Boaray 5000D/C Ventilator
User Manual

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Product Information

Product Name: Ventilator

Product Model: Boaray 5000C, Boaray 5000D

Legal Manufacturer: Shenzhen Prunus Medical Co., Ltd.

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Version Information

The version number of this user manual may be updated due to the software upgrades, Shenzhen Prunus Medical Co., Ltd. reserves the right to change it without giving prior notice.

Version information:

- **Version No.**: 18.0
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CE Mark

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The product is marked with CE, as it conforms to European Council Directive for Medical Devices (93/42/EEC), and meets basic requirements of appendix Ⅰ in the directive.

This product is the Type Ⅰ, Class B radio jamming protective equipment that complies with the EN55011. It meets the requirements of EN60601-1-2 standard “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”.

Declaration

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Users can, if need, ask for other technical information separately from the Company in order to understand, operate and maintenance the equipment, but should ensure the information not obtained by the third party.

User responsibility

Please check the product and accessories firstly when you receive the product, make sure it conforms to the contract. If any damage to the package or the product is found before or after opening the packing case, please contact the local office or the franchiser immediately.

Users must perform the installation, operation, maintenance and carry out regular inspection according to the instruction described in the manual. Replace the components immediately if any damage, loss, distortion or contamination is found. Stop use when malfunction occurs. Please contact the after service department of the Company for repairing and replacing. Any change of the product is verboten without agreement from the Company. The user must take responsibility for any malfunction which results from non-compliance with the servicing requirements detailed in this manual or the service or repairs are not performed by the personnel of the Company.

Free Maintenance

The user reserves the right to be served for free repairs and replacement within 12 months from the order delivered date only in the event that the product is purchased from the Company or the authorized distributor, it must be new product when purchased and it is operated according to the “User Responsibility”. Otherwise, the Company has no responsibility for any damages to the product.

Trademarks

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Preface

Description

This manual describes the intended use, function, installation, operation and maintenance of the product. Personnel must make themselves familiar with the contents of this manual and the machine's function before using the product. When you begin to use the ventilator, we consider that you have read the manual carefully.

In order to use the equipment accurately, effectively and avoid the accident, please read the manual carefully and comply with it strictly, especially pay attention to the "Warning", "Caution" and "Note".

The optional features may not be completely included in the manual, should you have any questions, please contact the Company.

Please put the manual near the product so that you can easily fetch it at any time.

Illustration

The illustrations in the manual are only for reference, some settings and data may not be consistent with the real display of the product; please refer to the real product.

Conventions

- ***Bold Italic***: The quoted section.
- **【Character】**: The character string on the software interface or in the control panel.

Contents

1 Safety Information

The safety information described in this chapter explains unsafe conditions that may occur if not performed correctly according to the manual. Please review all the warning, caution and Note prior to operating the ventilator.

This chapter contains important safety information of the ventilator, and some other safety information throughout each chapter of the manual. Please read and understand all the safety information before use to avoid security risks.

The ponderance of the safety requirement has nothing to do with the arrange order.

⚠Warning:

- Identify conditions or practices that could result in serious adverse reactions or potential safety hazards.

⚠Caution:

- Identify conditions or practices that could result in damage to the ventilator or other equipment.

Note:

- Identify supplemental information to help you better understand how the ventilator works.

1.1 Warnings

⚠Warnings:

- Only personnel trained and authorized by the manufacturer are permitted to operate the equipment. Operations of the equipment must be strictly according to the user manual.
- Please read this manual carefully before operating the Boaray 5000C/D Ventilator.
- Users must take the related responsibility for any malfunction which results from the package or product disassembled by the user.
- Only those conform to the latest IEC 60601-1 standard accessories and auxiliary equipment can be connected to the ventilator. If peripheral equipment such as computer, monitor or humidifier has been connected to the ventilator, the whole system should meet the IEC 60601-1 standard.
- All analog or digital products connected to this system must be certified passing the specified IEC standards (such as IEC 60601-1 for medical electrical equipment and IEC 60950 for safety of information technology equipment). All configurations shall comply with the valid version of IEC 60601-1. The personnel who are responsible for connecting the optional equipment to the I/O signal port shall be responsible for medical system configuration and system compliance with IEC 60601-1-1.
- Users have the responsibility to carry out the necessary measure to ensure that the curing environment is in line with the limited regulation of the IEC 60601-1-2 standard. Operating the equipment beyond the regular limit may cause damages or security risks to the system. The preventive measures may include (but not limited to) the following aspects:
    - More attention should be paid to the relative humidity and conductivity of clothes to minimize the possibility of the static gathering.
    - Avoid using the wireless radiate devices (such as the mobile phone) or high frequency devices near the ventilator.
- Due to the possible fire or explosion hazard, all the ignition sources must be away

⚠Warnings:

from the ventilator and the oxygen tube. Do not use the oxygen tube which is worn or effused or contaminated by the flammable liquid (such as grease or oil). In the environment of high oxygen concentration, textiles, oils and other combustible material are easy to cause fire. When you detect a burning odor, cut off the oxygen supply device, the power supply and the spare resource immediately.

- The ventilator is not designed for the MR environment that is suitable for the Medication reaction (MR) checking. Otherwise the system may lose some functions and it may cause permanent damage to the ventilator system.
- This equipment can only be used in the specified environment, and it cannot be used near the flammable or explosive resources and cannot be used in the mobile phone, radioactive rays or the MRI equipment environment.
- If the external interface at the rear of the ventilator is connected to the other equipment, leakage currents may increase.
- Always perform a regular clean and pre-use check before opening the package.
- The equipment must only be connected to a supply mains with protective earth to avoid electric shock.
- During the usage of equipment, please do not pull display screen wire, otherwise, it may result in alarm sound failure.
- When adding attachments or other components or sub-assemblies to the breathing system, the pressure gradient across the breathing system, measured with respect to the patient connection port, may increase.
- Operator will have to ensure that the inspiratory and expiratory resistances measured at the patient connection port during spontaneous breathing and normal operation shall not exceed 0.6 kPa at 60 l/min for adult use, 30 l/min for pediatric use.
- Please double-check the power cord before connected to the electrical outlet, make sure it has no damage, scratch or other factors which will lead to the inside conductor exposed issues.
- When there is any doubt about the integrality of the outside grounded protection or the

⚠Warnings:

grounded protection cord, the equipment must be replaced with: internal power supply (battery).

- Before the battery runs out, please use the AC power supply.
- Keep the ventilator upright during use.
- The ventilator shall not be covered or positioned in such a way that the operation or performance of the ventilator is adversely affected.
- Once any abnormal event occurs, such as the unfamiliar pop-up windows on the screen, unfamiliar sounds, alarms from the patient device, or high priority technology warning occurs, discontinue use of the ventilator and check it at once, replace the corresponding components as occasion requires.
- Set the warning limit to a proper parameter in order to ensure the safety of patient.
- Positive pressure breathing may be accompanied by the following side effects occur: barotrauma, hypoventilation, hyperventilation or circulatory injury.
- The maintenance is allowed only in the condition that the equipment is not connected to the patient.
- All personnel should be aware that Disassembling or clearing certain parts of the ventilator may cause infection risk.
- The equipment will produce some castoff, the one-off parts or the damageable parts which will lead to serious pollute or cross infection if discarded randomly, and should be managed and disposed according to the relative regulations.
- When the equipment or the accessories are about to exceed the limit time, they should be disposed according to the local regulations or the hospital systems.

1.2 Cautions

⚠ Cautions:

- The ventilator must be serviced and checked at regular intervals by professionals who have received specialized training. Please refer to the *chapter 7* for the maintenance time interval information. All service performed on the ventilator should be recorded in a service log in accordance with the regulations.
- The Company has no responsibility for the safe operation of the ventilator system if maintenance or repairs are not performed by personnel who are employed or authorized by the Company. It is recommended that you should maintain and repair the equipment in accord with the compact signed by both parties.
- The Company has no responsibility for the safe operation of the ventilator if it is used in other field described in the user manual.
- The data measured from the signal output port of the ventilator as well as the data managed by the auxiliary equipment cannot be regarded as the basic of treatment or diagnosis decisions. Such decisions can only be made by the experienced medical personnel based on the previous or accepted manner. The Company has no responsibility for the accuracy of the signal handling if auxiliary equipment not provided by the Company are used with the ventilator system.
- If there are differences between the information displayed on the user interface of the ventilator and the corresponding information displayed on the auxiliary equipment, the information on the user interface is considered as the main reason. It is the user's responsibility for the integrity and security of the system while using the accessories or auxiliary equipment not provided by the Company. As for the safety of the electrical system, only those accorded with the latest IEC 60601-1 standard accessories and auxiliary equipment could be connected to the signal input and output interface of the ventilator system.
- Only those accessories, spare parts or auxiliary equipment recommended by the Company can be used to be connected to the ventilator system. Otherwise it may

⚠ Cautions:

cause damage or security to the system.

- Please refer to the assembling instruction described in the user manual to assemble the system or the optional accessories.
- The gases used in the system must conform to the following standards for concentrations of water vapor and oil:

  Air: $H_2O < 7g/m^3$, Oil $< 0.5mg/m^3$

  Oxygen: $H_2O < 20mg/m^3$
- Pressure value is given in cmH_2O:

  $1kPa = 10cmH_2O$

  $100kPa = 1bar \approx 1atm \approx 1kgf/cm^2 \approx 14.5psi$
- As general rule, always be careful not to touch the pins of the external electric connector.
- The measuring value condition shown in this user manual is Ambient temperature and pressure, dry gas (ATPD) condition.
- Sharp tools should be away from the screen.
- Accumulation of excess liquid in the expiration sensor is not allowed (such as in clean and disinfection period, otherwise it may affect the function of the ventilator.
- When lifting or moving the ventilator system or some parts of the system, please comply with the instruction of the machine and do some preparation of the safety.
- Please do not use the soft tube with the characteristic of antistatic electricity or the electricity conducting.
- The ventilator contains no latex element.
- Make sure a resuscitator is always available.
- Make sure there is at least one battery as backup power supply.
- Once the system is connected to the patient, make sure there should always be someone professional to monitor the system operation.
- Do not disassemble the expiratory module during operating the ventilator.
- When the ventilator is powered off, please make sure the humidifier is also powered

⚠ Cautions:

off, in case that the water in the humidifier enters ventilator to cause damage.

- Always use a Heat and Moisture Exchanger (HME) or other equivalent equipment to prevent the dehydration of the lung system.
- The equipment may contain some hazardous waste (infectious) which should not be discarded in a normal way, please deal with them according to the local regulations.
- When disposing of the old oxygen sensor, observe the relevant regulations for biohazard and do not burn it.
- All the disposable components should be disposed according to the hospital regulations and in an environmental safe way.

Note:

- When the system is not used, it is recommended the device is connected to the main power supply in order to keep the battery power.
- If the system is connected to the main power supply, even if the system switch is in the closed state, the main power supply of the system is not interrupted.

2 Equipment Description

2.1 Introduction

The Boaray 5000 is a pneumatically driven and electronically controlled ventilator. Users can use the touchscreen, keys and the navigation wheel to operate the equipment conveniently and easily. According to the user's setting, the ventilator provides the air with the preset oxygen concentration to patients with continuous flow or continuous pressure to control the patients or support ventilation. Doctors can control the patients timely by real-time monitoring the several respiratory parameters of the ventilator to ensure patients safety and good treatment.

Boaray 5000 ventilator system is intended for used to treat and monitor children (weight above 5 kg) and adult patients with respiratory disturbance or insufficient breathing. The ventilator should be used only in hospitals or in facilities whose purpose is to provide health care or during transport of a patient within or between hospitals or health care facilities.

This ventilator consists of the mainframe, TFT displayer, trolley, Mechanical arm, and power supply.

The Boaray 5000 series ventilator has two models: Boaray 5000C and Boaray 5000D, the differences of configuration are shown as below:

Ventilation Mode	Boaray 5000C	Boaray 5000D
VCV	Yes	Yes
PCV	Yes	Yes
PRVC	Yes	Yes
SIMV (VCV) + PS	Yes	Yes
SIMV (PCV) + PS	Yes	Yes
SIMV (PRVC) + PS	Optional	Optional
DualPAP	Yes	Yes

Ventilation Mode	Boaray 5000C	Boaray 5000D
PSV	Yes	Yes
APRV	Optional	Optional
CPAP	Yes	Yes
NPPV	Yes	Yes
HFNC	Yes	Yes

Contraindications

1) Gas gathering of the pneumothorax and mediastinum diaphragm.
2) A large pleural effusion.
3) Bulla.
4) Acute myocardial infarction associated with heart dysfunction.

Caution:

- The ventilator can only be operated by professional medical personnel with experiences in respiratory disease treatment. Personnel not be trained or authorized cannot operate the ventilator.

2.2 System Overview

Caution:

- The illustration in this section is only for reference, due to different configuration, the illustration may not be entirely consistent to the product.

2.2.1 External connection view

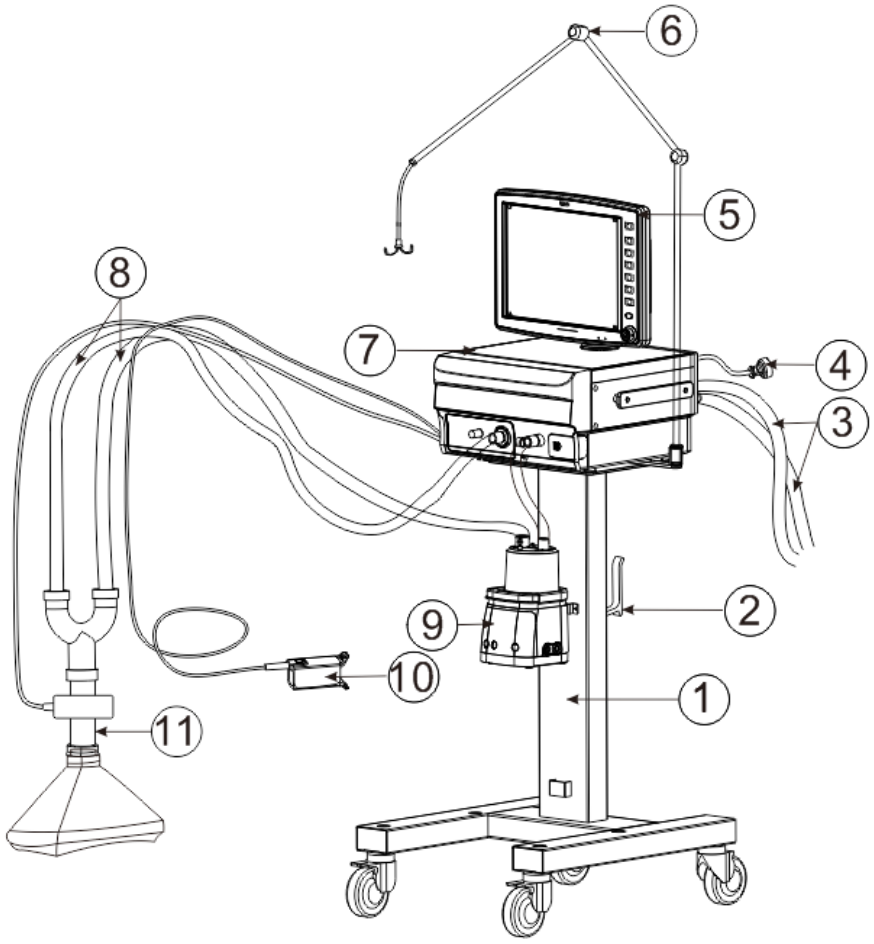


Figure 2-1 External connection view

1. Trolley	7. Main unit
2. Hooks	8. Patient system
3. Gas supply pipeline (Oxygen and AIR)	9. Humidifier
4. Mains power plug	10. SpO_2 finger clip
5. User screen	11. Sampling port of CO_2
6. Mechanical arm	

2.2.2 User screen front view

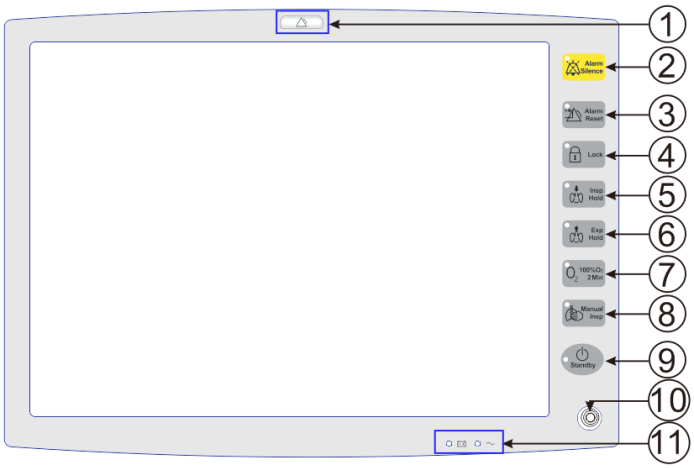


Figure 2-2 User screen front view

1. Alarm indicator	7. 100% O_2 2mins button
2. Alarm silence button	8. Manual inspiration button
3. Alarm reset button	9. Standby button
4. Lock/unlock button	10. Navigation wheel
5. Inspiration hold button	11. Power/battery status indicator
6. Expiration hold button	

2.2.3 User screen rear view

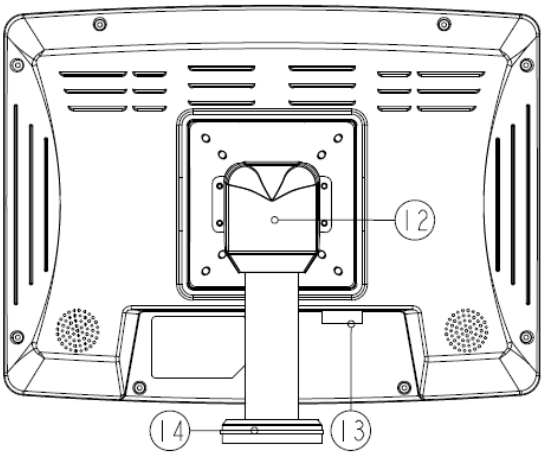


Figure 2-3 User screen rear view

12. Rotation axis	14. Display separating axis
13. Displayer interface	

2.2.4 Ventilator front view

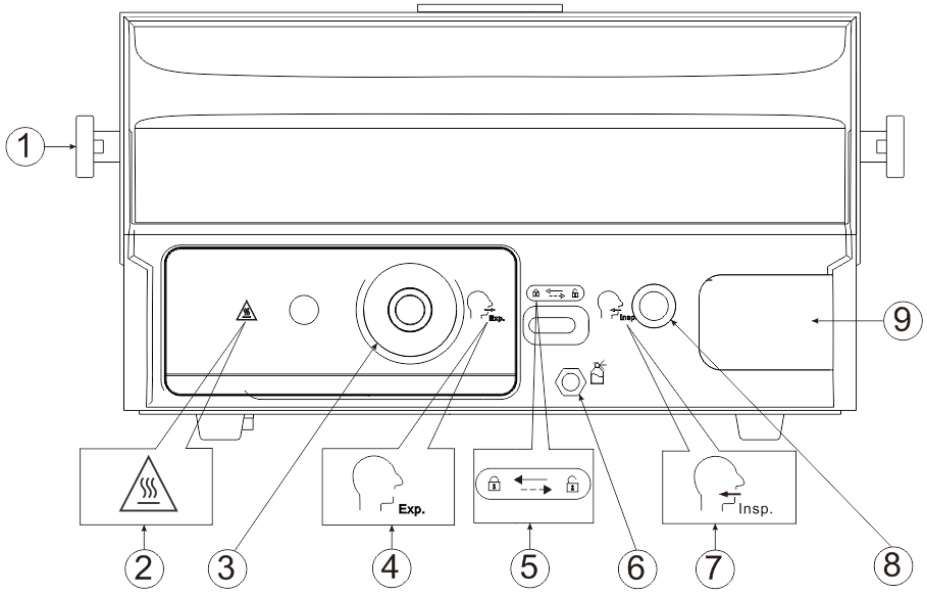


Figure 2-4 Ventilator front view

1. Holding arms	6. Nebulizer interface
2. Expiratory valve heating silk-screen	7. Inspiratory silk-screen
3. Expiratory port	8. Inspiratory port
4. Expiratory silk-screen	9. Oxygen sensor installation position
5. Expiratory valve unlock silk-screen	

2.2.5 Ventilator rear view

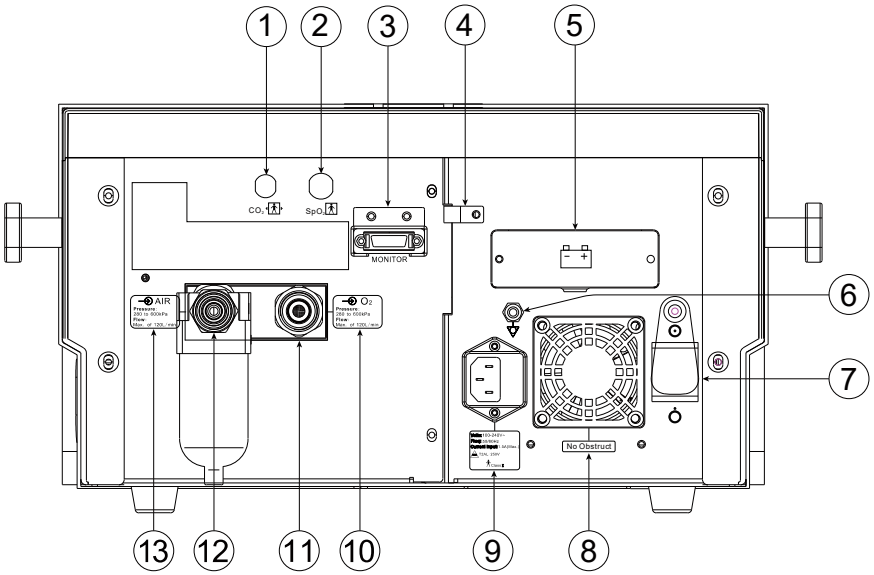


Figure 2-5 Ventilator rear view

1. CO_2 module interface	2. SpO_2 module interface
3. LVDS interface	4. Power cord clamp
5. Battery installation position	6. Ground pole
7. System switch	8. No obstruct silk-screen
9. Power input silk-screen	10. O_2 inlet silk-screen（0.28~0.6MPa）
11. O_2 inlet	12. Air inlet
13. Air inlet silk-screen（0.28~0.6MPa）	

2.2.6 Ventilator bottom view

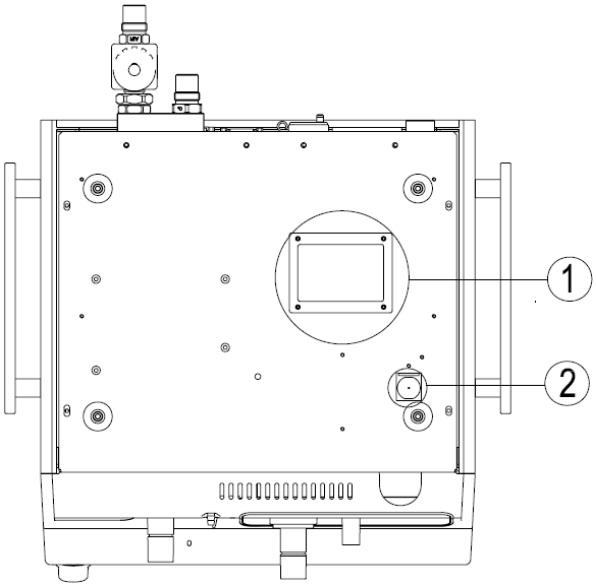


Figure 2-6 Ventilator bottom view

1. Emergency AIR suction port	2. Exhaust port

⚠Caution:

- Do not block the emergency AIR suction port and exhaust port located on the bottom of the equipment shown as above figure.

2.3 Power supply

1. Power supply specification: Input voltage:100~240V, Frequency: 50/60Hz; Current Input: 1.5A (Max.).
2. Fuse gear specification: T2AL/250V.

3. When connected to AC power supply, the AC indicator light turns on, when disconnected to AC power, the AC indicator light turns off.

2.4 Battery

Batteries can be used as backup power supply in ICU or during transporting patients. The ventilator is equipped with one battery module. It is recommended that there is always a battery module as backup power supply.

When the ventilator is connected to the main power supply and turned on, the inserted battery models will be charged. When AC power supply is cut off, the ventilator will switch to the battery power supply automatically, simultaneously, it will emit an AC power supply failure warning to prompt users, and will not lead to interruption of the ventilator work.

When operating from batteries, the status of the battery modules is continuously monitored by the ventilator. If the battery capacity is insufficient, the ventilator will give alarms “Low battery capacity” or “No battery capacity” to notify users.

- When “low battery capacity” alarm appears, the remaining time is about 10 minutes
- When “No battery capacity” alarm appears, the remaining time is about 5 minutes.

The battery module can supply power for about 120 minutes. New battery model should be charged for more than 10 hours for the first time, and about 5 hours in the future.

Battery specification: Please refer to the *Appendix B.1*.

Notes:

- Always remember to charge the batteries. When connected to the power supply, the ventilator will charge the battery modules automatically.
- Only batteries recommended by the Company can be used in the ventilator.

◆ If the battery is stored for a long period and it has been discharged, it needs a extended period to be charged.

2.5 Gas supply

There are two kinds of gas supply: Air and oxygen. It can be connected to the central supply system, and the required rated pressure range is 0.28~0.6 Mpa. There is a filter and an one-way valve installed in each pipeline. The pressure is released to the rated pressure range 0.28~0.6 Mpa by the pressure regulator. When using cylinder for gas supply, the output pressure will be regulated to 0.28~0.6 Mpa by the pressure regulator.

The ventilator system will monitor the pressure of the gas supply automatically. When the pressure reduces to affect the ventilation, it will generate an alarm to notify the users.

2.6 System switch

The ventilator has a specially designed system switch protective shield, which can avoid touching or impacting the switch accidentally to turn off the ventilator.

2.7 User screen

Refer to the *Chapter 5 Operations and settings*.

2.8 Ventilation types

The ventilator offers two types of ventilation:

- **Invasive ventilation**, which ventilates the patient through an artificial airway (e.g., Trach tube or ET tube).
- **Non-invasive ventilation**, which ventilates the patient through a nasal/facial mask.

To access **Invasive ventilation** or **Non-invasive ventilation**:

1. Start the system.
2. Select a patient type in the Standby mode.
3. Press the rotary knob to confirm the selection.

4. Select **Invasive ventilation** or **Non-invasive ventilation** in the ventilation configuration box.

Both types of ventilation include a variety of ventilation modes and assist-control modes (as listed in the following table), which meet the patients' demands and bring them great convenience.

Ventilation type	**Ventilation mode**	**Remark**
Invasive ventilation	VCV	Refer to 2.9 Ventilation modes for details about these ventilation modes.
	PCV	
	PRVC	
	SIMV (VCV) + PS	
	SIMV (PCV) + PS	
	SIMV (PRVC) + PS	
	DualPAP	
	PSV	
	APRV	
	CPAP	
Non-invasive ventilation	PCV	
	SIMV (PCV) + PS	
	DualPAP	
	PSV	
	NPPV	
	HFNC	
	APRV	
	CPAP	

2.9 Ventilation modes

2.9.1 VCV mode

VCV (Volume Control Ventilation). In the VCV mode, during the breathing period, the

ventilator provides the mandatory ventilation for the patients with constant flowrate and pre-set tidal volume. At the same time, in expiration phase, it monitors the pressure status or the flowrate in the airway (Pressure trigger or Flow trigger), when the trigger condition meets, it will provide the patient with a mandatory ventilation of the same settings.
In the VCV mode, you can set the breathing hold time (T_P) to improve the gas distribution conditions in the patient's lung, and set the PEEP to improve the vent of end-tidal CO_2 and increase oxygen in the breathing process.

In the VCV mode, the following parameters need to be set:

- 【V_T】
- 【Freq】
- 【T_I】
- 【T_P】
- 【FiO_2】
- 【PEEP】
- 【P_{TRIG} / F_{TRIG} 】

2.9.2 PCV mode

PCV (Pressure Control Ventilation). In the PCV mode, during inspiratory period, the ventilator provides the mandatory ventilation according to the pre-set pressure for the patient, during the whole inspiratory period, the airway pressure is stabilized at the set value, and the flow curve is in downward trend. The same with the VCV mode, in the PCV mode, the mandatory ventilation can be achieved by patient's triggering in the expiratory period.

In the PCV mode, the following parameters need to be set:

- 【P_{insp}】
- 【Freq】
- 【T_I】

- 【FiO_2】
- 【PEEP】
- 【P_{TRIG} / F_{TRIG}】
- 【P_{rate}】

2.9.3 PRVC mode

PRVC (Pressure Regulated Volume Control), it has the characteristics of pressure control ventilation (PCV) mode and volume control ventilation (VCV) mode. In PRVC mode, inspiration is completed with the preset tidal volume and frequency (times/min) within the preset inspiratory time, each inspiration is automatically adapt to the controlled inspiratory pressure, which changes the characteristic of lung/thoracic to ensure commonly using of the minimum pressure to deliver the preset tidal volume and minute ventilation volume. The inspiratory pressure keeps constant throughout the preset inspiratory time. The inspiratory flow rate is decreasing.

In PRVC mode, the following parameters need to be set:

- 【T_I】
- 【Freq】
- 【FiO_2】
- 【V_T】
- 【PEEP】
- 【P_{TRIG} / F_{TRIG}】
- 【P_{rate}】

2.9.4 SIMV mode

SIMV (Synchronized Intermittent Mandatory Ventilation). In the SIMV mode, the independent breathing frequency and the tidal volume (or inspiratory pressure) is controlled by the patient, and a synchronous control is active at a certain interval of time. If the trigger level is met in the waiting trigger window, the ventilator will provide a synchronized volume (pressure or pressure regulated volume control) control ventilation for the patient. If the trigger level is not achieved in the trigger window, at the end of the

trigger window, the ventilator will give a volume (pressure or pressure regulated volume control) control ventilation.

The SIMV mode includes three modes: SIMV (VCV) + PS, SIMV (PCV) + PS and SIMV (PRVC) + PS. Different modes determines whether the volume or the pressure control mode will be selected.

In the SIMV mode, the following parameters need to be set:

- 【P_{supp}】
- 【Freq】
- 【T_I】
- 【V_T or P_{insp}】
- 【FiO_2】
- 【PEEP】
- 【P_{TRIG} / F_{TRIG}】
- 【T_p】
- 【ETS】
- 【P_{rate}】

2.9.5 DualPAP mode

DualPAP (Dual Positive Airway Pressure). The ventilator forms the high pressure level and low pressure level according to the pre-set value, and switches by the pre-set frequency and inspiratory time. Patients can breathe spontaneously at the high pressure and low pressure level by trigger, and the ventilator provides support ventilation according to the pre-set pressure.

In the DualPAP mode, the following parameters need to be set:

- 【T_{high}】
- 【Freq】
- 【ETS】

- 【FiO_2】
- 【P_{high}】
- 【P_{low}】
- 【PS_{high}】
- 【PS_{low}】
- 【P_{TRIG} / F_{TRIG}】
- 【P_{rate}】

2.9.6 PSV mode

PSV (Pressure Support Ventilation). In the PSV mode, when the patient is activated spontaneously, the ventilator will support the patient's inspiration with the pre-set stable pressure, the flow curve is in downward trend. The end of the patient's inspiration can be changed by adjusting the sensitivity.

The PSV mode is combined with the SIMV mode.

In the PSV mode, the following parameters need to be set:

- 【P_{supp}】
- 【PEEP】
- 【FiO_2】
- 【P_{TRIG} / F_{TRIG}】
- 【ETS】
- 【T_{apnea}】
- 【P_{rate}】
- 【T_i】
- 【Freq】
- 【P_{insp} / V_T】

2.9.7 APRV mode

APRV (Airway Pressure Release Ventilation). It can be seen as periodical, short period

airway pressure release in CPAP mode.

In the APRV mode, the following parameters need to be set:

- 【T_{high}】
- 【Freq】
- 【FiO_2】
- 【P_{high}】
- 【P_{low}】
- 【P_{TRIG} / F_{TRIG}】
- 【P_{rate}】
- 【T_{apnea}】
- 【$Freq_{apnea}$】
- 【TI_{apnea}】
- 【P_{insp} / V_T】

2.9.8 CPAP mode

CPAP (Continuous Positive Airway Pressure). During the whole ventilation period, the system maintains the airway pressure at the positive pressure level preset by users; the patient's respiration is completely spontaneous; respiratory rate, respiratory time and respiratory volume are all decided by the patient. When the system detects that the period during which the patient has no effective spontaneous respiration exceeds the preset Tapnea, the apnea alarm will be generated, and backup ventilation (PCV) will be activated.

In CPAP mode, the following parameters need to be set:

- 【PEEP】
- 【FiO_2】
- 【P_{TRIG} / F_{TRIG}】
- 【T_{apnea}】

- 【T_I】
- 【Freq】
- 【Pinsp / V_T】

2.9.9 NPPV mode

NPPV (Non-invasive Positive Pressure Ventilation). In NPPV mode, ventilator supplies assistant ventilation for patients through non-invasive manner such as masks.

In NPPV mode, the following parameters need to be set:

- 【PEEP】
- 【P_{supp}】
- 【FiO_2】
- 【P_{TRIG}】
- 【ETS】
- 【T_{apnea}】
- 【P_{rate}】
- 【T_I】
- 【Freq】
- 【P_{insp}】

2.9.10 HFNC mode

High Flow Nasal Cannula (HFNC) is an oxygen therapy mode in which the gas mixture of high flow oxygen (with adjustable oxygen concentration), air and isothermic saturated steam is supplied to the patient via nasal cannula.

In HFNC mode, the following parameters need to be set:

- 【FiO_2】
- 【FLOW】

2.10 Special functions

Except the common ventilation modes, the ventilator also offers certain assistant ventilation functions, shown as follows:

2.10.1 Inspiratory hold

Refer to the section *2.2.2 user screen view.* When the【 

】membrane button is pressed, the ventilator will switch to a 30-second inspiratory holding phase when the ventilator completes the current inspiration, or press the 【 

】membrane button again to end inspiratory hold.

2.10.2 Expiratory hold

Refer to the section *2.2.2 user screen view.* When the【 

】membrane button is pressed, the ventilator will switch to a 30-second expiratory holding phase immediately, or press the 【 

】membrane button again to end expiratory hold.

2.10.3 100% O_2 2 min

Refer to the section *2.2.2 user screen view.* When the【 

】membrane button is pressed, the ventilator will provide 100% pure oxygen for 2 minutes for the patient, and 2 minutes later, the oxygen concentration will resume to the pre-set value. Within 2 minutes, press the【 

】membrane button again to end the 100% pure oxygen period early.

2.10.4 Suction

The Suction function is available only after the 

button is pressed. During the supply of 100% O_2, the Suction function starts automatically if the ventilator detects that

the patient tubing is disconnected. In this case, the ventilator stops supply of 100% O_2 until the patient tubing is connected again, and temporarily disables the relevant alarm messages.

The following demonstrates how the Suction function works:

1. During ventilation, press the 

membrane button so that the system provides pure oxygen for the patient. During oxygen supply, the ventilator will detect whether the patient tubing is disconnected. Please disconnect the patient tubing at this time.
2. After the patient tubing is disconnected, the system stops ventilating the patient and prompts “Patient tubing is disconnected! Reconnect the patient tubing after the end of suctioning!”. At this point, the patient can be manually suctioned.
3. After the manual suction, reconnect the patient tubing. The system will continue to provide 100% oxygen to the patient when it detects that the patient tubing is connected.
4. When the 2-minute pure oxygen supply is finished or the 

button is pressed again, the ventilator terminates pure oxygen supply.

2.10.5 Manual Inspiration

Refer to the section *2.2.2 user screen view.* When the 【 

】membrane button is pressed, the ventilator will provide a ventilation according to the current set parameter.

2.10.6 Freeze

Refer to the section *5.6 main screen.* Press 【  】button, after the ventilator” s waveform refreshes time abscissa, the system enters the freeze mode, and freezes the current screen, and suspends real-time update of data, and displays 30 seconds countdown.

When the screen is frozen, the user can view the values of tidal volume, pressure and flow by using touch or Navigation wheel.

2.10.7 P-V Tool

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

Operations guide for the P-V tool:

1. Set the setting parameter(s) first.

Parameter	**Range**	**Increment**	**Default value**
VT	100~3000 mL	50 mL	500 mL
Flow	1~10 L/min	0.5 L/min	2 L/min
PEEP	0~50 cmH_2O	1 cmH_2O	0 cmH_2O

2. Click Start to get the P-V loop diagram.
3. Modify the setting parameter(s), and then click Start to refresh the P-V loop diagram.
4. Turn the rotary knob to select different values. The 3 parameters on the right pane will change accordingly. Four groups of different data can be saved on the left pane.

2.10.8 Flow support

In Volume Controlled Ventilation mode, Flow support can be set in the Mode setting screen.

If the ventilator measures patient spontaneous breathing during inspiration (The Pressure decreases by the 2cmH_2O), the ventilator will recognize the patient demand and automatically “switch over” to deliver a Pressure Support Ventilation. This allows flow to exceed the set Peak flow, thereby meeting the patient’s demand.

Flow support is available in **VCV** and **SIMV (VCV) + PS** modes.

Default setting: Close.

2.11 Alarm system

2.11.1 General description

The ventilator is designed with a perfect alarm system to help insure patient safety. The ventilator has 3 types of alarms according to different potential risks during the alarm generated: High Priority, Medium Priority and Low Priority.

When alarm occurs, it will remind the user by the alarm indicator light, alarm tone and alarm messages, different categories of alarms have different alarm information.

The alarm signals and conditions are grouped into physiological alarm conditions and technical alarm conditions.

1) Physiological alarms: the monitored gas parameters or the patient physiological parameters exceed the specified range.
2) Technical alarms: Due to the improper operations or the malfunctions of the technical or the equipment, the machine cannot monitor exactly.

According to the different risks when alarm active, the alarms are grouped into: High Priority, Medium Priority and Low Priority alarm.

1) High priority: when the high priority alarm generates, it may endanger the patient's safety or the equipment cannot work normally, users must stop operating to deal with the malfunction.
2) Medium Priority: when the medium priority alarm generates, it may endanger the patient's safety if lasting a long time. There may be some unreasonable settings, users should adjust the parameters to clear the malfunction.
3) Low priority: when the low priority alarm generates, it will not endanger the patient's safety, there may be some unreasonable settings or some unimportant malfunctions, users could adjust the setting parameters properly or clear up the malfunctions when complete using the equipment.

When alarm generates, the ventilator will remind users by the following auditory and visual signals.

1) High priority:
   - Alarm indicator light: red flashes
   - Alarm tone: du- du - du -- du - du ---- du - du - du - du – du
   - Alarm message: red background, and displays “!!!” behind the alarm message.
2) Medium priority:
   - Alarm indicator light: yellow flashes
   - Alarm tone: du - du - du ----- du - du – du
   - Alarm message: yellow background, and displays “!!” behind the alarm message.
3) Low priority:
   - Alarm indicator light: yellow, static, not flashes
   - Alarm tone: du-----du
   - Alarm message: yellow background, and displays “!” behind the alarm message.

2.11.2 Alarm information and priority

Alarm types	Messages	Alarm priority
Physiological alarm	Tidal Volume Low!!	Med
	Tidal Volume High!!	Med
	Minute Volume High!!	Med
	Minute Volume Low!!	Med
	Frequency High!	Low
	Frequency Low!	Low
	FiO_2 Concentration High!!	Med
	FiO_2 Concentration low!!!	High
	Airway Pressure High!!!	High
	Airway Pressure Low!!!	High
	High Continues Pressure!!!	High
	Apnea!!!	High
	PRVC Airway Pressure limit!!!	High

Alarm types	Messages	Alarm priority
	Expiratory CO_2 High!!	Med
	Expiratory CO_2 Low!!	Med
	SPO_2 low!!	Med
	System leakage!!! Please check the breathing tubes and expiratory valve.	High
Technical alarm	O_2 supply pressure low!!!	High
	Air supply pressure low!!!	High
	AC Power Failure!!!	High
	Battery failure!!	Med
	Low battery capacity!!	Med
	Battery is exhausted!!!	High
	O_2 sensor is not connected or failure!!!	High
	The pipe is failed!!!	High
	Pressure Sensor is failure!!!	High
	5V Power Failure!!!	High
	10V Power Failure!!!	High
	-12V Power Failure!!!	High
	12V Power Failure!!!	High
	Inspiratory air Flow Sensor is failure!!!	High
	Inspiratory O_2 Flow Sensor is failure!!!	High

Table 2-1. Alarm information and priority

⚠Caution:

- When different priority of alarms occur simultaneously, only the alarm with highest priority will display.
- When the same priority alarms occur simultaneously, the current alarms are displayed alternately on the alarm information area.
- If high priority alarms and medium priority alarms occur simultaneously, the alarm indicator light flashes in red.
- If multiple alarms occur, the alarm messages are displayed in order of priority and time of occurrence.

2.11.3 Alarm limit setting

Refer to *5.9 alarm setting.* Press the 【Alarm setting】 to enter the alarm setting screen and set the alarm limit value.

Warning:

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

Caution:

- Please always pay attention to the alarm limit parameter and make sure it is set at a proper and reasonable level to avoid inaccurate alarms.
- When mains power is interrupted, the alarm limit setting does not change and the system saves the latest setting before interruption.

2.11.4 Alarm silence

When alarm generates, press the 【 

】membrane button, the alarm tone will be suspended, meanwhile, the alarm silence icon 

and 100 seconds countdown time will display in the status information area.

The alarm silence status lasts for 100 seconds, 100 seconds later, the alarm silence will be cancelled.

Press the 【 

】membrane button again before the 100 seconds period will cancel the “silence”.

Cautions:

- In alarm silence status, except for the alarm tone, the other alarm functions are working normally.

- In alarm silence status, if new alarms occur, the alarm silence will be cancelled and alarm tone will be activated according to the latest alarm.
- Pressing the 【 

】membrane button is invalid if no alarm occurs.

2.11.5 Alarm reset

When alarm generates, press the 【 

】 membrane button, all the alarms will be cleared , the system restarts monitoring.

Pressing the 【 

】membrane button is invalid if no alarm occurs.

3 Assembling and disassembling

3.1 Trolley

1. Assembling：

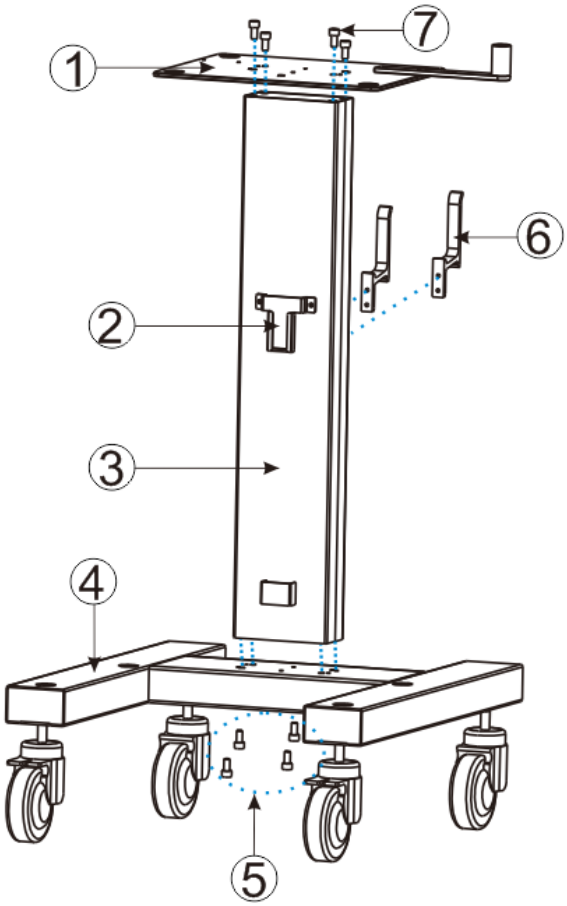


Figure 3-1 Trolley installation view

1. Trolley platform	5. M8 hexagon screws
2. Humidifier bracket	6. Hooks
3. Trolley pole	7. M8 hexagon screws
4. Trolley base	

Assembling procedure:

1) Install the trolley pole into the trolley base, and use the four M5 hexagon screws ⑤ to lock the pole from the bottom of the trolley.

2) Install the trolley platform① to the top of the pole, aligning the screw and lock the four M5 hexagon screws⑦ (Note that when installing the trolley platform, the 4 countersunk head holes must be upturned, they are the mounting holes of the host).

3) Use the M4 cross screw plus washer to fix the humidifier bracket ②.

4) Use the M4 hexagon screws to fix the hooks⑥.

2. Disassembling:

1) Use a cross screwdriver to demount the screws that fixed the humidifier bracket, then

disassembly the humidifier bracket.

2) Use a hexagonal wrench to demount the 12 hexagonal screws, then disassembly the pole, trolley base, the trolley platform and hooks.

3.2 Display system

1. Assembling:

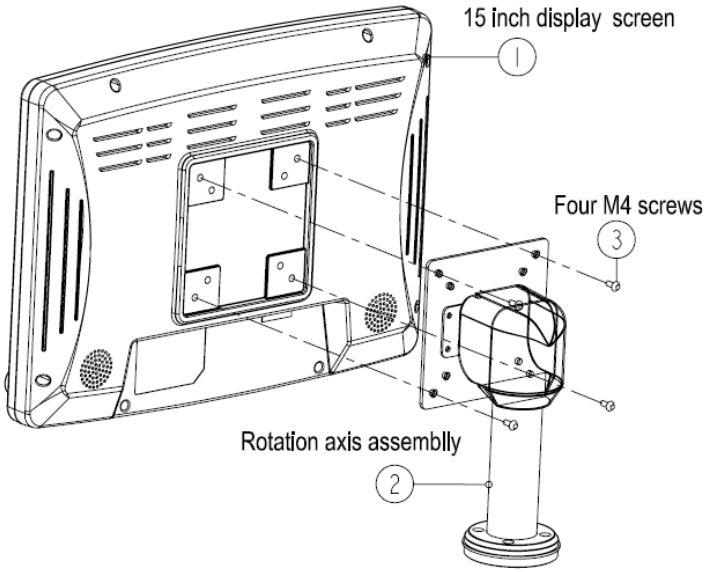


Figure 3-2 Display screen installation view

Assembling procedure:

1) Prepare the 15 inch display screen①, the rotation axis assembly ② and the M4 screws③ in the package.

2) As the above graphic shows, put the 15 inch display screen on the worktable (attention to protect the LCD), install the rotation axis assembly to the fixed hole on the rear of the display screen, aim at the screws and tighten the screws.

2. Disassembling:

Demount the M4 screws ③ to disassembly the display.

3.3 Ventilator system

1. Assembling:

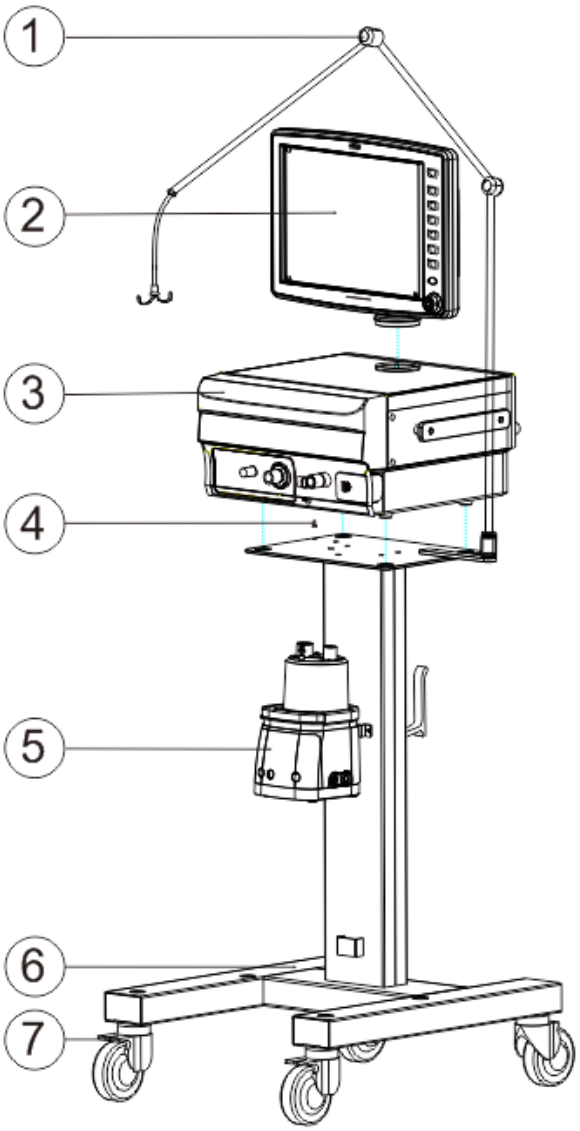


Figure 3-3 Ventilator system view

1. Mechanical arm	5. Humidifier
2. 15 inch display screen	6. Trolley
3. Main unit	7. Brake
4. Fixing screw for main unit	

Assembling procedure:

1) Lock the brakes⑦ of the trolley, align the four foot pads on the bottom of the main unit to the fixing holes of the trolley platform and make sure the four foot pads have been put into the countersunk head holes. Use the prepared screws ④ to lock the host upward from the bottom of the trolley platform.
2) Installing the 15 inch display screen assembly: install the 15 inch display ② into the

fixing seat above the main unit, tighten fixing screw to fix the display screen.

3) Installing the mechanical arm: tighten the mechanical arm ① to the mechanical arm holder on the side of the main unit, and lock the mechanical arm screws.

4) Install the humidifier: insert the humidifier⑤to the bracket on the middle of the pole.

2. Disassembling:

1) Loose the fixing screws to remove the display screen assembly.

2) Loose the screws reversely to disassembly the mechanical arm.

3) Loose the host fixing screw ④ to separate the ventilator's mainframe and trolley.

4) The humidifier can be pulled out directly.

3.4 Battery module

1. Assembling:

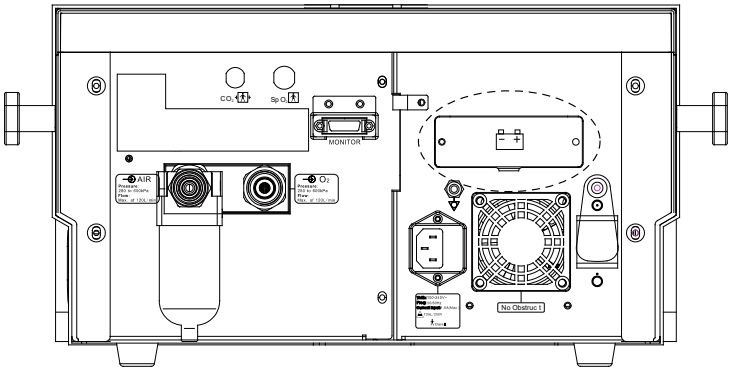


Figure 3-4 Battery module position view

Assembling procedure:

1) As the diagram shown above, remove the battery cover.

2) Insert the battery module into the hole, and press it to lock.

3) Install the battery cover, tighten the screws.

2. Disassembling:

Remove the battery cover, push down the lock, and pull the strap to remove the battery module.

3.5 Oxygen sensor

1. Assembling:

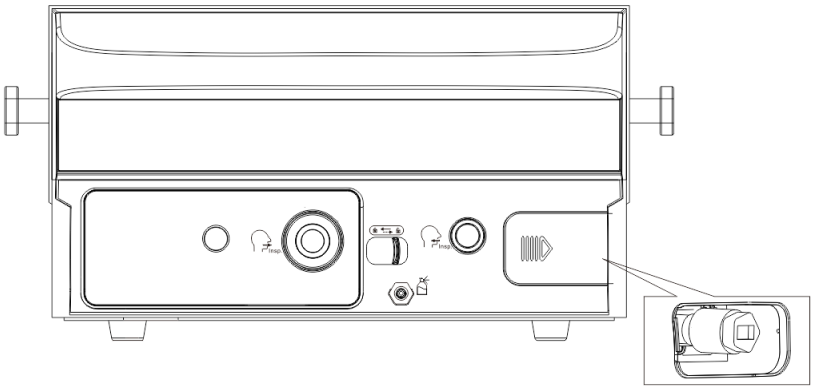


Figure 3-5 Oxygen sensor installation view

Assembling procedure:

1) Push the cover to the right and remove it.

2) Insert the new oxygen sensor forcefully, and then plug the oxygen sensor wire to the oxygen sensor

3) Install the cover.

2. Disassembling:

1) Push the power switch on the rear of the host to "⏻" and shut down the ventilator system.

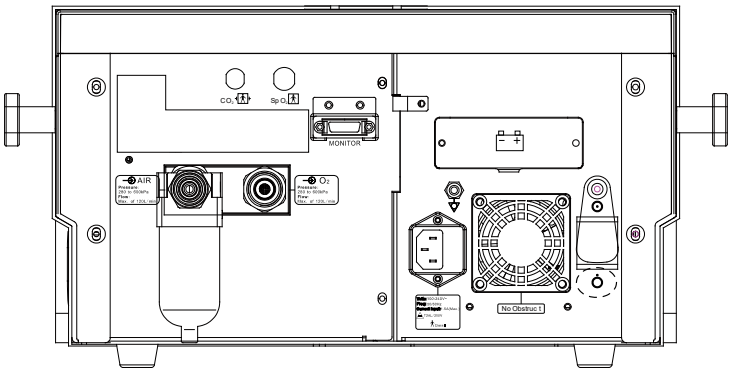


Figure 3-6 Power switch position view

2) Disconnect the ventilator form main power supply and gas supply device.

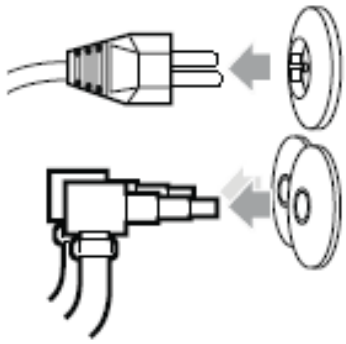


Figure 3-7 Main power supply and gas supply view

3) Push the cover to the right and remove it.

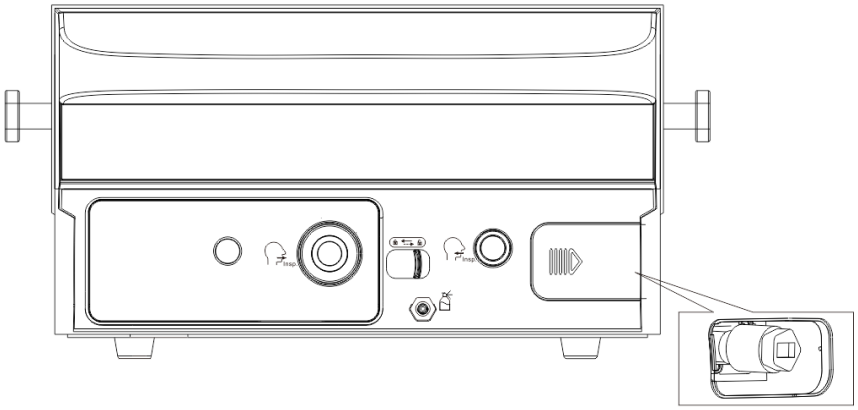


Figure 3-8 Oxygen sensor disassembly view

4) Unplug the sensor wire, and then pull out the oxygen sensor to take off the oxygen sensor.

3.6 Patient system

1. Assembling:

Please connect the patient system as the diagram shown below.

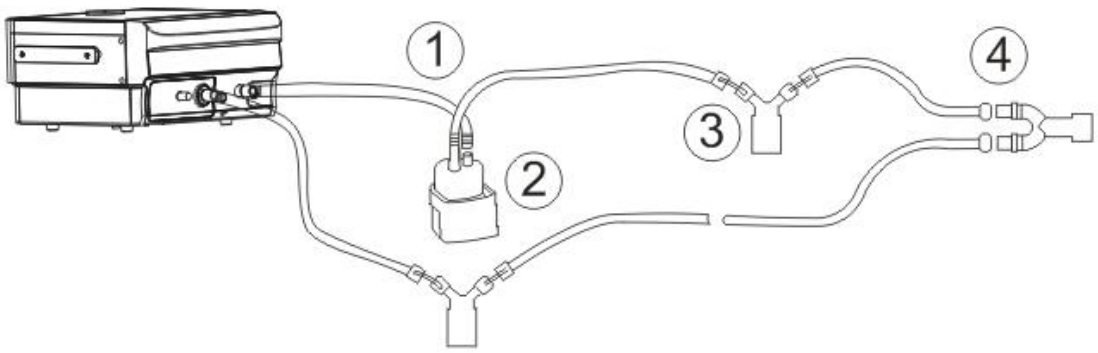


Figure 3-9 Patient system connection view

1. The patient’s pipeline	3. The water trap
2. Humidifier	4. Wye connector

2. Disassembling:

Dismantle the pipelines and the middle joint parts based on above graph. Note that the pipeline can not be dragged far away from the joint when it is dismantled. The joint should be held and pulled out carefully.

⚠Cautions:

- When disassembling the respiratory pipeline, make sure the humidifier has been shutoff and disconnected to the power supply.
- When disassembling the respiratory pipeline, please hold the tie-in on the two ends of the corrugated tube to avoid damages to the corrugated tube and the inspiratory/expiratory connection port.

3.7 Expiratory valve

1. Assembling:

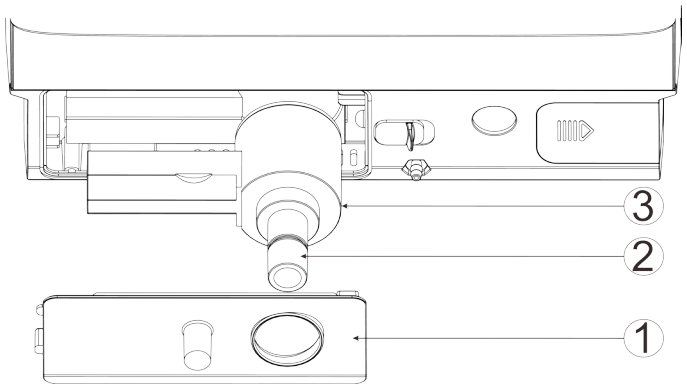


Figure 3-10 Expiratory valve view

1. Expiratory valve cover	3. Expiratory valve module
2. Expiratory port	

Assembling procedure:

1) Pull the lock plate to the left side by your left hand to unlock, Align the expiratory valve to the corresponding hole, and press the expiratory valve in parallel until it is tighten.

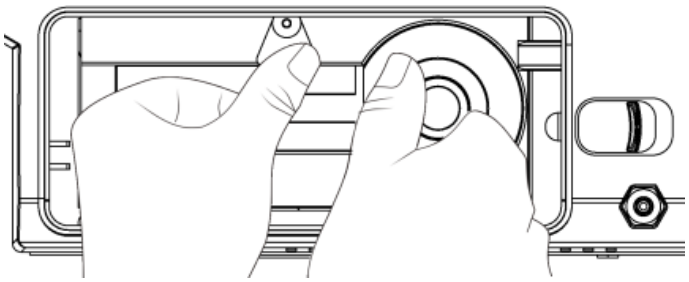


Figure 3-11 Expiratory valve installation view

2) Pull the lock plate to the right side to lock the expiratory valve.

3) Install the expiratory valve cover onto the left of the panel by your left hand, and unlock the cover lock according to the direction of the silk-screen simultaneously, and press the cover, and push the cover lock to lock.

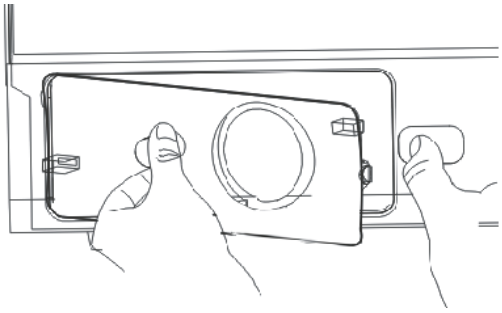


Figure 3-12 Expiratory valve cover installation view

2. Disassembling:

1) Push the cover lock to unlock according to the direction of the silk-screen, and take out the expiratory valve cover.

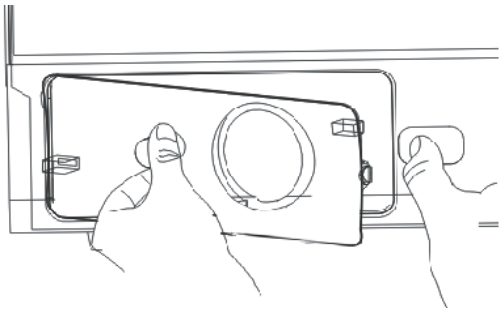


Figure 3-13 Expiratory valve cover disassembly view

2) Pull the lock plate to the left side by your left hand to unlock, and pull out the expiratory valve forcefully.

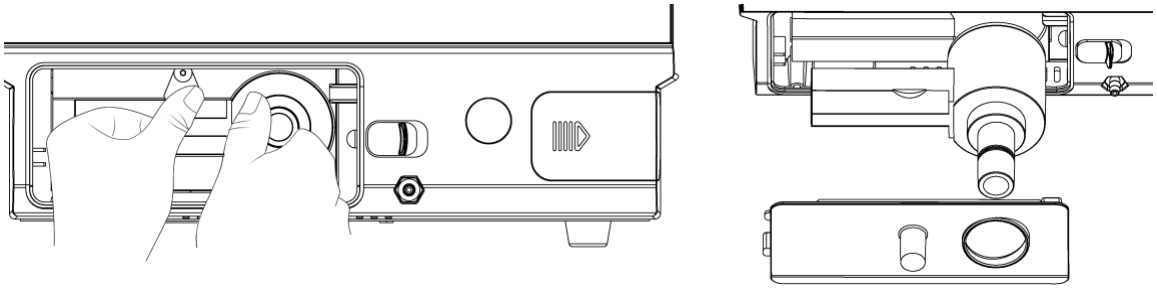


Figure 3-14 Expiratory valve disassembly view

3.8 Connecting the gas supply

1. Assembling:

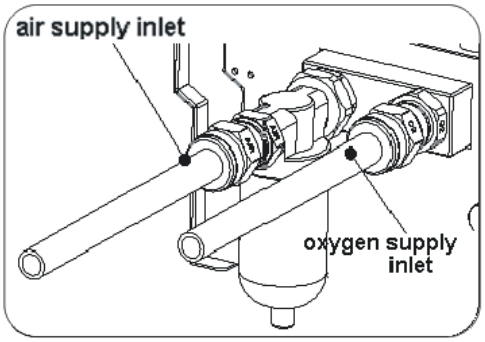


Figure 3-15 Gas supply connection view

Use a monkey wrench or special wrench to fasten the oxygen inlet connection tube and the air inlet connection tube.

2. Disassembling:

Cut off the air and oxygen supply, use a monkey wrench or special wrench to demount the oxygen inlet connection tube and the air inlet connection tube.

3.9 Connecting the power supply

⚠Caution:

- Please use the protective grounded power outlet, otherwise it will lead to increase of leakage current and result in risk.

1) In order to avoid the power plug off, fix the power cord by tightening the screw on the clamp, it shown as below.

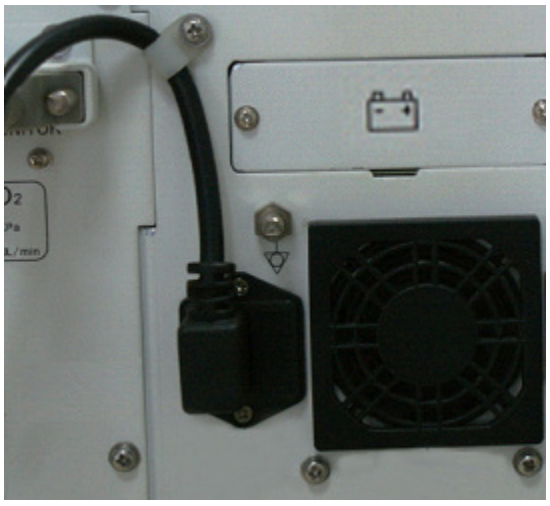


Figure 3-16 Power supply connection view

2) Plug the main power cord into the socket.

4 Pre-use check

4.1 System checking

Before using this equipment, please read the user manual and understand the operation and maintenance of each part of the equipment make sure it meets the following requirements.

1. The equipment is in good condition and with no damage.
2. All the components are connected accurately.
3. The respiratory system is connected accurately and with no damage.
4. The gas supply system is connected accurately and the pressure is normal.
5. All the emergency equipment is in ready and in good condition.
6. All the equipment that used for the maintenance of the pipeline and the intubations of the windpipe are available and in good condition.
7. Make sure there is no loose phenomenon on the wheels and the brakes have been locked and the ventilator cannot be moved.
8. Connect the power cord to the AC power supply, the AC power indicator and the battery indicator will light, if not, that means the system has no electricity.

⚠Warnings:

- Please always do a pre-use check before the patient is connected to the ventilator.
- Please connect the power cord to a protective grounded power outlet in order to avoid electric shock.
- The system carries out a functional checks during startup or test, if any functional failures is detected, and the equipment is not connected to the patient.
- Check the O_2 concentration value from set value and measured value, if value has a large deviation, calibration is required only by the authorized serviceman of the company. If the problem persists, O_2 sensor is replaced.

4.2 Alarm test

4.2.1 Preparations before alarm test

1) Connect the test lung to Y-piece of the breathing tube.
2) Turn on the system switch.
3) Parameters of ventilator set as below:
   - Patient type: Adult
   - Ventilation mode: VCV
   - V_T: 500 mL
   - Freq: 12bpm
   - T_I: 1.0s
   - FiO_2: 40%
   - PEEP: 0

4.2.2 High airway pressure alarm

1) Press the 【Alarm setting】touch key to enter the alarm setting screen.
2) Set the upper limit of PAW less than or equal to the measuring value.
3) Make sure the 【Airway pressure high!!!】appears in the alarm message display area.
4) Set the upper limit of PAW more than the measuring value.
5) Make sure the 【Airway pressure high!!!】disappears.

4.2.3 Low volume alarm

1) In the alarm setting screen, set the lower limit of V_{TE} more than or equal to the measuring value.
2) Make sure the 【Tidal Volume Low!!】appears in the alarm message display area.
3) Set the lower limit of V_{TE} less than the measuring value.
4) Make sure the 【Tidal Volume Low!!】alarm disappears.

4.2.4 Low oxygen concentration alarm

1) In the alarm setting screen, set the lower limit of FiO_2 more than or equal to the measuring value.

2) Make sure the 【O_2 Concentration Low!!!】appears in the alarm message display area.

3) Set the lower limit of FiO_2 less than the measuring value.

4) Make sure the 【O_2 Concentration Low!!!】 alarm disappears.

4.2.5 Pipeline falling off alarm

1) Pull out the patient's breathing pipeline.

2) Make sure the 【pipeline falling off!!!】appears in the alarm message display area.

3) Connect the patient's breathing pipeline again.

4) Make sure the 【pipeline falling off!!!】alarm disappears.

4.2.6 Alternating Current failure alarm

1) Disconnect the power supply when the ventilator is equipped with battery.

2) Make sure the 【AC Power Failure!!!】appears in the alarm message display area.

3) Connect the ventilator to the Power supply again.

4) Make sure the 【AC Power Failure!!!】alarm disappears.

4.2.7 Continuous airway pressure alarm

1) In the inspiratory phase, press the 【Insp Hold】membrane button.

2) About 15 seconds later, make sure the 【High Continues Pressure!!!】appears in the alarm message display area.

3) Press the 【Insp Hold】membrane button again.

4) Make sure the 【High Continues Pressure!!!】alarm disappears.

4.2.8 Apnea alarm

1) Press the【Modes Setting】touch key.

2) Set the ventilation mode to【SPONT】, do not press the test lung.

3) Make sure the 【Apnea!!!】appears in the alarm message display area within the set apnea time.

4) Press the test lung several times, make sure the 【Apnea!!!】alarm disappears.

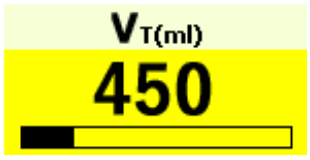
5 Operations and settings

5.1 Touch keys

Different color of touch keys shows the ventilator in different status:

- The blue key pad indicates the normal status, you can select or active the key by using the dial or touch. For example:

- The yellow key pad indicates the selected status, and its display highlight.



- The light blue frame indicates the active status, and the user can adjust the parameter by the navigation wheel. Rotate the navigation wheel with clockwise to increase the parameter, and rotate the navigation wheel with counterclockwise to decrease the parameter.

- The gray pad indicates the unusable status, the function is disabled, or the parameter can not be adjusted currently.

5.2 Start-up

1. Plug AC power cord into the main AC outlet and make sure the power supply works normally.
2. Turn on the system switch located on the rear of the equipment.

⚠Warnings:

- If abnormal alarms occur when the system starts up, do not use the equipment, contact the authorized serviceman or the after service department of the Company.
- Only the specified, protective grounded power supply can be used in this equipment.

Note:

- The current screen displays as DEMO, there may exist difference with the actual interface of the product. Please refer to the actual interface.
- When turning off the equipment, the system will save the current ventilation mode and relative parameters settings, which can be selected by the user as a patient category when the system is used in the next time.

5.3 Power-up screen

The power-up screen is the first screen displayed on the screen when the ventilator is turned on.

In Power-up screen, the system performs the functional check. The check items include power (10V, 5V, 12V, -12V), inspiratory pressure sensor, expiratory pressure sensor, oxygen sensor and so on. If the failure occurs, the error information is displayed in the screen and the system stops running. Please contact the Company Technical Support if need.

The system continues to the next screen until the failure is solved.

5.4 Start-up screen

The system enters the start-up screen after the self-test completed.

The start-up screen is the first screen that can be operated by users. It shown as below.

Figure 5-1 Start-up screen view

In this screen, users can perform the following operations:

1. Patient Category Selection:

【Previous Patient】,【Adult】 and 【Pediatric】.

If you choose the “Previous patient”, the ventilator will continue the ventilation according to the latest settings.

If you choose the “Adult” or “Pediatric”, the ventilator will provide ventilation according to the default settings.

Different parameter setting and operation is confirmed by selecting different patient categories.

Please follow the below procedures to set the patient category:

1) Touch or rotate the navigation wheel to select the needed patient category.

2) Press the navigation wheel to confirm setting.

If you select the needed patient category, the symbol of the selected patient category will appears in the status message display area.

2. Weight setting

You can set the patient's weight in this screen. The system calculates the referenced tidal volume value in the volume ventilation mode according to different weight of the patient.

For different patient categories, the setting range of the weight is different:

- Adult: 20-150kg
- Pediatric: 5-20kg

1) Touch or rotate the navigation wheel to select【Body weight】.
2) Press the navigation wheel to confirm.
3) Rotate the navigation wheel with clockwise to increase the value, and rotate the navigation wheel with counterclockwise to decrease the value.
4) Push the navigation wheel to confirm the value.

3. Mode setting

1) Touch or rotate the navigation wheel to 【Mode setting】.
2) Push the navigation wheel to confirm.
3) Select the mode in the drop-down menu.

4. Start to test system leakage and compliance

Touch or rotate the navigation wheel to 【Start】 on the left, and confirm by pressing the navigation wheel.

5. Startup to enter main screen

Touch or rotate the navigation wheel to 【Start】 on the right, and confirm by pressing the navigation wheel.

Note:

◆ In Start-up and Standby screen, only technical alarm can be activated, physiological alarm is invalid.

5.5 Standby

If needed, the ventilator can be set to the Standby mode. In this mode, the system stops the mechanical ventilation and monitored parameters function, but it allows to select patient categories and to set relevant parameters.

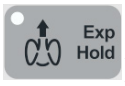
Press 【 

】 membrane button and confirm by pressing the navigation wheel to enter the Standby mode.

If you want to exit the Standby mode and enter the work state, highlight the 【Start Ventilation】 touch screen icon and confirm by pressing the navigation wheel.

In this mode, the following membrane buttons are disabled:

- 【 

】
- 【 

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- 【 

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】

5.6 Main screen

The Main screen provides the operator with displays of current mode of ventilation, alarm status, battery charge status, monitored parameters, waveforms display and so on. It shown as below.

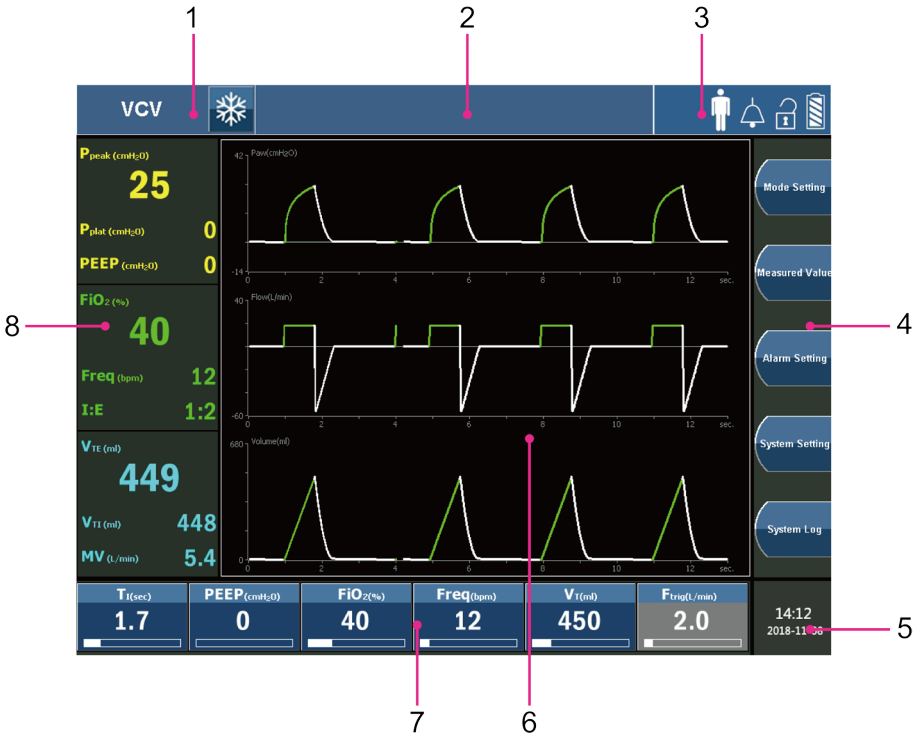


Figure 5-2 Main screen view

1. **Mode information display area:**

1） Displays the current ventilation mode.

2） Displays freeze 【  】 touch button.

2. **Alarm information display area:**

Displays the current alarm information.

3. **Status information display area:**

1） Displays the spontaneous breathing icon.

2） Displays the patient category.

3） Displays the screen lock / unlock icon.

4） Display the battery status icon.

5） Display the alarm silence icon.

4. **Function screens buttons area:**

There are 5 buttons:

1） Mode Setting

2） Measured value

3） Alarm Setting

4） System Setting

5） System Log

Different buttons can select different function screen.

5. **System time display area:**

Displays the current date and time.

6. **Waveform area:**

According to different configurations of models and different settings by users, it will display the waveform and loop graph of the current patient.

7. **Key parameters setting area:**

Except using the 【Mode setting】, users can set the relative ventilation parameter of the current ventilation mode in this area directly, the gray touch key means the parameter is disable in the current ventilation mode and cannot be adjusted.

8. **Measured parameter area:**

Display measured parameters of the current patient.

5.7 Mode setting

Touch the【Mode Setting】touch screen icon to enter the mode setting screen (as shown below).

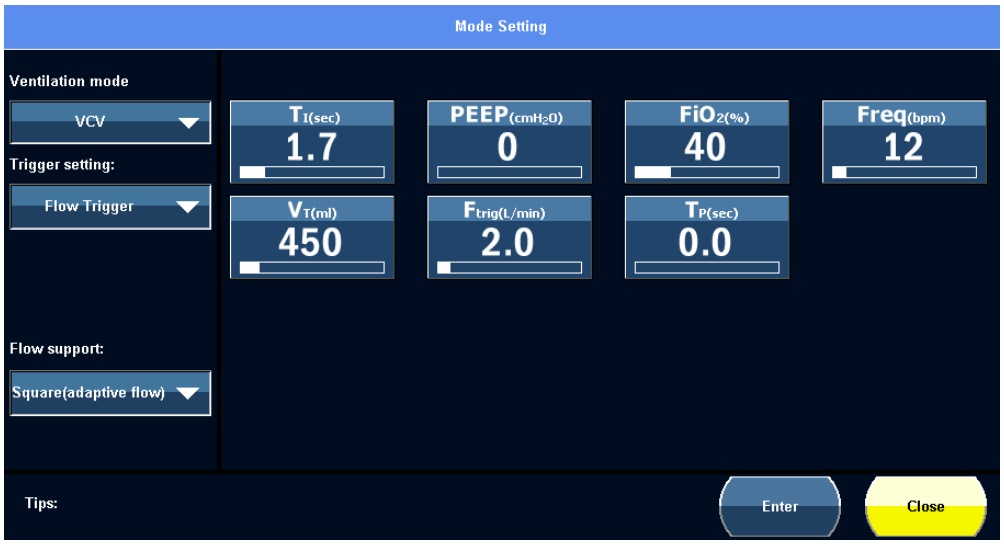


Figure 5-3 Mode setting screen view

In this screen, users can perform the following operations:

- To select ventilation mode
- To set ventilation parameters
- Trigger setting: 【Flow Trigger】, 【Pressure Trigger】, and 【Close】
- To set backup mode (SPONT mode): 【PCV】, 【VCV】, 【PRVC】
- Flow support setting: 【Square】, 【Ramp】and 【Exit】

Mode and parameters setting

1) In ventilation setting screen, touch or rotate the navigation wheel to【ventilation mode】 option frame, and select the ventilation mode in the drop-down menu.
2) Select the ventilation parameters that need to set, and rotate the navigation wheel to adjust the value and push the navigation wheel to confirm setting.
3) Backup mode can be set in SPONT mode. Touch 【Backup Mode】 option frame and select 【PCV】, 【VCV】or【PRVC】 in the drop-down menu.
4) Touch 【Flow support】 option frame to select 【Start】or【Exit】.

Note:

◆ The ventilation parameters is corresponding to the current ventilation mode. In other word, when you select a ventilation mode, only the parameters associated with the current ventilation mode will display on the screen.

5.8 Monitored parameter screen

Touch the【measured value】touch screen icon to enter the measured value screen. The monitored parameters screen displays measured values and setting parameters. it shown as below.

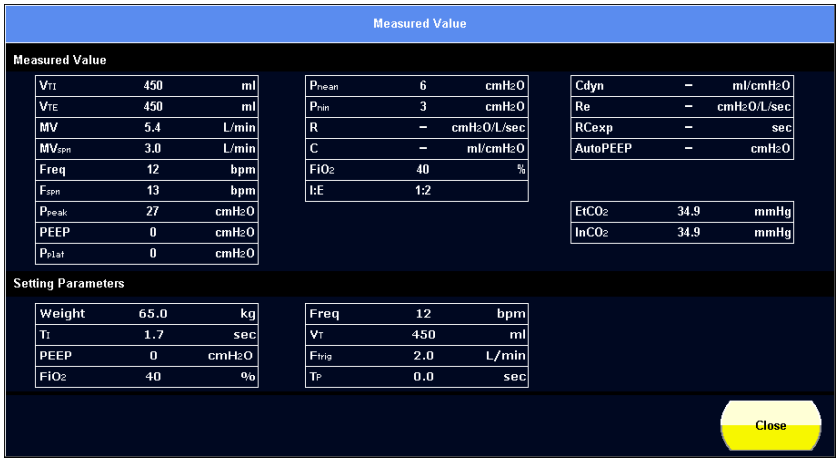


Figure 5-4 Measured value screen view

Touch 【Close】to return to the main screen.

5.9 Alarm settings

In this screen, users can adjust the alarm upper and lower limit parameters.

The parameters between the upper limits and the lower limits are the current monitored parameters.

The alarm setting screen is shown as below.

Figure 5-5 Alarm setting screen view

Adjust the alarm upper and lower limits as per the following procedures:

1) Touch or rotate the navigation wheel to select the parameter until it is highlighted.

2) Confirm by pressing the dial, and rotate the navigation wheel to adjust the parameter.

3) Then confirm the setting by pressing the navigation wheel.

Select 【Default setting】 to restore the default values, it will restores the upper and lower limit values to the default values.

Move the focus to select 【Close】, and then press the navigation wheel, the system will save your settings and exit the alarm setting screen.

The alarm parameters and setting range refer to the *Appendix B.5*.

The alarm default settings refers to the *Appendix F.*

5.10 System setting

Touch the 【System setting】 touch screen icon to enter the system setting screen, it is shown as below.

Figure 5-6 System setting screen view

1. Common settings

You can set the Date/Time, Alarm Volume (Range: 20~100) and Language.

1) Touch the parameter value that you desire to set.

2) Rotate the navigation wheel to adjust the value.

3) Press the navigation wheel to confirm settings.

2. View settings

You can configure the Waveform, Waveform + loop, Trend and Big Font displayed on the main screen.

Display format:

- Waveform1
- Waveform2
- Waveform + loop
- Trend

- Big Font

If 【Waveform1】 is selected, the waveform area displays the different color waveforms with yellow, green and light blue respectively. It shown as below.

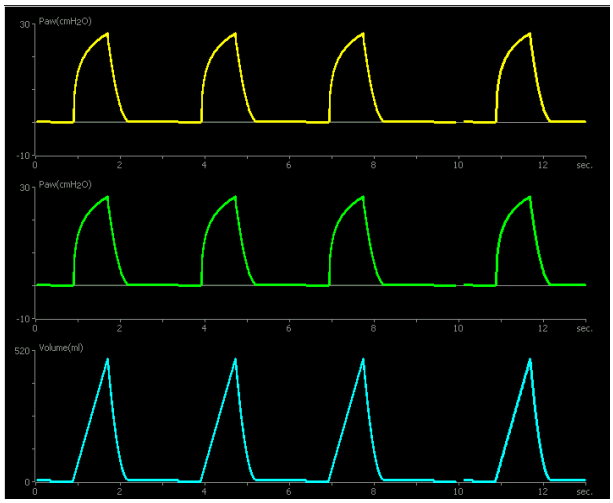


Figure 5-7 Waveform1 view

If 【Waveform2】 is selected，a green tracing indicates the inspiratory portion of a breath and a white tracing indicates the expiratory portion of a breath. It shown as below.

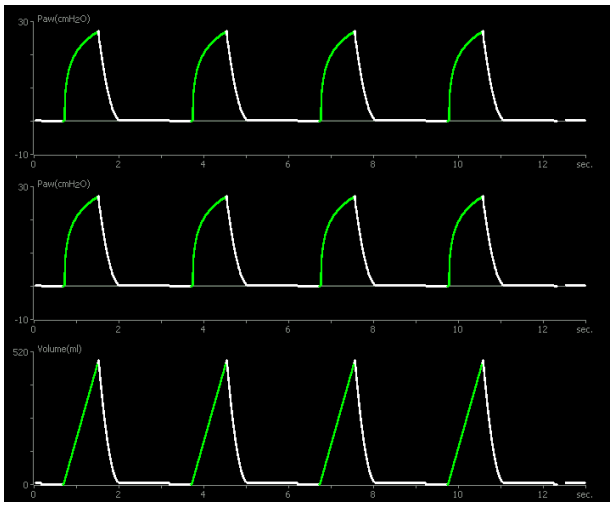


Figure 5-8 Waveform2 view

In System Setting screen, there are four waveform options for you to select:

1） The 1st waveform options:

- Paw-T
- Flow-T
- V-T
- SPO_2 -T (optional)
- CO_2 -T (optional)

2） The 2nd waveform options:

- Flow-T
- Paw-T
- V-T
- SPO_2-T (optional)
- CO_2-T (optional)

3） The 3rd waveform opotions:

- V-T
- Paw-T
- Flow-T
- SPO_2-T (optional)
- CO_2-T (optional)

4） The 4th waveform opotions:

- Hidden
- SPO_2-T (optional)
- Paw-T
- Flow-T
- V-T
- CO_2-T (optional)

If 【Hidden】is selected，the waveform area displays three waveforms, the four waveform is hidden.

If 【waveform + Loop】 is selected, the two Loops display on the right side of the screen. It shown as below.

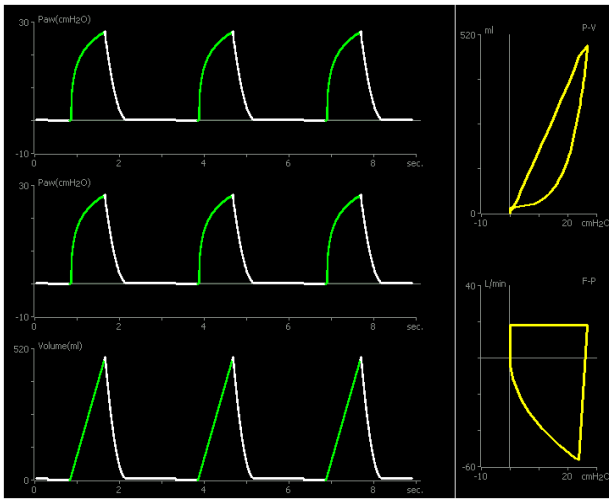


Figure 5-9 Waveform + Loop view

In System Setting screen, there are two loop options for you to select:

1） The 1st loop options:

- P-V
- F-P
- F-V
- V-CO_2(optional)

2） The 2st loop options:

- F-P
- P-V
- F-V
- V-CO_2(optional)

If 【Trend】is selected, the main screen can display six trends.

The time of trend:

- 1 h
- 4 h
- 8 h
- 12 h
- 24 h

If【Big Font】is selected, the main screen can display one waveform and the current big font monitoring values.

3. Other settings

Touch 【Other settings】to access the other settings screen. It shown as below.

Figure 5-10 Other settings view

1) Atomize

Touch the option frame and select “Disable”, “10 minutes”, “20 minutes” or “30 minutes” in the drop-down menu.

When O_2 supply is connected to the system and a nebulizer is attached to the ventilator, and the minimum flow is more than 10 L/min, after the nebulization button is pressed, the ventilator will automatically supply 7L/min (±0.5L/min) gas to the patient in inspiration phase, and the nebulization time can be selected in 10min, 20min and 30min (in system setting screen). You may end the nebulization period early by pushing the nebulization button again.

Note: When connecting nebulizer, it need install bacterium filter onto expiration end.

2) Percent of the leak

Touch the option frame and select the percent of the leak (Range: 20~80%).

When the system occurs leak, for example: $(V_{TI} - V_{TE}) / V_{TI} >$ set leak percent, 【System leakage!!! Please check the breathing tubes and expiratory valve. 】 alarm is activated.

Default setting: 20%.

3) Pipe compliance compensation

Set the pipe compliance compensation.

4) Sigh

Touch the option frame to select “Disable” or, “Enable” sigh.

When selecting “Enable”, the extra volume will increase by 50% above the tidal volume

set by the user (1.5xset volume) in the next inspiration cycle of the every 100 breaths.

Default setting: Disable.

5) Humidifier compensation

Touch the option frame to select “Close” or, “Start” compensation.

It advices that the operator select the “Start” compensation when the humidifier is connected with ventilator.

6) Leakage compensation

Leakage compensation range: Close, 20%~60%, Default setting: Close.

Touch the option frame to select “Close” or set the leakage compensation percentage, the user set the percentage according to the leakage volume of the system, the maximum compensation volume is 60% of the setting tidal volume.

7) Rapid shallow breathing (Optional)

It is a quotient of spontaneous breathing frequency and tidal volume, and the measured value is displayed on the measured value screen.

Parameter range: 0.0-1000.0 bpm/L.

Rapid shallow breathing can be set in SPONT mode.

8) Occlusion pressure P0.1 (Optional)

It is a measure of a patient’s neuromuscular breathing drive during a short occlusion at the start of spontaneous inspiration.

Occlusion pressure P0.1 can be set in SPONT mode.

Touch the option frame to select “Start”, and the P0.1 is performed automatically, and the measured value is displayed on the measured value screen.

Parameter range: 30>=P0.1>= 0

9) Negative inspiration force (Optional)

The negative inspiration force measures the maximum inspiration effort of a patient after a preceding expiration.

NIF can be set in SPONT mode.

Touch the option frame to select “Start”, and the NIF is performed automatically, and the measured value is displayed on the measured value screen.

Parameter range: -40~0cmH_2O.

10) Intubation diameter

Set the intubation diameter.

11) Compensation range

Set the compensation range.

12) AutoPEEP

It is a pressure differentials of the setting and measured PEEP.

Touch the option frame to select “AutoPEEP”, and the system is tested automatically, and the value is displayed on the measured value screen.

Parameter range: 0 ~ 100cmH2O.

AutoPEEP is available in all modes.

13) CO_2 module zeroing

For mainstream CO_2 module, they need to establish a zeroing every time you have any doubts about the accuracy of the measured values.

Touch 【CO_2 module zeroing】touch screen icon, the module will begin normal zeroing.

14) Close the setting screen

Touch 【Close】touch icon to exit the setting screen.

4. Version Information

The version information screen provides the operator with displays of software version information. It’s shown as below.

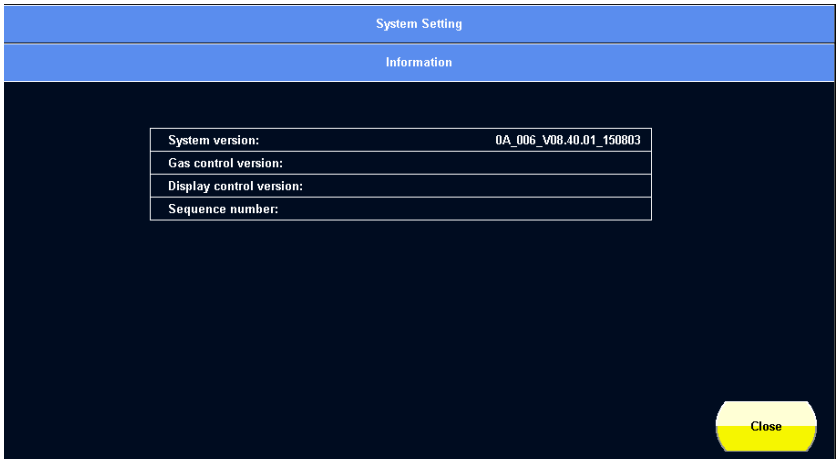


Figure 5-11 Information screen view

5. Biomed mode

In system setting screen, touch 【Biomed】 icon, and it needs password to enter Biomed screen. It is shown as below.

Biomed mode is mainly used by trained engineers of the Company to carry out the calibration, testing and software upgrade.

In Biomed mode, you can set altitude. Altitude setting range: -1000~8000m.

Default setting: 100m.

Figure 5-12 Password input screen view

5.11 System log

The System log screen provides the operator with reviews of previous alarm messages and setting, and it records time and contents.

The time of system logs are stored in accordance with their generated time sequence.

Touch to select【Page up】 or 【Page down】 to review more logs.

In the system log screen, the 【Close】 icon is highlighted, touch it to exit the screen.

Note:

◆ The system can store up to 500 records for your review.

5.12 System shutoff

When finishing using the system, shut off the system based on the following procedures:

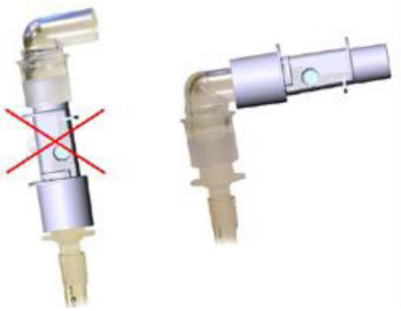
1. Disconnect the pipeline from patient.
2. Turn off the switch on the rear of the host.
3. Disconnect the AC power supply.
4. Clean the surface of the equipment if need.

6 CO_2 module (Optional)

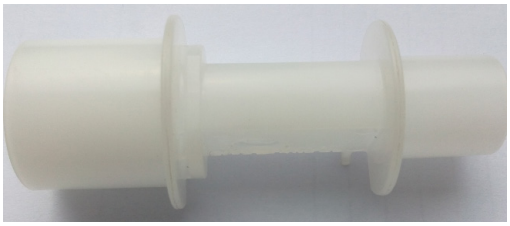
⚠Warning:

- The IRMA probe is intended for use by authorized and trained medical personnel only.
- The IRMA probe must not be used with flammable anesthetic agents.
- Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.
- Used airway adapters shall be disposed of in accordance with local regulations for medical waste.
- Do not use the IRMA infant airway adapter with adults as this may cause excessive flow resistance.
- Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.
- Use only Masimo manufactured IRMA airway adapters.
- Incorrect probe zeroing will result in false gas readings.
- No modification of this equipment is allowed.
- Replace the airway adapter if rainout/condensation occurs inside the airway adapter.
- The IRMA probe is not designed for MRI-environments.
- If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.
- 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.
- Do not place the IRMA airway adapter between the endotracheal tube and an elbow

as this may allow patient secretions to block the adapter windows and result in incorrect operation.



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



- 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.
- The IRMA probe is not intended to be in patient contact.

⚠Caution:

- Never sterilize or immerse the IRMA probe in liquid.
- The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
- Do not apply tension to the probe cable.
- Do not operate the IRMA probe outside the specified operating temperature environment.

6.1 Summarize

The ventilator adopts the MASIMO CO_2 module. You can select IRMA mainstream CO_2 module to measure the CO_2 concentration.

It 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 suite, intensive care unit, patient room and emergency medicine settings for adult, pediatric and infant patients.

It is not intended to be used as the only means of monitoring a patient. It shall always be used in combination with other vital signs monitoring devices and or professional human judgments of patient condition. The IRMA probe is intended to be used by trained and authorized health care professionals only.

6.2 Connection

Please follow the procedures below:

1) Plug the IRMA connector into the CO_2 interface on the rear plate of the main unit, the connection method shown as below.

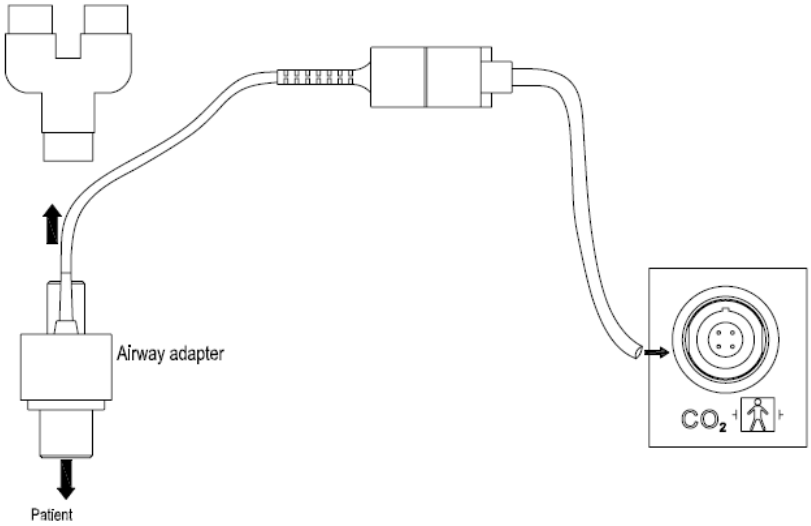


Figure 6-1 CO_2 module connection view

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

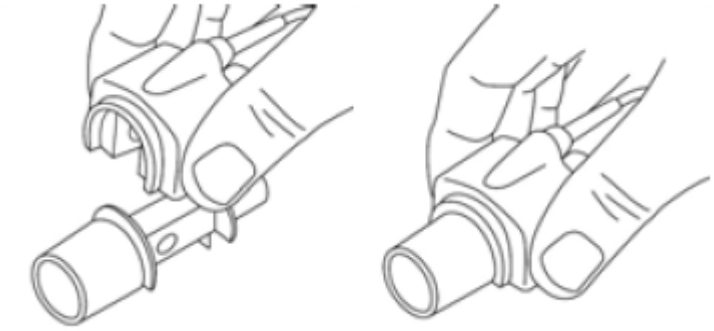


Figure 6-2 IRMA probe installation view

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

Figure 6-3 IRMA probe installation view

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

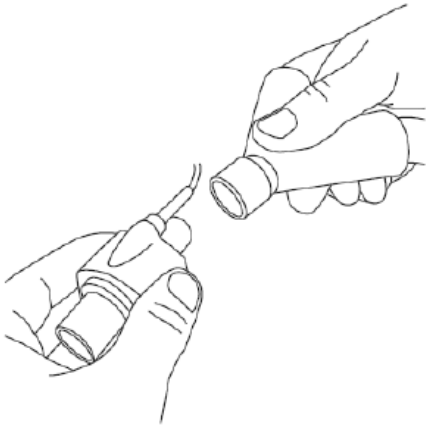


Figure 6-4 IRMA adapter connection view I

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

Figure 6-5 IRMA adapter connection view II

Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing an 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.

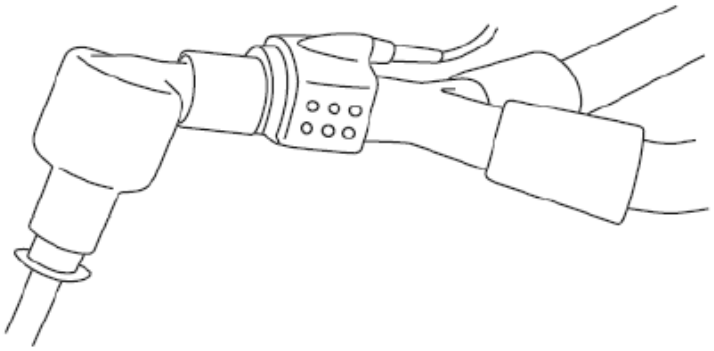


Figure 6-6 IRMA adapter and probe connection view

6) Unless the IRMA probe is protected with an HME always position the IRMA probe with the status LED pointing upwards.

Figure 6-7 IRMA probe LED upwards view

⚠Warning:

- The IRMA probe is not intended to be in patient contact.

6.3 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.

6.4 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 snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument 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 in the IRMA airway adapter is of crucial importance for a successful Zeroing.

Always perform a pre-use check after zeroing the probe.

Whenever an offset in gas values or an unspecified gas accuracy message is displayed.

Allow 10 seconds for warm up of the IRMA CO_2 after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

6.5 Alarms

The description of the status LED situated on the IRMA probe is as below:

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

7 User maintenance

⚠Warning:

- Everyone should realize that some components of the ventilator may be in danger of infection when dismantled and cleaned.

⚠Cautions:

- Some parts of this equipment can not be disposed in a normal way.
- All the disposable parts should be disposed in a safe and environmental way according to the hospital regulations.
- After every disassembled cleaning or reinstallation, it can be used regularly only after the *pre-use check* in chapter 4.
- In order to prevent damages, if you have any problem about the cleanser, please see the data provided by the manufacturer.
- Do not use organic cleanser, halogenations or organic solvent, anesthetic agent, glass cleanser, acetone or any other irritant cleanser.
- Do no use abrasive cleanser. (e.g. steel wool, silver polish or detergent)
- Place the liquids far away from the electronic components.
- Do not use equipment which is out of order. Please let authorized Customer Service representative of the Company complete all the necessary maintenance work whenever at possible or accomplish the maintenance work of listed parts in the user manual by some qualified and experienced staff.
- Use parts produced or sold by our company to replace those broken ones, and have a test after replacement to assure that they correspond with the specification requirements of the manufacturer.
- Any service support requirement, please contact after-sale service department of the Company.
- When taking any parts from the ventilator, you should abide by the hospital rules and

regulations about taking and disposing infectiousness materials. Because the way of cleaning, sterilizing in the Medical institutions is very different from the practice. Therefore the Company can not satisfy all the special needs and can not be responsible for cleaning, sterilizing or other hygienic measure taken by the hospital during therapeutic process. We suggest that you use the effective methods already proven in this user manual, specific equipment and steps. Other methods may be just as effectively, but we do not guaranteed unless the Company provides written authorization.

- We suggest that when cleaning or sterilizing, you should use drinking water at least or more healthful water, otherwise, the result may be affected.
- Cleaning is the most important step in cleaning and sterilizing process. If you clean the instrument improperly, it would be impossible to sterilize or high temperature sterilize effectively. Eliminating most of bacterium and filth by cleaning is significant guarantee for achieving the best sterilization.
- The instrument should be cleaned and sterilized immediately after using if possible. Filth like saliva or blood should not remain in the instrument and turn dry.

7.1 Maintenance schedule

Maintenance Frequency	Maintenance
Every patient	Respiratory valve, reusable breathing tube
Every day	The ventilator surface
Every half year	Fan filter, air water filter, battery
Every year, or as necessary	Oxygen sensor **Note:** ● Replace the oxygen sensor if damaged. (see ***3.5 Oxygen sensor*** for sensor installation procedures). ● Actual sensor life depends on operating environment. Operation at higher temperature or O2 concentration levels will result in shorter sensor life.
When cleaning and installation	Check the parts good or not, if necessary change or repair it

7.2 Maintenance of the ventilator surface

1. Using wet cloth that dipped in flexible cleanser (75% of medical alcohol) to wipe the surface of the ventilator.
2. After finish the clean of the surface, using dry, Lint-free clothe to wipe the residual detergent.

⚠Warning:

- If liquid dip into control units will damage the equipments or induce people in danger, please make sure there is no liquid dip into the control units, and must disconnect the equipment from the AC power during the process of cleaning the surface. Reconnect the AC power after all the parts that have cleaned are dried.

⚠Cautions:

- The screen must be cleaned by the cloth that is dry, soft and lint-free, do not use liquid.
- If there is too much dirt on the surface, you can use Ethylene glycol or isopropyl alcohol.

7.3 Maintenance of the water filter

Water filter is placed on the rear of the ventilator, it shown as below.

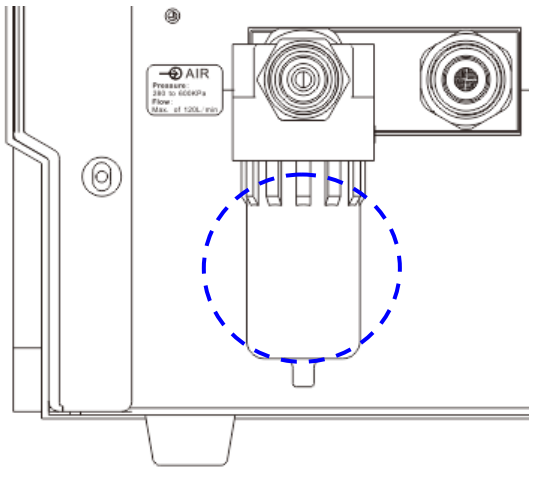


Figure 7-1 Water filter position view

⚠Cautions:

- Do not block the outfall of the water filter.
- Replace requiems: 1.Replace the filter core every year, and replace the filter core when the pressure difference reaches to 0.1 MPa.

7.4 Maintenance of the expiratory valve

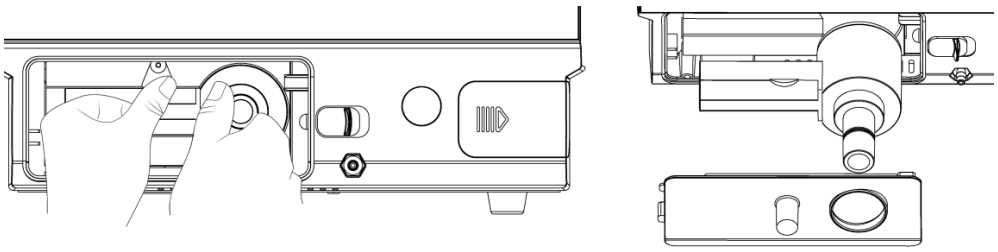


Figure 7-2 Expiratory valve disassembly view

1. Refer to the section 3.7 to disassemble the expiratory valve.
2. Clean the expiratory valve module with detergent or disinfectant for 10 minutes at least in the heating room (recommended temperature is 80℃), or use clean water or soft detergent (recommended water temperature is 40℃), and wipe with 75% medical alcohol; and then steam sterilization (autoclave), maximum temperature is 134℃.
3. Take them out and soak for 30 minutes in clean water, repeated twice.
4. Dry with soft cloth or allow to air dry.

7.5 Maintenance of the breathing tube

Disinfection of the reusable breathing tube:

Clean it with Detergent or disinfectant in the heating room (at least 10 minutes, the recommended temperature inside is 80 degree) or use clean water or mild detergent(the recommended temperature is 40 degree), and wipe it with the 75% of medical alcohol; or use the high-temperature, high-pressure steam sterilization(the maximum temperature is 134 degree).

7.6 Maintenance of the battery

Whenever the equipment is connected to the AC power source, the battery is being

charged automatically. Do not allow your battery become fully discharged as this may damage the system.

When the equipment is turned on, make sure that the battery indicator is illuminated, if the battery indicator is not illuminated, you should check or replace the battery if necessary. Replacement of the internal battery should be accomplished by trained technician of the Company.

⚠Cautions:

- In order to extend the battery life, use the battery at least one time every month, when the battery is being exhausted, charge it.
- The battery life depends on the frequency and time of use. Using the batteries in an improper way will affect the battery life.
- The exhausted batteries must be replaced or discarded according to the local regulations, and cannot be discarded in a normal way.
- Please take out the battery if the system is not used for a long period.
- It is recommended that the stored battery is charged once every 6 months.

7.7 Maintenance of the oxygen sensor

Refer to the section *3.5* to disassemble the oxygen sensor.

⚠Warnings:

- During cleaning and setup, inspect the seal ring for damage, replace immediately as necessary.
- In order to prevent the leakage of the patient circuit, when disassembling and installing, please pay attention to avoid the damage of the components, to ensure the correctness of the installation, especially to remember the installation of the seal ring. When cleaning and sterilizing, make sure that the disinfection method to all parts is the effectiveness and applicability.
- If any operation will induce danger to the patient, like change the O_2 sensor, then should disconnect the tube between the ventilator and the patient.

- The exhausted O_2 sensor must be replaced or discarded according to the local regulations, don't discard the obsolete O_2 sensor in a normal way.
- The O_2 sensor is a sealed part, it contains corrosive liquid which can burn the skin and eyes badly. If touches the skin carelessly, you should flush with clean water at least 15 minutes immediately and be treated by a doctor, especially when the corrosive liquid touches the eyes.
- Check the O_2 concentration value from set value and measured value, if value has a large deviation, calibration is required only by the authorized serviceman of the company.
- After replace the Oxygen sensor, it must be calibrated by the authorized serviceman.

7.8 Maintenance of the CO_2 module

1. The cleaning of IRMA probe

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.

2. Gas span check

Gas readings should be verified at regular intervals with a reference instrument. If great error of gas readings were found, please contact the manufacturers service department for maintenance by the after service engineers.

⚠Warnings:

- Never sterilize or immerse the IRMA probe in liquid.

8 Accessory list

⚠Warnings:

- Please use accessories provided by the Company in order to avoid the inaccurate data or equipment failure.
- The one-off accessories can be used only once, repeated using may lead to performance degradation or cross-infection.
- If you discover that the accessories package or the accessories are damaged, do not use the accessories.

1、The recommended accessories, damageable parts list:

No.	Name	Specification
1	Mask (Optional)	Adult/Pediatric
2	Manual bag	Adult Pediatric (optional)
3	Ventilator disposable absorber suit	Adult/Pediatric
4	Oxygen sensor	MOX-4

⚠Caution:

- The accessories listed above are recommended by the company, we have no responsibilities for the result if accessories of other specification are used.

Appendix A Working Principle

A.1 Pneumatic System

A.1.1 Pneumatic Diagram

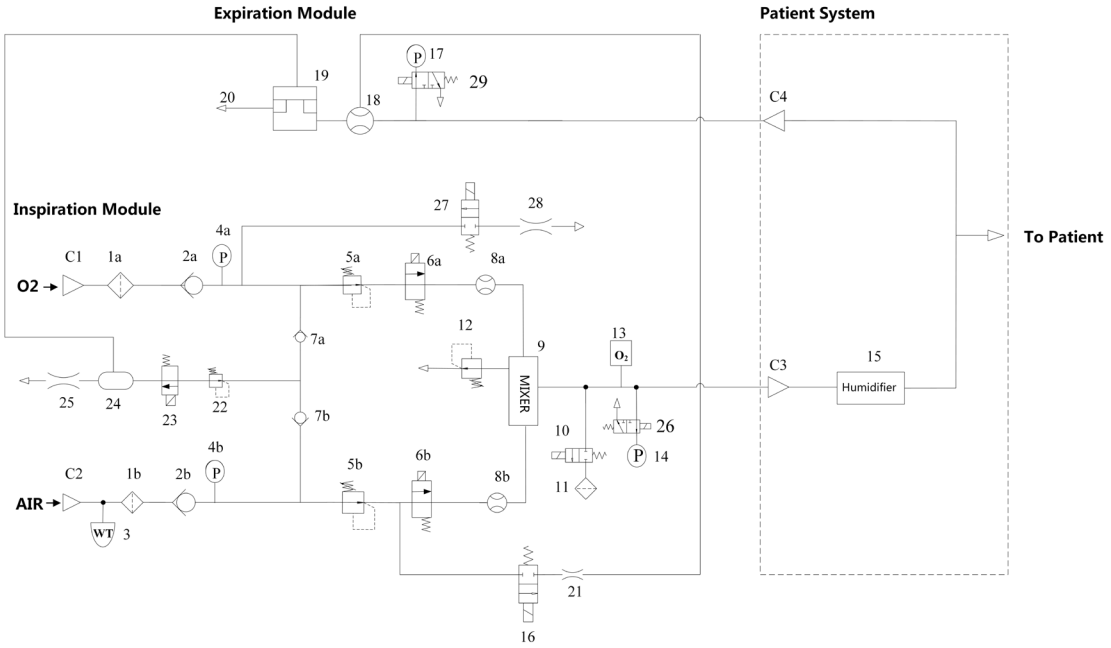


Figure A-1 Pneumatic diagram

1a/1b	Filter	16	Blowing valve
2a/2b	Check valve	17	Expiratory pressure sensor (P)
3	Water trap	18	Flow sensor
4a/4b	Pipeline pressure sensor	19	Expiratory valve
5a/5b	Pressure regulator	20	Expiratory outlet
6a/6b	Proportional electromagnetic valve	21	Gas resistor
7a/7b	Check valve	22	Pressure regulator
8a/8b	Flow sensor	23	Flow control valve

9	MIXER	24	Gas reservoir
10	Free breathing valve	25	Gas resistor
11	Air filter	26	Zero calibration valve
12	Safety valve	27	Nebulization On/Off valve
13	Oxygen sensor	28	Gas resistor
14	Inspiratory pressure sensor (P)	29	Zero calibration valve
15	Humidifier	C3	Inspiratory port
C1	O2 inlet	C4	Expiratory port
C2	Air inlet		

A.1.2 Summary

This ventilator is pneumatic-controlled. In the designing of the ventilator, we strive for the high accuracy, high frequency and intelligent. The ventilator will control the value of oxygen and the air flow according to the preset value, trough the entire airway pipe, the mechanical ventilation is completed. According to the functions, the ventilator system is divided into four parts: the inspiratory module, expiratory module, PEEP controlling module and patient circuit.

1. Inspiratory module
    1) The gas supply inlet and controlling module——import gas supply from the pipeline or cylinder to the ventilator, and provide stable gas flow.
    2) The gas flow controlling module——control the air and oxygen flow separately through the solenoid proportional valve in order to reach the pre-set ventilation standard.
    3) The gas mixer and safety valve system——realize that the air and the oxygen is mixed evenly, and deliver the mixed gases to the patient through the inspiration port. At the same time, when the patient's airway pressure is much higher, the safety releasing valve immediately opens to release the excessive pressure so

as to protect the patient" s lung from excessive pressure. The emergency inspiration port provide emergency ventilation in case the system ceases to operation.

2. PEEP controlling module

Achieve the PEEP function by electrical-controlling to reach the preset PEEP (positive end-expiratory pressure).

3. Expiratory module

To achieve the patient's expiratory function during mechanical ventilation, and assist the inspiratory module to realize different modes of mechanical ventilation.

4. Patient system

Connect the ventilator with patient through the patient system, and deliver the controlling gas to the patient.

The division of the modules is as below:

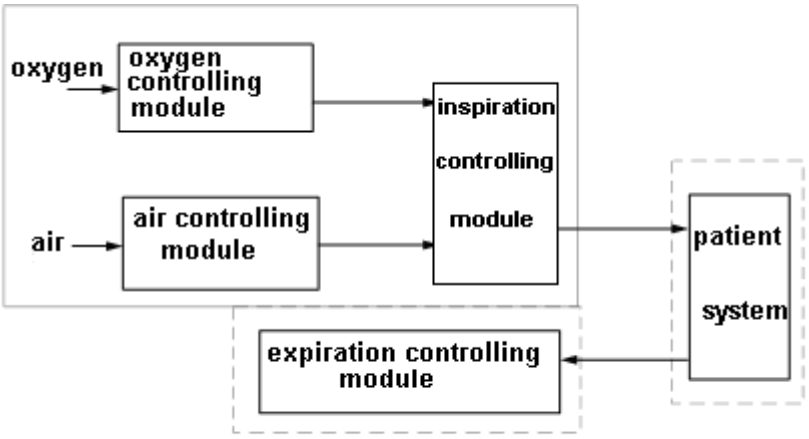


Figure A-2 Gas module connection view

A.2 Electrical system structure

A.2.1 General figure of the electrical system structure

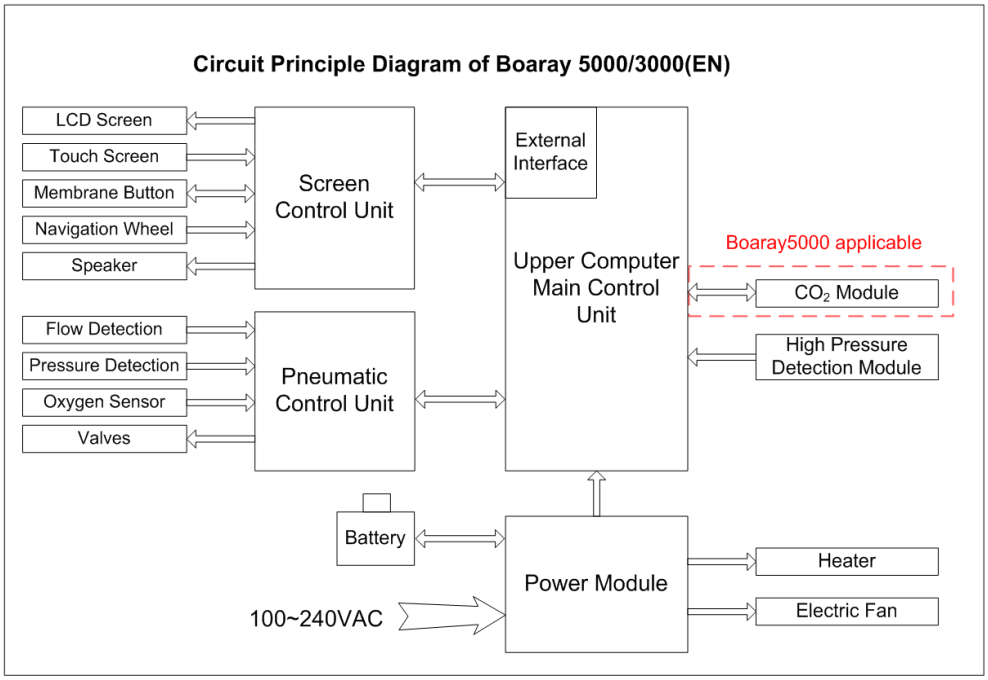


Figure A-3 Electrical system structure view

A.2.2 Principle

The hardware of the ventilator mainly consists of the power module, the main controlling unit, the pneumatic control unit and screen control unit. the diagram is shown as above, and the main function is described as following:

1. The power module, supply power for the boards, valves, sensors, heaters, fans etc. The input of the power module is selected in two ways, one is the network power (AC 100~240V), and the other is from lithium battery.
2. The main controlling unit, provide the running platform for the operation system; it is the center controlling unit and also the executive unit of the entire unit.
3. The airway controlling unit provides the drive and control for the valves and sensors, controlling the pressure and flow of the airway.
4. The display controlling unit provides the display and touches function, and do the coding of the encoder.

Appendix B Product specifications

This product conforms to the following standards.

- EN 60601-1/IEC60601-1 Medical electrical equipment Part I: General requirements for safety
- EN 60601-1-2 Medical electrical equipment -Part1-2: General Requirements for Safety- Collateral standard: Electromagnetic compatibility-Requirements and tests.
- ISO 80601-2-12 - Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.
- EN ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
- ISO 80601-2-55 Medical electrical equipment – Particular requirements for basic safety and essential performance of respiratory gas monitors
- IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

B.1 System

General information	**Contents**	
Classification	Ⅱb	
Electric shock defending type	TYPE: Ⅰ, containing the internal power supply When you have doubt about the integrality of the external protective grounded or the protective grounded cable, the equipment should be replaced by the internal power supply (batteries)	
Electic shock defending grade	TYPE B	
Waterproof level	IP 21	
Suitabel range	Pediatric (weight: 5 ~20kg) Adult (weight: 20 ~150kg)	
Power supply	External power supply	Power input: 100~240V, frequency 50/60Hz , Current input:1.5A (Max.)
	Backup	11.1VDC, 7800mAh

General information	Contents	
	batteries	
Gas supply	Pressure supply range	0.28~0.6MPa
	Gas impurity	The gas provided should not contain water, oil or impurity particle, and the content must be lower than the following standard. Air: H_2O<7g/m^3, Oil<0.5mg/m^3 Oxygen: H_2O<20mg/m^3
Environment	Working	Temperature: +10℃~+50℃ Humdity: ≤95%（non-condensation） Atmospheric pressure: 50 kPa~106 kPa
	Storage	Temperature: -20 ℃~55 ℃ Humdity: ≤95% (non-condensation) Atmospheric pressure: 50 kPa~106 kPa
The whole device	Trolley	Volume: 707×512×956 (mm), Weight: 18.7kg (net weight)
	Host	Volume: 489×443×541 (mm), Weight: 23.2kg (net weight)

B.2 Technical parameters

Parameter	Description
Category	Pneumatic electronically contronlled ventilator
Display	15 inch, TFT display, touch screen (optional)
Battery	Lithium batteries, power supply for at least 120 minutes.
Ventilation mode	VCV, PCV, PRVC, SIMV (VCV) + PS, SIMV (PCV) + PS, SIMV (PRVC) + PS (optional), DualPAP, PSV, APRV (optional), CPAP, NPPV, HFNC.
Graphics display	Waveform: prssure-time, flow-time, volume-time. Loop graph (optional): pressure-volume, flow-volume, flow-pressure. Others (optional): CO_2
Safe pressure in the airway system	≤125cmH_2O
Data communication interface	RS232 serial port, communication interface, LVDS interface
Sound pressure levels (Normal operation)	≤ 65dB (A)
Peak flow	180 L/min

B.3 Setting parameters

Parameter	Description	Accurancy
Tidal volume	Range: 20~3000 mL (D series) (Adult: 100-3000 mL; pediatric: 20-300 mL) Range: 50~1500 mL (C series) Increment: 20~100 mL: 5 mL 100~1000 mL: 10 mL 1000~2000 mL: 50 mL	±20mL, or ±15% of the set value, whichever is greater
Respiration frequency	Range: in SIMV mode: 1~40 bpm In other modes: 4~100 bpm, increment: 1 bpm	±2bpm or ±10% of the set value, whichever is greater
Inspiration time	Range: 0.1~10.0 s Increment: 0.1 s	±0.1s or ±10% of the set value, whichever is greater
Inspiratory to expiratory ratio	Range: 4:1~1:10 Increment: 0.5 Default I:E ratio: 1:2	
Breathing hold time	Range: 0~4 s Increment: 0.1 s	
Pressure trigger	Range: -20~-1 cmH_2O Increment: 1 cmH_2O	<-5 cmH_2O: ±1 cmH_2O, the other is ±20%
Flow trigger	Range: 0.5~20 L/min Increment: 0.5 L/min	<-5 L/min : ±1 L/min, the other is ±20%
PEEP	Range: 0~50 cmH_2O Increment: 1 cmH_2O	±2 cmH_2O or ±10% of the set value, whichever is greater
Pressure support	Range: 1~100 cmH_2O Increment: 1 cmH_2O P_{peak} (pressure support) = pressure setting (Pressure support) + PEEP	
Pressure control	Range: 5~100 cmH_2O Increment: 1 cmH_2O P_{peak} (pressure control) = pressure setting (pressure control) + PEEP	
High pressure level (optional)	Range: 5~100 cmH_2O Increment: 1 cmH_2O Not suitable for C series, and optional for D series	
Low pressure level (optional)	Range: 0~50 cmH_2O Increment: 1 cmH_2O Not suitable for C series, and optional for D series	
High pressure support (optional)	Range: 1~70 cmH_2O Increment: 1 cmH_2O	
Low pressure support (optional)	Range: 1~70 cmH_2O Increment: 1 cmH_2O	

Parameter	Description	Accurancy
Oxygen concentration	Range: 21~100% Increment: 1%	±6% of the set value
Apnea time	Range: 10~60 s Increment: 5 s	±1 s or ±10% of the set value
Oxygen therapy flow (HFNC)	Range: 2~100L/min Increment: 1L/min	± (1L/min+ 20% of the set value)
Expiratory trigger sensitivity	Range: 10~85% Increment: 5%	
P_{rate}	Range: 1~5 Increment: 1	

B.4 Monitoring parameters

Parameter	Description
Inspiration tidal volume	Range: 0~4000 mL, Resolution: 1 mL
Expiration tidal volume	Range: 0~4000 mL, Resolution: 1 mL
Spontaneous expiration tidal volume	Range: 0~4000 mL, Resolution: 1 mL
Minute ventilation volume	Range: 0~100 L, Resolution: 0.1 L
Spontaneous minute ventilation volume	Range: 0~100 L, Resolution: 0.1 L
Leakage minute volume	Range: 0~100 L, Resolution: 0.1 L
Total respiratory rate	Range: 0~200 bpm, Resolution: 1 bpm
Mandatory respiratory rate	Range: 0~200 bpm, Resolution: 1 bpm
Spontaneous respiratory rate	Range: 0~200 bpm, Resolution: 1 bpm
Inspiratory to expiratory ratio	Range: 100:1~1:150, Resolution: 0.1
Peak airway pressure	Range: -20~120 cmH_2O, Resolution: 1 cmH_2O
PEEP	Range: 0~120 cmH_2O, Resolution: 1 cmH_2O
Inspiration platform pressure	Range: -20~120 cmH_2O, Resolution: 1 cmH_2O
Average airway pressure	Range: -20~120 cmH_2O, Resolution: 1 cmH_2O
Minimum airway pressure	Range: -20~100 cmH_2O, Resolution: 1 cmH_2O
Expiratory time constant	Range: 0~10 s, Resolution: 0.01 s
Low tidal volume/Ideal body weight	Range: 0~50 mL/kg, Resolution: 0.1 mL/kg
Inspiratory time	Range: 0~60 s, Resolution: 0.1 s
Work of breathing	Range: 0~20 J/L, Resolution: 0.01 J/L
Fraction of inspired oxygen	Range: 0~100%, Resolution: 1%
Airway resistance	Range: 0~600 cmH_2O/(L/s), Resolution: 1 cmH_2O/(L/s)

Parameter	Description
Compliance	Range: 0~300 mL/cmH_2O, Resolution: 1 mL/cmH_2O
Rapid shallow breathing	Range: 0~1000 bpm/L, Resolution: 1 bpm/L
Occlusion pressure P0.1	Range: 0~30 cmH_2O, Resolution: 0.1 cmH_2O
Negative inspiration force	Range: -40~0cmH2O, Resolution: 0.1 cmH_2O
AutoPEEP	Range: 0~100cmH2O, Resolution: 0.1 cmH_2O
PR	Range: 30~250 bpm, Resolution: 1bpm
$EtCO_2$	Range: 0~99 mmHg, Resolution: 1mmHg
$InCO_2$	Range: 0~99 mmHg, Resolution: 1mmHg

B.5 Main alarm parameters

Alarm		Range
Tidal volume low	High	100~2000 mL, OFF
	Low	OFF, 20~2000 mL
Minute volume	High	0~40 L
	Low	OFF, 0~39 L
O_2 concentration	High	21~100%
	Low	OFF, 21~99%
Airway pressure	High	6~105 cmH_2O
	Low	0~99 cmH_2O
Frequency	High	1~100 bpm
	Low	0~99 bpm
$EtCO_2$ (optional)	High	1~99 mmHg
	Low	OFF, 0~98 mmHg
SPO_2 (optional)	Low	80~100%
O_2 supply pressure	High	110~750 KPa
	Low	100~740 KPa
Air supply pressure	High	110~750 KPa
	Low	100~740 KPa
PRVC airway pressure upper limits		Plimit≤Ppeak+5 cmH_2O
High Continues Pressure		It will give an alarm when the airway pressure is continuous above (PEEP+15) cmH_2O for 15 seconds
Apnea		Range:10~60 s, increment: 5 s

O_2 supply pressure low	The O_2 supply pressue is less than 0.28 MPa
Air supply pressure low	The O_2 supply pressue is less than 0.28 MPa
AC failure	The alarm time is more than 120s
Low battery capacity	The battery working time is 10 minutes after alarm
Battery exhausted	The battery working time is 5 minutes after alarm
Alarm silence count down	≤100 s
Alarm sound	>65dB

B.6 CO_2 module specification (Optional)

Parameters	**Specifications**	
Measuring mode	Mainstream	
Operation temperature	0~40℃/ 32-104℉	
Storage and transportation temperature	-40~75℃/ -40-167℉	
Operating humidity	< 40 hPa H2O (non-condensing) (95 %RH at 30 °C)	
Storage and transportation humidity	5~100 % RH, condensing	
Operation atmospheric pressure	525~1200 hPa (525 hPa corresponding to an altitude of 4572 m/15000 feet)	
Storage and transportation pressure	500~1200 hPa	
Total system response time	< 1 second	
Accuracy specifications (during standard conditions)	Range	Accuracy
	0~114 mmHg	±(0.2 mmHg + 2% of reading)

Appendix C Alarms

1.1 High priority alarms

Alarms content	**Possible reasons**	**Solutions**
Apnea	Exceed the pre-set value or the alarm limit. The interval time between the two continuous inspiring tries is above the preset limit value.	Check the patient and the breathing system. Check the settings of the ventilation.
Airway pressure high Note:	The airway pressure exceeds the preset upper limits pressure.	Check the patient and the breathing system.

Alarms content	Possible reasons	Solutions
If the airway pressure exceeds the pre-set up-limits pressure, the expiring valve opens.	The pipeline is twisted or blocked. Mucus or secretions blocks the airway pipeline or endotracheal. Patient's coughing or breathing rhythm is incompatible with the ventilator. alarm settings are Improper. Breath bacteria filter is blocked	Check the settings of the ventilation and the alarm limits.
Airway pressure low	The airway peek pressure is below the pre-set lower limit pressure. The tidal volume is set too low. The pipeline is falling off. Serious gas leakage. Improper alarm settings.	Check the patient and the breathing system. Check the settings of the ventilation and the alarm limits.
High Continues Pressure	The airway pressure is continuous above (PEEP+15) cmH2O for 15(±3) seconds.	Check the patient and the breathing system. Check the settings of the ventilation. If issues still exist,contact the maintenance technician.
O_2 supply pressure low	The opxygen supplying pressure is below 0.28Mpa. The oxygen supplying pipiline is cut off.	Check the oxygen supply pipeline, If issues still exist, contact the maintenance technician.
Air supply pressure low	The air supply pressure is lower than 0.28MPa. The air supply tube is cut off.	Check and connect the air supply pipeline. If issues still exist, contact the maintenance technicians.
The pipeline is falling off	The probe of the Patient's gas pipeline or breathing sensor has malfunctions. The Breathing sensor is disconnected. The breath sensor probe is pluged up. Ventilator breath sensor probe sampling tube stagnant water. The sampling tube of the sensor probe is stored with water. Leak excessive.	Remove the water from the pipeline and check the humidifier settings, such as the relative hummidity settings. Check the heating cable of the humidifier (if installed). Check the pipeline connections and the expiration sensor probe connections.
Battery exhausted	The battery power modules can maintain less than 5 minutes	Connected to the main power supply. Plug in the charged

Alarms content	Possible reasons	Solutions
		battery modules. (connect the ventilator to the power supply and charge the battery modules).
Inspiratoryh O_2 low	The measured oxygen concentration is lower than the per-set value or even lower. The gas supplied in the oxygen tube is not the oxygen. The oxygen sensor is malfunctioned or invalid. The oxygen sensor has not been calibrated. The oxygen modules have malfunction.	Check the oxygen supply pipeline
O_2 sensor is not connected or failure	O_2 sensor is disconnected or invalid.	connect and replace O_2 sensor.
System leakage	Breathing tubes and expiratory valve leak	Please check the breathing tubes and expiratory valve.
Inspiratory air Flow Sensor is failure	Inspiratory air Flow Sensor is invalid.	Please calibrate or replace.
Inspiratory O_2 Flow Sensor is failure	Inspiratory O_2 Flow Sensor is invalid.	Please calibrate or replace.
Pressure Sensor is failure	Pressure Sensor is invalid.	Please calibrate or replace.
5V power failure	5V voltage error	Please contact the after service dept. of the company.
10V power failure	10V voltage error	Please contact the after service dept. of the company.
12V power failure	12V voltage error	Please contact the after service dept. of the company.
-12V power failure	-12V voltage error	Please contact the after service dept. of the company.
AC failure	Not connected to the main power supply.	Connected to the main power supply.
Battery failure	Not connected to the battery.	Connected to the battery.

2.1 Medium priority alarms

Alarms content	Possible reasons	Solutions
Minute ventilation high	Exceeding the pre-set value or the default alarm limit value. The ventilator triggers automatically (auto-circle).	Check the patient and the breathing system. Check the settings of the trigger sensitivity.

Alarms content	Possible reasons	Solutions
	Improper alarm limit settings.	Check the alarm settings.
Minute volume low	Exceeding the pre-set value or the defaut alarm limit value. Note: this alarm is also for the disconnection of the patient. The patient's spontaneous breathing is reduced. There is leakage in the airwayand the patient's breathing system. The warning setting is improper.	Check the patient and the breathing system. Check the pipleline outlet hoop perssure. Check the patient's breathing system (do the leak test if possible) Check the paused time and the graphical display to verify. Considering use the ventilator to increase the patient's respiratory support.
Low battery capacity	The battery modules can maintain for less than 10 minutes	Plug in the new battery modules or connected to the main power supply.
Inspiratory O_2 concentraion high	The measured oxygen concentration exeeds the pre-set value or even more. The gas supply device or the air pipe line is disconnected. No air in the gas supply pipe line of the wall. Check if the air supply pressure is too low. The air modules are cut off. If failure to supply gas, the expiratory vavle and the safey valve will open.	Check the air supply device.
Tidal volume low	The gas supply pressure is low and leads to low tidal volume. there is leakage in the pipe line and leads to low tidal volume. The inspiratory valve faiures and leads to low inspiratory tidal volume. The pipe line is pluged, and the pressure protecting leads to low tidal volume.	Check the gas supply and the gas pipe. If issues still exist, contact the maintenance technicians.

3.1 Low priority alarms

Alarms content	Possible reasons	Solutions
Frequency high	The breathing frequency is too high. Triggering automatically. Leakage in the pipeline.	Check and take care of the patient Check the trigger settings. Check the connection of the

		patient’s pipiline.
Frequency low	The breathing frequency is too low. Improper setting of the trigger sensitivity. High tidal volume.	Check and take care of the patient Check the trigger settings. Check the inspiratory terminate settings.

Appendix D Symbols and glossary

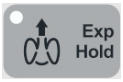
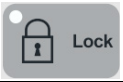
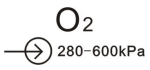
D.1 Glossary

Terminology	Definition
VCV	Volume control ventilation
PCV	Pressure vontrol ventilation
SIMV	Synchronized intermittent mandatory ventilation
PSV	Pressure support ventilation
DualPAP	Dual Positive Airway Pressure
SPONT	Spontaneous breathing
PRVC	Pressure Regulated Volume Control
CPAP	Continuous Positive Airway Pressure
NPPV	Noninvasive positive pressure ventilation
HFNC	High Flow Nasal Cannula
V_T	Tidal volume, unit: mL
V_{TI}	Inspiration tial volume, unit: mL
V_{TE}	Expiration tial volume, unit: mL
MV	Mechanical minute ventilation volume, unit: L/min
MVspn	Spontaneously minute ventilaion volume, unit: L/min
Freq	Setting: mechanical ventilaion frequency; monitoring:total breathing frequency; unit: bpm
f_{spn}	Spontaneous breathing frequency, unit: bpm
T_I	Inspiration time, unit: s
T_P	Breathing hold time,unit: s
I:E	Inspiration and Expiration rate
P_{TRIG}	Pressure trigger, unit: cmH_2O
F_{TRIG}	Flow trigger,unit: L/min or LPM
PEEP	Positive expiration end pressure,unit: cmH_2O
P_{supp}	Pressure spport, unit: cmH_2O
P_{insp}	pressure control, unit: cmH_2O
P_{limit}	Pressure limit, unit: cmH_2O
P_{high}	High pressure level, unit: cmH_2O

Terminology	Definition
T_{high}	High pressure time, unit: s
P_{low}	Low pressure level, unit: cmH_2O
PS_{high}	High pressure support , unit: cmH_2O
PS_{low}	Low pressure support, unit: cmH_2O
P_{peak}	Airway peek pressure, unit: cmH_2O
P_{mean}	The average airway pressure, unit: cmH_2O
P_{plat}	Inspiration platform pressure, unit: cmH_2O
P_{min}	Minimum airway pressure, unit: cmH_2O
P_{rate}	Time for the pressure to rise to target pressure
ETS	The expiration sensitivity, unit: %
FiO_2	The oxygen concentration, unit: %
R	The airway resistance, unit: $mH_2O(L/s)$
C	Compliance, unit: mL/cmH_2O
RSB	Rapid shallow breathing, unit: bpm/L
P0.1	Occlusion pressure, unit: cmH_2O
NIF	Negative inspiration force, unit: cmH_2O
AutoPEEP	Intrinsic PEEP, unit: cmH_2O
Weight	Weight, unit: kg
Kg	Kilogram
mL	Milliliter
L	Litre
bpm	Bit per minute
L/min or LPM	Litre per minute
cmH_2O	Centimeter water column
Paw-T	Pressure-time waveform
Flow-T	Flow-time waveform
V-T	Volume-time waveform
F-V	Flow-volume loop
P-V	Pressure-volume loop
F-P	Flow-pressure loop
O_2	Oxygen
$EtCO_2$	End expiratory CO_2
$InCO_2$	Inspiratory CO_2

Terminology	Definition
HME	Heat and moisture exchanger

D.2 Equipment symbols

	Consult instructions for use		Alarm silence icon
	Manual inspiration button		Inspiration hold button
	Expiration hold button		Alarm silence button
	100% O_2 2 minutes button		Alarm reset button
	Lock button		Standby button
	Expiration valve unlock label		AC power indicator light
	Battery indicator light		Battery
	Nebulizer		Screen and membrane button lock
	Screen and membrane button unlock		Inspiration port
	Expiration port		CE mark
	Vendor - special data serial port		Fuse
	The air source connector		The Oxygen source connector
RS 232 Serial port	Vendor - special data port		System switch
	Manufacturer		Year of manufacture
SN	Serial number		Authorized representative in the EUROPEAN COMMUNITY

	Adult		Pediatric
	Spontaneous breathing		Freeze
	This symbol indicates TYPE B applied part according to the IEC 601601-1 standard		
	Type BF applied part. Defibrillator-proof protection against electric shock.		
	This symbol indicates protective ground. Connected to the external protective grounded systems.		
	Equipotential terminals, used to connect the different parts of the equipment or the systems to the same potential, does not absolutely refer to the grounded potential.		
	The exhausted batteries should not be disposed in a normal way. In some areas, there may be no recycle facilities.		
	Proper disposal of products		

D.3 Package symbols

	THIS WAY UP		FRAGILE
	DO NOT ROLL		KEEP AWAY FROM RAIN
	STACK limit BY NUMBER		KEEP AWAY FROM SUNLIGHT

Caution：

- Due to the different configuration, some symbols may be not entirely consistent to the equipment, please take the equipment as valid.

Appendix E Electromagnetic Capability

⚠Cautions:

- Boaray 5000 C/D series should meet the requirement of electromagnetic compatibility in EN 60601-1-2:2015.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication devices may influence the system's performance, so it should be kept away from them during using.
- Please refer to the below section of guidance of electromagnetism compatibility and manufacturer's declaration.

⚠Warnings:

- Boaray 5000 C/D series should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.
- Type A equipment is intended for use in the industrial environment, due to the conduction and radiation disturbance of the Boaray 5000 C/D series. it is difficult to ensure the electromagnetic compatibility while using in other environments.
- Cables or components as the spare parts supplied by the manufacturer must be used for Boaray 5000 C/D series, otherwise, it might cause the increase of emissions or the decrease of immunity.

Attachments:

Guidance and manufacturer's declaration – electromagnetic emission		
Boaray 5000 C/D series is intended for use in the electromagnetic environment specified below. The customer or the user of Boaray 5000 C/D series should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Boaray 5000 C/D series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Boaray 5000 C/D series is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
Boaray 5000 C/D series is intended for use in the electromagnetic environment specified below. The customer or the user of the Boaray 5000 C/D series should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV for input/output lines ±2 kV for lines to ground	±1 kV for input/output lines ±2 kV for lines to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT)	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Boaray 5000 C/D series requires

input lines IEC 61000-4-11	for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	in UT) for 5 sec	continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity

Boaray 5000 C/D series is intended for use in the electromagnetic environment specified below. The customer or the user of the Boaray 5000 C/D series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V (effective value) 150 kHz~80 MHz	3V (effective value)	Portable and mobile RF communications equipment should be used no closer to any part of the Boaray 5000 C/D series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = $1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz~2.5 GHz	3V/m	d = $1.2\sqrt{P}$ 80 MHz~800 MHz d = $2.3\sqrt{P}$ 800 MHz~2.5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Boaray 5000 C/D series is used exceeds the applicable RF compliance level above, the Boaray 5000 C/D series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Boaray 5000 C/D series.

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

Recommended separation distances between portable and mobile RF communications equipment and the Boaray 5000 C/D series

Boaray 5000 C/D series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Boaray 5000 C/D series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Boaray 5000 C/D series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance/m according to frequency of transmitter		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Appendix F Default settings

The table below lists the default ventilator settings.

Power on default settings		
Patient category	Adult	Pediatric
Weight	65kg	7.5kg
Ventilation mode	VCV	VCV
Ventilation parameter default settings		
Patient category	Adult	Pediatric
T_i (s)	1.7	0.5
V_T (mL)	450	50
f (bpm)	12	30
T_P (s)	0	0
PEEP (cmH_2O)	0	0
F_{TRIG} (L/min)	2	2
P_{TRIG} (cmH_2O)	-3	-3
P_{supp} (cmH_2O)	PEEP+12	PEEP+6
P_{insp} (cmH_2O)	PEEP+12	PEEP+6
P_{High} (cmH_2O)	12	6
P_{Low} (cmH_2O)	0	0
ETS (%)	30	30
FiO_2 (%)	40	40
Prate	3	3
Tapnea (s)	20	20
Alarm default settings		
Tidal volume (mL)	Lower limit: Adult: 100; Pediatric: 30	
Minute ventilation volume (L)	Upper limit: 20 Lower limit: Adult: 3; Pediatric:1	
Respiratory frequency (bpm)	Upper limit: 40	

	Lower limit: 0
Inspiratory oxygen concentration (%)	Upper limit: 60 Lower limit: OFF
Airway pressure (cmH_2O)	Upper limit: Adult: 40; Pediatric: 20 Lower limit: 0
End expiratory CO_2 (mmHg)	Upper limit: 60 Lower limit: 30
Inspiratory CO_2 (mmHg)	Upper limit: 4 Lower limit: OFF
SPO_2 (%)	Lower limit: 90
Oxygen supply (kPa)	Upper limit: 600 Lower limit: 280
Air supply failure	Upper limit: 600 Lower limit: 280