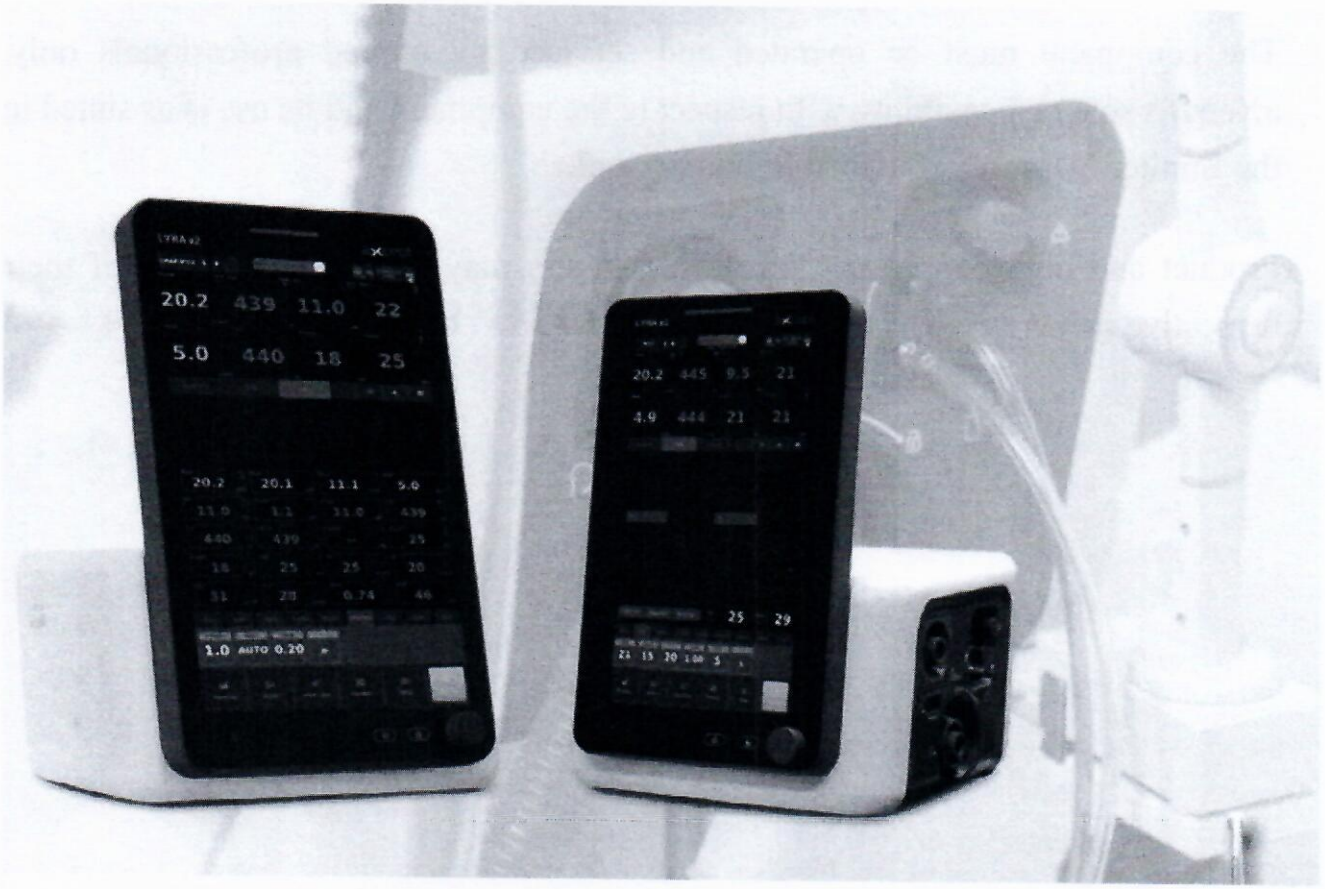
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Florina Iustina Ionescu
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axcent medical

LYRA x2 Ventilator

User Manual



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Product and company names mentioned herein may be the trademarks of their respective owners.

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1 Safety Information

Before using the LYRA x2 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 Definitions

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.

1.2 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.

- Be aware that a ventilator shutdown for any reason increases the patient's risk of CO2 rebreathing.
- 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 aXcent 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.
- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.
- The physiological parameters and alarm messages displayed on the screen of the 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 possible asphyxia and to reduce the risk of CO_2 rebreathing, take these precautions with respect to mask and exhalation port use:
  - Use only an oro-nasal mask with an anti-asphyxia valve or a nasal mask for noninvasive ventilation.
  - Do not occlude the exhalation port.
- To prevent unintentional disconnection of the power cord, always use the correct aXcent - supplied power cord and lock it into place with the power cord retainer before use.
- To reduce the risk of electric shock, connect the ventilator to an AC supply mains with protective earth only.
- To reduce the risk of electric shock, regularly inspect the AC power cord and verify that it is not frayed or cracked.
- A ventilator shutdown due to a total loss of power during ventilation poses serious risks to the patient. Always have a backup battery installed and fully charged.
- The backup battery must be installed 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.
- The buzzer of the ventilator alarm 120s and the exhalation valve is open, if the AC power supply and battery are not in place.
- 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.
- 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 with such monitoring function or this function is turned off, use a monitor which complies with the requirements of ISO 80601-2-55 for oxygen concentration monitoring.
- As required by the relevant rules and regulations, expiratory carbon dioxide concentration should be monitored when the equipment is used on the patient. If your ventilator is not configured with such monitoring function or this function is turned off, use a monitor which complies with the requirements of ISO 80601-2-55 for expiratory carbon dioxide 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.

1.3 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 ship it with the original packing material. If the original material is not available, please contact aXcent to order replacements.
- 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.

1.4 Note

- If an alarm persists for no apparent reason, discontinue ventilator use and contact aXcent.
- If you detect any unexplained changes in the performance or visual displays of the ventilator, discontinue ventilator use and contact aXcent.
- 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. If the airway pressure exceeds 85cmH2O, the ventilator opens the safety valve to release pressure. Make sure to set high pressure alarm limit properly to ensure patient safety.

2 Symbols

The following symbols may appear on device labels or packing.

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.
	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment).
IP21	Indicates the degree of protection provided by enclosure according to IEC 60601-1.
	Type BF Applied part (classification of medical electrical equipment, type B, as specified by IEC 60601-1).
	The device is not suitable for use in MRI environment.
	This way up at transport and storage.

Symbol	Definition
	Fragile, handle with care.
	Keep dry at transport and storage.
	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
RS232	RS-232 connector
HDMI	HDMI connector.
	USB connector
	Inspiration connector
	Expiration connector

Symbol	Definition
	Lock
	Unlock
	Nebulizer connector
	Proximal pressure port
	Alarm Audio pause

3 General Information

3.1 Intended Use

The LYRA x2 ventilator is a mechanical ventilator designed to provide invasive and non-invasive, continuous or intermittent, respiratory support for pediatric and adult patients.

Intended areas of use:

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

The LYRA x2 ventilator is intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

3.2 Noninvasive Ventilation Contraindications

- Inability to trigger breath
- Facial or brain injury
- Recent upper airway or esophageal surgery
- Hemodynamic instability
- Gastric distension
- Inability to protect airway

3.3 Potential Side Effects during Noninvasive Ventilation

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.

3.4 Functional Description

The LYRA x2 ventilator has provide continuous or intermittent ventilator support for pediatric and adult patients. It functions as a pressure/volume support ventilator by providing pressure- or volume-targeted breaths delivered via endotracheal or tracheostomy tube, as well as approved nasal, oro-nasal, and full face masks.

Ventilation types and modes

The LYRA x2 ventilator offers two ventilation configurations: single-limb noninvasive (NIV) and dual-limb invasive (INV). Each offers a range of modes.

For single-limb noninvasive:

- CPAP (Continuous Positive Airway Pressure).
- PCV (Pressure Control Ventilation).
- PPS (Proportional Pressure Support).
- S/T (Spontaneous/Timed).
- VS (Volume Support).

For dual-limb invasive:

- 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).

The available ventilation modes depend on the product models. See Chapter10.8 "Configuration Specifications".

Monitoring

The ventilator offers a variety of monitoring capabilities. It displays monitored parameters as numbers. You can also see this data graphically, as a combination of real-time waveforms, Loops

and Trends.

User interface

The ventilator's ergonomic design, including a color touchscreen, a control knob, and key panel, lets you easily access ventilator settings and monitored parameters.

Oxygen monitoring

An integrated sensor measures oxygen in the delivered gas mixture.

Alarms

The ventilator's operator-adjustable and nonadjustable alarms help ensure the patient's safety.

Power and gas supplies

The ventilator uses as its primary power source AC mains. Two backup batteries power the ventilator for a few hours using nominal settings.

The ventilator uses high-pressure oxygen. An integral blower pressurizes gas for delivery to the patient.

NOTE: Oxygen delivered through the compressed gas hose is used as fresh gas.

Communications interface

The ventilator can output data through the RS-232 serial port upon receiving a command from a host computer or bedside monitoring system. The ventilator is equipped with a remote alarm/nurse call connection to activate alarms remotely.

3.5 Physical Description

Breathing circuits and accessories

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

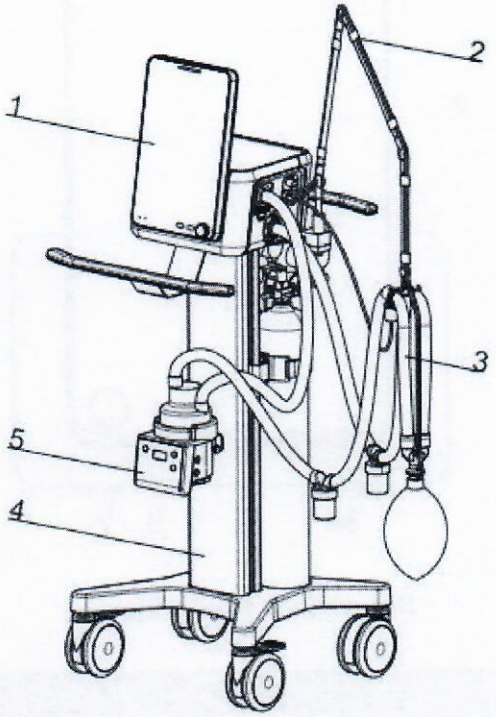


Figure 3-1. Ventilator with Accessories

No.	Description
1	Touch Screen
2	Support arm
3	Breathing circuit
4	Trolley
5	Humidifier

For more information about the compatible breathing circuits and accessories, see Appendix "Parts and Accessories".

Ventilator unit

Figure 3-2 through Figure 3-4 show the controls, indicators, and other important parts of the ventilator unit.

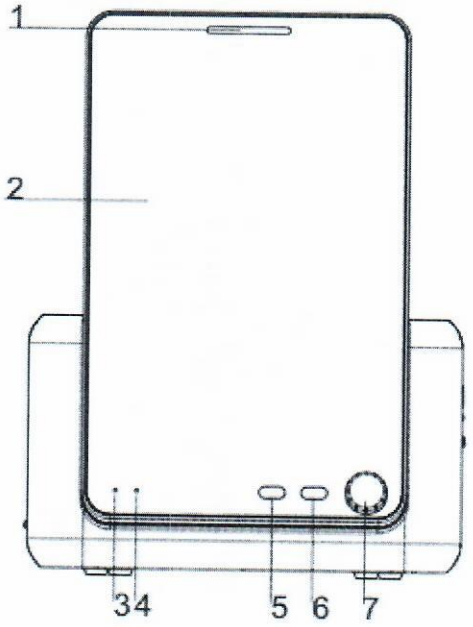


Figure 3-2. Front View

No.	Description
1	Alarm lamp
2	Touchscreen
3	External power supply LED
4	Battery LED Flashes when ventilator is running on battery. On continuously when battery is
5	Alarm Silence key
6	Screen lock/unlock key
7	Control knob

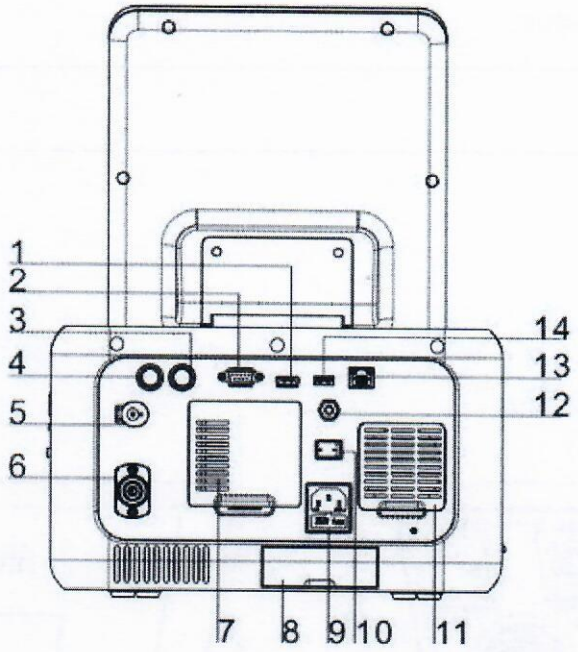


Figure 3-3. Rear View

No.	Description
1	HDMI 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	Removable battery
9	Power cord retainer
10	Power switch
11	Fresh air intake and cooling fan filter
12	Equipotentiality

13	Network connector
14	USB connector

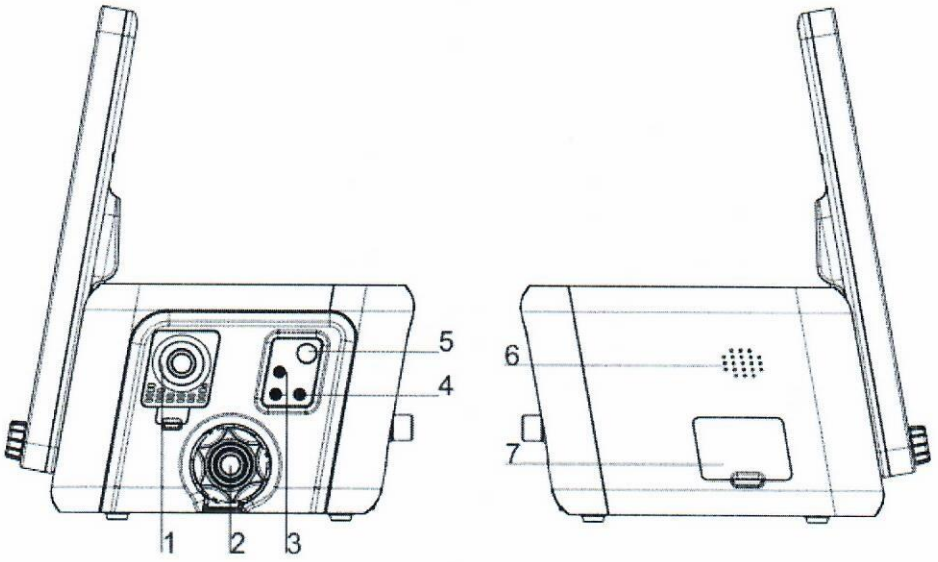


Figure 3-4. Side View

No.	Description
1	Inspiratory filter
2	Expiratory filter. Note: Expiratory filter is not available on RS100.
3	Flow sensor connectors
4	Nebulizer connector
5	Leak test plug
6	Speaker
7	Oxygen Sensor

Screen

Directly access all the windows for mode, controls, alarms, andmonitoring from the screen during normal ventilation. The default screen is shown as below.

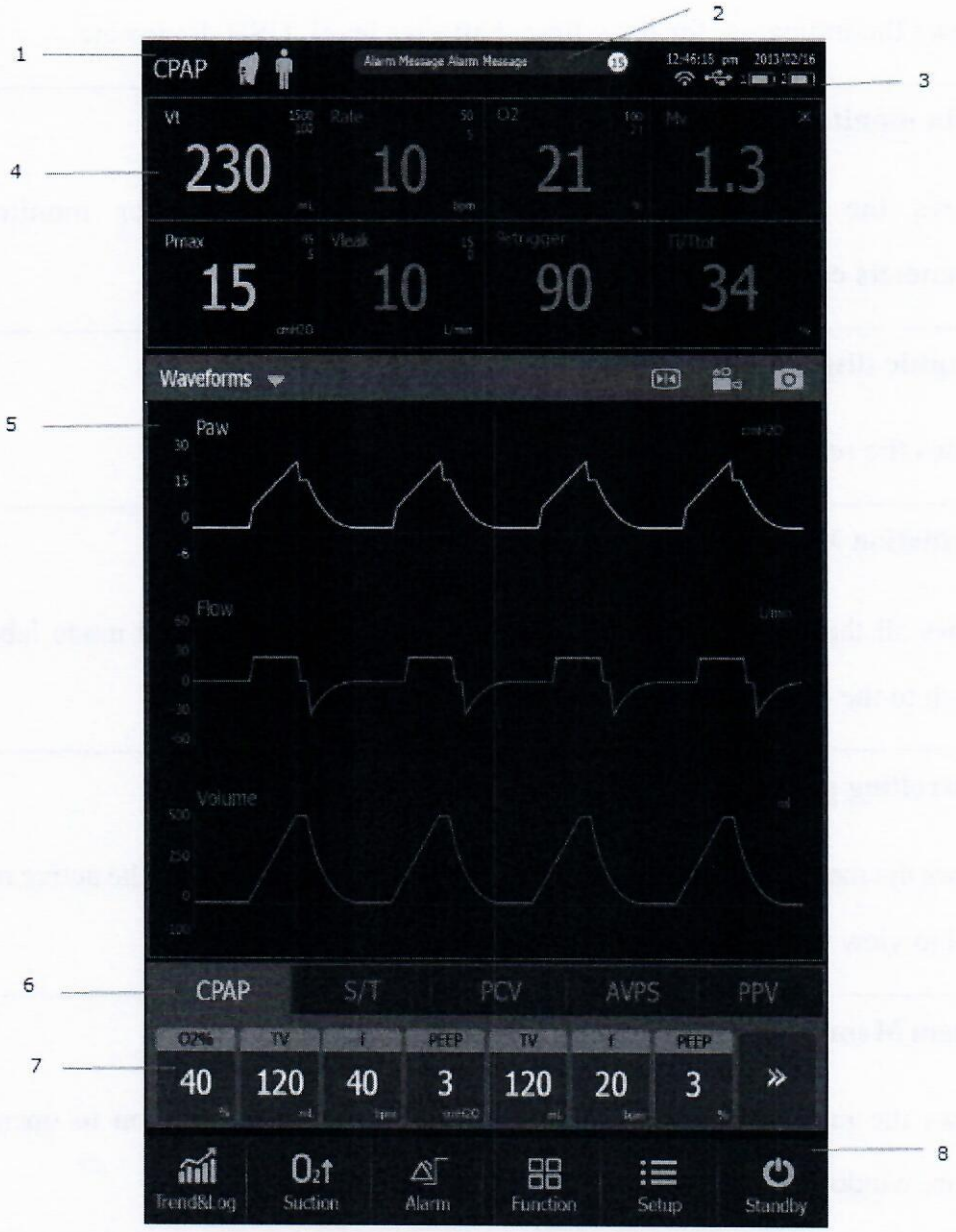


Figure 3-5. Main Screen

No.	Description
1	Active mode, ventilation type and patient group.
2	**Alarm Message bar** Shows the active alarm messages. Touching the Alarm message bar to view the

	alarm messages list.
3	**Indicators bar** Shows the indicators for date, time, batteries level, USB device etc.
4	**Main monitoring parameters** Shows the customized monitoring parameters. The other monitoring parameters can be viewed in the Value window.
5	**Graphic display** Shows the real time waveforms and loops.
6	**Ventilation Modes** Shows all the available ventilation modes. Touching the desired mode label to switch to the corresponding ventilation mode.
7	**Controlling parameters** Shows the main controlling parameters of active mode. Touching the active mode label to view the others controlling parameters.
8	**System Menu** Shows the main feature of ventilator. Touching the menu button to open the feature window.

4 Preparing for Ventilation

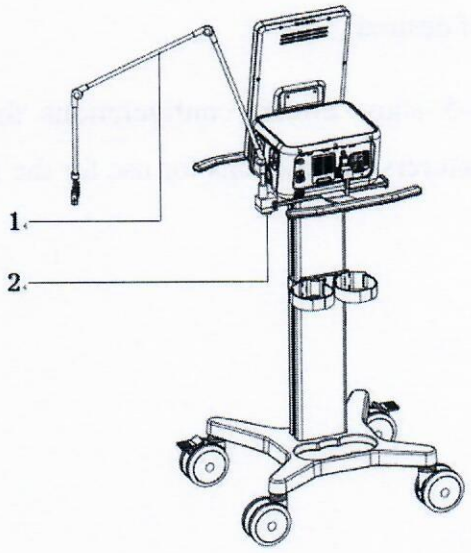
WARNING:

- 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.

4.1 Installing the Patient Tubing Support Arm

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



1. Fixing block. 2. Fixing block knob

Figure 4-1. 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.

4.2 Installing the Patient Breathing Circuit

Warning:

- To minimize the risk of bacterial contaminationor physical damage, handle bacteria filters withcare.
- 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 CO2 rebreathing during noninvasive ventilation, avoid introducing extra dead space to the patient circuit.

Install the patient circuit exactly as it will be used on the patient. For a list of compatible parts and accessories offered by aXcent, see Appendix "Parts and Accessories".

1. Determine the correct patient type. Press the **Adult** button or the **Pediatric** button.
2. Assemble the patient circuit, including the main flow (inspiratory) bacteria filter, proximal pressure line, and HME (if desired).

Figure 4-3 through Figure 4-5 show circuit configurations for single-limb and dual-limb ventilation. Follow the manufacturers' instructions for use for the individual parts, including the humidifier.

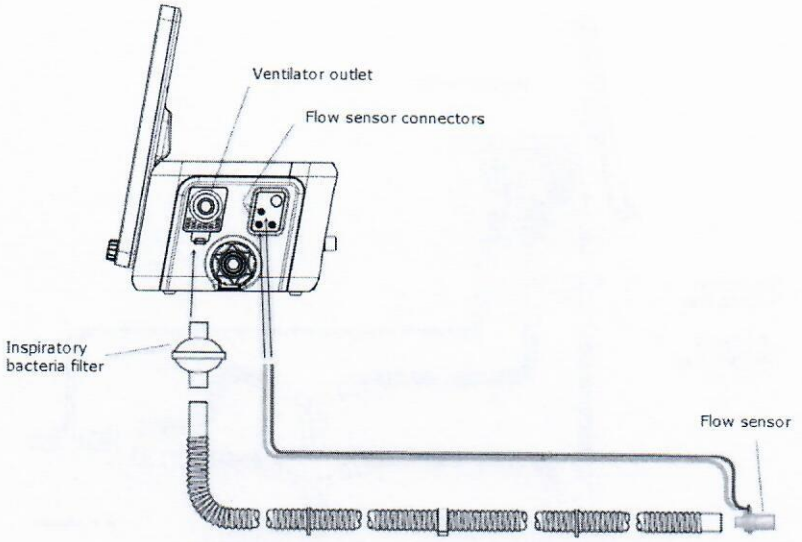


Figure 4-2. Single-limb, noninvasive circuit, without humidification

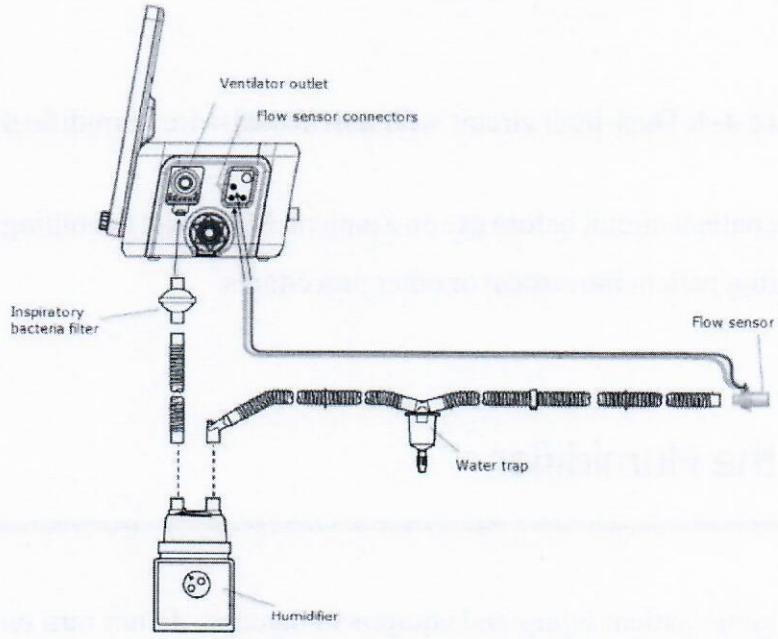


Figure 4-3 Single-limb, invasive circuit, with humidification

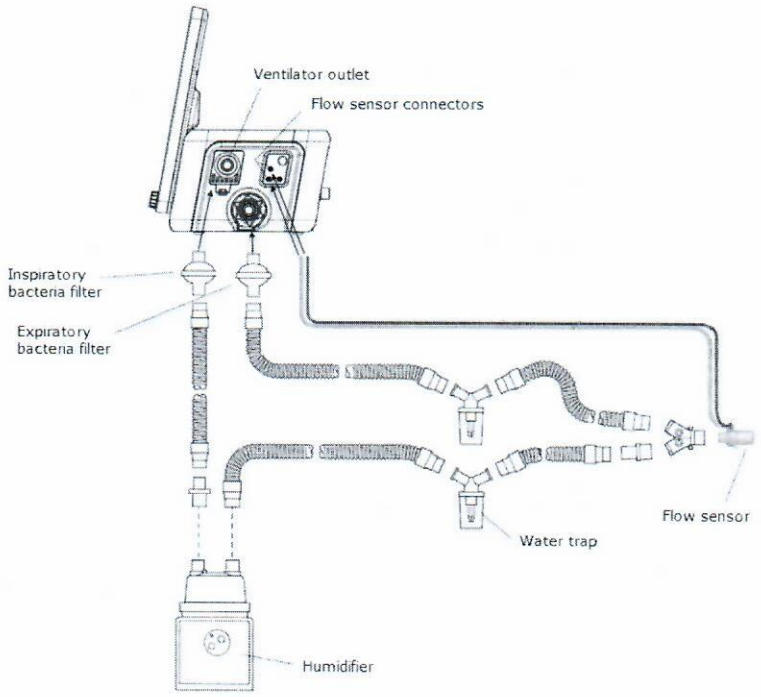


Figure 4-4. Dual-limb circuit with non heated-wire humidification

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.

4.3 Installing the Humidifier

Warning:

- To prevent possible patient injury and equipment damage, do not turn on the humidifier until the gas flow has started and is regulated.
- To prevent possible patient injury and equipment damage, 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.

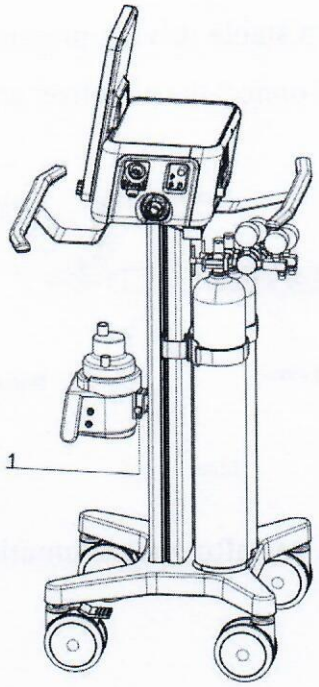


Figure 4-5. Installing the humidifier

4.4 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.

The nebulization feature provides a stable driving pressure to power a pneumatic nebulizer connected to the nebulizer outlet. Connect the nebulizer and accessories as shown below.

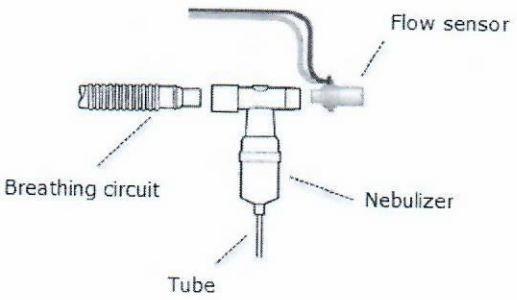


Figure 4-6. Installing a pneumatic nebulizer

4.5 Connecting the Oxygen Supply

WARNING:

- Connect the ventilator only to an appropriate medical-grade oxygen source.
- Inspect the O2 supply connector carefully and make sure there is no leakage. If gas leakage is significant, O2 concentration in the ambient environment will exceed normal atmosphere, resulting in potentially dangerous O2 enriched environment.
- To reduce the risk of hypoxia, connect only oxygen to the high-pressure connector at the rear of the ventilator.

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 O2 supply (for example, a gas cylinder) is available in case the low-pressure O2 supply fails.

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.

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.

4.6 Connecting to Primary Power Source

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 electric shock use only a aXcent-supplied (hospital-grade) power cord and connect the ventilator only to supply mains with protective earth.
- 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 checkthe reliability of the AC outlet. If you are using a 120 V outlet, make sure that it is hospital-grade.

4.7 About 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. The battery powers the ventilator typically for a few hours.

The ventilator charges the batteries whenever the ventilator is connected to AC, with or without the ventilator switched on. The battery LED flashes to show that the battery is using.

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.

4.8 Starting up the Ventilator

Switch on the ventilator power switch. The alarm indicator light flashes yellow and red once in turn and then the speaker and the buzzer give a check sound respectively.

After a short time, a start-up screen appear. Then the System Check window is displayed, you

can run the system self-test before using the ventilator.

4.9 Running the System Check

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.

We recommend that you run system check when:

- Before placing a new patient on the ventilator.
- After installing a new or decontaminated breathing circuit or component.
- When the oxygen sensor is replaced.

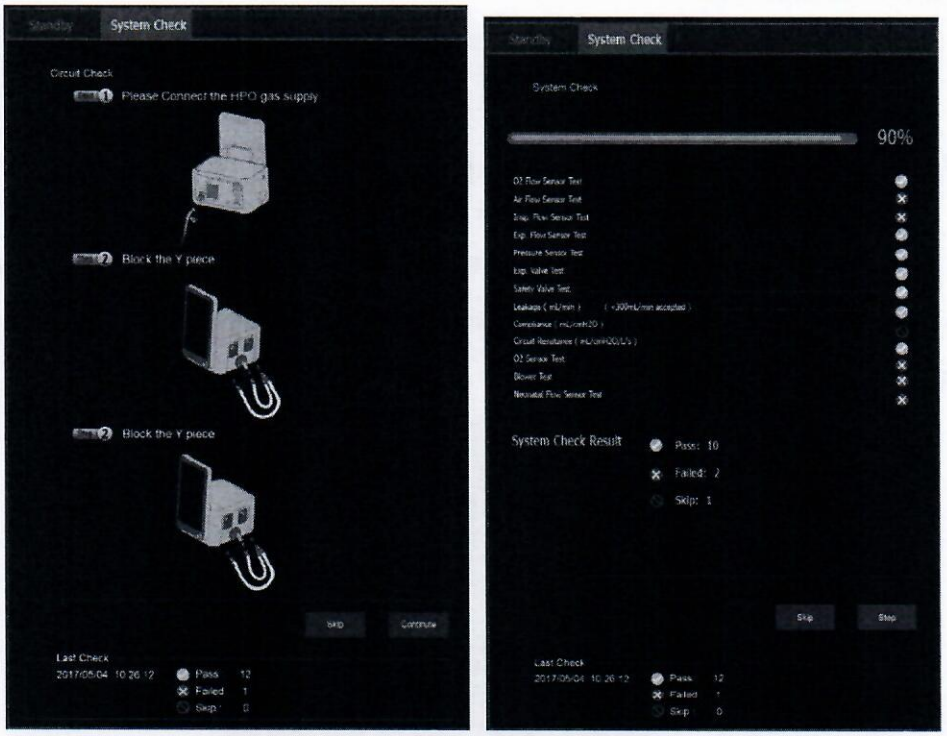


Figure 4-7. System Check

The System Check for INV including the below items:

- Blower Test
- Inhalation Branch Test
- O2 Branch Test
- O2 Cell Test
- Exhalation Branch Test
- Pressure Sensor Test

- Leakage （mL/min）
- Compliance （mL/cmH2O）
- Circuit Resistance （cmH2O/L/s）

The System Check for NIV including the below items:

- Blower Test
- Inhalation Branch Test
- O2 Branch Test
- O2 Cell Test
- Pressure Sensor Test

4.10 Ventilator Configuration Overview

After the Systgem Self-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.

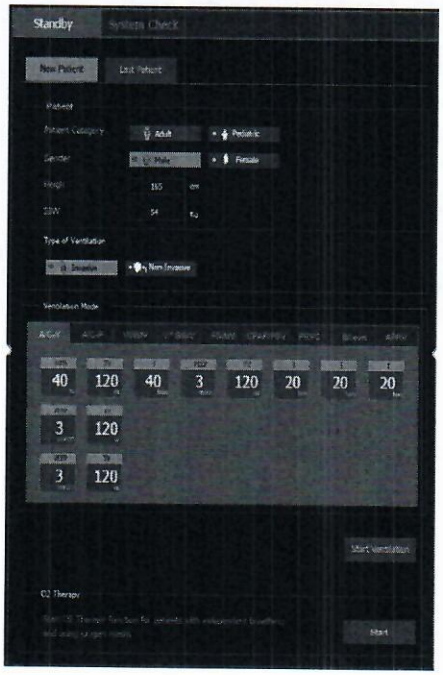


Figure 4-8. Ventilator Configuration

Configuring a New Patient

1. Select **New Patient** from the Standby window.
2. Select settings for patient type, circuit type, and ventilation mode that depending on which type of circuit you chose.
3. Adjust the control settings of the ventilation mode as needed.

Then you can press the **Start Ventilation** button to start ventilation.

Resume a Patient

Select **Las 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.

4.11 Navigating the Graphical User Interface

Use the touchscreen to access the ventilation menu on the screen. Use the press-and-turn knob to adjusting the ventilation parameters.

To open a window, touch the Menu button on the screen. 

To close a window, touch the Menu button or the  button in the upper left-hand corner of the window.

To adjust a parameter, touch the parameter button on the screen, the adjustment window will be popup. 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 **Check** button to apply the changing.



Figure 4-9. Parameter Settings

4.12 Shutting down the Ventilator

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.

To shut the ventilator down, please access the standby mode first, then press the power switch for > 3 s on the standby window.

5 Ventilator Settings

5.1. Ventilation Mode

Note:

- The PCV and PSIMV are the recommended ventilation modes for use with a closed-suction catheter. And the settings are decided by the operator according to the patient situation.

The active ventilation mode and control settings are displayed in the bottom of the screen. The displayed modes depends on the ventilation type and product model. For details about modes, see Appendix "Ventilation Modes".

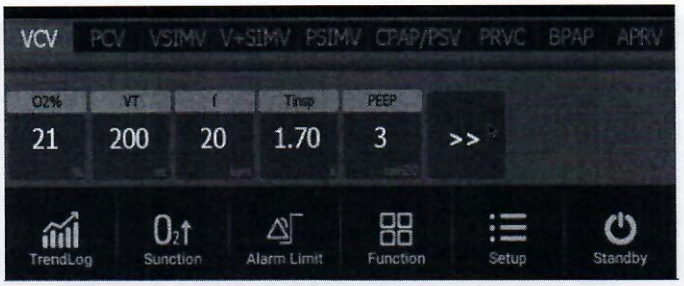


Figure 5-1. Ventilation Modes Menu

To change the mode as follows:

1. Click the desired mode label. A mode window with all the control settings of the selected mode will be popup.
2. Adjust the control settings as needed.
3. Click the **Start** button to confirm the selected mode.

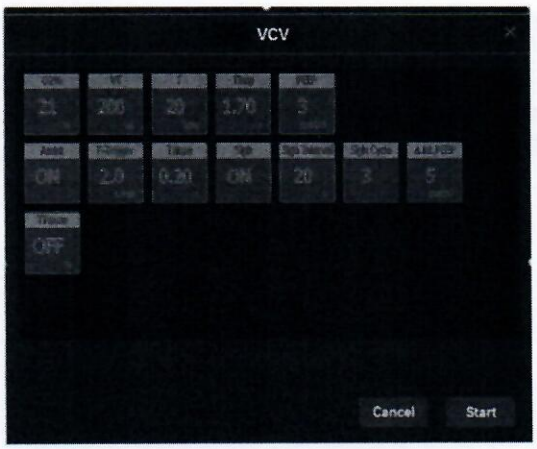


Figure 5-2. Controls of the Selected Modes

5.2 Control Settings

The key control settings of the active ventilation mode are displayed on the bottom of screen. You can adjust them using by touchscreen or knob as needed. Or touch the active mode button to view all the control settings, including the apnea control settings if the apnea backup mode is available in active mode.

For control setting ranges and standard settings, see Table 10.5.

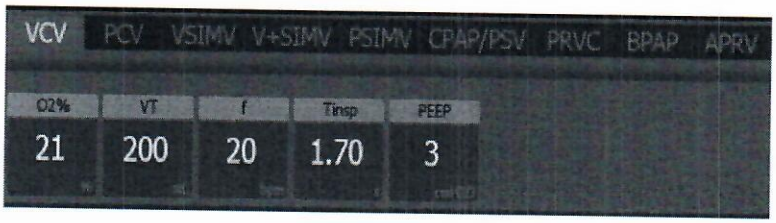


Figure 5-3. Ventilation Mode Control Settings

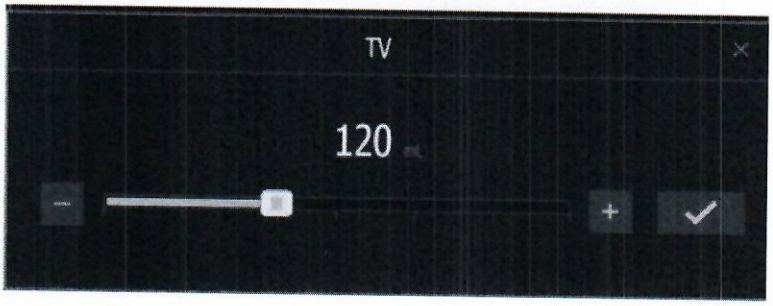


Figure 5-4. Adjusting the Control Settings

5.3 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.

The Alarm Limits window displays the operator adjustable alarm settings.

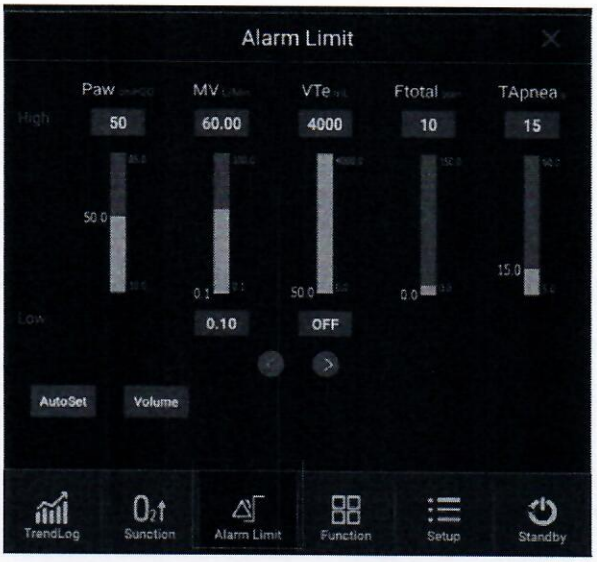


Figure 5-5. Adjusting the Control Settings

Review and adjust the alarm settings as follows:

1. Press the "Alarm Limit" on the screen menu to open the Alarm Settings window.
2. Select a parameter and adjust the value. Repeat for any other desired parameters.
3. Select Accept to apply. The ventilator alarms when a monitored value goes out of the range bounded by the alarm limits.

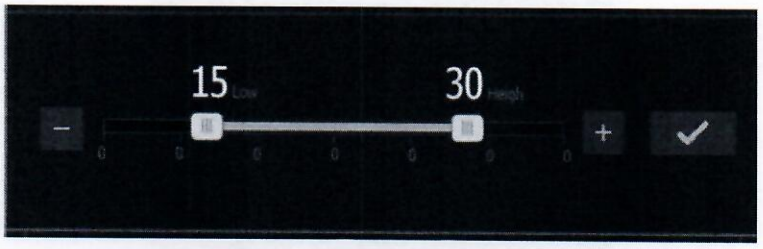


Figure 5-6. Adjusting the Alarm Settings

See chapter 10.7 "Alarms" for the details of alarm settings.

Adjusting Alarm Loudness

Adjust the alarm loudness as follows:

1. Click the **Volume** button on the Alarm Limit window.
2. Adjust the Loudness value as desired.

5.4 Standby

Warning:

- To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before entering the standby mode. Make sure that no patient is attached before entering standby.
- To prevent possible patient injury or damage to breathing circuit from overheated gas, please turn off the humidifier when entering standby.

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. 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.

To access the standby mode, click the **Standby** button on the button of the s.creen.

To start ventilation from Standby Mode, Click **Start Ventilation** button.

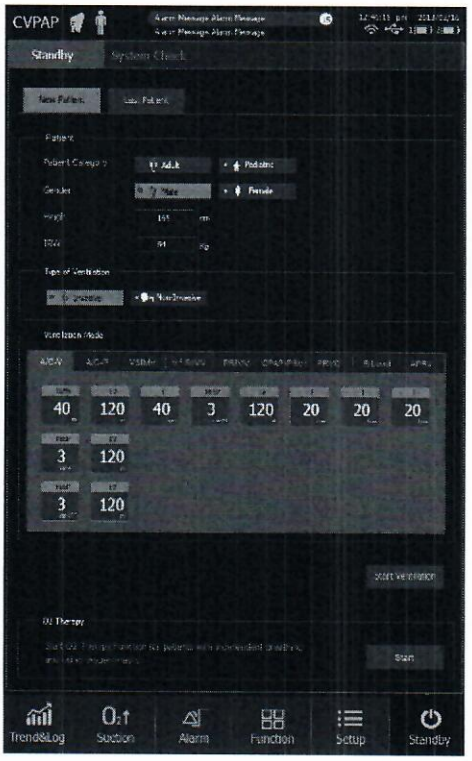


Figure 5-7. Standby Mode

5.5 System Settings

5.5.1 Sensor Settings

The Sensor Settings window lets you run the calibrations for Pressure, Flow and Oxygen sensors.

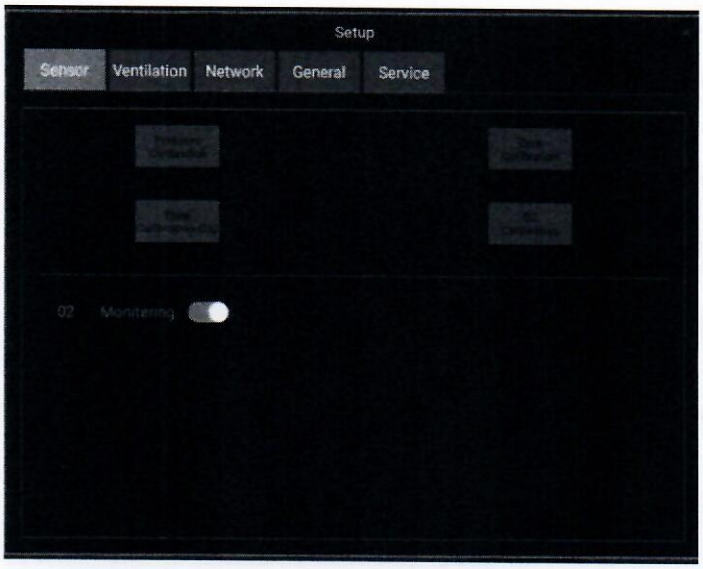


Figure 5-8. Sensor Settings

5.5.2 Ventilation Settings

The Ventilation Settings window lets you setup the configuration for Ventilation.

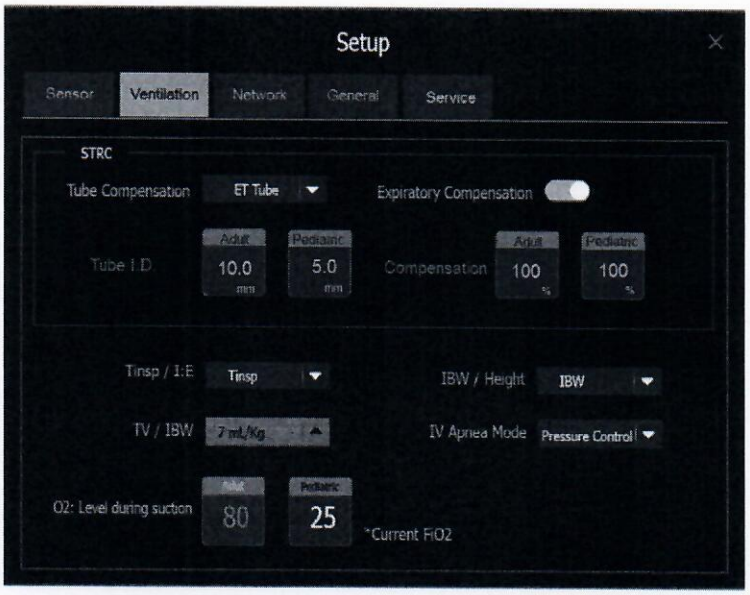


Figure 5-9. Ventilation Settings

Item	Description

Tinsp/I:E	Set up whether to set the inspiratory time over the parameter TI or I:E.
VT/IBW	Set up the VT/IBW ratio. The default VT value in ventilation mode will be set based on the selected ratio.
O2 Level	Set up the O2 concentration during O2 Enrichment.
STRC	Set up the Synchronized Tube Resistance Compensation (STRC) configuration. **Tube Type** Select the tube type for Compensation or disable the STRC feature. **Tube Size** Select the tube size of patient circuit. **Compensation** Set up the percentage of compensation. **Expiration** Turn on/off the expiration compensation.

5.5.3 General Settings

The General Settings window lets you setup the configuration for common features, such as system date, system time or screen brightness.

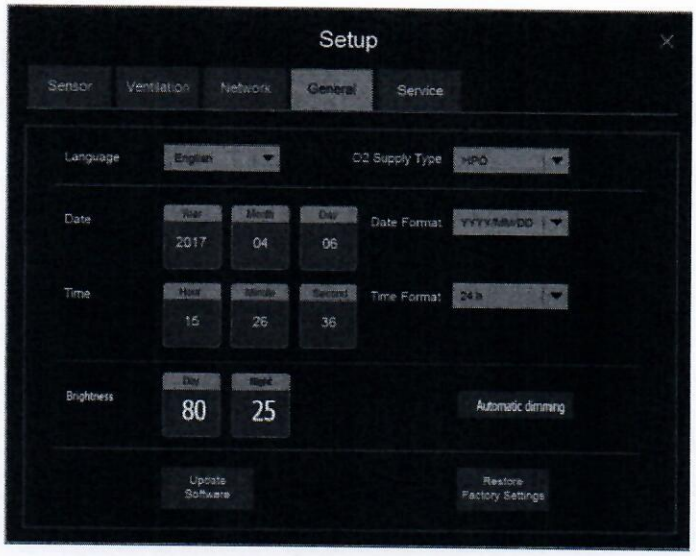


Figure 5-10. General Settings

Item	Description
Language	Set up the system displayed language.
Date	Set up the system date.
Date Format	Set up the system date format.
Time	Set up the system time.
Time Format	Set up the system time format.
Brightness	Set up the screen brightness for day and night. You can enable the automatic dimming feature.
O2 Supply	Set up the O2 supply source.

5.6 Other Functions

Screen Lock

The **Screen Lock** function lets you deactivates all buttons and tabs on the touchscreen. You can press the **Screen Lock** button on the bottom of the monitor to enable the Screen Lock function, and press again to disable it.

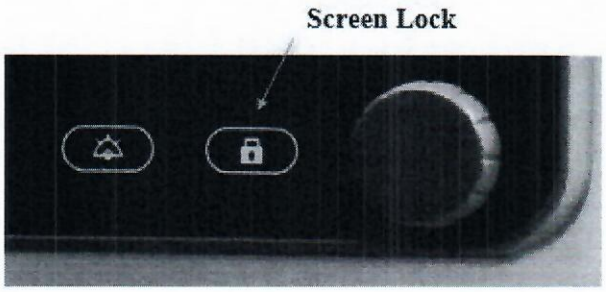


Figure 5-11. Screen Lock Key

6 Patient Monitoring

During ventilation, the ventilator displays the patient data on the screen, you can configure the screen layout with different waveforms, loops, values or trends to suit your institution's needs.

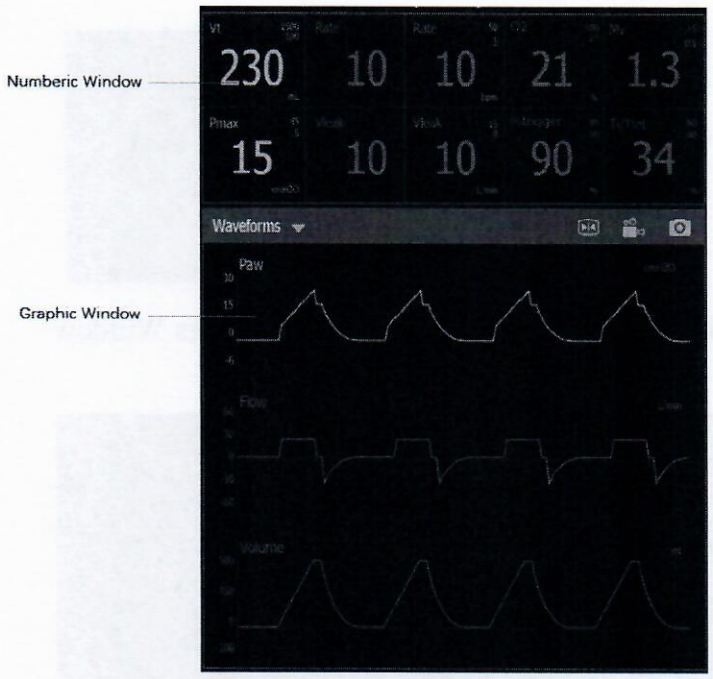


Figure 6-1. Monitoring Window

Press Waveforms button to switch displaying loop windows or values window.

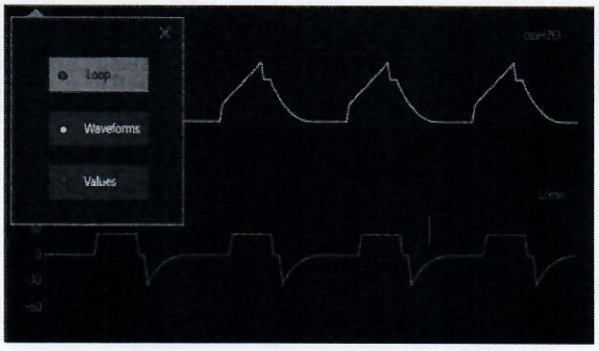


Figure 6-2. Switching Monitoring Window

6.1 Numeric Window

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.

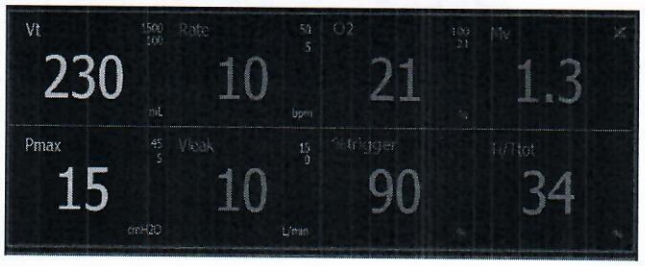


Figure 6-3. Key Monitored Parameters Window

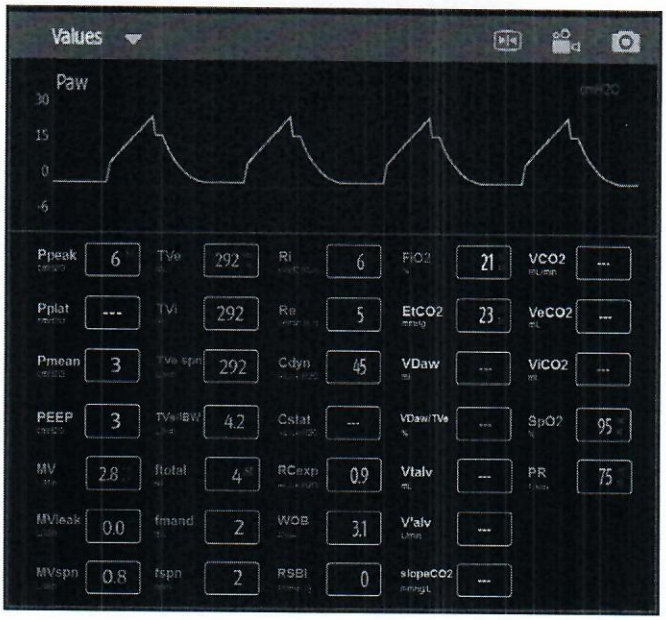


Figure 6-4. Value Window

6.2 Waveform Window

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

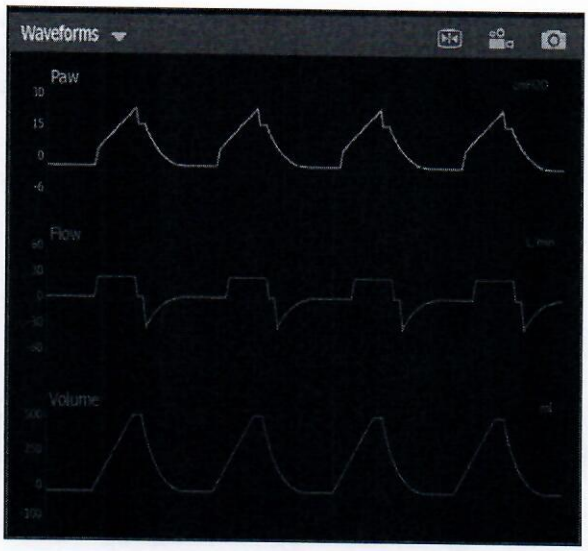


Figure 6-5. Waveforms Window

6.3 Loops Window

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 6-6. Loops Window

6.4 Trend

The Trend function lets you view the monitored parameters trends for the past period since you switched on the ventilator. You can choose to show monitored parameters as 1-, 3-, 6-, 12, 24, 48, or 72-hour trends since you switched on the ventilator for the past 1, 3,6, 12, 24,48 or 72 hours.

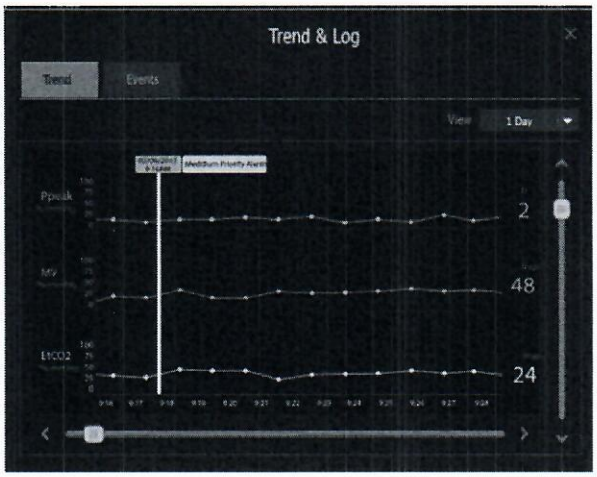


Figure 6-7. Trends Window

6.5 Freeze

This Freeze function lets you freeze the display of the waveforms or loops. it is particularly useful when you perform a breath hold maneuver.

To freeze the graphs, click the **Freeze** button on the top of the graphic window. when the graphs is frozen, a cursor is visible in the middle of the graphs window. You can reposition the cursor by touching the cursor directly. The data values at cursor location for pressure, flow, and volume are displayed in the graphs window.

To unfreeze the graphs, click the Freeze button again.

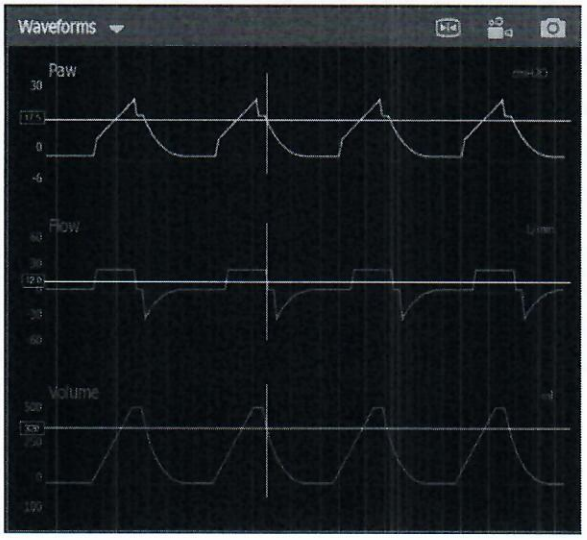


Figure 6-8. Freeze Waveforms

7 Alarms

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. 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.

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.

Table 7.1 Alarm indications

Alarm Type	Message Bar	Alarm Lamp	Alarm Audio	Action Require
High-priority	Red, with alarm message	Red	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, with alarm message	Yellow	A sequence of 3 beeps, repeated periodically.	The patient needs prompt attention.
Low-priority	Blue, with alarm message	Blue	Two sequences of beeps. This is not repeated.	Operator awareness is required.

The Alarm Message Bar is displayed on the top of screen when an alarm is triggered, you can press it to open the Alarm List window for details, or press the history alarm icon to see the inactivating alarms.

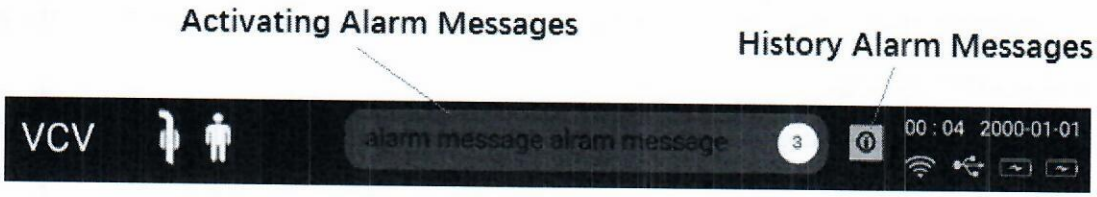


Figure 7-1. Alarm Signals on Screen

7.1 Responding to Alarms

Respond to an alarm as follows:

1. Approach the patient immediately. Secure sufficient and effective ventilation for the patient if required. You may silence the alarm if possible.
2. Correct the alarm condition, referring to the alarm messages in Table 7.2.

You can modify alarm settings at any time through the **Alarm Limit** window. When the alarm triggering condition is corrected, the ventilator automatically resets the alarm. For a technical fault alarm, switch off ventilator power first, then correct the problem.

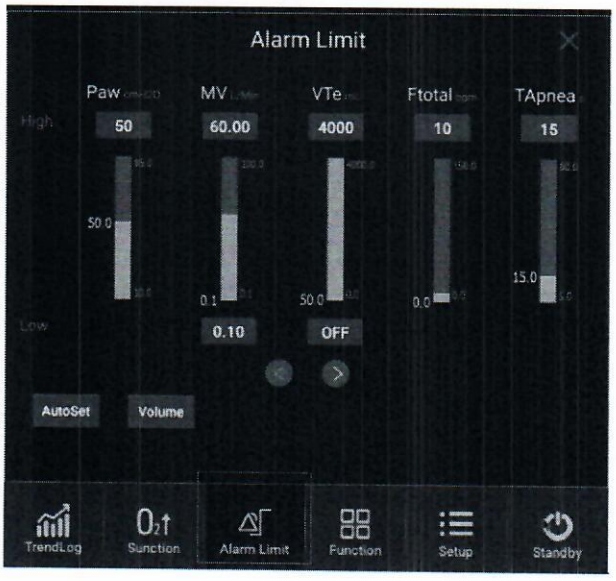


Figure 7-2. Alarm Limit window

7.2 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.

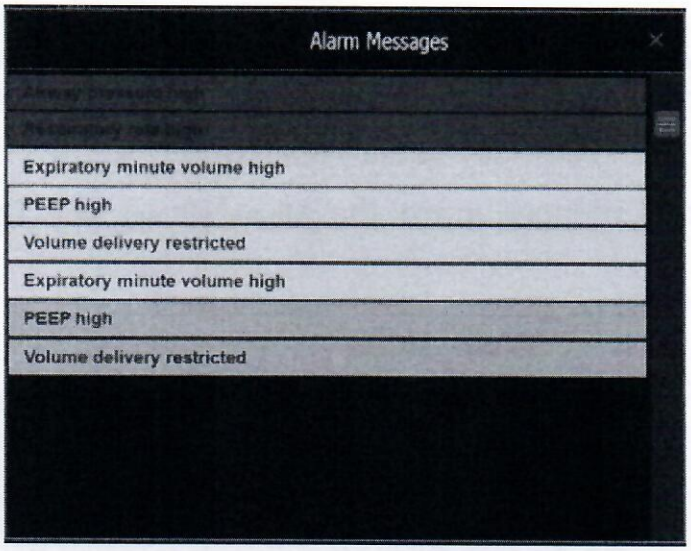


Figure 7-3. Active Alarms Window

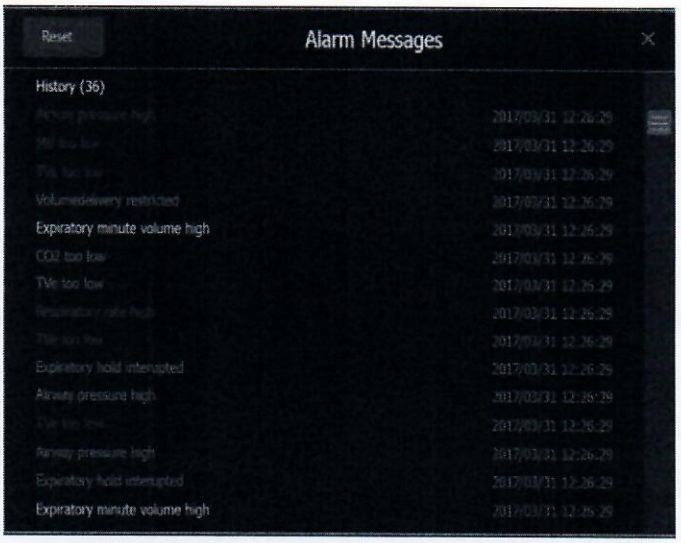


Figure 7-4. History Alarms Window

7.3 Silencing Alarms

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 **Alarm Silence** key on the bottom of the monitor.

When alarm audio is silenced, press the **Alarm Silence** key again to recover the alarm audio.

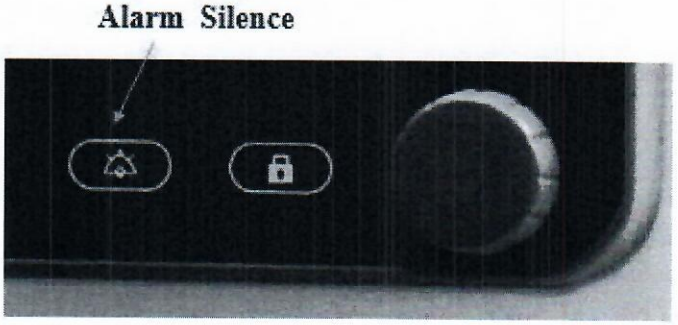


Figure 7-5. Alarm Silence Key

7.4 Event Log

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, calibrations, maneuvers, and special functions. The date, time, and description are included. If last patient is selected data before the ventilator was turned off is available.

7.5 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.

Table 7.2 Alarm Messages

Alarm	Priority	Definition	Action needed
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.
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.
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.
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.

Alarm	Priority	Definition	Action needed
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.
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.
Low Frequency	Medium	The measured frequency is less than the set alarm limit.	Check the patient. Adjust the low frequency alarm limit.
Apnea	High	No patient trigger within the operator-set Apnea time in ventilation mode.	Check the patient.
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.
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.

Alarm	Priority	Definition	Action needed
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.
High Sustained Airway Pressure	High	The measured airway pressure is greater than or equal to the setting PEEP+15cmH2O for continuous 15s.	Check the patient. Check the ventilation parameter setup. Check the breathing tubes for occlusion.
Patient Disconnected	High	The patient circuit is disconnected from the ventilator.	Check the patient. Reconnect patient circuit. If problem persists, provide alternative ventilation.
Patient circuit leak	Low	The breathing circuit is leaky.	Check the breathing circuit for leakage. Run system self-test to test the leakage.
Patient circuit occluded	High	The breathing circuit is occluded.	Check and clean the breathing circuit. Check and clean the expiration valve.
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.
O2 cell defective	Medium	The oxygen cell is depleted.	Install a new oxygen cell.

Alarm	Priority	Definition	Action needed
O2 cell missing	Low	There is no signal from the oxygen cell.	Install an oxygen cell or use an external monitor.
Oxygen Supply Failed	High	O2 pressure is low or high-pressure O2 is not connected.	Check the patient. Check connection with O2 supply. Check O2 supply pressure.
O2 cell calibration needed	Medium	Oxygen cell calibration data is not within expected range, or cell is new and requires calibration.	Calibrate the oxygen cell.
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.
Battery Temperature high	High	The battery temperature is higher than expected during discharge.	Connect the external power supply. Remove the ventilator from the
Battery missing	High	No battery is present.	Insert a battery.
Running on internal battery	Low	System is powered by the internal battery.	Connect ventilator to AC power when available.
HEPA replacement suggested	Low	The air inlet HEPA filter shows increased resistance.	Replace the HEPA filter.
Realtime clock failure	Low	Date and time not set.	Set date and time and restart the.
Fan failure	Medium	The cooling fan is malfunctioning.	Disconnect the ventilator from the patient. Have the ventilator serviced.

Alarm	Priority	Definition	Action needed
High PEEP	High	The measured positive end expiratory pressure is greater than or equal to	Check the patient. Confirm ventilator and alarm settings are appropriate.
High Blower Temperature	High	The blower temperature is too high.	The ventilation will be stopped. Contact service personnel.
Inspiratory Gas Temperature High	High	The gas temperature exceeds 45℃.	Disconnect the patient. Restart the ventilator.
Speaker Failure	High	The Speaker fails in self-test.	Contact service personnel.
Screen Failure	High	The blank screen occurs.	Contact service personnel.

7.6 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.

High Pressure

1. Make sure a demonstration lung is connected to the ventilator and start ventilation in PCV mode normally.
2. Set the Paw high alarm limit to current Peak+5cmH2O.
3. Squeeze the demonstration lung hard during inspiration.
4. Verify that the **High Pressure** alarm is activated, the ventilator cycles into exhalation, and airway pressure falls to PEEP level.

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.

Low Tidal Volume

1. Make sure a demonstration lung is connected 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.

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 Minute Volume** alarm is activated.

High PEEP

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.
3. Verify that the **High PEEP** alarm is activated.

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.

High Oxygen

1. Connect the ventilator to low-pressure oxygen supply. Set the oxygen supply type to LPO.
2. Make sure a demonstration lung is connected to the ventilator and start ventilation normally.
3. Set the oxygen high alarm limit to be less than the current oxygen concentration monitored value after ventilation is stable.
4. Verify that the **High Oxygen** alarm is activated.

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.

Running on Internal Battery

1. Connect the ventilator to AC power and push the power switch.
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 powered by AC again.

Battery Low

1. Connect the ventilator to AC power and push the power switch.
2. After the system starts up, disconnect the external power supply when the battery is fully charged.
3. Make sure a demonstration lung is connected to the ventilator and start ventilation normally.
4. The ventilation time is approximately 4 hours for the ventilator configured with one battery (approximately 8 hours for the ventilator configured with two batteries). The battery capacity is to be depleted. The **Battery Low** 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.

8 Special functions

8.1 O2 Enrichment

NOTE:

Oxygen alarms are suppressed while the O2 enrichment function is active.

O2 enrichment is not available with low pressure oxygen mode.

When the patient type is adult, the O2 enrichment function delivers 100% oxygen for 2 minutes. When the patient type is pediatric, the applied oxygen concentration during the enrichment maneuver is increased by 25% of the last oxygen setting (e.g. last oxygen setting 60%, resulting oxygen concentration during O2 enrichment maneuver 75%). This is useful for pre- or post-oxygenation before/after tracheal suctioning or for other clinical applications.

To start oxygen enrichment, press the O2 Suction button directly. After a short time, which is required for the oxygen concentration to rise, the ventilator starts delivering 100% oxygen (adult) or the current oxygen setting increased by 25% of the setting (pediatric). Afterwards the ventilator resets the concentration to the previous operator-set value.

To terminate delivery of O2 enrichment before the 2-min period is up, press the key again.

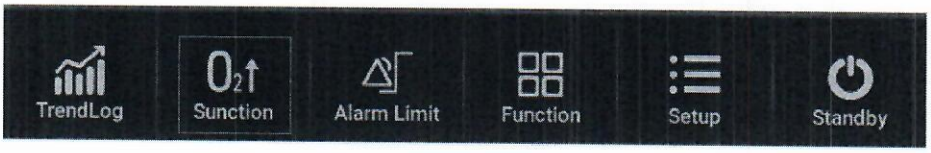


Figure 8-1. O2 Enrichment

8.2 Suctioning Tool

During suctioning, the patient's secretion can escape of the tubing. By using the suctioning tool the ventilation stops and prevents that secretion escapes.

1. To perform the suctioning manoeuvre press the O2 Enrichment button for pre-oxygenation.
2. Disconnection terminates the ventilation and starts the manoeuvre. For 60 seconds, all alarms are completely suppressed.

3. After reconnection the post-oxygenation starts and also for 60 seconds all acoustic alarms are suppressed. The alarm message and lamp is still active.
4. To terminate the pre- and post oxygenation manoeuvre press the O2 enrichment key.

8.3 Manual Breath

The Manual Breath function lets you deliver a manually triggered breath. Press and release the Manual Breath button on the Function window 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

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

To perform an inspiratory hold as follow:

1. Open the **Function** -> **Maneuvers** window.
2. Hold the button 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

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

To perform an expiratory hold as follows:

1. Open the **Function** -> **Maneuvers** window.
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 30 s additional.

8.6 Nebulizer

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 for 30 min. Nebulization can be activated in all modes of ventilation.

To start nebulization as follows:

1. Open the **Function** -> **Maneuvers** -> **Nebulization** window.
2. Set up the time period for nebulization.
3. Press the **Start** button to begin nebulization. To terminate nebulization press the button again.

8.7 STRC

Waring:

- Using the incorrect tube type or size setting can endanger the patient. To prevent possible patient injury due to inappropriate compensation, make sure to set these appropriately.
- STRC may induce auto triggering. If auto triggering occurs, first check the patient, breathing circuit, and other settings as possible causes before lowering the Compensate setting or disabling STRC.

To reduce the patient's work of breathing while on the ventilator, the ventilator's synchronized tube resistance compensation (STRC) feature offsets the flow resistance imposed by the endotracheal (ET) or tracheostomy (Trach) tube. STRC is active during inhalation. The compensation during exhalation can be optionally set.

To enable or disable STRC and adjust the settings as follows:

1. Open the **Menu** -> **Ventilation** window.
2. Select **ET tube** (endotracheal tube), **Trach tube** (tracheostomy tube), or **Disable STRC**.
3. If you selected **ET tube** or **Trach tube**, adjust the **Tube ID** and **Compensate** settings. If the ET tube is shortened, lower the **Compensate** setting.
4. Select **Expiration** to activate compensation during exhalation.
5. Confirm by selecting **Apply**.

8.8 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. Open the **Function** -> **Diagnostics** window.
2. Select **P0.1** on the screen.
3. Click **Start** button to start the measurement, and the result will be displayed after the measurement is completed.

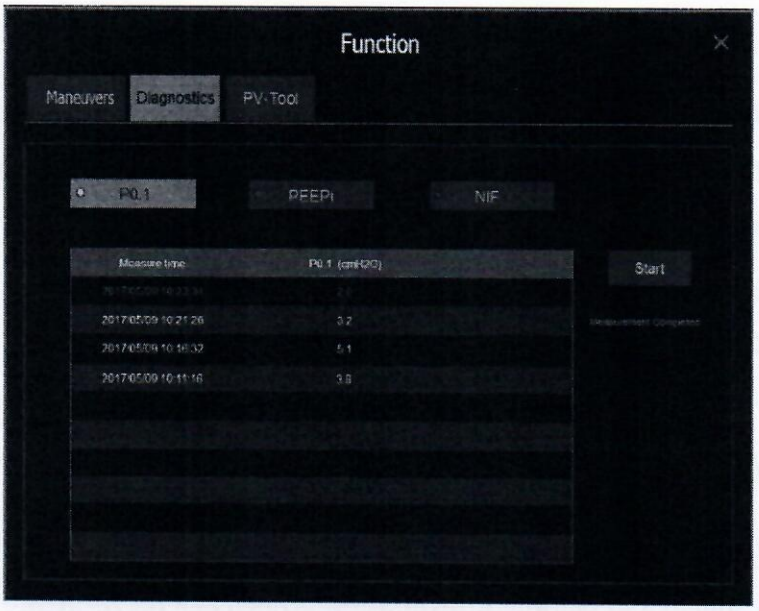


Figure 8-2. Diagnostics of Special Functions

8.9 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. Open the **Function** -> **Diagnostics** window.
2. Select **NIF** on the screen.
3. Click **Start** button to start the measurement, and the result will be displayed after the measurement is completed.

8.10 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. Open the **Function** -> **Diagnostics** window.
2. Select **PEEPi** on the screen.
3. Click **Start** button to start the measurement, and the result will be displayed after the measurement is completed.

8.11 O2 Therapy

O2 therapy is a method to increase O2 concentration in the airway at normal pressure through simple tube connections. O2 therapy is a way for hypoxia prevention or treatment, providing O2 concentration higher than that in the air.
To start O2 Therapy, Click the **Standby** button to enter the Standby mode, the Click the Start button for O2 Therapy.

8.12 Apnea Ventilation

The LYRA x2 ventilator provides apnea backup ventilation, a mechanism that minimizes possible patient injury due to apnea or cessation of respiration. Apnea can occur in any spontaneous mode, that is, one that relies solely on the patient to trigger. When the ventilator detects no inspiratory efforts or delivers no control breaths during the operator-set Apnea interval, it annunciates an Apnea alarm and starts apnea backup ventilation. It provides ventilation at the operator-selected apnea settings.
If the patient triggers two consecutive breaths, or the alarm is reset, the ventilator reverts to ventilation in the original support mode and at the original settings.

8.13 NIV

The NIV (Non Invasive Ventilation) is implementations of noninvasive positive pressure ventilation (NPPV). NPPV can use as its patient interface a mask, mouthpiece, or helmet-type interface, rather than an invasive conduit such as an endotracheal tube.

Intended for actively breathing patients, noninvasive ventilation is provided through a nonvented or nonported mask interface. Because this open breathing circuit permits air to leak around the mask or through the mouth, the ventilator achieves and maintains the prescribed pressure by adjusting the inspiratory flow.

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.

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 Cleaning, Disinfection and Sterilization

WARNING:

- Read the material safety data sheet for each cleaning agent.
- Wear gloves and safety glasses. A damaged O2 sensor can leak and cause burns (contains potassium hydroxide).
- Reuse of undisinfected reusable accessories or components may cause cross-contamination.

NOTE:

- Keep all liquids away from electronic parts.
- 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 safety valve assembly, and patient hose of the gas pathways through the ventilator can become contaminated with body fluids and expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

Ventilator exterior

Use a soft, moist, lint-free cloth to clean the outside surfaces of the ventilator.

The following cleaning agents are acceptable for use:

- Water
- Hydrogen peroxide (3%)

- Soapy water or mild detergent
- 70% isopropyl alcohol
- Germicidal disposable cloth (alkyl dimethyl benzyl ammonium chloride 0.07%; alkyl dimethyl ethybenzyl ammonium chloride 0.07%, remaining inert ingredients)
- Ammonium cleaner disinfectant
- Ethyl alcohol (75%)

Touchscreen

Dampen a soft cloth with isopropyl alcohol or a nonabrasive glass cleaner and wipe the screen. Avoid using cleaners other than glass cleaners. Do not use any vinegar-based solutions. Avoid using gritty cloths. Handle the touchscreen with care. To facilitate cleaning the touchscreen during ventilation, use the **Screen Lock** function.

Inspiration valve assembly and expiratory valve assembly

The following cleaning agents are acceptable for use:

- Water
- Alkalescent detergent (soap water etc.)

The following disinfection agents are acceptable for use:

- Medium- or high-efficiency detergent (alcohol or isopropyl alcohol etc.)
- Steam autoclave at maximum 134℃ (recommend for more than 20 minutes)

HEPA filter and Air intake filter

The following cleaning agents are acceptable for use:

- Water
- Alkalescent detergent (soap water etc.)
- Medium- or high-efficiency detergent (alcohol or isopropyl alcohol etc.)

Reusable patient circuit

The recommended interval for cleaning and disinfection is each patient or weekly.

The following cleaning agents are acceptable for use:

- Water (flush)
- Alkalescent detergent (soap water etc.).
- Water temperature 40°C (immersed for approximately three minutes).

The following disinfection agents are acceptable for use:

- Medium- or high-efficiency detergent (alcohol or isopropyl alcohol etc.)
- Steam autoclave at maximum 134℃ (recommend for more than 20 minutes)

Masks and other accessories

Follow the manufacturer's guidelines.

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 aXcent-approved 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
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 tightness test and the Flow Sensor calibration.

Interval	Part/accessory	Procedure
	Entire ventilator.	Run the system self-check.
Every day or as necessary	Breathing circuit.	Empty any water from breathing tubes or water traps. Inspect parts for damage. Replace as necessary.
Every month or as necessary	Air intake dust filters and fan filter	Check for dust and lint. If needed, clean or replace.
Every 6 months	Batteries	Recharge batteries by plugging ventilator into ac power source for at least 2 hours.
Yearly or every 5000h, or as necessary	Oxygen cell.	Replace if depleted.
	Air intake HEPA filter.	Replace.
	Ventilator.	Perform service-related preventive maintenance.
	Gas source sealing ring	Check the gas source sealing ring. Contact service personnel for replacement when necessary.
Every 30,000h	Turbine	Replace.
Every 4 years (30,000h)	Ventilator	Perform service-related preventive maintenance.
Every 6 years or as necessary	Battery of the clock module	Replace the battery of the clock module. Contact service personnel for replacement.

9.3 Disposal

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).

9.4 Storage

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 (see Chapter 10 Specifications).

9.5 Repacking and Shipping

If you must ship the ventilator, use the original packing materials. If these materials are not available, contact your aXcent representative for replacement materials.

9.6 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.

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 85%-100%.

 indicates the capacity of the battery is 65%-84%.

 indicates the capacity of the battery is 30%-64%.

 indicates the capacity of the battery is 0%-29%.

 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.

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

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.

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.

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 15℃ (60℉). Do not store batteries outside the environmental range of -20℃ (-4℉) to +60℃ (140℉).

10 Specifications

10.1 Physical Characteristic

Table 10.1 Physical Characteristic

Parameter	Specification
Dimensions (L*W*H)	310 mm * 323 mm * 400 mm 505 mm * 676 mm * 1380 mm (with trolley)
Weight	Approximately 9.9 kg Approximately 21 kg (with trolley)
Screen	Size: 13.1 TFT color touch screen Resolution: 1080*1920

10.2 Environmental Requirements

Table 10.2 Environment Requirement

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

10.3 Electrical Specifications

Table 10.3 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 T2.5AH/250V
Batteries	Number: One or Two (Optional) Type: Lithium-ion Voltage: 11.25 V Volume: 6400 mAh (for a single battery) Max. Charge Voltage: 13.05 V Recharge Time: 4.5 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: △Pinsp 15cmH2O / f 10bpm / Tinsp 2s / PEEP 5cmH20 / O2 21%.

10.4 Pneumatic Specifications

Table 10.4 Pneumatic Specification

Parameter	Specification
High-pressure oxygen inlet	Pressure:280 to 600KPa/41 to 87 psi/ 2.8 to 6.0 bar; Flow: ≥120L/min (STPD)
Low-pressure oxygen inlet	Pressure: < 100KPa/1bar/14.5psi Flow: ≤15L/min (STPD)
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
Compliance	Adult disposable circuit (including inspiratory safety valve, adult disposable breathing tubes, water trap, expiration valve): ≤4ml/cmH2O; Adult reusable circuit ((including inspiratory safety valve, adult reusable breathing tubes, water trap, expiration valve, Y piece): ≤2ml/cmH2O; Pediatric disposable circuit (including inspiratory safety valve, pediatric disposable breathing tubes, water trap, expiration valve):≤2 ml/cmH2O; Pediatric reusable circuit ((including inspiratory safety valve, pediatric reusable breathing tubes, water trap, expiration valve, Ypiece): ≤2 ml/cmH2O

Parameter	Specification
Inspiratory resistance	Not greater than 6 cm H2O at 60 L/min flow (adult reusable breathing tube) Not greater than 6 cmH2O at 30 L/min flow (pediatric reusable breathing tube)
Expiratory resistance	Not greater than 6 cm H2O at 60 L/min flow (adult reusable breathing tube) Not greater than 6 cmH2O at 30 L/min flow (pediatric reusable breathing tube)
Leakage	Not greater than 200mL/min@50cmH2O(adult tubes) Not greater than 100mL/min@40cmH2O(pediatric tubes)
Bacteria filter	Resistance: < 2 cmH2O at 60 l/min Particle size: Captures particles of 0.3 mm (micron) with > 99.99% efficiency Dead space ：< 80 ml
Pneumatic medicament Nebulizer	Synchronous with inspiration at 6 to 9 L/min flow

10.5 Control Settings

Table 10.5.1 Control Settings

Parameter	Range	Resolution
O2%	21%~100%	1%
VT	Adult: 100~2000 ml Pediatric: 20~300 ml	Adult: 10 ml Pediatric: 1 ml
f	1~100 bpm	1 bpm

Parameter	Range	Resolution
fSIMV	1~60 bpm	1 bpm
PEEP	OFF, 1~40 cmH2O	1 cmH2O
ΔPinsp	5~60 cmH2O	1 cmH2O
ΔPsupp	0~60 cmH2O	1 cmH2O
Tinsp	0.2~10 s	0.05 s
I:E	1:10~4:1	1:2
Tslope	0~2 s	0.05 s
Phigh	0~60 cmH2O	1 cmH2O
Plow	0~45 cmH2O	1 cmH2O
Thigh	0.2~30 s	0.1 s
Tlow	0.2~30 s	01 s
Trigger	-10 ~ -0.5 cmH2O 0.5~15 L/min	0.5 cmH2O 0.1 L/min
Exp%	Auto, 10%~85%	5%
Apnea Vent	On, Off	/
ΔPapnea	5~60 cmH2O	1 cmH2O
fapnea	1~80 bpm	1 bpm
VTapnea	Adult: 100~2000 ml Pediatric: 20 ~300 ml	Adult: 10 ml Pediatric: 1 ml

Parameter	Range	Resolution
Apnea Tinsp	0.2~10 s	0.05 s
Assist	On, Off	/
Sigh	On, Off	/
Sigh Interval	2 s~180 min	1 min
Sigh Cycle	1~20	1
∆int.PEEP	0~45 cmH2O	1 cmH2O
Tpause	OFF, 5~60%	1%
CPAP	4~25 cmH2O	1 cmH2O
EPAP	4~25 cmH2O	1 cmH2O
IPAP	4~25 cmH2O	1 cmH2O
Rise	1~5	1
Ramp	OFF, 5~45 min	1 min
Max P (VS maximum IPAP)	6~40 cmH2O	1 cmH2O
Min P (VS minimum IPAP)	4~25 cmH2O	1 cmH2O
Max P (PPV maximum pressure limit)	5~40 cmH2O	1 cmH2O

Parameter	Range	Resolution
Max V (PPV maximum volume limit)	200~3500 ml	5 ml
Max E	0~100 cmH2O/L	1 cmH2O/L
Max R	0~50 cmH2O/L/s	1 cmH2O/L/s
PPV%	0~100%	1%
Continuous Flow (O2 Therapy)	0-60 L/min	1 L/min
O2 Concentration (O2 Therapy)	21%~100%	1%

Table 10.5.2 Control Settings Accuracy

Parameter	Accuracy
O2%	Dual-limb: ±(3 vol.% +1% of setting)
	Single-limb: ±(5 vol.% +1% of setting)
VT	±(10 mL +10% of setting)
f	±1 bpm
fSIMV	±1 bpm
Tinsp	±0.1s or ±10% of setting, whichever is greater
I: E	2: 1 to 1: 4: ±10% of setting Other range: ±15% of setting
Tslope	±(0.2s+20% of setting)
PEEP	±(2.0 cmH2O + 5% of setting)

Parameter	Accuracy
△Pinsp	±(2.0 cmH2O + 5% of setting)
△Psupp	±(2.0 cmH2O + 5% of setting)
Phigh	±(2.0 cmH2O + 5% of setting)
Plow	±(2.0 cmH2O + 5% of setting)
Thigh	±0.2s or ±10% of setting, whichever is greater
Tlow	±0.2s or ±10% of setting, whichever is greater
Trigger	±(1.0 cmH2O + 10% of setting) ±(1.0 L/min + 10% of setting)
△int.PEEP	±(2.0 cmH2O + 5% of setting)
Exp%	±10%
fapnea	±1 bpm
△Papnea	±(2.0 cmH2O + 5% of setting)
VTapnea	±(10 mL +10% of setting)
Apnea Tinsp	±0.1s or ±10% of setting, whichever is greater
Tpause(%)	±0.1s or ±10% of setting, whichever is greater
CPAP	±(2.0 cmH2O + 5% of setting)
EPAP	±(2.0 cmH2O + 5% of setting)
IPAP	±(2.0 cmH2O + 5% of setting)
Rise	/
Ramp Time	±1 s

Parameter	Accuracy
Max P (VS maximum IPAP)	±(2.0 cmH2O + 5% of setting)
Min P (VS minimum IPAP)	±(2.0 cmH2O + 5% of setting)
Max P (PPV maximum pressure limit)	±(2.0 cmH2O + 5% of setting)
Max V (PPV maximum volume limit)	±15%
Max E	/
Max R	/
Continuous Flow (O2 Therapy)	±(2 L/min+10% of setting)
O2 Concentration (O2 Therapy)	±(3 vol.% +1% of setting)

Table 10.5.3 Control Settings Configuration

Parameter	Model
	c
O2%	√
VT	√
f	√
fSIMV	√
PEEP	√
ΔPinsp	√
ΔPsupp	√
Tinsp	√
I:E	√

Parameter	Model
	c
Tslope	√
Phigh	√
Plow	√
Thigh	√
Tlow	√
Trigger	√
Exp%	√
Apnea Vent	√
ΔPapnea	√
fapnea	√
VTapnea	√
Apnea Tinsp	√
Assist	√
Sigh	√
Sigh Interval	√
Sigh Cycle	√
Δint.PEEP	√
Tpause	√
CPAP	√
EPAP	√

Parameter	Model
	c
IPAP	√
Rise	√
Ramp	√
Max P (VS maximum IPAP)	√
Min P (VS minimum IPAP)	√
Max P (PPV maximum pressure limit)	√
Max V (PPV maximum volume limit)	√
Max E	√
Max R	√
PPV%	√
Continuous Flow (O2 Therapy)	√
O2 Concentration (O2 Therapy)	√

10.6 Monitored Parameters

Table 10.6.1 Monitored Parameters

Parameter	Range	Resolution	Accuracy
Paw	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
Ppeak	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
Pplat	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
Pmean	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
PEEP	0~100 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
MV	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
MVleak	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
MVspn	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
VTe	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTi	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTe spn	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)

Parameter	Range	Resolution	Accuracy
	100~4000 mL		±(3 mL + 10% of the actual reading)
VTe/IBW	0~100 mL	1 mL	±(10 ml + 3% of the actual reading)
	100~4000 mL		±(3 mL + 10% of the actual reading)
ftotal	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
fmand	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
fspn	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
Re	0~600 cmH2O/L/s	1 cmH2O/L/s	0~50cmH2O/(L/s): ±10cmH2O/(L/s) Other range: /
Ri	0~600 cmH2O/L/s	1 cmH2O/L/s	0~50cmH2O/(L/s): ±10cmH2O/(L/s) Other range: /
Cdyn	0~300 ml/cmH2O	1 ml/cmH2O	0~100ml/cmH2O: ±20 % of actual reading or ±10 ml/cmH2O, whichever is greater Other range: /
Cstat	0~300 ml/cmH2O	1 ml/cmH2O	0~100ml/cmH2O: ±20 % of actual reading or ±10 ml/cmH2O, whichever is greater Other range: /
Rcexp	0~10.0 s	0.01 s	/
WOB	0~100 J/min	1 J/min	/

Parameter	Range	Resolution	Accuracy
RSBI	0~999 1/(min·L)	1 1/(min·L)	0~1000 1/(min·L): ±15 % of actual reading or ±20 1/(min·L), whichever is greater
NIF	-45~0 cmH2O	0.1 cmH2O	± (2 cmH2O + 4% of the actual reading)
P0.1	-20~0 cmH2O	0.1 cmH2O	± (2 cmH2O + 4% of the actual reading)
PEEPi	0~100 cmH2O	1 cmH2O	/
PIP	0-50 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
EPAP	0-50 cmH2O	1 cmH2O	± (2 cmH2O + 4 % of actual reading)
MV	0~99.9 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater
VT	0~3000 mL	1 mL	± (4 mL + 10% of the actual reading)
f	0~200 bpm	1 bpm	±5 % of actual reading or ±1bmp, whichever is greater
Pt.leak	0~200 L/min	0.1 L/min	/
Pt.Trig	0~100%	1%	±10 %
Tot.leak	0~200 L/min	0.1 L/min	/
Ti/Ttot	0~91%	1%	±5 %

Parameter	Range	Resolution	Accuracy
FiO2	15~100 %	1%	±(2.5 vol. % + 2.5% of the actual reading) 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: ≤ 45 s.
Continuous Flow (O2 Therapy)	0~60 L/min	0.1 L/min	±8 % of actual reading or ± 0.3 L/min whichever is greater

Table 10.6.2 Monitored Parameters Configuration

Parameter	Model
Paw	√
Ppeak	√
Pplat	√
Pmean	√
PEEP	√
Insp Flow	√
Exp Flow	√
MV	√
MVleak	√
MVspn	√
VTe	√

Parameter	Model
VTi	√
VTe spn	√
VTe/IBW	√
ftotal	√
fmand	√
fspn	√
Re	√
Ri	√
Cdyn	√
Cstat	√
Rcexp	√
WOB	√
RSBI	√
NIF	√
P0.1	√
PEEPi	√
PIP	
EPAP	
Pt.leak	
Pt.Trig	

Parameter	Model
Tot.leak	
Ti/Ttot	
FiO2	√
Continuous Flow (O2 Therapy)	√

10.7 Alarms

Table 10.7.1 Alarms Settings (LYRA x2)

Alarms		Range
Paw	High Limit	10~85 cmH2O
MV	High Limit	Adult: Low Limit+0.1~100 L/min
		Pediatric: Low Limit+0.1~60 L/min
	Low Limit	Pediatric: 0.1~ (High Limit−0.1) or 30.0, whichever is smaller
		Adult: 0.1~ (High Limit−0.1) or 50.0, whichever is smaller
VTe	High Limit	Adult: off, (Low Limit +10 or 110 whichever is greater) ~4000
		Pediatric: off, Low Limit +10 or 25 whichever is greater ~600
	Low Limit	Adult: off, 50 ~ (High Limit -10) mL
		Pediatric: off, 10 ~ (High Limit -10) mL
ftotal	High Limit	Adult / Pediatric: off, 1~150 bpm
Tapnea	High Limit	Adult / Pediatric: 5~60 s
FiO2 (Low-pressure oxygen)	High Limit	Adult / Pediatric: (Low Limit +2) ~100 %
	Low Limit	Adult / Pediatric: 18 ~ (High Limit -2) %

Table 10.7.2 Alarms Settings (LYRA x2 b)

Alarms		Range
Inspiratory Pressure	High Limit	Adult / Pediatric: (Low Limit +2) ~ 50 cmH2O
	Low Limit	Adult / Pediatric: Off, 1 ~ (High Limit -2) cmH2O
MV	Low Limit	off, 1~99 L/min
VT	High Limit	Adult / Pediatric: (Low Limit +10) ~ 2500 mL
	Low Limit	Adult / Pediatric: off, 5 ~ (High Limit -10) mL
f	High Limit	Adult / Pediatric: (Low Limit +2) ~ 90 bpm
	Low Limit	Adult / Pediatric:1 ~ (High Limit -2) bpm
LIPT (Low Inspiratory Pressure Delay Time)	Low Limit	Adult / Pediatric:5~60 s

10.8 Configuration Specifications

Table 10.8.1 Feature Specifications

Features		Model		
		a	b	c
Ventilation Mode	CPAP (Continuous Positive Airway Pressure)	√	√	
	PCV (Pressure Control Ventilation)	√	√	√
	PPS (Proportional Pressure Support)	√	√	
	S/T (Spontaneous/Timed)	√	√	
	VS (Volume Support)	√	√	
	VCV (Volume Control Ventilation)	√		√
	VSIMV (Volume Synchronized Intermittent Mandatory Ventilation)	√		√
	PSIMV (Pressure Synchronized Intermittent Mandatory Ventilation)	√		√
	PRVC (Pressure Regulated Volume Control)	√		√
	V⁺SIMV (PRVC + SIMV)	√		√

Features		Model		
		a	b	c
	CPAP/PSV (Continuous Positive Airway Pressure/Pressure Support Ventilation)	√		√
	BPAP (Bilevel Positive Airway Pressure)	√		√
	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)	√		√
	O2 Enrichment	√		√
	Suction Tool	√		√
	Nebulization	√		√
	Manual breath	√		√
	Inspiratory Hold	√		√
	Expiratory Hold	√		√
	P0.1 (Airway Occlusion Pressure)	√		√
	NIF (Negative Inspiratory Force)	√		√
	PEEPi (Intrinsic PEEP)	√		√

Table 10.8.2 System Configuration

Items	Range
Screen brightness	0-100%
Tinsp/I:E	Tinsp , 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
O2 Monitoring	ON / OFF
System Date	/
System Time	/
Date Format	YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY
Time Format	12h, 24h

10.9 Factory Default Settings

Table 10.9.1 Ventilation Mode Settings

Mode	Parameter	Factory Default Settings
VCV	VT	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s

Mode	Parameter	Factory Default Settings
	I:E	1:2
	Tslope	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	5cmH2O
	Tpause	OFF
PCV (INV)	O2% (HPO)	21%
	f	Adult: 10 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	ΔPinsp	15 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	I:E	1:2
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Assist	ON
	Sigh	OFF
	Sigh Interval	1 min

Mode	Parameter	Factory Default Settings
	Sigh Cycles	3
	Δint.PEEP	5 cmH2O
CPAP/PSV	O2% (HPO)	21%
	PEEP	3 cmH2O
	ΔPsupp	0 cmH2O
	Tinsp (Only in NIV mode)	Adult: 2.00 s Pediatric: 1.00 s
	Tslope	0.2 s
	F-Trigger	Adult: 2.0 L/min Pediatric: 1.0 L/min
	Exp%	Auto
	Δpapnea	15 cmH2O
	fapnea	1 bpm
	Apnea Tinsp	Adult: 2.00 s Pediatric: 1.00 s
	VTapnea	Adult: max(7*mL/kg*IBW, 100) Pediatric: 7*mL/kg*IBW
PSIMV	O2% (HPO)	21%
	fSIMV	Adult: 5 bpm Pediatric: 20 bpm
	PEEP	3 cmH2O
	ΔPinsp	15 cmH2O
	ΔPsupp	0 cmH2O
	Tinsp	Adult: 2.00 s Pediatric: 1.00 s

S C DANSON srl **Formular** nr. 2

FORMULAR DE OFERTĂ

Către :

Spital Clinic Judetean de Urgenta Arad
Cod de identificare fiscala: 3519879;
Adresa: Strada: Andreny Karoly, nr. 2-4;
Localitate: Arad; Cod Postal: 310037

1. Examinând documentaţia de atribuire, subsemnaţii, reprezentanţi ai ofertantului S C DANSON srl, ne oferim ca, în conformitate cu prevederile şi cerinţele cuprinse în documentaţia mai sus menţionată, să furnizăm echipamentele medicale (dosar 3519879_2020_PAAPD1138914) din lotul 3respetiv 9buc aparate de ventilatie mecanica **(97.580lei/buc x 9buc = 878.220lei)** si lotul 2 respectiv 3ventilatoare de transport **(39.330lei/buc x 3buc = 117.990lei)** şi să asigurăm toate serviciile conexe/suport furnizării precizate în documentatia de atribuire pentru suma de **996.210lei** (nouasutenouazecisisasedemiidouasutezece lei) platibilă după recepţia produselor, , la care se adaugă TVA în valoare de **189.279.90lei** (unasutaoptzecisinouademiidouasutesaptezecisinoua de lei si 90%)

2. Ne angajăm ca, în cazul în care oferta noastră este stabilită câştigătoare, să furnizăm echipamentele medicale din lotul 3respetiv 9buc aparate de ventilatie mecanica si lotul 2 respectiv 3ventilatoare de transport şi să asigurăm toate serviciile conexe/suport furnizării precizate în documentatia de atribuire în termenul de livrare de 6-8saptamai de la semnarea contractului.

3. Ne angajăm să menţinem această ofertă valabilă pentru o durată de120zile, (unasutadouazeci de zile) respectiv până la data de 30.08.2020 şi ea va rămâne obligatorie pentru noi, şi poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

4. Am înţeles şi consimţim că, în cazul în care oferta noastră este stabilită ca fiind câştigătoare, să constituim garanţia de bună execuţie în conformitate cu prevederile din documentaţia de atribuire.

5. Precizăm că:
|_| depunem ofertă alternativă, ale carei detalii sunt prezentate într-un formular de ofertă separat, marcat în mod clar „alternativă"/"altă ofertă;".
X nu depunem ofertă alternativă.

6. Până la încheierea şi semnarea contractului de achiziţie publică aceasta ofertă, împreună cu comunicarea transmisă de dumneavoastră, prin care oferta noastră este acceptată ca fiind câştigătoare, vor constitui un contract angajant între noi.

7. Înţelegem că nu sunteţi obligaţi să acceptaţi oferta cu cel mai scăzut preţ sau orice ofertă primită.

Data 30.04.2020.

Dan Ionut Stroe

.....

în calitate de Director General
legal autorizat să semnez
oferta pentru şi în numele S C DANSON srl.

Anexa la formularul 2

S C DANSON srl

Centralizator preturi

Nr. Lot	Denumire achizitie	U.M.	Cant.	PU estimat lei fără TVA	Valoare estimata lei fără TVA
LOT 2	Ventilator de transport	buc	3	39.330	117.990
LOT 3	Aparat de ventilatie mecanica	buc	9	97.580	878.220
	TOTAL				**996.210**

Data 30.04.2020.

Dan Ionut Stroe

.....

în calitate de Director General
legal autorizat să semnez
oferta pentru şi în numele S C DANSON srl.