DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

DIXION

Aeros 4600 Ventilator

User Manual

Version No.: V1.2
Release Date: August 2024
Part No.: UM04-06-V1.2

Attention

DIXION Vertrieb medizinischer Geräte GmbH (hereinafter referred to as "Dixion") holds the copyrights to this non-public published manual, and reserves the rights to keep it as a secure document. Refer to this manual when operating, maintaining and repairing products only. Only Dixion may provide permission for the use of or copies of this document to others.

Proprietary materials protected by the copyright law are included in this manual. No section of it may be duplicated, copied, or translated into other languages without prior written approval from Dixion who reserves the copyright.

Everything written within this manual is considered to be correct, but it is not a substitute for the exercise of professional judgment. Dixion is not legally responsible for any mistakes printed within and/or any damages caused by incorrect connection and operation of equipment. Dixion does not supply privileges endowed by the patent law to any other parties. Dixion is not legally responsible for the results caused by patent law breaking or any rights of the third party violating.

Any user must read this article before using the products of Dixion. This article exposes the operating steps that must be read carefully. Improper use might endanger equipment or persons. The company will not undertake the responsibility for the safety, reliability and performance if equipment is used improperly. The company will not offer complimentary service for misused equipment.

Dixion has the right to revise any content in this manual without notice; and has no obligation to update either hardware or software of the equipment described herein to the useror owner.

Warning for use

Welcome to use our products!

In order to use this product correctly and effectively, please read these user manual carefully and completely before using the product for the first time.

When using the product, always proceed in accordance with the information provided in these user manual on the basis of fully understanding the information in this manual.

This product is only for intended use as described in these user manual.

Only specially trained service professionals are authorized to perform the connection and service of this product.

For any situation in the use process, please contact with us. We will provide you with warm service.

Product specifications are subject to change without notification.

Tables of Content

1 Introduction

Review all information in this manual thoroughly before attempting to use the equipment.

This equipment must be used under the supervision of a physician.

1.1 Manufacturer's Responsibility

Dixion is responsible for the security; reliability and functions of the equipment, only when the following requirements are adhered strictly to:

- Only individuals authorized by Dixion may perform connection, adjustments andrepairs.
- Necessary electrical equipment and the working environment must be in accordance with the national standards, professional standards and the requirements listed in this manual.
- Equipment must be used as instructed in this manual.

 **CAUTION:** This equipment is not for home use.

 **WARNING:** This ventilator must be used only under the responsibility and on the prescription of a doctor.

Dixion will supply service information to help customers, under the guidance of qualified technicians, to repair the equipment.

1.2 Operator's Responsibility for Patient Safety

The operator of this ventilator must recognize their full responsibility for choosing appropriate ventilation settings to ensure proper ventilation and patient safety. The responsibility for the selection of the appropriate level of patient monitoring depends solely on the equipment operator.

All the monitoring information is for reference only; it should not be used as the sole basis for therapeutic or diagnostic decisions.

Whenever a patient is connected to the ventilator, constant attention by qualified medical personnel is required in order to provide immediate corrective action in case of a malfunction and/or alarm occurrence.

The company will provide functional block diagram at the user's request for charge, accompanied by explanation on calibration method and other information, to help users assign appropriate technical staff to repair and maintain the equipment as stipulated.

1.3 Definitions

This manual uses three special indicators to convey information of a specific nature. They include:

WARNING:	Indicates a condition that can endanger the patient or the ventilator operator.
CAUTION:	Indicates a condition that can damage the equipment.
NOTE:	Indicates points of particular emphasis on making operation of the ventilator more efficient or convenient.

1.4 Warnings, Cautions and Notes

1.4.1 Warnings

WARNING: Do not use the system until you have read and understood this manual including:

- All connections of the system
- All warnings and cautions
- Operation procedure of each and every component of the system
- Test procedure of each and every component of the system

WARNING: Place the ventilator in a safe place when ventilating.

WARNING: Do not place the ventilator in a position where a child, pet or pest can reach it or in any position that might cause it to fall on the patient or someone else.

WARNING: Before using the ventilator, carry out pre-use inspection according to Chapter 5 of this manual, and use it only after the function is confirmed to be normal. The user is responsible for the consequences of using the function without performing the function confirmation.

 **WARNING:** Every 6 months after use, the ventilator needs a comprehensive preventive maintenance.

 **WARNING:** The users must familiarize themselves with the operation and use of this machine prior to first clinical use with a patient.

 **WARNING:** In the case of high ambient temperatures, it may take a significant period of time to cool the internal temperature of the ventilator to the proper operating range. To avoid injury to the patient, ensure that the air inspired by the patient does not exceed 41°C (106°F). If in doubt, replace the ventilator.

 **WARNING:** To avoid an electrical shock hazard while servicing the ventilator, be sure to remove all power to the ventilator by disconnecting the power source and turning off all ventilator power switches.

 **WARNING:** Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorized should repair, open or service the ventilator.

 **WARNING:** To ensure proper servicing and avoid the possibility of physical injury, only qualified personnel should attempt to service or make authorized modifications to the ventilator.

 **WARNING:** An authorized service engineer must first connect the ventilator by executing Dixion's connection procedure, which includes calibration of various system components, before connecting a patient to the ventilator.

 **WARNING:** If the ventilator is damaged or its external housing is not correctly closed or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor just like a burning odor, fire, alarms not triggered during the start-up procedure), the oxygen, power and backup power supplies should be disconnected and use of the device stopped immediately.

 **WARNING:** If a fault is detected in the ventilator so that its life support functions are no longer assured: start ventilation using an independent ventilation device (resuscitation bag) without delay, if necessary with PEEP and/or increased inspiratory O_2 concentration.

 **WARNING:** Before activating any part of the ventilator, be sure to check the equipment for proper operation and, if appropriate, run PUT (pre-use test) as described in this manual, see section 5.

 **WARNING:** An alternative source of ventilation, such as manual respiratory equipment, should always be available when using the ventilator.

 **WARNING:** Alarm volume should be adjusted with respect to the ventilator’s operating environment and so that the patient's caretakers can hear the alarms. The audible alarm vents located at the front of the device should never be obstructed. The alarm can be paused by pressing Alarm Silence button once the alarm has been declared.

 **WARNING:** The ventilator is not intended to be a comprehensive monitoring device and does not activate alarms for all types of dangerous conditions for patients on life-support equipment.

 **WARNING:** While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.

 **WARNING:** A ventilator-dependent patient should always be monitored by trained and competent medical personnel. Ensure that the patient’s caregiver is able and prepared to take suitable action in the event the ventilator identifies an alarmed condition or experiences a problem.

 **WARNING:** An alternative source of ventilation, such as manual respiratory equipment, should always be available when using the ventilator.

 **WARNING:** Do not connect inspiratory or expiratory circuits to the exhaust port.

 **WARNING:** Ensure that inspiratory and expiratory circuits are connected to the correct port before operation of equipment.

 **WARNING:** The expiratory gas pathway may become contaminated with body fluids or expired gases during normal use, and the inspiratory gas pathway may become contaminated during fault condition, such as occlusion, breath hoses disconnection.

 **WARNING:** Disposable breathing hoses shall not be reused. Reuse of the single use hoses can cause cross infection.

 **WARNING:** A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection.

 **WARNING:** To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

 **WARNING:** For the disposal methods of disposable components and accessories with potential biological hazards, follow the requirements of the local authorities.

 **WARNING:** Ensure the hoses used have the appropriate resistance and compliance to ensure proper therapy.

 **WARNING:** Ensure that the AC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.

 **WARNING:** Ensure that the DC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.

 **WARNING:** Do not disconnect the cable between the Main Control Unit and the display screen while Ventilator is operating.

 **WARNING:** The ventilator must not be connected to any anti-static or electrically conductive hoses, tubes or conduits.

 **WARNING:** Adding attachments or other components or sub-assemblies to the ventilator breathing system can change the pressure gradient across the ventilator breathing system and that such changes to the ventilation breathing system can affect the ventilator performance.

 **WARNING:** Expiratory module is heated; use caution to avoid burns.

 **WARNING:** Use caution when handling flammable or fragile components.

WARNING: Do not place containers of liquids (such as humidifier water reservoirs) on the top of or above ventilator. Liquids getting into the ventilator can cause equipment malfunction with the risk of patient injury.

WARNING: Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

WARNING: In particular, the use of nearby mobile and portable communications equipment using radio frequencies, such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation.

WARNING: Ventilator should not be used in hyperbaric oxygen chamber.

WARNING: Regularly check for leaks, If internal leakage is found, stop the ventilator.

WARNING: Do not install a humidifier upstream of the ventilator.

WARNING: Ensure that the ventilator is switched off and disconnected from all external power supplies before installation.

WARNING: To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the air inlet filter or the cooling apertures located in the side, rear, and bottom panels of the ventilator.

WARNING: To avoid a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (e.g., flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.

WARNING: The Ventilator is not intended for use in the areas with risk of explosion. Do not operate the ventilator in the presence of flammable anesthetics.

WARNING: The Ventilator is not designed for use in an MRI environment. Do not use the Ventilator near an MRI machine; could result in the injury or equipment damaged.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth. A “hospital grade” cord must be used and connected to a “hospital grade” electrical outlet.

1.4.2 Cautions

 **CAUTION:** Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.

 **CAUTION:** The breathing circuit must not be connected during the power up or pre-use test(PUT).

 **CAUTION:** If the system test failed, do not use the system. Attempt to troubleshoot and fix the failure. If you are unable to fix the device, ask an authorized service representative to repair the device.

 **CAUTION:** Check the ventilator periodically as outlined in this manual; do not use if defective. Immediately replace parts that are broken, missing, obviously worn, distorted, or contaminated.

 **CAUTION:** When used under normal circumstances–a relatively dust-free atmosphere, and without damage to the device and its components (shocks, cracks, significant dirt)–the intervals for replacing the ventilator's consumable elements are as follows: Chapter 8.2.2"Periodic Maintenance Schedule".

 **CAUTION:** Measurements can be affected by mobile and RF communications equipment.

 **CAUTION:** Do not use oxygen hoses that are worn, frayed, or contaminated by combustible materials such as grease or oils. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

 **CAUTION:** Follow your hospital infection control guidelines for handling infectious material. Dixion recognizes that cleaning, sterilization, sanitation, and disinfection practices vary widely among healthcare institutions. It is not possible for Dixion to specify or require specific practices that will meet all needs, or to be responsible for the effectiveness of cleaning, sterilization, and other practices carried out in the patient care setting.

 **CAUTION:** Equipment not suitable for use in the presence of a Flammable Anesthetic mixture with Air or with Oxygen or Nitrous Oxide.

 **CAUTION:** In case of fire or a burning odor, immediately disconnect the ventilator from the oxygen supply, facility power and backup power source.

 **CAUTION:** During operation, do not block: Speaker Holes, Exhaust Port, Air Inlet or Cooling Fan.

 **CAUTION:** Do not use the Ventilator in an MRI environment.

 **CAUTION:** The ventilator shall not be used in a hyperbaric chamber.

 **CAUTION:** The ventilator shall not be used with helium or mixtures with helium.

 **CAUTION:** Tip over hazard; use care when moving ventilator mounted to trolley as the device could tip over leading to injury or damage of equipment.

 **CAUTION:** Do not use sharp objects to make selections on the LCD touch screen or panel.

 **CAUTION:** To ensure stability, when the Ventilator is mounted on a trolley.

 **CAUTION:** The Network interface connection is for authorized service only.

 **CAUTION:** The battery should be removed if equipment will not be in service for more than 6 months. See Section 8.5 for battery replacement guidance.

 **CAUTION:** Do not immerse the oxygen sensor or the connector in any type of liquid.

 **CAUTION:** If the ventilator is not placed in the normal storage environment, it must be placed in the normal working environment for 24 hours before using.

 **CAUTION:** When the ambient temperature is 20°C, 2 hours are required to both warm the vent from the minimum storage temperature and to cool the vent from maximum storage temperature prior to use.

 **CAUTION:** Never immerse the device in any liquid or allow liquid to enter any device opening. Never place a container of liquid on top of the device. Immediately wipe away any

liquid on the surface of the device. To avoid damage to the batteries or electrical components, prevent fluids from entering the device.

 **CAUTION:** Storage environment: -20℃~+60℃ and ≤95%RH.

 **CAUTION:** Operating environment: 5℃~40℃ and 5%RH~95%RH.

 **CAUTION:** Do not connect items that are not specified as part of the system.

 **CAUTION:** The auxiliary outlet is only for the recommended humidifier; do not connect to any other equipment or an additional multiple socket outlets.

 **CAUTION:** When using a humidifier, user should frequently check the water trap and look for water in the hose. If water is found in the hose, the water should be removed. It is also important that the water trap is positioned in a way which is lower than the patient tubes.

 **CAUTION:** Connecting electrical equipment to auxiliary outlet effectively leads to creating a medical equipment system, and can result in a reduced level of safety, make sure the ME SYSTEM comply with requirements of IEC 60601-1:2005+AMD1:2012 CSV. The user who connects is responsible for the standard for the requirements applicable to the medical equipment system.

 **CAUTION:** When the ventilator is used in EM environment，the ventilator should be stopped immediately if the essential performance is degraded or lost.

 **CAUTION:** Long term continuous use of ventilator may lead to respiratory dependence, which has nothing to do with the performance of ventilator, so doctors need to adopt appropriate ventilation strategy.

 **CAUTION:** To minimize the risk of damage, you must use the Dual Bag to transport.

1.4.3 Notes

 **NOTE:** The user of this product shall have sole responsibility for any ventilator malfunction due to operation or maintenance performed by anyone not trained by Dixion.

 **NOTE:** Usage of a filter on the expiratory side will increase the resistance of the patient circuit.

NOTE: In non-invasive (NIV) ventilation, the exhaled volume of the patient can differ from the measured exhaled volume due to leaks around the mask

NOTE: Do not sterilize or immerse the Mainstream CO_2 Adapter in any fluids. See Section 3 for proper use of Mainstream CO_2 Adapter.

NOTE: All parts of the ventilator system are suitable for use within the patient environment.

NOTE: All gas volume, flow, and leakage specifications in this manual are expressed at STPD (standard temperature and pressure dry), except when specified with another condition.

NOTE: Users do not need to pay attention to the "Data Lost 3008" event information in the log, which has no impact on machine performance.

NOTE: Do not touch the switch while the ventilator is running.

NOTE: When the ventilator is working, ensure that the network power supply is normal.

NOTE: In order to prevent virus infection, ensure that the access equipment is safe.

1.5 Intended Use

The AEROS 4600 Ventilator is intended to provide continuous ventilation treatment to patients and monitoring of patients with respiratory failure or respiratory insufficiency, requiring respiratory support.

1.6 Indications for Use

The AEROS 4600 Critical Care Ventilator is an electrical control, electrical power machine, which is used in ICU for the critical care, in Respiratory Department or Emergency Department for the rescue and therapy of the patient with respiratory insufficiency, and in other departments for providing respiratory support for the patient.

The Critical Care Ventilator should only be used by:

• Professional health care providers;

• Technicians that have completed training in the use of this system.

The Critical Care Ventilator is applicable for patients requiring a tidal volume of 20 mL and up, who requires the following types of ventilatory support: Positive Pressure Ventilation, delivered invasively (by ET or Tracheotomy tube) or non-invasively (by mask) via Assist/Control, SIMV, CPAP and other modes of ventilation.

The Critical Care Ventilator is intended for use in hospital and hospital-type facilities. It may be used during intra-hospital transport provided that electrical power is supplied.

WARNING: The patients requiring a tidal volume below 20 mL must not be ventilated with this device.

1.7 Contraindication and Complication

1.7.1 Contraindication

AEROS 4600 Ventilator is contraindicated for patients with any of the following conditions:
- Pneumothorax and mediastinal emphysema without drainage.
- Massive pleural effusion.
- Giant lung bullae.
- Uncorrected hypovolemic shock.

1.7.2 Complication

The following complications may occur when using ventilator：
- Due to the long-term use of pressure control or volume control ventilation mode, the patient is dependent on the ventilator, and the respiratory system muscles of the patient can not be exercised and can not be weaning.
- Injuries associated with the intubation：laryngeal edema caused suffocate after extubation and infection caused pneumonia.
- Increased thoracic pressure： Circulatory depression caused hypotension or shock and Increased intracranial pressure (ICP) caused encephaledema.
- High oxygen concentration inhalation： Hperoxia and oxygen toxicity caused lung injury.
- Low oxygen concentration inhalation： Hypoxemia caused histanoxia, even life-threatening.
- Hypoventilation： Hypercapnia and carbon dioxide retention caused respiratory acidosis.
- Hyperventilation： Hypocapnia caused respiratory alkalosis.
- Due to immobilization, prolonged use of sedatives, use of neuromuscular blocking agents, systemic muscular weakness and amyotrophy are caused, resulting in difficulty in weaning.
- Lung hyperactivity and excessive setting of VT, PS and peep, caused hyperdistraction of the lung, resulting in ventilated lung injury.

1.8 Abbreviations and Definitions

(S)	Set average value
(M)	Measured average value
CPAP	Continuous Positive Airway Pressure (S)
f	Breath rate (frequency) in bpm, i.e. ventilation times per minute (S)
f_{spont}	Patient's spontaneous respiratory frequency (M)
f_{total}	Total breath rate, i.e. the sum of breath rate f and spontaneous breath rate f_{spont} (M)
O_2	Inspiratory O_2 concentration (S & M)
I : E	The ratio of Inspiration to Expiration (M)
MV	Expiratory minute volume (M)
MV_{spont}	Spontaneously breathed minute volume (M)
MV_{leak}	Leakage minute volume (M)
Paw	Patient airway pressure (M)
PEEP	Positive End-Expiratory Pressure, which can improve the patient's oxygenation (S & M)
PEEPi	Intrinsic Positive End-Expiratory Pressure (M)
P_{insp}	Upper pressure level in PCV mode (S)
P_{mean}	Mean airway pressure. This value is updated at the end of the last respiratory cycle, hence, is a continuous average (M)
P_{peak}	Airway pressure peak value during one ventilatory cycle (M)
P_{plat}	End-inspiratory airway pressure (M)
P_{min}	Minimum airway pressure (M)
P_{sens}	Pressure sensitivity (S)
P_{supp}	Pressure support (S)
P_{high}	Upper pressure level in BIVENT and APRV (S)
P_{low}	Lower pressure level in BIVENT and APRV (S)

T_{imax}	Maximum inspiratory time (S)
T_{insp}	Inspiratory Time (S)
T_{pause}	Inspiratory Pause Time, to increase the inspiratory time to improve the patient's oxygenation (S)
$\dot{V}sens$	Trigger by flow rate (S)
V_T	Tidal volume of mechanical ventilation (S)
V_{te}	Expiratory tidal volume (M)
V_{ti}	Inspiratory tidal volume (M)
E_{sens}	Expiratory trigger sensitivity (S)
$ETCO_2$	End-expiratory CO_2 concentration (M)
WOB	Work of breathing (M)
T_c	Time constant (M)
Leak%	Leakage percentage (M)
Cdyn	Dynamic compliance (M)
Cstatic	Static compliance (M)
Rinsp	Inspiratory resistance (M)
Rexp	Expiratory resistance (M)
Elastic	Elastic resistance (M)
IP21	Solid particle protection level 2; Liquid ingress protection level 1

1.9 Frequently Used functions

(1) Power On / Off Switch
(2) Connect patient hoses and gas supply
(3) Pre-Use Test
(4) Settings
(5) Start Ventilation/Standby
(6) Monitoring data
(7) Alarm, Event/Alarm log
(8) Calibration
(9) Cleaning and disinfection

(10) Breathing Circuit Components

(11) System interconnections for gas supply

(12) Humidifier and system interconnections

(13) Nebulizer and system interconnections

1.10 Symbols

Instead of illustrations, symbols may be utilized. Not all of these symbols may necessarily appear on the equipment or in this User manual. The symbols include:

	On (Power)		Protection Class Type B
	Off (Power)		Protection Class Type BF
	Follow user manual		Warning & Caution
	Protective earth ground		Dangerous voltage
	EQUIPOTENTIAL connection		loudspeaker
	Lock		Manufacturer
	Unlock		Date of production
	Inspiratory hold	SN	Serial Number
	Nebulization		Expiratory hold
$O_2\%$	Intelligent increase of oxygen		Manual inspiration

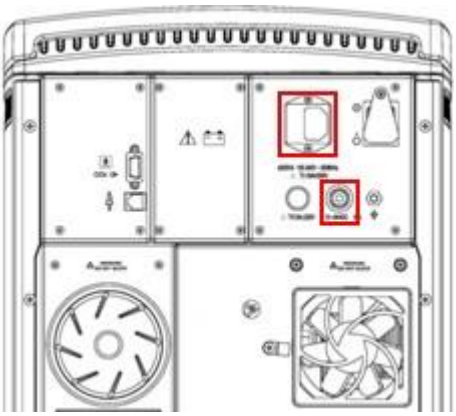
	Standby		Waveform freeze
	AC power	 int.	Internal Battery
	USB device		Refer to documentation
	Prompt message		Already online
	Flow trigger		Pressure trigger
	Adult		Manual trigger
	NIV modes		Child
	Main Menu		Invasive modes
	Neonate		Alarm Silence Button
	Single use		Disposal of Waste
IP21	Ingress Protection IP21		

1.11 AEROS 4600 Ventilator Quick Start Guide

Review all information in the Operator's Manual before attempting to use this equipment.

1. Connect Power Supply

Connect to AC Power Source, DC Power Source or Utilize Battery

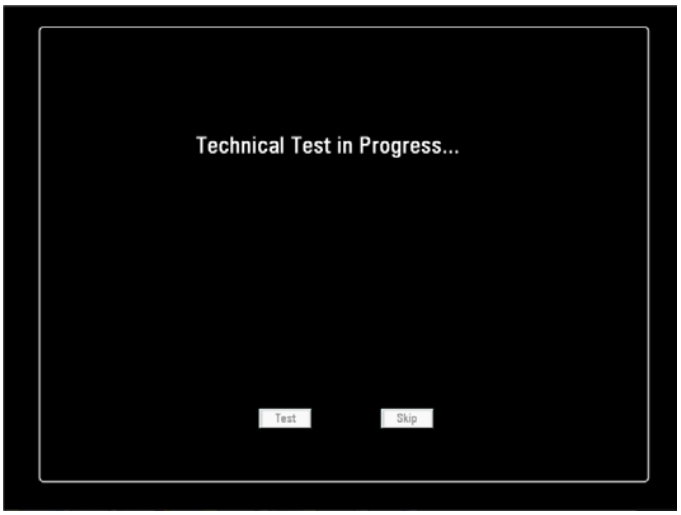


2. Connect Gas Source

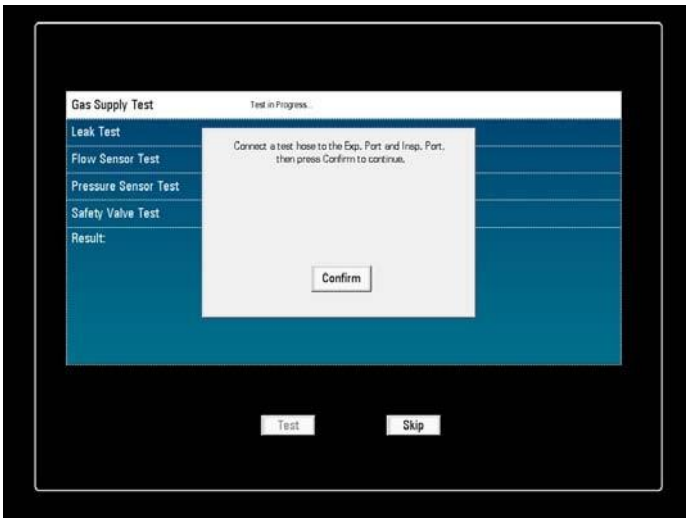
3. Power on Ventilator

Switch Ventilator on by turning to:

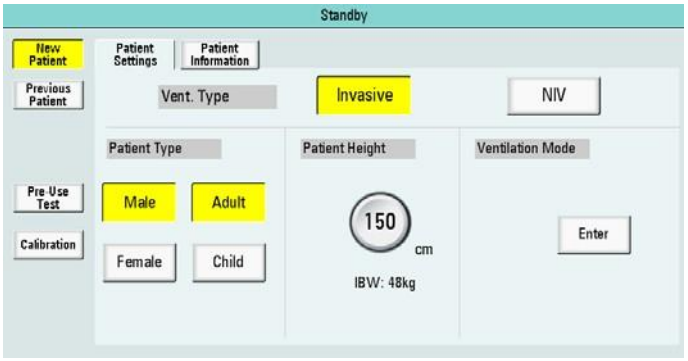
4. Technical Test



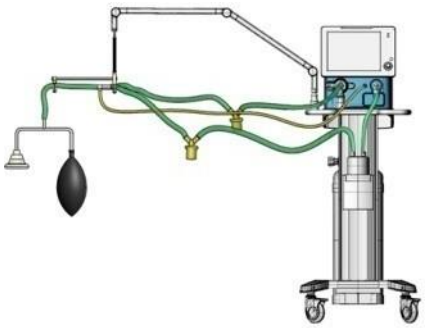
5. Pre-use Test



6. Select New Patient



7. Prepare Patient Circuit



8. Connect CO_2 Module (optional)

9. Connect IRMA Airway Adapter (optional)

10. Set Appropriate Ventilation Settings

2 System Overview

2.1 Ventilator Components

The AEROS 4600 Ventilator is composed of main unit (include main control unit, display screen), patient circuit, patient circuit positioning arm, optional trolley and accessories. As shown in Figure 2-1.

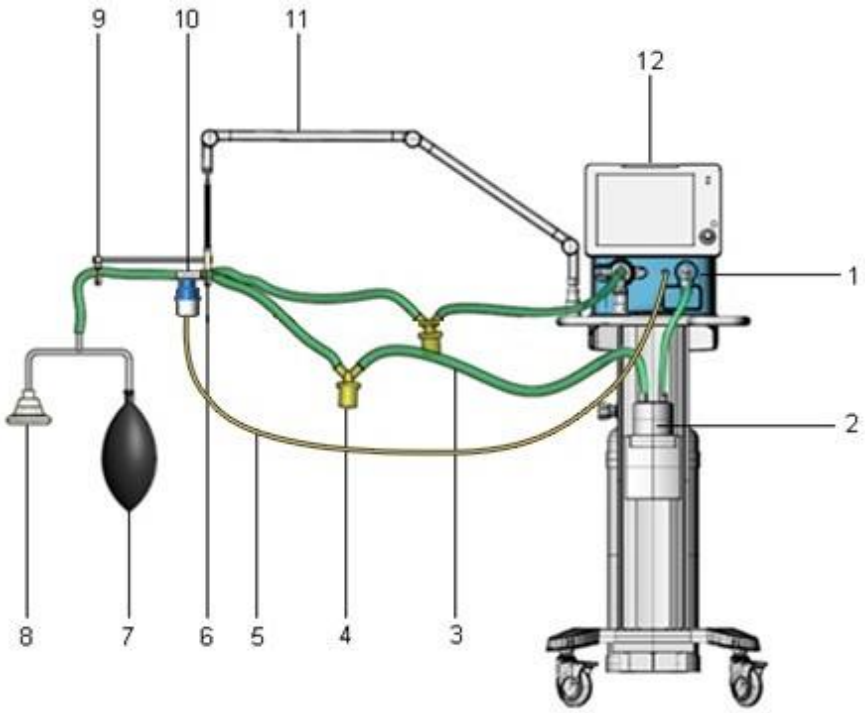


Figure 2-1 Main components of the AEROS 4600 Ventilator

1	Main Control Unit	2	Humidifier	3	Patient Circuit
4	Water Trap	5	Nebulizer Tube	6	Y-piece
7	Test Lung	8	Mask	9	Connector
10	Nebulizer Connector	11	Patient Circuit Positioning Arm	12	Display screen

The GUI controls ventilator settings: Settings can be selected and adjusted by using a finger on the screen and/or the encoder knob. The GUI verifies that all combinations of settings are obtainable and will notify the user of any setting limitations.

Breathing parameters are continuously measured by transducers and controlled by a feedback system in the Breathing Delivery Unit. The ventilator responds to a difference between the actual measured value of a parameter and the preset or calculated value by adjusting gas delivery to achieve the target value.

CAUTION: Always position a humidification device so that it is lower than both the ventilator and the patient. Use water traps, if necessary, to limit water in the patient circuit and precautions should be taken when discarding the fluid in the water trap, discard per local ordinance for proper disposal.

2.2 Display Screen Components

2.2.1 Display Screen Front Panel

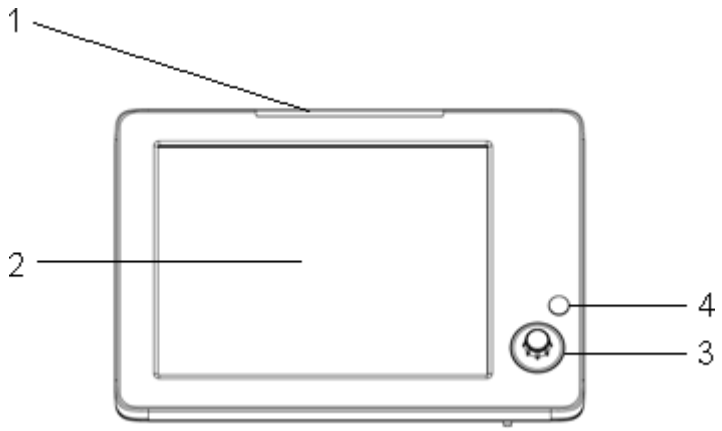


Figure 2-2 Display screen front panel

1. Alarm Lamp

2. Touch Screen

3. Encoder Knob

4. Alarm Silence Hard Button

The Alarm silence hard button enables the user to silence alarms for 2 minutes. Pressing the location on the Display screen will either bring up a sub-menu or will highlight a ventilator parameter or shortcut button. Rotating the encoder knob when the ventilator parameter is selected allows the user to scroll through the available range.

2.2.2 Display Screen Side Panel

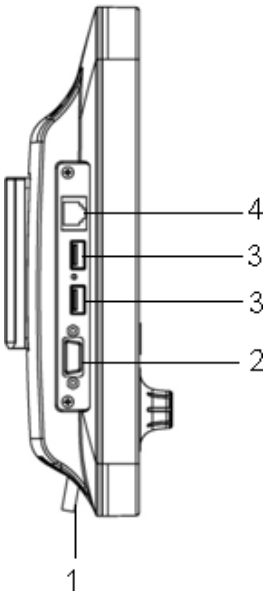


Figure 2-3 Display screen side panel

1. Main cable: This cable connects the Display screen and the main control unit.

CAUTION: Do not disconnect this cable when the ventilator is operating.

2. VGA interface: VGA interface is only used for teaching or devices display when an external expansion monitor or projector is connected, the connected devices must comply with the safety standards of the relevant industry.

CAUTION: VGA interface is forbidden to connect any devices when it is used for patients.

3. USB interface: USB interface can only be connected to non self powered U disk, mouse and keyboard.

CAUTION: USB interface is forbidden to connect other devices.

4. Network Interface: Reserved debugging interface.

CAUTION: Network interface is reserved for debugging, which is used for debugging by professionals of manufacturers and is not open to the public.

2.3 Main Control Unit

The main control unit is responsible for control of the ventilator. It has interfaces on the front and rear panels including pneumatic and electronic interfaces.

2.3.1 Front Panel

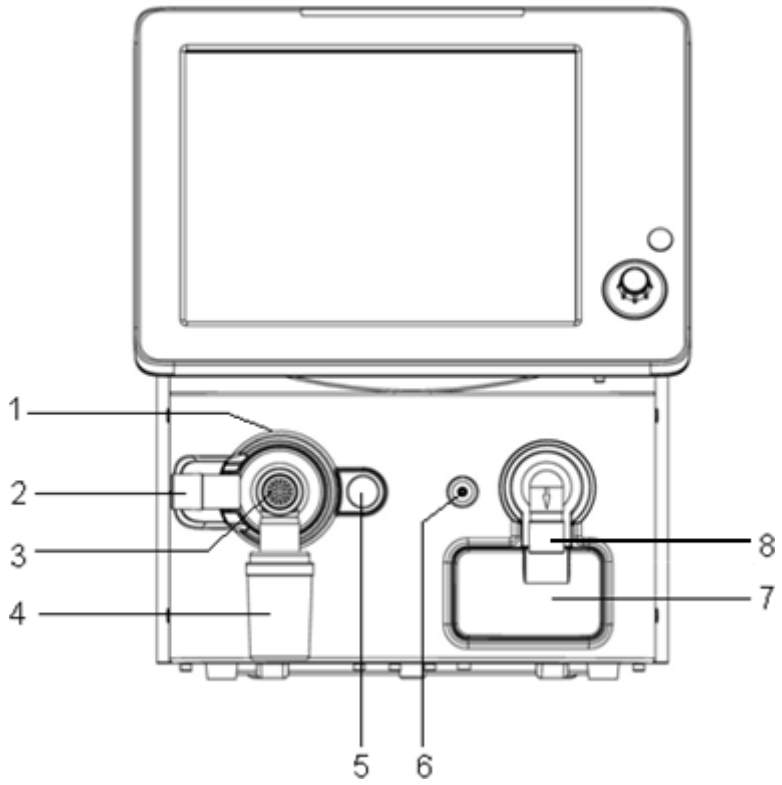


Figure 2-4 Front panel

1. Expiratory module: To remove the Expiratory module: Press the latch (5) on the right part of front cover (i.e. unlock it) and then take out the Expiratory module. After cleaning or high level disinfection, insert the module in the proper position until the locking latch returns to the locked state.

NOTE: Use caution when inserting the expiratory module to avoid leakage. A system leak test must be done before the machine is put into patient use.

WARNING: Expiratory module is heated to prevent water condensation, use caution due to high temperature.

 **WARNING:** If a heated humidifier is used, you should always monitor the temperature of the gas delivered to the patient. Gas delivered from the ventilator that becomes too hot may burn the patient's airway.

2. Exhaust port: Patient expiratory gas is released through this port to the room.

 **CAUTION:** Do not block this port.

 **CAUTION:** Do not connect inspiratory or expiratory circuits to this port.

3. Expiratory port

 **CAUTION:** Do not connect inspiratory limb circuit to this port.

4. Water trap cup: Collect condensed water to prevent it from going into expiratory valve.

5. Expiratory module latch: A latch that is used to lock or unlock the expiratory module.

 **WARNING:** Do not operate this latch or remove the Expiratory module while the Ventilator is in use on a patient.

6. Nebulizer output port: For nebulizer (single use) device connection.

7. Oxygen sensor cover

8. Inspiratory port: Delivers gas from the ventilator to the patient inspiratory limb hose.

 **CAUTION:** Do not connect expiratory circuit to this port.

2.3.2 Rear Panel

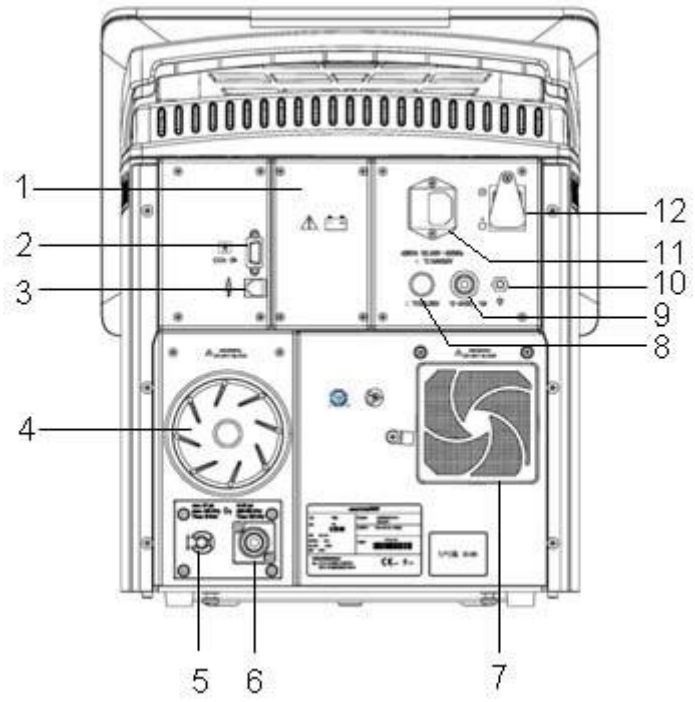


Figure 2-5 Rear panel

1	Battery Cover	2	CO_2 Module Connector	3	Nurse Call Connector
4	Air Inlet	5	Low-flow Oxygen Inlet	6	Hyperbaric Oxygen Inlet
7	Cooling Fan	8	DC Power Fuse	9	DC Power Input Port
10	Equipotential Terminal	11	Power Supply Socket	12	Power Supply Switch

CAUTION: The Equipotential Terminal is used to connect various parts of the equipment or of a medical equipment system to the same potential. When connected, it shall comply with the IEC 60601-1.

WARNING: Never block the ports of the exhaust cooling fan and the air inlet! Clean the filter regularly! Ventilator should not be covered or positioned in such a way that the operation or performance of the Ventilator is adversely affected (e.g. positioned next to a curtain that blocks the flow of cooling air, thereby causing the ventilator to overheat).

WARNING: Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required

cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.

WARNING: Pay attention to the protection of flammable and vulnerable components. Call for authorized service support when necessary.

CAUTION: CO_2 Module Connector is only for the specified CO_2 Module, and cannot be connected with other serial ports.

2.4 Trolley

An optional trolley may be used to mount the Ventilator. It applies to placing and moving the Ventilator. The trolley includes an auxiliary AC panel.

2.5 Humidifier

An optional Humidifier, like the Fisher & Paykel MR850, or similar product, should be used with the Ventilator. Dixion may supply humidifiers in your location – talk with Dixion's Sales Representative if you need more information.

2.6 Cylinder Kit

An optional Gas Cylinder Mounting Kit is available that holds 2 US E cylinders (O_2).

3 CO_2 Module

CAUTION: The CO_2 module is an optional module, which should be activated by professionals and can only be used after activation.

3.1 CO_2 Module Intended Use

The mainstream CO_2 module is intended to be connected to the Ventilator for display of real time and derived monitoring data of CO_2.

The mainstream CO_2 module is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during recovery and respiratory care. It may be used in the operating room, the intensive care unit, patient room and emergency medicine settings for adult and pediatric patients.

The CO_2 module is not intended to be used as the only means of monitoring a patient. It must always be used in combination with alternate monitoring systems.

3.2 CO_2 Module Specifications

3.2.1 General

Description	Extremely compact infared mainstream CO_2 probe.
Dimensions (WxDxH)	38 x 37 x 34 mm (1.49” x 1.45” x 1.34”)
Cable Length	2.50 m ±0.02 m
Weight	< 25 g (cable excluded)
Operating temperature	0 to 40°C / 32 to 104°F
Storage and transportation temperature	-40 to75°C / -40 to 167°F
Operating humidity	10 to 95% RH, non-condensing
Storage and Transportation humidity	5 to 100% RH, condensing[1)]
Operating atmospheric pressure	525 to 1200 hPa (525 hPa corresponding to an altitude of 4572 m / 15000 feet)

Storage and transportation pressure	500 to 1200 hPa
Mechanical strength	Withstands repeated 1.8 m drops on a hard surface. Complies with requirements for road ambulances according to EN1789:2007 (clause 6.4) and requirements for shock and vibration according to EN ISO 80601-2-55 (clause 201.15.3.5.101).
Surface temperature (at ambient temp. 23°C)	Max 41°C / 106°F
Airway adapters	Disposable adult/pediatric: Adds less than 6 ml dead space; Pressure drop less than 0.3 cmH_2O @ 30 LPM. Disposable infant: Adds less than 1 ml dead space; Pressure drop less than 1.3 cmH_2O @ 10 LPM.

NOTE 1: After being in a condensing atmosphere, the unit shall be stored for more than 24 hours in an environment equivalent to the operating humidity. The humidity range 50 ~ 100% is valid within the temperature range of -40 to 40°C only.

Gas analyzer	
Probe	2-9 channel NDIR type gas analyzer measuring at 4 to 10 µm. Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter.
Warm-up time	Full accuracy within 10 seconds
Rise time (@ 10 l/min)	≤ 90 ms
Total system response time	< 3 second

Accuracy specifications – during standard conditions

	Range [1)]	
Gas	**CO_2 (%)**	**Accuracy**
CO_2	0 – 15 15 – 25	±(0.2 vol% + 2% of reading) Unspecified

NOTE 1: Gas concentration reported in units of volume percent.

Accuracy specifications – during all conditions[1)]

Gas	Accuracy
CO_2	±(0.3 vol% + 4% of reading)

NOTE 1: The accuracy specification is valid for the operating temperature and humidity conditions specified, except for interference specified in the table “Interfering gas and vapor effects” below.

Interfering gas and vapor effects

Gas or vapor	Gas level	CO_2
N_2O [3)]	60 vol%	– [1)]
HAL [3)]	4 vol%	– [1)]
ENF, ISO, SEV [3)]	5 vol%	+8% of reading [2)]
DES [3)]	15 vol%	+12% of reading[2)]
Xe (Xenon) [3)]	80 vol%	-10% of reading [2)]
He (Helium) [3)]	50 vol%	-6% of reading [2)]
Metered dose inhaler propellants [3)]	Not for use with metered dose inhaler propellants	
C_2H_5OH (Ethanol) [3)]	0.3 vol%	– [1)]
C_3H_7OH (Isopropanol) [3)]	0.5 vol%	– [1)]
CH_3COCH_3 (Acetone) [3)]	1 vol%	– [1)]
CH_4 (Methane) [3)]	3 vol%	– [1)]
CO (Carbon monoxide) [4)]	1 vol%	– [1)]
NO (Nitrogen monoxide)[4)]	0.02 vol%	– [1)]
O_2 [4)]	100 vol%	– [1)]

NOTE 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

NOTE 2: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol%. Helium, the measured CO_2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol % CO_2.

NOTE 3: According to the ISO 80601-2-55 standard.

NOTE 4: In addition to the ISO 80601-2-55 standard.

CAUTION: The presence of oxygen can cause some interference in the CO_2 measurement. This is known as spectral broadening, and must be compensated. The Ventilator performs the O_2 compensation automatically for IRMA CO_2. Use valid O_2 sensor, mount O_2 sensor and connect cable to ventilator correctly, maintain regularly. Otherwise etCO_2 accuracy may be affected.

CAUTION: The presence of nitrous oxide can cause some interference in the CO_2 measurement. This is known as spectral broadening. The ventilator is not intended for use with nitrous oxide gas, and there is no compensation performed. Therefore, if nitrous oxide gas is used with the ventilator, the etCO_2 accuracy will be affected.

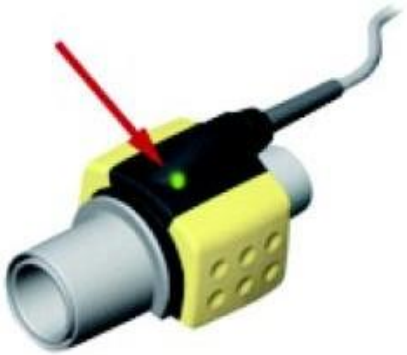
3.3 System Assembly Instruction

3.3.1 Set-up

1. Plug the IRMA connector into the CO_2 module connector on Ventilator rear panel and switch the power on.

2. Snap the IRMA probe on top of the IRMA airway adapter. It will click into place when properly seated.

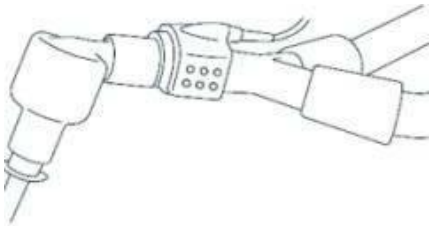
3. A green LED indicates that the IRMA probe is ready for use.



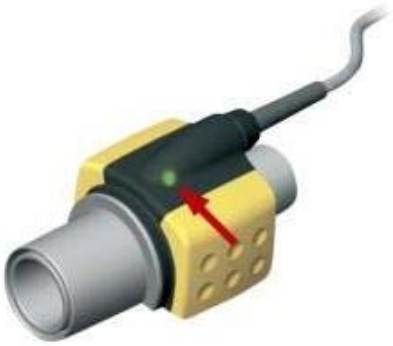
4. Connect IRMA/airway adapter 15 mm male connector to the breathing circuit Y-piece.

5. Connect the IRMA/airway adapter 15 mm female connector to the patient's endotracheal tube.

Alternatively, connect a HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing a HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.



6. Unless the IRMA probe is protected with a HME, always positioned the IRMA probe with the status LED pointing upwards.



3.3.2 Placement of IRMA Probe

When connecting IRMA probe to an infant patient circuit it is important to avoid a direct contact between the IRMA probe and the infant's body.

If, for any reason, the IRMA probe contacts with any parts of the infant's body indirectly, an insulation material shall be placed between the IRMA probe and the body.

WARNING: The IRMA probe is not intended to be in patient's contact.

3.4 Pre-use Check

Always verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit. Perform the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter.

3.4.1 Zeroing Procedure

WARNING: Incorrect probe zeroing will result in false gas readings.

In order to secure high precision of the IRMA probe measurements, the following zeroing recommendations should be followed.

Zeroing is performed by installing a new IRMA airway adapter onto the IRMA probe without connecting the airway adapter to the patient circuit, and then using the medical monitoring equipment to transmit a zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the zeroing procedure. The presence of ambient air without CO_2 in the IRMA airway adapter is of crucial importance for a successful zeroing. If an "ZERO_REQ" alarm appeared directly after a zeroing procedure, the procedure must be repeated.

After starting the IRMA CO_2 probe and replacing the IRMA airway adapter, wait for 10s for the probe to warm up before performing the zeroing procedure.

Zeroing needs to be performed only when an offset in gas values is observed, or when the display precision does not specify a message.

3.5 Alarms

The IRMA probe LED status is as follows:

Steady green light	System OK
Blinking green light	Zeroing in progress
Steady red light	Sensor error
Blinking red light	Check adapter

Refer to Section 8, Alarms and Troubleshooting, for $EtCO_2$ low and high signal alarms.

3.6 Cleaning

The IRMA probe can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA probe.

CAUTION: The airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.

CAUTION: Never sterilize or immerse the IRMA probe in liquid.

3.7 Warnings

WARNING: The IRMA probe is intended for use by authorized and trained medical personnel only.

WARNING: The IRMA probe must not be used with flammable anesthetic agents.

WARNING: Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.

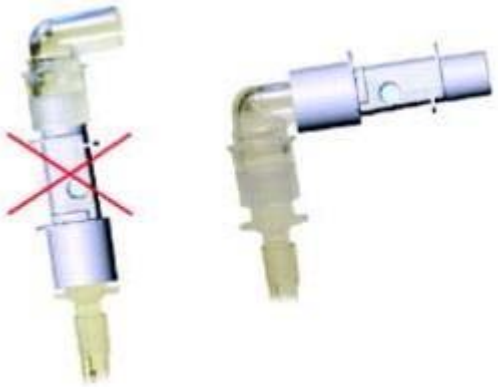
WARNING: Used airway adapters shall be disposed of in accordance with local regulations for medical waste.

WARNING: Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 mL dead space to the patient circuit

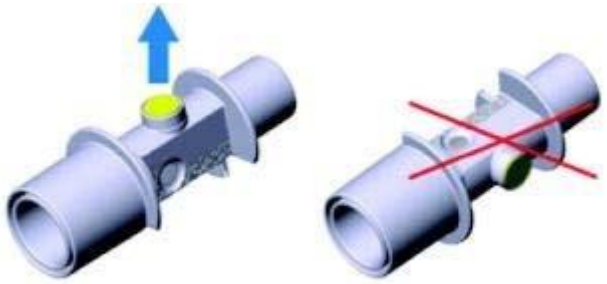
WARNING: Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.

WARNING: Measurements can be affected by mobile and RF communications equipment. Assure that the IRMA probe is used in the electromagnetic environment specified in this manual.

WARNING: Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.



WARNING: To keep secretions and moisture from pooling on the windows sensor port, always position the IRMA probe in a vertical position with the LED pointing upwards.



WARNING: Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.

 **WARNING:** The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

 **WARNING:** Incorrect probe zeroing will result in false gas readings.

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

 **WARNING:** Use only PHASEIN manufactured IRMA airway adapters.

3.8 Cautions

 **CAUTION:** Do not apply tension to the probe cable.

 **CAUTION:** Do not operate the IRMA probe outside the specified operating temperature environment.

3.9 Maintenance Information

The IRMA probe is permanently calibrated at the factory and requires verification in regular intervals using a service reference instrument.

4 Setup

This section describes the connection and preparation of the ventilator.

4.1 Connect Power Supply

The machine can work with either one of two power supply sources: internal battery and AC power supply. An icon on the right upper part of screen displays the supply being used. When operating on battery, all functions except the expiratory port heater, the cooling fan and the nebulizer are the same as under AC operation. The expiratory port heater, the cooling fan and the nebulizer are disabled in battery operation to improve battery run time. If “low battery” is displayed when the internal or extended battery is in use, the AC power supply must be connected to charge the battery, otherwise the Ventilator may lose power.

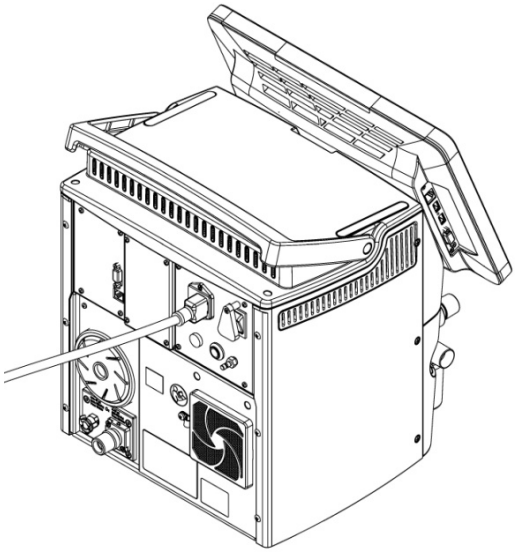


Figure 4-1 Connect power supply cable to AC inlet

After connecting the AC power supply, the AC power supply indicator will be shown indicating the battery is being charged. A typical charge period is 3.5 hours. The power supply indicator is lit yellow during periods of charging, and the light goes out when the battery is fully charged.

Remove AC Power supply cord from wall connection to disconnect ventilator from AC Mains.

WARNING: To connect the ventilator to an external power source, first ensure the ventilator’s I/O switch is off (O). Then, connect the desired power cable to the ventilator. Finally, connect the power cable to the external power source.

 **WARNING:** To disconnect the ventilator from an external power source, first power-down the ventilator. Then, disconnect the power cable from the external power source and, finally, the ventilator.

 **WARNING:** Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.

 **WARNING:** Do not leave power cables lying on the ground where they may pose a hazard.

 **WARNING:** When adding attachments or other components to the breathing system, the breathing resistance may increase, or the monitoring pressure of the patient connect port is higher than the actual pressure.

4.2 Connect Gas Source

Hyperbaric Oxygen Inlet of the ventilator can be connected to multiple gas sources: bottled oxygen and central supply O_2. The gas source pressure must be between 280 ~ 600 kPa (41 ~ 87 psi). Low pneumatic pressure will impair some functions of the ventilator.

For Low-flow Oxygen Inlet of the ventilator, the gas source pressure must be less than 600kPa, and the flow is less than 15L/min.

There are diameter limits on the two inlets to prevent miss-connection.

Oxygen connected to the high pressure input ports of the ventilator will be used as Fresh Gas and will be supplied to the patient.

 **WARNING:** The ventilator should be checked for gas leakage before use. If gas leakage is found, please stop using.

 **WARNING:** The coupler must not remain connected to the oxygen connector unless it also connected to a leak-proof, external oxygen gas source. When an oxygen supply is not being used with the ventilator, disconnect the oxygen source completely from the ventilator.

 **WARNING:** Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.

4.3 Connect Accessories

4.3.1 Connect Patient circuit

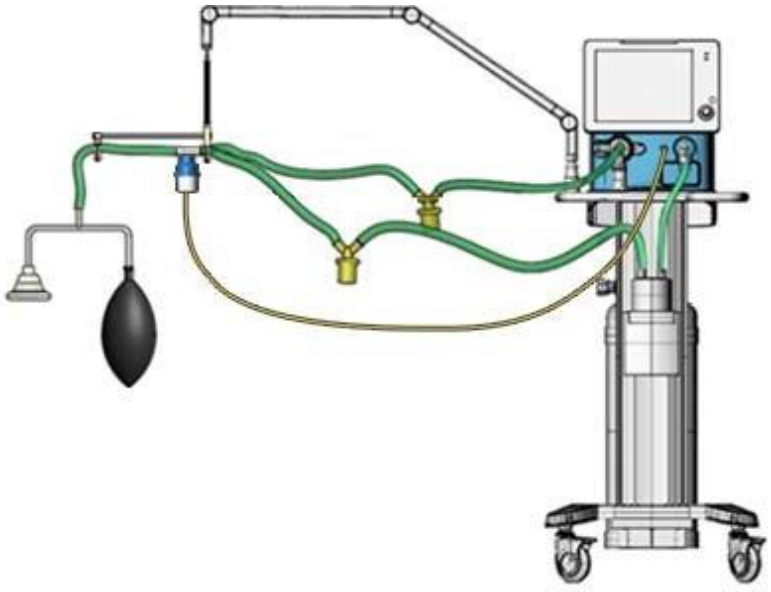


Figure 4-2

This figure shows the connection of patient circuit, including inspiratory port, water trap, Inspiratory tube, Y-piece, breathing hoses and expiratory filter.

CAUTION: Assure patient hoses used have the appropriate resistance so that patient receives proper therapy.

CAUTION: It is highly recommended that you install a bacteria filter on both single and double-limb circuits.

CAUTION: The patient circuit is intended for single use by a single patient and should be changed according to the manufacturer’s recommendations and according to the patient circuit lifetime. Refer to the instructions for use supplied by the manufacturer of the patient circuit (included with the ventilator) and refer to the attached manufacturer's packing instructions.

WARNING: The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection or leakage, and to minimize the risk of patient strangulation.

WARNING: The level of inspiratory resistance of the circuit and accessories (bacteria filter, humidifier, and so on) must be as low as possible. Settings – particularly the PATIENT DISCONNECTION alarm, High inspired volume (High VTI), and Low inspired volume (Low VTI) settings – must be periodically adjusted according to changes in the patient circuit resistance – especially when filters are replaced.

WARNING: Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

WARNING: The gas leakage high alarm limit must be set high enough to suit the patient, and low enough to trigger high gas leakage alarm. Refer to the maximum gas leakage test in Chapter 5 to ensure that the alarm can be normal when the gas leakage is high. This alarm is only applicable to non-invasive ventilation leakage setting.

WARNING: The patient circuit should not be changed during ventilation.

WARNING: The user must have a spare patient circuit and expiratory valve

NOTE: When adding attachments or other components to the breathing system, the breathing resistance may increase, or the monitoring pressure of the patient connect port is higher than the actual pressure.

4.3.2 Connect Humidifier (optional)

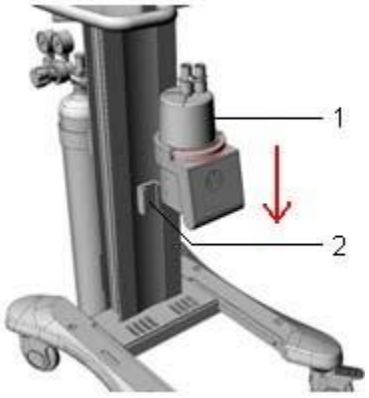


Figure 4-3

Connect humidifier (1) into channel of mounting block (2).

WARNING: During invasive ventilation (when an artificial airway bypasses the patient's upper respiratory system), the patient's upper respiratory system cannot humidify the incoming gas. For this reason, the use of a humidifier, to minimise drying of the patient's airways and subsequent irritation and discomfort, must be used.

4.3.3 Connect Patient Circuit Positioning Arm (optional)

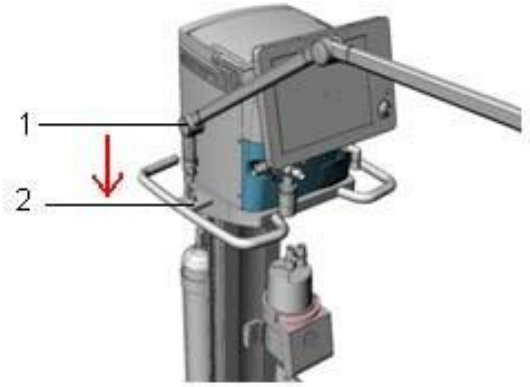


Figure 4-4

Connect positioning arm (1) onto mounting block (2).

4.3.4 Connect User Interface Screen

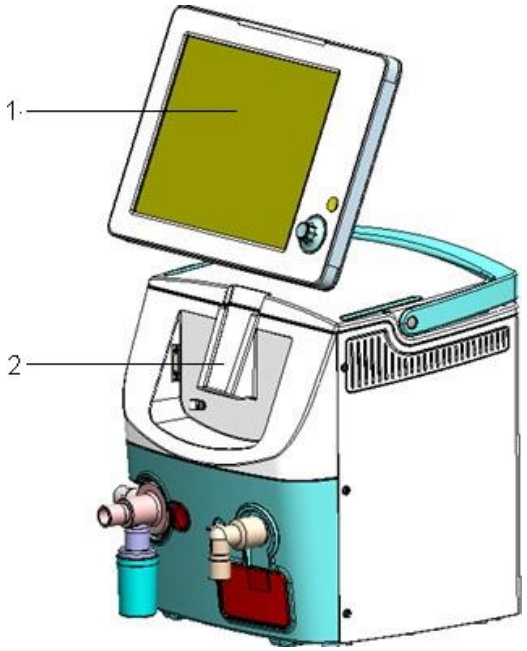


Figure 4-5

Connect User Interface (1) to the location (2).

4.3.5 Connect Cylinder Kit (optional)

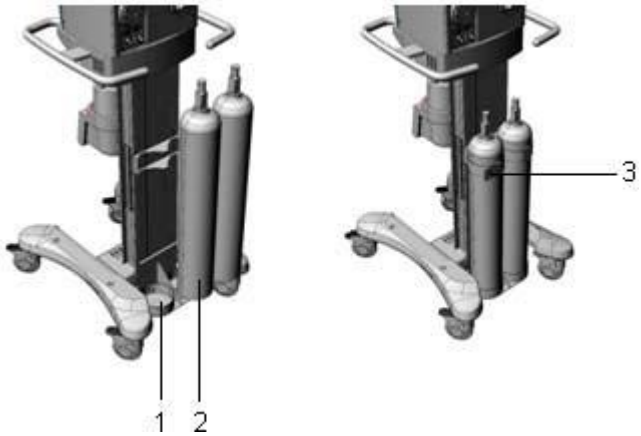


Figure 4-6

Connect O_2 cylinder (2) into the right side of holder (1). Secure cylinder using strap (3). Repeat for the other O_2 cylinder on the left side.

NOTE: The kit includes only the mounting brackets and attachments. User must supply the Gas Cylinders with Gas Regulators and hoses compatible with the AEROS 4600 Gas Inlet Connections and at the proper Pressure per AEROS 4600 Specifications.

5 Pre-use Test

5.1 When to carry out pre-use test

- Before use of the Ventilator on a new patient
- After patient hose or patient filter replacement
- After maintenance or repair

WARNING: Do not use the system until you have read and understood all the operation and maintenance manuals of the components.

WARNING: If the system test fails, do not use the system. Attempt to troubleshoot and fix the failure. If you are unable to fix the device, ask an authorized service representative to repair the device.

CAUTION: The following measures should be taken to minimize risks in the ventilator system.

5.2 Pre-use Test Procedure

After power on and technical test, the machine will enter the pre-use test following display of the power-on page. Items included: Gas supply test, Leak test, Flow sensor test, Pressure sensor test and Safety valve test in the power-on self-test: For details on testing, please refer to Section 6.1.

There is also a “Pre-Use Test” button on Standby screen. There are more test items in the “Pre-Use Test” page. Items included:

Test Items	**Remarks**
Technical Test	After each system has completed its initialization technical tests will be performed, including: voltage checks at critical points in the circuitry; data collection necessary for system operation; test of communication between sub-systems; tests of measurement circuits and valve control circuits.
AC/Battery test	This test will verify whether the batteries can supply enough power to operate the ventilator normally. Please follow instructions as displayed.

Test Items	Remarks
Gas supply test	Test will proceed when hyperbaric oxygen is functional.
Oxygen sensor test.	This test requires that oxygen supply is available. If oxygen source is not available then a message “oxygen source is inadequate” and the test cannot be carried out.
Leak test	Internal leakage test.
Flow sensor test	Flow sensors function and accuracy test.
Pressure sensor test	Pressure sensors function and accuracy test.
Safety valve test	Safety valve function and accuracy test.
Patient circuit test	Circuit compliance value measurement.
CO_2 Sensor test	Performed if a CO_2 module is detected. An Alert will be posted if the test fails.

Below is a method for testing the function of the alarm system for conditions specified by IEC60601-2-12. Alarm system tests are to be performed at the user’s discretion.

Perform the following procedure to verify operation of the Low MVe and High Airway pressure alarms:

1. Set the Power switch to ON.
2. Connect a breathing circuit and test lung to the ventilator.
3. Press Start Ventilation and ventilate with default settings except set O_2 to 21%.
4. After 5 breaths, observe the MVe reading on the display.
5. Set the MVe low alarm limit to a value greater than the observed MVe reading.
6. Verify that a low level MVe low alarm is present on the 3rd breath.
7. Return the MVe low alarm limit to original setting.
8. After 5 breaths, observe the Ppeak reading on the display.
9. Set the PAW upper alarm limit to a value lower than the observed Ppeak reading.
10. Verify that a low level High Airway Pressure alarm is present after 1 breath and that a high level High Airway Pressure alarm is present at the start of the 4th breath.
11. Return the PAW upper alarm limit to original setting.
12. Set the Power switch to OFF.

6 Ventilator Operation

WARNING: Ensure the patient circuit is correctly connected to both the ventilator and the patient, and that the patient circuit, including all hoses, is not damaged or obstructed.

WARNING: Never put ventilator into service until patient setup is completed.

Clinical safety is a major consideration in design of the machine, but operator should still be very cautious when operating the machine.

WARNING: Before opening the packaging for the Patient Circuit, ensure that no damage is evident to the packaging or its contents. Do not use if evidence of damage exists.

WARNING: Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.

WARNING: Before operating the ventilator, please read, understand and strictly follow the instructions in Chapter 1 safety information.

CAUTION: Do not start ventilation until you ensure the device is correctly assembled, that the air inlet filter is properly installed and unobstructed, and that there is proper clearance all around the unit.

CAUTION: In case any measured value seems suspect, operator should first examine the patient's vital signs using other means, and then check the ventilator.

6.1 Starting Up

Step 1: Connect to AC power supply

Connect power supply cable to power supply socket on the wall, and the AC power supply indicator will be lit green.

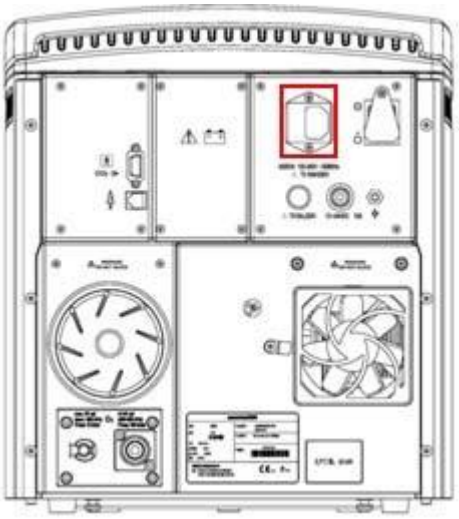


Figure 6-1 Connect power supply

Step 2: Switching on

To switch on ventilator, actuate the power switch of ventilator from " ○ " to " ⊙ ". The machine will then be turned on; initialization of the GUI Display, Main Control unit and other systems will start, the power-on interface and then the company logo will be displayed.

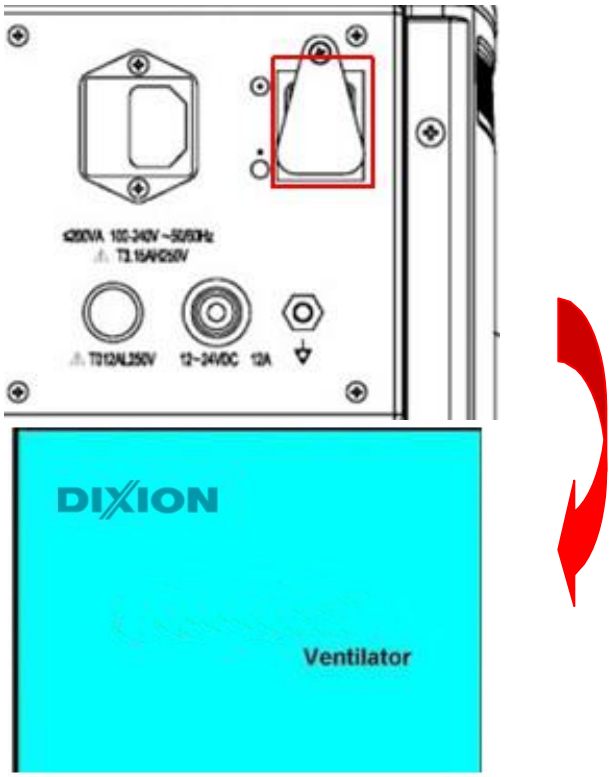


Figure 6-2 Switching on

Step 3: Technical test

After each system has completed its initialization, technical test will be performed, including voltages tests, data tests, communications tests, AD and DA converter tests, and valve control tests. The ventilator is not operational during this period.

The technical test should be performed for 10 seconds then waiting for all results to be sent to GUI. If all tests pass, the technical test finished and continue to the pre-use test. If some test failed or waiting timed out, the failure information shall be displayed on screen, the “Test” and “Skip” button’s state will be changed to enable. User can choose “Test” to do technical test again, or choose “Skip” to skip technical test.

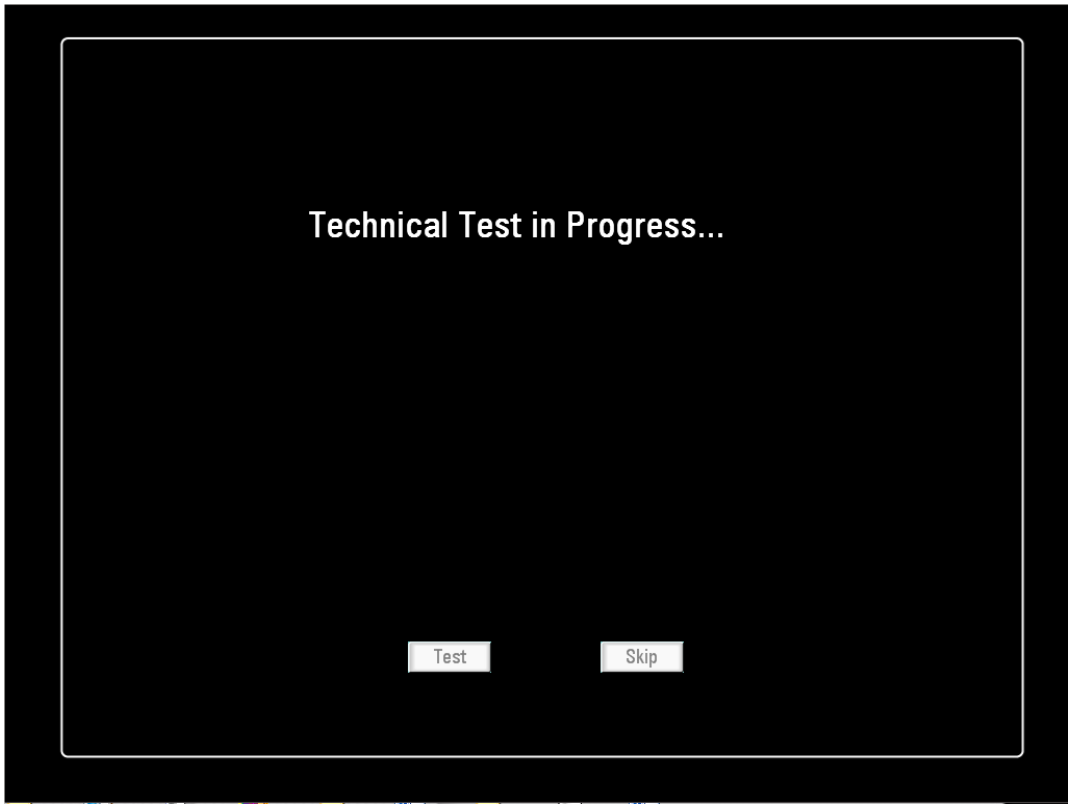


Figure 6-3 Technical test

Step 4: Pre-use test

After the unit has finished the technical test, it shall enter into the pre-use test routine.

Test Items include: Gas supply test, Leak test, Flow sensor test, Pressure sensor test and Safety valve test. The pre-use test is an interactive test requiring the user to read and follow screen prompts. See Figure 6-4 for sample screen. Along the bottom of the screen shall be 2 buttons: Test and Skip.

Test Items shall be performed one by one. If all tests passed, it shall enter Standby screen. If some tests failed, the failed information shall be displayed on screen, the “Test” button’s state change to enable. Choose “Test” to do the test again, or choose “Skip” to enter Standby screen.

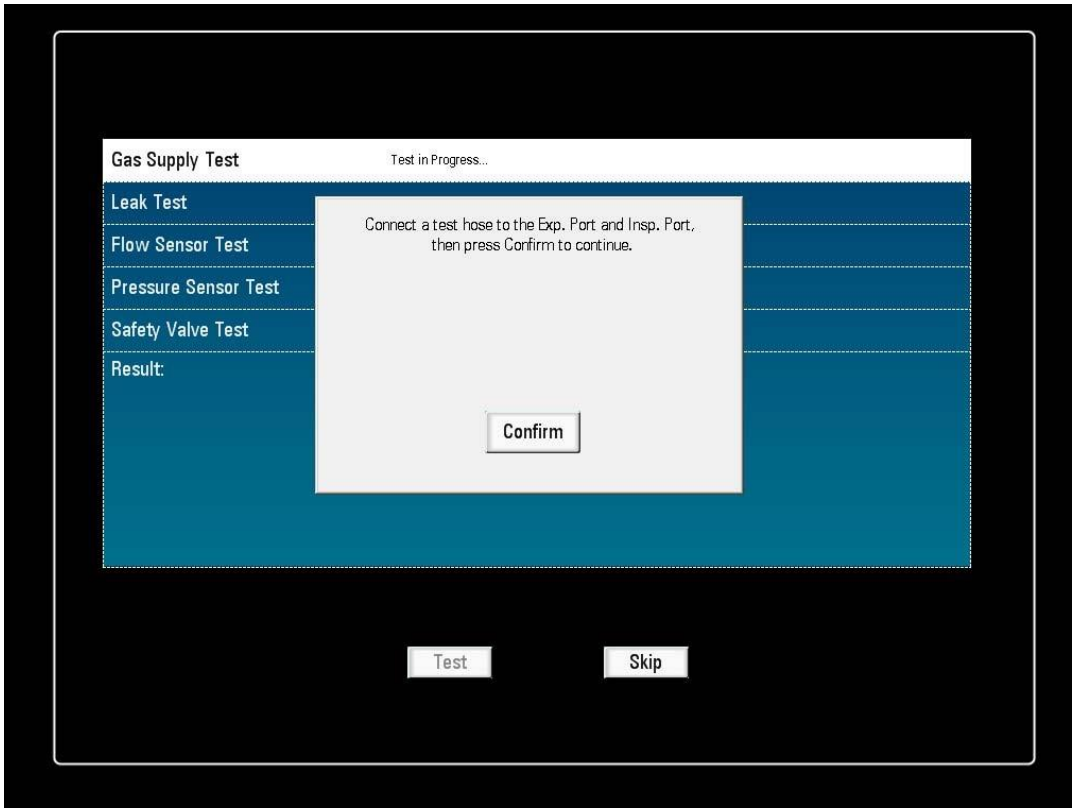


Figure 6-4 Pre-use Screen

NOTE: The ventilator does not support patient ventilation during the pre-use, since the Inspiratory valve is closed, and Expiratory valve is opened.

6.2 Interface Layout

After the Power-on self-test is finished or the “Skip” button has been clicked. Press the blue button with the text “Start ventilation” ( ) to enter the currently selected ventilation mode and the blue button will be changed to orange with text “standby” on it ( ). After pressing and holding the standby button for 4 seconds, it will go back to “Start Ventilation” again.

6.2.1 Standby Interface Layout

In the standby interface (see Figure 6-5), the user can set the information of the new patient, view the information of the previous patient, and do the pre-use test.

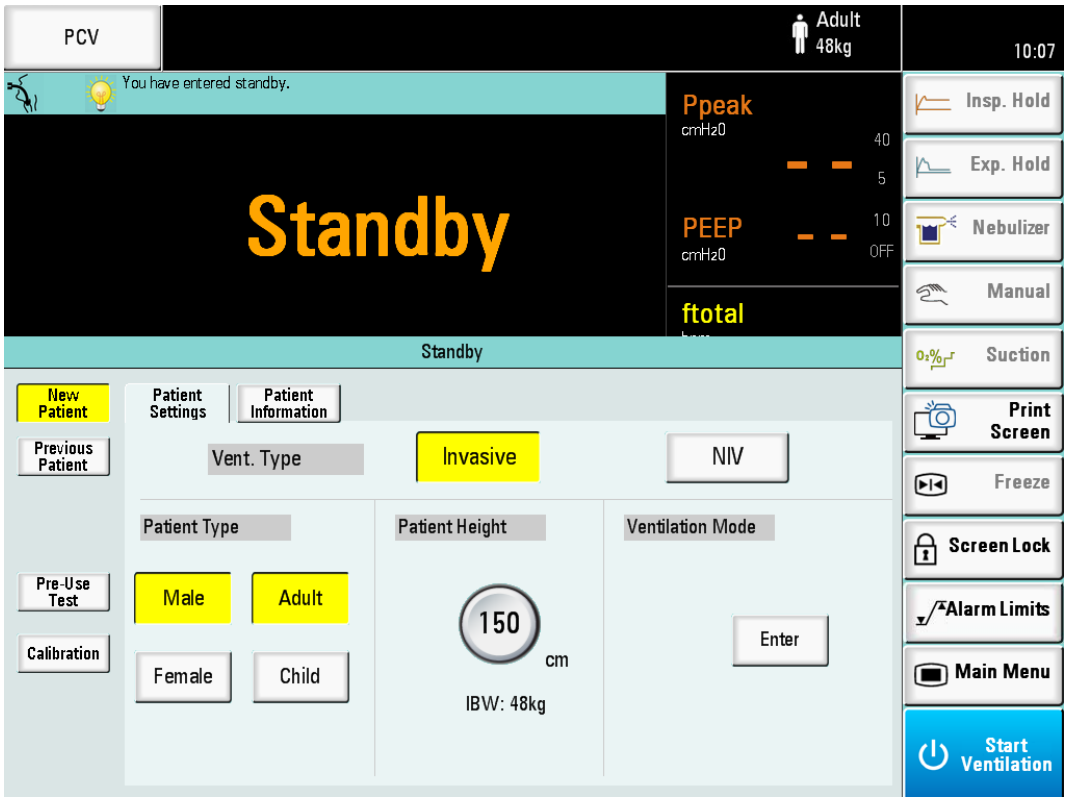


Figure 6-5

6.2.1.1 New Patient

a) Patient Settings

Step 1: Choose patient type (Adult or Child, default is adult)

Step 2: Ventilation type (Invasive or NIV, default is Invasive), Patient height (default is 150cm) and Ventilation mode. See example in Figure 6-6.

NOTE: In the Ventilation Mode area, there is an “Enter” button. Pressing the “Enter” button will enter the Mode of main menu.

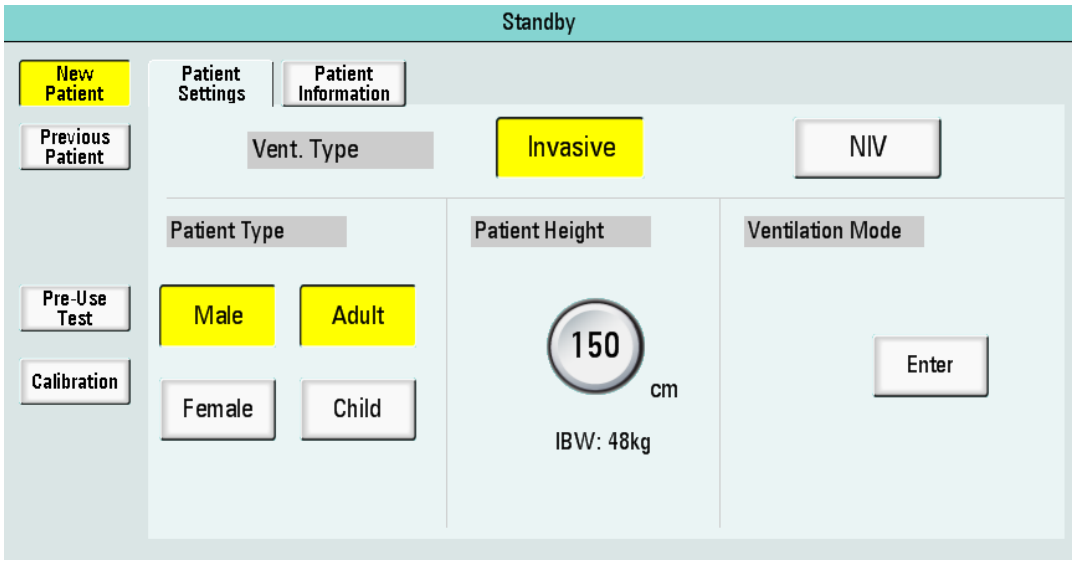


Figure 6-6

b) Patient Information

Click the Patient Information button to enter patient's information for a new patient. In this page, the user can enter the patient's name, Medical Record Number, Admission Date, Birth Date and Height (cm). There is a small button board on the right side of the Patient Information. The format of the admission date and birth date is YYYY/MM/DD, and the default date is the computer date. In the lower right corner, there is "Clear" button to clear all the information. See the example in Figure 6-7.

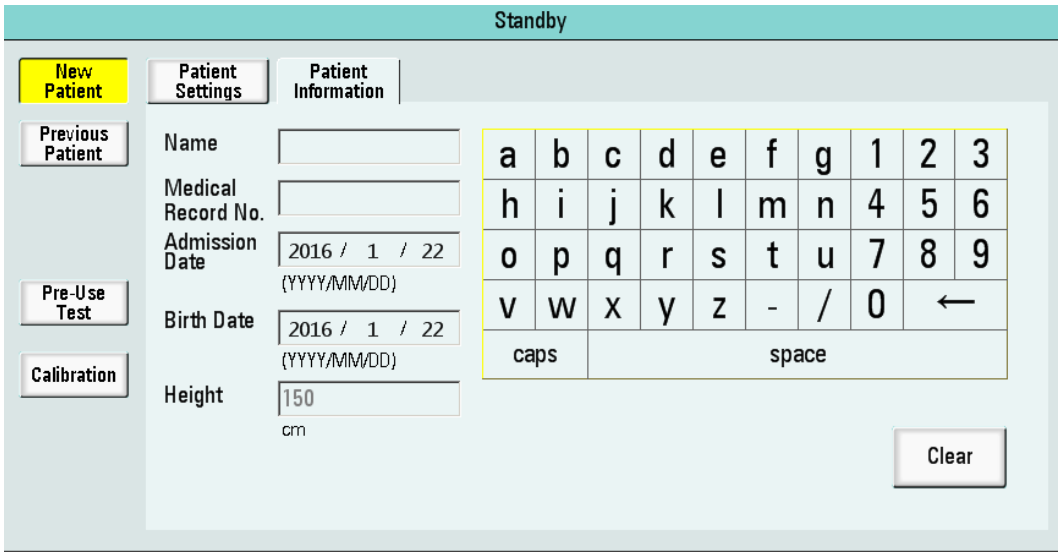


Figure 6-7

6.2.1.2 Previous Patient

For the Previous Patient button, the same content displays as for a new patient, except the Patient Type and Vent Type appear on the Patient Settings page and the Patient information cannot be changed, as shown in Figure 6-8.

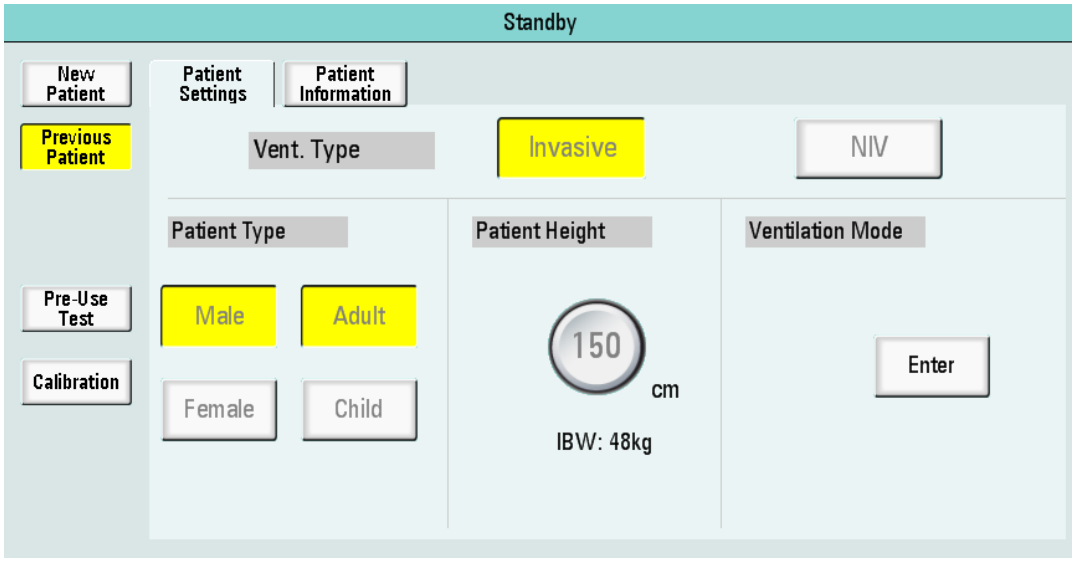


Figure 6-8

6.2.1.3 Pre-use Test

Click the Pre-Use test button to enter the pre-use test page. There are ten tests that must be completed before the ventilator is connected to a patient: Technical test, AC/Battery Test, Gas Supply Test, Oxygen Test, Leak Test, Flow Sensor Test, Pressure Sensor Test, Safety Valve Test, Patient Circuit Test, and etCO_2 Sensor Test, as shown in Figure 6-9.

There is a label with "√" at the front of each test item. Touch the test item can change the selected state of it. At the bottom of items there is a label with "√" and text "Select All", touch it can select all test items.

NOTE: Before the ventilator is connected to a patient, we suggest that the user complete all tests.

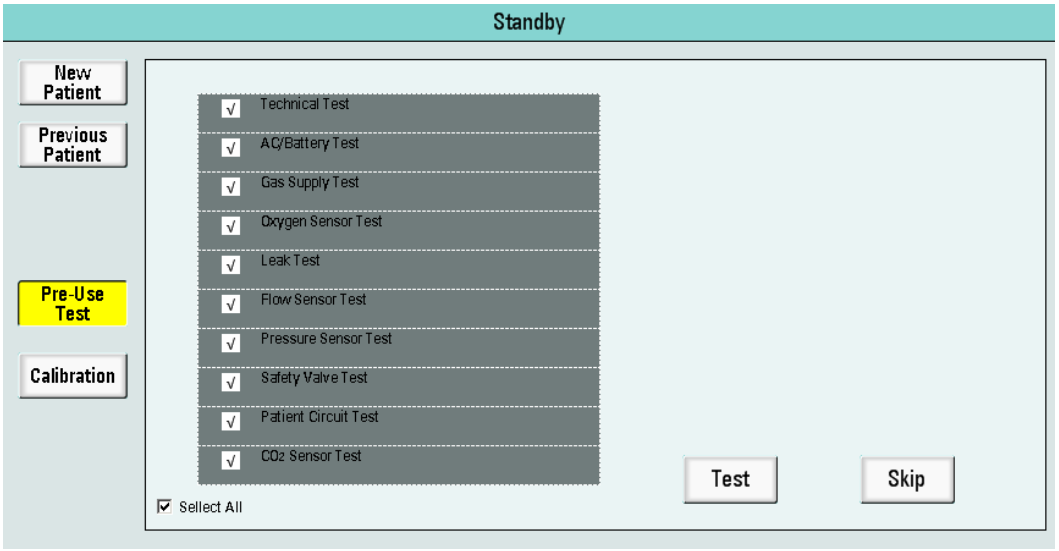


Figure 6-9

6.2.1.4 Calibration

Click the calibration button to enter the calibration page, as shown in Figure 6-10. In this page, the user can calibrate O_2 sensor and flow sensor.

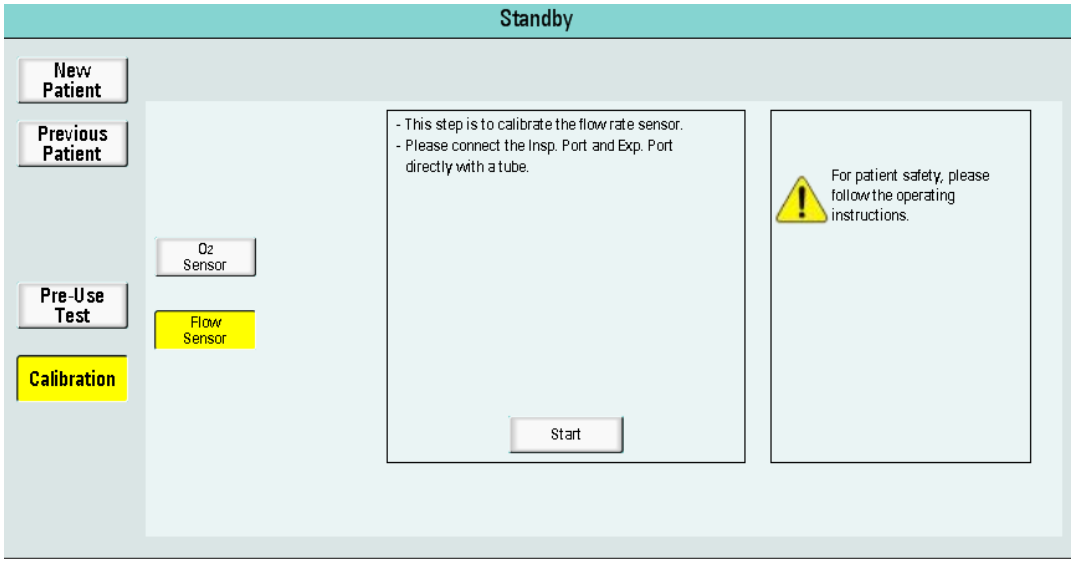


Figure 6-10

6.2.2 Ventilator Interface Layout

The ventilator interface can be divided into six parts: Parameter setup area, Short Cut buttons area, Patient Measured Parameters area, Patient Waveforms area, Information area and User Message Prompts area, as shown in Figure 6-11.

<table>
<tr><td colspan="5">Information Area</td></tr>
<tr><td colspan="3">User Message Prompts Area</td><td rowspan="2">Patient Measured Parameter 1</td><td>Short Cut Key 1</td></tr>
<tr><td colspan="3" rowspan="3">Patient Waveform 1</td><td>Short Cut Key 2</td></tr>
<tr><td rowspan="3">Short Cut Key 3</td></tr>
<tr><td rowspan="2">Patient Measured Parameter 2</td></tr>
<tr><td colspan="3" rowspan="2">Patient Waveform 2</td><td>Short Cut Key 4</td></tr>
<tr><td>Short Cut Key 5</td></tr>
<tr><td colspan="3" rowspan="2">Patient Waveform 3</td><td rowspan="2">Patient Measured Parameter 3</td><td>Short Cut Key 6</td></tr>
<tr><td>Short Cut Key 7</td></tr>
<tr><td>Parameter Setup 1</td><td>Parameter Setup 2</td><td>Parameter Setup 3</td><td>Parameter Setup 4</td><td>More Settings</td><td>Short Cut Key 8
Short Cut Key 9
Short Cut Key 10
Short Cut Key 11</td></tr>
</table>

Figure 6-11

Figure 6-12 shows the actual operational screen layout of the ventilator.

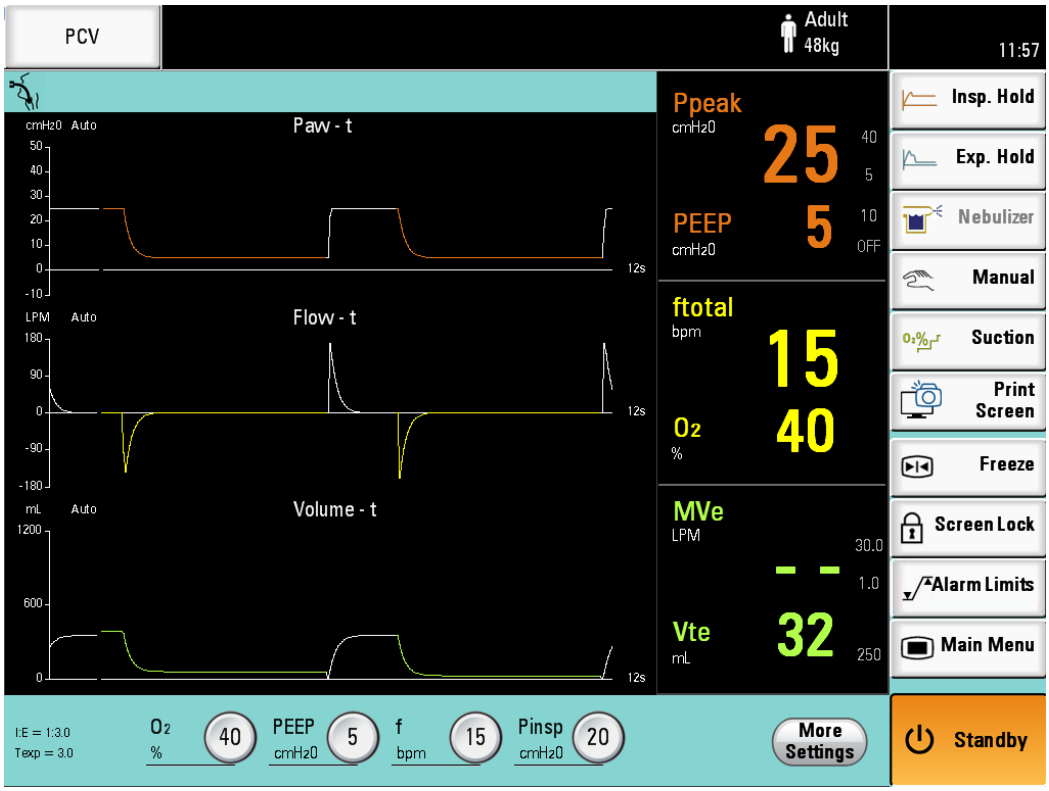


Figure 6-15

6.2.1 Information Area

The Information area includes seven sections: Ventilation Mode, Alarm Messages, Network and USB connection, Trigger, Patient Type and weight, AC and Battery indicators, and Time.

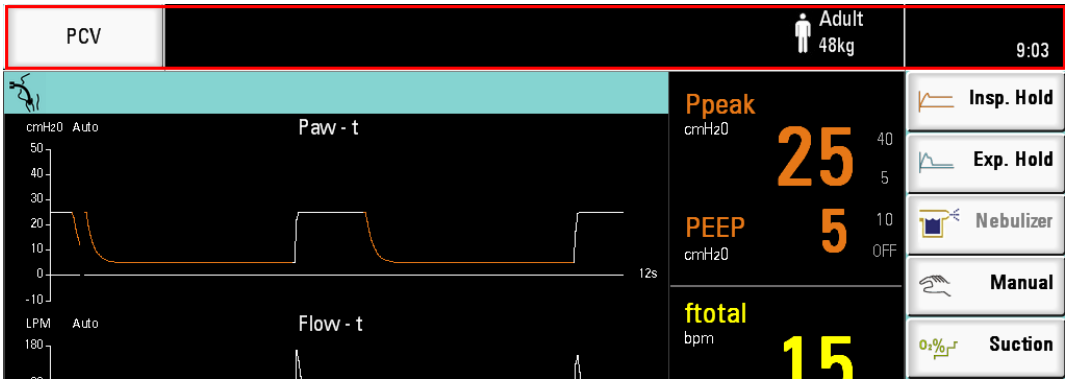


Figure 6-13

Ventilation Mode area: Displays the current mode of Ventilation.

Alarm Messages area: When there is no alarm message, this area is same background color as other screen areas; when a technical or functional alarm occurs, the background color will be changed to either red or yellow and the text information will be displayed.

Network and USB connection indicator area: Displays the Network and USB connection status.

AC and Battery indicators area: Displays the AC, internal battery and extended battery connection status.

Trigger area: Displays the current ventilator trigger type. There are three trigger types: Pressure Trigger, Flow Trigger, and Manual Trigger. If there is currently no trigger in use, the trigger symbol will disappear.

WARNING: If the trigger sensitivity is set too high, a self-triggering (auto-triggering) condition may be reached. Triggering will then be initiated by the system and not by the patient. This should always be avoided by decreasing the trigger sensitivity. This is also important during transport as the movement of the body and the breathing system may lead to false triggering.

Patient Type and weight area: Displays the current patient's type (

or 

) and current patient's weight.

Time area: Displays the current time. There are two formats, 12-hour or 24-hour.

6.2.2.2 User Message Prompts Area

If no prompt message is displayed, this area will have the same background color as other parts of the screen. If a prompt message is available, it will have a flashing bulb icon in front of the relevant prompt message.

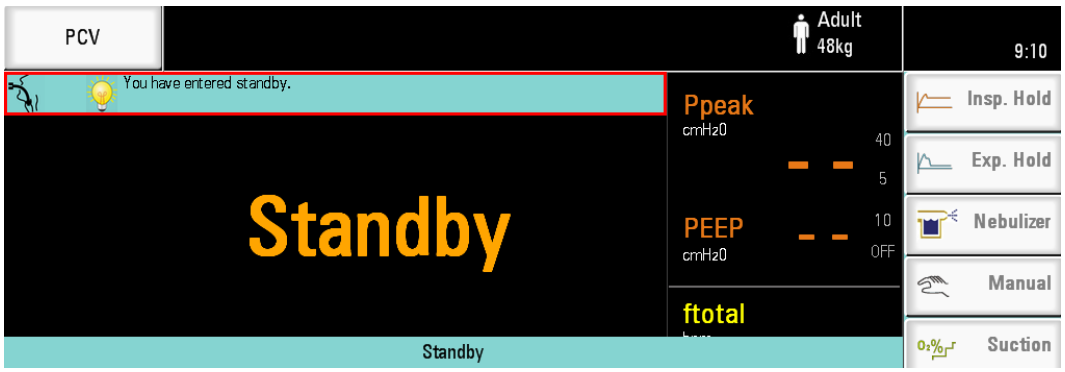


Figure 6-14

6.2.2.3 Patient Waveform Area

At center of the screen, the Patient Waveforms area is the main display area. In the default state, this area will display three waveforms: Pressure waveform, Flow waveform and Volume waveform. See the example in Figure 6-15.

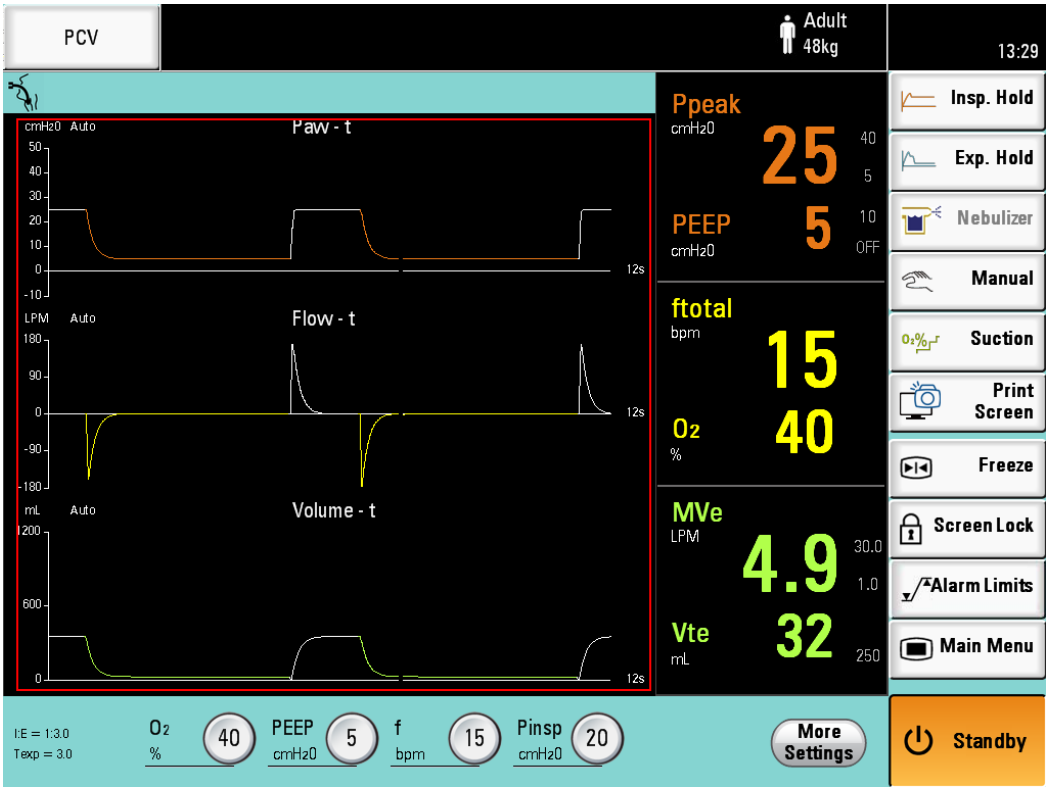


Figure 6-15

6.2.2.4 Patient Measured Parameters Area

This area displays parts of the monitored patient parameters which are very important. When in Standby mode, the monitoring values of all parameters will be displayed as “---”. The background color for Parameters with alarm limits will be changed to between black and red when a high-level alarm occurs. The flash rate will be at 2 Hz ± 10 % and it will be synchronized with the high-level alarm displayed in the Alarm Message Area. All the parameters can be changed to other parameters by a sub menu which on the monitor. The parameters were separated into 3 groups, each group contain 2 parameters.

The parameters shall be divided into 3 groups: Group 1, 2 and 3. See example in Figure 6-16.

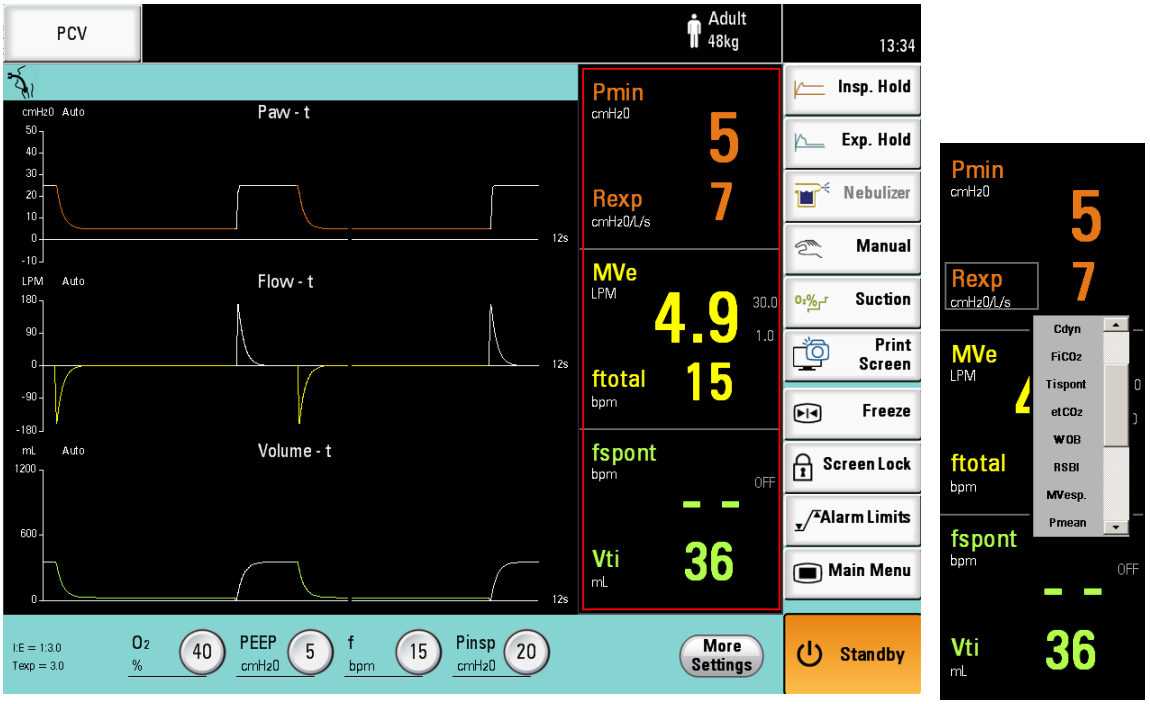


Figure 6-16

6.2.2.5 Ventilation Parameter Set-up Area

The ventilation parameter setup area is at the bottom of the screen. The breathing parameters settings necessary for the current ventilation mode are displayed in this area. See the example as shown in Figure 6-17. If the ventilation parameter setup items for the selected Ventilation mode do not fit in this space, the “More Settings” button will allow the user to access and change the other setup items.

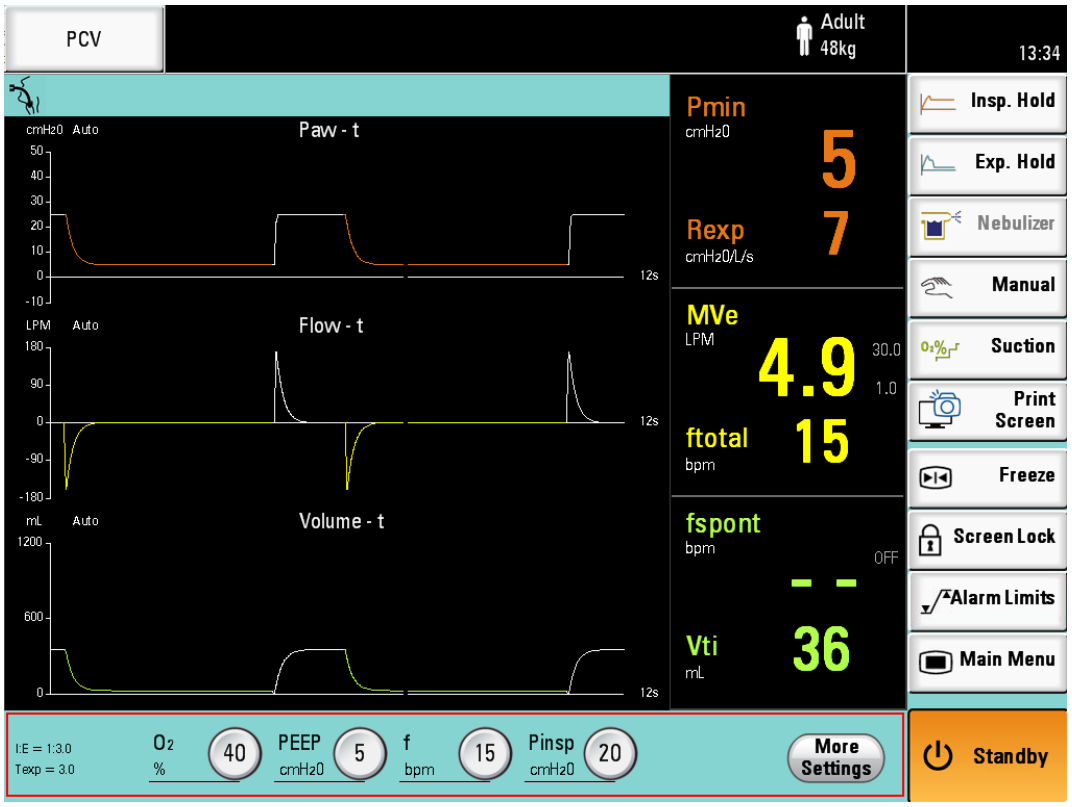


Figure 6-17

6.2.2.6 Shortcut Buttons Part

The ventilator has shortcut buttons to access many ventilator operations, including Inspiratory Hold, Expiratory Hold, Nebulizer, Manual breath delivery, Suction, Print screen, Freeze, Screen Lock, Alarm Limits, Main Menu and Standby/Start Ventilation.

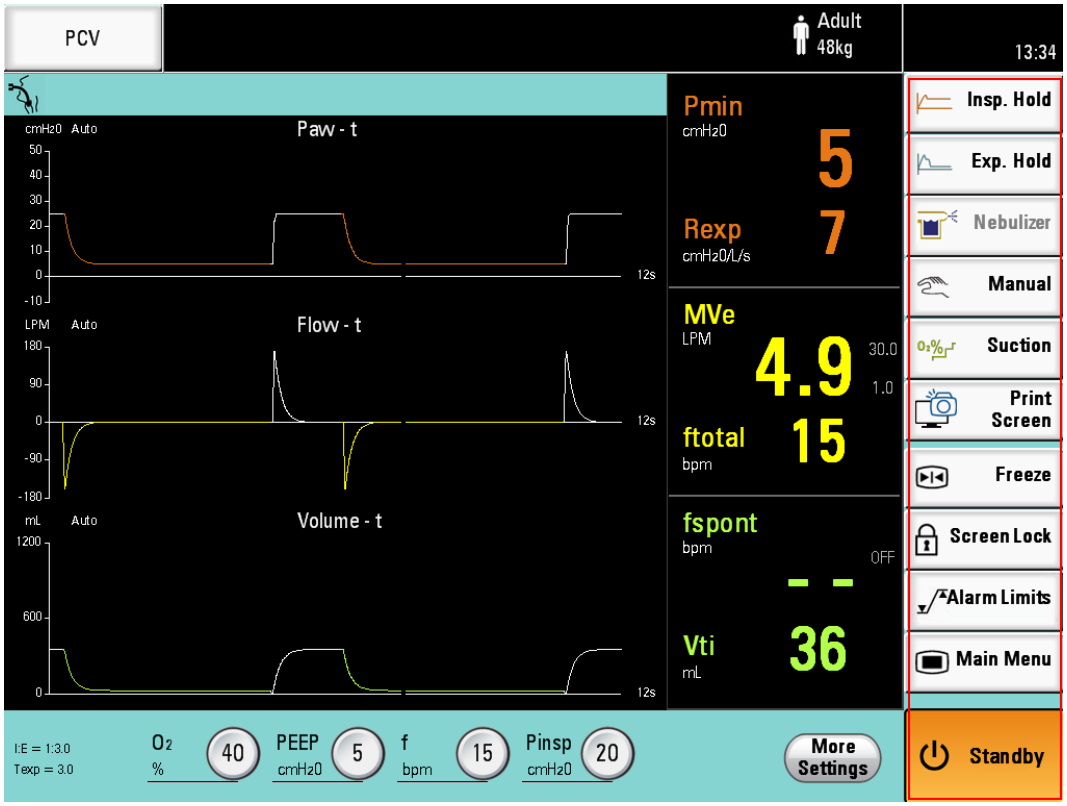


Figure 6-18

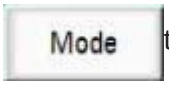
6.3 Operation of Main Manu

Click “Main Menu” of the shortcut button on the right side of the screen, the user can set Mode, Alarm Limits, Monitoring Data, Lung Mechanic, Log, System. Specific operation is as follows.

6.3.1 Ventilation Mode

6.3.1.1 Ventilation Mode Set-up

Step 1: Click 

in the shortcut buttons area to enter the Main Menu, then click 

to enter mode Setup interface, as shown in Figure 6-19.

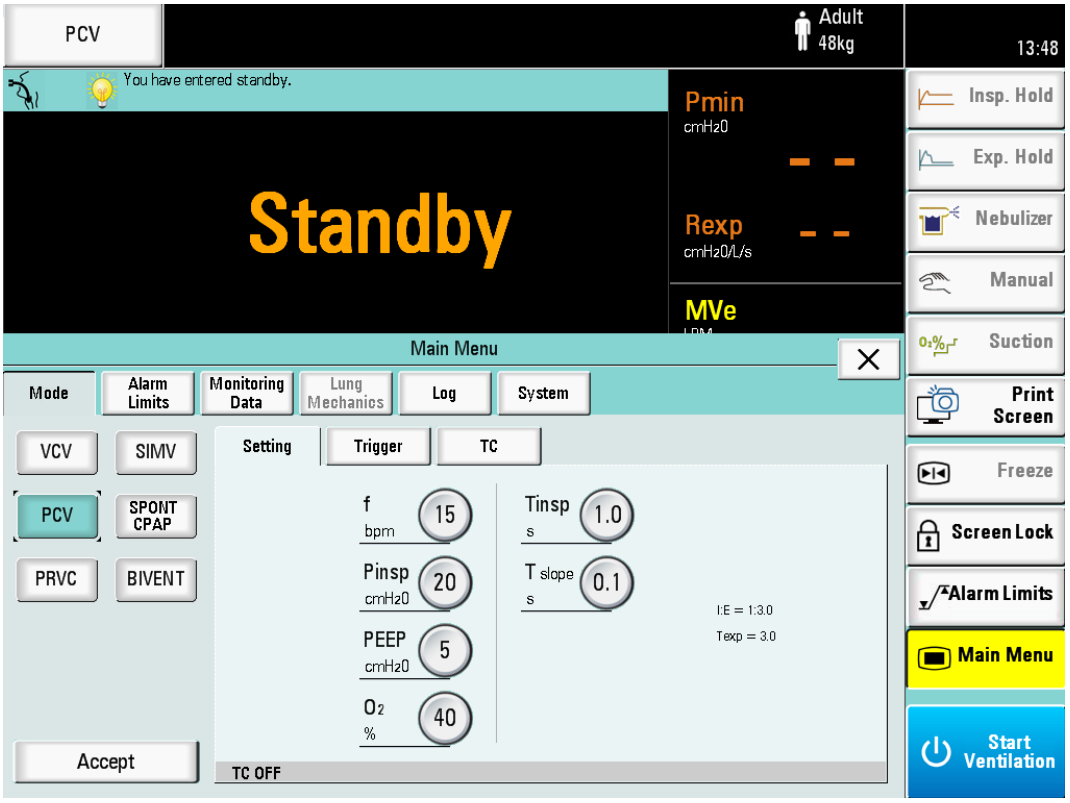


Figure 6-19

Step 2: Click the mode you want, for example:

Click [VCV] to enter the [VCV] mode setup page. The [VCV] button will become yellow as shown in Figure 6-20. Then the user can set every parameter of VCV mode.

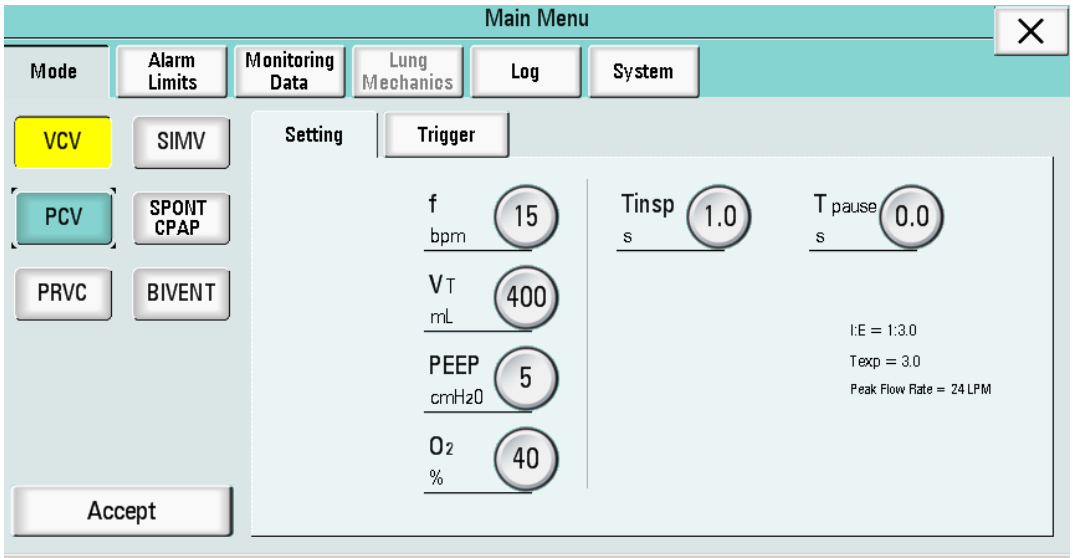


Figure 6-20

Step 3: Click [Accept], now VCV mode is set as the ventilation mode. See Figure 6-21.

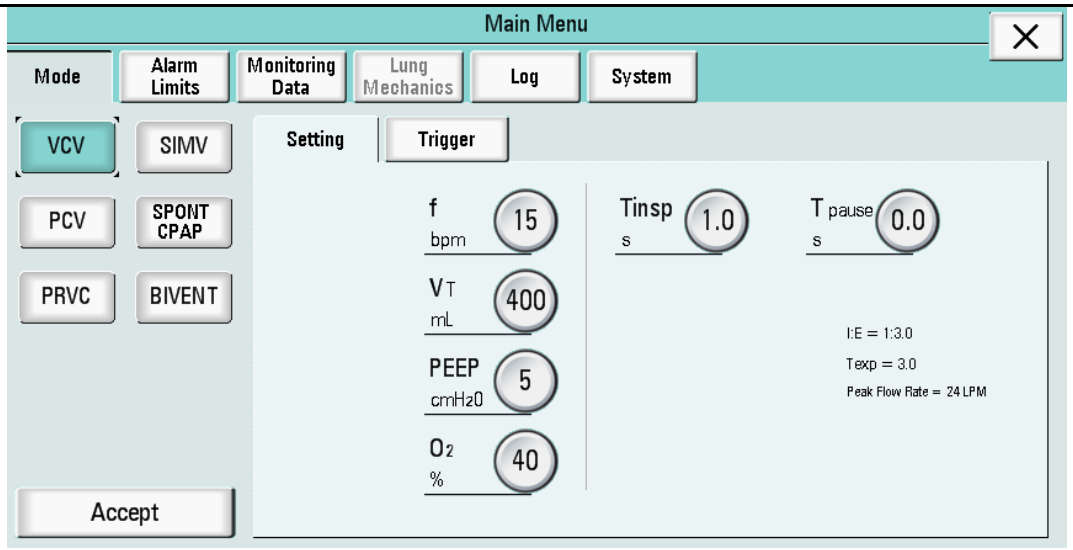


Figure 6-21

NOTE: The setup procedures of other modes are similar to the one above.

CAUTION: If “Accept” is not clicked, the screen will return to the main menu, and the last setup changes made will have no effect.

6.3.1.2 Mode Descriptions

Backup ventilation mode is included for: SPONT/CPAP+PSV, SIMV (VCV) +PSV, SIMV (PCV) +PSV, SIMV (PRVC) +PSV, and BIVENT+PSV. To setup the PSV mode, the user must set Psupp setting to a value not equal to 0, then “+PSV” will be added to the bottom of the mode name, as shown in Figure 6-22. Remember that mode changes are only in effect after Accept is pressed, as shown in Figure 6-23.

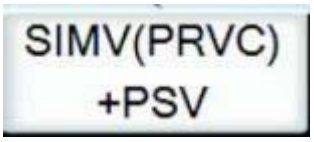


Figure 6-22

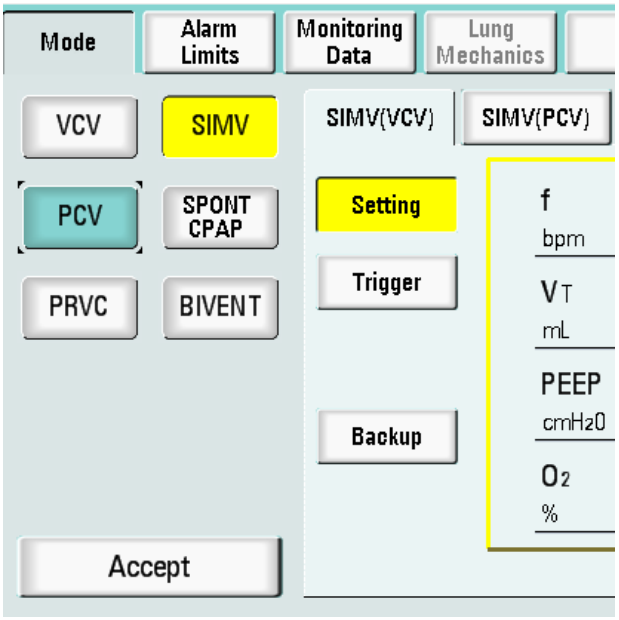


Figure 6-23

The spontaneous ventilation modes include: SPONT/CPAP+PSV, SIMV (VCV) + PSV, SIMV (PCV) + PSV, SIMV (PRVC) + PSV, and BIVENT + PSV. The backup ventilation mode will be PCV.

There are two measures for recovery from apnea: patient triggering and operator resetting.

When setting the above ventilation modes, the operator should set the backup ventilation mode. The default values and the range of the parameters are shown in the Table 6-1.

Table 6-1

Parameter	Factory default setup		Setup range		Adjustment step
	Adult	Child	Adult	Child	
Mode	PCV	PCV	VCV, PCV, PRVC, SIMV (VCV, PCV, PRVC) , BIVENT, SPONT/CPAP, NIV/CPAP, NIV-T, NIV-S/T	VCV, PCV, PRVC, SIMV (VCV, PCV, PRVC) , BIVENT, SPONT/CPAP, NIV/CPAP, NIV-T, NIV-S/T	-
V_T(mL)	400	80	50-2000	20-300	5mL for under 100mL(incl.), 10mL for over 100mL, 50mL over 1000mL

Parameter	Factory default setup		Setup range		Adjustment step
	Adult	Child	Adult	Child	
f(bpm)	15	30	1-80	1-80	1
f(SIMV)(bpm)	10	20	1-40	1-40	1
f(NIV-T) (bpm)	15	30	4-20	4-40	1
PEEP/Plow(cmH_2O)	5	5	0-35	0-35	1
CPAP(cmH_2O)	5	5	2-20	2-20	1
O_2	40%	40%	21%-100%	21%-100%	1%
P_{insp}(cmH_2O) in invasive modes	20	10	5-(70-PEEP)	5-(70-PEEP)	1
P_{insp}(cmH_2O) in NIV-T	20	10	5-(50-PEEP)	5-(50-PEEP)	1
T_p(s)	0	0	0-4	0-2.5	0.1
T_{slope}(s)	0.1	0.1	0-2	0-2	0.1
Trigger mode	$\dot{V}sens$	$\dot{V}sens$	$\dot{V}sens$,Psens	$\dot{V}sens$,Psens	--
Psens(cmH_2O)	-3	-3	-20-0	-20-0	1
$\dot{V}sens$(LPM)	2	2	0.5-20	0.5-20	0.5
T_{Insp}(s)	1	0.6	0.2-9	0.2-5	0.1
I:E	1:2	1:2	1:10~4:1	1:10~4:1	0.5
P_{supp} (cmH_2O) in invasive modes	0	0	0-(70-PEEP)	0-(70-PEEP)	1
P_{supp} (cmH_2O) in NIV-S/T	0	0	0-(50-PEEP)	0-(50-PEEP)	1
P_{high}(cmH_2O)	15	15	5-60	5-60	1
P_{low}(cmH_2O)	5	5	0-35	0-35	1
T_{high}(s)	1	0.6	0.2-30	0.2-30	0.1
T_{low}(s)	3	1.4	0.2-30	0.2-30	0.1
E_{sens}	25%	25%	5%-80%	5%-80%	1%
High Spont Insp Time	1.99 + (0.02x	(1.99 + (0.02x	0.4 sec to (1.99 + (0.02 x	0.4 sec to (1.99 + (0.02 x	0.1

Parameter	Factory default setup		Setup range		Adjustment step
	Adult	Child	Adult	Child	
	IBW)) sec) or 5 sec if no IBW	IBW)) sec) or 5 sec if no IBW	IBW)) sec	IBW)) sec	
Patient height(cm)	150	100	60-260	30-140	2
TC	OFF	OFF	ON, OFF	ON, OFF	--
Compliance compensation	ON	ON	ON, OFF	ON, OFF	--
Pipe diameter (mm)	7.5	5.0	5-12	2.5-8	0.5

All modes in the mode menu include trigger type selection: pressure or flow. User can also set the value for P_{sens} or V_{sens} after choosing the trigger type. See Figure 6-24.

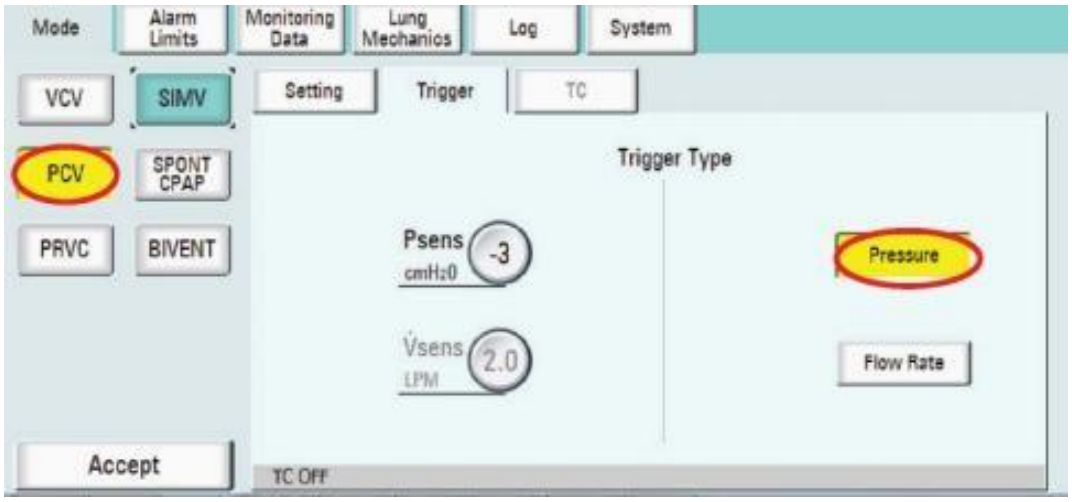


Figure 6-24

Tube compensation (TC) will be available only in pressure modes (PCV, SIMV (PCV), SPONT/CPAP and BIVENT). Select tube compensation “On” and the “On” button will become yellow as an acknowledgement, as shown in Figure 6-25.

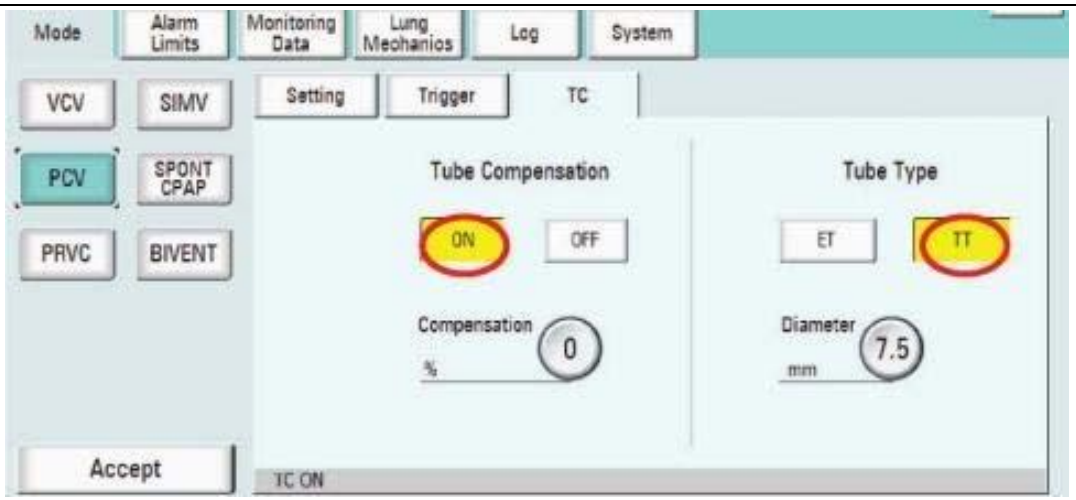


Figure 6-25

Select the tube type in this interface: ET (Endotracheal Tube) or TT (Tracheotomy Tube), and the selected one will become yellow as shown in Figure 6-25.

Tube inside diameter (mm) and Tube compensation amount (%) may be modified after being clicked. Click “Accept” to store the new value.

When tube compensation is enabled, a message will be presented at the bottom of screen: TC ON, as shown in Figure 6-26. Also a tube icon will display in the information area, see Figure 6-27.

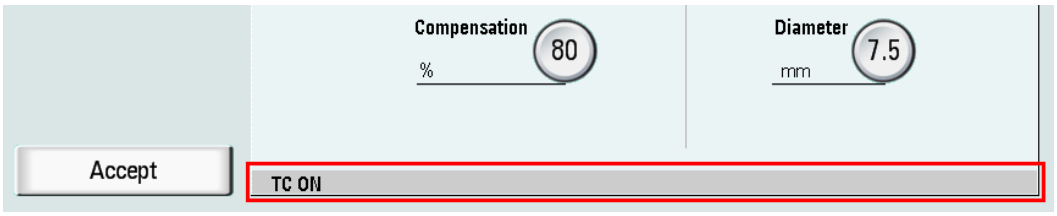


Figure 6 -26

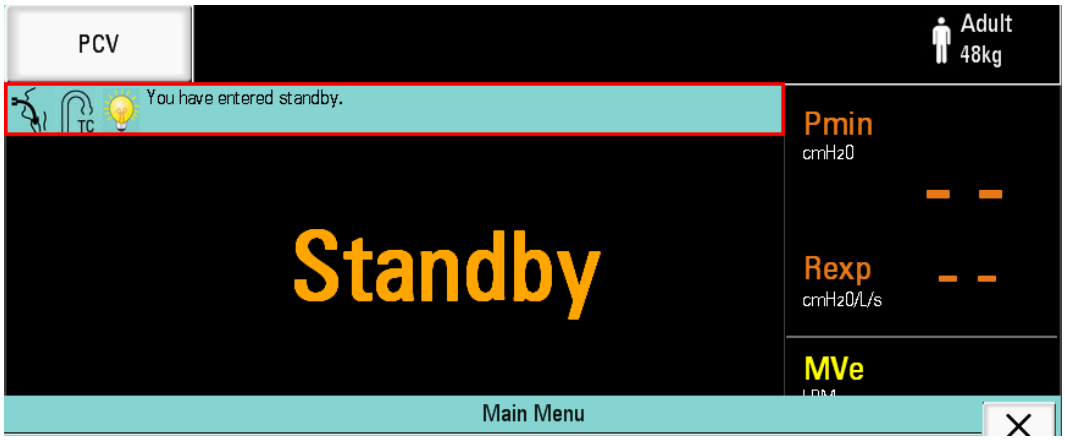


Figure 6-27

Tube inside diameter ranges are: 5 to 12mm for adult, 2.5 to 8mm for child; increment: 0.5mm for both adult and child.

Since the flow trigger is the default trigger mode, “pressure” is displayed on the trigger type menu. SIMV’s input interface is different from that of the other modes. The SIMV setup interface is shown in Figure 6-28, and the other modes in Figure 6-29.

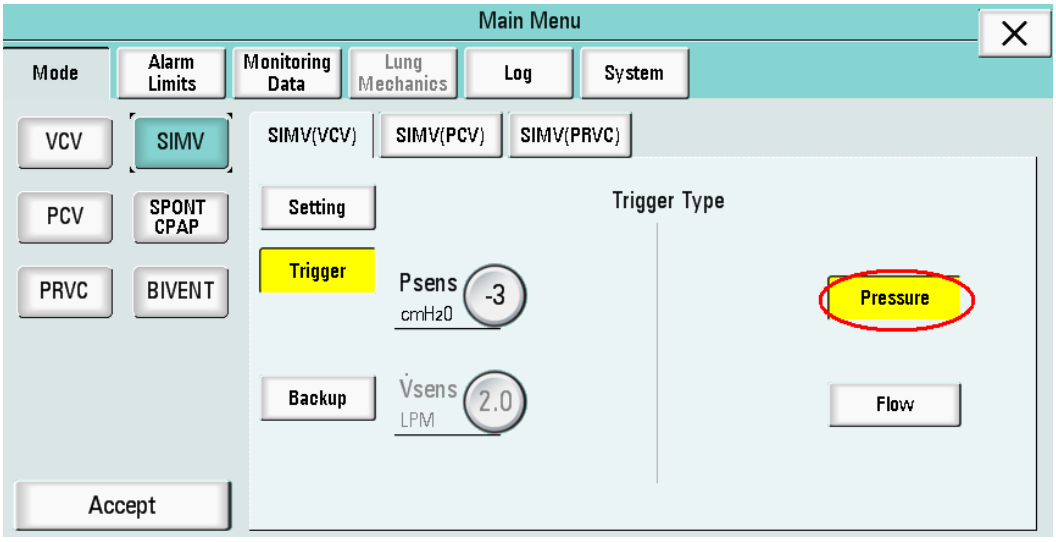


Figure 6-28

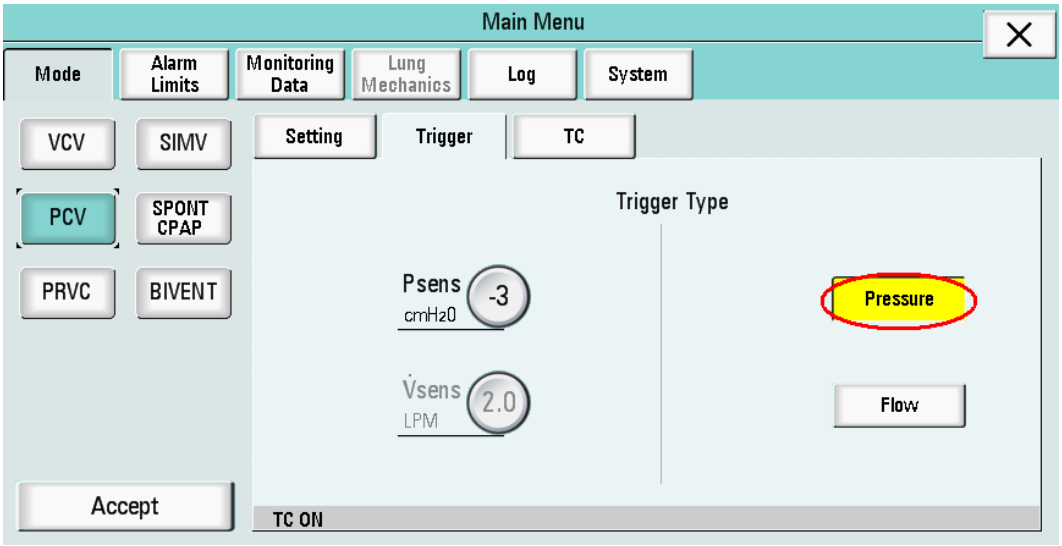


Figure 6-29

After the “pressure” trigger mode is selected, the P_{sens} button can be adjusted and the V_{sens} button will become gray.

6.3.2 Alarm Limits

Click “Alarm Limits” in the “main menu” to enter the “Alarm Limits” menu interface, as shown in Figure 6-30.

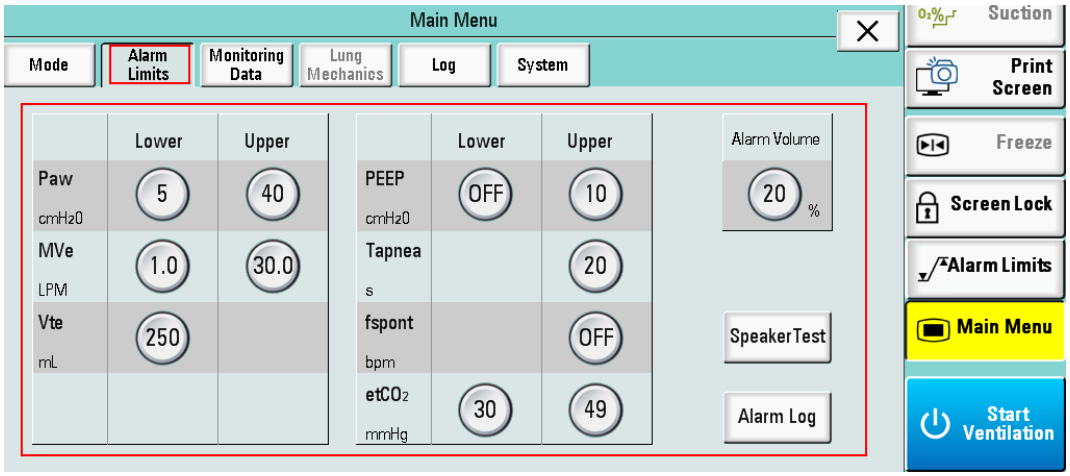


Figure 6-30

The Alarm Limits setting includes:

Paw: high and low limits of patient airway pressure (unit: cmH_2O)

MV_e: high and low limits of minute volume (unit: LPM)

V_{te}: low limit of tidal volume for Expiratory (unit: mL)

PEEP: high and low limits of positive pressure at expiratory end (unit: cmH_2O)

Tapnea: apnea duration (unit: second)

f_{spont}: high limits of rate of spontaneous breaths (unit: breath per minute)

$etCO_2$: high and low limits of CO_2 concentration at the end of Expiration (unit: mmHg)

The limit setup ranges are shown in the following table:

High limit of flow volume per minute	1 to 60L, OFF, 0.1step, default $30L_o$
Low limit of flow volume per minute	OFF, 0.1 to 40L, 0.1 step, default 1L for adult and 0.5L for child.
Low limit of tidal volume	5 to 400mL for child, 5 to 4000mL for adult. Step: 5mL for<100mL (incl.), 10mL for >100mL. Default: 250mL for adult and 50mL for child.
High limit of airway pressure	Not less than PEEP+5 or PEEP+PCV (PSV)(Phigh)+5; 5 to 80 cmH_2O, step 1 cmH_2O, default 40cmH_2O.
Low limit of airway pressure	OFF, 1 to 60 cmH_2O, step 1 cmH_2O, default 5 cmH_2O.
high limit of PEEP in Invasive Ventilation	1 to 35 cmH_2O, OFF, step 1 cmH_2O, default 10 cmH_2O.
Low limit of PEEP in Invasive Ventilation	OFF, 1 to 35 cmH_2O, step 1 cmH_2O, default OFF.

high limit of PEEP in NIV	1 to 20 cmH_2O, OFF, step 1 cmH_2O, default OFF.
Low limit of PEEP in NIV	OFF, 1 to 20 cmH_2O, step 1 cmH_2O, default OFF.
High limit of apnea duration	10 to 60s, OFF, step 1s, default 20s.
High limit of spontaneous breath rate	10 to 80BPM, OFF. Default: OFF.
High limit of etCO_2	0.1%～13.3% (1mmHg～100mmHg or 0.1kPa～13.3kPa), default 6.5% (49mmHg or 6.5kPa).
Low limit of etCO_2	OFF, 0.1%～13.2% (OFF, 1mmHg～99mmHg or OFF, 0.1kPa～13.2kPa), default 4.0% (30mmHg or 4.0kPa).

WARNING: Do not set alarm limit parameter to extreme values that can render the alarm system useless.

WARNING: A potential hazard can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

WARNING: When selecting “New patient”, confirm all alarm limits parameters are appropriate prior to use on each patient.

WARNING: If its value is set to more than 60/Control R, the apnea alarm will not alarm. If apnea alarm is required, select it in the setting screen.

WARNING: It depends on the patient's condition whether to need setting apnea alarm.

NOTE: The “default” values are manufacturer-configured alarm presets, user-configured alarm presets can be made different from the manufacturer-configured alarm presets in [Configurations] menu.

NOTE: To set alarm parameter to “OFF”, set the data display to the lowest or highest value. Press the encoder knob, turn encoder knob one more click and confirm by pressing encoder knob once more.

NOTE: All alarm limit setting parameters are retained during power interruption and can be restored when power returns.

Alarm volume can be adjusted to 5 levels: 20%, 40%, 60%, 80%, 100%. The default volume is 20%.

NOTE: If [Alarm volume] requires adjustment, the procedure is as follows (the same procedure is used for other alarm parameter setup):

Step 1: Click “Alarm volume” when the button’s background color becomes yellow, then you can adjust the level of alarm volume, as shown in Figure 6-31.

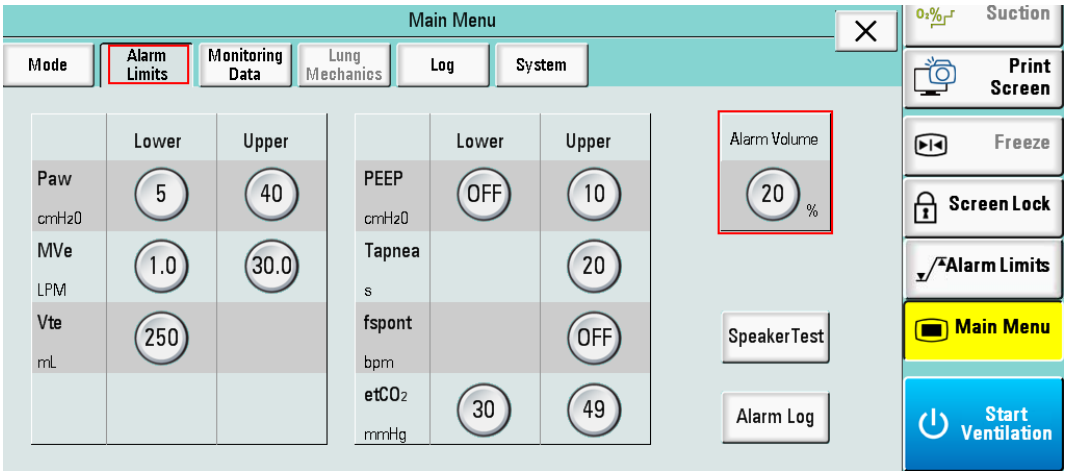


Figure 6-31

Step 2: Turn the encoder knob left or right to adjust the alarm volume, press the encoder knob to confirm when proper value is reached. Background color will return to its original color, as shown in Figure 6-32.

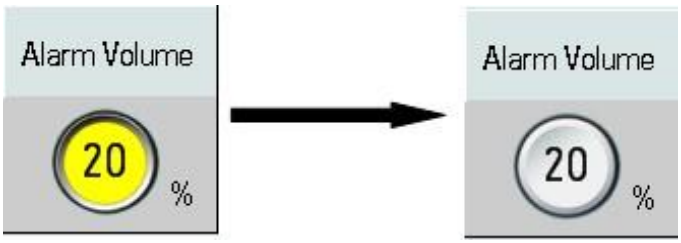


Figure 6-32

CAUTION: If the encoder knob is not pressed at the end, the system will go back to the original value after 10 seconds, i.e. the new setting will have no effect.

CAUTION: In the case of an alarm during operation, the following cases may have occurred:

1) Improper breathing parameter setting or alarm limit setting;

2) Leakage in patient circuit; turn off the machine first and then check. In case of no resolution, contact service representative.

3) Problems with patient;

4) Power supply failure or ventilator failure.

In case there is not sufficient gas volume given to the patient, disconnect the ventilator from the patient, use artificial respiration or other emergency devices for the patient. Check the machine thoroughly.

6.3.3 Monitoring Data

Click “Monitoring data” on main menu to enter “Monitoring data” interface. The parameters are listed in four columns in this interface, as shown in Figure 6-33. All parameters will be also shown in the main interface.

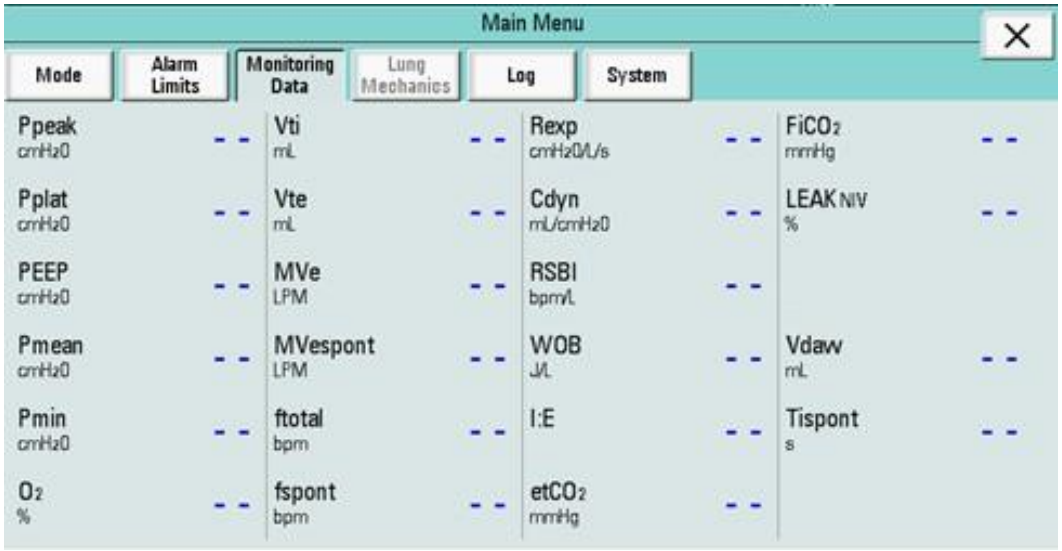


Figure 6-33

6.3.4 Lung Mechanics

Click “Lung Mechanics” on “main menu” to enter “Lung Mechanics” page. On this page, you can select the test items on the left (from the top down): Rinsp, C static and PEEPi. The results of last test for the six parameters are listed on the right, as shown in Figure 6-34.

Figure 6-34

Step 1:

Click “Rinsp” to enter the test menu. The basic information is displayed in the middle of the screen, which includes the result of last and current inspiratory Resistance measurement. The result with date and time of last measurement is on the left, and the result of current measurement with time and date is on the right, as shown in Figure 6-35. If the measurement is not started, the results are “--”.

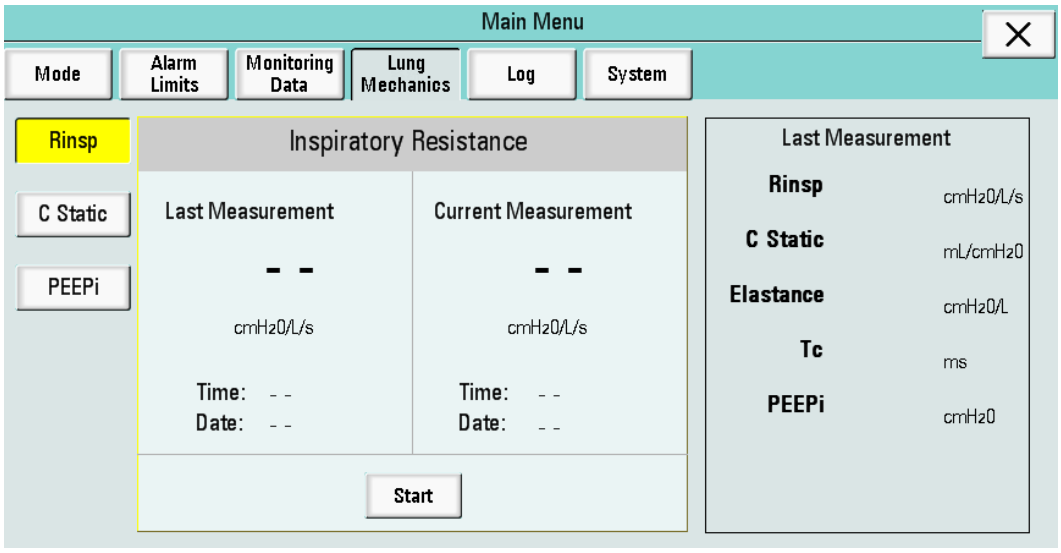


Figure 6-35

Step 2:

When the measurement is completed, current measured values with date and time will be present. “Start” button appears again for another measurement.

NOTE: The test procedures of parameter C static and PEEPi are similar to “Rinsp”.

6.3.5 Log

Click “Log” on “main menu” to enter log menu. There are two buttons on the left of the page: Event/Alarm and trend, as shown in Figure 6-36.

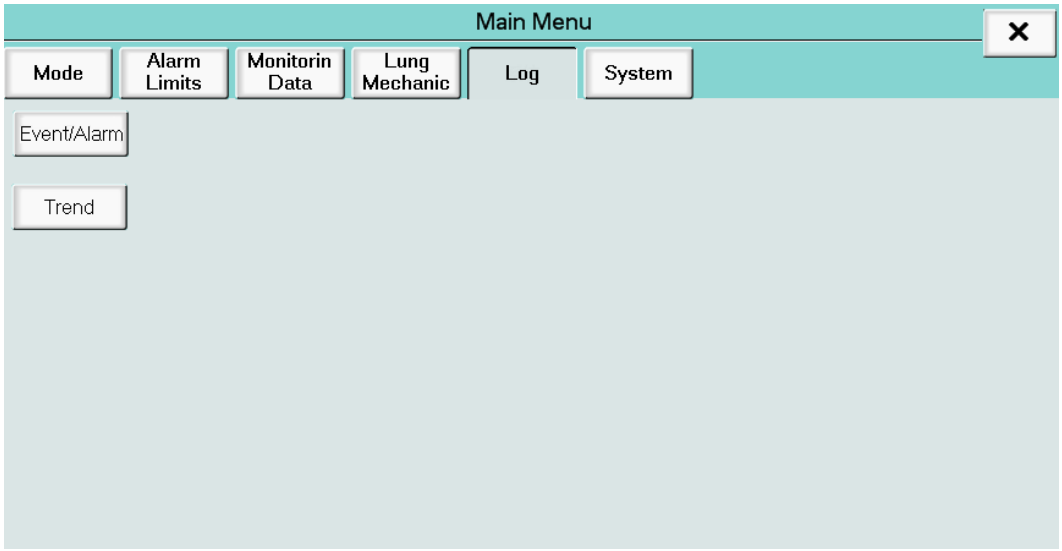


Figure 6-36

Step 1:

Click “Event/Alarm” on log menu to enter the submenu, as shown in Figure 6-37.

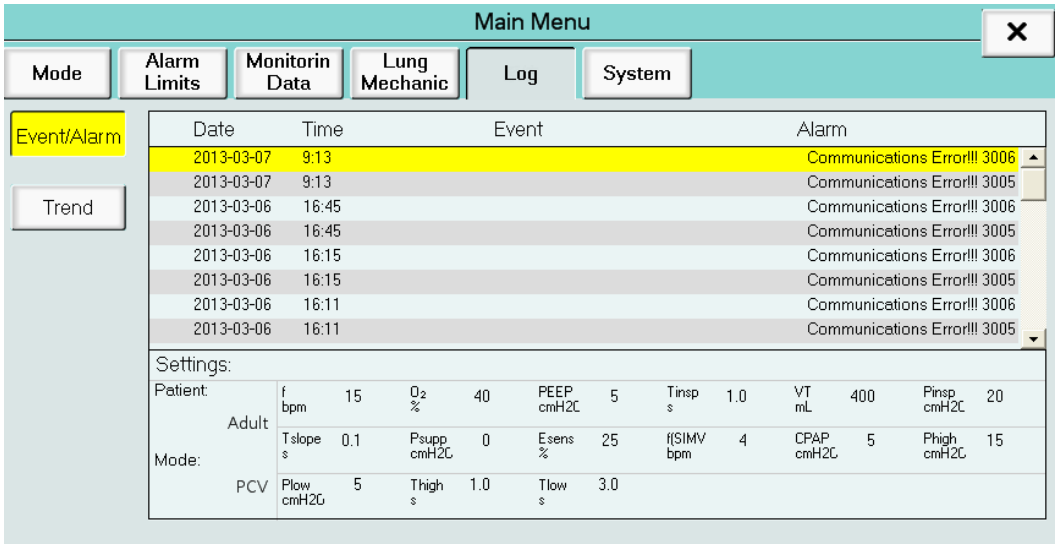


Figure 6-37

The middle area of this page is the message area. It can store up to 1000 messages, including event messages and alarm messages. All messages will be listed in time sequence. The top is the latest event or alarm message, and the bottom is the oldest. Use the scroll bar to check all the messages. An asterisk (*) in front of an alarm message indicates that alarm message was not displayed in the alarm message area. As shown in Figure 6-38. The event/alarm log records all alarms and most actions.

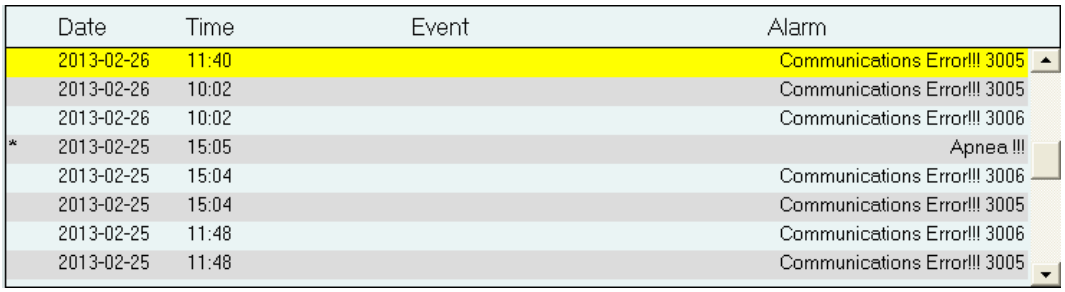


Figure 6-38

Below is the message area of the Settings area resulting from highlighting an alarm. All settings will be given here, as shown in Figure 6-39.

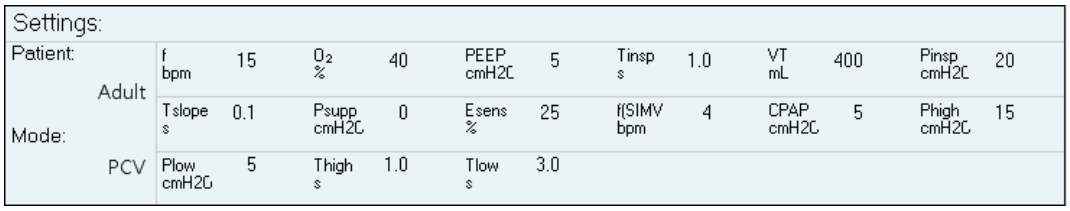


Figure 6-39

NOTE: Alarm/Event Log data is retained during a power interruption and can be viewed when power returns.

Step 2:

Click “Trend” to enter trend interface. There are two trend types: graphical trend and tabular trend, See Figure 6-40 & Figure 6-41.The default is graphical trend. Choose the tabular trend to get more information.

In “Graphical Trend”, the first page displayed is trend map of pressure-related parameters, including Ppeak, Pplat, PEEP, with timeline within 72h. See Figure 6-40.

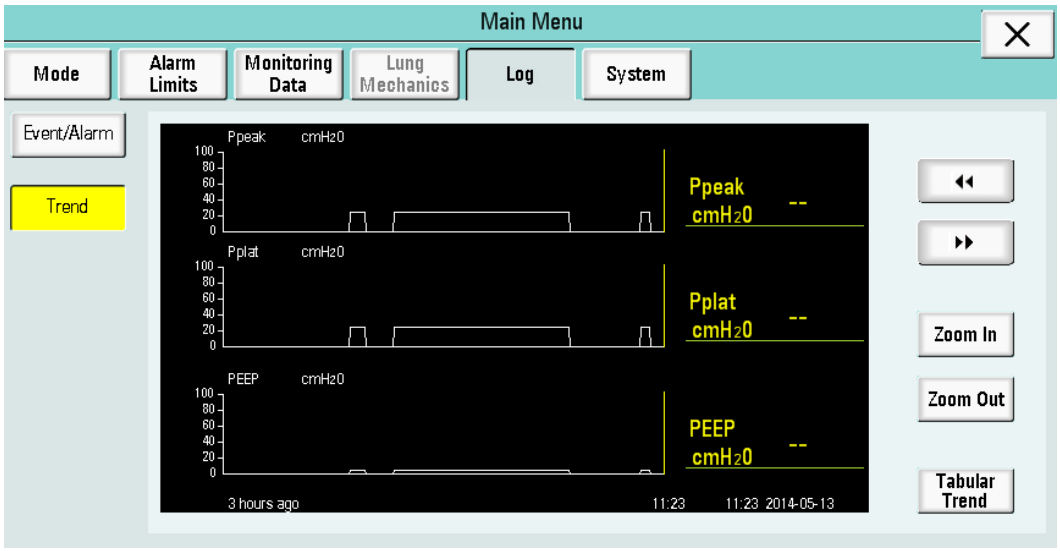


Figure 6-40

Each graph shall have parameter as a title, the units of the parameter and range scale. Six time bases shall be 1, 3, 6, 12, 24, and 72.The displayed parameter for each Trend graph shall be selected from a pop-up menu that will give the user 8 parameters to choose from. The 8 parameter choices in the pop-up menu shall be configured in the Systems tab. “Zoom In” and “Zoom Out” buttons shall be available so that there is better resolution of the Graphs. “Left Arrow” and “Right Arrow” buttons shall be available to move a measuring line to the left or right. The measured value shall be displayed to the right of the parameter label on the right side of each graph. “Zoom In” shall decrease the time base. “Zoom Out” shall increase the time base. A Tabular trend button shall be available for the user to select.

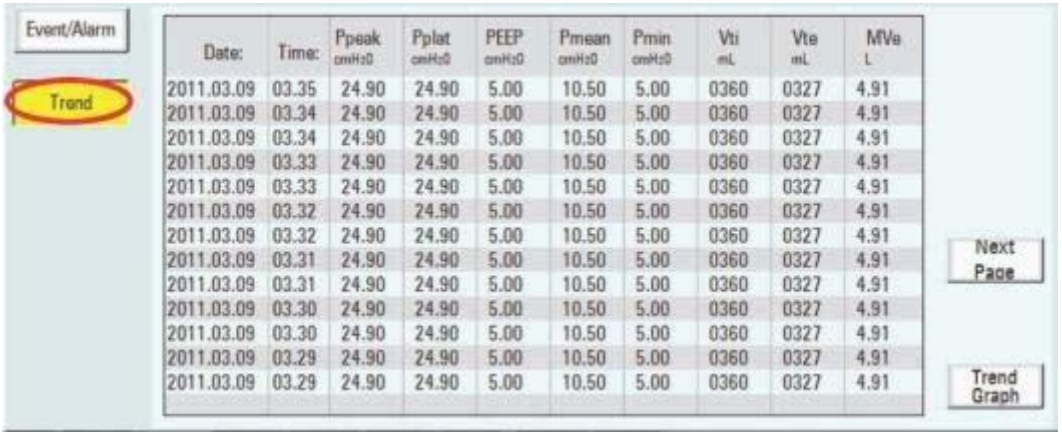


Figure 6-41

NOTE: The X-axis is timeline for all trend maps and Y-axis is the corresponding parameter units.

The waveform on trend map is refreshed from left to right, with latest data on the very left. Y-axis is set for full scale range display.

6.3.6 System

Click “System” button to enter the System interface, as shown in Figure 6-42.

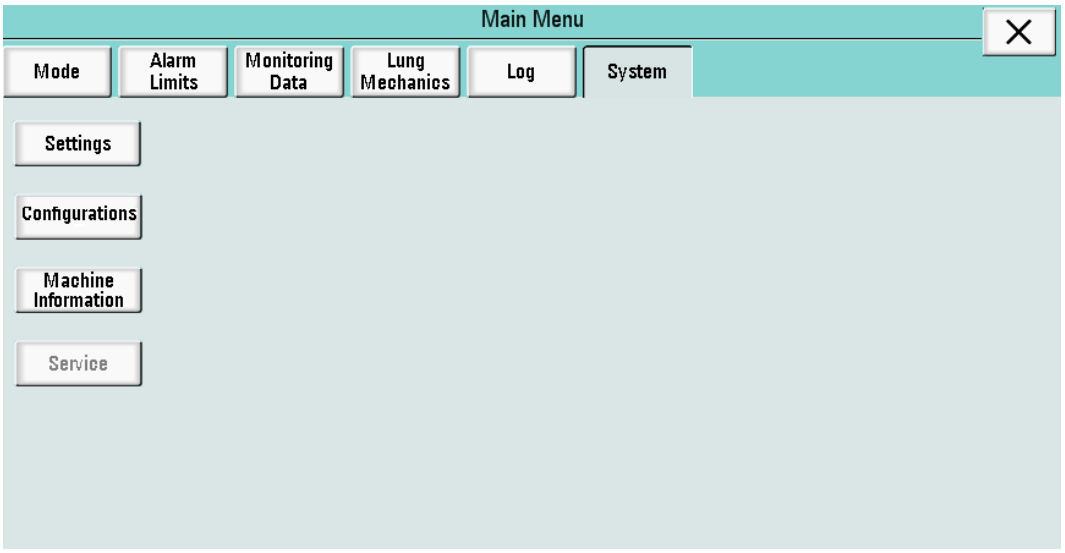


Figure 6-42

There are four buttons on the left of the page: Settings, configurations, machine information and service.

6.3.6.1 Settings

Click “settings” to enter the settings interface, as shown in Figure 6-43.

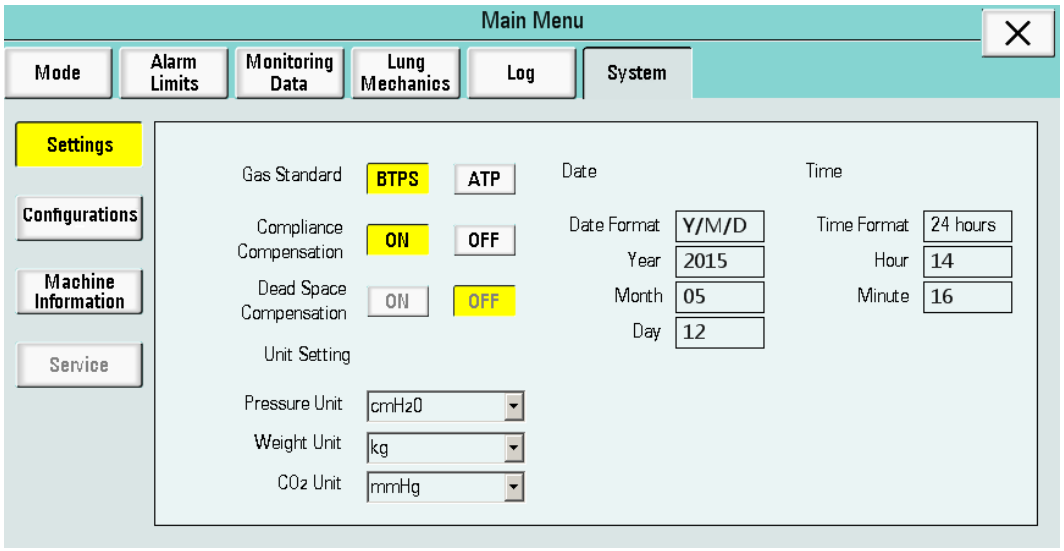


Figure 6-43

You can set the Gas standard, time and date, unit setting, and compliance compensation in this page,

(1) Gas standard

There are two Gas Standard options available to the user: BTPS (Body Temperature and Pressure Saturated) and ATP (Ambient Temperature and Pressure). When selected, the button background color shall be yellow. The default is BTPS and it is chosen with a dot.

(2) Compliance compensation: ON or OFF.

(3) Dead space compensation: ON or OFF.

(4) Unit setting

Pressure unit: Two options: cmH_2O and hPa. When a unit is selected, all pressure units are converted to this unit, such as pressure unit in parameter setting area and parameter monitor area. Default: cmH_2O.

Weight unit: Two options: kg and lb. When a unit is selected, all body weight units are converted to this unit. Default: kg.

CO_2 unit: Three options: mmHg, kPa and %. When a unit is selected, all CO_2 units are converted to this unit. Default: mmHg.

(5) Time and date

Date format: YYYY/MM/DD; Time format: 24hours.

When the date/time format is modified, all date/time areas on the screen will be modified simultaneously. Modify date by clicking directly the numerical value at electronic calendar.

6.3.6.2 Configurations

Click “Configurations” button to enter the configuration interface, as shown in Figure 6-44.

There are three choices in this page: Graphic Trend, Screen Brightness and Site configuration.

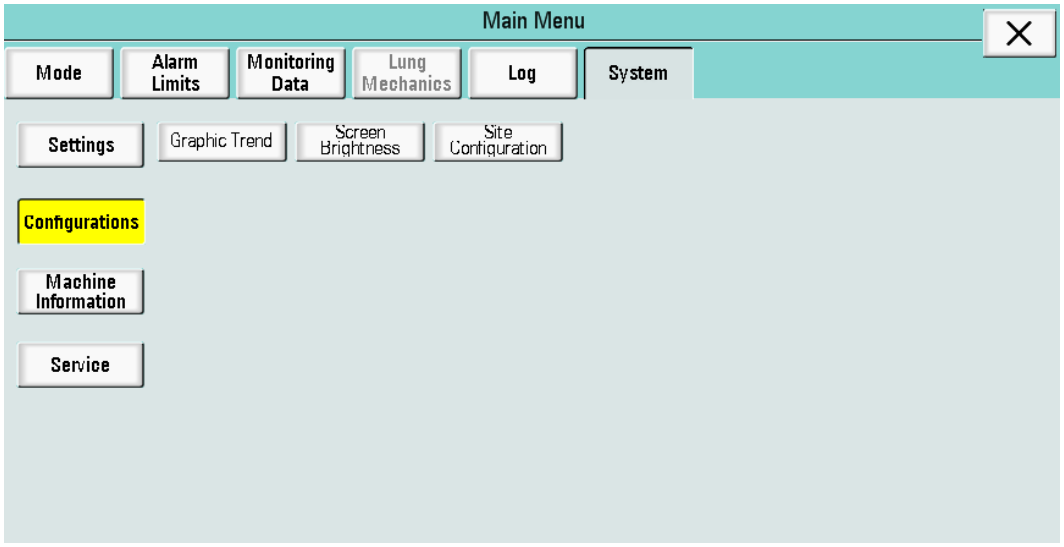


Figure 6-44

6.3.6.2.1 Graphic Trend

Click “Graphic Trend” to the “Graphic Trend” interface, as shown in Figure 6-45.

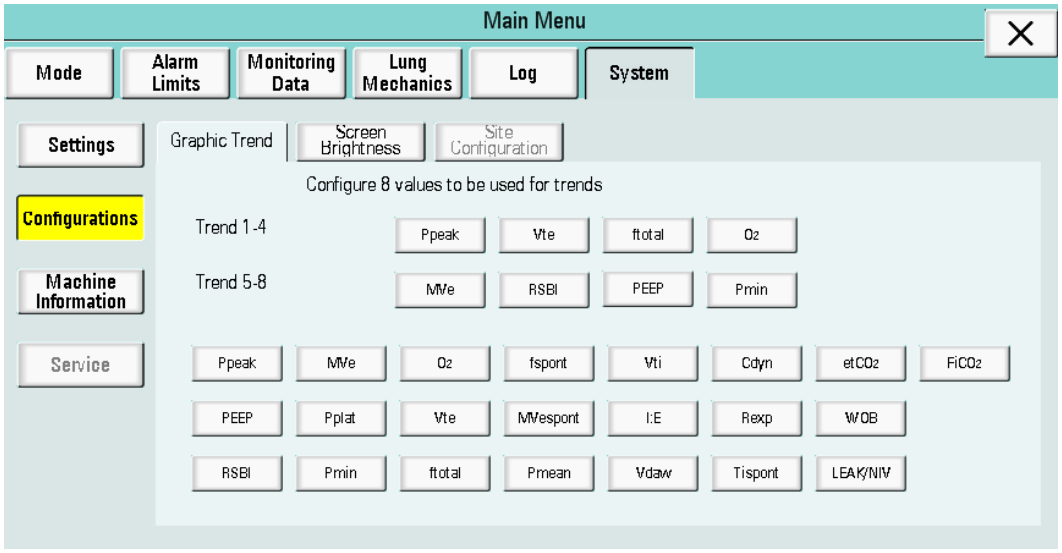


Figure 6-45

On this page, the Patient Measured Parameters can be set. All graphic trends recorded are chosen from this screen. Trend 1-4 are the maps on the first page, and trend 5-8 are the maps on the second page. Below the 8 parameter, there is a monitoring parameter list, including 18 parameters. The Trend 1-8 can be changed according to the need from the parameter list. When a new parameters is chosen, the parameter on the main screen will be replaced at the same time.

6.3.6.2.2 Screen Brightness

Click “Screen Brightness” to enter this page, and click the screen to choose day or night. As shown in Figure 6-46. Day is the default.

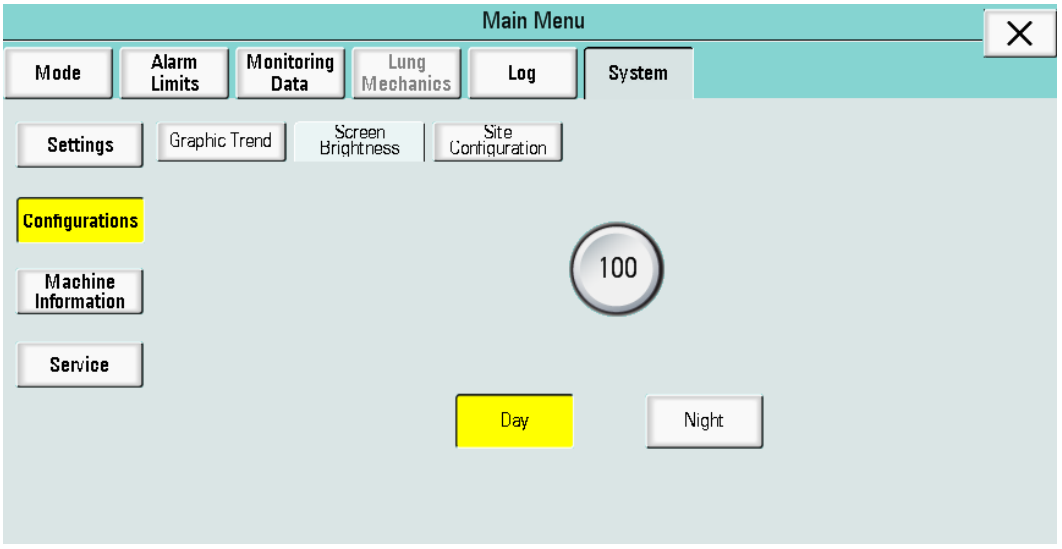


Figure 6-46

6.3.6.2.3 Site Configuration

Step 1

Click “Site Configuration” to enter this page. Set a 4 digit numeric password in the dialog box to have protected access to set Configuration. As shown in Figure 6-47.

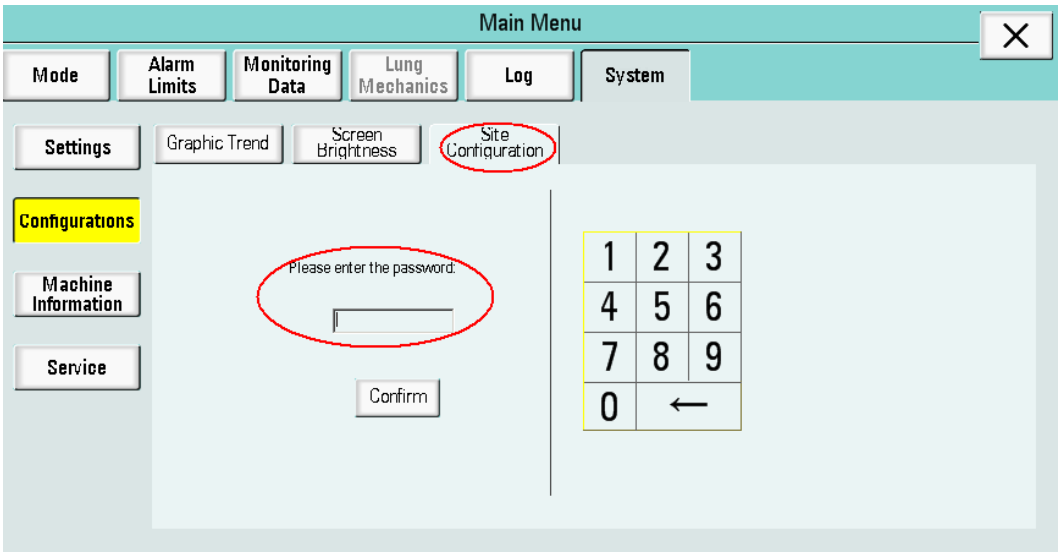


Figure 6-47

Step 2

After entering the password correctly, configure the submenu: As shown in Figure 6-48.

1) Ventilation;
2) Alarms;
3) TC;
4) Monitoring;
5) Others;
6) Network;
7) Load/Save;
8) Export.

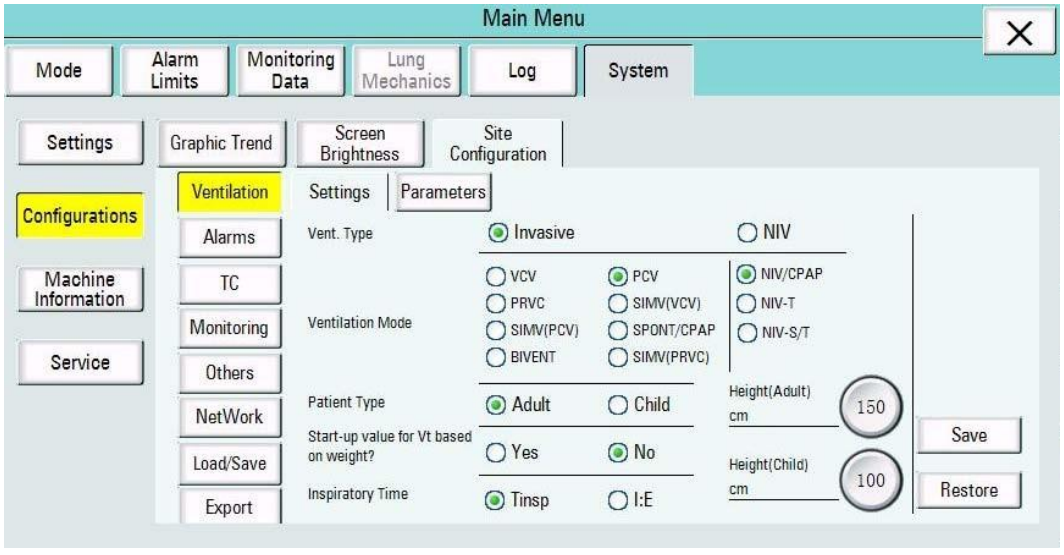


Figure 6-48

(1) Ventilation

a. Settings

Click “Ventilation” button, the background color will be changed to yellow and the default page “settings” will be displayed, as shown in Figure 6-48. User can configure this page for 1) Vent Type, 2) Ventilation Mode, 3) Patient Type, 4) Start-Up value for Vt based on weight?, and 5) Inspiratory time. Touching the button to choose the relative setting will remove the previously selected configuration. Only one choice shall be selected per setting. A selection shall also be provided to enable the user to restore the initial settings to factory defaults. Pressing the “Restore” button shall immediately restore all displayed choices to their factory default.

I. Vent type: Invasive or NIV (Non-Invasive), the factory default is Invasive.

II. Ventilation Mode: VCV, PCV, PRVC, SIMV (VCV), SIMV (PCV), SIMV (PRVC), BIVENT, and SPONT/CPAP for invasive mode, and for NIV are NIV/CPAP, NIV-T and NIV-S/T. The factory default is PCV for Invasive mode and NIV/CPAP for NIV mode.

III. Patient Type: Adult or Child. The factory default is Adult.

IV. Start-up value for Vt based on weight? : Yes or No. The factory default is No.

V. Height: Adult or Child. The default for adult is 150cm and for child is 100cm.

VI. Inspiratory time: Tinsp or I:E. The factory default is Tinsp.

After setting all the values needed, press the “Save” button, otherwise all the settings are lost. Another button “Restore” is under the “Save” button, pressing it restores all displayed choices to their factory default.

b. Parameters

Selecting “Parameters” button, will display a parameters configuration page. This includes the adult and child initial parameter settings. The user can configure for 1)Vt, 2) f, 3) Tinsp, 4) Pinsp, 5) Tslope, 6) PEEP, and 7) Psupp 8) O_2. As shown in Figure 6-49.

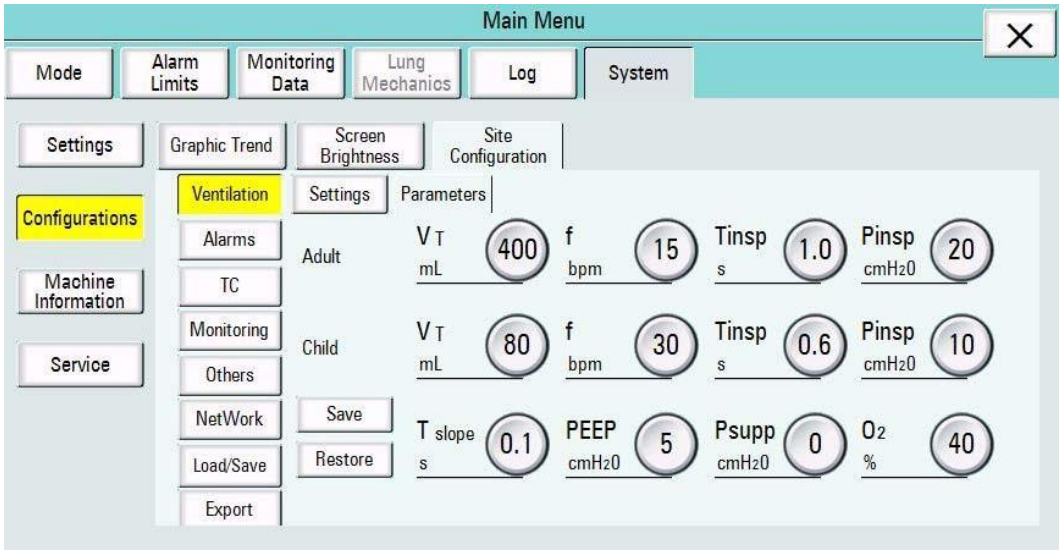


Figure 6-49

Each setting button represents a location that the user can select. Touching the button will be changed to the background color of the button, indicating that it has been chosen and can be changed by rotating the encoder knob left or right to adjust the value. When the selection reaches its maximum or minimum allowable setting, further rotation shall result in the minimum or maximum value displayed continuously. Pressing the button or the encoder knob again confirms the change.

NOTE: Touching any other buttons (or touchable area), will deselect the change and the parameter will be restored to the original setting. The background color will return to normal if the encoder knob is not pressed within 10 seconds

After setting all the values needed, the user will press the “Save” button. Pressing the “Restore” button restores all displayed settings to their factory default.

About the range of the parameters setting, please refer to Table 6-1.

(2) Alarms

Click the Alarms button to enter the alarms configuration page. There shall be 3 pages of configurable alarms. Page 1 configurable alarms shall contain: 1) Paw, 2) etCO_2(optional), 3) f spont, 4) PEEP, 5) Tapnea, 6) MVe. As shown in Figure 6-50.

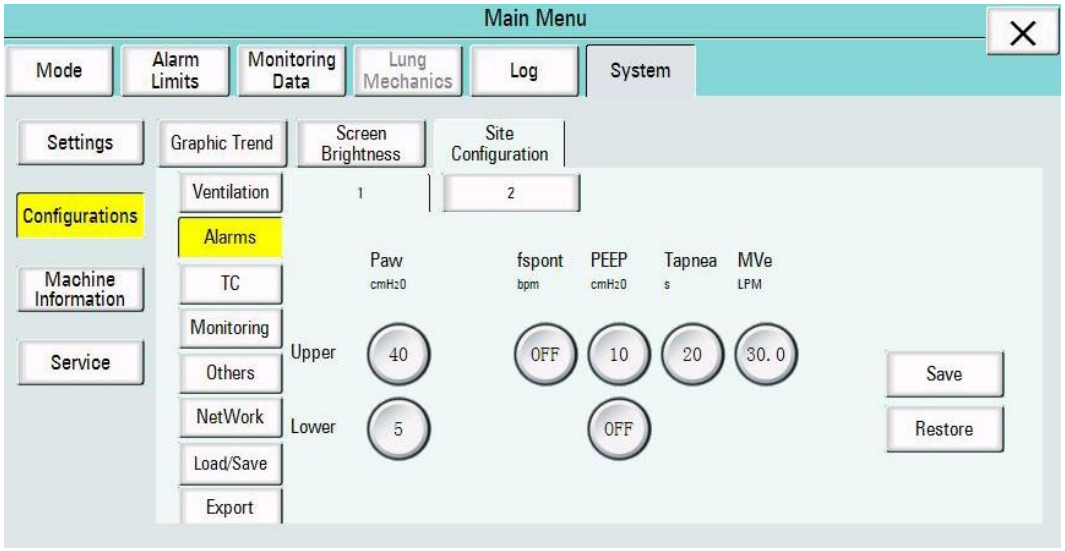


Figure 6-50

Each setting button represents a location that the user can select. Touching the button to choose or change the value, enter the upper and lower limits needed for each alarm, then press the Save button to confirm. There are three configurable alarms available for the user in the second page: 1) MVe, 2) Vte. You can change the alarm limits based on whether the patient is an adult or child, then press the Save button to save the new alarm limits.

Also there is a Restore button under the Save button. Pressing the Restore button restores all displayed settings to their factory default,as shown in Figure 6-51.

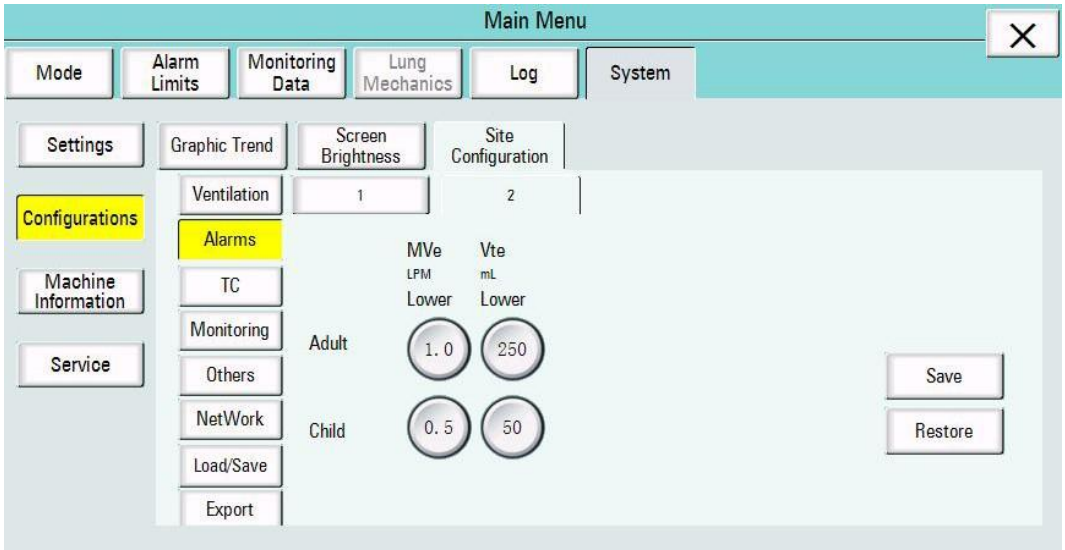


Figure 6-51

(3) TC

Click the TC (Tube Compensation) button to enter the TC configuration page. In this page, you can configure for 1) Tube Compensation, 2) Tube Type, 3) Compensation %,4) Diameter Adult and 5) Diameter Child, as shown in Figure 6-52.

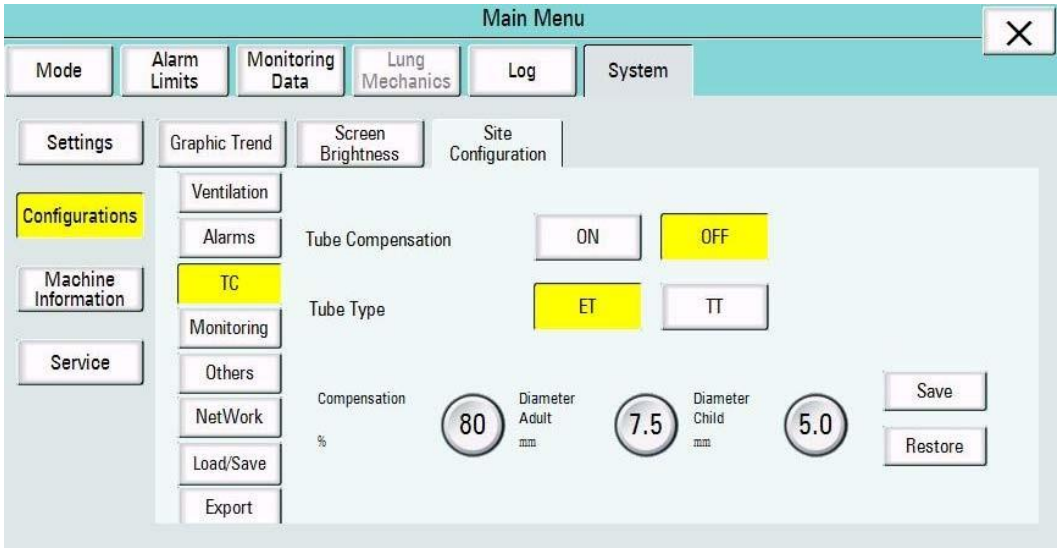


Figure 6-52

1) Tube compensation: ON or OFF, the factory default is OFF

2) Tube Type: ET or TT, the factory default is ET.

3) Compensation %, including Diameter Adult or Diameter Child. The range for Compensation is 0 to 100 in 1% increments and the factory default is 0. Diameter Adult range is 5.0 to 12.0 mm and the default is 7.5 mm. Diameter Child range is 2.5 to 8.0 mm and the default is 5.0 mm.

After finishing all the settings, the user shall press the Save button. Pressing the Restore button restores all displayed settings to their factory default.

(4) Monitoring

Click the Monitoring button to enter the Monitoring configuration page. On this page, you can configure whether the monitoring is ON or OFF, as shown in Figure 6-53.

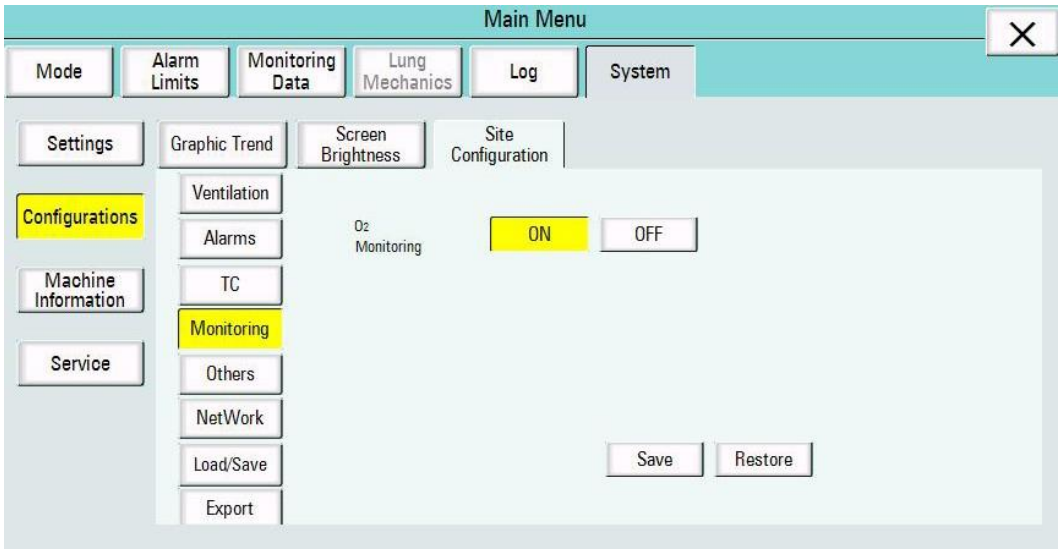


Figure 6-53

(5) Others

Click the “Other” button to enter the others configuration page. On this page, you can choose the oxygen supply type, either HPO or LPO. The factory default shall be HPO. As shown in Figure 6-54.

When the Oxygen Supply Type is LPO, the ventilator should:

- Cancel the O_2 high/low concentration alarm and low Oxygen Supply Pressure alarm.
- O_2 parameter adjustment shall be disabled.
- The nebulizer, suction, O_2 sensor calibration functions shall be invalid.
- No Oxygen Supply Pressure monitor and calibration.
- When performing Pre Use Test, skip Gas supply test and Oxygen sensor test.

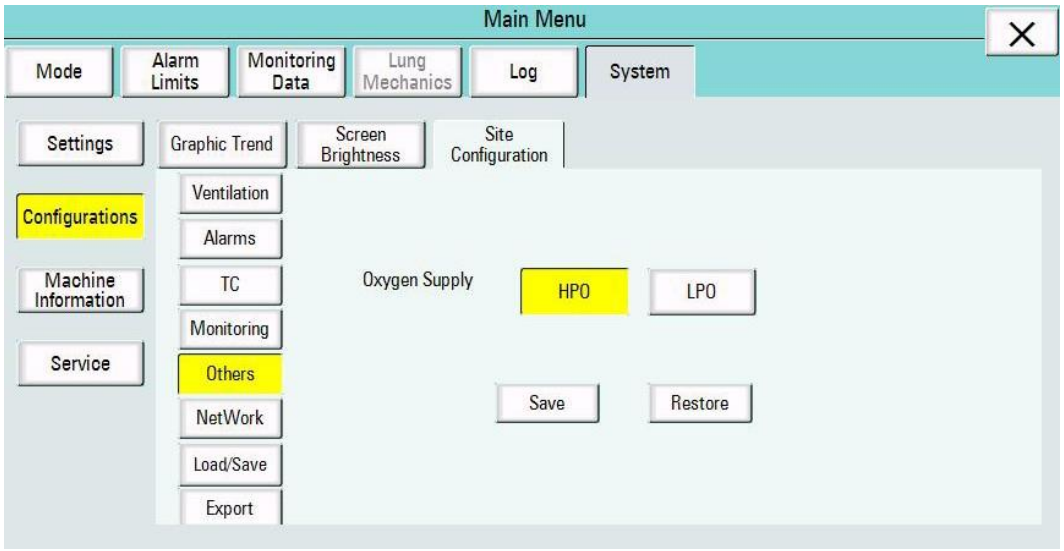


Figure 6-54

(6) Network

Ventilator data is shared by NetWork. As shown in Figure 6-55.

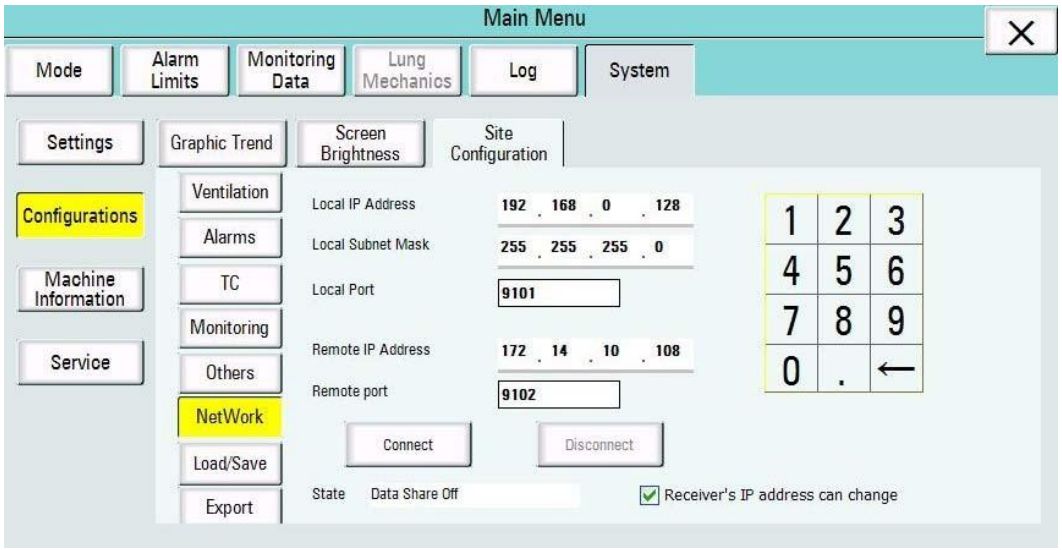


Figure 6-55

CAUTION: Network interface is reserved for debugging, which is used for debugging by professionals of manufacturers and is not open to the public.

(7) Load/Save

Click the “Load/Save” button to enter the Load/Save configuration page. On this page, the load button shall be load the user configuration to the machine, and the save button shall be save the current configuration to the file which you saved. As shown in Figure 6-56.

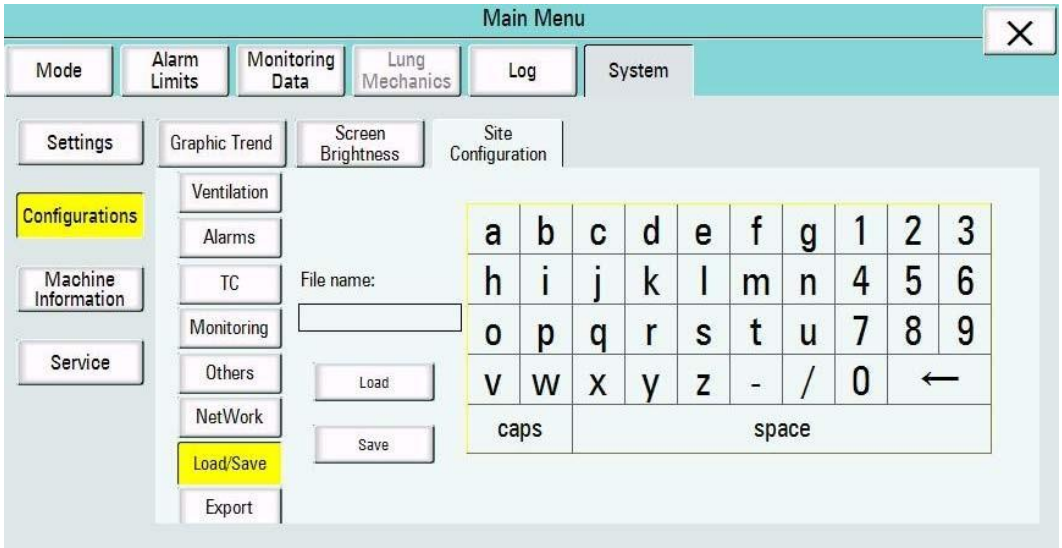


Figure 6-56

(8) Export

Click the “Export” shall change the button background color to yellow and the Export screen shall be displayed. The screen shall include a dialog box with a keyboard, enter the password in the text box, as shown in Figure 6-57.

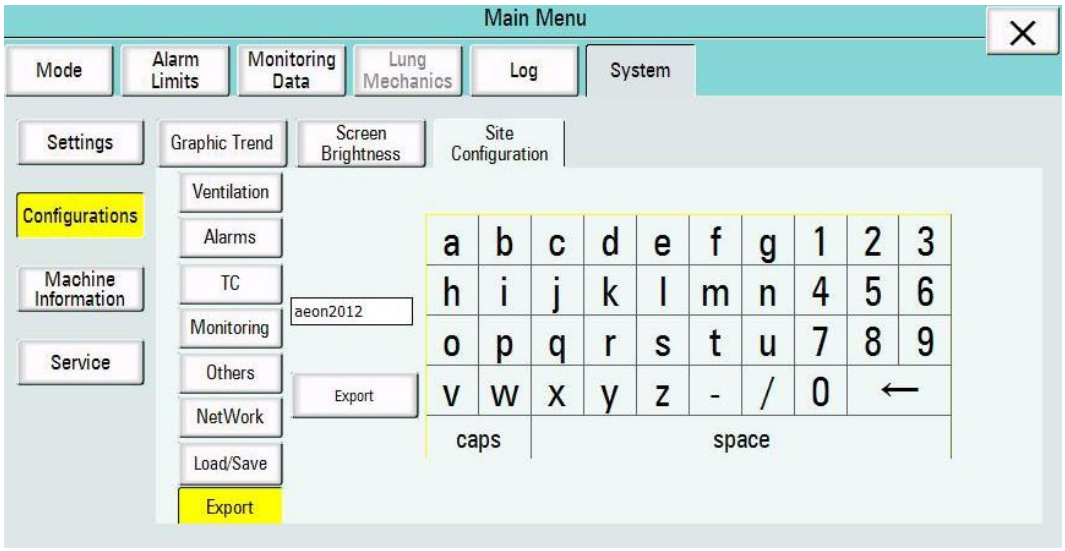


Figure 6-57

6.3.6.3 Machine Information

Click “Machine Information” to enter the device information interface, as shown in Figure 6-58.

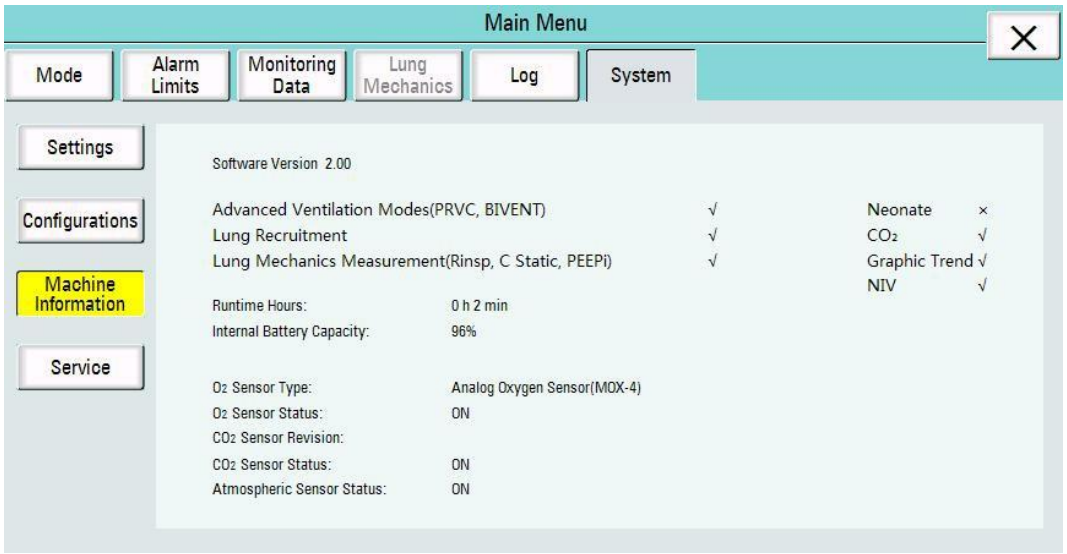


Figure 6-58

When the equipment is not equipped with the atmospheric sensor, the status of the atmospheric sensor shows “OFF (The currently set altitude is 50m)”, as shown in Figure 6-59. When the equipment is installed for the first time, the altitude should be put in manually.

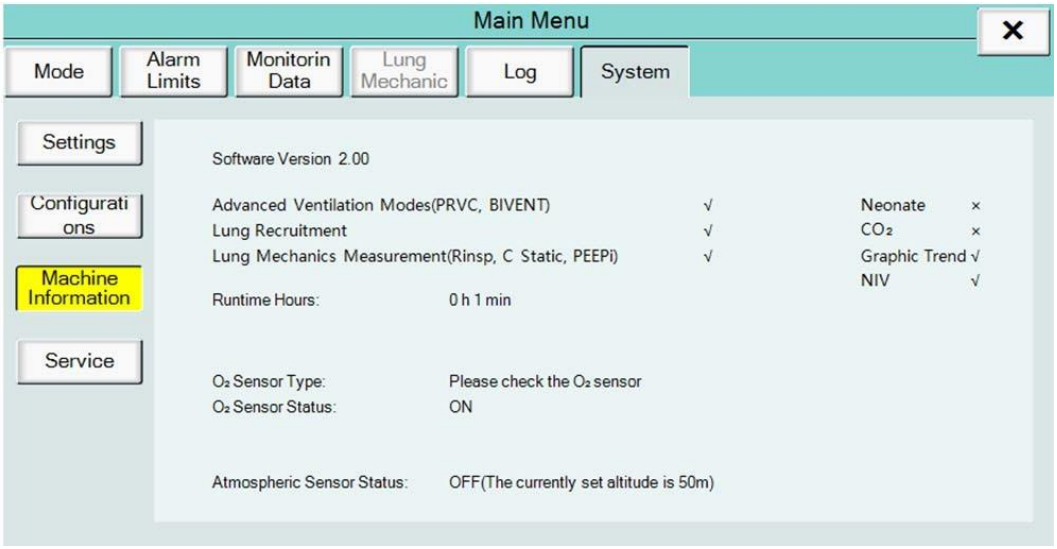


Figure 6-59

If the altitude of where the machine is has been changed, the altitude value should be modified.

WARNING: This device can only be operated at this location/ intra-hospital. Before change of location, please inform manufacturer to first check whether a correction of the ambient pressure settings must be made.

CAUTION: The input of altitude should be operated by professionals and users are not allowed to modify it without authorization.

6.3.6.4 Service

Click “Service” to enter the “Service” page. On this page, the user needs to enter the password, as shown in Figure 6-60.

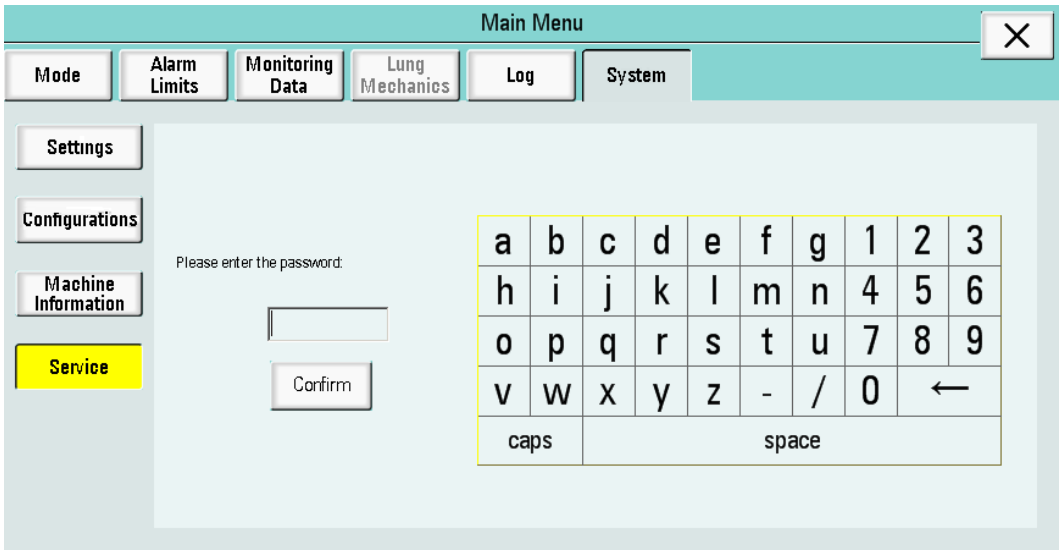


Figure 6-60

Input the correct password to enter, there are seven choices on this page: Calibration, Event/alarm log, Machine Information, Language, Test Page, Update and Optional. The default page is Calibration. See Figure 6-61.

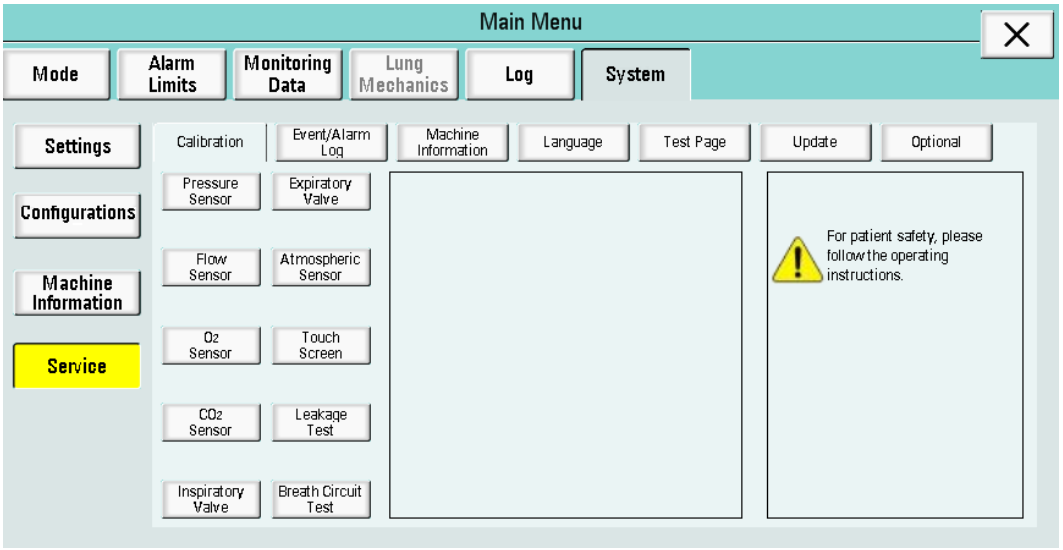


Figure 6-61

6.3.6.4.1 Calibration

The calibration choices include: Pressure Sensor Calibration, Flow Sensor Calibration, O_2 Sensor Calibration, CO_2 Sensor Calibration, Inspiratory valve Calibration, Expiratory Valve Calibration, Atmospheric Sensor Calibration, Touch Screen Calibration, Leak Test and Breath Circuit test, as shown in Figure 6-62.

CAUTION: The calibration will be performed under the patient circuit of adult or child. Please select the correct one during calibration.

(1) Pressure Sensor Calibration: Click “Pressure Sensor” to enter the calibration interface. A message is displayed: “This step is to zero the pressure sensor. Please remove the breathing circuit from the ventilator before calibration.” A legend is displayed as well, as shown in Figure 6-62.

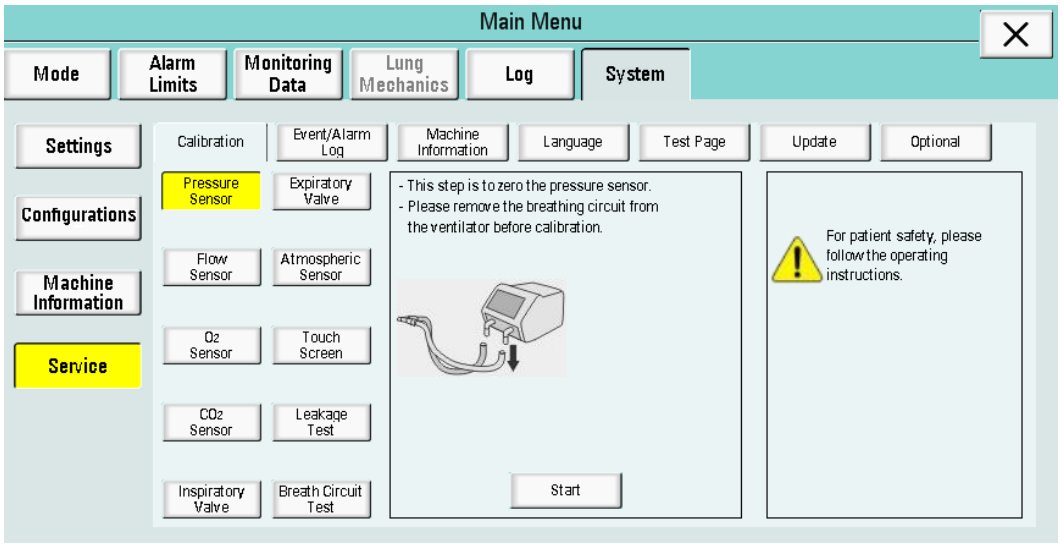


Figure 6-62

Click “Start” to start pressure sensor calibration. A progress bar and a message “Calibration in progress, please wait” will be displayed as shown in Figure 6-63. After calibration, the result will appear: Calibration succeeded or Calibration failed. If failed, restart the calibration.

NOTE: During this period no other operation can be performed. Clicking other areas will have no response.

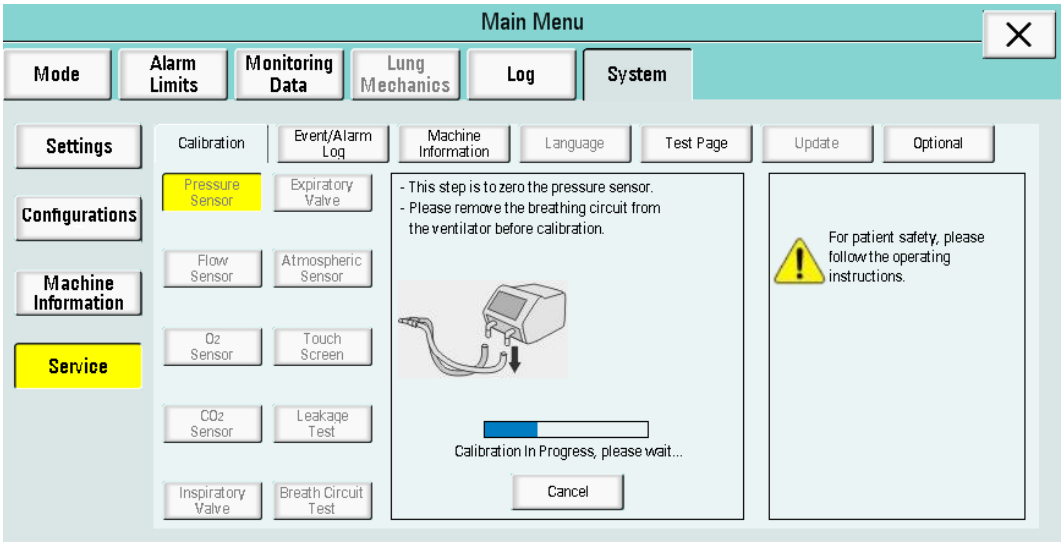


Figure 6-63

(2) Flow Sensor Calibration: Click “Flow Sensor” to enter the interface. A message is displayed: “This step is to calibrate the flow sensor. Please connect the insp. Port and Exp. Port directly with a tube” as shown in Figure 6-64.

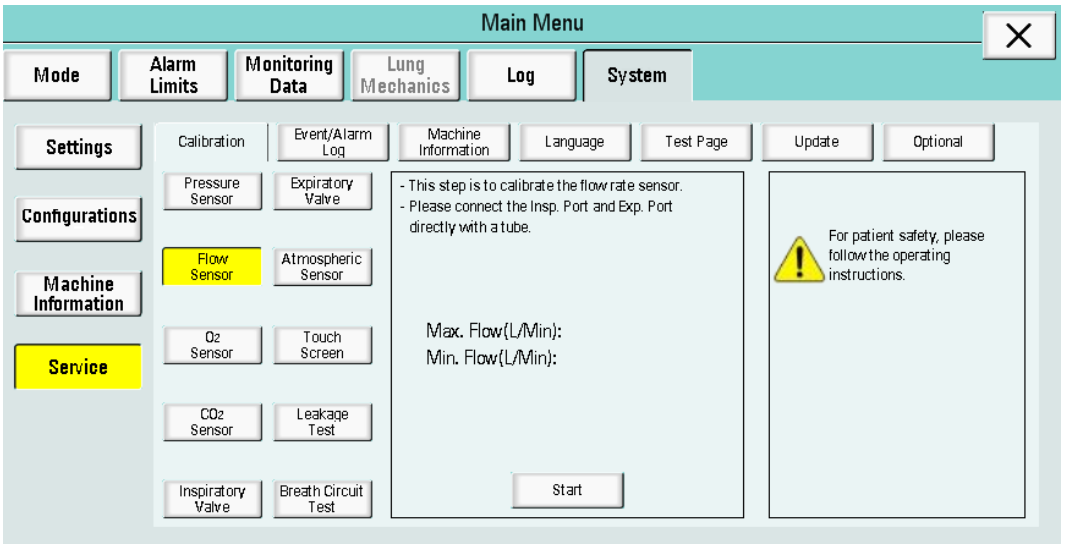


Figure 6-64

Click the “Start” button to start flow sensor calibration, the remaining procedure is the same as the pressure sensor calibration.

(3) O_2 Sensor Calibration: Click “O_2 Sensor” to enter the interface. A message displayed: “Please verify that the oxygen source are connected correctly. Verify that the gas inlet pressure is within specification.” A legend will also be shown. There are two buttons below the legend: “Start 21%” and “Start 100%”. Choose the needed one and click, as shown in Figure 6-65. The remaining procedure is the same as described above.

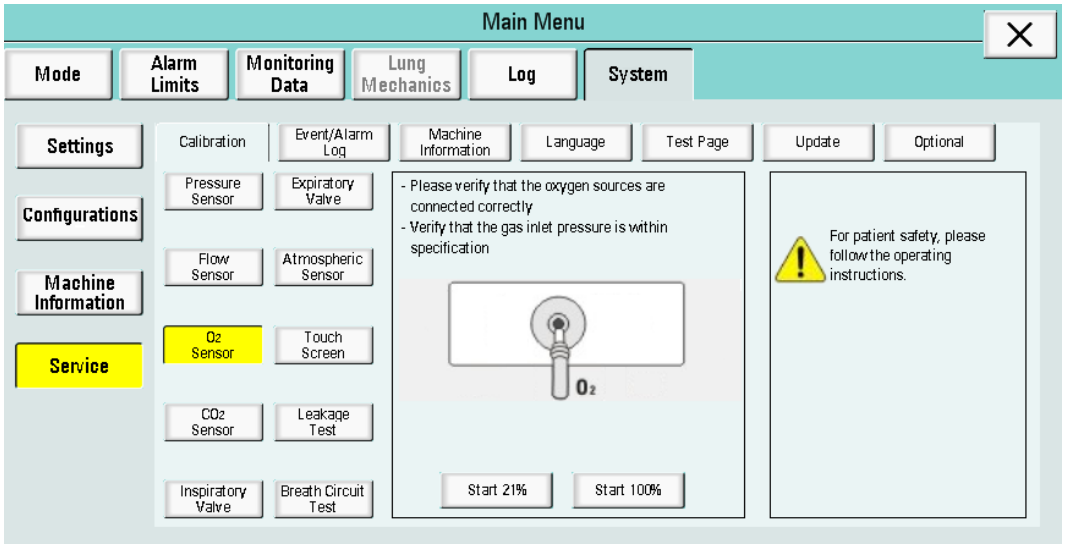


Figure 6-65

WARNING: If the oxygen sensor is not installed or calibrated according to the instructions, or fails to calibrate, the control of oxygen concentration will be affected and the patient's treatment will be delayed.

(4) CO_2 sensor Calibration: Click "CO_2 Sensor" to enter the interface, as shown in Figure 6-66. A message displayed: "Disconnect the CO_2 sensor with the adapter from breathing circuit and ensure it is in ambient air. Wait 1 minute to warm up after the unit is powered on or after connecting an airway adapter. Press "Zero" when the State-Area turns green". Please follow the prompt message to calibrate.

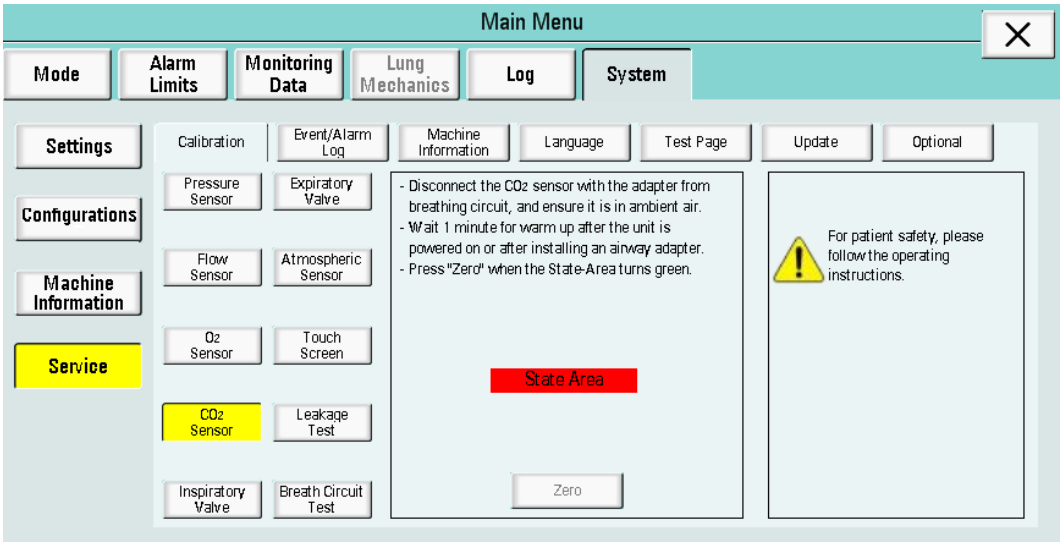


Figure 6-66

CAUTION: Calibration is required only after the CO_2 module is activated. If it is not activated, there is no such function.

(5) Inspiratory Valve Calibration: Click "Inspiratory Valve" to enter the interface. A message displayed: "This step is to calibrate the inspiratory valve. Please connect the Insp. Port and Exp. Port directly with a tube", as shown in Figure 6-67.

Click the "Start" button to start inspiratory valve calibration, the remaining procedure is the same as the pressure sensor calibration.

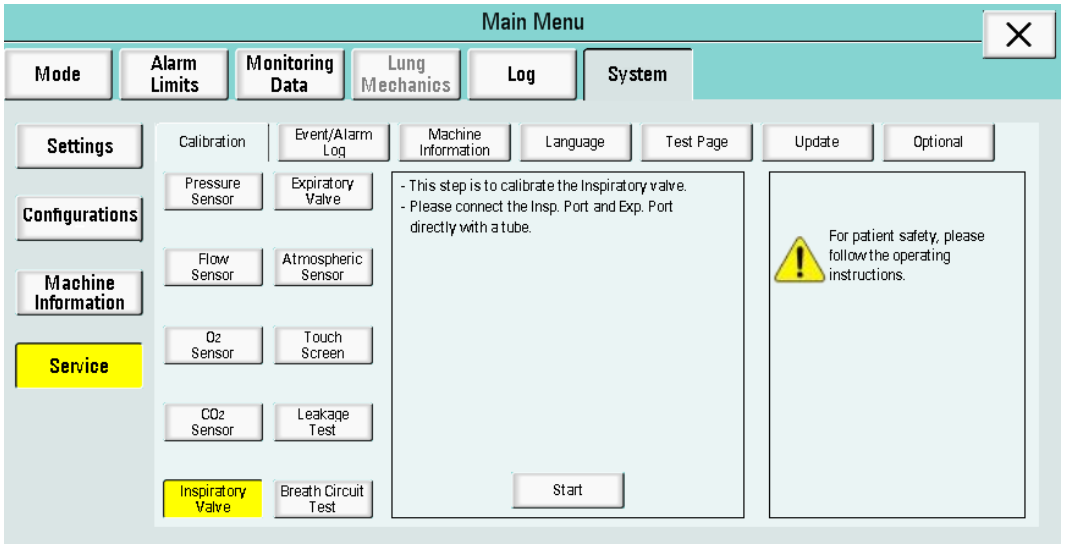


Figure 6-67

(6) Expiratory Valve Calibration: Click “Expiratory Valve” to enter the interface. A message displayed: “This step is to calibrate the expiratory valve. Please connect patient circut and test lung before calibration”, as shown in Figure 6-68.

Click the “Start” button to start expiratory valve calibration, the remaining procedure is the same as the pressure sensor calibration.

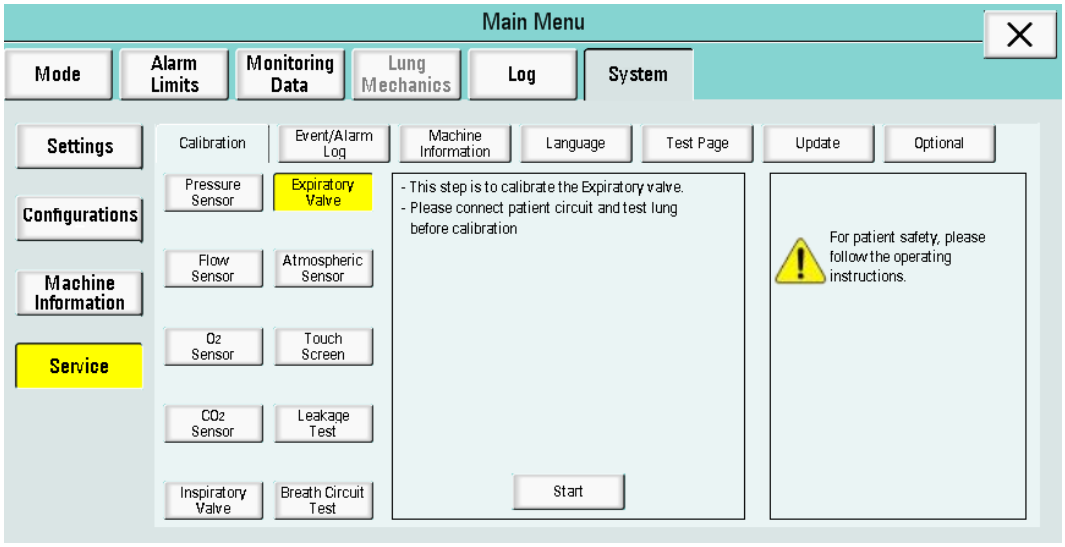


Figure 6-68

(7) Atmospheric Sensor Calibration: Click “Atmospheric Sensor” to enter the atmospheric sensor interface, as shown in Figure 6-69.

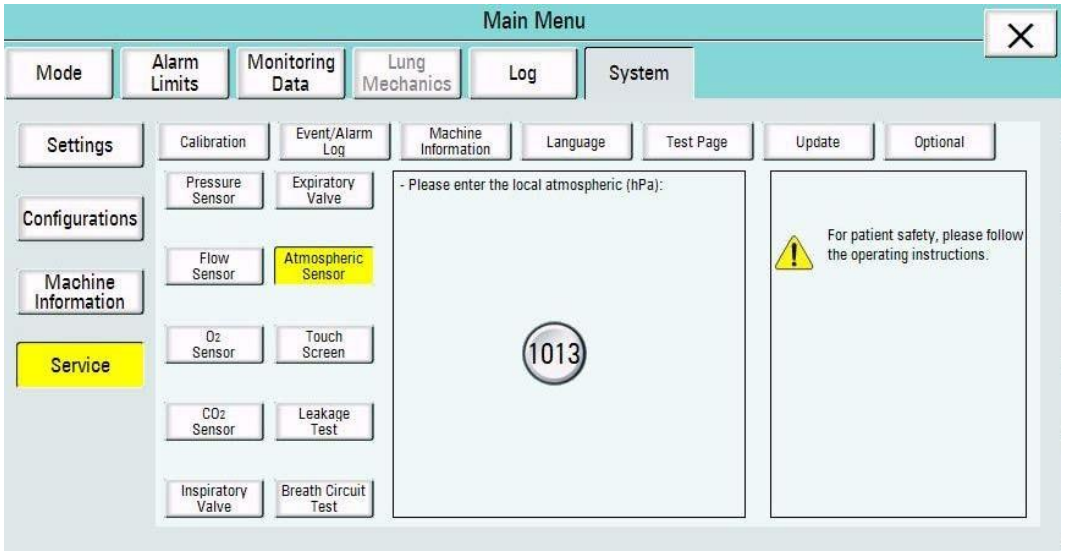


Figure 6-69

CAUTION: When the atmospheric sensor displays “ON” (Figure 6-58), it needs to be calibrated.

When the equipment is not equipped with the atmospheric sensor, as shown in Figure 6-70.

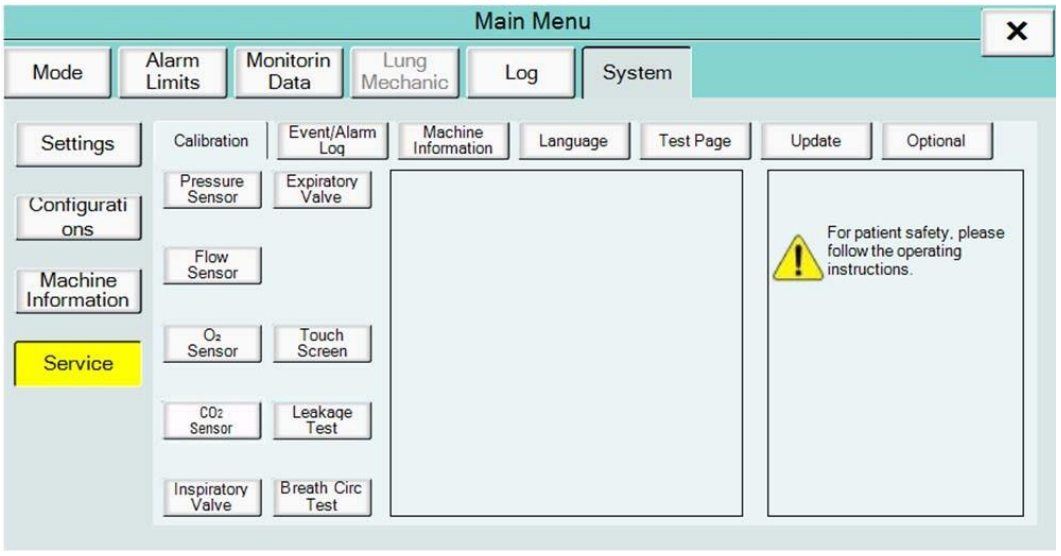


Figure 6-70

CAUTION: When the atmospheric sensor displays “OFF” (Figure 6-59), it doesn't need to be calibrated.

(8) Touch Screen Calibration: Click “Touch screen” to enter the calibration interface. A message is displayed: “This step is to calibrate the touch screen. The ventilator’s screen will disappear during the calibration. Please follow the instruction in the calibration program.” as shown in Figure 6-71.

CAUTION: When the touch screen fails to work, please stop or replace the ventilator and repair it in time under the condition of ensuring the patient's safety.

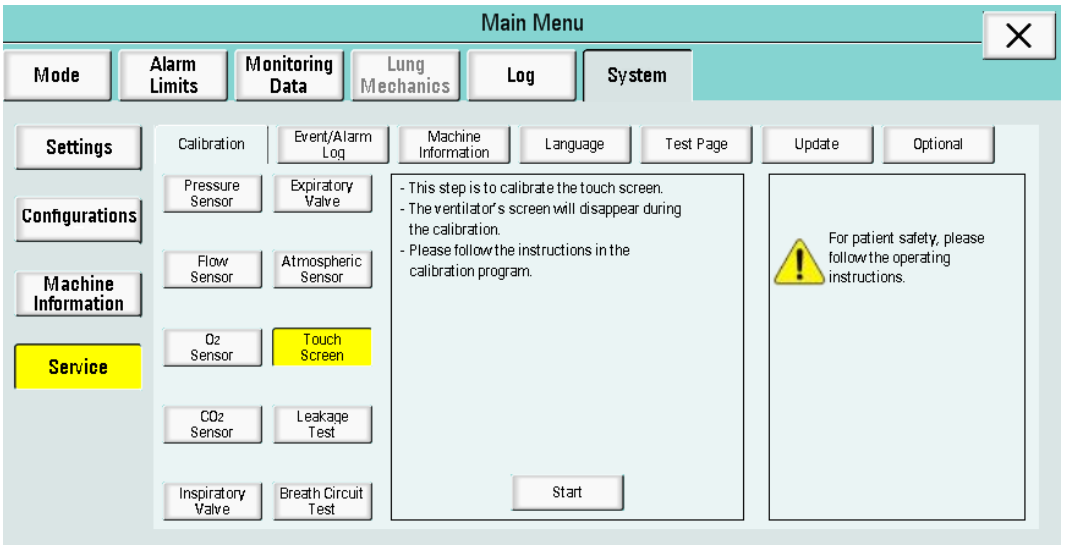


Figure 6-71

Click the “Start” button to start, the remaining procedure is as described in steps above.

(9) Leakage Test Calibration: Click “Leakage Test” to enter the test interface. A message is displayed: “This step is to test the internal leakage of ventilator. Please connect the Insp. Port and Exp. Port directly with a tube”, as shown in Figure 6-72.

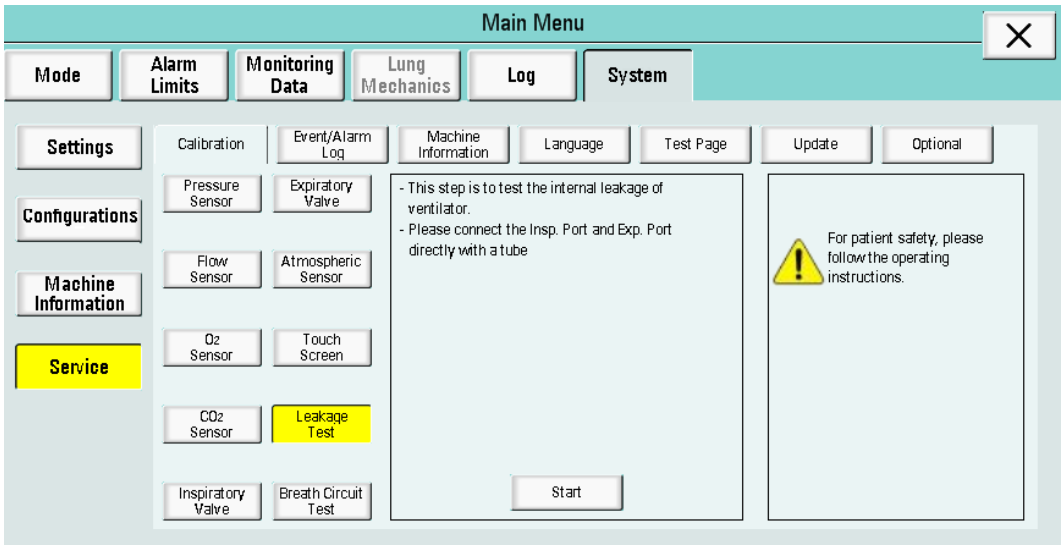


Figure 6-72

Click “Start” to start the leakage test. A progress bar and a message “Test in progress, please wait” will be displayed as shown in Figure 6-73. After test, the result will appear: Test succeeded or Test failed. If failed, restart the test.

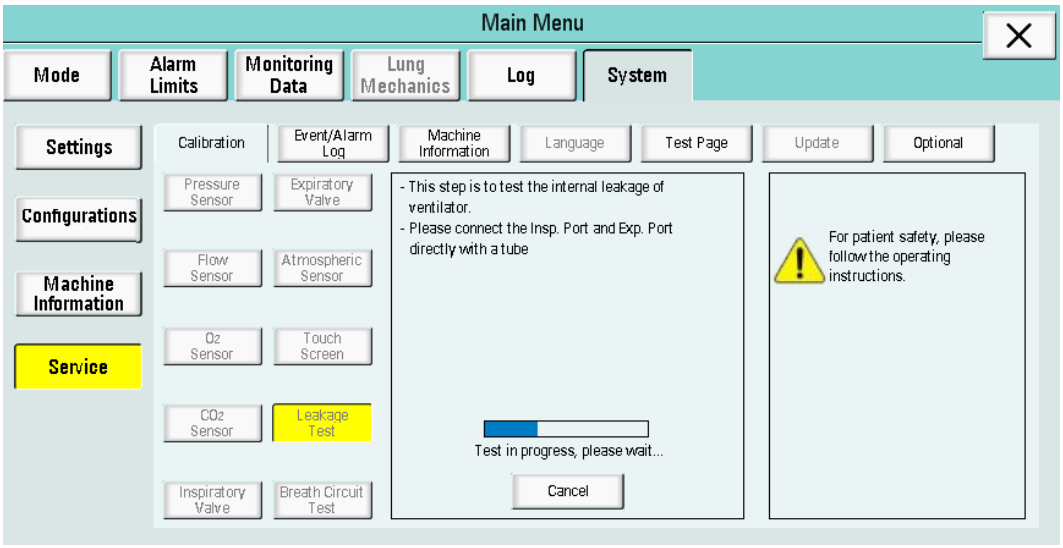


Figure 6-73

(10) Breath Circuit Test Calibration: Click “Breath Circuit Test” to enter the test interface. A message is displayed: “This step is to test the compliance and leakage of breathing circuit. Please connect the patient circuit to the T-piece, and plug up the patient end of the T-piece”, as shown in Figure 6-74.

Before starting the test, ensure the patient circuit has been connected to the T-piece and the patient end of the T-piece has been plugged up. Click the “Start” button to start the breath circuit test, the remaining procedure is the same as the leakage test.

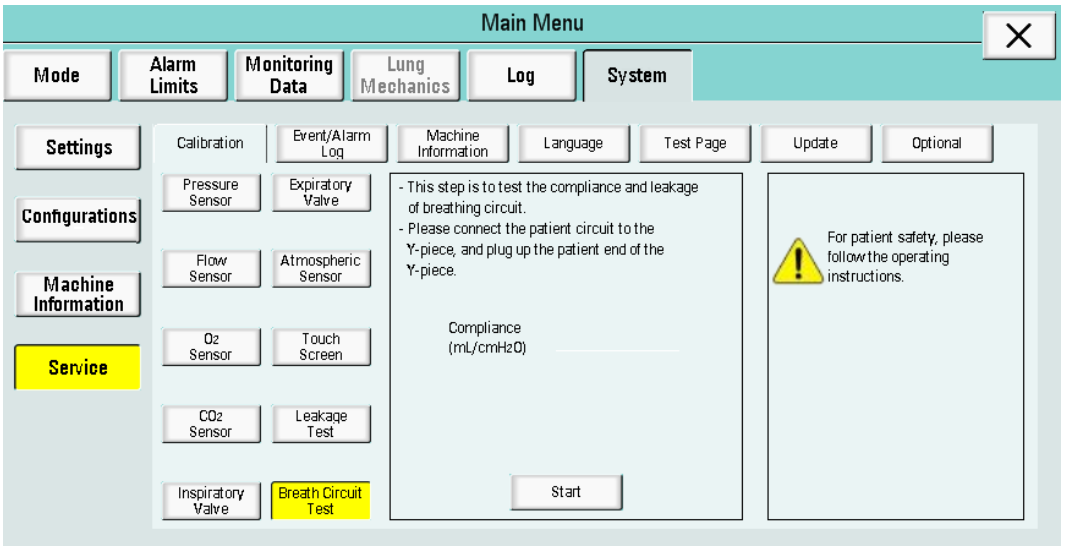


Figure 6-74

6.3.6.4.2 Event/Alarm Log

See Section 6.3.5 for detailed description.

6.3.6.4.3 Machine Information

Click the “Machine information” button to enter the Machine information page, this area includes the following information, as shown in Figure 6-75.

1. Software Version:
    a. UI
    b. BDU
    c. Power Supply
2. Runtime Hours
3. O_2 Source Pressure
4. Atmospheric Pressure

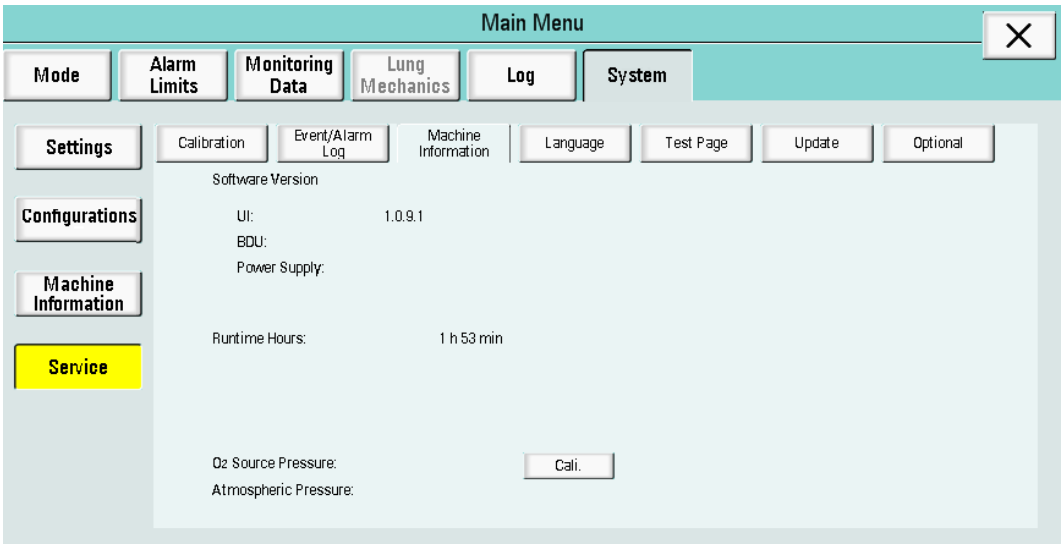


Figure 6-75

6.3.6.4.4 Language

Click the Language button to enter the language screen. English and other languages are available for the user to choose.

6.4 Operation of Other Shortcut Buttons

The ventilator has 11 shortcut buttons: Inspiratory Hold, Expiratory Hold, Nebulizer, Manual, Suction, Print Screen, Freeze, Screen Lock, Alarm limits, Main Menu and Start Ventilation/Standby. The shortcut buttons are located on the right side of the screen, see Figure 6-76.

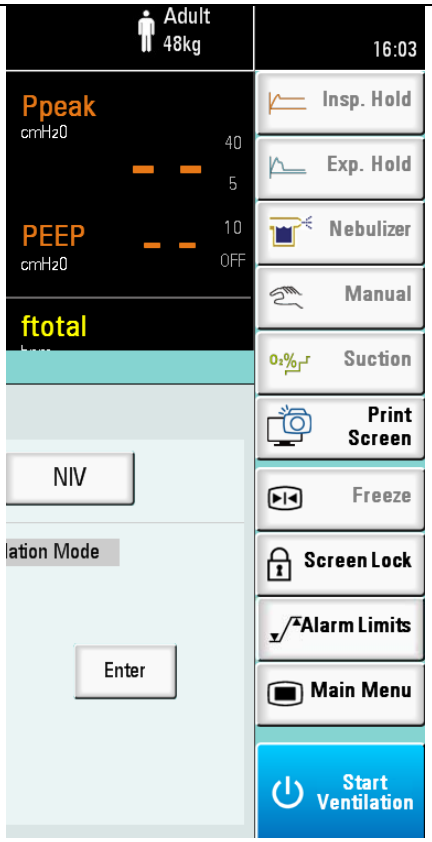


Figure 6-76

6.4.1 Inspiratory Hold

Inspiratory hold is available within the period of mandatory ventilation and in all modes except full spontaneous breath modes as SPONT/CPAP+PSV, NIV/CPAP.

Press the Inspiratory Hold button during the Inspiratory phase. The operation becomes active when a message stating “Inspiratory Hold” appears with a countdown timer. Keep pressing the Inspiratory Hold button. The expiratory phase will not start until the button is released or after 30 seconds, whichever comes first. If the button is not released after 30 seconds, the system will go to Expiratory state automatically and display a message “Inspiratory hold interrupted!”, as shown in Figure 6-77.

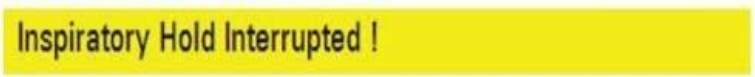


Figure 6-77

6.4.2 Expiratory Hold

Expiratory hold is available in all modes. In Expiratory phase, press the Expiratory hold button and the expiratory operation will become active when a message “Expiratory Hold” appears

with a countdown timer. The ventilator will stay in the expiratory phase and not transition to the inspiratory phase until either 1) the button is released or 2) 30 seconds have elapsed.

When selected during the expiratory phase, the ventilator will stay in the expiratory phase and not transfer to the inspiratory phase until either 1) the button is released and the current expiratory phase is completed or 2) 30 seconds have elapsed.

Pressing the Expiratory Hold button for more than 30 seconds will cause a message to be displayed. See example in Figure 6-78. Only one expiratory hold will be produced per button press. When Inspiratory hold button is released or if the button is not released after 30 seconds, the button background will revert to normal.

Figure 6-78

6.4.3 Nebulizer

The nebulizer function is available in all ventilation modes. Press the Nebulizer button turning the button background color to yellow. Meanwhile, a low level alarm “Nebulizer On” is displayed and the message “Nebulizer On, MM min SS s” with countdown timer is displayed in the message area, as shown in Figure 6-79.

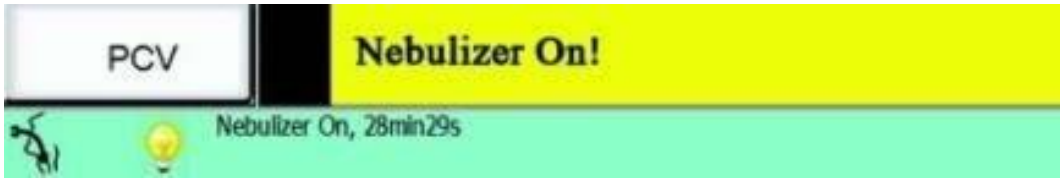


Figure 6-79

Nebulizer flow may be provided by high-pressure O_2, and the flow rate is 6L/min±1L/min. To ensure the delivery of tidal volume, the nebulizer is switched off when inspiratory flow rate is less than 15L/min.

The nebulizer will start as inspiratory starts, and the nebulizer will last for the whole inspiratory cycle. When Ventilation mode changes or if the flow is less than 15 L/min, the nebulizer operation will be interrupted and a medium level alarm “Nebulizer Interrupted” will replace “Nebulizer On” alarm and the countdown timer will stop.

⚠ **CAUTION**: During nebulization, please connect the filter in front of the expiration valve to prevent the nebulization drug from damaging the expiration flow sensor; inspect, clean and replace the filter regularly.

The nebulizer operation will be cancelled by touching the nebulizer button for more than 3 seconds in all ventilation modes. The user has two options to clear the “Nebulizer Interrupted” alarm:

1) Remove the source of the shutdown and press the Nebulizer button to restart the Nebulizer operation. Low level alarm “Nebulizer On” will replace “Nebulizer Interrupted” alarm and the message countdown timer will continue or;

2) Acknowledge the alarm by pressing the Alarm Silence button. Nebulizer operation is cancelled and the “Nebulizer Interrupt” alarm is cleared. Pressing the Nebulizer button during a “Nebulizer Interrupted” condition without removing the source of the shutdown will result in the Nebulizer not restarting.

CAUTION: The ventilator accuracy can be affected by the gas added by use of a nebulizer.

NOTE: Nebulizer function is not suggested when breath rate is less than 12, to ensure tidal volume delivery.

NOTE: To ensure the flow volume accuracy, the nebulizer function is disabled if the flow rate of the delivered breath is less than 15 LPM.

CAUTION: Using nebulizer use is not available in noninvasive (NIV) modes.

6.4.4 Manual

Manual Trigger is available in all ventilation modes. Press the manual trigger button to initiate a manual breath control as follows, as shown in Figure 6-80.

For VCV, PRVC, SIMV (VCV): set Vt and Tinsp, to control ventilation.

For BIVENT: set P_{high} and P_{low}, to control ventilation switchover.

For PCV, SIMV (PCV): Set P_{insp}, to control ventilation.

For modes or breath phase with PSV, set P_{supp}, to control ventilation.

Manual trigger is also available during backup ventilation period. When initiated during backup mode, the ventilator will remain in backup mode.

Figure 6-80

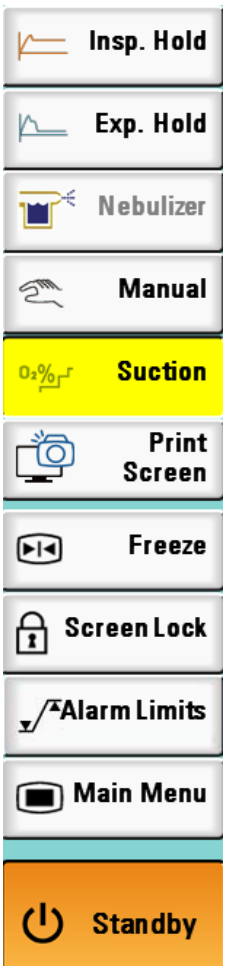


Figure 6-81

6.4.5 Suction

Suction support is available in ventilation modes. Pressing Suction button will turn the button color to yellow signifying the start of Suction support as shown in Figure 6-81.

If the system detects that the circuit is disconnected, ventilation will be interrupted. During sputum aspiration, all physiological alarms will be off and audio alarms will be suspended.

The Ventilator will provide a low flow rate when the circuit is disconnected in order to detect reconnection of circuit. When pressing the suction support button, a message will be displayed in the message prompt area, as shown in Figure 6-82.

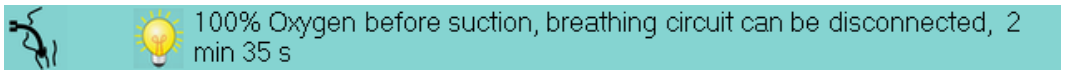


Figure 6-82

The process of Suction support is performed in 3 phases as follows:

• Before aspiration of sputum – 3 minutes of increased oxygen concentration in preparation of airway disconnection;

• Suction Phase - Airway disconnection for suction.

• Post aspiration of sputum – 2 minutes of increased oxygen concentration after reconnection of the airway.

6.4.6 Print Screen

After clicking the "Print Screen" button, the screen can be copied,except the information of the patient.
When there is no USB storage device inserted in the machine, after clicking "Print Screen " button, a prompt message will appear on the screen, as shown in Figure 6-83.

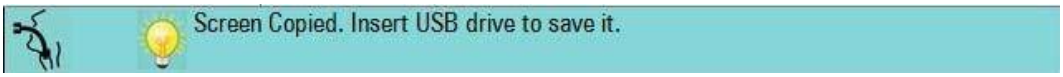


Figure 6-83

When you click the "Export" button, you need to enter the password. The screenshots of the product are stored in the memory card, and up to 5 photos are stored,see Chapter 6.3.6.2. for details.

6.4.7 Freeze

Press “Freeze” button and the current real-time waveforms and loops freeze simultaneously in the main screen when waveform drawing is completed. See example in Figure 6-84. Turning the encoder knob to move the cursor over each point of the waveform and the corresponding measured value is displayed. Pressing Freeze again will restart the waveform and any information displayed during waveform freeze will disappear, and the Freeze button color returns to normal. Waveform Freeze will automatically end 3 minutes after touching the freeze button.

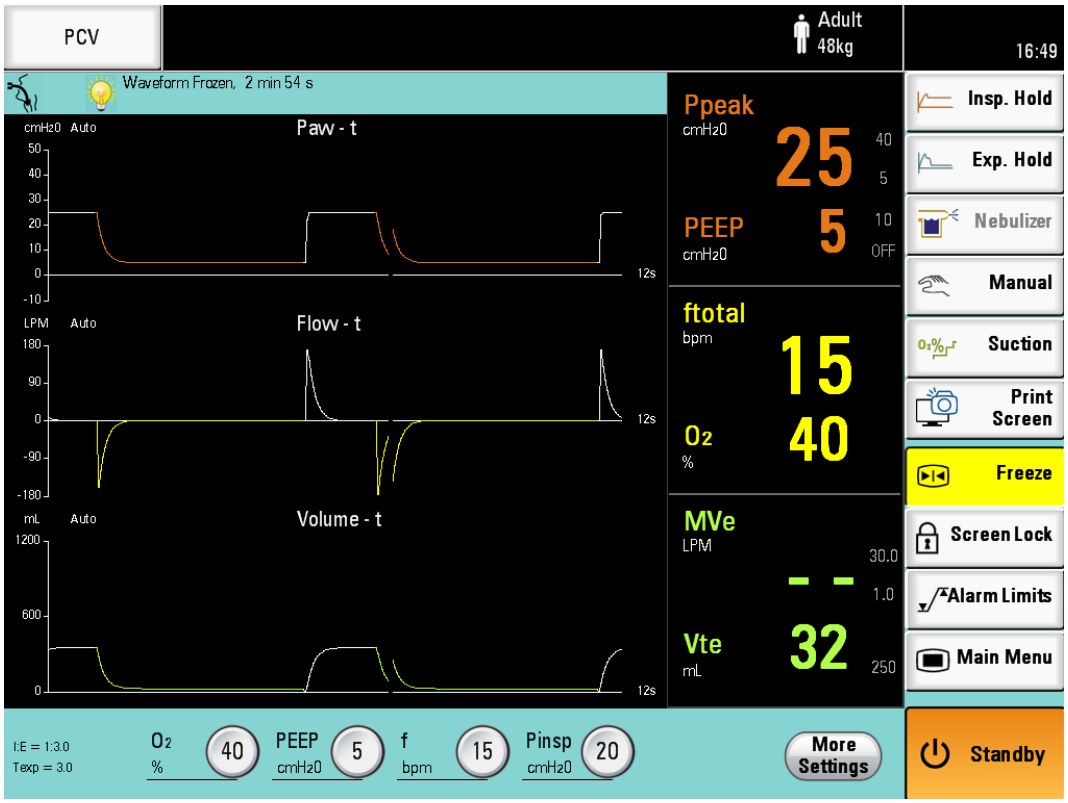


Figure 6-84

6.4.8 Screen Lock

Press the “Screen Lock” button, displaying a message in the message prompt area. Press and hold Screen Lock for 3 seconds to lock the screen, as shown in Figure 6-85. 3 seconds later, the background color of Screen lock buttonwill turn to yellow and all buttons on the touch screen are locked. Instead of the pre-message, a new message is displayed in the message prompt area “Screen Locked. Press Screen Lock for 3 seconds to unlock the screen as shown in Figure 6-86.

Figure 6-85

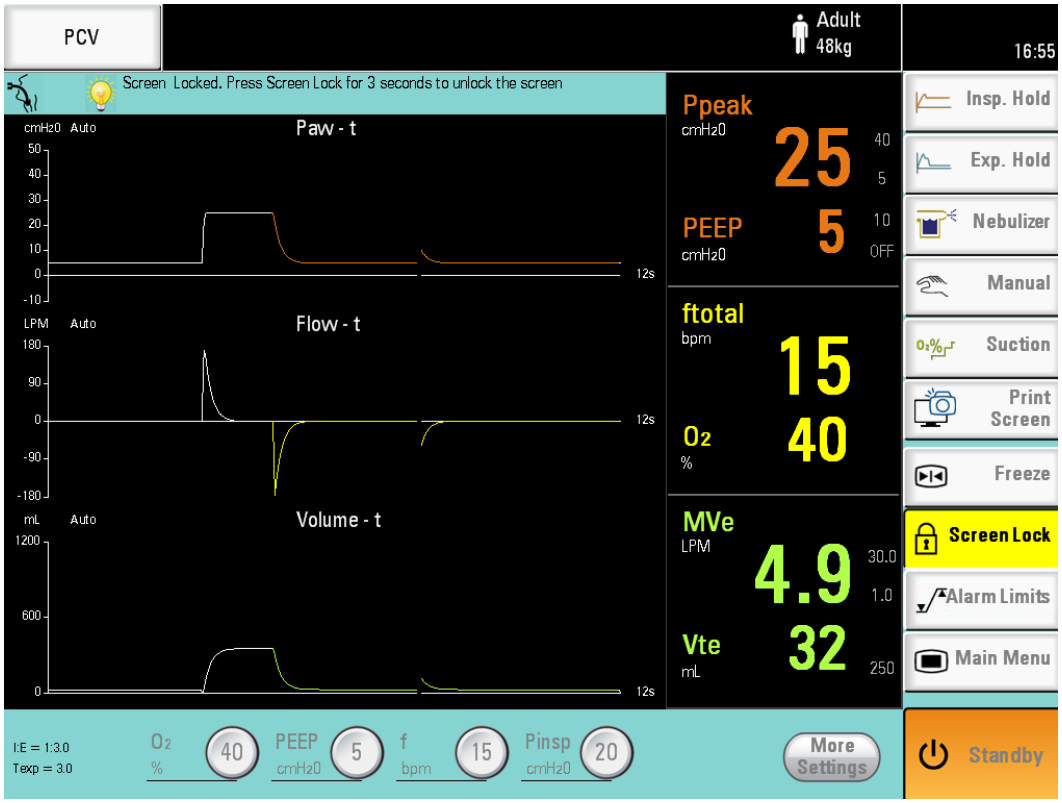


Figure 6-86

Holding for 3 seconds, the screen lock is cleared, the background color of Screen Lock button turns to normal and a message ”Screen Unlocked” is displayed in message prompt area as shown in Figure 6-87.

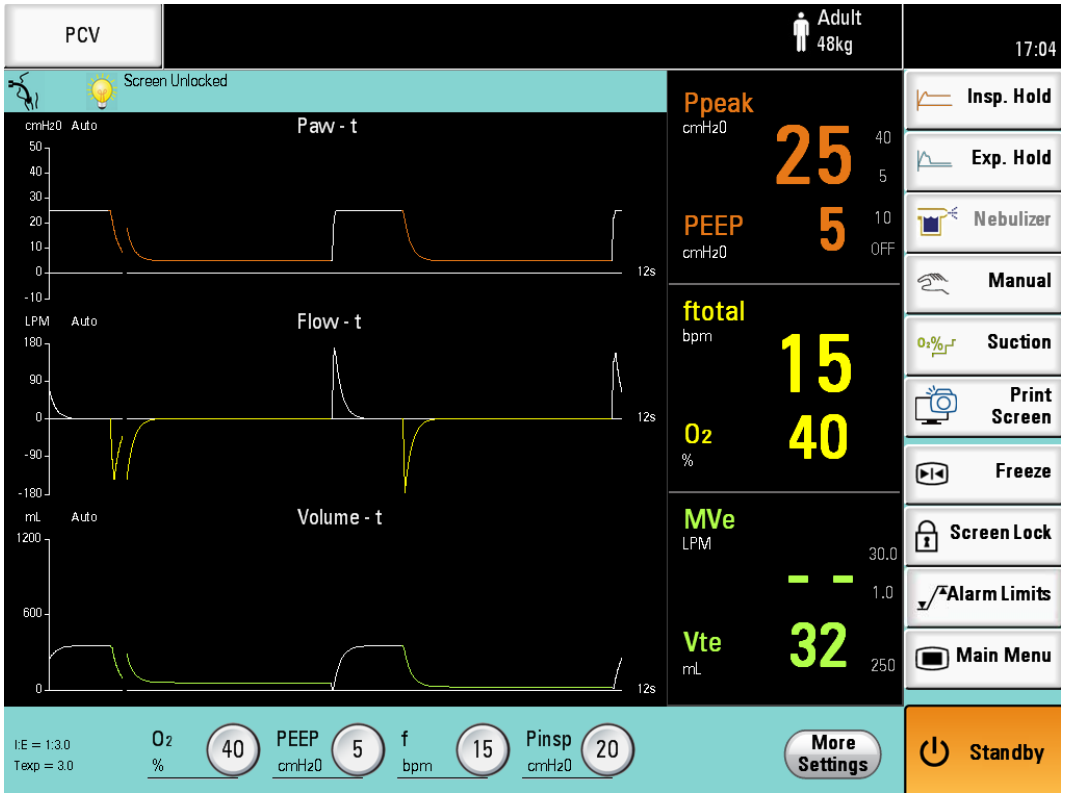


Figure 6-87

6.4.9 Alarm Limits

Press the “Alarm limits” button to enter the alarm limits page in the main menu, as shown in Figure 6-88. For detail information and operation refer to Section 6.3.2.

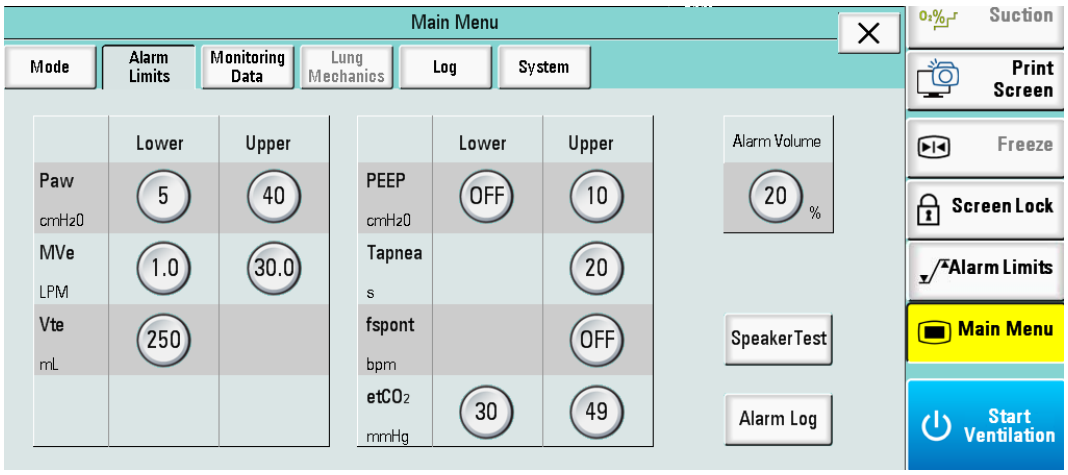


Figure 6-88

6.5 Ventilation Parameter Setup

NOTE: If ventilation parameter setup buttons are not visible along bottom of screen, close the main menu by pressing Main Menu button. See ventilation parameter setup in the main screen as shown in Figure 6-89.

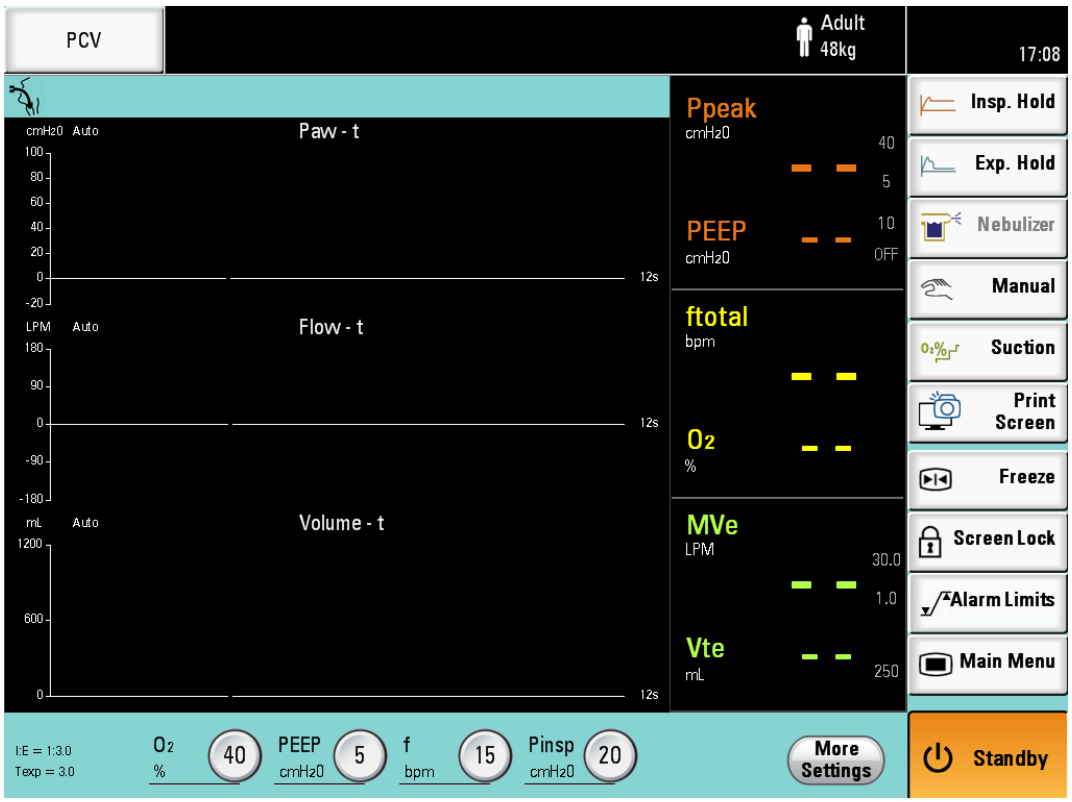


Figure 6-89

Press the parameter button, turning it yellow. Rotate the encoder knob left or right to modify the parameter value. Press the parameter button again or press the encoder knob to confirm the modified value. If any other area on the screen is touched before confirmation, the new parameter selection is canceled and the previous value will be displayed. As shown in Figure 6-90.

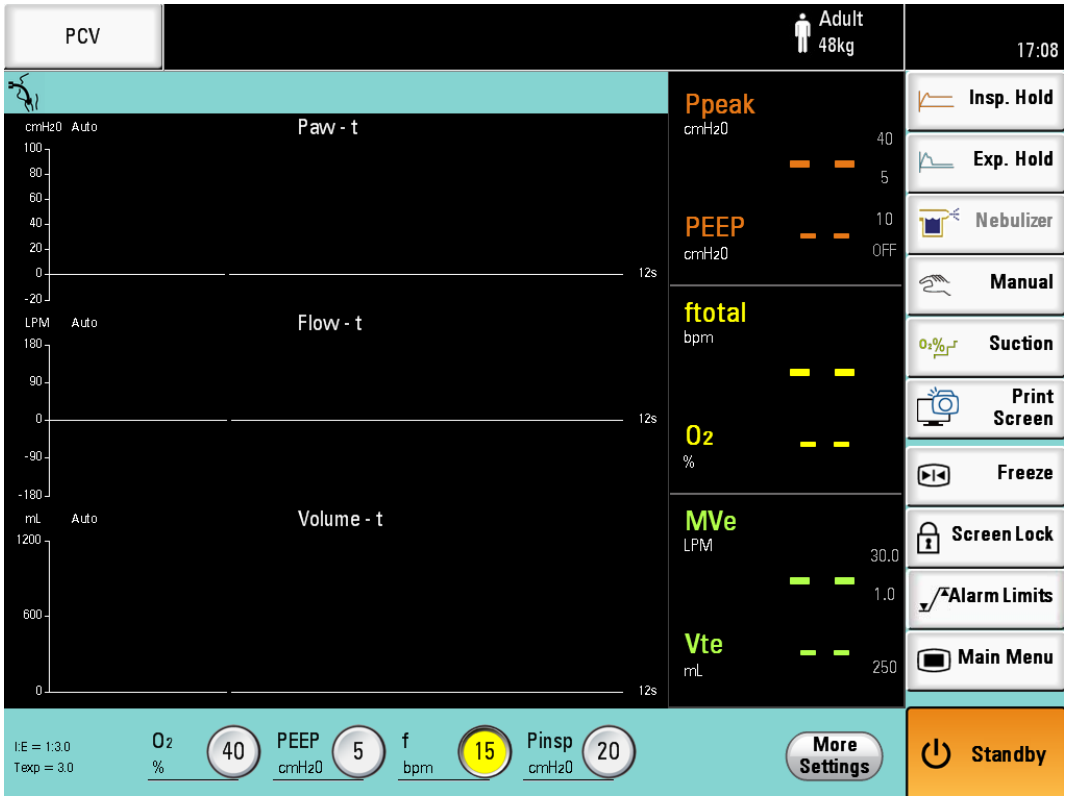


Figure 6-90

When ventilation mode is changed, the values of the parameter buttons displayed will be changed to correspond to the new ventilation mode.

CAUTION: If the encoder knob is not pressed for confirmation, the previous value will be displayed.

The following conditions should be noticed in parameter setting:

a) In order to make parameter setting more safe and reasonable, interlock mode is used for tidal volume V_{TI}, ventilator rate and inspiratory time T_I setting. In case any one of the three parameters cannot be adjusted to required value within limits, modify the other two first.

b) Pressure parameter setting is subject to high pressure limit.

c) P_{SUPP} and P_{INSP} are relative pressure to PEEP.

6.6 Turn off the Ventilator

(1) Disconnect the breathing hoses from the patient.

(2) Return back to Standby by pressing the Standby button for more than 3 seconds.

(3) Turn off the power switch.

(4) Disconnect the gas supply.

(5) Disconnect the power cord from the power supply.

 **NOTE:** Detachable power cord is a means to isolate circuits electrically from AC supply on all poles simultaneously.

7 Alarms and Troubleshooting

WARNING: Only authorized person is permitted to perform maintenance.

7.1 Alarms

WARNING: When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

An alarm message will appear in alarm information area and alarm indicator will light up. The different colors of alarm in alarm area indicate different priority levels: red is high level (!!!, red indicator flash), yellow is medium (!!, yellow indicator flash) or low level (!, yellow indicator constantly lit).

The operator may be positioned anywhere around the unit to view the alarm light. The alarm light is visible from a distance of 3 meters. To observe the alarm messages the operator position must be in front of the display and within a distance of 1 meter.

7.2 Alarm Message Table

CAUTION: Operation instructions are not included in the table.

CAUTION: Except for the normal alarm settings, other default alarm settings are changed only by changing the control program and restricted access to changing or to the storage of changes.

WARNING: Never leave patient unattended when alarm silence is activated.

NOTE: In the table below, L means low level, M means medium level, and H means high lever; for the same level, the bigger the alarm number, the higher the alarm level, such as L2 level is higher than L1 level.

Alarm Message	Priority	Type	Cause	Remedy
High Airway Pressure	L1	Physiological	Airway Pressure exceeds the setting limit within one ventilation. When the airway pressure exceeds the setting value, the inspiratory phase changes into the expiratory phase within 200 ms and the pressure shall be reduced below PEEP level.	Airway pressure is lower than the alarm limit for three consecutive cycles or at most 15sec.
Leakage	L2	Physiological	The measured minute volume leak MV_{LEAK} is higher than the minute volume measured on the expiration path for 3 consecutive ventilation cycles or for 10 seconds.	The measured minute volume leak MV_{LEAK} is in normal range for 3 consecutive breaths or for 10 seconds.
Low Oxygen Supply Pressure	L3	Physiological	Oxygen source is lower than 160kPa O_2 is set to 21%.	Oxygen supply is above 160kPa.
AC Failure	L4	Technical	During ventilator operation, when an AC power failure occurs and there is no battery power, the power board will alarm for 120 seconds minimum. When powered from batteries, an “AC Failure” alarm would occur.	When no battery is supplied or battery is invalid, the power fault alarm is of high-priority and lasts for longer than 120s. When battery is supplied, produces a low-level alarm and gives the prompt message of “AC power faulty” alarm. Alarm cancellation condition: Restoration of AC.

Alarm Message	Priority	Type	Cause	Remedy
Nebulizer On	L5	Physiological	Start Nebulizer operation	Nebulizer operation is completed or Interrupted.
Int. Battery Calibration required	L6.1	Technical	During ventilator operation, when an AC power failure occurs and there is the int. battery power, an “Int. Battery Calibration required” alarm occurs. When the ventilator starts running and there is the int. battery power, an “Int. Battery Calibration required” alarm occurs.	Calibrate the int. battery. Then restart the ventilator.
Opt. Battery Calibration required	L6.2	Technical	During ventilator operation, when an AC power failure occurs and there is the opt. battery power, an “Opt. Battery Calibration required” alarm occurs. When the ventilator starts running and there is the opt. battery power, an “Opt. Battery Calibration required” alarm occurs.	Calibrate the opt. battery. Then restart the ventilator.
Expiratory Hold Interrupted	L7	Physiological	Start Expiratory holding	Expiratory hold operation is completed.
Inspiratory Hold Interrupted	L8	Physiological	Start the inspiratory holding	Inspiratory holding operation is completed.
Low Battery	M1	Technical	Under the battery operation, the remaining battery run time is less than 30min.	When “Limited Battery Capacity” alarm appears or AC power supply starts.

Alarm Message	Priority	Type	Cause	Remedy
High Respiration Rate	M2	Physiological	Respiration Rate has exceeded the set limit for four consecutive ventilation cycles or continuously for 20sec.	Respiration Rate is less than the set limit for four consecutive ventilation cycles.
Oxygen Sensor Failure	M3	Physiological	Checked during pre-inspection before use.	Measure signals of the sensor through equipment inspection.
High Oxygen Concentration	M4	Physiological	Oxygen concentration exceeds the preset oxygen concentration +6% continuously for 30sec.	Oxygen concentration is lower than the preset oxygen concentration+ 6% for 30sec continuously.
Low Oxygen Concentration	M5	Physiological	Oxygen concentration is lower than the preset oxygen concentration -6% or lower than 18% continuously for 30sec.	Oxygen concentration is higher than the preset oxygen concentration- 6% or higher than 18% for 30sec continuously.
High Expiratory Minute Volume	M6	Physiological	Minute Volume exceeds the set limit, after 1min of ventilation	Minute Volume lower than the set limit for 15sec.
Low Expiratory Minute Volume	M7	Physiological	Minute Volume is lower than the set limit within 1min.	Minute Volume higher than the set limit for 15sec.

Alarm Message	Priority	Type	Cause	Remedy
Maximum Inspiratory Time	M8	Physiological	NIV – inspiration duration exceeds Tispont setting for three times in succession Invasive - inspiration duration exceeds 5 seconds for adult and 2 seconds for child for three times in succession	Inspiratory period is normal under NIV mode. Within the specified condition for two consecutive PSV ventilation under invasive mode.
Nebulizer Interrupted	M13	Physiological	Nebulizer operation has been interrupted by mode changes.	Nebulizer operation continued or alarm is acknowledged by pressing Alarm Silence button.
Low Inspiratory Tidal Volume	M14	Physiological	Inspiratory Tidal Volume exceeds the upper limit for one ventilation.	Inspiratory Tidal Volume is lower than the alarm limit for one ventilation.
Limited Battery Capacity	H1	Technical	Under the battery operation, the remaining battery run time is less than 10min.	AC power supply starts.
Internal Error	H2.1	Technical	Internal computing error	Cycle AC Power-if alarm occurs again stop using Ventilator, note code displayed and call for Service.
Communication Error BDU	H2.2	Technical	Failure detected in BDU communications.	Cycle power. If the alarm occurs multiple times, call for Service.

Alarm Message	Priority	Type	Cause	Remedy
Communication Error PS	H2.3	Technical	Failure detected in PS communications.	Cycle power. If the alarm occurs multiple times, call for Service.
S/W Mismatch Error	H2.4	Technical	System detects software versions are incorrect.	Call Service.
Exp. Valve Heater Failure	H2.5	Technical	System detects expiratory valve heater fails.	Call Service.
Fan Blocked	H2.6	Technical	System detects cooling fan failure	Remove any obstructions. Cycle Power. If the alarm occurs again, call Service.
BDU Failure	H2.7	Technical	Internal hardware failure detected.	Check to make sure inspiratory and expiratory circuits have no obstruction. Retry power-up tests. If this alarm persists, Call Service.
Continuous Airway Pressure	H3	Physiological	Airway pressure has exceeded PEEP+15cmH_2O continuously for 15sec. Expiratory valve is opened for gas release.	Airway pressure is lower than PEEP+15cmH_2O continuously for 5sec.
High Airway Pressure	H4	Physiological	Airway Pressure is lower than the set limit within three consecutive ventilation cycles.	Airway pressure exceeds the alarm limit for three consecutive cycles or at most 15sec.

Alarm Message	Priority	Type	Cause	Remedy
Apnea	H5	Physiological	No ventilation cycles within the apnea period.	Refer to Chapter 11.1.3 for Apnea resetting details.
Low Expiratory Tidal Volume	H6	Physiological	Expiratory Tidal Volume is lower than the setting value for three consecutive ventilation cycles or continuously for 30s.	Expiratory Tidal Volume is higher than the setting value for three consecutive ventilation cycles or continuously for 30s.
High PEEP	H7	Physiological	PEEP measurement is higher than the alarm limit for three consecutive ventilation cycles.	PEEP is lower than the alarm limit for three consecutive cycles or at most 15sec.
Circuit Disconnect	H8	Physiological	Ventilating circuit is disconnected.	Re-connect patient circuit.
Occlusion	H9	Physiological	Ventilating circuit is occluded.	Occlusion is removed.
Leakage out of range	H10	Physiological	NIV Mode only- Leak exceeds 75% of the maximum volume compensation capacity.	Leak is within 75% of the maximum volume compensation capacity.
Low Airway Pressure	H11	Physiological	Airway pressure is lower than the set limit for three consecutive ventilation cycles.	Airway pressure is higher than the alarm limit for three consecutive ventilation cycles or at most 15 sec.
Low Oxygen Supply Pressure	H12	Physiological	Oxygen supply is lower than 160kPa.	Oxygen supply is above 160kPa.

Alarm Message	Priority	Type	Cause	Remedy
Low PEEP	H13	Physiological	PEEP measurement is lower than the alarm limit for three consecutive ventilation cycles.	PEEP is higher than the alarm limit for three consecutive cycles or at most 15sec.
CO_2 Accuracy Error	H14	Physiological	The CO_2 module is not detected during the probation period or the CO_2 module fails.	Redetect or replace the CO_2 module.
CO_2 Adapter Failure	H15	Physiological	Detected by CO_2 Sensor.	Reconnect the CO_2 Adapter. If alarm occurs again, replace the CO_2 Adapter.
CO_2 sensor Comm. Failure	H16	Physiological	The communication between the CO_2 module and the host instrument fails.	Check the cable between the CO_2 module and the host instrument.
CO_2 Sensor Error	H17	Physiological	Detected by CO_2 Sensor.	Reconnect the CO_2 sensor. If alarm occurs again, replace the CO_2 sensor.
Low $EtCO_2$	H18	Physiological	$EtCO_2$ is lower than the setting value.	Increase $EtCO_2$ or reduce the setting value.
High $EtCO_2$	H19	Physiological	$EtCO_2$ is higher than the setting value.	Reduce $EtCO_2$ or increase the setting value.

8 User Maintenance

8.1 Cleaning and Disinfection

8.1.1 General rules for cleaning and disinfection

 **WARNING:** This notice warns the user of the possibility of injury, death or other serious undesirable reactions associated with the use or misuse of the device.

 **WARNING:** To prevent electrical shock hazard and possible personal injury, always disconnect electrical power sources before servicing the ventilator. Follow accepted safety practices for electrical equipment when testing or making equipment, adjustment, or repairs.

 **WARNING:** Our company recognizes that cleaning and disinfection practices vary widely among medical institutions. It is not possible to specify or require specific practices that will meet all needs, or to be responsible for the effectiveness of cleaning, disinfection, and other practices carried out in the patient care setting.

 **WARNING:** Do not use talc, zinc stearate, calcuim carbonate, corn starch or similar material to prevent sticking, as these materials may enter the patient's lungs or airway, causing irritation or injury.

 **WARNING:** Never use a ventilator or any components or accessories that appear to be damaged. If any signs of damage are evident, contact your equipment supplier.

 **WARNING:** Please wear safety gloves and glasses for cleaning and disinfection.

 **WARNING:** Do not inhale any gas or fumes that are generated in cleaning and disinfection process.

WARNING: Before the first use clean and disinfect the ventilator. Disposable components must be disposed in accordance with local regulations. Don't use hard brushes or other sharp tools in cleaning to avoid damage to parts.

WARNING: Before cleaning the ventilator, first disconnect the ventilator and the patient circuit.

NOTE: Cleaning and disinfection guidance must be in accordance with EN ISO 17664.

CAUTION: This notice warns the user of the possibility of a problem with the device in connection with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to third parties.

8.1.2 Expiratory Valve

Expiratory valve is suitable for AEROS 4600 and VG60. Expiratory valve materials mainly include aluminum alloy、polysulfone、silicone rubber.. All materials used are heat resistant up to 137°C(278.6°F).

Expiratory valve components are shown in Figure 8-1.

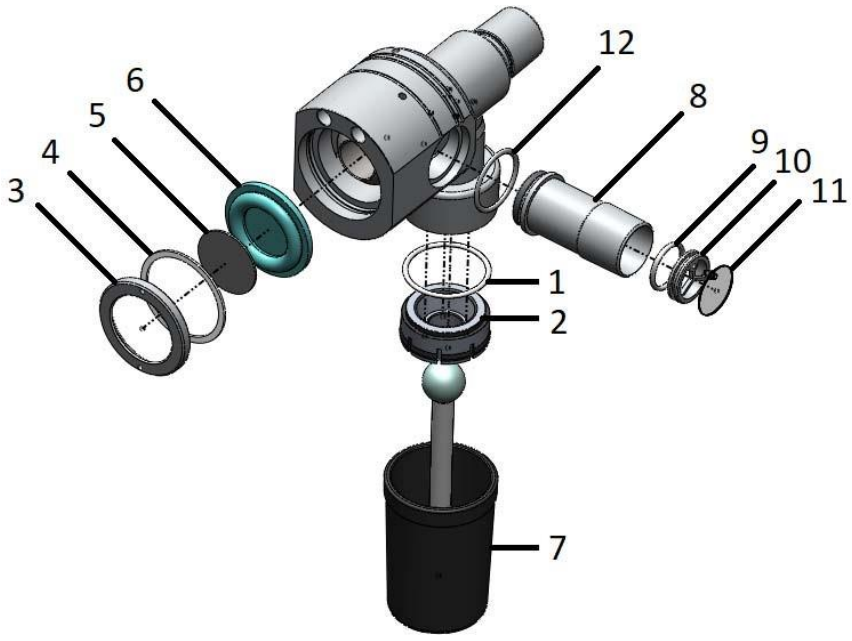


Figure 8-1 Expiratory valve components

NO.	Part Number	Part Name	Replacement Period
1	304000105	Rubber o-sealing ring for 29x1.8	Need to be changed in every 20 times of sterilization
2	130009661	Water tray	Need to be changed in every 20 times of sterilization
3	130004350	End cover	
4	130012614	Gasket	Need to be changed in every 20 times of sterilization
5	130000229	Scale board	
6	130000231	Diaphragm	Need to be changed in every 20 times of sterilization
7	130009651	Water trap cup	6 months or as needed
8	130009945	Expiratory connector	
9	304000099	Rubber o-sealing ring for 16x1.8	One year or as needed
10	130007655	One-way valve core	
11	130001347	One-way diaphragm	One year or as needed
12	304000102	Rubber o-sealing ring for 22x1.8	One year or as needed

Diaphragm and gasket replacement method: refer to section 8.1.5.2.1 and 8.1.5.2.7.

Water tray replacement method:

Rotate the water trap cup (Part 7), then pull it out, then you can see water tray (Part 2), remove it, reassemble the water tray in the reverse order, as shown in Figure 8-1.

Rubber o-sealing ring for 29x1.8 replacement method:

After remove the water tray (Part 2), and then you can see there is a rubber o-sealing ring for 29x1.8 (Part 1), remove it, reassemble the rubber o-sealing ring for 29x1.8 in the reverse order, as shown in Figure 8-1.

WARNING:

- Clean and disinfect the expiratory valve directly after use.
- Follow hospital infection control procedures, as well as local laws and regulations. This applies in particular to the various regulations regarding an effective deactivation of prions.
- Our company cannot be held responsible for the correct functioning of expiratory valve components that are not reprocessed and used according to these instructions.
- Disposal: A used expiratory valve must be handled as a contaminated item. Follow all local, state, and federal regulations with respect to environmental protection when disposing of used expiratory valve.

CAUTION:

- The expiratory valve has a limited life span. The expiratory valve may be damaged due to the use of hard brushes, scouring agents, or by the exertion of too much force.
- After disinfection the components of the ventilator, they should be dried before being stored for use.
- The use of rinse aids will reduce the life span of the expiratory valve, as it can lead to early failure and cracks in the plastic expiratory valve housing.
- For Europe: disinfectant approved for cleaning and disinfection of medical devices.
- (USA only): Only use EPA registered cleaning and disinfection solutions.

8.1.3 Reprocessing the expiratory valve in accordance with EN ISO 17664

Make sure that the reprocessing does not damage the expiratory valve components, especially Diaphragm and One-way diaphragm.

8.1.3.1 Reprocessing overview

The expiratory valve components must be cleaned and disinfected after each use. After each reprocessing cycle, the expiratory valve housing must be inspected for damage. If any changes are visible, the valve must be discarded. Perform a tightness test after each reprocessing cycle. If the test fails, it may be repeated once. The expiratory valve must be replaced if the tightness test fails the second time.
It is recommended to use drinking quality water for rinsing. Rinse aid can cause premature damage and shorten the life of the product. Unsuitable rinse aid should therefore not be used. Our company does not guarantee the lifespan of the expiratory valve components if unsuitable cleaning agents are used.

8.1.3.2 Preparation and reprocessing after use

Reprocess the expiratory valve components immediately after use. The reprocessing cycle comprises cleaning and disinfection. Remove macroscopic impurities of the expiratory valve by rinsing or wiping. You can add an aldehyde-free disinfection agent to the rinse water. You must not use any hard tools or hard brushes to remove resilient impurities.

8.1.4 Cleaning and Disinfection Agents

Agent	Classification
• Mild dishwashing detergent • Soapy water with detergent ph between 7.0 and 10.5 • Sodium hypochloride- (bleach) in water (10% solution) • Hydrogen peroxide (3% solution)	Detergent Detergent Disinfectant Disinfectant
• Alkaline solution dominated by glutaraldehyde	Approved disinfectant

CAUTION: It is recommended to use only the appropriate detergents and disinfectants, as shown here. Hospitals can select detergents agents and disinfectants corresponding to these specifications and according to their own needs.

8.1.5 Cleaning and Disinfection of Components

8.1.5.1 External Surfaces

Using a soft cloth with a water-soluble detergent or disinfectant, wipe the surface.
Recommended disinfectant：75% (± 5%) ethanol solution、Glutaraldehyde 2% solution、Hydrogen peroxide 3% solution、Ammonia water 15% solution.
For example, wipe the surface with 75% (± 5%) ethanol solution for 3 minutes.

8.1.5.2 Expiratory Valve

8.1.5.2.1 Disassembly

Figure 8-2

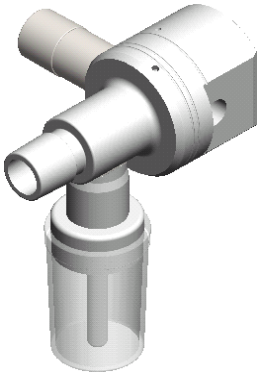


Figure 8-3

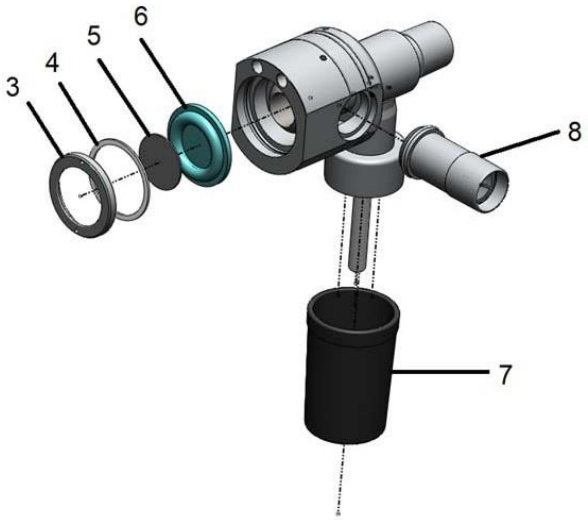


Figure 8-4

To remove the components from expiratory valve:

a. Press the button(Part 1);

b. Pull out the expiratory valve component (Part 2 in Figure 8-2, Figure 8- 3);

c. Use a suitable tool (such as end cover tooling, part number 130015084) to remove the end cover(Part 3) and the gasket (Part 4);

d. Remove the scale board(Part 5)and the diaphragm(Part 6);

e. Rotate the water trap cup (Part 7), then pull it out.

f. Rotate the expiratory connector (Part 8) clockwise, then pull it out.

8.1.5.2.2 Manual Cleaning

When selecting the cleaning agent, consider whether the agents in question are suitable for the expiratory valve components. In addition, instructions for cleaning with the selected agents must be available.

In addition, instructions for cleaning with the selected agents must be available.

8.1.5.2.2.1 Manual Cleaning

1. Disassemble the expiratory valve.
2. The expiratory valve components include end cover、gasket、scale board 、diaphragm、water trap cup、expiratory connector and so on.
3. Recommend detergent neodisher MediClean forte. Submerge the expiratory valve components in the 1% neodisher MediClean forte solution; at 60℃, duration 10 minutes. Make sure that all parts of the expiratory valve components are fully submerged in the solution.
4. Repeat the cleaning process if the last cleaning solution was not clear or there are still visible impurities on the expiratory valve components.
5. Rinse after cleaning. Rinse with purify water at room temperature for 1 minute.

8.1.5.2.3 Mechanical Cleaning and Disinfection

Automatic disinfection process meets standardization requirements, the effect of automatic disinfection is better than manual disinfection, so manual disinfection is not used.
The expiratory valve components must be reprocessed in such a manner that hygienic and safe reuse can be assured. Cleaning / disinfection should only be carried out in a cleaning and disinfection device that complies with EN ISO 15883 and has been proven to be effective. Place the expiratory valve components in such a manner that it is easy to clean and the effectiveness of cleaning and disinfection is not impaired.

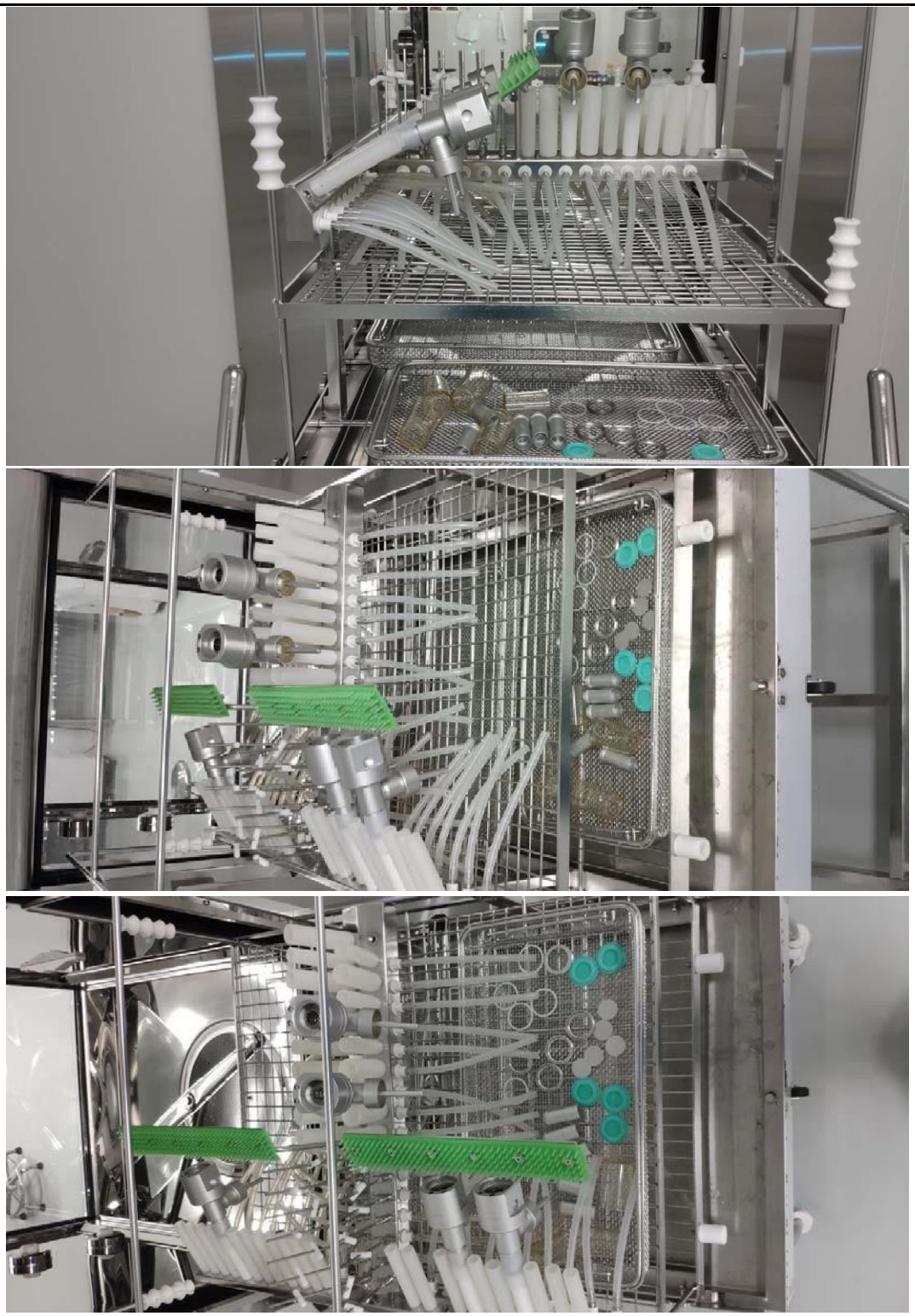


Figure 8-5 Arranging components in the device

To ensure safe cleaning, the expiratory valve housing must be connected to the corresponding receptors. The expiratory valve must not disconnect from the receptor during reprocessing. Expiratory valves that disconnect during reprocessing must be processed again. After the cleaning process is completed, check that the expiratory valve is completely dry and undamaged. Damaged expiratory valve components must be discarded. The program parameters in Table 8-1 must be met for successful mechanical cleaning.

Table 8-1 Mechanical cleaning program parameters

Program parameters	**Specification**
Pre-rinse	one cycle using cold water for 1 min
Cleaning	one cycle at 60℃ (140°F) for 10 min
Rinsing	one cycle using cold water for 1 min
Thermic disinfection	one cycle at 90℃ (194°F) for 5 min
Drying	＞100℃ (212°F) for 10 min

Table 8-2 Supported cleaning agents

Manufacturer	**Product**	**Concentration**
Dr. Weigert	Neodisher Mediclean forte	max. 1.00%

8.1.5.2.4 Packaging

Make sure that the expiratory valve components are not moist during packaging.
The packaging must conform to ISO 11607 and EN 868.
(USA only): For packaging, only use an FDA approved sterilization pouch.
Recommended material for self-sealing sterilization pouch: France PPF (60g) medicalself-adhesive paper + PET/CPP complex film.

8.1.5.2.5 Visual test

After each cleaning and disinfection cycle, the expiratory valve must be macroscopically clean, that is, free of visible residual matter and other impurities. If it is not, the entire cleaning and disinfection process must be repeated. Visually check for external damage, such as cracks, broken or deformed parts, or discoloration.

8.1.5.2.6 Sterilization

For each sterilization cycle, recommending ten (10) test articles as a maximum load specified by the manufacturer.
Sterilize the expiratory valve components after cleaning and disinfection and prior to reuse according to the following: Steam sterilization, fractional vacuum process validated according to EN ISO 17665, sterilization at 134 ° C, with an exposure time of at least 3 min.
Place the expiratory valve components horizontally into the sterilizer; do not stack them. Note that our company is not responsible for the efficacy of any sterilization method, including but not limited to hot-air, ethylene oxide, formaldehyde, radiation, and low-temperature plasma sterilization.
After sterilization, dry the expiratory valve components for at least 16 minutes.

8.1.5.2.7 Assembly

Reassemble the components in the reverse order.

After connection, please perform a pre-use test and verify all tests passed. Pre-use test mainly includes pressure sensor test, flow sensor test, inspiratory valve test, expiratory valve test, leakage test and patient circuit test.

CAUTION: Each time the expiratory module or line is removed and reinstalled, or a new expiratory module is reinstalled, the expiratory flow sensor must be calibrated prior to use of the ventilator. The whole process is automated and no other third party test equipment is required. Refer to chapter 6.3.6.4.1 for expiratory flow sensor calibration during calibration.

8.1.6 Testing before use

WARNING: Defective expiratory valve must not be used.

Carry out a visual check and a tightness test as described in your ventilator's User Manual. Replace defective expiratory valve components.

8.1.7 Expiratory valve life span

As long as the expiratory valve passes the tightness test during the preoperational check, the expiratory valve can be used. Tests and calibrations must be carried out as specified in the ventilator's User Manual. It is the user's responsibility to validate the processes used if the reprocessing procedures used differ from those in this guide.

8.1.8 Packaged expiratory valve: life span and storage conditions

The lifespan of a packaged expiratory valve depends on how long the packaging of the expiratory valve can be kept sterile. Follow the packaging manufacturer's specifications.

The guidelines for storage of expiratory valve are the same as for the ventilator itself and this is specified in the User Manual.

8.2 Regular Maintenance

8.2.1 Maintenance Principles

Do not use a faulty machine. Ask an authorized agent of Dixion to carry out all necessary maintenance tasks. Test the machine after maintenance for normal operation. Every parameter should meet requirement in specification.

In order to ensure the reliability of the machine, all maintenance and repair work should be carried out by an authorized agent of Dixion.

CAUTION: Only authorized personnel are permitted to perform maintenance.

Use products of Dixion to replace damaged ones and test, ensuring all specifications met.

Contact local service agent of Dixion in case support is needed. In all cases, maintenance fee is the current component price plus reasonable labor cost, except for those within guarantee period.

8.2.2 Periodic Maintenance Schedule

The schedule is designed based on the typical condition, that is to say, the least maintenance times vs 2000h operating per year. In case the actual operating time is longer than 2000h per year, the maintenance times should be more.

If necessary, Dixion can provide circuit diagram, service part list, calibration instructions to assist authorized service personnel.

Minimum maintenance interval	**Task**
Daily	Drain water in gas supply inlet filter, check liquid in expiratory module water trap (collected liquid volume cannot be more than half of the bottle).
Weekly	Calibrate oxygen sensor
1-3 month(s)	Clean air filter Clean cooling fan filter on rear of machine.
Every year	Calibrate flow sensor and pressure sensors; Calibrate inspiratory valve and expiratory valve (if necessary).
Every 6 months	Charge and discharge the batteries once (Charge time: at least 3.5h).
Every year or after a failed calibration	Replace the O_2 sensor (actual life depends on temperature and O_2 concentration)
After cleaning and connecting	Check components and replace or repair when necessary.

WARNING: If the Ventilator will not be in use for a period of more than 6 months, the internal batteries must be disconnected or removed to prevent possible damage to the equipment or risk to users or service personnel.

WARNING: If the inspiratory valve is not calibrated correctly, the ventilator may deliver inaccurate tidal volume or airway pressure.

WARNING: If the inspiratory valve is not calibrated correctly, the ventilator may deliver inaccurate PEEP.

CAUTION: The liquid in the water trap cup needs to be cleaned when it is close to half, otherwise it may overflow, and the virus or bacteria in the liquid will pollute the environment.

CAUTION: If the ventilator is used indoors, the condition of the air inlet filter should be checked monthly. If the ventilator is used outdoors or in a dusty environment, the filter should be checked weekly and replaced as necessary.

CAUTION: Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see Chapter 8.4.8, “Filter Element of Gas Inlet Replacement”). This is particularly important when transport intra-hospital, because environmental conditions may cause the filter to become dirty more rapidly.

CAUTION: The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it. Failing to replace a dirty air inlet filter, or operating the ventilator without a filter, may cause serious damage to the ventilator.

CAUTION: Avoid using the ventilator, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake and other filters.

CAUTION: To ensure proper performance of the ventilator, the preventative maintenance schedule should be followed. For further information contact your equipment supplier..

8.2.3 Service Life of Product/Accessories

Service Life is defined as the time that the manufactured device can be expected to be 'serviceable' or supported by Dixion and the maximum time the device can be used safely. Some items within the device may require maintenance, repair or replacement within this time. Such items will be available from Dixion for the service life of the product. The calculation of the service life begins at the connection of the product at the customer site. Dixion recommends for safe use that each device is replaced after its service life is completed.

CAUTION: The service life of the following items is based on specified operating conditions.

Mask, patient breathing circuit	Sterilize for 20 times at 121℃
Power supply cable, gas supply pipe	8 years
Machine	8 years
Battery	500 cycles of full charge(The battery from exhausted to full)

8.3 Maintenance in Operation and Transportation

The location of machine should be proper so that it cannot be obstructed or be disturbed by medical care personnel. Fix power supply cable well to avoid failure. Use caution not to touch accidental buttons on the panel, which may make tidal volume setting wrong.

During transportation of the ventilator, with or without a patient connected, make sure that the following conditions are fulfilled:

- Gas cylinders are connected with a sufficient amount of gas and the Battery module is functioning. Follow the hospital guidelines.
- Use the handles on the Mobile Trolley. Transport the bed and the ventilator slowly, and watch the patient connection carefully to see that no pulling or other movement occurs.
- Be careful not to tip the Mobile Trolley when crossing an obstacle such as a doorstep.

8.3.1 Transportation

Using carefully when moving machine within hospital or clinical environment.

WARNING: If Control Unit of Ventilator is dropped or damaged during transportation, equipment failure could result in patient injury.

WARNING: Tip over hazard – use care when moving Ventilator mounted to Trolley as device could tip over leading to injury or damage to the equipment and possible subsequent patient injury.

User can carry packaged machine while riding in vehicle, plane and train. Impact, severe shock and moisture should be avoided during transportation, with ambient temperature -20°C~+60°C and relative humidity not more than 95%. In case transportation conditions do not meet this requirement, put the machine in specified operating environment for at least 24h before using.

8.3.2 Storage

CAUTION: Do not put ventilator into the vibration environment.

CAUTION: Do not put heavy items on the top of the ventilator.

The machine should be stored in a room with temperature -20°C to + 60°C and relative humidity not more than 95% non-condensing, with ventilation and no corrosive gases.

CAUTION: If the storage environment conditions don't agree, put the machine in specified operating environment at least 24h before using.

CAUTION: The device should be stored at the room that is ventilated and in which no corrosive gases exist.

CAUTION: When the storage conditions are beyond the requirements of operational environment, and the storage state is transferred into operation state, the product only can be used after being stored in environment for over 24 hours.

8.4 Consumables Replacement

8.4.1 Fuse Replacement

WARNING : Before replacing the fuse, first disconnect AC power. Otherwise, it will cause injury or even death.

WARNING : When replacing the fuse, make sure the new fuse is the same type and size as the old one; otherwise, the ventilator will be damaged.

CAUTION: Fuse is a damageable part, which shall be replaced with moderate force and speed.

1. AC Circuit Fuse

Fuse replacement steps:

- Insert screwdriver into the trench (Part 2) of end of fuse box, see Figure 8-6.
- Pull out fuse holder (Part 1).
- Remove the fuse (Part 3).
- Load new fuse.
- Push the new fuse into the original position gently.
- Connect AC power, and then start the ventilator to test.

Figure 8-6

2. DC Power Fuse

Fuse replacement steps:

- Insert screwdriver into the trench (Part 1) of end of fuse box, see Figure 8-7.
- Pull out fuse holder (Part 2).
- Remove the fuse (Part 3).
- Load new fuse.
- Push the new fuse into the original position gently.

Figure 8-7

8.4.2 Battery Maintenance

⚠ **NOTE:** One or more batteries must be used.

⚠ **NOTE:** Before the machine is put into patient use, the battery must be fully charged. If the battery must not be fully charged and AC power supply fails, be careful about the battery power.

• **Battery specification**

Battery module:

-- DC12V, 6.6AH, 14.4V lithium-ion battery
-- Typical charge time: 3.5 hours

-- Typical discharge time: 2 hour

When the main power supply voltage is too low or the main power supply fails, two backup batteries (one is necessary, and one is optional) can protect the ventilator. When having a power failure, the ventilator can switch to battery supply automatically, and can normally work without pneumatic power supply failure. The two batteries are usually available for the ventilator working for 4 hours.

• **Precautions**

Charge: When operating with AC power supply on, the system will maintain the battery automatically. Charge time is less than 3.5 hours.

Discharge: The machine is operating on battery.

In case of low battery condition, an alarm message “Low battery” will appear, notifying the user to restore AC power supply to charge, otherwise the batteries will be depleted and another alarm “Limited Battery Capacity” will be displayed, and eventually the system will shut down (for safety reason, manual power-on is required to start the machines again after an automatic shutdown).

Before the machine is put into patient use, or disconnect AC power for the transport or other purposes, check the battery power. If the battery is not fully charged, connect the ventilator to AC power for at least 3.5h and recharge the battery until the power reaches 80%~100%.

• **Battery storage**

In case the battery is to be stored for a long time, charge it fully prior to storage.

To keep the battery power and prolong the battery life, please ensure that the ventilator is connected to the main power. Charge the battery every six months, while the actual time depends on the storage environment.

High humidity and high temperature environments should be avoided for storage.

• **Battery replacement**

Open the battery cover (See Figure 2-5), then remove the battery from its housing.

Same model battery with CE certification is suggested. Make sure AC power supply is disconnected before replacing.

 **CAUTION:** An authorized service representative can replace the battery. If the battery is not to be used for a long-time, please contact the service representative to disconnect the battery. The waste battery should be disposed of in accordance with the local policies.

• **Battery charging and calibration**

Use the battery charger supplied by Dixion to charge or calibrate the battery. After calibrating the battery, the ventilator can read the residual battery capacity accurately.

Please charge or calibrate the battery according to the instructions of the battery charger.

WARNING: Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators or those in storage should be connected to an AC power source to protect the integrity of the battery.

WARNING: When the "LOW BATTERY" alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.

WARNING: To ensure that ventilation continues uninterrupted ensure alternative power sources are available (AC power source, extra batteries). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use-particularly for ventilator-dependent patients.

WARNING: Even if the internal battery charging indicator shows 100%, charging of the battery may sometimes be incomplete if the ambient temperature is above 40°C (104°F) because of the battery's internal heat safety device.

CAUTION: Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

CAUTION: Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.

CAUTION: When the battery power consumption is extremely fast or abnormal, please stop or replace the ventilator and repair it in time under the condition of ensuring the patient's safety.

CAUTION: When the battery charging is abnormal or unable to charge, please stop or replace the ventilator and repair it in time under the condition of ensuring the patient's safety.

8.4.3 Oxygen Sensor

The oxygen sensor can be used to measure the local oxygen concentration when it is connected to the ventilator or other equipments. The oxygen sensor is suitable for adult and child.

8.4.3.1 Oxygen Sensor Replacement

Disassembly

Step 1: Open outward (Part 1), and then remove the cover(Part 2).

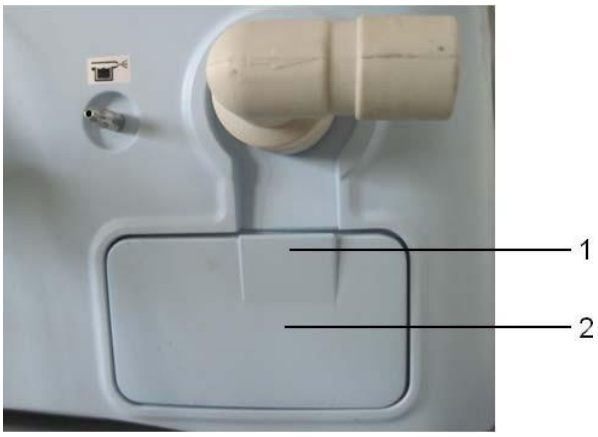


Figure 8-8

Step 2: Turn the oxygen sensor (Part 3) anticlockwise, and then remove it.

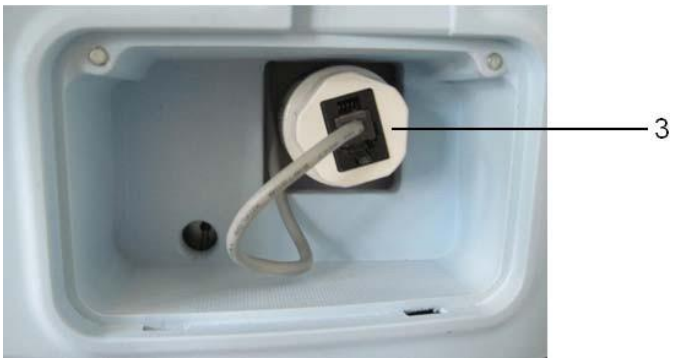


Figure 8-9

Assembly

Inspect the oxygen sensor for damage and replace as necessary. Then reassemble the oxygen sensor.

8.4.3.2 Oxygen Sensor Calibration

For oxygen sensor calibration, refer to section 6.3.6.4.

8.4.3.3 Technical Specifications of Oxygen Sensor

Measure range	0 ~1500 mBar O_2
Measure accuracy	<1%
Response time	<15 s (air to 100% O_2)
Operating temperature	-20℃ ~ +50℃
Operating pressure	0.5 ~ 2.0 Bar
Operating humidity	0 ~ 99% RH non-condensing
Storage temperature	0℃ to 20℃
Drift	<200 μV
Reproducibility	±1%
Type	Chemical fuel cell
Expect life time	0.94 x 10^6% O_2 hours at 20°C 0.6 x 10^6% O_2 hours at 40°C
Total system response time	<60s
Working principle of O_2 monitor	The O_2 monitor surveys and displays the O_2 concentration in the patient loop. The oxygen sensor component contains an oxygen sensor, which can produce the voltage proportional to the oxygen partial pressure (concentration) on its detection surface. The oxygen sensor is an electrochemical device (chemical battery). Oxygen expands in this device through a layer of film and oxidizes the base metal electrode. The oxidation process produces a current with an amplitude proportional to the oxygen partial pressure indicated by the electrode sensor. The base metal electrode is gradually exhausted during the oxidation process. The voltage of the sensor is influenced by the temperature of the monitoring gas mixture. The surgical thermosensitive resistor of the sensor automatically compensates temperature change in the sensor. The O_2 monitor converts the sensor signal into the corresponding oxygen percentage value by using signal processing and circuit analysis. The system displays the value and compares it with the stored alarm limit value. If the value exceeds the threshold, the monitor will alarm.

NOTE: After being in a condensing atmosphere, the oxygen sensor shall be stored for more than 24 hours in an environment equivalent to operating humidity.

8.4.3.4 Oxygen Sensor Maintenance

The oxygen sensor should be regularly calibrated. For the calibration interval, refer to section 8.2.2.

To improve the life time of the oxygen sensor, when the ventilator is not in use the oxygen sensor should be avoided contact with the high-concentration oxygen.

The oxygen sensor is consumptive, and the period of valid is ordinarily 12 months. So the user should pay attention to the valid of the oxygen sensor. When the oxygen sensor fails, please contact the manufacturer.

The recommended oxygen sensor is produced by Dixion.

WARNING: Do not immerse oxygen sensor in liquid. Do not conduct autoclave or high temperature fumigation on the oxygen sensor.

8.4.4 Paramagnetic Oxygen Sensor (optional)

The paramagnetic oxygen sensor can be used to measure the local oxygen concentration when it is connected to the ventilator or other equipment. The oxygen sensor is suitable for adult and child.

8.4.4.1 Paramagnetic Oxygen Sensor Calibration

For the paramagnetic oxygen sensor calibration, refer to section 6.3.6.4.1.

8.4.4.2 Technical Specifications of Paramagnetic Oxygen Sensor

Performance	
Technology	Paramagnetic
Range	0-100% O_2 (with over range -15% O_2 to 200% O_2)
Accuracy (Intrinsic Error)	＜± 0.2% O_2
Linearity	＜± 0.2% O_2
Repeatability	＜± 0.2% O_2
Zero Drift	＜± 0.4% O_2 in first 24 hours, then ＜± 0.2% O_2/week, then ＜± 0.2% O_2/month
Response Time (T_{10} –T_{90})	8 to 20 seconds dependent on application and filter selection (biological filter on request)
Outputs/Controls	

Signal Output	Digital UART or linear mV output (0.5mV or 10mV per % O_2)
Physical	
Weight	70g (2.47oz)
Dimensions	Molex low profile connector: 33.5×30.0×46.1mm (1.32×1.18×1.81”)
Diffusion Port	Aperture diameter: 15.5mm (0.61”)
Sample condition	
Sample Gas Condition	Clean dry gas, free of entrained oil, particulates ＜3μm, non-condensing
Gas Exchange	Diffusion
Ambient conditions	
Operation Temperature	5℃ to 50℃ (41℉ to 122℉)
Storage Temperature	-30℃ to 70℃ (-22℉ to 158℉)
Temperature Coefficient	Within a range of 0℃ to 50℃: Zero ＜± 0.5% O_2 /10℃, Span: ＜ ±0.5% O_2 /10℃
Operating Pressure Range	±33kPag (±5psig)
Ambient Humidity	0 to 95% non-condensing
External Power Supply	5V dc, 70mA nominal
Power Consumption	350mW

8.4.5 Diaphragm Replacement

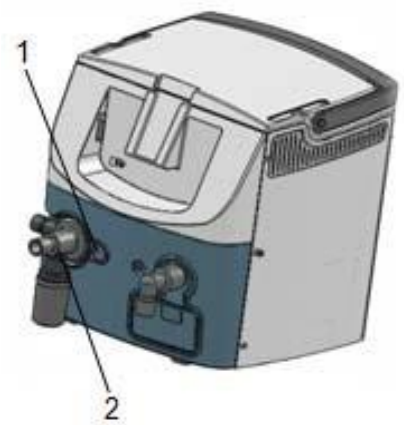


Figure 8-10

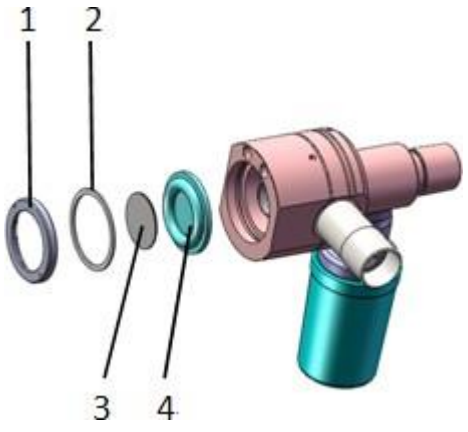


Figure 8-11

Diaphragm replacement method:

a. Press the button (Part1 in Figure 8-10);

b. Pull out the expiratory valve core component (Part 2 in Figure 8-10);

c. Remove the safety valve cover (Part 1 in Figure 8-11) and the gasket (Part 2 in Figure 8-11);

d. Remove the scale board (Part 3 in Figure 8-11) and the diaphragm (Part 4 in Figure 8-11)；

e. Reassemble the above components in the reverse order.

Test: When the diaphragm and scale board are replaced, the inspiratory valve must be calibrated. Also, perform a pre-use test and verify all test pass.

8.4.6 One-way Diaphragm Replacement

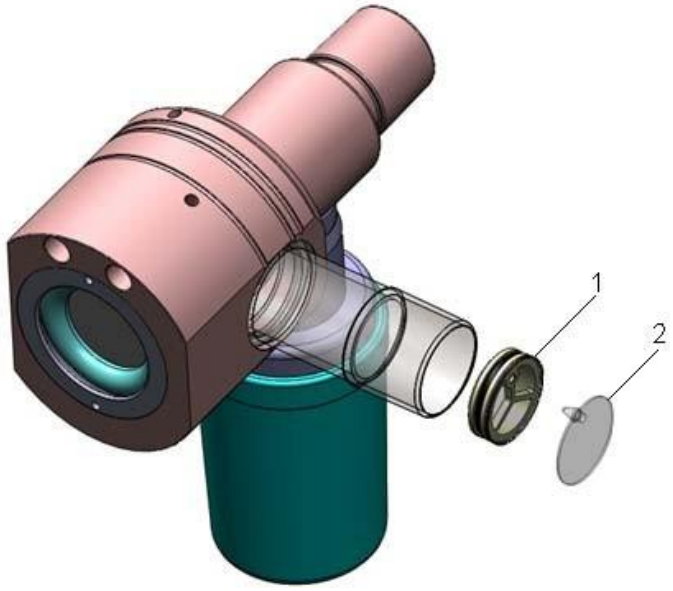


Figure 8-12

The one-way diaphragm replacement method：

a. Remove the expiratory valve core component;

b. Remove the one-way valve core component (Part 1);

c. Remove one-way diaphragm(Part 2);

d. Reassemble the above components in the reverse order.

Test: When the one-way diaphragm has been replaced, the inspiratory valve must be calibrated.

8.4.7 Fan Filter Cotton Replacement

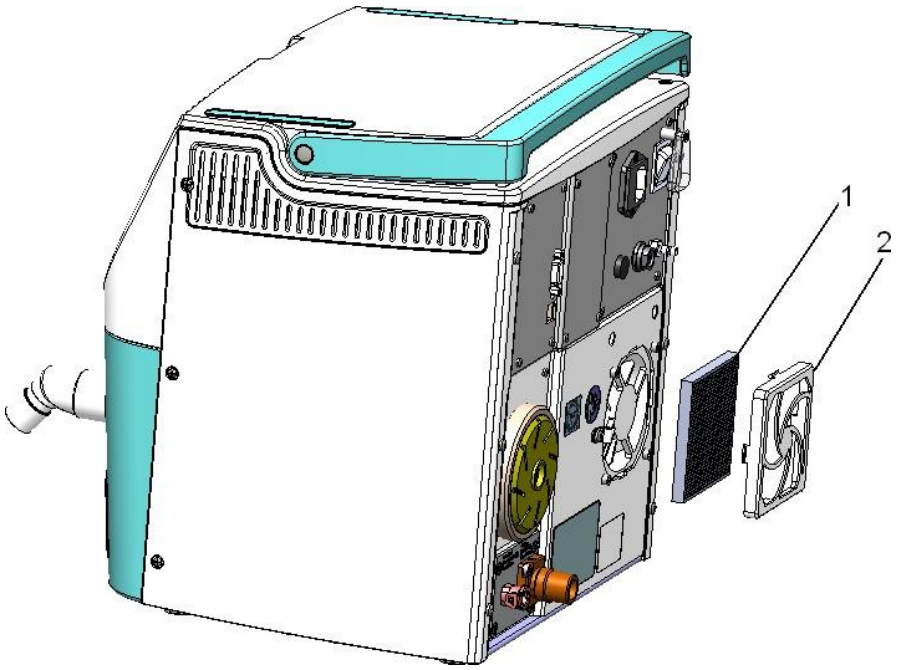


Figure 8-13

The replacement method of the fan filter cotton:

a. Remove the fan filter cotton cover(Part 2)；

b. Remove the fan filter cotton(Part 1);

c. Reassemble the above components in the reverse order.

8.4.8 Filter Element of Gas Inlet Replacement

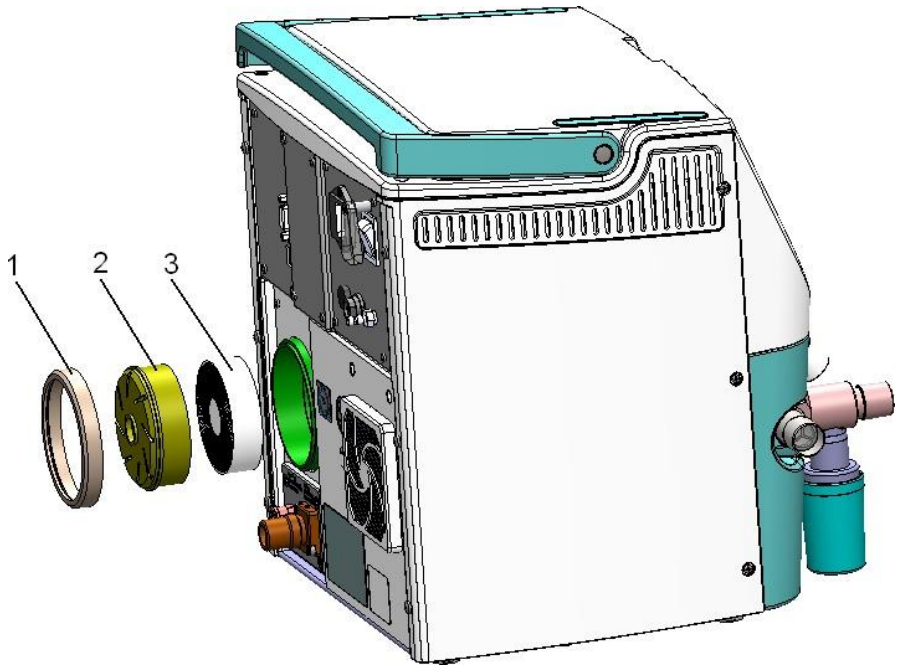


Figure 8-14

Filter element of gas inlet replacement method:

a. Remove the filter cover(Part 1)；

b. Remove the filter support sleeve(Part 2);

c. Remove the filter element of gas inlet(Part 3);

d. Reassemble the above components in the reverse order.

8.4.9 Filter Replacement(Part No.:130003930)

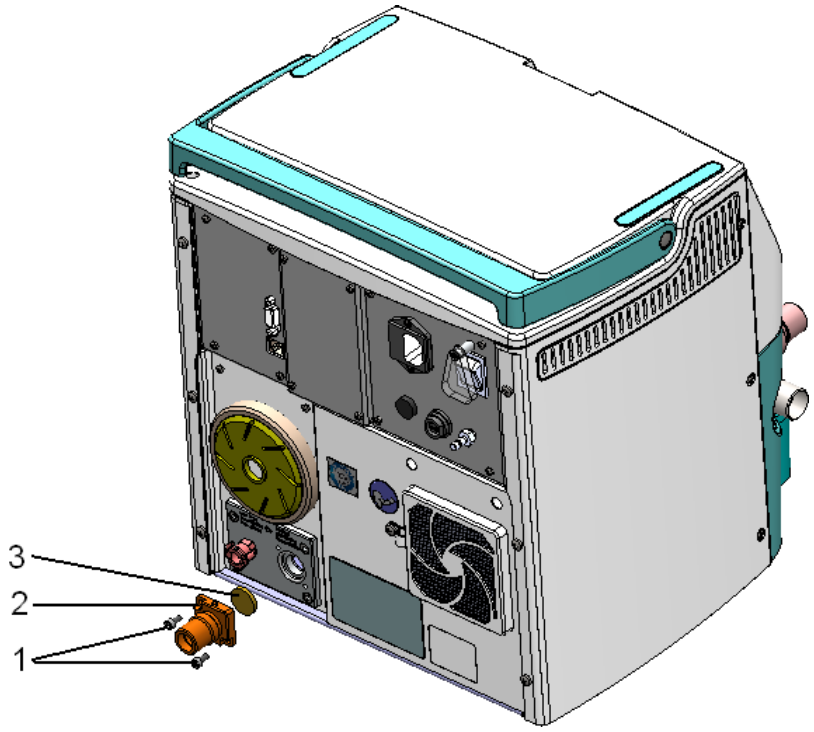


Figure 8-15

The filter replacement method:

a. Remove the two screws (Part 1) (Hexagon socket head cap screws M4×10)；

b. Remove the oxygen inlet connector(Part 2);

c. Remove the filter(Part 3);

d. Reassemble the above components in the reverse order.

8.5 Disposal

This product must not be disposed of with your other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment, or by returning it to Dixion for reprocessing. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your waste disposal service, or your product distributor or retailer.

Correct Disposal of Batteries and O_2 Sensor.

WARNING: Treatment of batteries and O_2 sensor:

- Follow all local regulations with respect to environmental protection when disposing of batteries and O_2 sensor. These products contain toxic compounds irrespective of physical condition. They should be disposed of according to local waste management requirements and environmental legislation. They should not be burned since they may give off toxic fumes.
- Do not throw into fire! Risk of explosion.
- Do not force open! Danger of bodily injury.

9 Warranty

Manufacturing techniques and materials:

Warranty is valid for 18 months after ship date when the cargo is picked-up at factory, the components and assemblies of this product is guaranteed to be free from defects manufacturing techniques and materials, provided that the equipment is properly operated under conditions of normal use and that the equipment is regularly maintained per requirements specified by Dixion. The warranty period for spare parts is three months from shipping date. Consumable parts are not included in this warranty. Dixion's obligation under the above warranty is limited to repairing the equipment free of charge.

(For other period of warranty, please refer to the corresponding contract.)

Freedom Obligations:

Dixion's obligation under the above warranties does not include the freight and other fees. Dixion is not responsible for any direct, indirect or final product broken and delay which due to improper use, alteration by using the assemblies ungratified and maintenance by anyone other than Dixion.This warranty shall not extend to:

- Machines without maintenance or machines are broken.This warranty does not apply to the following situations:
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Any Dixion product which has been subjected to misuse, negligence or accident;
- Any Dixion product from which Dixion 's original serial number tag or product identification markings have been altered or removed;
- Any product of any other manufacturer.

Security, reliability and operating condition:

Dixion is not responsible for the security; reliability and operating condition of this product in cases where:

- The assemblies are disassembled, extended and readjusted
- The product is not operated correctly in accordance with these User manual instructions.
- The AC power used or the operating environment does not follow the requirements in this manual.

9.1 Return

Follow these steps in case the product must be returned to Dixion:

1. Obtain the rights of return (Return Material Authorization Number)
Contact our Customer Service and inform us of the part number and type of the product. The part number is marked on the surface of the product. Return is not allowed if the number cannot be identified. Receive an RMA number from Dixion and mark it on the exterior of the

product package. Enclose a statement of the product number, product type and also the reason for return.

2. Transportation charges

Transportation and insurance charges must be prepaid by the user for transporting the product to Dixion for repair.

10 Theory of Operation

10.1 Ventilation Modes

WARNING: The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient, based on clinical judgment, the condition and needs of the patient, and the benefits, limitations, and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether those are best for the patient's current needs.

WARNING: When using noninvasive ventilation, nasal mask or face mask with gas leak hole should be used when not equipped with expiratory valve, or mask without leak hole but equipped with leak valve. When using noninvasive ventilation and equipped with expiratory valve, the mask without gas leak hole should be used.

There are Invasive and non-invasive (NIV) ventilation modes in the ventilator. All the modes are suitable for children and adults.

Invasive ventilation modes include:

• Assist/Control ventilation (A/C) modes. These modes allow mandatory ventilation and include VCV, PCV and PRVC.
• Synchronous Intermittent Mandatory Ventilation (SIMV) modes. These modes allow both mandatory ventilation (including VCV, PCV and PRVC) and spontaneous ventilation (including spontaneous ventilation and pressure support ventilation - PSV).
• Spontaneous/ Continuous Positive Airway Pressure ventilation (SPONT/CPAP) mode. This mode only allows spontaneous ventilation.
• Bi Level ventilation (BIVENT) mode. This mode allows both mandatory ventilation (switching between high level CPAP and low level CPAP) and spontaneous ventilation.

NIV modes, include:

• NIV/CPAP mode – CPAP mode in NIV.

• NIV-T mode – A/C (PCV) mode in NIV.

• NIV-S/T mode – SPONT mode in NIV.

10.1.1 Assist/Control Ventilation

In Assist/Control ventilation, breaths are controlled by the ventilator (mandatory) or triggered by the patient (spontaneous) or triggered by the operator. When controlled by the ventilator, Ventilator Initiated Mandatory (VIM) breaths are flow controlled and time cycled, thus delivering an operator set volume (Tidal Volume) or pressure. Extra breaths, called Patient Initiated Mandatory (PIM) breaths, shall be possible if the patient overcomes the pre-set trigger level. PIM breaths are either pressure or flow triggered. If the trigger setting is adjusted so that the patient cannot trigger the ventilator, all breaths shall be VIM breaths, including operator triggered breaths.

1. Volume Control Ventilation:

In VCV, VIM breaths deliver the set volume (Tidal Volume - Vt).

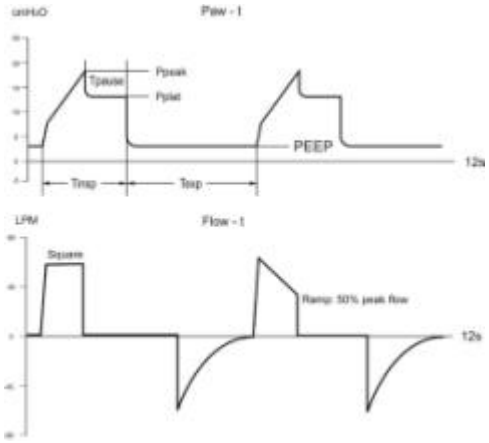


Figure 10-1

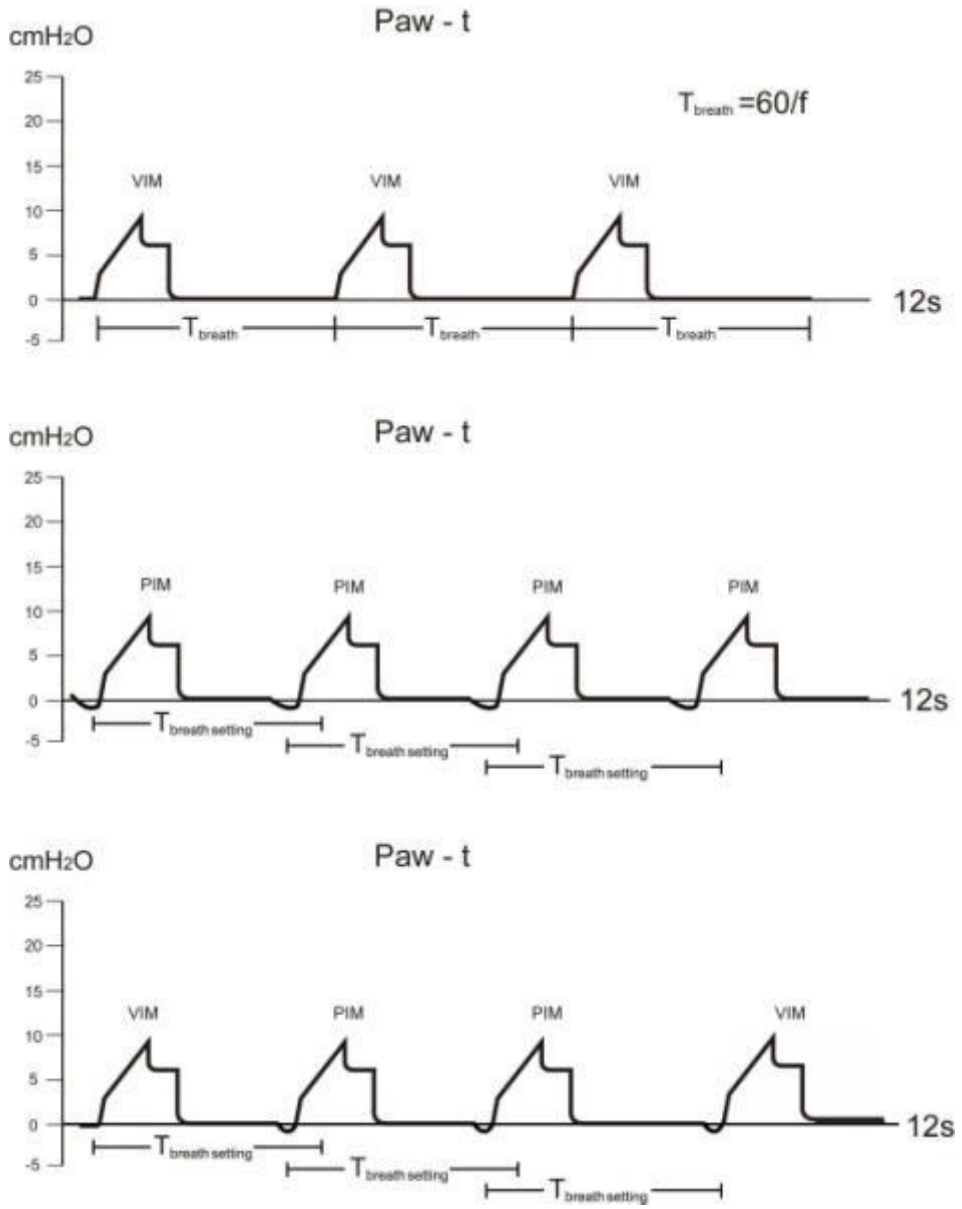


Figure 10-2

2. PCV Pressure Controlled ventilation

In PCV, VIM breaths deliver the set Pressure (Pinsp) using a decelerating flow pattern.

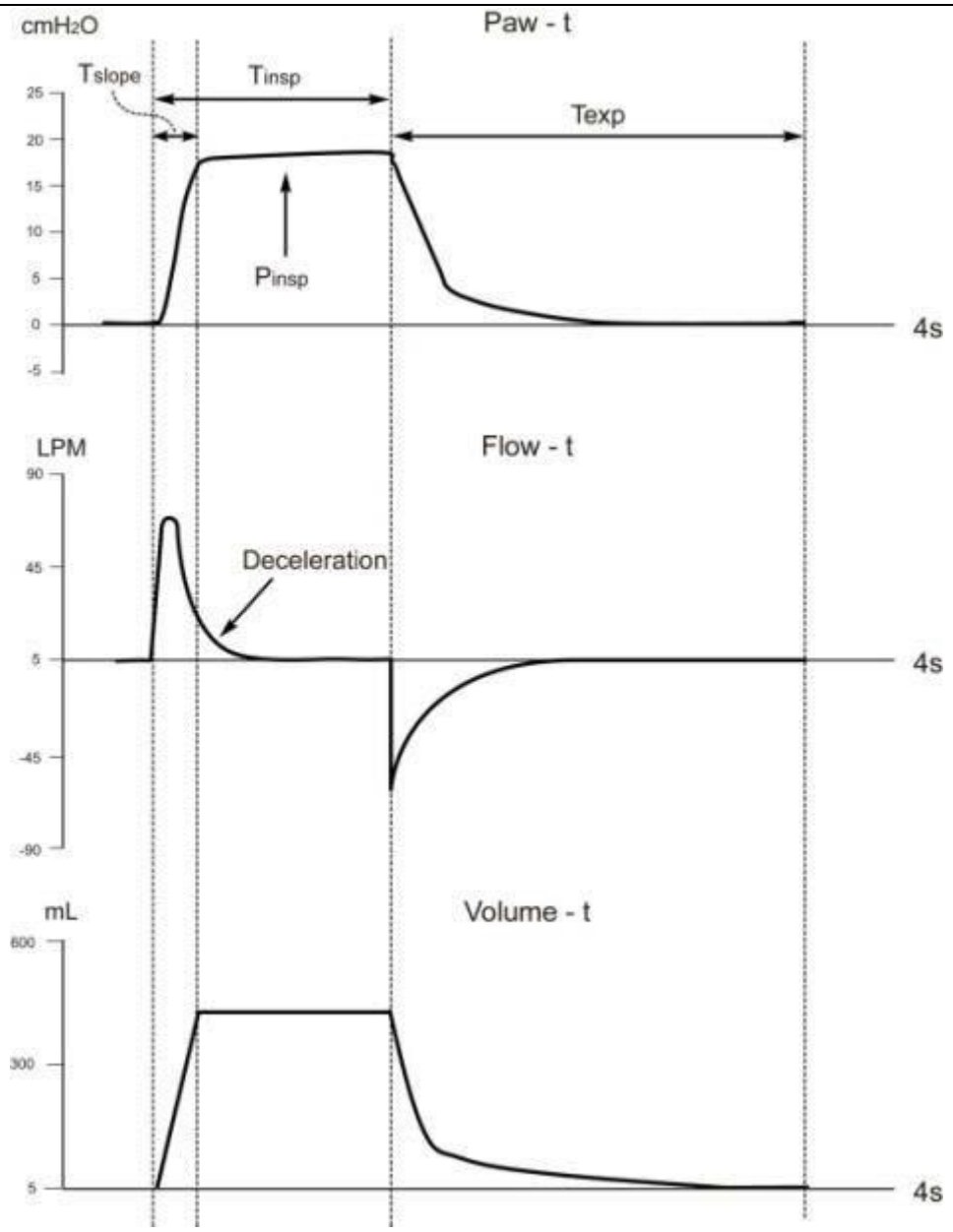


Figure 10-3

3. Pressure Regulated Volume Control Ventilation

PRVC breaths will be delivered at a set rate and set volume (VT). The flow pattern resembles PCV. Inspiratory pressure will be regulated in PRVC to achieve the operator set volume (Tidal Volume). The first ventilation in PRVC will have a square flow waveform and each successive ventilation will have a ramp flow (decelerating) waveform.

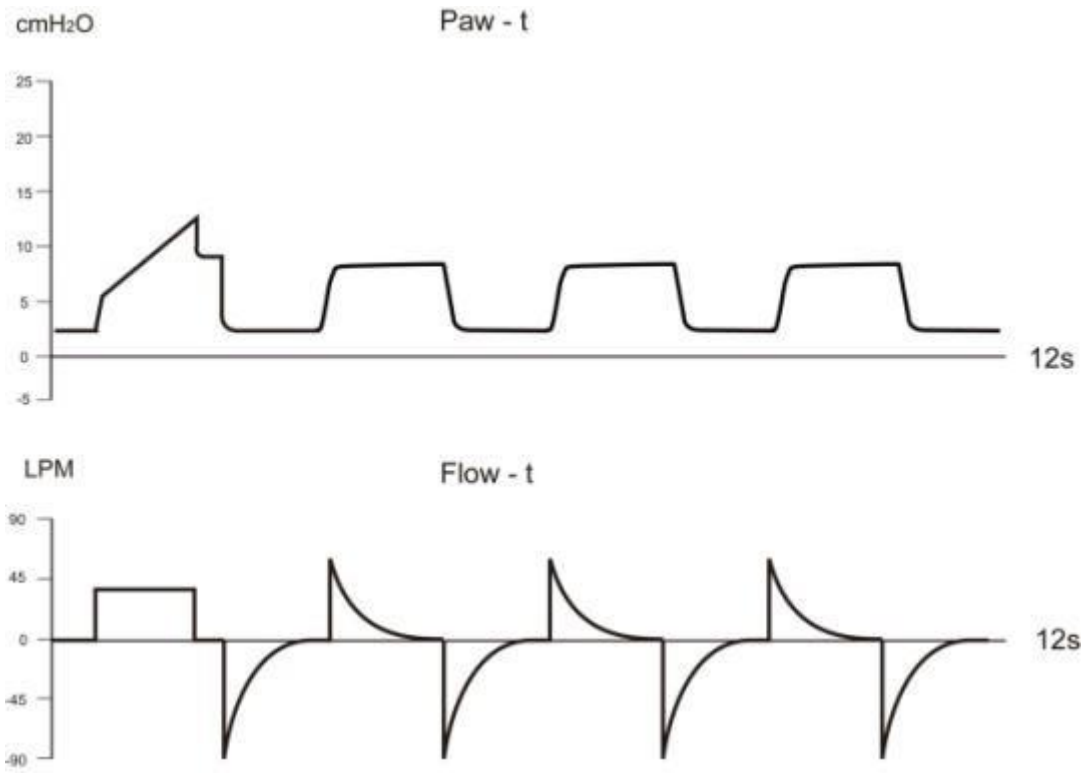


Figure 10-4

PRVC ventilation operation shall be as follows:

When PRVC is selected, a volume controlled test breath will be delivered to the patient according to the set tidal volume. The ventilator will set the target pressure for the first pressure control breath to the end inspiratory pressure of the test breath.

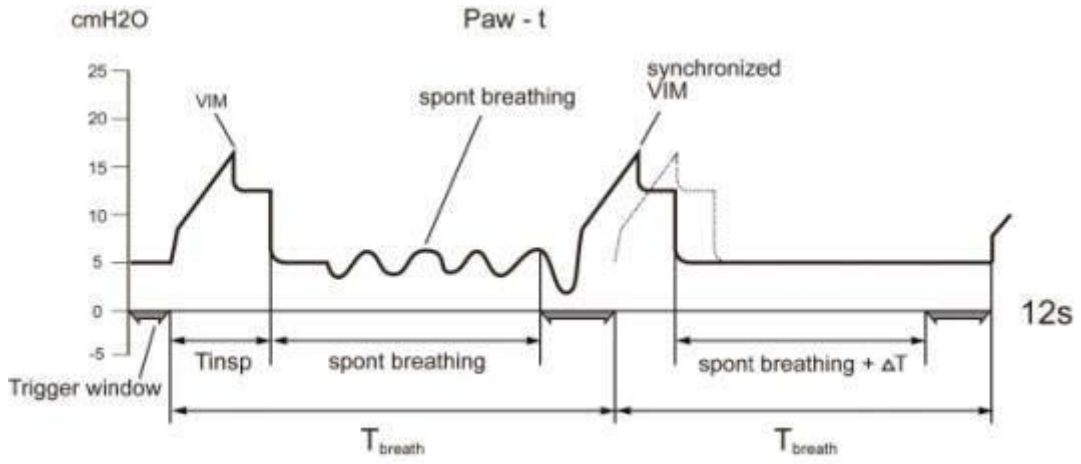
The next ventilation and all subsequent breaths will be delivered as pressure control breaths. The inspiratory pressure will be based on the dynamic compliance of the previous ventilation and the set tidal volume. Inspiratory pressure will be adjusted automatically by the ventilator to maintain the target tidal volume. The maximum step change between two consecutive breaths shall be 3 centimeters of water pressure. The maximum tidal volume delivered in a single ventilation shall be 1.5 times the Vt setting.

The test ventilation sequence shall be initiated when any of the following events occur: Entering the Mode (PRVC) mode; Changing the set tidal volume while in PRVC; Delivered tidal volume >= 1.5 times the set volume; Flow termination of the test ventilation; activation of any of the following alarms - High Peak Pressure Alarm; Low Peak Pressure Alarm; Low PEEP alarm; Patient Circuit Disconnect Alarm; I-Time Limit; I:E Limit.

10.1.2 Synchronized Intermittent Mandatory Ventilation

SIMV is a ventilation mode where the patient is allowed to breathe spontaneously and the machine delivers VC mandatory breaths in synchrony with the patient’s effort at the operator set rate and volume (or pressure). This is accomplished by a combination of spontaneous and mandatory windows that open and close. The type of ventilation delivered depends upon

whether the event during the window is patient initiated, operator initiated or time initiated. Spontaneous breaths occurring between mandatory breaths can be pressure supported. Synchronized breaths shall be either pressure or flow triggered. Back-up (Apnea) ventilation shall be provided when there is no patient trigger, mandatory ventilation or manual ventilation for a period that exceeds the apnea alarm setting. Backup Ventilation shall be available in SIMV - See section on Backup Ventilation for details on these modes and settings.



SIMV ventilation cycle, PIM delivered within mandatory interval and SIMV ventilation cycle, PIM not delivered within mandatory interval

Figure 10-5

1. SIMV (VCV)

In SIMV (VCV), mandatory ventilator breaths are volume controlled. Between the mandatory breaths the patient can breathe spontaneously. These spontaneous breaths can be pressure supported. Backup ventilation will be PCV.

2. SIMV (PCV)

In SIMV (PCV),mandatory ventilator breaths are pressure controlled. Between the mandatory breaths the patient can breathe spontaneously. These spontaneous breaths can be pressure supported. Backup ventilation will be PCV.

3. SIMV (PRVC)

In SIMV (PRVC), mandatory ventilator breaths are pressure-regulated volume controlled. Between the mandatory breaths the patient can breathe spontaneously. These spontaneous breaths can be pressure supported. Backup ventilation will be PCV.

10.1.3 Back-up Ventilation (Apnea Ventilation)

1. Transition into Back-up Ventilation

The current Ventilation mode shall transit to Back-up Ventilation - PCV when an apnea occurs in SPONT/CPAP mode.

The current Ventilation mode shall transit to Back-up Ventilation - PCV when an apnea occurs in BIVENT mode.

The current Ventilation mode shall transit to Back-up Ventilation - PCV when an apnea occurs in NIV-S/T mode.

The current Ventilation mode shall transit to Back-up Ventilation - PCV when an apnea occurs in an SIMV mode.

2. Characteristics of Back-up Ventilation

Apnea ventilation settings include Pinsp, Tinsp or I:E.

3. Exiting Back-up Ventilation

Two methods to exit Back-up Ventilation shall be supported: trigger by patient or reset by operator.

When in Back-up Ventilation and the patient triggers two consecutive breaths and also the Expiratory Vt >= 0.5 x Inspiratory Vt for those two breaths, then the ventilator shall return to the Ventilation mode and settings prior to the Apnea event.

When in Back-up Ventilation and the operator resets the Apnea Alarm and confirms the reset by pressing the Encoder Knob, then the ventilator will return to the Ventilation mode and settings prior to the Apnea event.

Mode transitions when exiting Back-up Ventilation shall occur only when an Expiratory has been completed.

10.1.4 Spontaneous/CPAP Ventilation

In SPONT/CPAP Ventilation, the patient breathes spontaneously at a pressure level determined by the PEEP setting. Spontaneous ventilation may also be assisted by the ventilator at an operator set level of inspiratory pressure (Pressure Support). Inspiration is initiated by the patient and terminated when the inspiratory flow falls below an operator set percentage of the peak flow during this ventilation. During SPONT/CPAP, the patient determines the respiratory rate, and the patient and ventilator determine the inspiratory time and tidal volume. Ventilation detection shall be either pressure or flow triggered. PCV back-up ventilation shall be provided when there is no patient trigger, for a period that exceeds the apnea alarm setting. (See Section on Back-up ventilation for details)

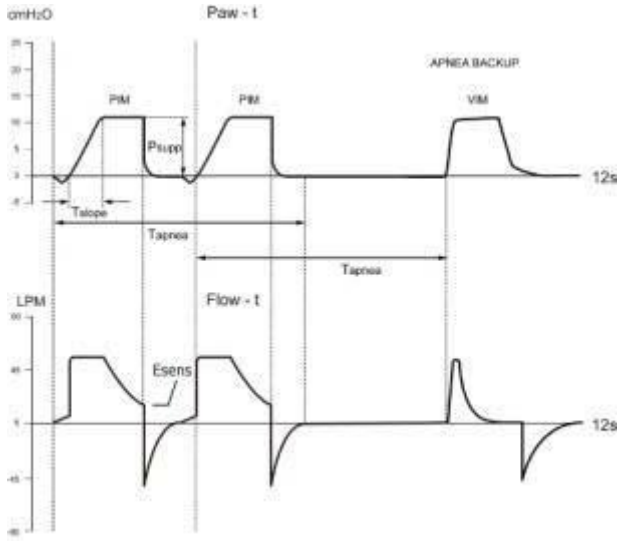


Figure 10-6 Spontaneous /CPAP ventilation

10.1.5 BiLevel Ventilation (BIVENT)

In BIVENT, breaths shall be controlled by the ventilator (mandatory). Pressure controlled breaths are provided by switching between a high and low airway pressure in an adjustable time sequence. Spontaneous breaths can be pressure supported at the high and low pressure levels. When the expiratory time (Tlow) is less than the inspiratory time (Thigh) the displayed ventilation mode shall be Bi Vent APRV. PCV back-up ventilation shall be provided when there is no patient trigger, mandatory ventilation or manual ventilation for a period that exceeds the apnea alarm setting. (See Section on Back-up ventilation for details)

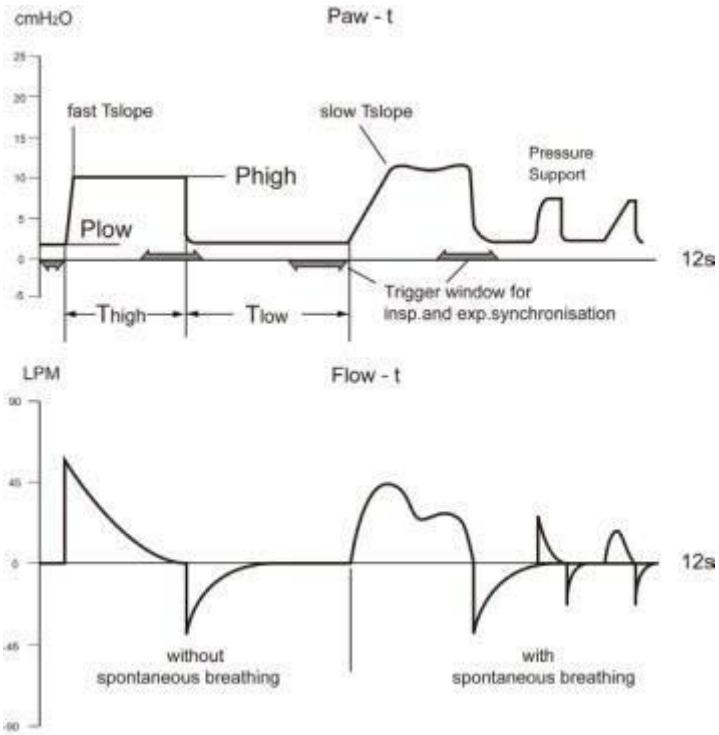


Figure 10-7 BIVENT

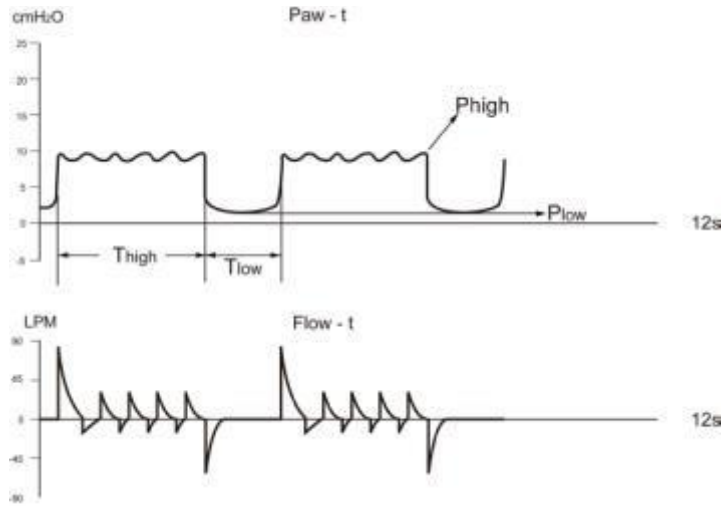


Figure 10-8 BIVENT APRV

10.1.6 Non Invasive/Continuous Positive Airway Pressure

NIV/CPAP is a spontaneous mode of operation and no ventilator controlled breaths are provided. Throughout the ventilation cycle, an operator set pressure (CPAP) may be provided. In NIV/CPAP, the ventilator controls the airway pressure as the preset PEEP value.

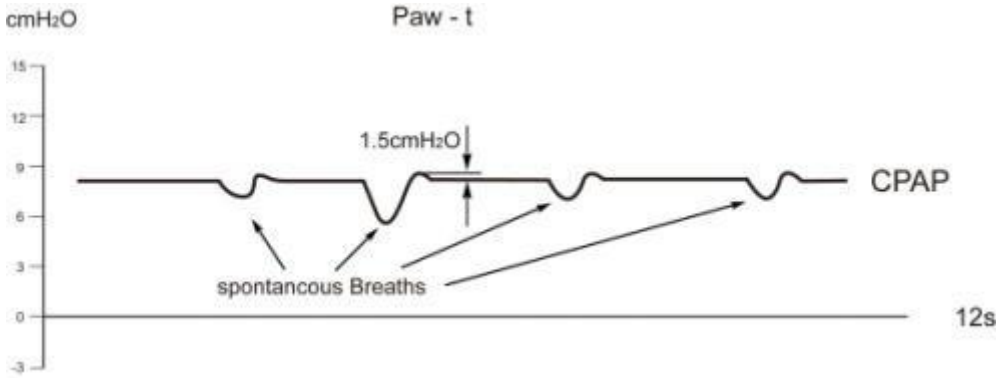


Figure 10-9

Illustration shows NIV/CPAP. Pressure shall rise according to the selected rise time, with target pressure 1.5 cmH_2O above PEEP to improve work of ventilating.

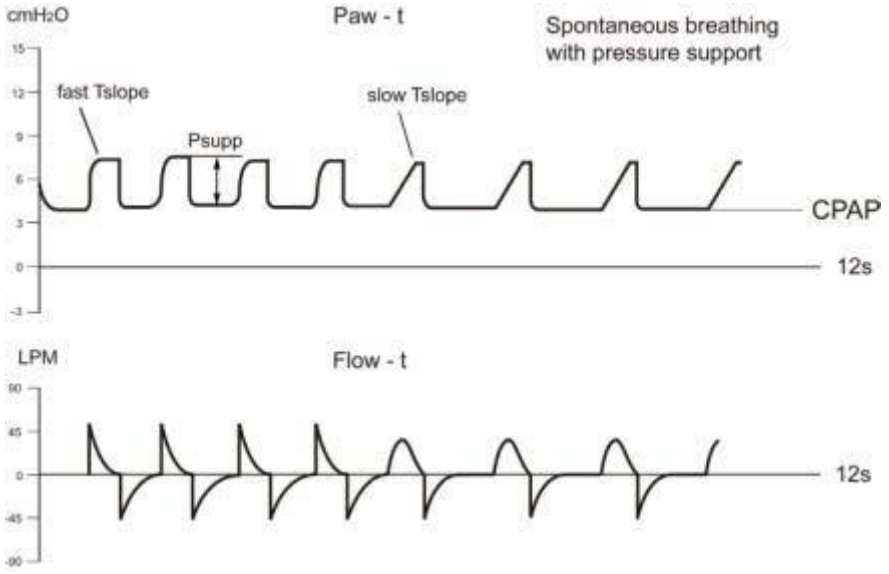


Figure 10-10

This illustration shows NIV/CPAP spontaneous breaths with Pressure Support

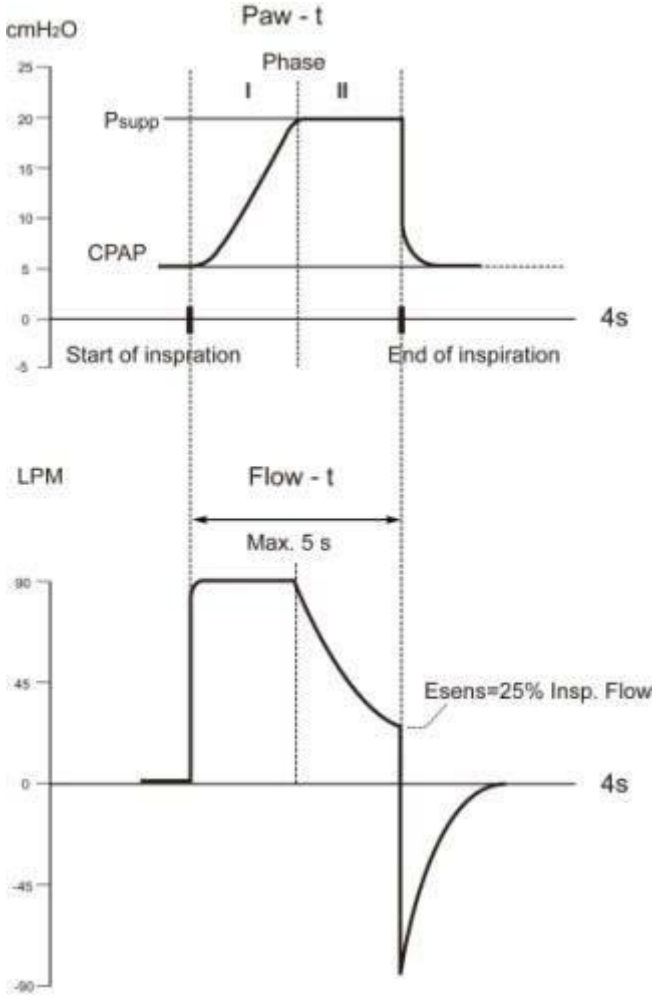


Figure 10-11

Pressure support will be terminated when:

- Inspiratory flow returns to zero during phase 1 of inspiration, (i.e. when the patient exhales or fights the ventilator),
- Inspiratory flow in phase 2 of inspiration phase falls below a certain ratio (Esens) of the maximum value previously supplied when compared to the peak inspiratory flow supplied

or

- Based on high Spont Inspiratory Time setting is exceeded

10.1.7 NIV-T

In NIV-T, breaths shall be controlled by the ventilator (mandatory) or shall be triggered by the patient (spontaneous) or shall be triggered by the operator. When controlled by the ventilator, breaths shall be pressure limited and time cycled, resulting in an operator set pressure (Pinsp) being delivered for an operator set period (Tinsp). Extra breaths shall be possible if the patient overcomes the pre-set trigger level or if the operator selects a manual ventilation. Patient triggered breaths shall be flow triggered.

10.1.8 NIV-S/T

NIV-S/T is a spontaneous mode of operation and no ventilator controlled breaths are provided. Throughout the ventilation cycle, spontaneouse ventilation may also be assisted by the ventilator at an operator set of inspiratory pressure (Pressure Support). If the trigger time of the patient exceeds the setting value of the apnea time, the mode will enter into back-up ventilation.

NIV-S/Td is a spontaneous mode of operation and no ventilator controlled breaths are provided. Throughout the ventilation cycle, an operator set pressure (CPAP) may be provided. In NIV/CPAP, the ventilator controls the airway pressure as the preset PEEP value.

11 AEROS 4600 Ventilator System Specifications

WARNING: Do not operate the Ventilator outside specified operating ranges or patient injury or equipment damage could result.

NOTE: To add a measure of safety, an electronic hardware watchdog timer monitors the system operation at all times. In cases where the system software does not respond in a safe time period, the watchdog timer will reset the system. This enables the system software to be in control at all times.

11.1 System

11.1.1 General

This device complies with requirements of Medical Device Directive 93/42/EEC.

Standards

IEC 60601-1: The device classification is: Class I, Type B applied part (ventilator breathing tube and mask), type BF applied part (CO_2 module), ordinary enclosed equipment without protection against ingress of liquids, continuous operation
ISO 80601-2-12

WARNING: Equipment not suitable for use in the presence of a Flammable Anesthetic mixture with Air or with Oxygen or Nitrous Oxide.

Electromagnetic Compatibility (EMC)

According to IEC 60601-1-2

Patient Range (cm)

Adult: 60 – 260
Child: 30 – 140

NOTE：Leakage from VBS COMPLIANCE：

- 50 ml/min at 20 hPa for a VENTILATOR intended to provide DELIVERED VOLUME less than 50 ml;
- 100 ml/min at 40 hPa for a VENTILATOR intended to provide DELIVERED VOLUME between 300 ml and 50 ml;
- 200 ml/min at 50 hPa for a VENTILATOR intended to provide DELIVERED VOLUME greater than 300 ml.

11.1.2 Operating Conditions

Operating Temperature Range: +5 to +40℃
Relative Humidity: 5 to 95% non-condensing
Atmospheric Pressure: 700 to 1060 hPa

Enclosure Protection Rating IP21 per IEC 60529

11.1.3 Non-operating Conditions

Storage Temperature Range: -20 to +60 C
Storage Relative Humidity: ≤95% non-condensing
Storage Atmospheric Pressure: 700 to 1060 hPa

11.1.4 Power Supply

Ventilator

Power Supply	100-240VAC 50/60 Hz
DC Power	12-24 VDC
Battery Backup (Standard)	Two rechargeable lithium-ion battery modules, 14.4 V, 6.6 Ah each. Recharge time approximately 3.5 hours. Battery backup time of 120 minutes minimum with only standard internal battery.
Maximum Power Consumption	200VA
AC Circuit Fuse	UDA3.15
DC Power Fuse	GDA012

Trolley

Output	**Humidifier**	**Socket**	115V 2A 60Hz 220V 1A 50Hz 230V 1A 50/60Hz
		Fuse	250V H3.5A
	Ventilator	115V 5A 60Hz 220V 5A 50Hz 230V 5A 50/60Hz	
Input		115V 8A 60Hz 220V 8A 50Hz 230V 8A 50/60Hz	

CAUTION: DC power conforms to IEC 60601-1.

CAUTION: The Power Supply should meet the above specifications.

WARNING: Connecting any equipment that has not been supplied as a part of the ventilator system to the socket of the trolley may generate the risk.

WARNING: The power supply to which the ventilator is connected must comply with all applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the rear of the ventilator to ensure correct operation. (Refer also to the electrical specifications found in Chapter 11, “AEROS 4600 Ventilator System Specifications”.)

11.2 Ventilator

11.2.1 General

Dimensions	User Interface: 350 wide x 55 deep x 244 high (mm) Ventilation Delivery Unit: 322 wide x 375 deep x 366 high (mm) System with Trolley (optional): 547 wide x 675 deep x 950 high (mm)
Weight (Approximate)	Total: 40 kg User Interface: 2.5 kg Ventilation Delivery Unit: 12.5 kg Trolley: 25 kg
Trigger Method	Flow and Pressure
Maximum limited pressure	80 cmH_2O

Maximum working pressure	80cmH_2O
Warm-up time	⩾20 min
Pressure compensation	Manually set the altitude to compensate.
	The ventilator has the automatic atmospheric pressure compensatory function.

11.2.2 Gas Supply

Supplied gases must be free of water, oil and particles.

Inlet Gas Pressure

O_2: 280 kPa to 600 kPa (41 – 87 psi)

Connection Standards Available

DISS, NIST

The maximum 10 s average input flow required by ventilator for O_2 is 60.69 LPM at a pressure of 280 kPa. For a 3 second average and at a pressure of 280kPa, the maximum averaged transient input flow required by the Ventilator is 64.44 LPM for O_2.

CAUTION: The ventilator is a high flow device and should only be connected to a pipeline connection designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of adjacent equipment.

11.2.3 Patient System Connectors

Male 22 mm Conical Fittings in accordance with ISO 5356-1.

11.2.4 User Interface

Attach to the ventilation delivery unit, the head mast, or other mounting system.

11.2.5 Acoustic Energy

The A-weighted sound pressure level of the ventilator is 45 dB; the A-weighted sound power level is 52 dB.

11.2.6 Cyber Security Instruction

The ventilator is available for data transmission and is configured as follows:

- CPU: Cortex A8 frame, i.MX53 series
- Operation system: Windows CE
- Compilation environment: Microsoft Visual Studio 2005
- Hardware interface: Ethernet * 1 (for engineer debugging), USB * 2 (for users to export Trend Graph, Event Log and screenshot; and for service engineers to upgrade the software)

11.3 Standard Conditions Specifications

Error ranges in this document assume the following standard conditions:

- Ambient pressure: 101.3 kPa (1 atmosphere)
- Room temperature: 20℃
- Dry gases in patient system
- Inlet pressure: 345 kPa (50 psi)

11.4 Inspiratory Channel

Pressure Drop

Maximum 5 cmH_2O at a flow of 60 liters/min.

Rated Inspiratory Gas Pathway Resistance

Less or equal to 50 $cmH_2O/L/s$

Compliance

Maximum 2 mL/cmH_2O (With Fisher & Paykel MR 810 Humidifier and Patient Circuit of reusable silica gel).

Gas Delivery System

Microprocessor controlled valves.

Gas Delivery Device

Flow Range:
Adult: 1 to 180 liters/min
Child: 0 to 60 liters/min

Maximum Pressure Setting: 70 cmH_2O

NIV Max leakage compensation level

Adult: 60 lpm
Child: 30 lpm

11.5 Expiratory Channel

Pressure Drop (Resistance)

Maximum 5 cmH_2O at a flow of 60 lpm.

Rated Expiratory Gas Pathway Resistance

Less or equal to 20 $cmH_2O/L/s$

Compliance

Maximum 2 mL/cmH_2O (With Fisher & Paykel MR 810 Humidifier and Patient Circuit of reusable silica gel).

PEEP Regulation

Microprocessor controlled valve

PEEP Setting Range

0 ~ 35 cmH_2O

Expiratory Flow Measurements

Range: 0 ~ 180 lpm.

Because of power failure or partial loss power, the ventilatory capacity is unnormal. When the ventilator supplies 60L/min volume, for the expiratory valve the pressure drop is 0.18kPa in inspiration, the pressure drop is 0.11kPa in expiration.

11.6 Monitoring

Inspiratory and Expiratory Minute Volume

Range: 0 ~ 60 lpm.
Accuracy: +/- 1 LPM or +/- 15% of measured value (whichever is greater)
Resolution: 0.1 lpm > 1 lpm, 0.001 lpm < 1 lpm

Inspiratory and Expiratory Tidal Volume

Range: 0 ~ 4000 mL
Adult Accuracy: +/- 25 ml or ±15% of the measured value (whichever is greater)
Child Accuracy: +/- 10 ml or ±10% of the measured value (whichever is greater)
Resolution: 1 mL

O_2 Concentration

Range: 18 ~100%
Accuracy: +/- 3 vol. %
Resolution: 1%

Airway Pressure

Range: -20 to 80 cmH_2O
Accuracy: ± (2 cmH_2O + 4% of reading)
Resolution: 1 cmH_2O

Measurement uncertainty
Volume: +/- 2% of reading or +/- 20 mL (whichever is greater)

Pressure: +/- 0.75% of reading or +/- 0.1 cmH_2O (whichever is greater)

O_2: +/- 1%

Airway Pressure and Flow Rate Waveform

Filtering of 5 samples is performed for smoothing.

11.7 Alarms

CAUTION: A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, ventilation will resume without having to press the VENTILATION ON/OFF button.

11.7.1 Allowed Alarm Settings

Airway Pressure (upper limit)

5 to 80 cmH_2O

High Continuous Pressure

Set PEEP level + 15 cmH_2O for at least 15 sec

O_2 Concentration

Set value +/- 6 vol % or <= 18 vol %

Expired Minute Volume (Upper alarm limit)

1 ~ 60 liters/min; OFF

Expired Minute Volume (Lower alarm limit)

0.1 ~ 40 liters/min; OFF

Apnea Time

10 ~ 60 sec; OFF

Respiratory Frequency

10 ~ 80 bpm; OFF

Low End Expiratory Pressure

1 ~ 35 cmH_2O; OFF
Or 1 ~ 20 cmH_2O; OFF (NIV modes only)

End-Tidal CO_2 (Upper alarm limit)

0.1% to 13.3% or 1 mmHg to 100 mmHg or 0.1 kPa to 13.3 kPa

End-Tidal CO_2 (Lower alarm limit)

OFF, 0.1% to 13.2% or OFF, 1 mmHg to 99 mmHg or OFF, 0.1 kPa to13.2 kPa

11.7.2 Alarms Miscellaneous

Gas Supply

< 160 kPa (29 psi) +10% for 5 seconds or more

Alarm Silence/reset

Press this button to silence alarms for two minutes. This button also resets latched alarms.

Alarm Sound Pressure

The alarm sound pressure is above 60 dB at lowest volume setting at a distance of 1 meter from the front of the ventilator.

11.8 Ventilation Modes

11.8.1 Controlled Ventilation

Pressure Control (PCV)

Pressure controlled ventilation

Volume Control (VCV)

Volume controlled ventilation

Pressure Regulated Volume Control (PRVC)

Pressure regulated volume controlled ventilation

Noninvasive Pressure Control (NIV-T)

Noninvasive pressure controlled ventilation

11.8.2 Supported Ventilation

SPONT/CPAP+PSV

Spontaneous continuous positive airway pressure ventilation with pressure supported ventilation

NIV-S/T

Noninvasive pressure supported ventilation

11.8.3 Combined Ventilation

SIMV (PCV) + PSV

Synchronized intermittent mandatory ventilation based on pressure controlled ventilation with pressure supported ventilation

SIMV (VCV) + PSV

Synchronized intermittent mandatory ventilation based on volume controlled ventilation with pressure supported ventilation

SIMV (PRVC) + PSV

Synchronized intermittent mandatory ventilation based on pressure regulated volume controlled ventilation with pressure supported ventilation at high and low pressure levels

BIVENT

Pressure controlled ventilation that allows the patient the opportunity of unrestricted spontaneous ventilating with pressure support at high and low pressure levels

11.9 Trend Function

Peak Airway Pressure	**Ppeak**
Plateau Airway Pressure	**Pplat**
Mean Airway Pressure	**Pmean**

End Expiratory Pressure	**PEEP**
Minimum Airway Pressure	**Pmin**
Inspiratory Tidal Volume	**Vti**
Expiratory Tidal Volume	**Vte**
Expiratory Minute Volume	**MVe**
Spontaneous Minute Volume	**MVespont**
Inspiratory/Expiratory Ratio	**I:E**
Total Ventilating Frequency	**ftotal**
Spontaneous Ventilating Frequency	**fspont**
Oxygen Concentration	**O_2**
Expiratory Resistance	**Rexp**
Dynamic Compliance	**Cdyn**
Rapid - shallow ventilating index	**RSBI**
Work of Ventilating	**WOB**
Leak	**Leak NIV**

11.10 Log Function

Alarm/Event Log

Alarms
Ventilator Settings
Shortcut button functions

Service Page

Technical alarms
Test results
Calibration results
Configuration log

11.11 Shortcut Button Functions

Insp. Hold

Inspiratory Hold

Exp. Hold

Expiratory Hold

Nebulizer

Start and stop the Nebulizer operation

Manual

Initiation of 1 ventilation in all ventilation modes except SPONT/CPAP

Suction

Initiate and terminate the suction support process.
Disconnection detection – Automatic
Reconnection detection – Automatic
Pre-oxygenation – Max.3 minutes
Active Suction phase – Max.2 minutes
Post-oxygenation – 2 minutes

Freeze

Freeze the current waveforms and loops, or unfreeze the Waveform display

Screen Lock

Lock or unlock the touch screen

Main Menu

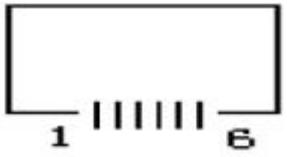
Return to the main menu

11.12 Communication/Interface

11.12.1 Nurse Call Port

The Ventilator has a modular jack configured to interface with external systems and is wired for normally open (N.O., close on alarm) signals. Contacts close on High priority alarms, loss of AC power and Speaker failure.

Floating DC contact
Voltage: Max. 50V
Current: Max. 200mA



Pin assignment:

1	Normally open	2	Normally open	3	Normally open
4	Common pin	5	Common pin	6	Common pin

CAUTION: To connect the ventilator to a Nurse Call device, contact your equipment supplier to check the ventilator's compatibility with the Nurse Call device and order a suitable connection cable.

CAUTION: Before using the Nurse Call system, ensure that its connections are secure and it operates properly.

11.12.2 Ethernet Port

Ethernet Port per IEE 802.3 to disable the AEROS 4600 to connect to external equipment.

CAUTION:

- Connection of the AEROS 4600 to an equipment could result in previously unidentified risks topatients, operators or third parties.
- The facility should identify, analyze, evaluate and control these risks.
- Subsequent changes to the Ethernet port could introduce new risks and require additional analysis; and
- changes to the Ethernet Port include:
  - changes in Ethernet Port configuration;
  - connection of additional items to the Ethernet Port;
  - disconnecting items from the Ethernet Port;
  - update of equipment connected to the Ethernet Port.

11.12.3 Nebulizer Output Port

Output port for connection to nebulizer locates in the front of the ventilator. The whole nebulizer lasts for 30 minutes.

11.12.4 Cyber security description

There are two USB interfaces for data export and software upgrade. Users can access USB devices, export trend chart, log and screenshot pictures, and customer service engineers can access USB devices to complete software online upgrade.

11.13 Accessories

Mobile Trolley

Weight: 25Kg

Dimensions: 547 wide x 675 deep x 950 high (mm)

Gas Cylinder Kit

Capacity is two cylinders max, US E cylinders

Humidifier

Fisher & Paykel MR850, MR810

Vincent Medical: VHB10A

Nebulizer

Part number: 230000728

Nebulizer with CE certification.

The nebulizer meets the requirements of EN13544-1-2007+A1-2009.

There is no special requirements on the nebulizer connector and no limitation on the types of drugs. The connection of nebulizer is shown in Figure 2-1 of the user manual.

Breath circuit

Fisher & Paykel reusable breathing circuit:

MV1006 (F&P)	900MR761 Adult Circuit Kit
MV1005 (F&P)	900MR742 Adult Single Limb Heated Circuit Kit
MV1007 (F&P)	900MR780 Adult Circuit Kit, Dual Heated 4 LPM
MV1008 (F&P)	900MR781 Infant Circuit Kit, Dual Heated 4 LPM

Other recommended breathing circuit:

122000761	Adult breathing circuit (Disposable): mask, headband, elbow, breathing circuit etc. Produced by INSPIRED MEDICAL
230000934	Adult Breathing Circuit, headband, elbow, breathing circuit etc. Produced by VADI medical
230000935	Pediatric Breathing Circuit, headband, elbow, breathing circuit etc. Produced by VADI medical
230001094	Adult Mask. Produced by Acare Technology Co.,ltd.
51005800	Adult breathing circuit (Disposable). Produced by INSPIRED MEDICAL
51008400	Pediatric breathing circuit (Disposable). Produced by INSPIRED MEDICAL

Oxygen Sensor: To be replaced every 2 years or as necessary. Part number: 210001975

CO_2 Module

240000415	IRMA CO_2 module
240000416	IRMA Adult airway adapter
240000417	IRMA Pediatric airway Adapter

Statement

a) Ventilator breathing systems, their parts and accessories are validated for use with specific ventilators,

b) Incompatible parts can result in degraded performance, and

c) The responsible organization is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use.

11.14 Ventilating Parameters: Default Values and Allowed Settings (Standard Configuration)

Parameter	Factory Set Default		Setting Range	
	Child	Adult	Child	Adult
ATC Tube Compensation	OFF	OFF	ON/OFF	ON/OFF
ATC Tube Type	ET	ET	ET/Tracheotomy	ET/Tracheotomy
ATC Tube Compensation (%)	80	80	0 – 100	0 – 100
ATC Tube Diameter (mm)	5.0	7.5	2.5 – 8.0	5.0 – 12.0
Backup Ventilation Pressure above PEEP (cmH_2O)	10	20	5 – (70-PEEP)	5 – (70-PEEP)
Backup Ventilation Tinsp (s)	0.6	1.0	0.2 – 5	0.2 - 9
Compliance Compensation	ON	ON	ON/OFF	ON/OFF
CPAP (cmH_2O) in NIV	5	5	2 – 20	2 – 20

Parameter	Factory Set Default		Setting Range	
	Child	Adult	Child	Adult
Expiratory Trigger Sensitivity - Esens(%)	25	25	5 – 80	5 – 80
Flow Trigger – Vsens (l/min)	2.0	2.0	0.5 – 20	0.5 – 20
Frequency - VCV bpm	30	15	1 – 80	1 – 80
Patient Height (cm)	100	150	30 – 140	60 – 260
I:E ratio	1:2	1:2	1:10 – 4:1	1:10 – 4:1
Maximum inspiratory flow (liters/min)	60	180	---	---
Maximum permitted pressure – safety valve (cmH_2O)	110	110	---	---
Mode (in NIV)	NIV/CPAP	NIV/CPAP	---	---
Mode(in Invasive Ventilation)	PCV	PCV	---	---
Nebulizer	OFF	OFF	ON/OFF	ON/OFF
Nebulizer Time (minutes)	30	30	---	---
NIV Rate (bpm)	30	15	4 – 20	4 – 40
O_2 Concentration (%)	40	40	21 – 100	21 – 100
PEEP (cmH_2O)	5	5	0 – 35	0 – 35
PEEP in NIV (cmH_2O)	5	5	2 – 20	2 – 20
Phigh(cmH_2O)	15	15	5 – 60	5 – 60
Plow (cmH_2O)	5	5	0 – 35	0 – 35
Press trig sensitivity level (cmH_2O)	-3	-3	-20 – 0	-20 – 0
Pressure level above PEEP (cmH_2O)	10	20	5 – (70-PEEP)	5 – (70-PEEP)
PS above PEEP (cmH_2O)	0	0	0 – (70-PEEP)	0 – (70-PEEP)
PS– BIVENT above PEEP (cmH_2O)	0	0	0 – (70-PEEP)	0 – (70-PEEP)

Parameter	Factory Set Default		Setting Range	
	Child	Adult	Child	Adult
PS– NIV above PEEP (cmH_2O)	0	0	0 – (50-PEEP)	0 – (50-PEEP)
SIMV rate (bpm)	20	4	1 – 40	1 – 40
Thigh(s)	0.6	1.0	0.2 – 30	0.2 – 30
Tinsp(s)	0.6	1.0	0.2 – 5	0.2 – 9
Tidal Volume (mL)	80	400	20 – 300	50 – 2000
Tlow (s)	1.4	3.0	0.2 – 30	0.2 – 30
Tpause (s)	0	0	0 – 4	0 – 4
Tslope(s)	0.1	0.1	0 – 2	0 – 2

Alarm Settings: Default Settings and Allowed Ranges

Alarm Limits	Factory Set Default		Setting Range	
	Child	Adult	Child	Adult
Airway Pressure, high limit (cmH_2O)	40	40	5 – 100	5 –100
Airway Pressure, low limit (cmH_2O)	5	5	OFF, 1 – 60	OFF, 1 – 60
PEEP Low limit in Invasive Ventilation(cmH_2O)	OFF	OFF	OFF, 1 – 35	OFF, 1 – 35
PEEP Low limit in NIV (cmH_2O)	OFF	OFF	OFF, 1 – 20	OFF, 1 – 20
PEEP high limit in Invasive Ventilation (cmH_2O)	10	10	1 – 35, OFF	1 – 35, OFF
PEEP high limit in NIV (cmH_2O)	OFF	OFF	1 – 20, OFF	1– 20, OFF
$etCO_2$ low limit %	4.0	4.0	OFF, 0.1 – 13.2	OFF, 0.1 – 13.2
$etCO_2$ low limit mmHg	30	30	OFF, 1 – 99	OFF, 1 – 99
$etCO_2$ low limit kPa	4.0	4.0	OFF, 0.1 – 13.2	OFF, 0.1 – 13.2
$etCO_2$ high limit %	6.5	6.5	0.1 – 13.3	0.1 – 13.3
$etCO_2$ high limit mmHg	49	49	1 – 100	1 – 100
$etCO_2$ high limit kPa	6.5	6.5	0.1 – 13.3	0.1 – 13.3
Expired Minute Volume, low limit (lpm)	0.5	1.0	OFF, 0.1 – 40	OFF, 0.1 – 40

Alarm Limits	Factory Set Default		Setting Range	
	Child	Adult	Child	Adult
Expired Minute Volume, high limit (lpm)	30	30	1 – 60, OFF	1 – 60, OFF
Expired Tidal Volume, low limit (mL)	50	250	5 - 400	5 - 4000
Respiratory Frequency, Spontaneous, Upper limit (bpm)	OFF	OFF	10 – 80, OFF	10 – 80, OFF
Time, Apnea – until alarm (sec)	20	20	10 – 60, OFF	10 – 60, OFF

NOTE: Regarding occlusion detection and continuing pressure events:

Occlusion detection occurs in every ventilation mode. In the case that the Patient Airway Pressure is positive for more than 15 seconds at an unexpected level, the system will treat this continuing pressure event as an occlusion and behave accordingly.

NOTE: Regarding Nebulizer usage while on battery power:

The nebulizer function is disabled when the Ventilator is powered by either the internal or external battery.

Ventilating Parameters: Default Values and Allowed Settings (Standard Configuration).

11.15 Delivery Accuracy

Airway Pressure

+/- 10% of settings or +/- 3 cmH_2O (whichever is greater)

Tidal Volume

Adult Accuracy: +/- 10% of settings +/- 25 mL (whichever is greater)

Child Accuracy: +/- 10% of settings +/- 10 mL (whichever is greater)

O_2 Concentration

+/- 5% full scale for all modes

21% to 90% rising time (at worst case): 3 min 22 s

PEEP

+/- 10% of settings or +/- 2 cmH_2O (whichever is greater) for all modes

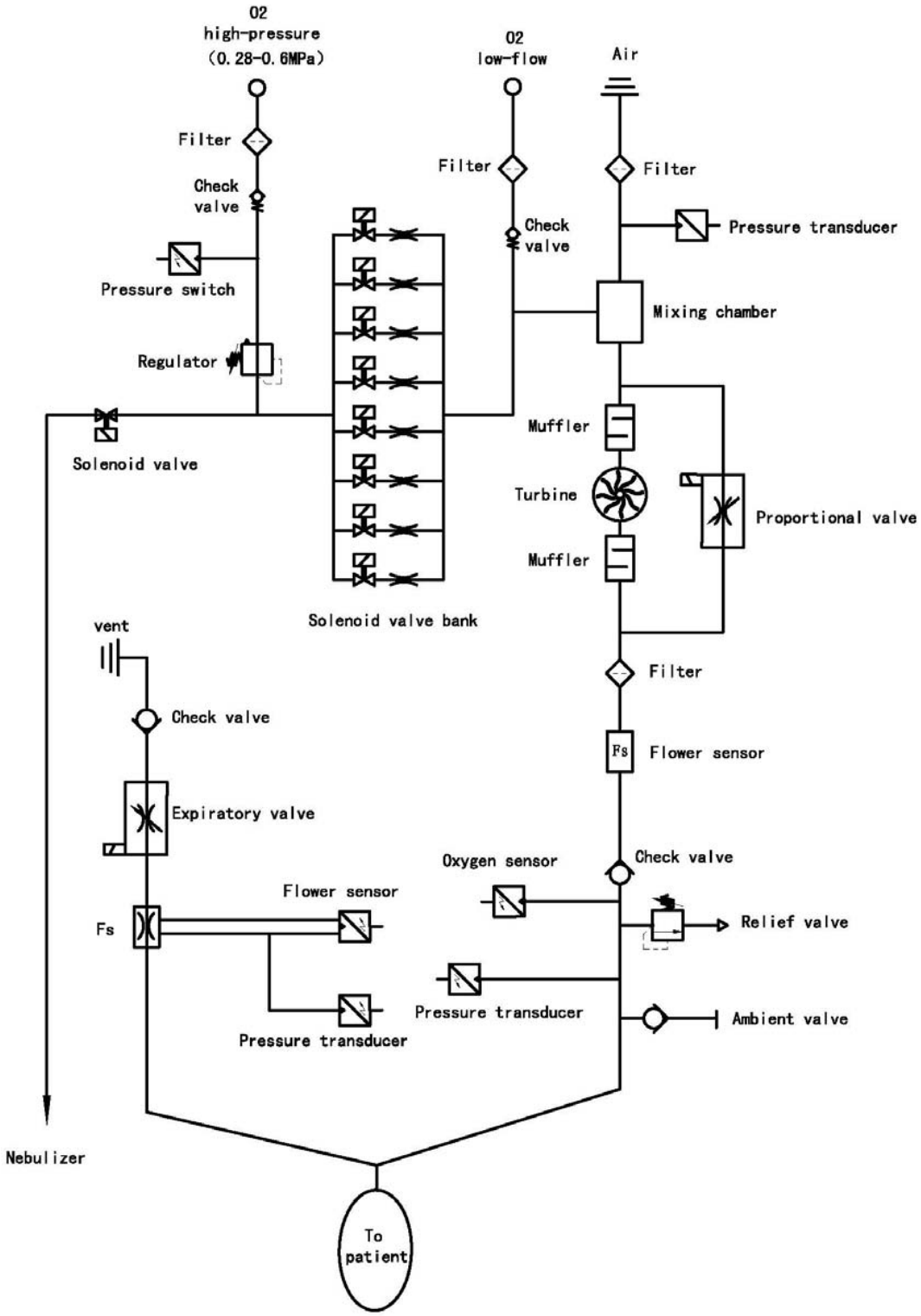
Measurement uncertainty

Volume: +/- 2% of reading or +/- 20 mL (whichever is greater)

Pressure: +/- 0.75% of reading or +/- 0.1 cmH_2O (whichever is greater)

O_2: +/- 1%

12 Pneumatic Diagram



13 EMC Guidelines

Important information regarding Electromagnetic Compatibility (EMC):

AEROS 4600 VENTILATOR needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; AEROS 4600 conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautionsneed to be observed.

- AEROS 4600 VENTILATOR with Following ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment.
- WARNING: Use of AEROS 4600 VENTILATOR adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
AC cable	5.0m	Unshielded	1 Set	AC Power

- WARNING: The Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the AEROS 4600 VENTILATOR could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment andresult in improper operation.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AEROS 4600 VENTILATOR, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

EMI&EMS Compliance Table

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 - Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 - Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 05 cycle-11s between 0.15MHz and 80MHzdstcommu
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0t
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table 5 - Signal input/output parts Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients/burst	IEC 61000-4-4	±1 kV 100kHz repetition frequency
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz

ESSENTIAL PERFORMANCE:

Requirement	Essential Performance
Oxygen level ALARM CONDITIONS	**O_2 Concentration Monitoring Range**: 18 ~100% **O_2 Concentration Setting Range:**21~100% **High Oxygen Concentration Alarm**: Oxygen concentration exceeds the preset oxygen concentration +6% continuously for 30sec. **Low Oxygen Concentration Alarm**: Oxygen concentration is lower than the preset oxygen concentration -6% or lower than 18% continuously for 30sec **Oxygen Sensor Failure Alarm**: Checked during pre-inspection before use. With only 21% Air applied, O_2 reading after 20 seconds is <=11% and >=36%
AIRWAY PRESSURE	**PEEP Setting Range:**0-35 cmH_2O, 2 – 20 in NIV **Low PEEP Alarm:** PEEP measurement is lower than the alarm limit for three consecutive breath cycles. **High PEEP Alarm:** PEEP measurement is high than the alarm limit for three consecutive breath cycles
	Occlusion Alarm: Breathing circuit is occluded
Expired Volume	**Expired volume range:20-2000ml** **Expired volume monitoring range:** 0～4000 mL **High Expiratory Minute Volume** : Minute Volume exceeds the set limit, after 1min of ventilation, for three consecutive breath cycles or at most 10sec. The upper limit is larger than the lower limit by 1L at least **Low Expiratory Minute Volume:** Minute Volume is lower than the set limit within 1min after ventilation for three consecutive breath cycles or at most 10sec
Electrical supply failure	**AC Failure:** During ventilator operation, when an AC power failure occurs and there is no battery power, the power board shall alarm for 120 seconds minimum. When powered from batteries, an “AC Failure” alarm would occur.
INTERNAL ELECTRICAL POWER SOURCE near depletion	**Low Battery:** Under the battery operation, the remaining battery run time is less than 30min **Limited Battery Capacity:** Under the battery operation, the remaining battery run time is less than 10min
Gas supply failure	There is a safety suction port for emergency suction in case of gas supply failure. **Low Airway Pressure Alarm**: Airway pressure is lower than the set limit for three consecutive breath cycles.
Gas failure cross flow	There are check valve or switch valve to limit reverse gas leakage flow into the supply system. **Low Oxygen Supply Pressure Alarm**: Oxygen supply is lower than 160kPa continuously for 5 sec.

DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

Schiessstraße 55, 40549 Düsseldorf, Germany
Tel: +4921138838868, Fax: +4921138838697