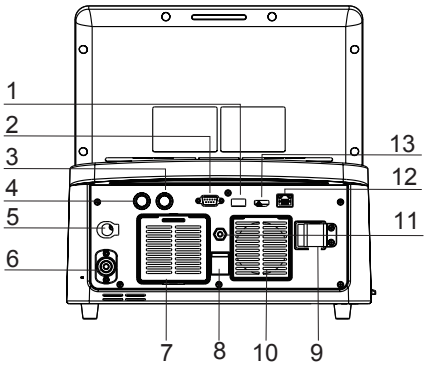


Figure 2-3.Rear view

Table 2-3.Description of rear view

No.	Description
1	USB connector
2	RS-232 connector
3	Reserved for future use
4	Reserved for future use
5	Low-pressure oxygen inlet connector
6	High-pressure oxygen inlet connector
7	High Efficiency Particle Air (HEPA) Filter
8	Power cord retainer
9	Power switch
10	Fresh air intake and cooling fan filter
11	Equipotentiality
12	Network connector
13	HDMI connector

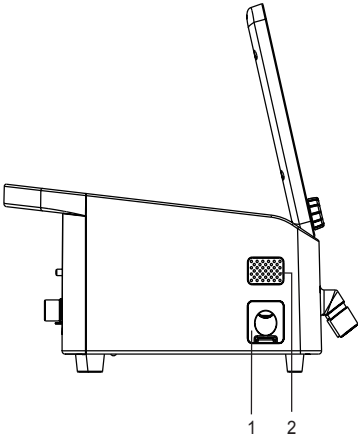


Figure 2-4.Side view

Table 2-4.Description of side view

No.	Description
1	Exhaust port
2	Speaker

Chapter 3

3. Installations and Connections

⚠ **WARNING**

- **Do not cover or position the ventilator so as to adversely affect its operation or performance.**
- **To reduce the risk of the device overheating and possible burn injury, do not block the fan intake at the rear of the ventilator.**
- **To ensure normal air circulation and exchange, do not cover or block the ports on the ventilator.**
- **To reduce the risk that an alarm will go unnoticed or be disregarded, do not block the speakers.**
- **To reduce the risk of electric shock from liquid entering the device, do not put a container filled with a liquid on the ventilator.**

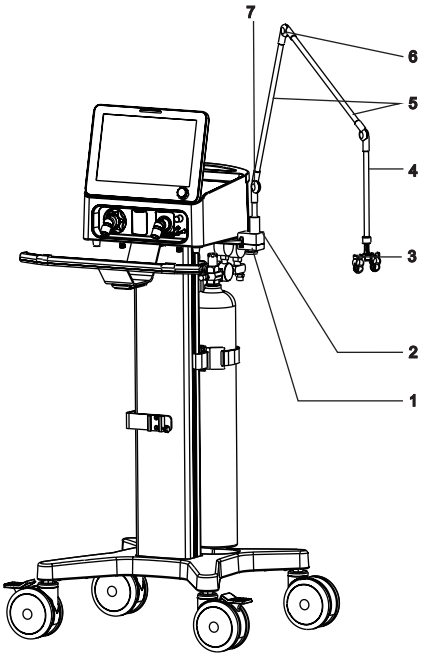
Set up the ventilator for each patient use as described in this chapter.

3.1 Installing the Support Arm

⚠ **WARNING**

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

Install the patient tubing support arm on either left or right side of the ventilator trolley. The arm snaps into place.



1	Fixing block knob
2	Fixing block
3	Tube hook
4	Support arm joint
5	Support bar
6	Support arm joint
7	Support arm joint

Figure 3-1.Installing the patient tubing support arm

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

- Support arm joint F or G: to adjust the upward-bending angle of the support arm, only lift up the support bar

to the desired position without the need to push the white unlocking key . To adjust the downward-bending angle of the support arm, lift up the support bar, and then push and hold the white unlocking key on support arm joint with one hand, and hold the support bar and press it downward with the other hand. Release the white unlocking key after adjusting the support bar to the desired position. Support arm joint F or G can be adjusted for up to 130º.

- Support arm joint D: swivel upward or downward to the desired position.
- Hold the bottom of support arm or the support bar beside support arm joint G and swivel it to the left, or to the right, with force to rotate the support arm to the desired position.

4. Place the patient tubing onto the tube hook.

NOTE

- Operate support arm joint F or G with both hands as the picture shown aside. Operating with a single hand will bring some risks.
- The maximum weight of the support arm is 1.5 kg.
- The support arm can be fixed onto the handle on the either side of the ventilator.

3.2 Installing the Patient Tubing

⚠ **WARNING**

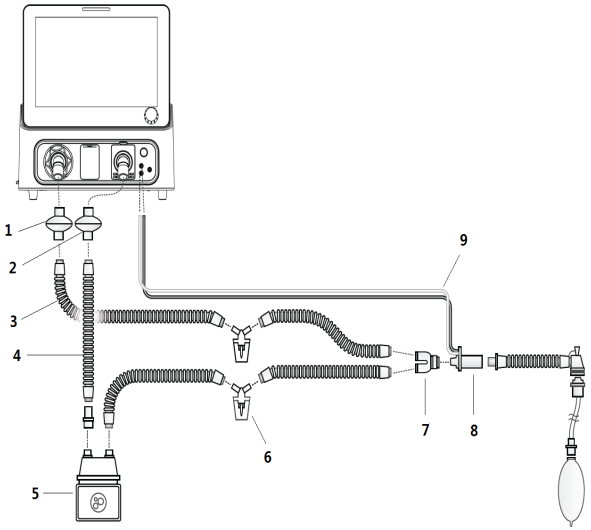
- **To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.**
- **To prevent patient or ventilator contamination, always use a bacteria filter between the ventilator and the inspiratory limb of the patient breathing circuit.**
- **The use of an expiratory filter may lead to a significant increase in expiratory resistance. Excessive expiratory resistance may compromise ventilation and increase patient work of breathing and intrinsic PEEP.**

- **To reduce the risk of CO_2 rebreathing during noninvasive ventilation, avoid introducing extra dead space to the patient circuit.**

  Adding accessories or other components to the breathing system of the ventilator can increase system inspiratory and expiratory resistance.

  Install the patient circuit exactly as it will be used on the patient. For a list of compatible parts and accessories specified, see ***Appendix B Parts and Accessories***.

  1. Determine the correct patient type. Press the Adult button or the Pediatric button.
  2. Assemble the patient circuit, including the inspiratory bacteria filter, proximal pressure line, and HME (if desired).Figure 3-2 shows circuit configurations for dual-limb ventilation. Follow the manufacturers' instructions for use for the individual parts, including the humidifier.



1	Expiratory bacteria filter
2	Inspiratory bacteria filter
3	Expiratory tube
4	Inspiratory tube
5	Humidifier
6	Water trap
7	Y-piece
8	Flow sensor
9	Proximal pressure line

Figure 3-2.Dual-limb circuit with humidifier

Properly position the patient circuit before use on a patient. Make sure the tubing will not be pushed, pulled, or kinked during patient movement or other procedures.

To install the patient tubes as follow:

1. Mount the filters onto the inspiratory and expiratory ports.
2. Connect the inspiratory filter to the water trap via the tubing. Then connect the water trap to the Y piece via the tubing.
3. Connect the expiratory filter to the water trap via the tubing. Then connect the water trap to the Y piece via the tubing.
4. Connect the flow sensor tubing to the ventilator. Connect the small end of the flow sensor to the Y piece, and the large end to the test lung.
5. Place the patient tubing onto the support arm hook.

3.3 Installing the Humidifier

⚠ **WARNING**

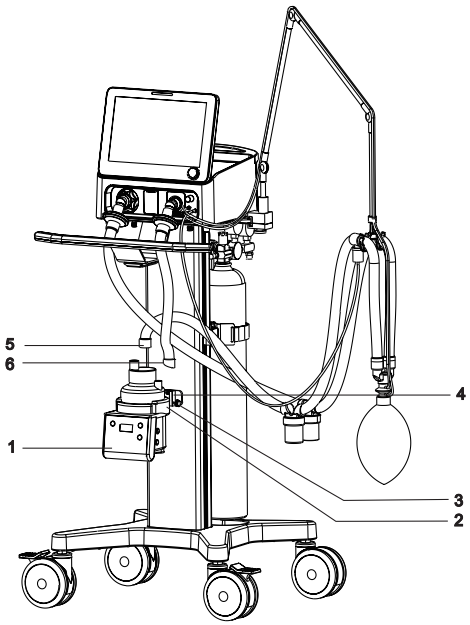
- **To prevent possible patient injury and equipment damage, do not turn the humidifier on until the gas flow has started and is regulated. Starting the heater or leaving it on without gas flow for prolonged periods may result in heat build-up, causing a bolus of hot air to be delivered to the patient. Circuit tubing may melt under these conditions. Turn the heater power switch off before stopping gas flow.**
- **To prevent possible patient injury and equipment damage, make sure the humidifier is set to appropriate temperature and humidity.**

NOTE

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

  Install a humidifier to the ventilator using the slide bracket on the trolley column. Prepare the humidifier as described in the manufacturer's operation manual.

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



1	Humidifier
2	Humidifier mounting plate
3	Screw
4	Humidifier bracket slot
5	Humidifier outlet
6	Humidifier inlet

Figure 3-3.Installing the humidifier

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

VBS compliance: 0 to 5 ml/cmH_2O.

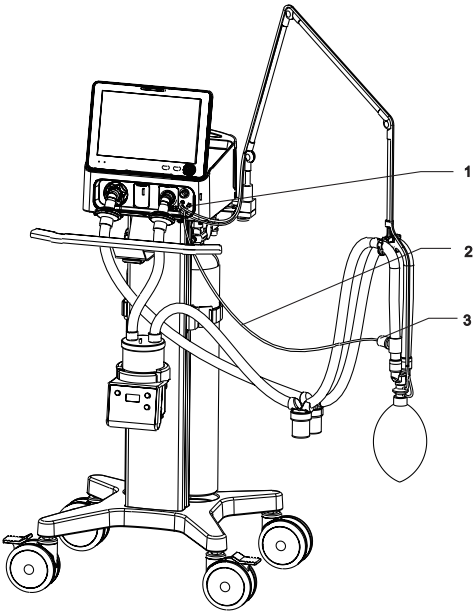
3.4 Installing the Nebulizer

NOTE

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

  The nebulization feature provides a stable driving pressure to power a pneumatic nebulizer connected to the nebulizer outlet. optimally specified for 6 to 9 L/min flow. The nebulizer and accessories as shown in Figure 3-4.

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



1	Nebulizer connector
2	Nebulizer
3	Nebulizer tube

Figure 3-4.A pneumatic nebulizer

3.5 Connecting the Oxygen Supply

⚠ **WARNING**

- **Connect the ventilator only to an appropriate medical-grade oxygen source.**
- **Inspect the O_2 supply connector carefully and make sure there is no leakage. If gas leakage is significant, O_2 concentration in the ambient environment will exceed normal atmosphere, resulting in potentially dangerous O_2 enriched environment.**
- **To reduce the risk of hypoxia, connect only oxygen to the high-pressure connector at the rear of the ventilator.**

- **To avoid oxygen leakage, the device cannot be connected to both high and low pressure oxygen supply sources.**

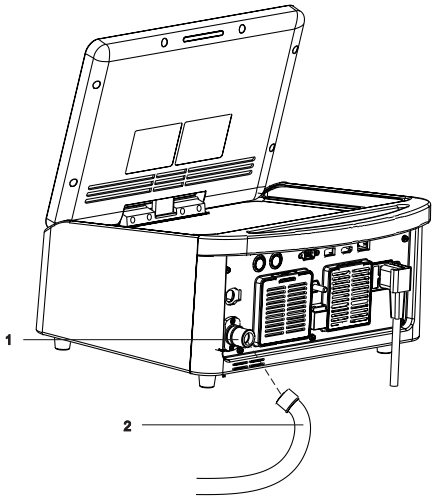
CAUTION

- **To prevent possible damage to the ventilator, ensure that the connection to the oxygen supply is clean and unlubricated, and that there is no water in the oxygen supply gas.**
- **The ventilator's oxygen control is not active when low-pressure oxygen is used. To prevent possible patient injury, use low-pressure oxygen only in cases where the low-pressure supply can provide an adequate level of oxygenation.**
- **To prevent possible patient injury, make sure that an emergency backup O_2 supply (for example, a gas cylinder) is available in case the low-pressure O_2 supply fails.**
- **Do not connect the ventilator to both high pressure and low pressure oxygen supply.**

  Oxygen for the ventilator can come from a high- or low- pressure source.

  When the high pressure oxygen supply is connected, the normal pressure of the gas source is 280~600kPa. If the gas supply pressure is less than 280kPa, it will compromise the performance of the ventilator and even stop the ventilation.

  When the low-pressure oxygen supply is connected, the supply of low-pressure oxygen does not exceed 15 L/min. To reduce the risk of fire, do not use a low-pressure oxygen supply that delivers a flow rate of more than 15 L/min.



1	Oxygen supply inlet
2	Oxygen supply hose

Figure 3-5.Connecting the oxygen supply

To connect the high-pressure oxygen supply as follows:

1. Before connecting the oxygen supply hose, check if the sealing ring at the gas supply connection is in good condition. If the sealing ring is damaged, do not use the hose and replace the sealing ring to prevent leakage.
2. Align and connect the fitting to the inlet of the high-pressure oxygen supply at the back of the ventilator.
3. Make sure the gas supply hose is connected to the gas supply inlet, then tighten the hose nut.

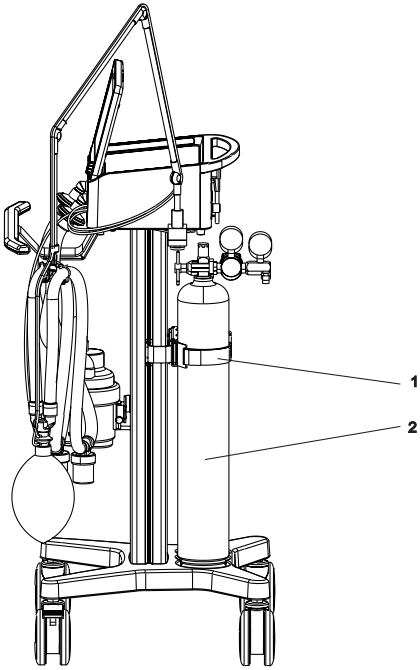
To connect the low-pressure oxygen supply as follows:

1. Depress the metal dome on the low-pressure oxygen supply connector.
2. Align the oxygen supply hose with and insert it into the low-pressure oxygen supply connector.

3.6 Installing the Gas Cylinder

CAUTION

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



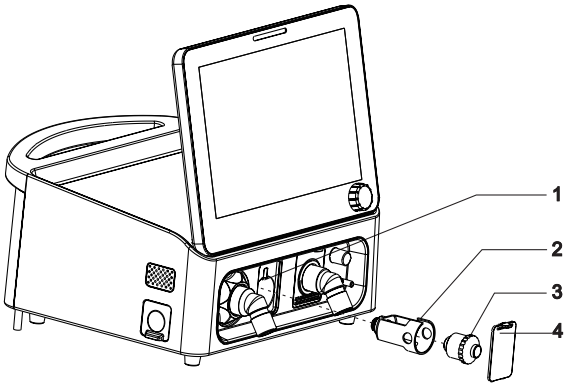
1	Hook & Loop Tapes
2	Gas cylinder

Figure 3-6.Installing the gas cylinder

1. Place the gas cylinder onto the trolley base.
2. Fix the gas cylinder via Hook & Loop tapes.

3.7 Installing the Oxygen Sensor

This ventilator could be equipped with O_2 cell. O_2 cell is a consumable product and the service life is around 1 year and thus needs to be replace periodically. The O_2 sensors need to be calibrated reguarlly. Please refer to 9.6 Maintenance Schedule for calibration cycle.



1	O_2 cell connection cable
2	O_2 cell adaptor
3	O_2 cell
4	O_2 cell cover

Figure 3-7.Installing the oxygen sensor

1. Insert the O_2 cell directly to install it.
2. Connect the O_2 cell connection cable.
3. Install the O_2 cell cover on to machine casing.

CAUTION

- **To reduce the risk of explosion, do not burn the O_2 cell or force the cell open.**

NOTE

- If ICU work normally, the service life of O_2 cell is one year. The service life of O_2 cell is an approximate specification only. The actual cell life depends

on operating environment. Operation at higher temperatures or higher O_2 % shortens the life.

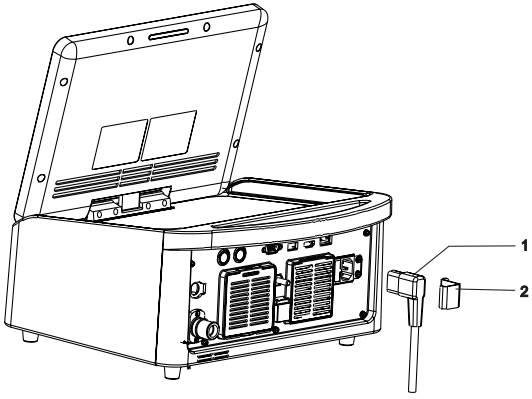
3.8 Connecting the Power Supply

⚠ **WARNING**

- **To reduce the risk of electric shock, connect the ventilator to an AC supply mains with protective earth only.**
- **To reduce the risk of strangulation, route the power cord to avoid entanglement.**

CAUTION

- **Grounding reliability can only be achieved when equipment is connected to an appropriate voltage receptacle marked "hospital only" or "hospital grade."**
- **Connect the ventilator to an outlet that supplies AC power between 100 and 240 V AC, 50/60 Hz. Always check the reliability of the AC outlet. If you are using a 120 V outlet, make sure that it is hospital-grade.**



1	AC power cord
2	Anti-unplugging hook

Figure 3-8.Connecting to primary power source

1. Remove the anti-unplugging hook of power.
2. Insert the AC power cord into the AC power receptacle.
3. Install anti-unplugging hook of power to clamp the power cord in place.

3.9 Inspecting the Batteries

⚠ **WARNING**

- **To reduce the risk of power failure, pay close attention to the battery's charge level. The battery's operation time is approximate and is affected by ventilator settings, discharge and recharge cycles, battery age, and ambient temperature. Battery charge is reduced at low ambient temperatures or in situations where the alarm is continuously sounding.**

NOTE

- The backup batteries are intended for short-term use only. They are not intended to be a primary power source.

  The ventilator comes with two backup batteries, one mandatory and the other optional. The backup batteries protects the ventilator from AC power interruptions. If AC power fails, the ventilator automatically switches to operation on backup batteries with no interruption in ventilation. The batteries powers the ventilator until AC power is restored or until the battery is depleted. One battery powers the ventilator typically for at least 3 hours.

  The ventilator charges the batteries when ever the ventilator is connected to AC, with or without the ventilator switched on. If the battery is not fully charged, recharge it by connecting the ventilator to AC power for a minimum of 4 hours.

  In case of two installed batteries each battery has its own icon. The power source symbols in the top right-

hand corner of the screen show the available power sources. A frame around a symbol indicates the current ventilator power source. A green symbol indicates a fully charged battery. A crossed-out symbol means not available.

Check the batteries charge level before putting a patient on the ventilator and before unplugging the ventilator for transport or other purposes. If the ventilator is running on batteries, the level of batteries charge is shown at the top right-hand corner of the screen. If the battery is not fully charged, recharge it by connecting the ventilator to AC power.

Figure 3-9.Power source symbols and battery charge indicator

Chapter 4

4. User Interface

4.1 Screen Display

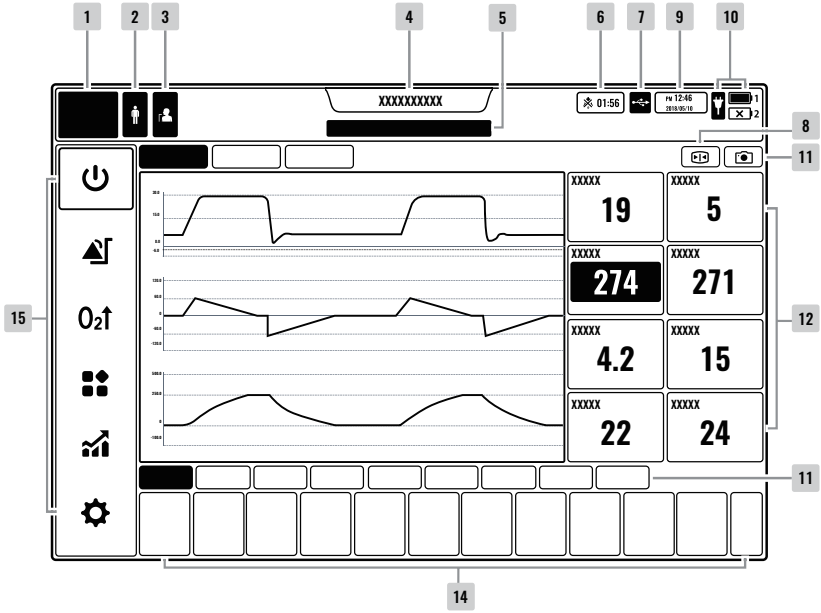


Figure 4-1.Screen display

1. **Ventilation mode field**

   Displays Standby or active ventilation mode and ventilation assist indication.

2. **Patient type / Inspiratory trigger icon field**

   Indicates current patient type. The icon for Inspiratory trigger is lung symbol.

3. **Ventilation type field**

   Displays Non-invasive or Invasive ventilation type:

   Displays icon when the ventilation type is Non-

invasive.

Displays icon when the ventilation type is invasive.

4. **Alarm message bar**

   Displays the active alarm messages. When there are multiple alarm messages, the number of alarms is displayed. Clicking the alarm message bar to view the alarm messages list.

5. **Prompt message field**

   Displays the active prompt messages.

6. **Alarm AUDIO PAUSED field**

When the icon for 120-second alarm AUDIO PAUSED countdown is displayed, it indicates that the audible alarm tones are paused.

7. **USB icon field**

The icon is highlighted when the system is connected to an identifiable USB device. By selecting this icon you can export screen, data and transfer settings in the opened interface.

8. **System time field**

   Displays current system time. By selecting this field, you can set the system time in the opened menu.

9. **Freeze icon field**

   Select this icon to enter freeze status. In this status, the system temporarily pauses the real-time refreshing of waveforms and loop graphs on the screen, so that you can review specific patient data.

10. **Power status icon field**

    Displays the status of currently-used power supply.

11. **Screen capture icon field**

    By select this icon, you can capture and save the screen.

12. **Patient data field**

    Displays Waveforms, Loop, Values or Big Numeric Screen.

13.Ventilation mode setup field

Displays the keys for setting up ventilation modes.

14.Parameter setup quick key field

Displays ventilation setting parameters corresponding to the active ventilation mode.

15.Soft key field

Displays soft keys: Setup, Trend&Log, Function, O_2 ↑ Suction, Alarm Limit,Standby and so on.

4.2 Waveform Window

Select the [**Waveforms**] key to access the interface as shown below.

The ventilator displays the real-time pressure/ time, flow/time and volume/time waveforms in the waveforms window.

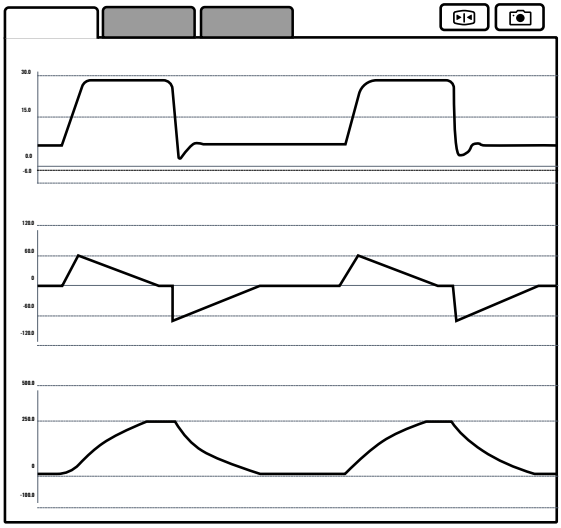


Figure 4-2.Waveforms window

4.3 Loops Window

Select the [**Loops**] key to access the screen as shown below.

The ventilator displays the two real-time loops in the loops window. To view the different type of loop: Pressure-Volume, Pressure-Flow or Flow-Volume, Click the drop-down menu and select the loop type you desired.

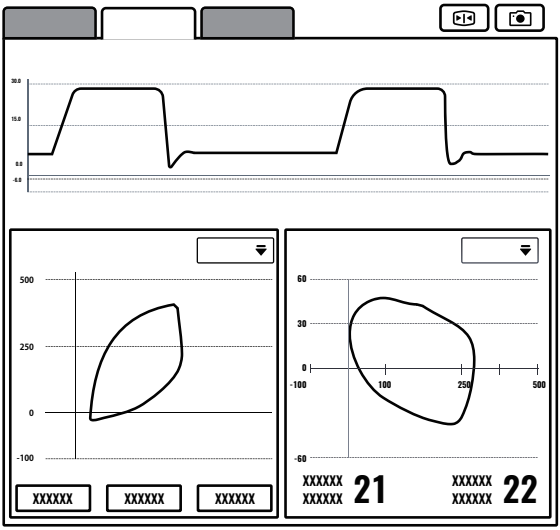


Figure 4-3.Loops window

4.4 Values Window

Select the [**Values**] key on the screen to open the interface as shown below.

The ventilator displays the numeric patient data on the screen. You can configure the main monitored parameters which are always displayed on the top of the screen. All the monitored parameters can be viewed in the values window.

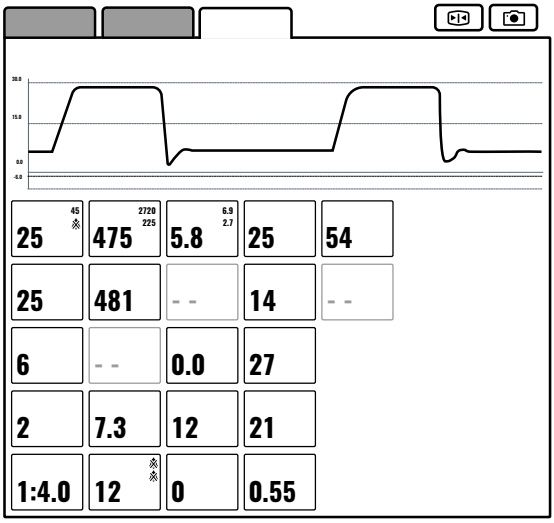


Figure 4-4.Values window

4.5 Trend

The system can display a rolling 72 hours of continuous trend data. Select the [**Trend&Log**] key on the screen to view trend graphic, trend table and logbook in the opened window.

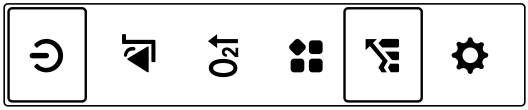


Figure 4-5.Trend&Log key

4.5.1 Graphic Trend

Graphic trend records the trend of parameter values. It is reflected through a curve. Every point on the curve corresponds to the value of physiological parameter at a specific time point. Graphic trend also records parameter alarm events. Graphic trend data displays at one-minute intervals by default unless the zoom is selected.

Graphic Trend highlights the parameter data in the corresponding alarm color if an alarm condition existed for the parameter at the time of trend record storage.

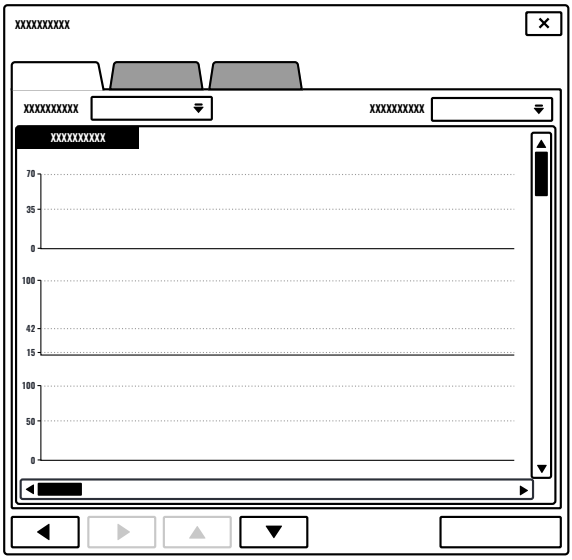


Figure 4-6.Graphic trends window

1. Current cursor: The corresponding time displays above the cursor. .
2. Alarm marker: The dotted, colored line indicates a parameter alarm event occurred at that time. A parameter alarm event is indicated by a dotted line in the same color with alarm.
3. Parameter value: The parameter data of the time indicated by cursor.

4. Zoom: You can set the display interval to [**5 Minutes**], [**10 Minutes**], [**15 Minutes**], [**30 Minutes**], [**1 Hour**] and [**2 Hours**].
5. Group: You can set the displayed parameter group to [**Press**], [**Flow**], [**Volume**], [**Time**], [**Gas**], [**Others**] and [**All**].

4.5.2 Tabular Trend

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

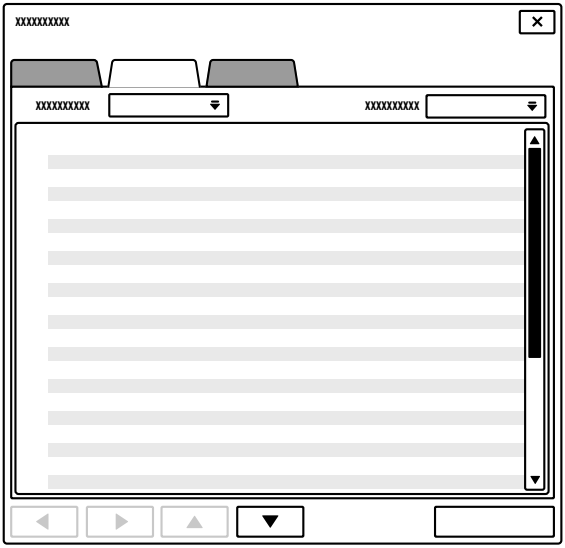


Figure 4-7.Tabular trends window

1. Interval: You can set the display interval to [**5 Minutes**], [**10 Minutes**], [**15 Minutes**], [**30 Minutes**], [**1 Hour**] and [**2 Hours**].
2. Group: You can set the displayed parameter group to [**Press**], [**Flow**], [**Volume**], [**Time**], [**Gas**], [**Others**] and [**All**].

4.5.3 Event Logbook

The Event Log window shows the event log, or data about clinically relevant ventilator occurrences since the ventilator was powered on, including alarms, setting changes and operations. The date, time, and description are included.

The event log can maintain alarm log when the alarm system is powered down, and can capture the time of powering on, but the time of powering down cannot be captured.

The contents of the log after the alarm system has experienced a total loss of power (supply mains and internal electrical source) of a finite duration can maintain the same as that before the loss of power.

The contents of the log as it reaches capacity will replace the oldest log that is FIFO.

Event Logbook displays the most recent record at the top. The system can store up to 20000 records of Event Logbook.

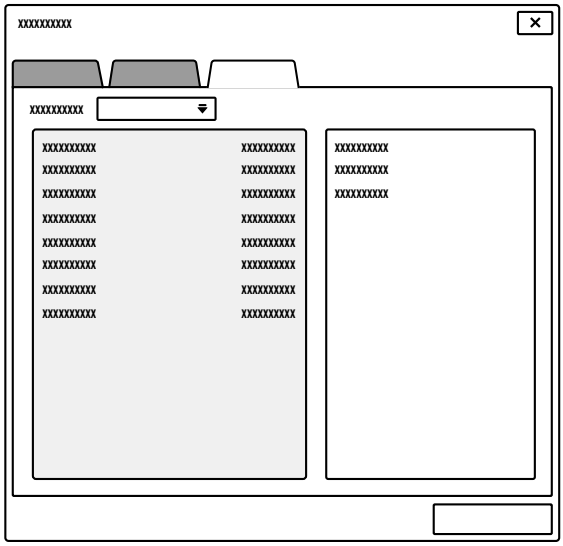


Figure 4-8.Event logbook

In the Event Logbook window, you can set [**Display**] to [**All Events**], [**All Alarms**],[**High Alarms**], [**Med Alarms**], [**Low Alarms**], [**All Alarms**] and [**Operation Log**].

NOTE

- The system can store up to 20000 records of Event Logbook. When a new event occurs after 20000 events are already stored, the new event overwrites the earliest one.

4.6 Freeze

The freeze function's feature is that it can pause the real-time refreshing of waveforms and spirometry loops on the screen, so that you can have a close examination of the patient's status within this time period. The reviewed data are waveforms and spirometry loops in the 60 seconds before entering freeze state.

4.6.1 Enter or Exit Freeze Status

When in non-standby status and non-freeze status, press the key will display the [**Freezing, press Freeze key again to unfreeze.**] prompt message on the screen and the system will enter freeze status. Freeze cursors will appear on the screen near the waveforms and loops. All displayed waves and loops are frozen, namely, they are not refreshed. The data in the parameter area are refreshed normally.

When in freeze status, press the [**Freeze**] key again to exit the freeze status.

4.6.2 View Frozen Waveforms or Loop

In freeze status, cursors appear on the waveforms or loops. You can reposition the cursor by touching the cursor directly.

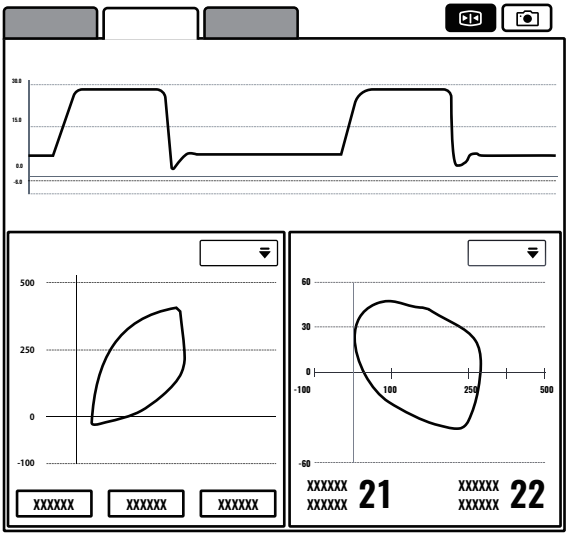


Figure 4-9.Freeze waveforms and loops

In freeze status, the [**Capture Ref.**] key is disabled, and you cannot save a loop as a reference loop. However, you can view reference loops that are already saved.

4.7 Screen Capture

By pressing the key on the main screen, the system will capture and save the screen automatically. The screen capture is saved in “bmp” format. The system can store up to 500 screen captures.

You can select [**Setup**]->[**Media**] to view the captured pictures.

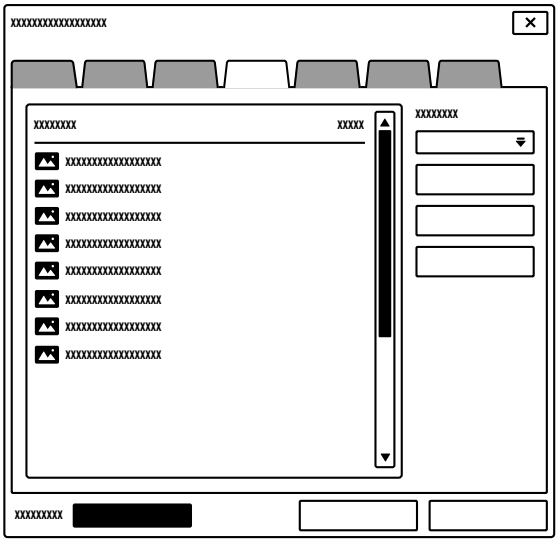


Figure 4-10.View captured pictures

4.8 Lock Screen

By pressing the [**Screen Lock**] key to enter locked status. During the period of screen locked, all keys on the main screen are disabled. Touch screen, control knob, and other keys are disabled. Press this key again to unlock the screen.

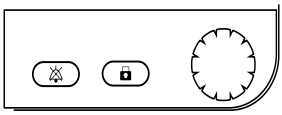


Figure 4-11.Screen lock key

(For your note.)

Chapter 5

5. System Settings

5.1 Date and Time Settings

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

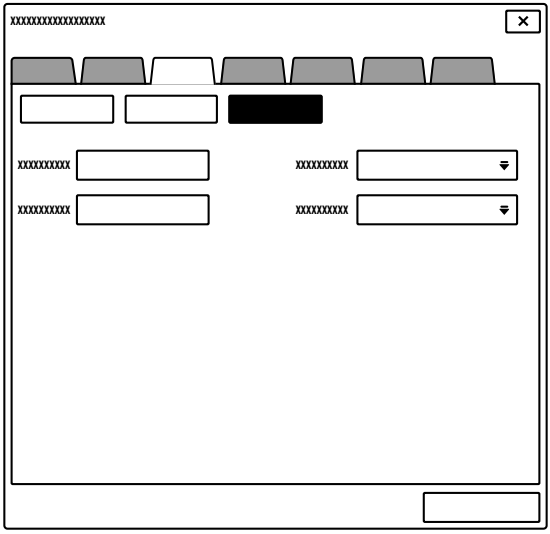


Figure 5-1.Date&Time settings

5.2 Screen Settings

5.2.1 Screen Brightness

1. Select [**Setup**] → [**System**] → [**Screen**].
2. If the current screen brightness is not satisfactory, set day or night in [**Screen Brightness**] filed directly: 10% to 100%. Level 10% is the darkest setting and 100% is the brightest. If the ventilator is battery powered, you can select a less bright screen to save battery capacity.

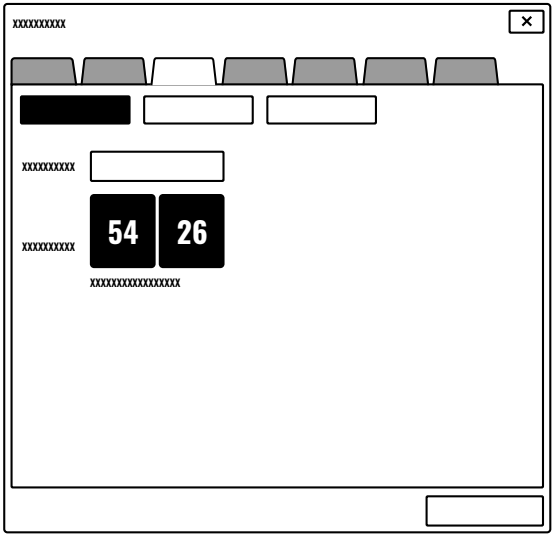


Figure 5-2.Screen settings

5.2.2 Screen Layout

1. Select [**Setup**] → [**System**] → [**Screen**] → [**Settings**].
2. Select corresponding icons to set the displayed number of waveforms and the value count.
3. If you need to adjust the specific waveform and measured values at each position, please select the

waveform or measured value in the main screen and set the name or color in the interface that is displayed.

4. Select [**Default**] when necessary to restore the settings to default.

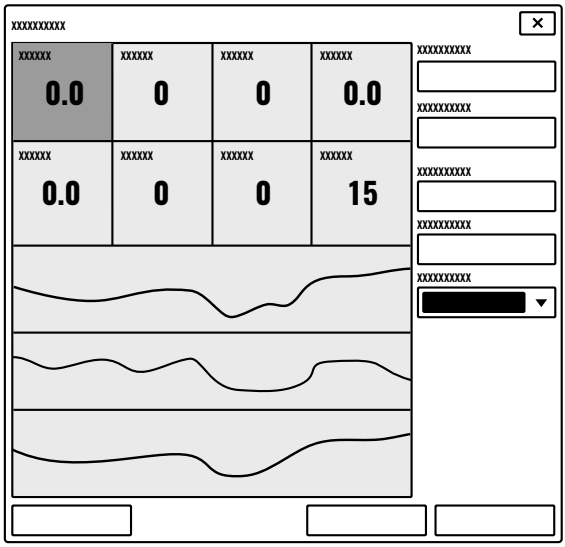


Figure 5-3.Screen layout settings

5.3 Export Settings

5.3.1 Screen Capture

The Media window displays all the screen capture files, you can preview, delete or export them.The exported file is saved in “bmp” format.

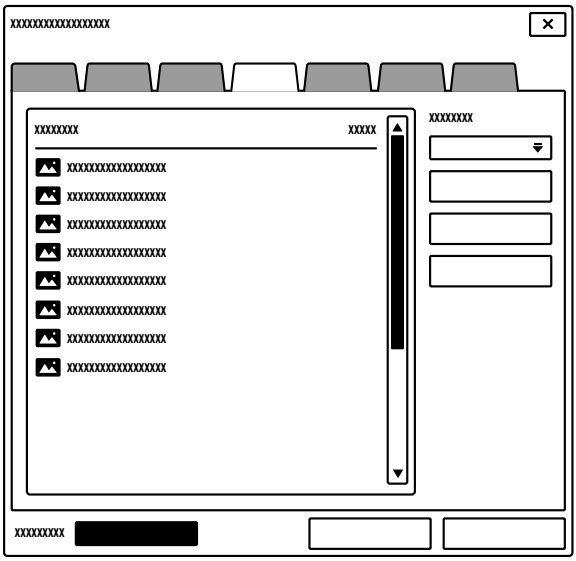


Figure 5-4.Media window

To export screen capture,

1. Insert the USB device into the USB connector of the ventilator. The USB symbol key is highlighted on the main screen.
2. Select [**Setup**] → [**Media**] to view the capture pictures. Select the desired pictures.
3. Select [**Export**].The system will run a check to verify that there is enough storage space available on the USB device. If there is sufficient space, the system will start to export the screen.

5.3.2 Patient and Setting Data

Exporting data means to export data from the ventilator, such as patient demographics, current setting parameters, current alarm limits, trend data and so on.

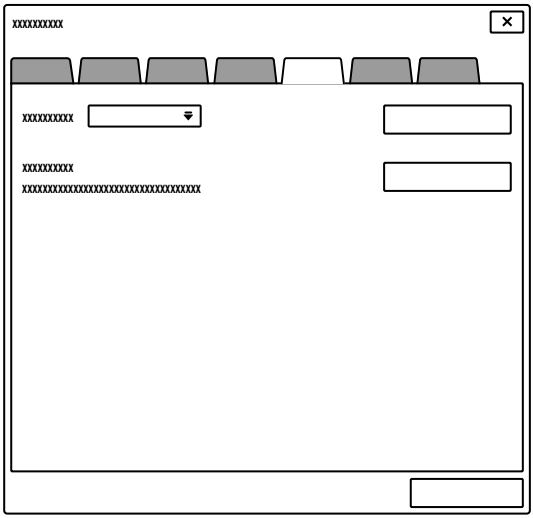


Figure 5-5.Export window

To export data,

1. Insert the USB device into the USB connector of the ventilator. The USB symbol key is highlighted on the main screen.
2. By selecting the symbol key, the system will open the Export interface.
3. On the opened interface, select the [**Export**] key. The system will run a check to verify that there is enough storage space available on the USB device. If there is sufficient space, the system will export data including patient information, current parameter settings, current alarm limits, tabular trend, measured value,
4. After exporting is completed, select [**Remove USB Device**] to remove the USB device.

NOTE

- If you need to check the exported data,please contact the Customer Service Department.

5.3.3 Transfer Settings

You can export or import settings, while unit is in standby.

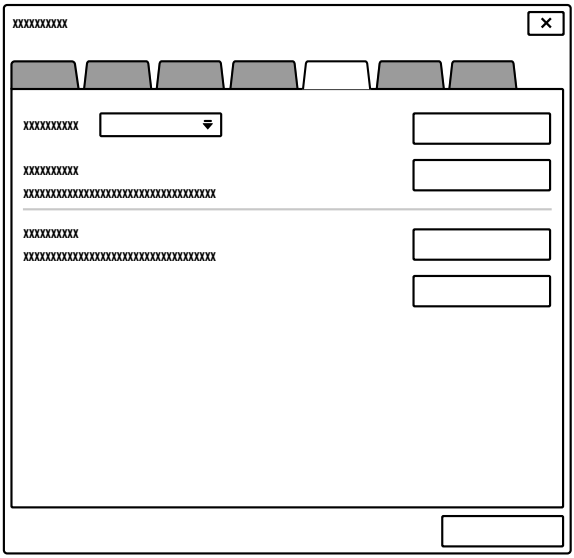


Figure 5-6.Export and import window

To export settings,

1. Make sure that the machine is in Standby status.
2. Insert the USB device into the USB connector of the ventilator. The USB symbol key is highlighted on the main screen .
3. By selecting the USB symbol key, the system will open the Export interface.
4. Select [**Maintain**] → Enter system password → [**Export**]. Select the [**Export**] key in configuration filed. The system will run a check to verify that there is sufficient storage space available on the USB device. If there is sufficient space, the system will save the current settings and machine defaults to the USB device.
5. After exporting is completed, select [**Remove USB**

Device] to remove the USB device.

To import settings,

1. Make sure that the machine is in Standby status.
2. Insert the USB device into the USB connector of the ventilator. The USB symbol key is highlighted on the main screen .
3. By selecting the USB symbol key, the system will open the USB settings interface.
4. Select [**Maintain**] → Enter system password → [**Export**] . Select the [**Import**] key in configuration filed. The system will upload the Ventilator settings saved in the USB device.
5. After exporting is completed, select [**Remove USB Device**] to remove the USB device.

5.4 Basic Settings

5.4.1 Set T-insp/I:E

1. Select[**Setup**] → [**Vent**] → [**Setting**].
2. Set [**T-insp/I:E**] and toggle between [**T-insp**] and [**I:E**] Based on [**T-insp/I:E**], adopt the corresponding T-insp or I:E ventilation parameter settings for ventilation modes.

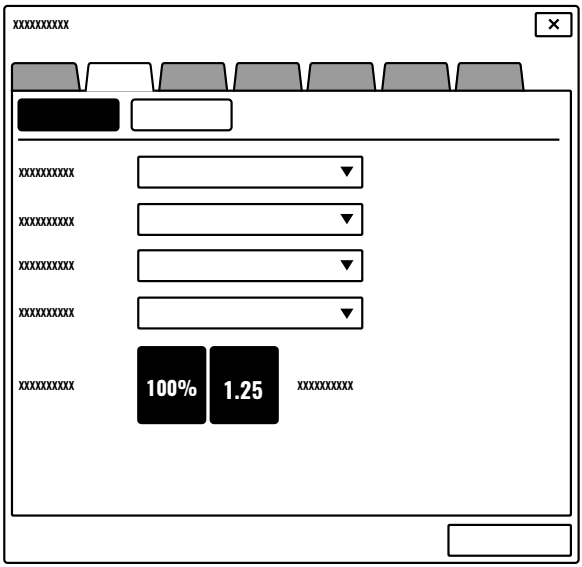


Figure 5-7.Ventilation settings windows

5.4.2 Set VT/IBW

1. Select[**Setup**] → [**Vent**] → [**Setting**].
2. Set [**VT/IBW**]: set to an appropriate ratio. The system will calculate the default tidal volume (VT) in the ventilation mode depending on [**VT/IBW**].

5.4.3 Set IBW/Height

1. Select[**Setup**] → [**Vent**] → [**Setting**].
2. Set [**IBW/Height**] and toggle between [**IBW**] and [Height]. When the ventilator is in the standby mode, set the ideal body weight or height. The system calculates default values of VT, f, and fapnea in the ventilation mode utomatically based on the set IBW or height and gender.

5.4.4 Set IV Apnea Mode

1. Select[**Setup**] → [**Vent**] → [**Setting**].
2. Set [**IV Apnea mode**]: [**Volume Control**] or [**Pressure Control**].

In case of invasive ventilation, the settable apnea ventilation control parameter is [**VT-apnea**], if [**IV Apnea Mode**] is set to [**Volume Control**], while is [**ΔP-apnea**] if [**IV Apnea Mode**] is set to [**Pressure Control**].

5.4.5 Set Oxygen Concentration During Suction

1. Select [**Setup**] → [**Maintain**] → [**Vent**] → [**Setting**].
2. Set [**O_2 % during suction**]: set oxygen enrichment in accordance with different patient types. After initiation of oxygen enrichment, the system will compare “current oxygen concentration + oxygen enrichment” with “100vol.%” and start ventilation according to the lower of the two values.

5.4.6 Set Oxygen Sensor Monitoring

1. Select [**Setup**] → [**Maintain**] → [**Vent**] → [**Sensor**].
2. Set the [**Monitoring**]: (ON) or (OFF). When the switch is ON, oxygen concentration of patient’s inhaled gas can be monitored. You can switched off if oxygen concentration monitoring function accompanying the ventilator is not needed. In this case, the [**O_2**

Monitoring Off] prompt message is displayed on the screen. After Oxygen Sensor Monitoring off, the ventilator will disable relevant alarm messages and prompt messages.

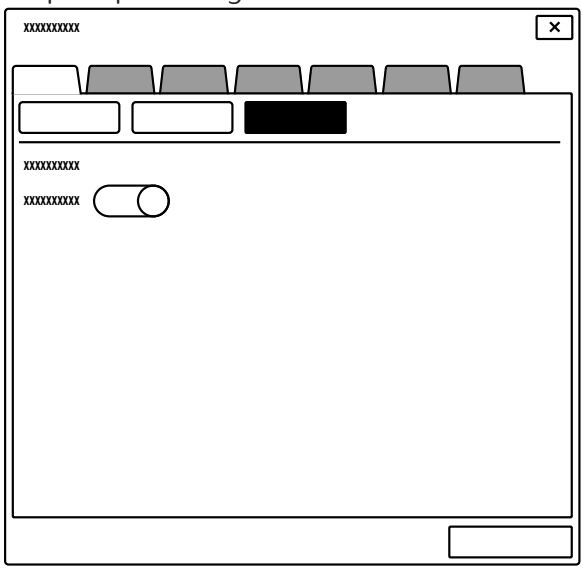


Figure 5-8.Sensor windows

NOTE

- The system total response time for oxygen concentration monitoring is 23s.
- It takes approximately 3 minutes from powering on the ventilator to reaching the oxygen concentration monitoring performance specified in section B.7 of this manual.

CAUTION

- **Disabling oxygen concentration monitoring is allowable. To prevent potential patient injury, it is suggested not to switch off oxygen concentration monitoring continuously.**

5.4.7 Set Oxygen Supply

1. Select [**Setup**] → [**Maintain**] → Enter system password → [**System**].
2. Select [**Gas supply**] and select a desired Oxygen.

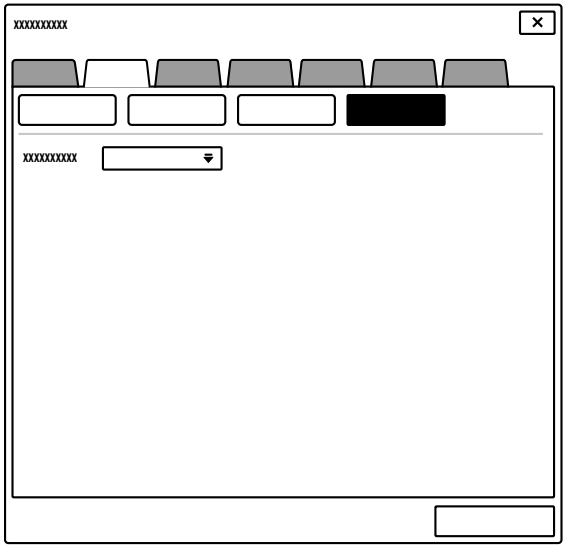


Figure 5-9.Oxygen supply settings window

5.4.8 Set Language

1. Select [**Setup**] → [**System**].
2. Select [**Language**] and select the desired language.
3. restart the ventilator to activate the selected language.

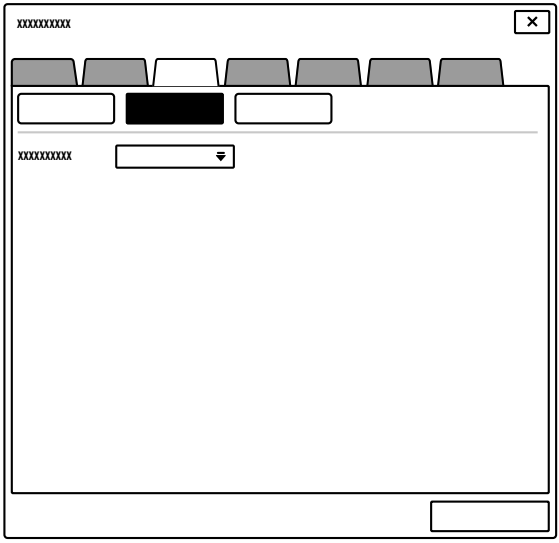


Figure 5-10.Language settings windows

5.4.9 Set Unit

Set Paw Unit

1. Select [**Setup**] → [**Maintain**] → Enter password → [**System**].
2. Set [**Pressure Unit**]: [**cmH_2O**], [**hPa**] or [**mbar**].

Set Weight Unit

1. Select [**Setup**] → [**Maintain**] → Enter password → [**System**].
2. Set [**Weight Unit**]: [**kg**] or [**lb**].

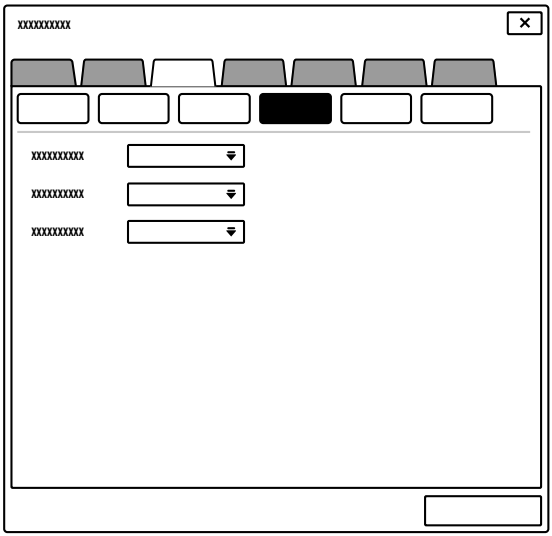


Figure 5-11.Unit settings windows

5.4.10 System Information

Version Information

Select [**Setup**] → [**Info**] to check the system software version.

Configuration Information

Select [**Setup**] → [**Maintain**] → Enter system password → [**Configuration**] to view the configuration information of the ventilator such as ventilation mode.

Maintenance Information

Select [**Setup**] → [**Maintain**] → Enter system password → [**Info**] to view the system total running time, system startup time, O_2 sensor last calibration time, flow sensor last calibration time, time left for the next backup air supply maintenance, and time of last maintenance.

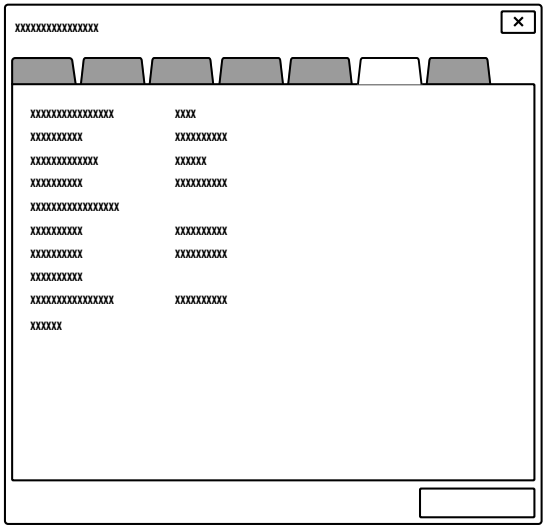


Figure 5-12.Info window

Chapter 6

6. Start ventilation

6.1 Turning on the Ventilator

NOTE

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

1. Insert the power cord into the power receptacle. Ensure the external power indicator light is lit.
2. Press the power switch on the rear side of machine.
3. The alarm indicator light flashes yellow and red once in turn, and then the system conducts a self check of the speaker and buzzer once respectively.
4. A start-up screen and start-up check progress bar appear. Then the System Check screen is displayed.

6.2 System Check

CAUTION

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

NOTE

- To ensure optimum performance of the ventilator, re-do system check each time when accessories or components like tubes, humidifiers, or filters are replaced.

To enter the System Check screen,the System Check screen is accessed automatically after powering on the system.

On the non-standby screen, select the [**Standby**] key and enter the Standby status after your confirmation. Select the [**System Check**] key in the Standby status to enter the System Check screen.

The system check screen displays the last system check time and total system check result.

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

The system check is performed by following the on-screen steps, instructions, and messages. Make sure the tests pass before you return the ventilator to clinical use.

The System Check for dual-limb including the below items:

- Blower Test: test the speed of the blower
- Inhalation Branch Test: test the inspiratory flow sensor, inspiratory pressure sensor and patient pressure sensor.
- O_2 Branch Test : test the O_2 flow sensor and O_2 Proportional Valve
- O_2 cell Test : test the O_2 sensor.
- Exhalation Branch Test : test the expiratory valve.
- Pressure Sensor Test: test the pressure sensor.
- Leakage
- Compliance

- Circuit Resistance
- Pressure Release Valve Test

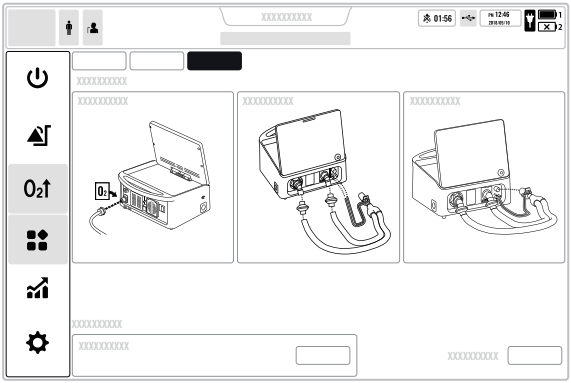


Figure 6-1.Dual-limb system check prepareation& system check items

System Check result can be:

Pass: indicates that check of this item is completed and is passed;

Fail: indicates that check of this item is completed but is failed;

Cancel: indicates that check of this item is cancelled.

Select the[**Detail**] key to query the system check information of the ventilator system, including system check items and System Check results.

Total selftest results are listed as follows after all selftest items have been completed:

Pass: all selftest items successfully pass the seftest.

Partially Pass: some selftest items fail, but the mechanical ventilation is allowed.

Fail: some selftest items fail, but the mechanical ventilation is not allowed.

Cancel: some selftest items canceled and other selftest items have been successfully passed.

During system check, if you select [**Skip**], the system stops check of this item immediately and begins to check the next item. If you select [**Stop**], the system stops all the items.

When checks of all items are completed, if you select [**Retry**], the system starts a new round of check.

6.3 Select Patient

Open the patient setting menu in standby and select the patient information:

- If selecting [**New Patient**], please set [**Patient Category**], [**Gender**], [**Height**]/[**IBW**] and [**Ventilation Type**] in the accessed [**New Patient**] menu.
- If selecting [**Last Patient**], only the [**Ventilation Type**] can be set.
- Upon alteration of [**Gender**], [**Height**] or [**IBW**], the settings of [**VT**], [**VTapnea**], [**f**] and [**fapnea**] will change accordingly, as well as tidal volume high alarm limit, tidal volume low alarm limit, minute ventilation high alarm limit and minute ventilation low alarm limit.
- The [**Patient 1**]/[**Patient 2**]/[**Patient 3**] are the user preset for ventilation settings, you can customize them for different patients.

NOTE

- To prevent the possible patient injury, make sure the ventilator is set up for the appropriate patient type with the appropriate breathing circuit parts.

After the System Check pass, the ventilator configuration is displayed on the Standby Windows. You can set up the patient type, patient circuit, and components of the breathing system for new and resuming patients.

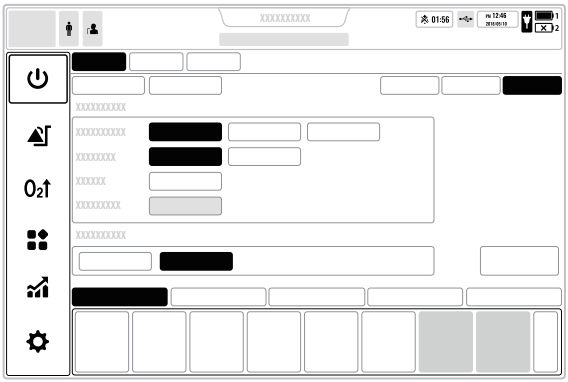


Figure 6-2.Ventilation settings

Select [**Last Patient**] from the Standby window. The ventilator will start up with the same mode and settings as last power down. Then you can press the [**Start Ventilation**] button to start ventilation.

6.4 Ventilation Type

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

⚠ **WARNING**

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

6.4.1 Invasive Ventilation

Invasive ventilation means to ventilate the patient through manual airway (ET tube or Trach tube).

In dual-limb invasive ventilation, the enabled ventilation modes include:

- VCV (Volume Control Ventilation).
- PCV (Pressure Control Ventilation).
- VSIMV (Volume Synchronized Intermittent

Mandatory Ventilation).

- PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation).
- PRVC (Pressure Regulated Volume Control).
- V+SIMV (PRVC + SIMV).
- CPAP/PSV (Continuous Positive Airway Pressure/ Pressure Support Ventilation).
- BPAP (Bilevel Positive Airway Pressure).
- APRV (Airway Pressure Release Ventilation).

Select the invasive ventilation type. Select vent in the setup page and then make the STRC settings.

⚠ **WARNING**

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

CAUTION

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

6.4.2 Non-Invasive Ventilation (NIV)

NIV means to ventilate the patient by using a nasal mask or facial mask instead of ET tube or Trach tube.

In dual-limb NIV, the enabled ventilation modes include:

- PCV (Pressure Control Ventilation).
- PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation).
- CPAP/PSV (Continuous Positive Airway Pressure/ Pressure Support Ventilation).
- BPAP (Bilevel Positive Airway Pressure).
- APRV (Airway Pressure Release Ventilation).

CAUTION

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

6.4.3 Set Ventilation Type

To set ventilation type,

1. Select the patient type icon, or select [**Last Patient**] or [**New Patient**] in the standby mode.
2. Set the [**Ventilation Type**] to [**NIV**] or [**Invasive**]on the accessed screen.

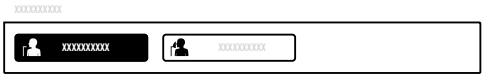


Figure 6-3.Ventilation type

6.5 Ventilation Mode

NOTE

- At the inspiratory phase, the ventilator will not automatically generate negative pressure. However, it may cause negative pressure because patients inhale air.
- The user can set high-pressure alarm limit. If the pressure reaches the high pressure alarm limit in the inspiratory phase, the [**High Pressure**] high-level alarm is triggered. The ventilator opens the expiration valve and switches to expiratory phase until the airway pressure reaches the preset PEEP value. If the airway pressure exceeds high pressure alarm limit+5 cmH_2O (adjustable pressure limit) , the ventilator opens the pressure release valve so that the airway pressure falls to 3 cmH_2O for

continuous 0.5 s. Make sure to set high pressure alarm limit properly to ensure patient safety.

- As false triggering of the ventilator can easily be caused by negative pressure produced during closed suction, it is recommended that the pressure-controlled ventilation mode, in which ventilation trigger can be turned off, be used first. The operator should complete ventilation parameter settings in accordance with the patient's condition.

6.5.1 Ventilation Mode and Parameters Setup

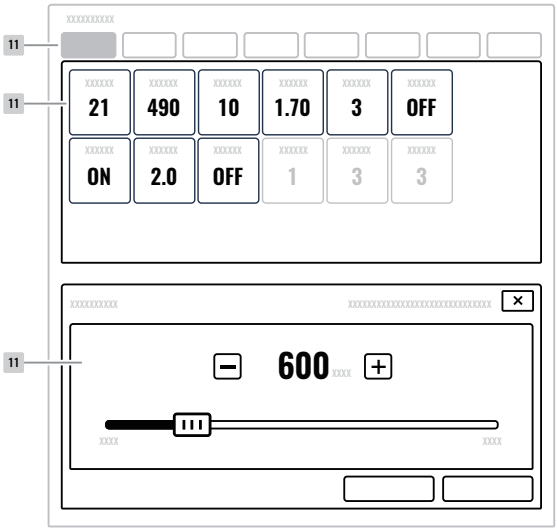


Figure 6-4.Ventilation mode and parameters

1. **Ventilation mode field**

   Displays the keys for setting up ventilation modes.

2. **Parameter setup quick key field**

   Displays ventilation parameter settings corresponding to the ventilation mode.

3. **Parameter adjustment window**

   Displays ventilation parameter value adjustment.

To set ventilation mode,

1. In the ventilation mode area, select the required ventilation mode key, and the ventilation parameters can be set in this ventilation mode will be displayed in the opened menu.
2. Select the key for the ventilation parameter to be set.
3. Set the selected parameter to the appropriate value. Press [**OK**] to confirm the setting.

4. Set other parameters in the same way.

NOTE

- To adjust a parameter, using the scroll bar to adjust the control value quickly, or touching the Plus or Minus button increment or decrement the control value step by step. Touch the OK button to apply the changing.

6.5.2 Apnea Ventilation

Apnea ventilation is a backup vent mode initiated when the ventilator detects patient apnea

in CPAP/PSV, V-SIMV, P-SIMV, V+SIMV, BPAP and APRV modes.

If no spontaneous breathing time beyond apnea time, mandatory breaths are triggered with apnea ventilation.

Apnea ventilation mode includes volume-controlled and pressure-controlled Ventilation.

Table 6-1.Apnea settings

Parameter	Description
f-apnea	Controlled breaths per minute in apnea ventlation
Apnea T-insp.	Time of inspiration in apnea ventlation
△ P-apnea	Pinsp Inspiratory pressure (relative above PEEP)in apnea ventlation
VT-apnea	Tidal volume of controlled breaths in apnea ventlation

6.5.3 Sigh Ventilation

The sigh function can be configured in Configuration Assist.

The sigh function can be enabled in the ventilation window.

Sighs are displayed as curves with filled strip.

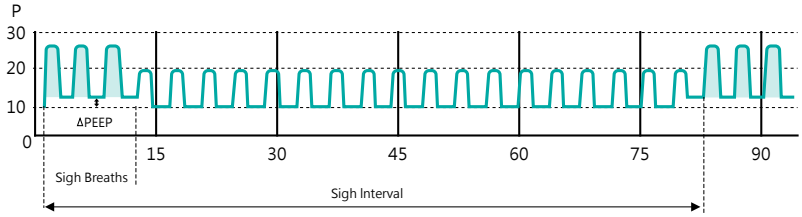


Figure 6-5.Sigh waveform

Table 6-2.Sigh support modes

Mode	Sigh
CPAP/PSV,BPAP,APRV	Not available
VCV,PCV,PRVC,P-SIMV,V-SIMV,V+SIMV	Increase in PEEP

Table 6-3.Sigh settings

Parameter	Description
Sigh	Switch for turning on sigh function
Interval	Time interval between two groups of sigh
Cycles Sigh	Number of sigh cycles
▵ int.PEEP	PEEP added in sigh cycle

6.5.4 VCV

(Volume-Controlled Ventilation Mode)

Volume-controlled mandatory breaths are administered at a set rate.

Spontaneous respiratory efforts only trigger controlled breaths in the case of VCV.

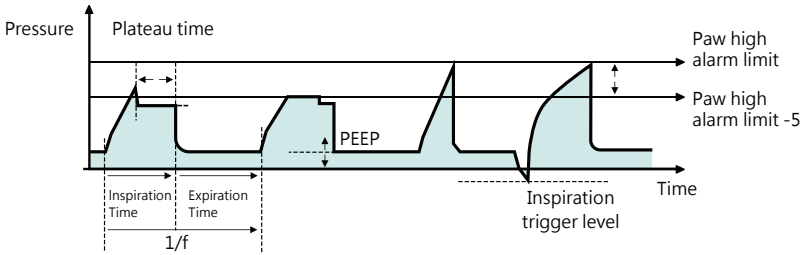


Figure 6-6.VCV waveform

Table 6-4.VCV settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
VT	Tidal volume of controlled breaths
T-insp. / I:E	Time of inspiration or ratio of inspiratory time to expiratory time
PEEP	Positive end-expiratory pressure
f	Controlled breaths per minute
Assist	Assistant trigger
T-pause(%)	Percent of inspiratory pause time
F-trigger /P-trigger	Inspiration trigger level

6.5.5 PCV

(Pressure Controlled Ventilation Mode)

Pressure-controlled mandatory breaths are administered at a set rate.

Spontaneous respiratory efforts only trigger controlled breaths in the case of PCV.

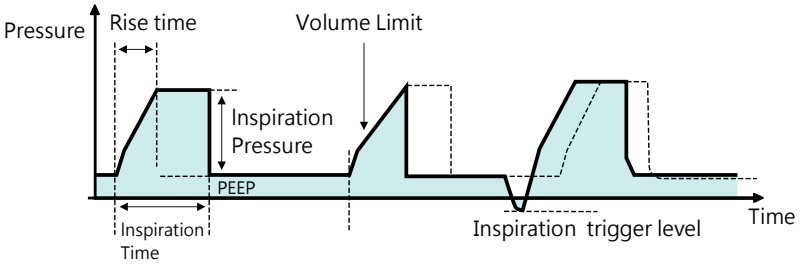


Figure 6-7.PCV waveform

Table 6-5.PCV settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
▵ P-insp.	Pinsp Inspiratory pressure (relative above PEEP)
T-insp. / I:E	Time of inspiration or ratio of inspiratory time to expiratory time
PEEP	Positive end-expiratory pressure
f	Controlled breaths per minute
Assist	Assistant trigger
T-slope	Rise time of inspiratory pressure
F-trigger /P-trigger	Inspiration trigger level

6.5.6 PRVC

(Pressure Regulated Volume Controlled Ventilation Mode)

Volume-controlled mandatory breaths(PRVC) are administered at a set rate.

Spontaneous respiratory efforts only trigger controlled breaths in the case of PRVC.

Pressure adjustment increase of the ventilator cannot exceed 10cmH_2O for the first 3 cycles and cannot exceed 3cmH_2O for each of the following cycles.

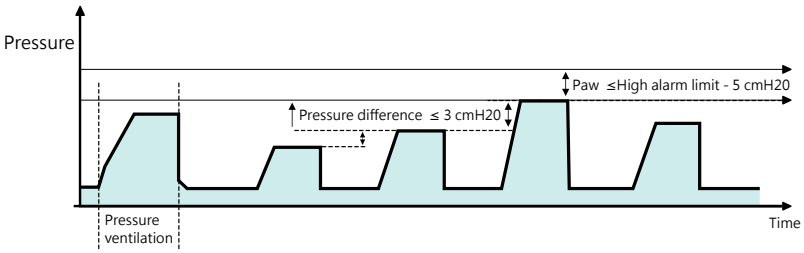


Figure 6-8.PRVC waveform

Table 6-6.PRVC settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
VT	Tidal volume of controlled breaths
T-insp. / I:E	Time of inspiration or ratio of inspiratory time to expiratory time
PEEP	Positive end-expiratory pressure
f	Controlled breaths per minute
Assist	Assistant trigger
T-slope	Rise time of inspiratory pressure
F-trigger /P-trigger	Inspiration trigger level

6.5.7 VSIMV

(Volume Controlled Synchronized Intermittent Mandatory Ventilation Mode)

Volume-controlled mandatory breaths(VCV) are delivered at the set rate.

Intermittently the patient can trigger pressure-supported breaths.

The controlled breaths are preceded by a trigger window, which allows comfortable patient-triggered delivery without compromising the set rate.

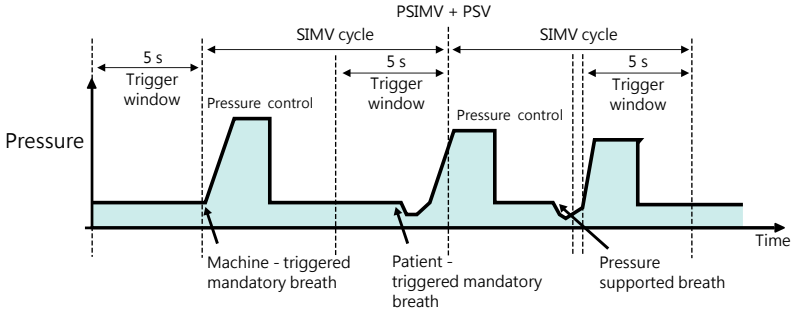


Figure 6-9.VSIMV waveform

Table 6-7.VSIMV settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
VT	Tidal volume of controlled breaths
T-insp. / I:E	Time of inspiration or ratio of inspiratory time to expiratory time
PEEP	Positive end-expiratory pressure
f-SIMV	Controlled breaths per minute
Assist	Assistant trigger
Tpause(%)	Percent of inspiratory pause time
F-trigger /P-trigger	Inspiration trigger level

Exp%	Expiration trigger level
▵ P-supp.	Pressure support (relative above PEEP)

6.5.8 PSIMV

(Pressure Controlled Synchronized Intermittent Mandatory Ventilation Mode)

Pressure-controlled mandatory breaths are delivered at the set rate.

After mandatory breath, the patient is free to take any number of spontaneous breaths which are supported by corresponding pressure in set in the rest time of IMV cycle.

The controlled breaths are preceded by a trigger expectation window,which allows comfortable patient-triggered delivery without compromising the set rate.

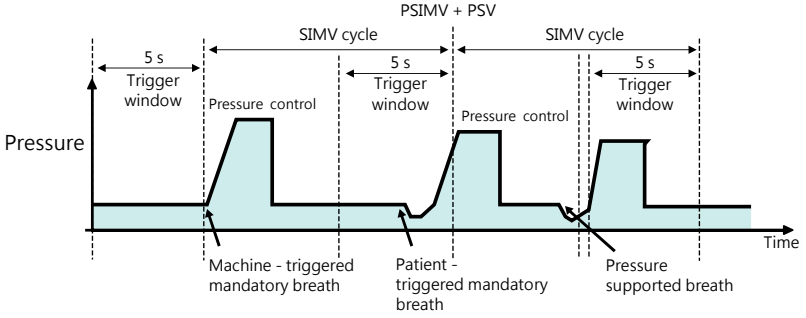


Figure 6-10.PSIMV waveform

Table 6-8.PSIMV settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
▵ P-insp.	Pinsp Inspiratory pressure (relative above PEEP)
T-insp. / I:E	Time of inspiration or ratio of inspiratory time to expiratory time
PEEP	Positive end-expiratory pressure

f-SIMV	Controlled breaths per minute
T-slope	Rise time of inspiratory pressure
F-trigger /P-trigger	Inspiration trigger level
Exp%	Expiration trigger level
▵ P-supp.	Pressure support (relative above PEEP)

6.5.9 V+SIMV

(Pressure Regulated Volume Controlled Synchronized Intermittent Mandatory Ventilation Mode)

Pressure-controlled mandatory breaths, which are volume targeted(PRVC), are delivered at the set rate.

After mandatory breath, the patient is free to take any number of spontaneous breaths which are supported by corresponding pressure in set in the rest time of IMV cycle.

The controlled breaths are preceded by a trigger expectation window,which allows comfortable patient-triggered delivery without compromising the set rate.

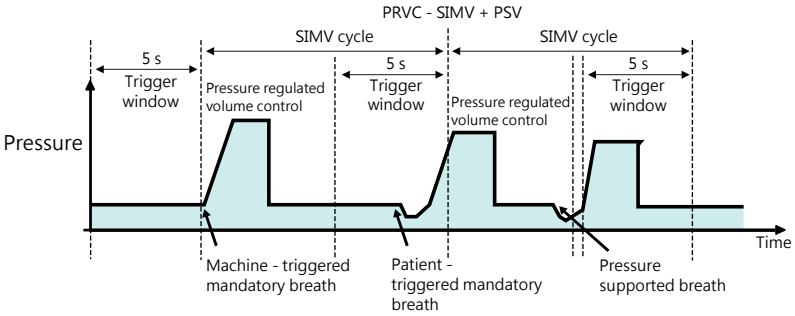


Figure 6-11.V+SIMV waveform

Table 6-9.V+SIMV settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
VT	Tidal volume of controlled breaths
T-insp. / I:E	Time of inspiration or ratio of inspiratory time to expiratory time
PEEP	Positive end-expiratory pressure
f-SIMV	Controlled breaths per minute
T-slope	Rise time of inspiratory pressure
F-trigger /P-trigger	Inspiration trigger level
Exp%	Expiration trigger level
▵ P-supp.	Pressure support (relative above PEEP)

6.5.10 CPAP/PSV

(Continuous Positive Airway Pressure/Pressure Support Ventilation Mode)

Pressure-supported breaths are triggered on a synchronised basis.

Inspiration ends as soon as the flow has dropped to an adjustable percentage of peak flow.

Expiration is initiated when Tinsp-max (4s) is exceeded.

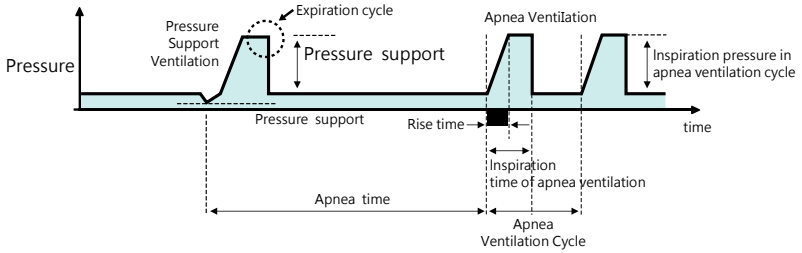


Figure 6-12.CPAP/PSV waveform

Table 6-10.CPAP/PSV settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
T-insp. / I:E	Time of inspiration or ratio of inspiratory time to expiratory time
PEEP	Positive end-expiratory pressure
T-slope	Rise time of inspiratory pressure
F-trigger /P-trigger	Inspiration trigger level
Exp%	Expiration trigger level
▵ P-supp.	Pressure support (relative above PEEP)

6.5.11 BPAP

(Bilevel Positive Airway Pressure Mode)

Airway pressure switches between two pressure levels, P-low and P-high.

The patient can breathe spontaneously at both pressure levels.

Pressure support can only be set for P-low.

If a spontaneous breathing is detected in trigger window,the transition from P-High to P-Low will be activated,if not,mechine-trigger will activate the trainsition instead.

BPAP is a highly flexible ventilation mode and can be set like CPAP, PCV, SIMV, PSV or APRV, depending on the application.

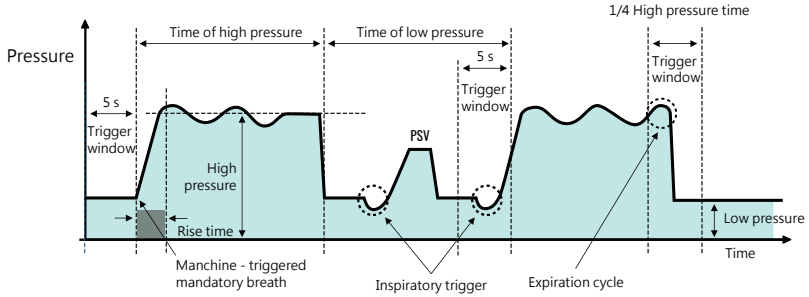


Figure 6-13.BPAP waveform

Table 6-11.BPAP settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
P-high	Upper pressure level (absolute pressure)
P-low	Lower pressure level
T-high	Time of high pressure
T-low	Time of low pressure
T-slope	Rise time of inspiratory pressure

6.5.12 APRV

(Airway Pressure Release Ventilation Mode)

The patient can breathe spontaneously at both pressure levels.

If a spontaneous breathing is detected in trigger window,the transition from P-High to P-Low will be activated,if not,mechine-trigger will activate the trainsition instead.

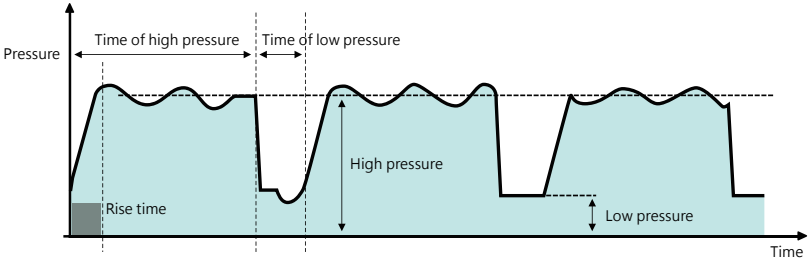


Figure 6-14.APRV waveform

Table 6-12.APRV settings

Parameter	Description
O_2%	Adjustment of oxygen concentration
P-high	Upper pressure level (absolute pressure)
P-low	Lower pressure level
T-high	Time of high pressure
T-low	Time of low pressure
T-slope	Rise time of inspiratory pressure

6.6 Tube Resistance Compensation

Synchronized tube resistance compensation (STRC) stands for the function of automatic tube resistance compensation. By selecting appropriate endotracheal (ET) tube or tracheostomy (Trach) tube of different diameters for the user, the ventilator can adjust gas delivery pressure automatically, so that the pressure at the end of the tube is consistent with the ventilator's pressure setting value as much as possible.

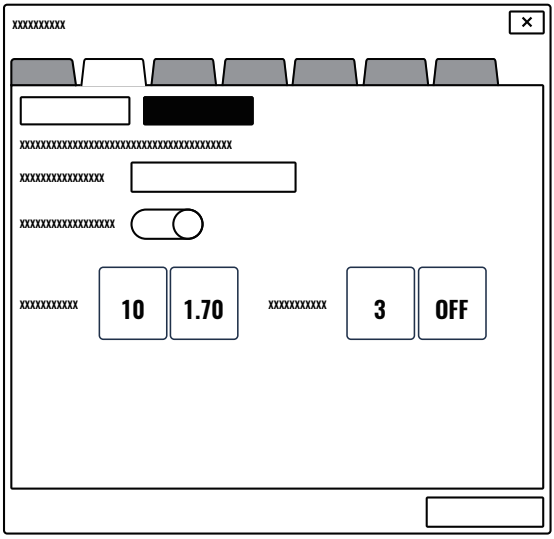


Figure 6-15.STRC settings

1. Select [**Setup**] → [**Vent**] → [**STRC**].
2. Set the items below on the accessed screen:

- [**Tube Compensation**]: disable,ET Tube or Trach Tube.
- [**TubeID**]: ET tube diameter.
- [**Compensation**]: percentage of STRC.
- [**Expiratory Compensation**] : enable or disable compensation during exhalation.

3. Select [**Exit**] for the system to initiate STRC. After

STRC has been enabled, if you enter the STRC interface and then select [**Disable**], the system will terminate STRC immediately in the ventilation.

When STRC is enabled, Ptrach waveform is displayed with the Paw waveform.

⚠ **WARNING**

- **STRC may induce autotriggering. If autotriggering occurs, first check the patient, breathing circuit, and other possible causes.**

NOTE

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

6.7 Start Ventilation

⚠ **WARNING**

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

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

6.8 Standby Status

Press the [**Standby**] key to enter the Standby interface after confirmation.

Standby is a waiting mode that lets you safely suspend ventilation to temporarily disconnect the patient from the ventilator or to set up the ventilator before connecting the patient. Physiological alarms are disabled and oxygen is turned off during standby.

You can also change ventilator settings and most menu functions during standby. The settings changes are effective when you exit standby.

⚠ **WARNING**

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

6.9 Turn the Ventilator Off

Press the power switch on the rear side of machine for more than 3s in Standby status to turn the system off.

In non-standby status, if you press the power switch, the system will prompt [**Please enter Standby mode to shut down the system.]** Select [**OK**], and the system will remain in non-standby status. Then select the [**Standby**] key to enter the standby interface after confirmation. Then select the power switch in Standby to turn the system off.

NOTE

- The ventilator remains connected to power when the power switch is switched off. This permits the batteries to charge. To completely disconnect the ventilator from power, unplug it from the mains power outlet.

Chapter 7

7. Alarms

NOTE

- The delay time from the onset of an alarm condition to the point that the alarm signal leaves the ventilator input/output port is typically 500ms. The time it takes the message to appear on an external device such as a remote alarm depends on the characteristics of the device.
- The delay in the determination of an alarm for FiO_2 exceeds high or low limit is at least 30s.
- When there are changes in alarm settings, the system stores the changed data in the flash memory chips of the main board automatically. When the equipment restarts, the data are restored automatically.
- When the contents of the log reaches capacity, the system will automatically erase the old information by the principle: first in, first out.
- If the alarm system is power down, there is no time for the log is maintained. But an audible alarm will be annunciated by the buzzer.
- The expiratory-limb-partial-occlusion alarm condition is determined by exhalation flow and pressure measurements.

The ventilator's alarms notify the operator of problems. These alarm types, including their audiovisual characteristics and required actions, are summarized in Table 7-1.

Table 7-1.Alarm indications

Alarm Type	Alarm Type Symbol	Alarm Lamp Color	Alarm Message Bar	Alarm Audio	Action Require
High-priority	!!!	Red	Red, with alarm message	A sequence of 5 beeps, repeated until the alarm is reset.	The patient's safety is compromised. The problem needs immediate attention.
Medium-priority	!!	Yellow	Yellow, with alarm message	A sequence of 3 beeps, repeated periodically.	The patient needs prompt attention.
Low-priority	!	Cyan	Cyan, with alarm message	Two sequences of beeps. This is not repeated.	Operator awareness is required.

You can view active or inactive alarms, as applicable, in the Alarm list window. Information about the alarm is also stored in an event log with occurrence time.

When a low-, medium-, or high-priority alarm occurs, ventilation typically continues. When the condition that caused the alarm is corrected, the ventilator automatically resets the alarm.

7.1 Introduction

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

NOTE

- When the ventilator is started, the system detects whether audible alarm tones and alarm lamp function normally. If yes, the alarm lamp flashes

red and yellow successively, and the speaker and the buzzer give check tones. If not, do not use the equipment and contact us immediately.

- When multiple alarms of different priorities occur simultaneously, the ventilator selects the alarm of the highest priority and gives visual and audible alarm indications accordingly.
- If more than one alarms are triggered at the same level, alarm messages will be shown by the sequence of alarms triggered.

7.2 Alarm Categories

By nature, the ventilator's alarms fall into three categories: physiological alarms, technical alarms and prompt messages.

1. **Physiological alarms**

   Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition.

   Physiological alarm messages are displayed in the alarm message field.

2. **Technical alarms**

   Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to proper operation or mechanical problems. Technical alarm messages are displayed in the alarm message field.

3. **Prompt messages**

   As a matter of fact, prompt messages are not alarm messages. Apart from the

   physiological and technical alarm messages, the ventilator will show some messages telling the system status. Messages of this kind are included into the prompt message category and are usually displayed in the prompt message field.

7.3 Alarm Priority Levels

By severity, the ventilator's alarms fall into three categories: high priority alarms, medium priority alarms and low priority alarms.

The priorities for all alarms are preset before the ventilator leaves the factory and are not user adjustable.

Table 7-2.The alarm priority and action required

Alarm Priority	Action Required
High priority	The patient's safety is compromised. The problem needs immediate attention.
Medium priority	The patient needs prompt attention.
Low priority	Operator awareness is required.

7.4 Alarm Signals

When an alarm occurs, the ventilator will indicate it to the user through visual or audible alarm signals.

- Alarm Lamp
- Audible alarm
- Alarm Messages
- Flashing numeric

Among them, the alarm lamp, audible alarm tones and alarm messages distinguish the priority of the alarm in different ways.

Visual alarm indicators are located on the front panel of the ventilator and are best seen from directly in front of the unit. Alarm speakers are located on the side of the ventilator. They can be heard from any direction and should never be blocked in any way.

Alarms and messages on the ventilator alert you to situations that require your attention. The ventilator can also activate remote alarms when connected.

7.4.1 Alarm Lamp

If a technical alarm or physiological alarm occurs, the alarm lamp will flash. The flashing color and frequency match the alarm priority as follows:

- High priority alarms: the lamp quickly flashes red.
- Medium priority alarms: the lamp slowly flashes yellow.
- Low priority alarms: the lamp turns cyan without flashing.

7.4.2 Audible Alarm

The ventilator uses different alarm tone patterns to match the alarm priority:

- High priority alarms: broadcasts the high priority alarm tone.
- Medium priority alarms: broadcasts the medium priority alarm tone.
- Low priority alarms: broadcasts the low priority alarm tone.
- A-weighted sound pressure level of audible alarm signals:
- Position of the operator: 1-meter in front of and 1.5-meter above the ventilator.
- A-weighted sound pressure level: not less than 45dB and not greater than 85 dB. The high priority alarm volume is not less than 60dB at the default alarm volume level.

7.4.3 Alarm Messages

When an alarm occurs, an alarm message will appear in the ventilator's alarm message filed.

The alarm message uses a different background color to match the alarm priority:

- High priority alarms: red
- Medium priority alarms: yellow
- Low priority alarms: cyan

The exclamatory marks (!) before the alarm message match the alarm priority as follows:

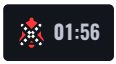
- High priority alarms: ! ! !
- Medium priority alarms: ! !
- Low priority alarms: !

7.4.4 Flashing Alarm Numeric

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

7.4.5 Alarm Status Symbol

Apart from the aforementioned alarm indicators, the ventilator still uses the following symbols telling the alarm status:



: indicates that the alarm audio is paused and the alarm system is in AUDIO PAUSED mode.

: indicates multiple alarm messages when this icon is displayed before alarm messages to show the number of alarms.

The alarm message uses a different background color to match the alarm priority. Red background means that the highest priority of the multiple alarm messages is high while yellow background means that the highest priority of the multiple alarm messages is medium. You

can view active alarms by selecting the alarm message field.

: indicates that there is inactivated alarms for which the alarm triggercondition has disappeared. Press this icon to view the most recent inactivated alarms in the Alarm list window. You can also clear the most recent alarms with the [Reset] key.

: indicates that the alarm of a parameter is closed and the alarm signal is in the ALARM OFF mode.

7.5 Alarm Volume Settings

Set Alarm Volume:

1. Select [**Alarm limit**] → [**Volume**].
2. Set [**Alarm Volume**]: X-10, with X being the minimum alarm volume and 10 the maximum alarm volume. If there are no currently active alarms, you can also select one level. The system will emit a low-priority alarm tone once based on the selected alarm volume.

Set minimum alarm volume:

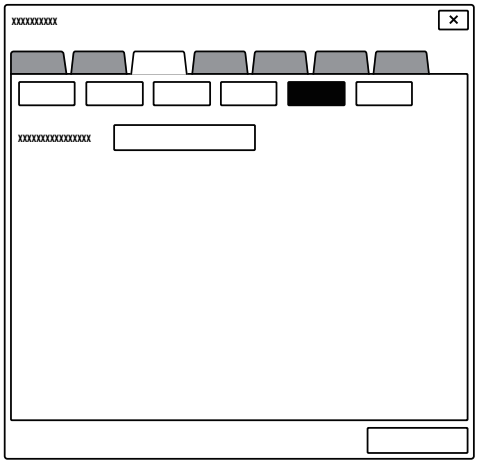


Figure 7-1.Alarm Volume settings windows

1. Select [**Setup**] → [**Maintain**] → Enter systemmaintain password → [**System**] → [**Alarm**].
2. Set [**Minimum Alarm Volume**] to an appropriate value.

⚠ **WARNING**

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

7.6 Alarm List

The Alarm button is displayed on the top of screen while the active alarms happen. Click the Alarm button to open the Alarm List window which shows the most recent active alarms. If no alarms are active, the alarm buffer shows the most recent inactive alarms. You can click Reset button to clear all the inactive alarms in the Alarm List window.

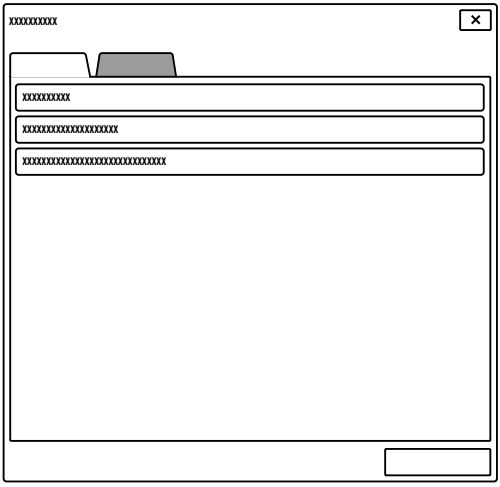


Figure 7-2.Active alarms window

7.7 Alarm Limits

⚠ **WARNING**

- **To prevent possible patient injury, avoid setting alarm limits to extreme values, which can render the alarm system useless.**
- **To reduce patient risk from inappropriate ventilatory support, avoid turning off the alarms.**

CAUTION

- **In the case that high pressure alarm limit of 60 cmH_2O is not required under clinical conditions, setting the high pressure alarm limit to 60 cmH_2O or less is recommended so as to extend the service life of the spare air supply and the battery.**

NOTE

- An alarm is triggered when the parameter value is higher than the high limit or lower than the low limit.

When using the ventilator, always keep an eye on whether the alarm limits of a specific parameter are set to the appropriate values.

Select [**Alarm Limit**] to set ventilation or module-related alarm limits.

The Alarm Limits window displays the operator adjustable alarm settings.

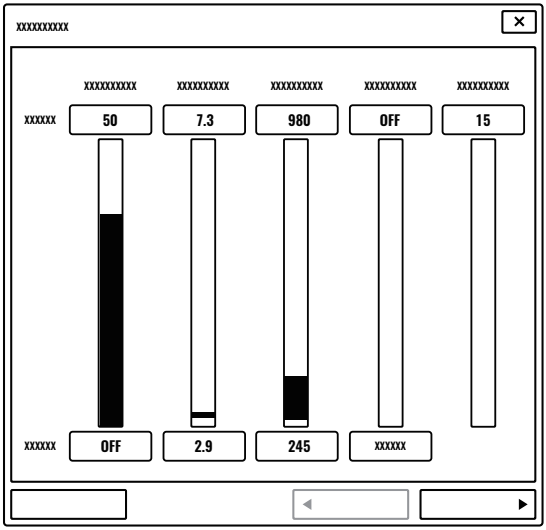


Figure 7-3.Adjusting the control settings

Review and adjust the alarm settings as follows:

Select [**Alarm Limit**] on the screen menu to open the Alarm Settings window.

Select a parameter and adjust the value. Repeat for any other desired parameters.

Select Accept to apply. The ventilator alarms when a monitored value goes out of the range bounded by the alarm limits.

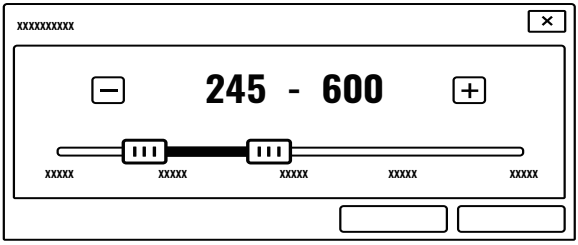


Figure 7-4.Adjusting the alarm settings

7.8 Nurse Call

The ventilator provides nurse call function that enables the ventilator to output nurse call signals to the nurse call system when an alarm meeting the user set requirements occurs.

The nurse call function is activated only when:

1. The nurse call function is switched on;
2. An alarm which meets the user set requirements occurs;
3. The ventilator is not in AUDIO PAUSED status.

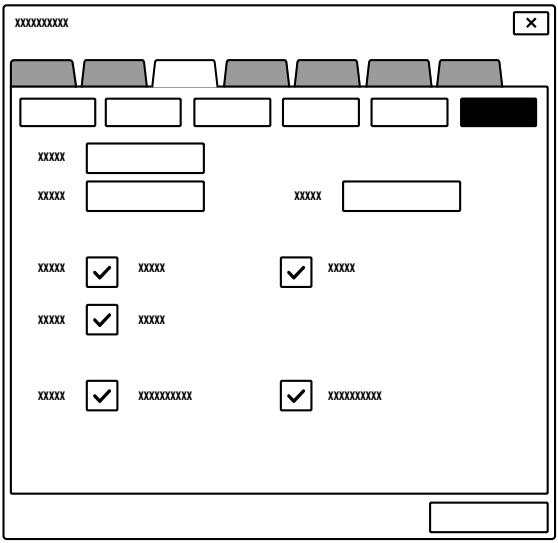


Figure 7-5.Nurse call settings

Follow the steps below to set nurse call:

1. Select [**Setup**] → [**Maintain**] → Enter user password → [**System**] → [**Nurse Call**].
2. Select [**Switch**] and toggle between [**ON**] and [**OFF**].

   [**ON**]: to switch on the nurse call function.

   [**OFF**]: to switch the nurse call function off.
3. Set [**Signal type**].

[**Pulse**]: indicates that the nurse call signals outputted are pulse signals lasting for one second. When multiple alarms occur simultaneously, only one pulse signal is outputted. If a new alarm occurs when the ongoing alarm is not cleared yet, a new pulse signal will be outputted.

[**Continuous**]: indicates that the nurse call signal lasts until the alarm ends, i.e. the duration of a nurse call signal equals to that of the alarm.

4. Select [**Contact Type**].

   [**Normally Open**]: to trigger nurse call with normally open signal .

   [**Normally Closed**]: to trigger nurse call with normally closed signal.

5. Select [**Alarm Level**] and select levels of alarm that will trigger nurse call signal.
6. Select [**Alarm Type**] and select types of alarm that will trigger nurse call signal.

   If no setting is made for [**Alarm Level**] or [**Alarm Type**], nurse call signals will not be triggered no matter what alarm occurs.If no setting is made for [**Alarm Level**] or [**Alarm Type**], nurse call signals will not be triggered no matter what alarm occurs.

⚠ **WARNING**

- **Do not rely exclusively on the nurse call system for alarm notification. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.**

7.9 Responding to Alarms

⚠ **WARNING**

- **If AC power fails and the backup battery is depleted, an audible alarm annunciates for at least 2 minutes. Immediately discontinue ventilator use**

and secure an alternative means of ventilation. As with most ventilators, when power is lost, exhaled air may be rebreathed.

- **To ensure the alarm will be heard, make sure the alarm loudness is adequate and avoid blocking the alarm speakers.**
- **Avoid blocking the LED indicators on the front panel of the ventilator.**
- **A potential hazard can exist if different ALARM PRE-SETS are used for the same or similar equipment in any single area.**
- **To prevent possible patient injury when alarms are active, check the patient for adequate ventilation. Identify and remove the cause of the alarms. Readjust the alarm limits only when they are inappropriately set for the current conditions.**
- **To prevent possible patient injury arising from an equipment malfunction, we recommends that you immediately remove any ventilator with a technical fault from use, record the technical fault code, and have the ventilator serviced.**
- **To prevent possible patient injury when alarms are active, ensure that the patient receives adequate ventilation. Identify and remove the cause of the alarms. Readjust the alarm limits only when they are inappropriately set for the current conditions.**

CAUTION

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

NOTE

- Be aware that an alarm may result from either a clinical condition or an equipment problem.
- Be aware that one alarm condition can induce multi-ple alarms. Normally only one or two indicate

the root cause of the alarm; the rest are resultant. Your search for the causes of the alarm condition should be assisted by, but not limited to, the alarm messages displayed.

- If an alarm persists for no apparent reason, discontinue ventilator use and contact your service representative .

When an alarm occurs, do as follows:

1. Check the patient's condition. Secure sufficient and effective ventilation for the patient if required.
2. Determine the alarming parameter or alarm category.
3. Identify the alarm source.
4. Take proper actions to eliminate the alarm condition.
5. Make sure the alarm condition is corrected.

For details about how to troubleshoot alarms, refer to 7-13 Alarm Troubleshooting Table.

7.10 Silencing Alarms

⚠ **WARNING**

- **Pay close attention to the patient and ventilator to ensure no alarm messages are ignored during the period of AUDIO PAUSED. Possible patient or equipment hazard may be produced if the alarm condition continues while no action is taken.**

NOTE

- When alarm audio is silenced, all the alarm indicators work normally except audible alarm tones.
- When alarm audio is silenced, if a new alarm occurs, the alarm audio will be restored automatically.

Silence an alarm for 2 minutes by pressing the [**AUDIO**

PAUSED] key on the bottom of the monitor.When the 120 s countdown time is up, the AUDIO PAUSED status terminates and audible alarm tones start again.

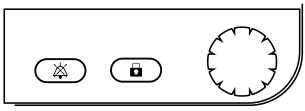


Figure 7-6.Alarm AUDIO PAUSED key

When alarm audio is silenced, press the [**AUDIO PAUSED**] key again to recover the alarm audio.

7.11 ALARM OFF

When the alarm limit is set as [**OFF**] or alarm is disabled, the system will display an ALARM OFF icon showing the parameter alarm limits, and corresponding

physiological alarms will be closed. Namely, the alarm message, alarm lamp, audible alarm tones, and flashing alarm numeric for this physiological alarm will be all switched off.

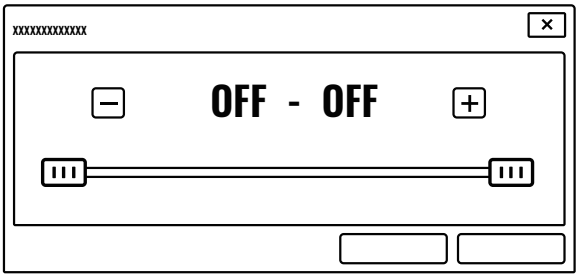


Figure 7-7.Alarm limit settings

⚠ **WARNING**

- **Switching off alarms can endanger the patient. Handle with care.**

7.12 Alarm Test

The Ventilator performs a self-check during start-up and continuously during operation. You may want to run alarm tests to demonstrate the alarm's operation.

Position of the operator: 1-meter distance and 1.5-meter high from the front of the ventilator.

The sum of the mean alarm condition delay plus the mean alarm signal generation delay is less than 5s.

7.12.1 Low PEEP

1. Remove the expiration valve membrane and install the expiration valve.
2. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
3. Set PEEP to 5 cmH_2O. Verify that the [**Low PEEP**] alarm is activated.

7.12.2 Patient Circuit Occluded

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in PCV mode normally.
2. Nip the inspiration tube with the hands, make sure the monitoring value of VTi is lower than 10 ml.
3. Verify that the Patient Circuit Occluded alarm is activated after several breathing cycles.
4. Loosen the inspiration tube and verify this alarm is reset automatically.

7.12.3 High Oxygen

1. Correctly connect the oxygen supply and close the air intake.
2. Connect a test lung to the ventilator, set FiO_2 to

60%, and start ventilation.

3. Verify that the [**High Oxygen**] alarm is activated.

7.12.4 Low Oxygen

1. Connect the ventilator to high-pressure oxygen supply. Set the oxygen supply type to HPO.
2. Make sure a demonstration lung is connected to the ventilator and start ventilation normally.
3. Switch off the high-pressure oxygen supply after ventilation is stable.
4. Verify that the Low Oxygen alarm is activated.

7.12.5 Running on Internal Battery

1. Connect the ventilator to AC power and push the power switch to switch on.
2. Disconnect the AC power after the system starts up.
3. Verify that the [**Running on Internal Battery**] alarm is activated and the ventilator is powered by batteries.
4. Reconnect the AC power.
5. Verify that the alarm resets and the ventilator is again powered by AC.

7.12.6 Loss of Power

1. Connect the ventilator to AC power and push the power switch to switch on.
2. After the system starts up, disconnect the external power supply when the battery is fully charged.
3. Connect a test lung to the ventilator and start normal ventilation.
4. Ventilation time is approximately 3 hours for a ventilator configured with one battery, and approximately 6 hours for a ventilator configured

with two batteries. When the battery power is depleted, the [**System will shut off soon. Connect with External Power Supply.**] alarm is activated.

5. Reconnect the external power supply.
6. Verify that the alarm resets and the ventilator is again powered by external power supply.

7.12.7 High Pressure

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set Paw high alarm limit to current Peak+5 cmH_2O.
3. Squeeze the test lung hard during inspiration.
4. Verify that the [**High Pressure**] alarm is activated, the ventilator cycles into expiration, and airway pressure falls to PEEP level.

7.12.8 Low Pressure

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set Paw low alarm limit to current Peak+5 cmH_2O.
3. Check whether the [**Low pressure**] alarm is activated.

7.12.9 High Tidal Volume

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in VCV mode normally.
2. Set the VT high alarm limit to be less than the current VTe.
3. Verify that the High Tidal Volume alarm is activated.

7.12.10 Low Tidal Volume

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation in VCV mode normally.
2. Set the VT low alarm limit to be greater than the current VTe.
3. Verify that the [**Low Tidal Volume**] alarm is activated.

7.12.11 Low Minute Volume

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in VCV mode normally.
2. Set the MV low alarm limit to be greater than the current MV.
3. Verify that the Low Tidal Volume alarm is activated.

7.12.12 Alarm Troubleshooting Table

The below table is a list of the alarm messages displayed by the ventilator, along with their definitions and suggested corrective actions. These corrective actions are sequenced to correct the most probable malfunction or to present the most efficient corrective action first. The proposed actions, however, may not always correct the particular problem.

This chapter lists physiological and technical alarm messages.

Table 7-3.Physiological alarm messages

Item	Alarm	Priority	Definition	Action needed
1	High Pressure	High	The measured inspiratory pressure exceeds the set Pressure alarm limit.	Check the patient. Adjust the Pressure alarm limit. Check the breathing circuit and Flow Sensor tubes for kinks and occlusions. Provide alternative ventilation once the ventilator enters the ambient state.
2	High Minute Volume	High	The measured Minute Volume is greater the set alarm limit.	Check the patient. Check and adjust the ventilator settings, including alarms.
3	Low Minute Volume	High	The measured Minute Volume is less the set alarm limit.	Check the patient. Check the breathing circuit. Check and adjust the ventilator settings, including alarms.
4	High Tidal Volume	Medium	The measured tidal volume is greater than the set high alarm limit.	Reduce the support pressure setting. Adjust the high tidal volume alarm limit.

Item	Alarm	Priority	Definition	Action needed
5	Low Tidal Volume	Medium	The measured tidal volume is less than the set high alarm limit.	Check the patient. Check and adjust the ventilator settings, including alarm limits. Check for leaks and disconnects.
6	High Frequency	Medium	The measured frequency is greater than the set alarm limit.	Check the patient for adequate ventilation. Adjust the high frequency alarm limit.
7	Low Frequency	Medium	The measured frequency is less than the set alarm limit.	Check the patient. Adjust the low frequency alarm limit.
8	Apnea	High	No patient trigger within the operator-set Apnea time in ventilation mode.	Check the patient.
9	High Oxygen	High	Measured Oxygen is greater the set alarm limit (low-pressure oxygen) or the operator-set Oxygen + 5% (high-pressure oxygen).	Calibrate the oxygen cell. Install a new oxygen cell.

Item	Alarm	Priority	Definition	Action needed
10	Low Oxygen	High	Measured Oxygen is less the set alarm limit (low-pressure oxygen) or the operator-set Oxygen - 5% (high-pressure oxygen).	Check the patient. Check the oxygen supply. Provide an alternative source of oxygen, if necessary. Calibrate the oxygen cell. Install a new oxygen cell.
11	High pressure during sigh	Low	A sigh cannot be fully delivered.	Check the patient. Check the breathing circuit. Adjust the Pressure alarm limit. Consider disabling the sigh function.
12	High Sustained Airway Pressure	High	The measured airway pressure is greater than or equal to the setting PEEP+15cmH_2O for continuous 15s.	Check the patient. Check the ventilation parameter setup. Check the breathing tubes for occlusion.
13	Patient Disconnected	High	The patient circuit is disconnected from the ventilator.	Check the patient. Reconnect patient circuit. If problem persists, provide alternative ventilation.
14	Patient circuit leak	Low	The breathing circuit is leaky.	Check the breathing circuit for leakage. Run system self-test to test the leakage.

Item	Alarm	Priority	Definition	Action needed
15	Patient circuit occluded	High	The breathing circuit is occluded.	Check and clean the breathing circuit. Check and clean the expiration valve.
16	Flow sensor calibration needed	High	The flow sensor does not have correct calibration data or automatic recalibration of the flow sensor is impossible.	Check the flow sensor. Try to calibrate the flow sensor.
17	O_2 cell defective	Medium	The oxygen cell is depleted.	Install a new oxygen cell.
18	O_2 cell missing	Low	There is no signal from the oxygen cell.	Install an oxygen cell or use an external monitor.
19	Oxygen Supply Failed	High	O_2 pressure is low or high-pressure O_2 is not connected.	Check the patient. Check connection with O_2 supply. Check O_2 supply pressure.
20	O_2 cell calibration needed	Medium	Oxygen cell calibration data is not within expected range, or cell is new and requires calibration.	Calibrate the oxygen cell.

Table 7-4.Technical alarm messages

Item	Alarm	Priority	Definition	Action needed
1	Battery Low	High	The ventilator is running on battery, and the battery capacity is less than 15%.	Connect the ventilator to its external power source.
2	Battery Temperature high	High	The battery temperature is higher than expected during discharge.	Connect the external power supply. Remove the ventilator from the sun or other heat source.
3	Battery missing	High	No battery is present.	Insert a battery.
4	Running on internal battery	Low	System is powered by the internal battery.	Connect ventilator to AC power when available.
5	HEPA replacement suggested	Low	The air inlet HEPA filter shows increased resistance.	Replace the HEPA filter.
6	Fan failure	Medium	The cooling fan is malfunctioning.	Disconnect the ventilator from the patient. Have the ventilator serviced.

Item	Alarm	Priority	Definition	Action needed
7	High PEEP	High	The measured positive end expiratory pressure is greater than or equal to the setting PEEP+5cmH_2O for continuous 10s.	Check the patient. Confirm ventilator and alarm settings are appropriate.
8	High Blower Temperature	High	The blower temperature is too high.	The ventilation will be stopped. Contact service personnel.
9	Inspiratory Gas Temperature High	High	The gas temperature exceeds 45℃ .	Disconnect the patient. Restart the ventilator.
10	Speaker Failure	High	The Speaker fails in self-test.	Contact service personnel.

7.13 Alarm Parameter

Table 7-5.Alarms for dual-limb ventilation

Parameter	Range	Resolution	Factory default
Paw High Limit	10 ~ 65 cmH_2O	1cmH_2O	50cmH_2O
Paw Low Limit	Off · 10 ~ 63 cmH_2O	1cmH_2O	Off
MV High Limit	Adult: 0.2 ~ 100.0 L/min;Pediatric: 0.2 ~ 60.0 L/min	0.1 L/min	VT*f*1.5
MV Low Limit	Adult: 0.1 ~ 50.0 L/min; Pediatric: 0.1 ~ 30.0 L/min;	0.1 L/min	VT*f*0.6
VTe High Limit	Adult: Off, 110 ~ 4000 mL; Pediatric: Off, 25 ~ 600 mL;	5 mL	VT*2
VTe Low Limit	Adult: Off, 50 ~ 3990 mL; Pediatric: Off, 10 ~ 590 mL	5 mL	VT*0.5
f-total High Limit	off, 1~90 bpm	1bpm	Off
f-total Low Limit	off, 1~89 bpm	1bpm	Off
T-apnea High Limit	5~60 s	1s	15s
FiO_2 High Limit(Low-pressure oxygen supply)	20 ~ 100%	1%	100%
FiO_2 Low Limit(Low-pressure oxygen supply)	18 ~ 98%	1%	21%

Chapter 8

8. Special Functions

8.1 O_2↑ (O_2 Enrichment)

NOTE

- Oxygen alarms are suppressed while the O_2 ↑ function is active.
- O_2 ↑ is not available with low pressure oxygen mode.
- The system cannot start O_2 ↑ while the PV tool is active.

O_2 ↑ is also called as O_2 enrichment. For adult patient, the O_2 enrichment function delivers 100% oxygen for 2 minutes. For pediatric patient, the default applied oxygen concentration during the enrichment maneuver is increased by 25% of the last oxygen setting (The applied oxygen concentration can be set under the [**Setup**] -> [**Vent**]->[**O_2% during suction**] window.).

Press the [**O_2↑ Suction**] key and the ventilator starts oxygen enrichment. The indicator light for [**O_2↑ Suction**] key is illuminated and the remaining oxygen enrichment time is displayed in the prompt message field. Oxygen enrichment is active for maximum two minutes.

During oxygen enrichment, the currently set oxygen concentration is displayed for the O_2% parameter in the parameter setup quick key field.

To terminate delivery of O_2 enrichment before the 2-min period is up, press the key again.

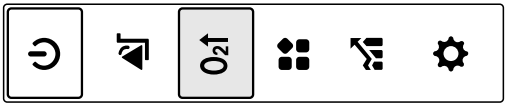


Figure 8-1.O_2↑ key on screen

8.2 Suctioning Tool

NOTE

- P0.1, PEEPi and NIF are disabled after suction is activated.
- The system cannot start O_2 ↑ Suction in the Standby modes or O_2 therapy modes .During suctioning, the patient's secretion can escape of the tubing. By using the suctioning tool the ventilation stops and prevents that secretion escapes.Press the [**O_2↑ Suction**] key and the suction function is activated.
- After the suction function is activated, the system delivers oxygen enrichment to the patient (the 1st stage of suction) and makes the judgment within the 120-second period of oxygen enrichment. If the patient tubes are disconnected, the suction procedure starts.
- Disconnecting the patient tubes starts the 2nd stage of suction. The system prompts [**The Patient is Disconnected! Reconnect Patient after Suction Completed!**] and stops ventilating the patient. In this case, you can apply manual suction to the patient.
- Reconnecting the patient tubes starts the 3rd stage of suction after patient connection is detected. The system delivers oxygen enrichment to the patient.
- During the 1st or 3rd stage of suction, pressing the [**O_2↑ Suction**] key can terminate the suction procedure.

8.3 Manual Breath

Select the [**Function**] ->[**Maneuvers**] ->[**Manual Breath**] and the ventilator system delivers a manually triggered breath during exhalation.

If you try to initiate a manual breath during the early

stage of inspiration or the early stage of exhalation, the breath will not be delivered.

8.4 Inspiratory Hold

NOTE

- There is at least one expiratory phase between two inspiration holds.
- Inspiration Hold function is disabled in CPAP mode and is supported when apnea ventilation occurs.
- If any hydrops in the patient side of flow sensor or the inspiration water trap(refer to ***Figure 10-5.D***), the hydrops should be drained.

The Inspiratory Hold function lets you perform an inspiratory hold maneuver.

To perform an inspiratory hold as follow:

1. Select the [**Function**] ->[**Maneuvers**] ->[**Inspiratory Hold**].
2. Hold the [**Inspiratory Hold**] key down during the stage of inspiration, it performs a hold maneuver at the end of inspiration, lasting until the key is released, for up to 30 s additional.

8.5 Expiratory Hold

NOTE

- There is at least one inspiratory phase between two expiration holds.
- Expiration Hold function is disabled in CPAP mode and is supported when apnea ventilation occurs.

The Expiratory Hold function lets you perform an expiratory hold maneuver.

To perform an expiratory hold as follows:

1. Select the [**Function**] ->[**Maneuvers**] ->[**Expiratory Hold**].

2. Hold the button down during the stage of exhalation, it performs a hold maneuver at the end of exhalation, lasting until the key is released, for up to 30s additional.

8.6 Nebulizer

CAUTION

- **Remove the nebulizer after nebulization,otherwise the ventilation may be affected.**
- **The remaining nebulizer drug will affect the surrouding air.**

NOTE

- For adults or pediatric patients, the nebulization flow of ventilator is zero when the inspiratory flow is less than 15 L/min.

The nebulization function powers a standard inline nebulizer for delivery of prescribed medications in the ventilator circuit. When nebulization is active, the nebulizer flow is synchronized with the inspiratory phase of each breath. Nebulization can be activated in all modes of ventilation.

To start nebulization as follows:

1. Select the [**Function**] ->[**Maneuvers**] ->[**Nebulization**].
2. Set up the time period for nebulization or select continuous nebulization.
3. Press the [**Start Nebulization**] key to begin nebulization. To terminate nebulization press the key again.

8.7 P0.1

The airway occlusion pressure (P0.1) maneuver is used to determine the patient's neuromuscular drive to breathe. The P0.1 results are based on a four-breath

average. This maneuver cannot be attempted while any alarm is active.

To perform the P0.1 as follows:

1. Select the [**Function**] ->[**Diagnostics**] → [**P0.1**].
2. Press the [**Start**] key to start the measurement, and the result will be displayed after the measurement is completed.

8.8 NIF

The Negative Inspiratory Force (NIF) maneuver is used to determine the patient's ability to pull a negative inspiratory pressure against an occluded airway.

To perform the NIF as follows:

1. Select the Select the [**Function**] ->[**Diagnostics**] ->[**NIF**].
2. Press the [**Start**] key to start the measurement, and the result will be displayed after the measurement is completed.

8.9 PEEPi

The Intrinsic PEEP (PEEPi) maneuver is used to measure the PEEPi and Vtrap. PEEPi is the positive end-expiratory pressure produced by the trapped gas and Vtrap is the trapped gas volume.

To perform the PEEPi as follows:

1. Select the [**Function**] ->[**Diagnostics**] ->[**PEEPi**].
2. Press the [**Start**] key to start the measurement, and the result will be displayed after the measurement is completed.

8.10 PV Tool

NOTE

- The PV tool function is disabled in the following cases: patient type of pediatric, CPAP/PSV, NIV or apnea vent mode, oxygen enrichment, during P0.1 measurement, during nebulization or suction, within one minute after nebulization or suction, within one minute after last PV loop test.
- The PV tool function is not recommended when there is great leakage or when the patient has spontaneous breathing. The relevant characteristic points the PV tool function provides are only for your reference.
- If no operation is performed on PV tool screen within three minutes, the measurement screen exits automatically.

The PV tool is the method that records a quasi-static pressure/volume curve showing both the inflation and the deflation curve to determine the optimal PEEP. The doctor is able to determine the optimal PEEP for the patient with the help of this function.

To perform the PV tool as follow:

1. Select the [**Function**] ->[**PV Tool**].
2. Setup the below parameters for PV tool.

- **P-start**: starting pressure of the static P-V loop.
- **P-top**: maximum pressure of the static P-V loop can reach.
- **End PEEP**: ending pressure of the static P-V loop.
- **T-pause**: pause time when the static P-V loop reach the maximum pressure.
- **Ramp Speed**: the speed of the starting pressure rising to maximum pressure during the static P-V loop.

The system acquires T-total parameter value based on

the calculation formula and displays it on the window.

3. Press the [**Start**] key to start PV tool measurement. Press the [**Stop**] key during measurement, the system aborts measurement immediately.
4. After the measurement is completed, you can set the desired positions of [**Cursor 1**] and [**Cursor 2**]. When you select [**Cursor 1**] or [**Cursor 2**], you can move the position of the cursor to determine the characteristic points. The system also displays the volume value and pressure value in the inspiratory limb and expiratory limb corresponding to the cursor position and displays the compliance of these limbs.
5. Press the [**History**] key to select the desired loop in the accessed list. The system only displays the history loop you are viewing.
6. Press the [**Ref. Loop**] key to select the desired loop in the accessed list. The system displays the reference loop you are viewing and the current loop as well.

8.11 O_2 Therapy

O_2 therapy is a method to increase O_2 concentration in the airway at normal pressure through simple tube connections. O_2 therapy is a way for hypoxia prevention or treatment, providing O_2 concentration higher than that in the air.

To start O_2 Therapy, Select the [**Standby**]->[**Start O_2 Therapy**].->[**O_2 Therapy**].

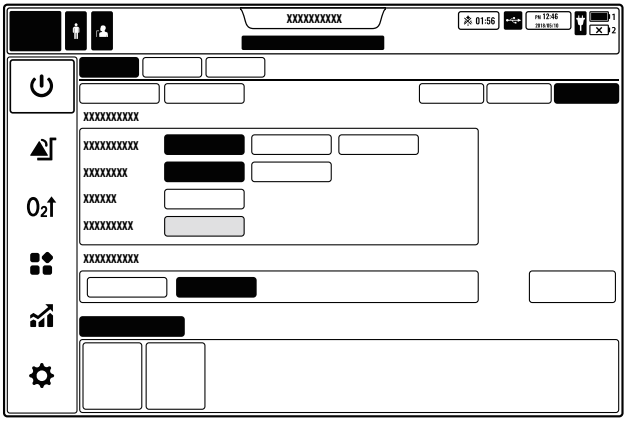


Figure 8-2.O_2 therapy

Chapter 9

9. Maintenance

⚠ **WARNING**

- **To reduce the risk of electric shock, power down the ventilator and disconnect it from AC power before cleaning or servicing it.**
- **Movable parts and removable components may present a pinch or a crush hazard. Use care when moving or replacing system parts and components.**
- **The batteries can only be charged by this ventilator.**
- **Use batteries at least once every month to extend their life. Charge the batteries before they are depleted.**
- **Inspect and replace batteries regularly. Battery life depends on how frequent and how long it is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 2 years. For more aggressive use models, life expectancy can be shortened. We recommend replacing lithium batteries every 2 years.**
- **In case of battery failure, contact us or have your service personnel replace it. Do not replace the battery without permission.**
- **If the running time of the battery is noticeably shorter than that stated in the specifications, replace the battery or contact the service personnel.**

NOTE

- It is the user's responsibility to comply with the information provided in this chapter.
- To ensure the safety and reliability of your ventilator, follow these maintenance procedures

along with your own institutional policies for cleaning, disinfecting, and maintaining equipment. All the procedures in this manual are intended to be performed by the operator. For further maintenance, contact your service representative.

9.1 Instructions

⚠ **WARNING**

- **Obey infection control and safety procedures. Used equipment may contain blood and body fluids.**
- **Movable parts and removable components may present a pinch or a crush hazard. Take care to move or replace system parts and components.**
- **Do not use lubricants that contain oil or grease, which will burn or explode when exposed to high O_2 concentrations.**

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

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

NOTE

- No repair should ever be attempted by anyone not having experience in the repair of devices of this nature.
- Replace damaged parts with components manufactured or sold by us. Then test the unit to make sure that it complies with the manufacturer's published specifications.
- Contact us for service assistance.

- For further information about the product, contact us. We can provide documents about some parts depending on the actual condition.

9.2 Preventive Maintenance

⚠ **WARNING**

- **To prevent patient or ventilator contamination, inspect and replace the main flow bacteria filter between patients and at regular intervals (or as stated by the manufacturer).**
- **To prevent possible patient injury, inspect and verify the proper operation of the exhalation port regularly during use.**

CAUTION

- **Because some environments cause a quicker collection of lint and dust than others, inspect the filters more often when needed. The air inlet filter should be replaced; the cooling fan filter should be cleaned.**
- **To ensure proper system performance, use a specifed air inlet filter.**

Perform preventive maintenance on the ventilator according to the schedule in Table 9-1. The following subsections provide details for some of these preventive maintenance procedures.

Table 9-1.Schedule of preventive maintenance

Interval	Part/accessory	Procedure
As necessary	Inspiration valve assembly	When the patient's exhaled gas may contaminate the inspiratory valve assembly, this must be replaced with a disinfected valve.
	Expiration valve	Replace the expiratory valve if it is damaged
Every 6 years or as necessary	Battery of the clock module	Replace the battery of the clock module.Contact service personnel for replacement.
Several times a day or as necessary	Patient Tubing	Check the patient tubing and water traps for water build-up. Empty water build-up if there is.Inspect the parts for damage. Replace as necessary
During cleaning and setup	Ventilator	Inspect the parts for damage. Replace as necessary.
Each patient or as necessary	Breathing circuit (including mask, inspiratory filter, Flow Sensor, nebulizer jar, expiratory valve cover and membrane).	Replace with sterilized or new single use parts. Run the Flow Sensor calibration.
	Entire ventilator.	Run the system self-check.

Interval	Part/accessory	Procedure
Every day or as necessary	Breathing circuit.	Empty any water from breathing tubes or water traps.Inspect parts for damage. Replace as necessary.
	Ventilator	Clean the external surfaces
	O_2 sensor	Please calibrate the O_2 sensor.Replace CO_2 sensor if it is damaged.
Every month or as necessary	Air intake dust filters and fan filter	Check for dust and lint. If needed, clean or replace.
Check every 6 months and replace every two years	Batteries	Check the charging and discharging of the lithium battery every 6 months and replace the lithium battery every two years. Contact us for replacement.
Every 6 years or as necessary	Battery of the clock module	Replace the battery of the clock module.Contact service personnel for replacement.

Interval	Part/accessory	Procedure
Yearly or every 5000h, or as necessary	Oxygen cell.	Replace the O_2 cell if it is damaged.[Note] If ICU work normally, the service life of chemical O_2 Sensor is one year. The service life of O_2 sensor is an approximate specification only. The actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.
	Air intake HEPA filter.	Replace.Replace.Check the HEPA filter for occlusion,replace it when necessary.
	Ventilator.	Perform service-related preventive maintenance.
	Gas source sealing ring	Check the gas source sealing ring. Contact service personnel for replacement when necessary.
	Inspiration valve membrane	Check the sealing ring and the sealing plug.
	expiration valve membrane	Check the expiration valve membrane. Contact us for replacement if necessary.

9.3 Battery Maintenance

CAUTION

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

NOTE

- Use batteries at least once every month to extend their life. Charge the batteries before they are depleted.
- Inspect and replace batteries regularly. Battery life depends on how frequent and how long it is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 2 years. For more aggressive use models, life expectancy can be shortened. We recommend replacing lithium batteries every 2 years.
- In case of battery failure, contact service personnel replace it. Do not replace the battery without permission.
- To maintain the battery charge and to prolong the life of the batteries, keep the ventilator connected to its primary power source. Have the batteries recharged every 6 months, depending on storage conditions.
- Please set the battery to ship mode if the ventilator is not likely to be used for some time.The battery provides 12 months shelf life with initial charge state of 30%, when stored in shipping mode at 25° C.For longer storage time(>12 month), recommended state of charge is 40-60%

The ventilator is designed to operate on battery power whenever external power supply becomes interrupted. When the ventilator is connected to the external power source, the batteries are charged regardless of whether or not the ventilator is currently on. In case of power failure, the ventilator will automatically be powered

by the internal batteries. When external power source is restored within the specified time, power supply is switched from battery to external power supply automatically to ensure continuous system use.

The battery icon displayed on the screen indicates the battery statuses as follows:

 indicates the capacity of the battery is 81%-100%.

 indicates the capacity of the battery is 61%-80%.

 indicates the capacity of the battery is 41%-60%.

 indicates the capacity of the battery is 21%-40%.

 indicates the capacity of the battery is 0%-20%.

 indicates the battery is charging.

If the battery capacity is too low, the alarm "Battery low" will be triggered. In this case, apply external power to the ventilator.

9.3.1 Battery Use Guidance

Inspect and replace batteries regularly. Battery life depends on how frequent and how long it is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 2 years. For more aggressive use models, life expectancy can be shortened.

We recommend replacing lithium batteries every 2 years.

To ensure maximum battery capacity:

- Check battery performance once every six months. Checking battery performance is also required before ventilator repair is carried out or when battery is doubted to be the source for ventilator failure.
- Condition batteries once every time when they have been used for three months, or when the battery running time becomes noticeably short.

9.3.2 Battery Performance Checking

NOTE

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

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

Follow the below steps to check battery performance:

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

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

9.3.3 Battery Performance Conditioning

NOTE

- Condition batteries every time when they have been used for three months or when the battery running time becomes noticeably shorter.
- Over time and with the use of the battery, the actual

battery capacity will decrease. For an old battery, the battery full icon does not indicate that the battery capacity or battery running time still meets the requirement specified. When conditioning batteries, replace the battery when its running time becomes noticeably shorter.

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

Follow the below steps to condition batteries:

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

9.3.4 Battery Storage

If the ventilator is not used for a long time, contact service personnel to remove the batteries from the ventilator. Failure to do so will over-discharge the batteries and extend the battery charging time noticeably. Not fully charge the batteries once every 2 months and keep battery power at 40-60%. Fully charge the batteries before use.

When storing batteries, make sure the battery electrodes do not get in touch with metal goods. In case of long-time storage, place batteries in a cool

environment and keep battery power at 40-60%.

Placing batteries in a cool environment can delay battery aging. Ideally, batteries should be stored in a cool environment of -20℃ (-4 ℉) to +25℃ (77 ℉). Do not store batteries outside the environmental range of -20℃ (-4 ℉) to +40℃ (104 ℉)

9.3.5 Battery Recycling

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

⚠ **WARNING**

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

9.3.6 Battery Ship Mode

The system has the possibilty to cut the battery output from external connector to achieve safe shipment of the battery.

To enter the ship mode:

1. Remove the AC power supply.
2. Select [**Setup**] → [**Maintain**] → enter password → [**Setting**] → [**Battery Mode**].
3. Change the battery mode to [**Ship**].
4. Turn off the machine, then the battery enter the ship mode.

To exit the ship mode:

1. Make sure the AC power supply. To exit the ship mode the battery must be charged first.
2. Turn on the machine, then the battery exit the ship mode.

9.4 Pressure and Flow Zeroing

Zero pressure and flow when the monitored pressure or flow value has a great deviation. Zeroing can be performed in standby mode only.

Follow these steps to zero pressure and flow:

1. Open the [**Setup]**->[**Sensor]**->[**Zeroing]**->[**Paw&Flow]** window to access the pressure and flow zeroing, then press [**Start**] to begin the zeroing.
2. If the zeroing failed, you need to do the zeroing again.

9.5 Flow Calibration

NOTE

- Make sure another source of ventilatory support is available during this calibration. The patient must be disconnected from the ventilator during it.
- Do not perform flow calibration when low-pressure oxygen source is used.
- During calibration, do not operate the pneumatic parts. Do not move or press the breathing tubes especially.
- Make sure that the system is Standby mode.
- It is recommended not to connect the humidifier to the ventilator before the calibration.
- In case of calibration failure, check for relevant malfunctioning alarm and then troubleshoot it if there is. If it still fails or great measurement error occurs after calibration, replace the flow sensor and repeat the above operation. If the measurement error is still great, contact the authorized service personnel.

This calibration checks and resets the calibration points specific to the flow sensor in use. Please calibrate the flow sensor when the measured value has a great

deviation or when the flow sensor is replaced.

Follow the steps below to calibrate flow:

1. Connect the breathing tubes and insert the patient flow sensor into the Y piece.
2. Disconnect patient or test lung from breathing tube.
3. Open the [**Setup**]->[**Sensor**]->[**Calibration**]->[**Flow**] window to access the flow calibration, press Start to begin the calibration.
4. During the calibration, you can press [**Stop**] to cancel the calibration.
5. The sensor needs to be calibrated in both directions, and the sensor direction should be turn during calibration. The 'turning' operation must be done in 5 senconds after the prompt message listed.

Figure 9-1.Turn the direction of flow sensor

6. After the calibration completed, the message indicating calibration failure is displayed if the calibration is failed. In this case, you need to do the calibration again.

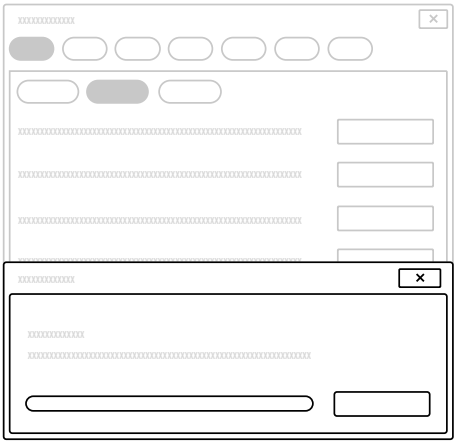


Figure 9-2.Flow calibration

9.6 Oxygen Concentration Calibration

NOTE

- Make sure another source of ventilatory support is available during this calibration. The patient must be disconnected from the ventilator during it.
- Do not perform oxygen concentration calibration when low-pressure oxygen source is used.
- Make sure that the system is Standby mode.
- Handle and dispose of the O_2 sensor according to your biohazard policies. Do not incinerate.
- Oxygen concentration monitoring does not provide automatic atmospheric pressure compensation. Do oxygen concentration calibration again when atmospheric pressure has changed.
- Increasing to periodical pressure of 10 kPa (100 cmH_2O) has no effect upon oxygen concentration monitoring accuracy.
- O_2 cell measures the partial pressure of oxygen.

Increase or decrease of pressure (absolute pressure) affects the partial pressure of oxygen. Increase of pressure (absolute pressure) by 10% causes oxygen concentration to increase by 10%. Decrease of pressure (absolute pressure) by 10% causes oxygen concentration to decrease by 10%. Do oxygen concentration calibration when atmospheric pressure has changed.

- In case of calibration failure, check for relevant malfunctioning alarm and then troubleshoot it if there is. Then do the calibration again. In case of repeated calibration failures, replace the O_2 sensor and do the calibration again. If it still fails, contact your service personnel or us.

This calibration tests the oxygen cell and resets the calibration points specific to the oxygen cell in use. Please calibrate the oxygen concentration when the measured oxygen concentration has a great deviation or when the O_2 sensor is replaced.

Follow these steps to calibrate the oxygen concentration:

1. Make sure high-pressure oxygen source is connected.
2. Open the [**Setup**]->[**Sensor**]->[**Calibration**]->[**O_2**] window to access the O_2 calibration, press Start to begin the calibration.
3. During the calibration, if you press [**Stop]** to abort the calibration.
4. After the calibration completed, the message indicating calibration failure is displayed if the calibration is failed. In this case, you need to do the calibration again.

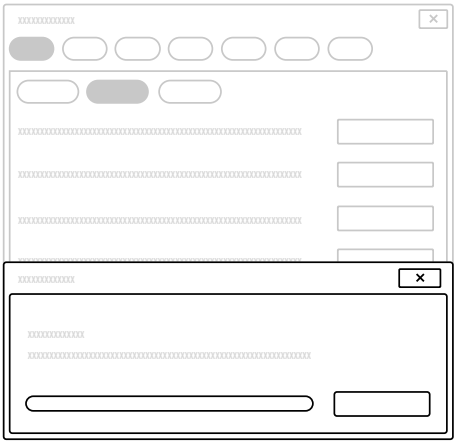


Figure 9-3.O_2 calibration

9.7 Electrical Safety Inspection

NOTE

- Perform an electrical safety inspection after servicing or routine maintenance. Before performing the electrical safety inspection, ensure that all the covers, panels, and screws are correctly installed.
- It is recommended that a specialized company or the manufacturer be entrusted to conduct electrical safety tests. The electrical safety inspection should be performed once a year.

1. Perform protective earth resistance test:

- a.Plug the probes of the analyzer into the protective earth terminal of the AC power cord and the screw.
- b.Test the earth resistance with a current of 25 A.
- c.Verify the resistance is less than 0.1 ohms (100 mohms).
- d.If the resistance is larger than 0.1 ohms (100

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

2. Perform the following earth leakage current tests:

- normal polarity
- reverse polarity
- normal polarity with open neutral
- reverse polarity with open neutral.

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

3. Perform the following patient leakage current tests:

- normal polarity
- reverse polarity
- normal polarity with open neutral
- reverse polarity with open neutral.
- normal polarity with open earth.
- reverse polarity with open earth.
- Mains on applied part (mains on AP), normal polarity
- Mains on applied part (mains on AP), reverse polarity Verify that the maximum leakage current in the first two tests is not higher than 10 µA (0.01 mA) on the CF type applied parts and not higher than 100 uA (0.1 mA) on the BF type applied parts; that the maximum leakage current in the middle four tests is not higher than 50 µA (0.05 mA) on the CF type applied parts and not higher than 500 uA (0.5 mA) on the BF type applied parts; that the maximum leakage current in the last two tests is not higher than 50 µA (0.05 mA) on the CF type

applied parts and not higher than 5000 uA (5 mA) on the BF type applied parts.

NOTE

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

Chapter 10

10. Cleaning and Disinfection

⚠ **WARNING**

- **Read the material safety data sheet for each cleaning agent.**
- **Wear gloves and safety glasses. A damaged O_2 sensor can leak and cause burns (contains potassium hydroxide).**
- **Reuse of undisinfected reusable accessories or components may cause cross-contamination.**
- **Wear gloves and safety glasses. A damaged O_2 sensor can leak and cause burns(contains potassium hydroxide).**
- **Improper disassembling and reassembling may cause breathing system to leak and compromise normal system use.**
- **Seeping liquid into the control assembly can damage the equipment or cause personal injury. When cleaning the housing, ensure that no liquid flows into the control assemblies and always disconnect the equipment from the AC mains. Reconnect the AC mains after the cleaned parts are fully dry.**
- **To avoid sticky residuals, do not use talc, zinc stearate, calcium carbonate, corn starch, or equivalent materials. These materials can go into the patient's lungs and airways and cause irritation or injury.**

NOTE

- Keep all liquids away from electronic parts,disconnect electrical power from the ventilator before cleaning and disinfection
- After cleaning and disinfection is completed, run system check before using the ventilator. Use the

ventilator only when system check is passed.

- The expiration valve assembly, inspiration valve assembly, and patient hose of the gas pathways through the ventilator can become contaminated with body fluids and expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.
- Do not use organic, halogenated, or petroleum based solvents, anesthetic agents,glass cleaners, acetone, or other harsh cleaning agents.
- Do not use abrasive cleaning agents (such as steel wool, silver polish, or cleaner).

10.1 Methods

Parts marked 134℃ are autoclavable. Recommended temperature is 134ºC. By using autoclave to increase vapor pressure, the temperature also increases, rapidly solidifying bacterioprotein. The disinfection effect of this method is fast and reliable.

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

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

Cleaning Methods:

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

Immersion: flush with water first and then immerse it in alkalescent detergent (soapy water, etc., water

temperature of 40ºC recommended) for approximately three minutes. Finally, clean with water and dry completely.

Methods for Disinfection:

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

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

Steam autoclave at 134ºC for 10 to 20 minutes (recommended time).

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

The table below lists the cleaning and disinfecting method can be selected for ventilator part.

Table 10-1.The methods of cleaning and disinfecting

Part	Frequency	Cleaning		Disinfection			
		Wipe	Immersion	Wipe	Immersion	Autoclaving	Ultraviolet radiation
External ventilator surface(including housing, plug-in , power cord and gas supply hose).	Each patient	√		√			√
Trolley and support arm	Each patient	√		√			√
Touch screen	Each patient	√		√			√

Fan dust filter	Every four weeks/as necessary		√		√		
Air intake dust filter	Every four weeks/ asnecessary		√		√		
Inspiration valve assembly	as necessary		√		√	√	
Expiration valve membrane (silicone)	Each patient /weekly		√		√	√	
Expiration valve assembly (except membrane)			√		√	√	
Reusable patient tubing(including water trap, Y piece and adapter)	Each patient /weekly		√		√	√	
Humidifier	Each patient /weekly	Refer to the cleaning and disinfection methods provided by the humidifier vendor.					

Cleaning Methods:

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

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

Methods for Disinfection:

Wipe: wipe with a damp cloth immersed in medium- or high-efficiency detergent and then wipe off the

remaining detergent with a dry lint free cloth.

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

Steam autoclave at 134ºC for 10 to 20 minutes (recommended time).

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

NOTE

- As necessary: shorten the cleaning and disinfection intervals if the equipment is used in dusty environment to ensure that the equipment surface is not covered by dust.
- Clean and disinfect the inspiration valve assembly only when the patient's exhaled gas may contaminate the inspiratory limb.
- When cleaning or disinfecting, choose one of the supported disinfection methods and do not require that all methods be used.

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

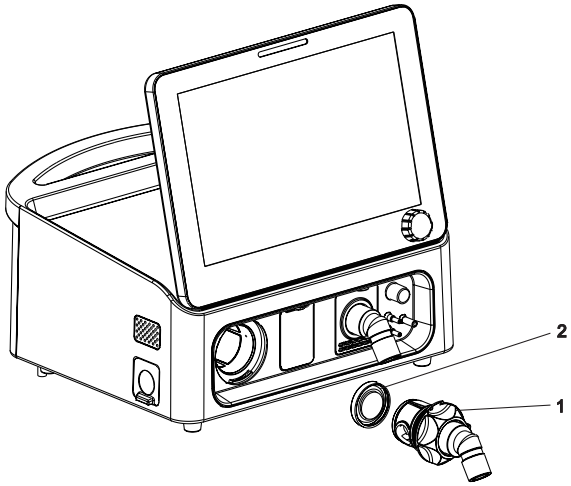
Table 10-2.Cleaning and disinfecting agents&autoclaving process

Item	Explanation
Hydrogen peroxide (3%)	Highly efficient disinfectant
Glutaraldehyde (2%).	Highly efficient disinfectant
Ethanol (75%).	Moderately efficient disinfectant
Isopropyl alcohol (70%).	Moderately efficient disinfectant
Are propanol	Moderately efficient disinfectant
Pure water	Rinsing agent
Soap and water	Rinsing agent

Item	Explanation
Steam autoclave	Highly efficient disinfection The recommended temperature of this disinfection method is 134°C.

10.2 Part Disassemble

10.2.1 Expiration Valve Assembly and Membrane



1	Expiration valve handwheel
2	Expiration valve membrane

Figure 10-1.Disassemble expiration valve and membrane

To disassemble:

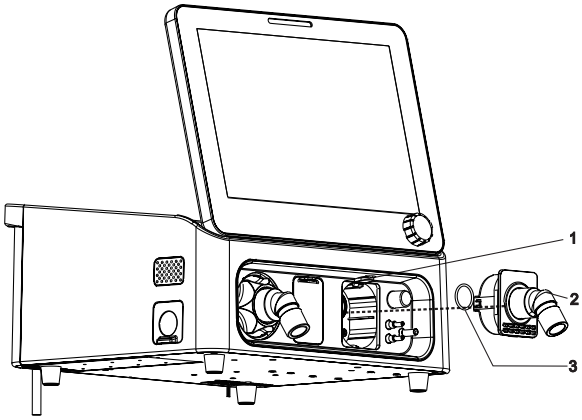
1. Rotate the expiration valve handwheel until the indicating arrow on the handwheel is aligned with the unlock position. Then pull the expiration valve assembly out of the assembly horizontally.
2. Remove the expiration valve membrane.

To install:

1. Install the expiration valve membrane onto the expiration valve assembly.
2. Ensure that the indicating arrow on the handwheel is aligned with the unlock position.

Push the expiratory valve assembly into the corresponding connector on the ventilator horizontally until it is fully inserted. Then rotate the expiratory valve handwheel (and press the handwheel in the direction the expiratory valve is installed) until the indicating arrow on the handwheel is aligned with the lock position.

10.2.2 Inspiratory Valve Assembly



1 Silicone plug
2 Inspiratory valve
3 Sealing ring

Figure 10-2. Disassemble inspiration valve

To disassemble:

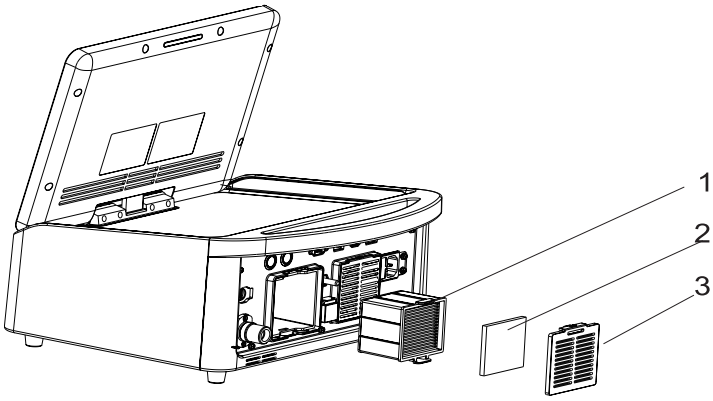
Ensure the ventilator in standby or off status. Push the plug up,then pull out the inspiratory valve assembly horizontally. Check if the sealing ring at the end of the

inspiration valve is disconnected. If it is disconnected, re-install the sealing ring onto the inspiration valve.

To install:

Push the inspiratory valve assembly into the corresponding connector on the ventilator horizontally until it is fully inserted. Ensure that the inspiration valve is fully locked by the button.

10.2.3 HEPA Filter and Air Intake Dust Filter



1	HEPA filter
2	Air intake dust filter
3	Cover

Figure 10-3. Disassemble filters

To disassemble:

1. Open the cover at the air intake.
2. Pull the latch over the HEPA filter to remove. If it is necessary to remove the air intake dust filter, pinch the dust filter with two fingers and take it out.

To install:

1. Align the HEPA filter with the corresponding slot,

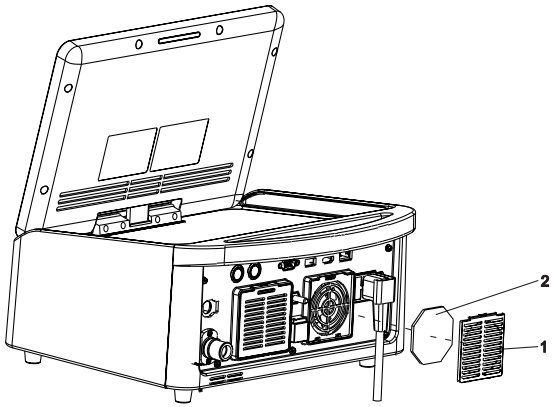
and push in the direction the HEPA filter is installed. When there is a clatter, it is fully locked.

2. Install the air intake dust filter.

NOTE

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

10.2.4 Cooling Fan Dust Filter



1 the fan cover
2 dust filter

Figure 10-4.Disassemble cooling fan dust filter

To disassemble:

1. Open the cover at the fan.
2. Pinch the backup air supply cooling fan dust filter with two fingers and remove.

To install:

1. Place the fan dust filter of backup air supply in the corresponding position inside the cooling fan.
2. Close the cover.

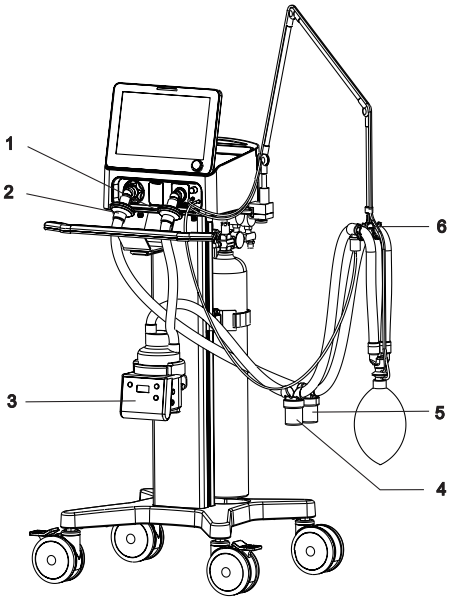
10.2.5 Patient Tubing

⚠ **WARNING**

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

CAUTION

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



1	Inspiratory filter
2	Expiratory filter
3	Humidifier
4	Inspiratory water trap
5	Expiratory water trap
6	Support arm hook

Figure 10-5.Disassemble patient tube

To disassemble:

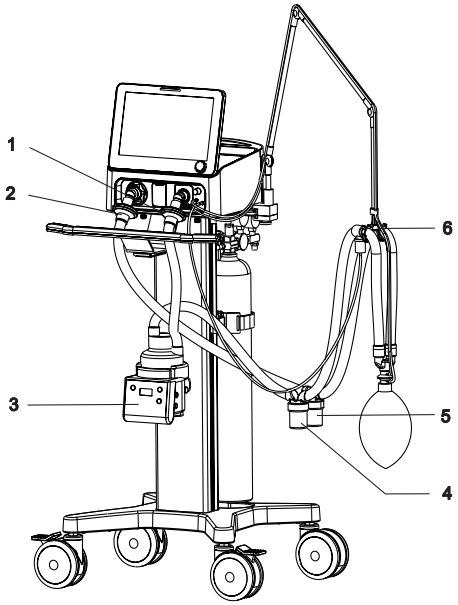
Pull out the patient tubing one by one.

To install:Refer to ***3.2 Installing the patient tubing.***

10.2.6 Humidifier

NOTE

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



1	Humidifier
2	Humidifier mounting plate
3	Screw
4	Humidifier bracket slot
4	Humidifier outlet
5	Humidifier inlet

Figure 10-6.Disassemble humidifier

To disassemble:

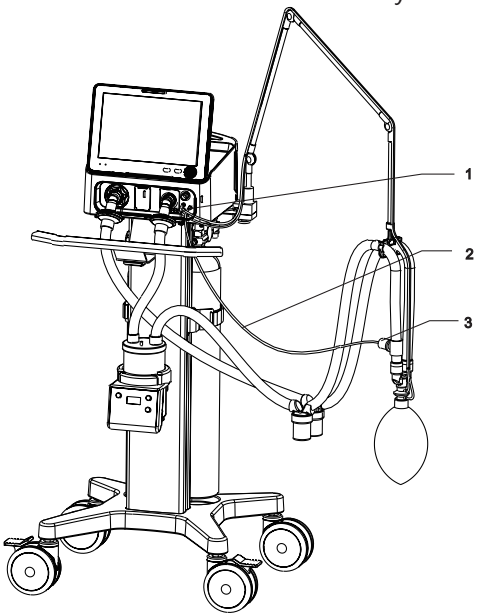
1. Disconnect the tubes from the humidifier.
2. Remove the screw.
3. Lift up the humidifier to remove it from the humidifier bracket fixed seat.

To install:Refer to ***3.3 Installing the humidifier.***

10.2.7 Nebulizer

NOTE

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



1	Nebulizer connect
2	Nebulizer
3	Nebulizer tube

Figure 10-7. Disassemble nebulizer

To disassemble:

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

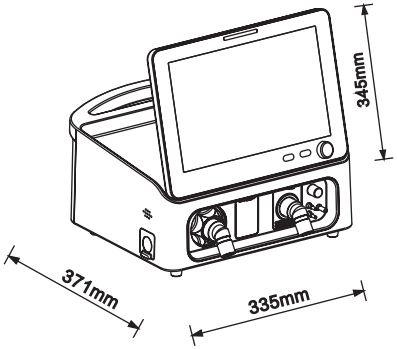
To install:Refer to ***3.4 Installing the nebulizer.***

(For your note.)

Chapter 11

11. Specifications

11.1 Physical Characteristic



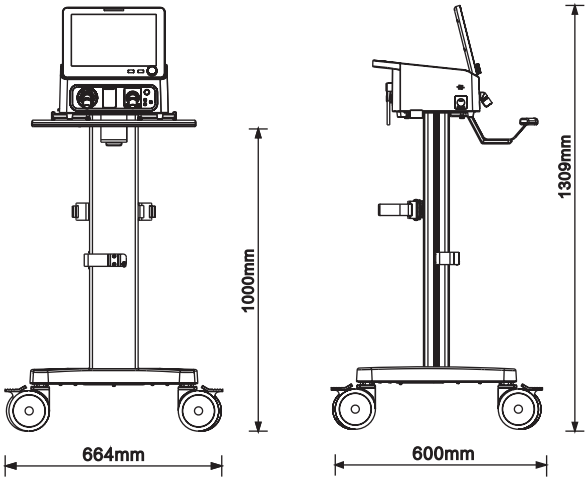


Table 11-1.Physical characteristic

Parameter	Specification
Dimensions (L*W*H)	371 mm * 335 mm * 345 mm 664 mm * 600 mm * 1309 mm (with trolley)
Weight	Approximately 9.8 kg Approximately 30.5 kg (with trolley)
Screen	Size: 12.1 TFT color touch screen Resolution: 1280*800

11.2 Environmental Requirements

Table 11-2.Environment requirement

Parameter	Specification
Temperature	Operating: 5 to 40 ℃ (41 to 104° F) Storage: -20 to 60 ℃ (-4 to 140° F)
Relative humidity	Operating: 10 to 95 %RH, non-condensing Storage: 10 to 95 %RH, non-condensing
Altitudes	Operating: 62 to 106 kPa Storage: 50 to 106 kPa

NOTE

The maximum pressure provided by the ventilator will decrease with the altitude increases.

The ventilator is not recommended to work under extreme load for long time, which will make the turbine temperature incresing rapidly and its service life being shorted.

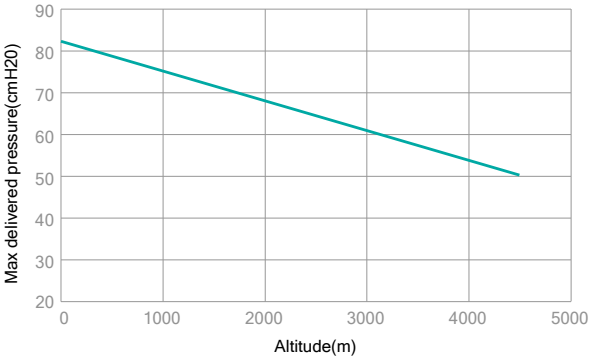


Figure 11-1.Altitude/Pressure changes

NOTE

- The environment required for oxygen sensor is listed as follows table.

Item	Temperature	Relative humidity(non-condensing)	Barometric pressure
Operating	0 to 50 ℃	0 to 99 %RH	0.6 to 2 bar
Storage	-20 to 50 ℃ Recommend 5 to 15 ℃	0 to 99 %RH	0.6 to 2 bar

The environment required for battery is listed as follows table.

Item	Temperature	Relative humidity(non-condensing)	Barometric pressure
Operating	Charge: 0 to 45 ℃ Discharge: -20 to 60 ℃	10 to 96 %RH	0 to 5000 m
Storage	-20 to 50 ℃ Recommend -20 to 25 ℃	10 to 96 %RH	0 to 5000 m

11.3 Electrical Specifications

Table 11-1.Electrical specification

Parameter	Specification
Input power	AC voltage:100 to 240 V AC frequency:50 to 60 Hz AC current:2.5 to 1.1 A Fuse:T3.15AH/250V
Classification	Class I / Internally powered equipment; Type BF applied part; IP21; Not Sterilized; Not Category AP / APG equipment; Mode of operation: Continuous
Batteries	Number: One or Two (Optional)Type: Lithium-ion Voltage: 14.4 V Volume: 6900 mAh (for a single battery) Max Charge Voltage: 16.8 V Recharge Time: 4 hours (for a single battery) Operating Time: 3 hours under standard working condition

NOTE

- The standard working condition of the ventilator is as below: Ventilation mode: PCV.Control Settings: △ P-insp. 15cmH_2O / f 10/min / T-insp. 2s / PEEP 5cmH_2O/ O_2 21%.

11.4 Pneumatic Specifications

Table 11-2.Pneumatic specification

Parameter	Specification
High-pressure oxygen inlet	Pressure: 280 to 600 kPa/41 to 87 psi/ 2.8 to 6.0 bar; Flow: 40 to 120 L/min STPD Connector: NIST or DISS
Low-pressure oxygen inlet	Pressure: < 100kPa/1bar/14.5psi Flow: ⩽ 15L/min (STPD) Connector: CPC quick connector
Air supply	Integrated turbine
Inspiratory outlet (To patient port)	Coaxial 15 mm/22 mm conical connector
Expiratory outlet (From patient port)	Coaxial 15 mm/22 mm conical connector
Inspiratory resistance	Not greater than 6 cm H_2O at 40 L/min flow (adult reusable breathing tube) Not greater than 6 cmH_2O at 30 L/min flow (pediatric reusable breathing tube)
Expiratory resistance	Not greater than 6 cm H_2O at 60 L/min flow (adult reusable breathing tube) Not greater than 6 cmH_2O at 30 L/min flow (pediatric reusable breathing tube)
Leakage	Not greater than 200mL/min@50cmH_2O(adult tubes)Not greater than 100mL/ min@40cmH_2O(pediatric tubes)
Pneumatic medicament	Synchronous with inspiration at 6 to 9 L/min flow
Bacteria filter	Resistance: < 2 cmH_2O at 60 l/min Particle size: Captures particles of 0.3 mm (micron) with > 99.97% efficiencyDead space : < 80 ml

Compliance	Adult disposable circuit (including inspiratory valve, adult disposable breathing tubes, water trap, expiration valve): ⩽ 4ml/cmH2O; Adult reusable circuit ((including inspiratory valve, adult reusable breathing tubes, water trap, expiration valve, Y piece): ⩽ 2ml/cmH2O; Pediatric disposable circuit (including inspiratory valve, pediatric disposable breathing tubes, water trap, expiration valve): ⩽ 2 ml/cmH2O; Pediatric reusable circuit ((including inspiratory valve, pediatric reusable breathing tubes, water trap, expiration valve, Ypiece): ⩽ 2 ml/cmH2O.

11.5 Control Settings

Timing trigger, pressure trigger and flow trigger are used for initiating and terminating the inspiratory phase in ventilator, but different mode use different means.

Table 11-3.Control settings

Parameter	Range	Resolution	Accuracy
VT	Adult:100 to 2000 ml	Adult:10 ml	±(10 mL + 10% of set value)
	Pediatric:20 to 300 ml	Pediatric:1 ml	
O_2%	21 to 100 vol.%	1 vol.%	±3 vol.% or ± 10% of set value, whichever is greater Relation expanded uncertainty: k=2,U=2.60

Parameter	Range	Resolution	Accuracy
f	1 to 80 /min	1 /min	±1 /min Relation expanded uncertainty: k=2,U=2.22%
f-SIMV	1 to 80 /min	1 /min	±1 /min
I:E	1:10 to 4:1	0.5	"2:1 to 1:4:± 10% Other range : ± 15%"
T-insp.	0.2 to 10 s	0.05 s	±0.1s or ± 10%, whichever is greater
PEEP	off, 1 to 45 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5% of set value) Relation expanded uncertainty: k=2,U=0.9 cmH_2O
▵ P-insp.	5 to 80 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5%) Relation expanded uncertainty: k=2,U=1.2 cmH_2O
▵ P-supp.	0 to 80 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5%)
P-high	0 to 80 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5%)
P-low	0 to 45 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5%)
T-high	0.2 to 30 s	0.1 s	±0.2 s or ± 10% of set value, whichever is greater
T-low	0.2 to 30 s	0.1 s	±0.2s or ± 10% of set value, whichever is greater
T-slope	0 to 2 s	0.05 s	±0.2 s

Parameter	Range	Resolution	Accuracy
P-trigger F-trigger	-10 to -0.5 cmH_2O 0.5 to 15 L/min	0.5 cmH_2O 0.1 L/min	±(1.0 cmH_2O + 10% of set value) ±1.0 L/min or 10% of set value, whichever is greater
Exp%	Auto, 10% to 85%	0.05	±10%
ΔP-apnea	5 to 80 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5% of set value)
VT-apnea	Adult : 100 to 2000 ml Pediatric : 20 to 300 ml	Adult : 10 ml Pediatric : 1 ml	±(10 mL + 10% of set value)
f-apnea	1 to 80 /min	1 /min	±1 /min
Apnea T-insp.	0.2 to 10 s	0.05 s	±0.1s or ± 10% of set value, whichever is greater
▵ int.PEEP	0 to 45 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5% of set value)
Sigh Interval	20 s to 180 min	1 s (20 to 59 s) 1 min(1 min to 180 min)	±0.2 s or ±10% of set value, whichever is greater
Sigh Cycle	1 to 20	1	±1
T-pause	off, 5% to 60%	0.01	±0.1s or ±10% of set value, whichever is greater
Flow	2 to 60 L/min	1 L/min	±(2 L/min+ 10% of set value)
O_2%	21 to 100 vol.%	1vol.%	±3 vol.% or ± 10% of set value, whichever is greater

Parameter	Range	Resolution	Accuracy
Assist	on,off	/	/
Apnea Vent	on,off	/	/
Sigh	on,off	/	/

Oxygen concentration controlling response time

The responded time of the oxygen concentration in the delivered volume to change from a volume fraction of 21 % to 90 % of the maximum settable oxygen concentration:

when TV=500 ml, f=10 /min, I:E=1:2, ≤50 s ;

when TV=150 ml, f=20 /min, I:E=1:2, ≤100 s;

when TV=30 ml, f=30 /min, I:E=1:2, ≤150 s.

11.6 Monitored Parameters

For all measured and computed variables that are displayed or used for control, the low pass filtering and moving average smoothing techniques is used.

Table 11-4. Monitored parameters

Parameter	Range	Resolution	Accuracy
Paw	0~100 cmH_2O	1 cmH_2O	/
Ptrachea	0~100 cmH2O	1 cmH_2O	/
Flow	-200~200 L/min	-99.9 to 99.9L/min：0.1L/min -200 to -100/100 to 200L/min：1L/min	/
Volume	0~4000 mL	1mL	/
P-peak	-10 ~100 cmH_2O	1 cmH_2O	± (2 cmH_2O + 4 % of actual reading)
P-plat.	-10~100 cmH_2O	≥10: 1 cmH_2O <10: 0.1 cmH_2O	± (2 cmH_2O + 4 % of actual reading)

Parameter	Range	Resolution	Accuracy
P-mean	-10~100 cmH_2O	≥10: 1 cmH_2O <10: 0.1 cmH_2O	± (2 cmH_2O + 4 % of actual reading)
PEEP	-10~100 cmH_2O	≥10: 1cmH_2O <10: 0.1 cmH_2O	± (2 cmH_2O + 4 % of actual reading)
MV	0~99.9 L/min	≥ 3.0: 0.1 L/min < 3.0: 0.01 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
MV-leak	0~99.9 L/min	≥ 3.0: 0.1 L/min < 3.0: 0.01 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
MV-spn.	0~99.9 L/min	≥ 3.0: 0.1 L/min < 3.0: 0.01 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
VTe	0~20 mL	≥10: 1cmH_2O <10: 0.1 cmH_2O	±(2 ml + 3% of the actual reading)
	20~100 ml		±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTi	0~20 mL	≥10: 1cmH_2O <10: 0.1 cmH_2O	±(2 ml + 3% of the actual reading)
	20~100 ml		±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTe-spn.	0~20 mL	≥10: 1cmH_2O <10: 0.1 cmH_2O	±(2 ml + 3% of the actual reading)
	20~100 ml		±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)

Parameter	Range	Resolution	Accuracy
VTe/IBW	0.0~99.9 mL/kg	0.1 mL/kg	±(1 mL/kg + 10% of the actual reading)
f-total	0~99 /min	1 /min	±5 % of actual reading or ±1 / min, whichever is greater
f-mand.	0~99 /min	1 /min	±5 % of actual reading or ±1 / min, whichever is greater
f-spn.	0~99 /min	1 /min	±5 % of actual reading or ±1 / min, whichever is greater
I:E	9.9 : 1 to 1 : 99	9.9:1-1:9.9: 0.1 1:10-1:99: 1	±0.1 or ±10 % of actual reading, whichever is greater.
FiO_2	15 to 100 vol.%	1vol.%	±(2.5vol.% + 2.5% of actual reading)
Re	0~600 cmH_2O/L/s	1 cmH_2O/L/s	0~50cmH_2O/(L/s):±10cmH_2O/(L/s) Other range: 50% of the actual reading
Ri	0~600 cmH_2O/L/s	1 cmH2O/L/s	0~50cmH_2O/(L/s):±10cmH_2O/(L/s) Other range: 50% of the actual reading
C-dyn.	0~300 ml/cmH_2O	≥10: 1cmH_2O <10: 0.1 cmH_2O	±(3 ml/cmH_2O + 25% of the actual reading)

Parameter	Range	Resolution	Accuracy
C-stat.	0~300 ml/ cmH_2O	≥10: 1cmH_2O <10: 0.1 cmH_2O	±(3 ml/cmH_2O + 25% of the actual reading)
RC-exp.	0~10.0 s	0.01 s	± (0.2 s + 20 % of actual reading)
WOB	0~100 J/min	1 J/min	± (1 J/min + 15 % of actual reading)
RSBI	0~999 1/(min·L)	1 1/(min·L)	±(3 1/(min·L) ±15 % of actual reading)
NIF	-45-0 cmH_2O	0.1 cmH_2O	± (2 cmH_2O +4% of actual reading)
P0.1	-20-0 cmH_2O	0.1 cmH_2O	± (2 cmH_2O +4% of actual reading)
Flow	0 to 70 L/min	0.1 L/min	± 0.3 L/min or ± 8 % of actual reading, whichever is greater.
O_2%	15 to 100 vol.%	1 vol.%	±(2.5 vol.% + 2.5% of actual reading)
$EtCO_2$	0 to 150 mmHg	1 mmHg	0mmHg to 40mmHg:±2 mmHg ; 41mmHg to 150mmHg: ±8 % of actual reading ;
$EtCO_2$	0 to 150 mmHg	1 mmHg	0mmHg to 40mmHg:±2 mmHg ; 41mmHg to 100 mmHg: ±8 % of actual reading 101mmHg to 150 mmHg: ±10 % of actual reading
PEEPi	0 to 100 cmH_2O	0.1 cmH_2O	/

Parameter	Range	Resolution	Accuracy
VDaw	0 to 999 mL	1mL	/
VDaw/VTe	0 to 100%	1%	/
Vtalv	0 to 9999mL	1mL	/
MVtalv	0 to 20 L/min	< 1 L/min:0.01 L/min ≥1L/min:0.1L/min	/
slopeCO_2	0 to 75 mmHg/L 0 to 9.99 kPa/L 0 to 9.99 %/L	1mmHg/L 0.01kPa/L 0.01kPa/L	/
V'CO_2	0 to 9999 mL/min	1mL/min	/
VeCO_2	0 to 999 mL	1mL	/
ViCO_2	0 to 999 mL	1mL	/

The system total response time for oxygen concentration monitoring is 15s.

The time from powering on the ventilator to reaching the oxygen concentration monitoring performance specified in this manual is approximately 30s.

11.7 Configuration Specifications

Table 11-5.Feature specifications

Features		Model
		LYRA x1
Ventilation Mode	VCV (Volume Control Ventilation)	√
	VSIMV (Volume Synchronized Intermittent Mandatory Ventilation)	√
	PRVC (Pressure Regulated Volume Control)	√
	V+SIMV (PRVC+SIMV)	√
	PCV (Pressure Control Ventilation)	√
	PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation)	√
	CPAP/PSV (Continuous Positive Airway Pressure/Pressure Support Ventilation)	√
	BPAP (Bilevel Positive Airway Pressure)	√

Features		Model
		LYRA x1
	APRV (Airway Pressure Release Ventilation)	√
Therapy Mode	Oxygen Therapy	√
Monitoring	Waveform	√
	Numeric	√
	Loop	√
	Trend	√
Special Functions	NIV (Non Invasive Ventilation)	√
	Apnea Ventilation	√
	STRC (Synchronized Tube Resistance Compensation)	√
	O_2 Enrichment	√
	Suction Tool	√
	Nebulization	√
	Manual breath	√
	Inspiratory Hold	√
	Expiratory Hold	√
	PV Tool	√
	P0.1 (Airway Occlusion Pressure)	√
	NIF (Negative Inspiratory Force)	√
	PEEPi (Intrinsic PEEP)	√

Table 11-6.System configuration

Items	Range
Screen brightness	0-100%
T-insp./I:E	T-insp. , I:E
Height/IBW	Height , IBW
IV Apnea Mode	Pressure Control
VT/IBW	6mL/kg , 7mL/kg , 8mL/kg , 9mL/kg , 10mL/kg , 11mL/kg , 12mL/kg
O_2 Monitoring	ON / OFF
System Date	/
System Time	/
Date Format	YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY
Time Format	12h, 24h

11.8 Factory Default Settings

Table 11-7.Ventilation mode settings

Mode	Parameter	Factory Default Settings
VCV	VT	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW
	O_2% (HPO)	21%
	f	Adult: 10 /min
		Pediatric: 20 /min
	PEEP	3 cmH_2O
	T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	I:E	1:2
	T-slope	0.2 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Assist	ON

Mode	Parameter	Factory Default Settings
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	ΔInt.PEEP	5cmH_2O
	T-pause	OFF
PCV (INV)	O_2% (HPO)	21%
	f	Adult: 10 /min
		Pediatric: 20 /min
	PEEP	3 cmH_2O
	▵ P-insp.	15 cmH_2O
	T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	I:E	1:2
	T-slope	0.2 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Assist	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	ΔInt.PEEP	5 cmH_2O
CPAP/PSV	O_2% (HPO)	21%
	PEEP	3 cmH_2O
	▵ P-supp.	0 cmH_2O
	T-insp.(Only in NIV mode)	Adult: 2.00 s
		Pediatric: 1.00 s
	T-slope	0.2 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Exp%	Auto
	ΔP-apnea	15 cmH_2O

Mode	Parameter	Factory Default Settings
	f-apnea	1 /min
	Apnea T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	VT-apnea	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW
PSIMV	O_2% (HPO)	21%
	f-SIMV	Adult: 5 /min
	PEEP	3 cmH_2O
	▵ P-insp.	15 cmH_2O
	▵ P-supp.	0 cmH_2O
	T-insp.	Adult: 2.00 s
	T-slope.	0.2 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Exp%	Auto
	ΔP-apnea	15 cmH_2O
	f-apnea	1 /min
	Apnea T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	VT-apnea	Adult: max(7* mL/kg*IBW, 100)
		Pediatric: 7* mL/kg*IBW
	Apnea Vent	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5 cmH_2O
VSIMV	VT	Adult: max(7* mL/kg*IBW, 100)
		Pediatric: 7* mL/kg*IBW
	O_2% (HPO)	21%
	f-SIMV	Adult: 5 /min
		Pediatric: 20 /min

Mode	Parameter	Factory Default Settings
	PEEP	3 cmH_2O
	△ P-supp.	0 cmH_2O
	T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	T-slope	0.2 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Exp%	Auto
	ΔP-apnea	15 cmH_2O
	f-apnea	1 /min
	Apnea T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	VT-apnea	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW
	Apnea Vent	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5 cmH_2O
	T-pause	OFF
V+SIMV	VT	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW
	O_2% (HPO)	21%
	f-SIMV	Adult: 5 /min
		Pediatric: 20 /min
	PEEP	3 cmH_2O
	△ P-supp.	0 cmH_2O
	T-slope.	0.2 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Exp%	Auto

Mode	Parameter	Factory Default Settings
	ΔP-apnea	15 cmH_2O
	f-apnea	1 /min
	Apnea T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	VT-apnea	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW
	Apnea Vent	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5 cmH_2O
BPAP	O_2% (HPO)	21%
	△ P-supp.	0 cmH_2O
	T-slope	0.2 s
	P-high	15 cmH_2O
	P-low	3 cmH_2O
	T-high	Adult: 1.7 s
		Pediatric: 0.7 s
	T-low	Adult: 3.3 s
		Pediatric: 1.4 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Exp%	Auto
	ΔP-apnea	15 cmH_2O
	f-apnea	1 /min
	Apnea T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	VT-apnea	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW
PRVC	VT	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW

Mode	Parameter	Factory Default Settings
	O_2% (HPO)	21%
	f	Adult: 10 /min
		Pediatric: 20 /min
	PEEP	3 cmH_2O
	T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	I:E	1:2
	T-slope	0.2 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	Assist	ON
	Sigh	OFF
	Sigh Interval	1 min
	Sigh Cycles	3
	Δint.PEEP	5cmH_2O
APRV	O_2% (HPO)	21%
	T-slope	0.2 s
	P-high	15 cmH_2O
	P-low	3 cmH_2O
	T-high	Adult: 1.7 s
		Pediatric: 0.7 s
	T-low	Adult: 3.3 s
		Pediatric: 1.4 s
	F-trigger	Adult: 2.0 L/min
		Pediatric: 1.0 L/min
	ΔP-apnea	15 cmH_2O
	f-apnea	1 /min
	Apnea T-insp.	Adult: 2.00 s
		Pediatric: 1.00 s
	VT-apnea	Adult: max(7*mL/kg*IBW, 100)
		Pediatric: 7*mL/kg*IBW

Table 11-8.O_2 Therapy settings

Parameter	Factory Default Settings
O_2%	21%
Flow	25 L/min

Table 11-9.System configuration

Items	Factory Default Setting
Screen brightness	50%
T-insp./I:E	T-insp.
Height/IBW	Height
IV Apnea Mode	Pressure Control
VT/IBW	7mL/kg
O_2 Monitoring	ON
System Date	2017.01.01
System Time	00:00:00
Date Format	YYYY-MM-DD
Time Format	24h
Paw Unit	cmH_2O
Weight Unit	kg
O_2 Supply	HPO
STRC	Tube Compensation: Disable
	Tube I.D.: 8.0mm (Adult) 5.0mm (Pediatric)
	Compensation: 80%
	Expiratory Compensation: On
Nurse Call	Switch: OFF.
	Signal Type: Continuous.
	Contact Type: Normally Closed.
	Alarm Level: High Alarms & Med Alarms
	Alarm Type: Phys. Alarms & Tech Alarms

11.9 Residual Risk

Table 11-10.Residual risk

Number	Risk item	Residual Risk
1	The battery is charging and the charging voltage is over than the manufacturer specified	It will lead to overcharging and cause fire or safety risk
2	The battery is charging and the charging current is over than the manufacturer specified	
3	The battery is charging full and do not stop the charging in time	
4	When both batteries are in deputy, there is a case of a higher voltage battery charging a lower voltage battery. How to consider the design	Two batteries is connected by the diode. The high-voltage diode will be switched on, while the low-voltage diode will stop and protect charging from high voltage to low voltage battery.

11.10 Other Technical Data

Table 11-11.Technical data

Parameter	Specification
Flow delivery	150 L/min with 40 cmH_2O airway pressure and 608 mmHg barometric pressure
Flow range	-240 to 240 L/min BTPS
Dynamic pressure regulation	± (2 cmH_2O + 4% of target) Negative (subatmospheric) pressure settings are not available
Start-up time	Ready to ventilate 9 s after power on

Parameter	Specification
Inspiratory and expiratory pressure drop following equipment failure	≤ 6.0 cmH_2O at 2.5 L/min, using a 10 mm circuit
	≤ 6.0 cmH_2O at 15 L/min, using a 15 mm circuit
	≤ 6.0 cmH_2O at 30 L/min, using a 22 mm circuit
Audio alarm loudness	45 to 85 dB(A) (primary alarm)
	80 dB(A) (backup alarm)
Acoustic noise	Sound pressure level ≤ 39.5 dB(A)
	Sound power level ≤ 51.9 dB(A)

Appendix

A. Pneumatic Diagram

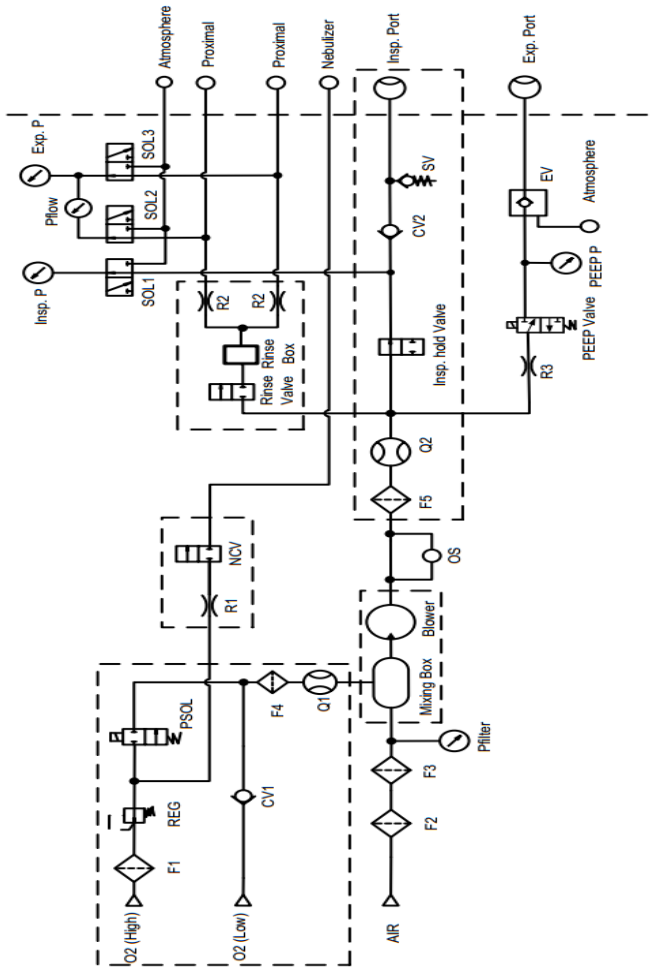


Figure A-1.Pneumatic diagram

Table A-1.Description of pneumatic diagram

Symbol	Name	Symbol	Name
AIR	Low-pressure Air inlet	Q2	Flow sensor of the mixed gas
O_2 (Low)	Low-pressure O_2 inlet	Insp. hold valve	Inspiratory hold valve
O_2(High)	High-pressure O_2 inlet	CV2	Check valve
F1	Filter	SV	Pressure release valve
F2	Dust filter	Rinse valve	Switch valve
F3	HEPA filter	Rinse box	Rinse box
Pfilter	Pressure sensor	R2	Rinse resistor
CV1	Self-closing cut-off valve	SOL1	Zeroing three-way valve
REG	Regulator	SOL2	zeroing three-way valve
PSOL	Proportional valve	SOL3	zeroing three-way valve
F4	Filter net	Insp. P	Inspiratory pressure sensor
Q1	O_2 flow sensor	Pflow	Differential pressure sensor
Mixing Box	Air&O_2 mixed chamber	Exp. P	Expiratory pressure sensor
Blower	Turbo blower	R3	PEEP resistor
OS	O_2 sensor	PEEP Valve	Proportional solenoid valve
R1	Nebulizer needle valve	EV	Expiratory valve
NCV	Nebulizer control valve	PEEP P	PEEP pressure sensor
F5	Filter net	/	/

B. Parts and Accessories

⚠ WARNING

- **Use only accessories specified in this chapter. Using other accessories may cause incorrect measured values or equipment malfunction.**
- **Check the accessories and their packages for damage. Do not use them if any sign of damage is detected.**
- **Disposable accessories cannot be reused. Reuse may degrade performance or cause cross infection of the next patient.**
- **Parts which are intended to contact patients must comply with the biocompatibility requirement of ISO10993-1 to prevent any adverse reactions arising from such contact. The duration of contact category should be less than 24 hours.**
- **Disposal of the accessories shall comply with the applicable waste control regulations.**
- **The user shall buy legally launched products for other accessories required to implement the functions of the machine.**

NOTE

- All the accessories listed are validated for use with this specific ventilator. And the hospital is responsible for ensuring the compatibility of the ventilator and the accessories before use. The incompatible parts can result in degraded performance.

Table B-1.Parts and accessories

Description	Part No.	Manufacturer
LYRA x1 | Expiration valve | Adult + pediatric | Reusable	401-010	aXcent
LYRA x1 | Expiration valve | Neonate | Reusable	401-011	aXcent
LYRA | Expiration valve | Membrane	401-015	aXcent
LYRA x1 | Inspiration valve cpl.	401-020	aXcent
Patient circuit | Ventilation | Adult | Reusable	402-000	Vadi
Patient circuit | Ventilation | Pediatric | Reusable	402-001	Vadi
Patient circuit | Ventilation | Neonate | Reusable	402-002	Vadi
Patient circuit | Ventilation | Adult | Disposable | 20x	402-010	Vadi
Patient circuit | Ventilation | Pediatric | Disposable | 20x	402-011	Vadi
Patient circuit | Ventilation | Neonate | Disposable | 20x	402-012	Vadi
Ventilation mask | PVC | Size 0	402-021	Vadi
Ventilation mask | PVC | Size 1	402-022	Vadi
Ventilation mask | PVC | Size 2	402-023	Vadi
Ventilation mask | PVC | Size 3	402-024	Vadi
Ventilation mask | PVC | Size 4	402-025	Vadi
Ventilation mask | PVC | Size 5	402-026	Vadi
Ventilation mask | Silicone | Size 0	402-030	Vadi
Ventilation mask | Silicone | Size 1	402-031	Vadi
Ventilation mask | Silicone | Size 2	402-032	Vadi
Ventilation mask | Silicone | Size 3	402-033	Vadi
Ventilation mask | Silicone | Size 4	402-034	Vadi
Ventilation mask | Silicone | Size 5	402-035	Vadi
Ventilation mask | Hook for mask belt	402-036	Vadi
Ventilation mask | Mask belt | Silicone	402-037	Vadi
Drug nebulizer kit | Disposable	402-040	Vadi
Test lung | Pediatric - adult | Reusable	402-050	Vadi
Test lung | Neonatal - Infant | Reusable	402-051	Vadi
Bacteria filter | Electrostatic | Disposable | 50 pcs	402-060	Vadi

HME Filter | Adult | Disposable | 20 pcs	402-061	Vadi
HME Filter | Pediatric | Disposable | 20 pcs	402-062	Vadi
HME Filter | Neonate - infant | Disposable | 20 pcs	402-063	Vadi
LYRA | Flow sensor | Pediatric - adult | Disposable	402-071	aXcent
LYRA | Flow sensor | Neonate - infant | Disposable	402-072	aXcent
LYRA | O2 Sensor | OOM202	402-075	Envitec
LYRA | Lithium ion battery	402-076	RRC
LYRA | HEPA inlet filter	402-080	aXcent
LYRA | Inlet filter coarse	402-081	aXcent
LYRA | Filter cooling fan	402-082	aXcent
LYRA | Patient circuit support arm	402-090	aXcent
LYRA x1 | Trolley with humidifier and cylinder mount	402-091	aXcent
Humidifier | VH-1500 | 220 V	402-100	Vadi
Humidifier | VH-1500 | 110 V	402-101	Vadi
Humidifier | VH-3000 | 220 V	402-102	Vadi
Humidifier | VH-3000 | 110 V	402-103	Vadi
Humidifier chamber | Pediatric - adult | Reusable	402-104	Vadi
Humidifier chamber | Neonate - infant | Reusable	402-105	Vadi
Humidifier paper | Absorbent | For 402-104 | 100 sheets	402-106	Vadi
Humidifier paper | Absorbent | For 402-105 | 100 sheets	402-107	Vadi
VH-3000 | Temperature probe | 150 cm | Reusable	402-111	Vadi
VH-3000 | Heater wire | 150 cm | Reusable	402-113	Vadi
VH-3000 | Heater wire | 110 cm | Reusable	402-114	Vadi
VH-3000 | Power adapter for heater wire | Insp.	402-115	Vadi
VH-3000 | Draw wire | 150 cm	402-120	Vadi
Aerogen Pro | Nebulizer System	402-200	Aerogen
Aerogen Pro | T-piece | Adult | Reusable	402-201	Aerogen
Aerogen Pro | T-piece | Pediatric | Reusable	402-202	Aerogen
Aerogen Pro | T-piece | Neonate | Reusable	402-203	Aerogen

(For your note.)

C. Communications Interface

⚠ **WARNING**

- **Connect to the ventilator only items that are specified as part of or compatible with the ventilator system. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards. Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of edition 3 of IEC 60601-1, respectively).**
- **The USB port is currently approved for data export. NEVER connect or attempt to power any other equipment from the USB port.**
- **It is the responsibility of the end user to validate the compatibility and use of information transmitted from the ventilator to the device to be connected to the ventilator.**

HDMI Interface

The ventilator can output the video signals to an external monitor via HDMI interface.

RS-232 serial port

The ventilator can connect to the Nurse Call device via the RS-232 serial port.

USB Interface

The ventilator can transfer data via the external storage device via the USB interface.

(For your note.)

D. EMC Declarations

NOTE

- Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The ventilator or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ventilator or its components should be observed to verify normal operation in the configuration in which it will be used.
- The ventilator needs special precautions regarding EMC and needs to be mounted and put into service according to the EMC information provided below.
- Other devices may interfere with this equipment even though they meet the requirements of CISPR.
- When the input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Use of portable or mobile communications devices can degrade the performance of the equipment.

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

  The essential performance verified during the immunity testing based the below settings:

  VCV mode, O_2%: 21%, VT: 500 ml, T-insp.: 2.00 s, I:E: 1:2, f: 10 bpm, PEEP: 5 cmH_2O.

Table D-1.Guidance and manufacturer's declaration-electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ventilator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Com plies	

TableD-2.Guidance and manufacturer's declaration-electromagnetic immunity

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic Environment - guidance
Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV con tact ±15 kV air	±8 kV con tact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power sup- ply lines ±1 kV for input/out-put lines (>3 m)	±2 kV for power sup-ply lines ±1 kV for input/out-put lines (>3 m)	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic Environment - guidance
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV (line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic Environment - guidance
Conducted RF IEC 61 000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 MHz (for RGM, SpO_2 performance)3 Vrms 150 kHz to 80 MHz Outside ISM bandsa (for Ventilator performance) 10 Vrms 150 kHz to 80 MHz In ISM bandsa (for Ventilator performance) 3V/m 80MHz ~ 2.5GHz (for RGM, SpO2 performance) 10V/m 80MHz ~ 2.5GHz (for Ventilator performance)	3 Vrms 3 Vrms 10 Vrms 3 V/m 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ventilator, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances.Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey c, should be less than the compliance level in each frequency range d.Interference may occur in the vicinity of equipment marked with the following symbol: 

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic Environment - guidance

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

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

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

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

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

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

Table D-3.Recommended separation distances between portable and mobile RF communications equipment and the ventilator

Rated maximum output power of transmitter(W)	Separation distance in meters (m) according to frequency of the transmitter		
	150 kHz to 80 MHz	80 kHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Note 2 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.			
Note 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

E. Compliance

IEC Standard	EN Standard	Designation
IEC 60601-1	EN 60601-1	General requirements for basic safety and essencial performance
IEC 60601-1-2	EN 60601-1-2	Electromagnetic compatibility
IEC 60601-1-6	EN 60601-1-6	Usability
IEC 62366-1	EN 62366-1	Usability
IEC 60601-1-8	EN 60601-1-8	Alarm systems
ISO 80601-2-55	EN ISO 80601-2-55	Repiratory gas monitors
ISO 14971	EN ISO 14971	Application of risk management to medical devices
ISO 80601-2-12	EN ISO 80601-2-12	Critical care ventilators

(For your note.)

F. Infant Ventilation

⚠ WARNING

- **Check the infant flow sensor before use. DO NOT use the infant flow sensor if the sensor's main body, tubing or connector is damaged or occluded.**
- **DO NOT use the infant flow sensor if the infant flow sensor tubing is twisted.**
- **Before using the infant flow sensor for ventilation, please run a system check after configuration of all components required for ventilation.**
- **Configuration includes infant tubing, infant flow sensor and accessories required for the patient circuit. In the event that infant flow sensor failure is detected in the system check, please check the patient circuit and the infant flow sensor for leak and/or occlusion. Replace the infant flow sensor if necessary.**
- **After conducting the system check, DO NOT add or remove any accessories to or from the circuit, so as not to alter the system resistance and compliance.**
- **If a infant flow sensor error occurs, stop using the infant flow sensor until the error is fixed.**
- **The infant flow sensor measures the gas flow on the patient's Y piece side.**
- **However, the actual flow delivered to the patient will be affected by system leakage between the patient and the infant flow sensor.**
- **Install the infant flow sensor in accordance with the instructions provided in this manual. Sensor installation errors will result in data misinterpretation or incorrect ventilator setup.**
- **DO NOT place the infant flow sensor in a position where the tubing or cables may become easily entangled, knotted or detached. Otherwise, this**

may result in hypercarbia or hypoxemia.

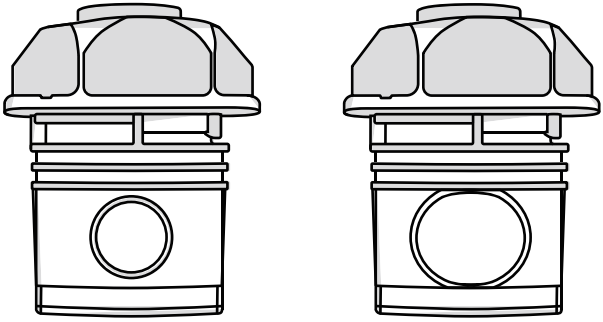
- **Please DO NOT apply pressure to the infant flow sensor by pulling the infant flow sensor tubing, or rotate the infant flow sensor. Otherwise, this will result in increased risk of detachment or disconnection.**
- **Please DO NOT install the infant flow sensor onto the patient tubing if the sensor is not connected to the corresponding ventilator connector.**
- **Excessive moisture in the infant flow sensor tubing may result in inaccurate measurement. Check the sensor and the tubing periodically to avoid excessive moisture and/or accumulation of secretions.**
- **The infant flow sensor is disposable and may not be used repeatedly. Attempts to clean or disinfect the infant flow sensor may result in a risk of biological incompatibility, infection or product failure.**
- **Remove the infant flow sensors from patient's ventilator tubing before initiating nebulization. Infant flow cannot be measured in the aerosolized medication environment.**
- **DO NOT administer nebulized medications when the infant flow sensor is used. The drug may damage the infant flow sensor.**

NOTE

- In non-invasive ventilation, infant flow sensor is disabled.

F.1 Infant Expiration Valve Assembly

The infant expiration valve assembly is different from the adult/pediatric expiration valve assembly. The confirm of the expiration valve assembly must be done before connecting the tube. If it is not a infant expiration valve assembly, please replace it.



1- infant expiration valve assembly

2-adult/pediatric expiration valve assembly

To disassemble:

1. Rotate the expiration valve handwheel until the indicating arrow on the handwheel is aligned with the unlock position. Then pull the expiration valve assembly out of the assembly horizontally.
2. Remove the expiration valve membrane.

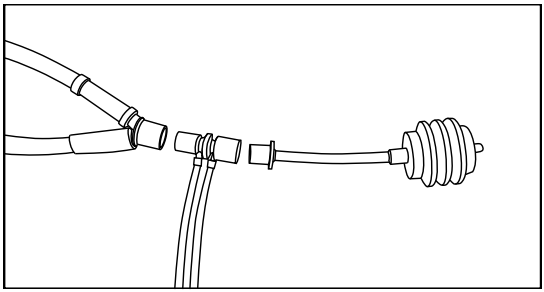
To install:

1. Install the expiration valve membrane onto the infant expiration valve assembly.
2. Ensure that the indicating arrow on the handwheel is aligned with the unlock position.Push the infant expiratory valve assembly into the corresponding connector on the ventilator horizontally until it is fully inserted.
3. Rotate the infant expiratory valve handwheel with pressing the handwheel in the direction the expiratory valve is installed until the indicating arrow on the handwheel is aligned with the lock position.

F.2 Installing Infant Tubing

Refer to ***3.2 Installing the Patient Tubing***.The use of a humidifier is recommended when installing infant tubing.

1. Mount the filters onto the inspiratory and expiratory ports.
2. Connect the inspiratory filter to the humidifier inlet via the infant tube.
3. Connect the humidifier outlet to the water trap via the infant tubing. Then connect the water trap to the Y piece via the infant tubing.
4. Connect the expiratory filter to the water trap via the infant tubing. Then connect the water trap to the Y piece via the infant tubing.
5. Connect the infant flow sensor tubing to the ventilator.
6. Connect the small end of the infant flow sensor to the Y piece, and the large end to the infant test lung.
7. Place the infant tubing onto the support arm hook.



1-Y piece of the infant tubing

2-Infant flow sensor

3-Infant test lung

F.3 System check

Refer to ***6.3 System check***.Please make sure that the system check is completed before initiation of infant ventilation.

F.4 Start Ventilation

⚠ **WARNING**

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

1. For patient information setup, please see 6.3Select Patient.
2. For ventilation type setup, please see 6.4Ventilation Type.
3. For ventilation mode setup, please see 6.5Ventilation Mode.
4. For alarm setup, please see 7Chapter Alarms".
5. Select the [Start Ventilation] key in Standby status, and the system begins to ventilate the patient according to your settings.

F.5 Backup Ventilation

In the event of a infant flow sensor error, the ventilator will switch to backup ventilation.During backup ventilation, the user should take corrective measures in a timely manner, including replacing the infant flow sensor or using external flow monitoring.

During backup ventilation, the ventilator runs the pressure mode with the delivered inspiratory pressure being equal to PEEP +15 cmH20. Other ventilation parameters are identical to those in the original ventilation mode.

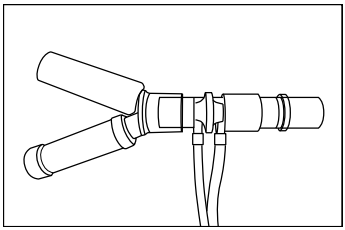
When the infant flow sensor returns to normal, the ventilator will switch back to the original ventilation mode automatically.

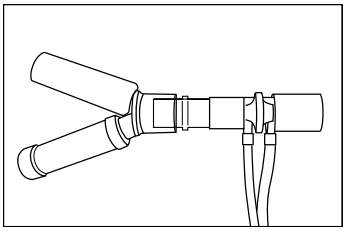
F.6 Infant Flow Sensor calibration

Please perform calibration of the infant flow sensor when the measured value has a great deviation. Refer to ***9.5 Flow sensor calibration***.

NOTE

- Please pay attention to the connection direction of the sensor during calibration.
- First the forward ventilation, then the reverse ventilation.





F.7 Control Settings

Timing trigger, pressure trigger and flow trigger are used for initiating and terminating the inspiratory phase in ventilator, but different mode use different means.

NOTE

- The unlisted parameters are the same as the corresponding parameters of adult.

Table F-1.Control settings

Parameter	Range	Resolution	Accuracy
VT	2 to 300mL	1ml	20 to 2000mL: ±(10mL+10% of setting)
			2 to 20mL: ±(2mL+10% of setting)"
f	1 to 150 /min	1 /min	±1 /min
f-SIMV	1 to 150 /min	1 /min	±1 /min
T-insp.	0.1 to 10s	0.05s	±0.1s or ±10% of setting, whichever is greater
PEEP	OFF, 1 to 25 cmH_2O	1 cmH_2O	±(2.0 cmH_2O+ 5% of setting)
▵ P-insp.	3 to 60 cmH_2O	1 cmH_2O	±(2.0 cmH_2O+ 5% of setting)
▵ P-supp.	0 to 45 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5% of setting)
P-high	0 to 45 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5% of setting)
P-low	0 to 25 cmH_2O	1 cmH_2O	±(2.0 cmH_2O+ 5% of setting)
T-slope	0 to 0.6 s	0.01 s	±(0.2s+20% of setting)
P-trigger	/		
F-trigger	0.1 to 5 L/min	0.1 L/min	±(1.0 L/min + 10% of setting)
ΔP-apnea	3 to 60 cmH_2O	1 cmH_2O	±(2.0 cmH_2O + 5% of setting)
VT-apnea	2 to 300 mL	1 ml	±(10mL+10% of setting)
f-apnea	15 to 150 /min	1 /min	±1 /min
Flow	2 to 12 L/min	1 L/min	±(2 L/min+10% of setting)

F.8 Monitored Parameters

For all measured and computed variables that are displayed or used for control, the low pass filtering and moving average smoothing techniques is used.

NOTE

- The unlisted parameters are the same as the corresponding parameters of adult.

Table F-2.Monitored parameters

Parameter	Range	Resolution	Accuracy
f-total	0 to 200 /min	1 /min	±5 % of actual reading or ±1 /min, whichever is greater
f-spn.	0 to 200 /min	1 /min	
f-mand.	0 to 200 /min	1 /min	

Glossary

Apnea T-insp.	Inspiration time set in apnea ventilation mode.
Apnea Vent	Apnea ventilation.
Assist	Assisted trigger function.
APRV	Airway Pressure Release Ventilation.
ATPD	Ambient Temperature and Pressure Dry.
BPAP	Bilevel Positive Airway Pressure.
BTPS	Body Temperature and Pressure Saturated
C-dyn.	Dynamic Compliance
CPAP	Continuous positive airway pressure.
CPAP/PSV	Continuous Positive Airway Pressure/Pressure Support Ventilation.
C-stat.	Static Compliance
E-cycle	Expiratory cycle sensitivity
E-max	Maximum elastance (volume assist).
EPAP	Expiratory positive airway pressure.
ET	Endotracheal.
$EtCO_2$	End-tidal Carbon Dioxide.
Exp%	Inspiratory termination level. The ventilator is switched to the expiratory phase when the inspiratory flow drops to peak flow*Exp%.
f	Respiratory frequency, the number of mechanically controlled breaths delivered to the patient in one minute.
f-apnea	Breathing frequency set in apnea ventilation mode.
FiO_2	Inspired Oxygen Concentration
f-mand.	The accumulated number of breaths in one minute.
f-SIMV	Breathing frequency set in SIMV mode.
f-spn.	The accumulated number of spontaneous breaths in one minute.
f-total	Total breathing frequency
I:E	The ratio of inspiratory to expiratory time.

IPAP	Inspiratory positive airway pressure. A control setting. The application and maintenance of pressure above atmospheric at the airway throughout the inspiration phase of positive-pressure mechanical ventilation.
I-trigger	Inspiratory trigger sensitivity
MV	The accumulated expired tidal volume in one minute.
MV-leak	The accumulated leakage (inspiratory volume minus expiratory volume) in one minute.
MV-spn.	The accumulated spontaneous expired tidal volume in one minute.
NIF	Negative Inspiratory Force
NIV	Non-Invasive Ventilation
O_2 %	Oxygen concentration, the volume percentage of oxygen in the mixed gas delivered to the patient.
P0.1	100ms Occlusion Pressure
Paw	Airway Pressure
PCV	Pressure Control Ventilation.
PEEP	Positive End-Expiratory Pressure
PEEPi	Intrinsic PEEP
P-high	High pressure level at which the patient can spontaneously breathe.
PIP	Peak inspiratory pressure
P-low	Low pressure level at which the patient can spontaneously breathe.
P-max	Maximum pressure limit in PPV mode.
P-max	Maximum IPAP Pressure in VS mode.
P-mean	Mean Pressure
P-min	Minimum IPAP Pressure in VS mode.
P-peak	Peak Pressure.
P-plat	Plateau Pressure.
PPS	Proportional Pressure Support
PPV%	The percent of proportional pressure ventilation supplied by the ventilator.
PR	Pulse Rate.

PRVC	Pressure Regulated Volume Control.
PSIMV	Pressure Synchronized Intermittent Mandatory Ventilation.
Pt.-leak	Patient leak, the leak resulting from leaks around the mask or from unintentional leaks in the circuit. A monitored parameter shown when the intentional leak is known.
Pt.-trig.	Patient trigger, Percentage of patient-triggered breaths. Patient-initiated breaths as a percentage of total breaths during the last 15 minutes.
P-trigger/ F-trigger	Pressure trigger and flow trigger included. When the trigger level is detected, the ventilator starts to enter the inspiratory phase. When F-Trig is active, at the late stage of exhalation the ventilator delivers a base flow from the inspiratory limb to the expiratory limb.
Ramp	Can be used to allow the patient to become accustomed to respiratory ventilatory therapy over time. Ramp will allow the pressure to linearly increase over a user-set period.
RC-exp	Patient's expiratory time constant.
Re	Inspiration Resistance
Ri	Expiration Resistance
Rise	Rise time, the time required for a pressure-supported or pressure-controlled breath to reach its target pressure,
R-max	Maximum resistance (flow assist).
RSBI	Rapid Shallow Breath Index
Sigh	Breaths delivered to deliberately increase tidal volume at a regular interval.
Sigh Cycle	It is the setting value of number of cycles of every group of sigh ventilation.
Sigh Interval	It is the setting value of time interval between two groups of sigh ventilation.
slopeCO_2	CO_2 rising slope
SpO_2	Arterial oxygen saturation from pulse oximetry.
S/T	Spontaneous/Timed

T-exp	Time of Expiration
T-high	Time of High Pressure
Ti/Ttot.	Inspiratory duty cycle. Inspiratory time divided by total cycle time, averaged over 8 breaths, a monitored parameter.
T-insp.	Time of Inspiration. The duration of inspiration in one breathing cycle.
T-low	T-low is the time that the ventilator will hold the low pressure level.
Tot.-leak	Total leak, Estimated total leak, both intentional and unintentional. A monitored parameter shown when the mask leak and type of exhalation port are not known.
T-pause	Percent of Inspiratory Pause Time
T-slope	Controls pressure rise slope in pressure mode.
V'alv	alveolar minute ventilation
V'CO_2	CO_2 elimination
VDaw	Airway dead space
VDaw/VTe	Ratio of airway dead space to tidal volume
VeCO_2	Exhaled CO_2 volume
ViCO_2	Inspired CO_2 volume.
V-max	maximum volume limit in PPV mode.
Volume	Gas Volume
VSIMV	Volume Synchronized Intermittent Mandatory Ventilation.
V+SIMV	PRVC+SIMV
VT	Tidal Volume · the gas volume the patient inspires or expires each time during resting breathing.
Vtalv	alveolar tidal ventilation
VT-apnea	It is delivered tidal volume in apnea ventilation when volume mode is selected for apnea ventilation.
VTe	Expired Tidal Volume
VTe/IBW	Tidal Volume Per Ideal Body Weight
VTe-spn.	Spontaneous Expired Tidal Volume
VTi	Inspired tidal Volume

Vtrap	Volume of Trap Gas
WOB	Work of Breath
Δint.PEEP	Intermittent Positive End-Expiratory Pressure. It is a relative value relative to PEEP.
ΔP-insp.	It is a relative value relative to PEEP.
ΔP-supp.	Pressure Support Level. It is a relative value relative to PEEP or P-low.
ΔP-apnea	Pressure of Apnea Ventilation. It is a relative value relative to PEEP or P-low.