

SH200 Emergency Ventilator

User Manual

Beijing Eternity Electronic Technology Co. Ltd.

User Responsibility

This product will perform in conformity with the description contained in the operating manual and accompanying labels and inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked periodically. Do not use product if defective. Replace all broken, missing, worn, distorted or contaminated parts. If repair or replacement becomes necessary, a telephone call or written request for service advice should be made to the nearest Eternity customer service center. This product or any of its parts must be repaired in accordance with the written instructions provided by Eternity and by Eternity trained personnel. The product must not be altered without the prior written approval of Eternity. The user of this product shall assume the full responsibility for any malfunction resulting from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Eternity personnel.

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Foreword

Thank you for purchasing and utilizing Eternity equipment.

For using the apparatus rightly and effectively, please read throughly and carefully the User Manual before use.

Any use of the apparatus requires full understanding and strict observation of these instructions.

The apparatus is only to be used for purpose specified here.

One who is not authorized by Eternity shall not be allowed to open and dismantle the apparatus for maintaining, checking and repairing.

For further assistance contact Eternity, good service would be supplied.

While this manual covers the ventilator configurations currently supported by Eternity, it may not be all-inclusive and may not be applicable to your ventilator.

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Conformity according to the Council Directive 93/42/EEC concerning Medical Devices

1 Introduction

1.1 What's SH200?

The SH200 emergency and transport ventilator is designed to manage work of breathing, offer different modes of breath delivery, and help a practitioner select the most appropriate ventilator settings. The user interface is intended to be intuitive to anyone who knows how to operate a ventilator, and can be learned with minimal training. The user interface includes 5.6" TFT screens that display monitored data separately from ventilator settings for easy assessment of your patient's condition.

 **WARNING:** The user of SH200 must be professional and trained.

 **WARNING:** SH200 is unsuitable for use in a magnetic resonance imaging (MRI) environment.

 **WARNING:** SH200 shall not be covered or positioned in such a way that the operation or performance of the ventilator is adversely affected positioned next to a curtain that blocks the flow of cooling air, thereby causing the EQUIPMENT to overheat.

The SH200 Ventilator is a high-capability ventilator intended for acute and subacute care of pediatrics, and adult patients. The user interface, breath delivery, and patient monitoring capabilities are designed for easy future enhancement. Mobile use for emergency medical care or primary care of emergency patients:

- During transport in emergency rescue vehicles or aircraft including helicopters,
- In accident and emergency departments, in the recovery room.

 **WARNING:** SH200 is not to be used with infant.

1.2 Symbols

 Warnings and  Cautions indicate all the possible dangers in case of violation of the stipulations in this manual. Refer to and follow them.

 **WARNING:** indicates potential hazards to operators or patients

 **CAUTION:** indicates potential damage to equipment

Instead of illustrations, other symbols may also be utilized. Not all of them may necessarily appear in the equipment and manual. The symbols include:

	ON (Power)		Type B equipment
	OFF (Power)	SN	Serial Number

	Protectively earth		Warning or Caution, refer to the manual
IPX4	Device protected from water sprayed from all directions, limited entrance allowed		Assist breath
	Battery		Buzzer silence
	Date of manufacture		Address of manufacture
	Alternating Current		Do not dispose of the device as municipal waste, but dispose of at municipal collection points for waste electrical and electronic equipment.
	Warning light		

1.3 Definitions, Acronyms, and Abbreviations

Rate	Respiratory rate.breaths per minute
fspn	Respiratory rate of spontaneous breathing by the patient
f	Total respiratory rate
FiO ₂	Delivered oxygen percentage
R	Inspiratory resistance
C	Lung compliance
MV	Exhaled minute volume
MVspn	Minute volume of spontaneous expiration by the patient
Paw	Real time patient airway pressure
flow	Real time gas flow
PEEP	Positive end expiratory pressure
Pmean	Mean airway pressure is updated every at the end of last breath cycle, i.e. a running mean
Ppeak	Maximum patient airway pressure during a patient breath
F-tr	Triggerflow

TI	Inspiration time
Volume	Real time gas volume
VT	Tidal volume of mechanically delivered breaths
VTE	Exhaled tidal volume
VTI	Inhaled tidal volum
Pmax	Pressure limit

2 Structure

2.1 Frontview

CAUTION: Monitoring conditions of this system: inspiratory module: ATPD, Expiratory module: BTPS.

WARNING: Independent means of ventilation (e.g. a self-inflating manually powered resuscitator with mask) should be available whenever the SH200 Ventilator is in use.

WARNING: Do not use antistatic or electrically-conductive breathing tubes, hose or mask.

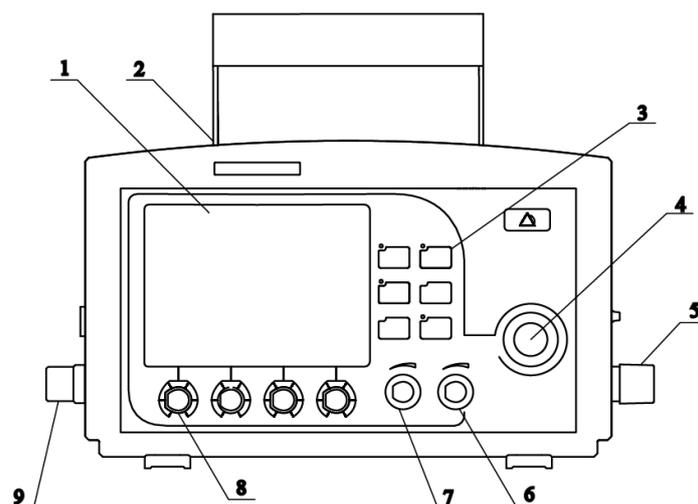


Figure 2-1 Front view of SH200

- | | |
|------------------------|------------------------------|
| 1. Display monitor | 2. Holder |
| 3. keys and indicators | 4. ComWheel |
| 5. Insp hole | 6. tidal volume setting |
| 7. FiO2 setting | 8. breath parameters setting |
| 9. Oxygen inlet | |

1. display monitor

it displays the most information including alarm message, patient data, waveform monitored etc. More details refer to section 2.2.

2. holder
3. keys and indicators

	Alarm silence	Alarm silence key. Turns off alarm sound for 2 minutes . The yellow light on the alarm silence key lights during the silence period, and turns off if you press the alarm silence key again or the 2-minute interval times out.
	Alarm reset	Clears inactive alarms
	Return	Return to home page directly.
	Standby/Start	System turned ON first is in a state of standby, and the indicator light is ON. Push standby key to start ventilation, the indicator light is OFF.
	Menu	Push to show corresponding menu. The yellow light on the menu key lights during menu operating period.
	AC power indicator lamp	When the ventilator connected AC power, the lamp is on.
	Internal battery indicator lamp	When the ventilator work use battery , the lamp is on.
	battery charging indicator lamp	When battery charging, the lamp is on ,when the battery is full the lamp is off.
	Parameters knob	Set breath parameters directly.Rotate to increase or decrease.
	ComWheel	Push to select a menu item or confirm a setting. Turn clockwise or counterclockwise to scroll menu items or change settings.
	Tidal volume knob	Set Tidal volume.Rotate to increase or decrease.
	Oxygen concentration knob	Set Oxygen concentration.Rotate to increase or decrease.

2.2 LCD screen

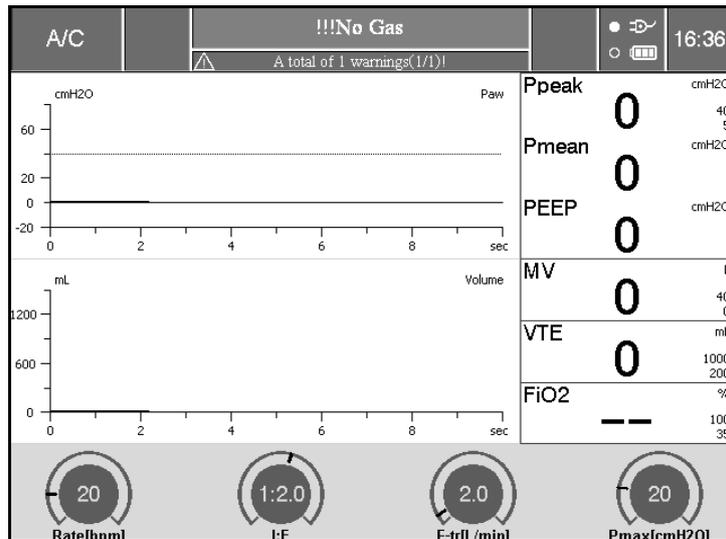


Figure 2-2 Main interface

1. Parameters monitored area

Parameters monitored on the main interface are: MV, VTE, PEEP, FiO₂, etc. the upper and lower limit can be set on the *alarm settings* menu.

2. Waveforms

In fault, it has two types of waveform to display, more types of waveform can be set on the *system configure* menu.

3. Parameters setting bar

Ventilating parameters are on the bottom of screen, you can use the ComWheel to setup.

4. Information bar

In the information bar, the left is ventilation mode and assist symbol; alarm message at the middle; the right is additional information such as power, time, or locking icon.

- When silencing, the icon  appears behind the alarm message and 2-minute counts down.
- When triggering, the icon  appears until inspiratory phase ending.
- The icon  indicates internal battery capacity statement, it has four states from full to empty. When mains fails, the internal battery will supply to ventilator automatically.

2.3 Side view 1

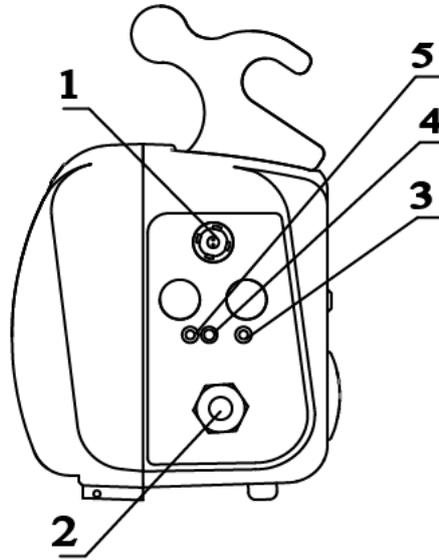


Figure 2-3 Side view 1 of SH200

- 1. oxygen sensor connector
- 2. Insp hole
- 3. Sockets for Exhaust valve control hoses
- 4. Sockets for pressure measuring hoses (low pressure)
- 5. Sockets for pressure measuring hoses (high pressure)

2.4 Side view 2

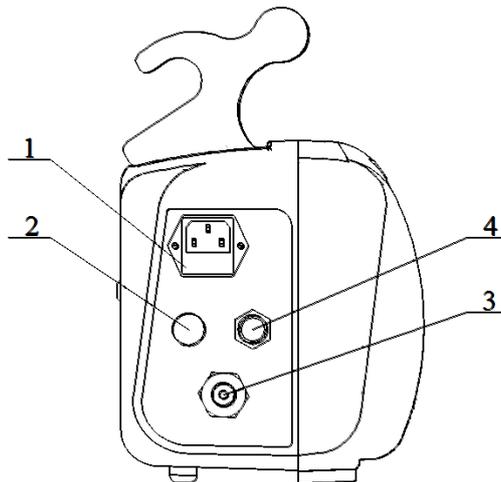


Figure 2-4 Side view 2 of SH200

- 1. Power connect
- 2. DC power supply socket
- 3. Oxygen inlet
- 4. Power switch

2.5 Back view

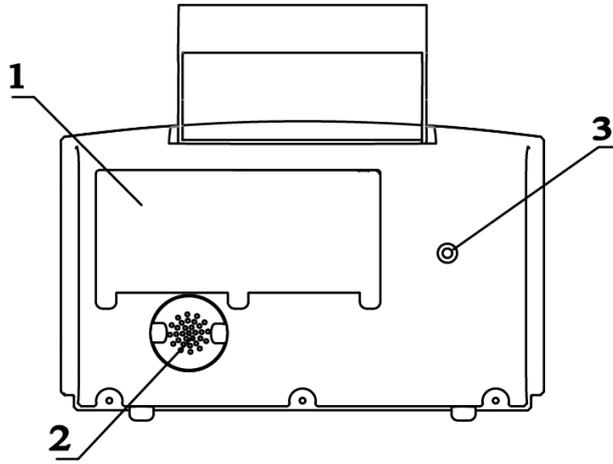


Figure 2-5 Back view of SH200

1. Battery box

2. Fresh gas inlet

3. Exhaust

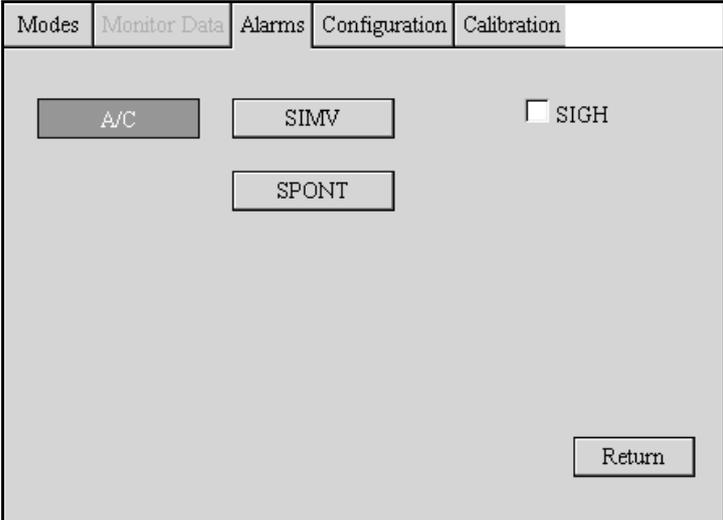
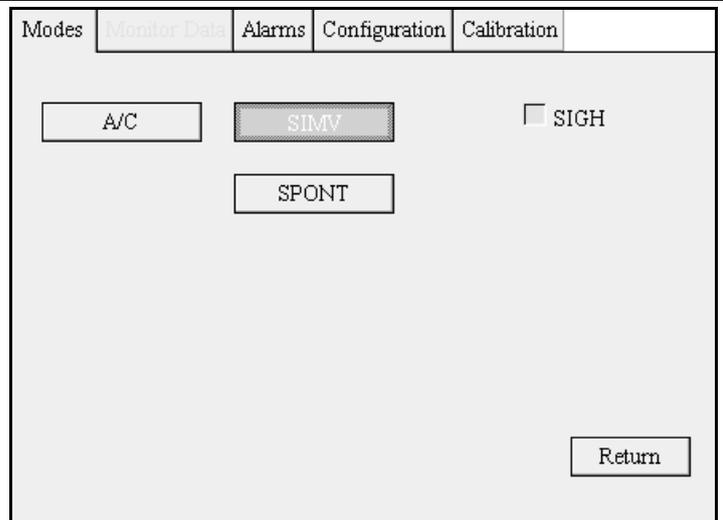
3 Operating Guide

3.1 Starting System

<p>Step 1 Connect power supply</p> <p>Plug the power cord into AC power outlet. The power indicator light will be bright when power is connected.</p>	
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<p>Step 2 Power On</p> <p>Set power switch to ON (“”).</p> <p>The ventilator startup, the display screen lights and shows startup interface, see figure 3-1. After a while, Standby interface appears on the screen. See figure 3-2.</p> <p>Press the <i>Standby</i> key, the display screen switches to main interface.</p> <p>Switch to standby interface from main interface by pressing the Standby key for 3 to 5 seconds.</p>	<div style="text-align: center;">  <p>Figure 3-1 Startup interface</p> </div> <div style="text-align: center;">  <p>Figure 3-2 Standby interface</p> </div>
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3.2 Setup ventilation mode

<p>Step 1</p> <p>Press the <i>menu</i> key, the ventilation mode menu appears on the screen as showed right figure,the mode of focused item is current ventilation mode.</p>	 <p>The screenshot shows a menu with five tabs: Modes, Monitor Data, Alarms, Configuration, and Calibration. The 'Modes' tab is active. Below the tabs are five buttons: A/C, SIMV, SPONT, SIGH (with an unchecked checkbox), and Return. The A/C button is highlighted with a dark grey background, indicating it is the selected mode.</p>
<p>Step 2</p> <p>Turn the ComWheel, the cursor will move by selected item. Push the ComWheel, selected item will be focused to display like right figure. At the same time,vent parameters will be changed in Parameters setting bar.</p>	 <p>The screenshot shows the same menu as in Step 1. In this step, the SIMV button is highlighted with a dark grey background, indicating it is the selected mode. The other elements (tabs, A/C, SPONT, SIGH, Return) remain the same.</p>

Setting other ventilation mode is similar to the above.

3.3 Ventilation mode introduction

3.3.1 A/C

In A/C mode, the ventilator delivers only mandatory breaths by setting tidal volume. When the ventilator detects patient inspiratory effort, it delivers a patient-initiated mandatory (PIM) breath (also called an assisted breath). If the ventilator does not detect inspiratory effort, it delivers a ventilator-initiated mandatory (VIM) breath (also called a control breath) at an interval based on the set respiratory rate. Breaths can be pressure-triggered or flow-triggered in A/C mode.

Figure 3-3 shows A/C breath delivery when no patient inspiratory effort is detected and all inspirations are VIMs. And T_b is the breath period in seconds.

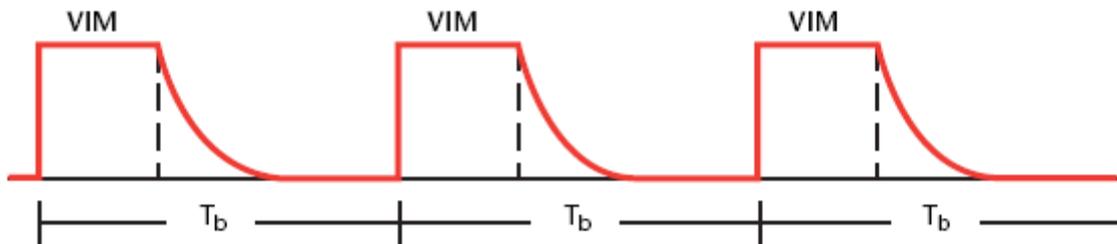


Figure 3-3 A/C mode, no patient effort detected

Figure 3-4 shows A/C breath delivery when patient inspiratory effort is detected. The ventilator delivers PIM breaths at a rate more than the set respiratory rate. And T_b is the breath period in seconds.

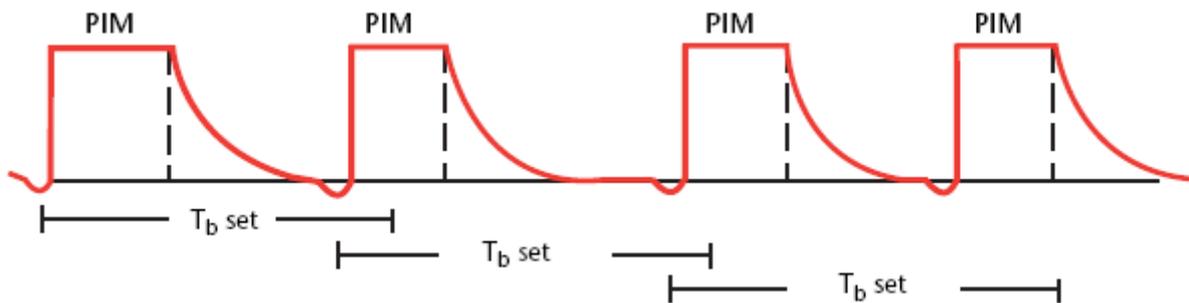


Figure 3-4 A/C mode, patient effort detected

Figure 3-5 shows A/C breath delivery when there is a combination of VIM and PIM breaths. And T_b is the breath period in seconds.

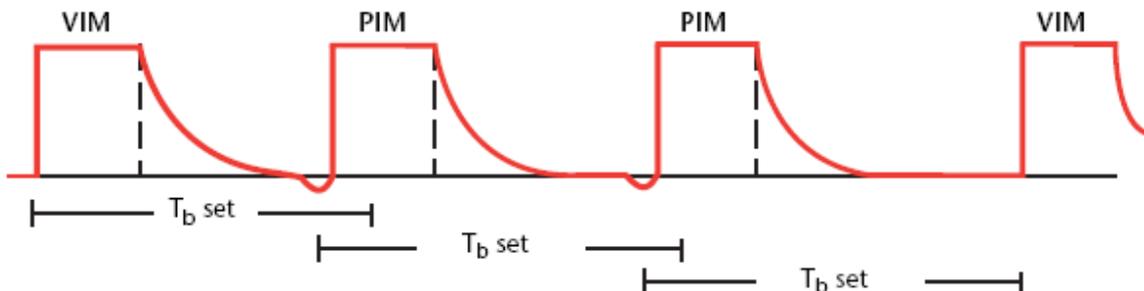


Figure 3-5 A/C mode VIM and PIM breaths

⚠ Caution :

Setting of trigger pressure' false or ability for breath of patient intensify may lead to A/C mode delivers too much.

3.3.2 A/C+SIGH

A/C+SIGH, base on A/C mode. The difference is a high tidal volume (1.5 times as set) delivers every 100 breath.

3.3.3 SIMV

SIMV (Synchronized Intermittent Mandatory Ventilation) is a mixed ventilator mode that allows both mandatory and spontaneous breaths. The mandatory breaths can be only volume(**SIMV-V**), and the spontaneous breaths can be pressure-assisted (6 cmH₂O above baseline).

The SIMV algorithm is designed to guarantee one mandatory breath each SIMV breath cycle. This mandatory breath is either a patient-initiated mandatory (PIM) breath (also called an assisted breath) or a ventilator-initiated mandatory (VIM) breath (in case the patient's inspiratory effort is not sensed within the breath cycle).

As Figure 3-6 shown, each SIMV breath cycle (T_b) has two parts: the first part of the cycle is the mandatory interval (T_m) and is reserved for a PIM. If a PIM is delivered, the T_m interval ends and the ventilator switches to the second part of the cycle, the spontaneous interval (T_s), which is reserved for spontaneous breathing throughout the remainder of the breath cycle. At the end of an SIMV breath cycle, the cycle repeats. If a PIM is not delivered, the ventilator delivers a VIM at the mandatory interval, then switch to the spontaneous interval.

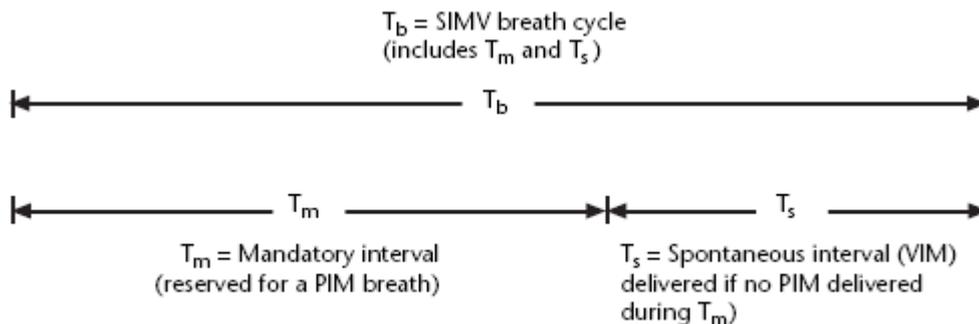


Figure 3-6 SIMV breath cycle (mandatory and spontaneous intervals)

⚠ Warning

This mode may cause insufficient ventilation or apnea if patient 'state becomes depravation.

Apnea Backup ventilation is active in spont mode. During Apnea Backup, the ventilator automatically initiates a breath when no breaths have been delivered during the preset apnea "time out" interval. The apnea "time out" interval is the Apnea Interval alarm setting. At the onset of apnea backup ventilation, the ventilator delivers a mandatory breath. The ventilator continues to deliver breaths until the patient initiates two consecutive breaths.

⚠ Warning

Volume breaths is offered for apnea backup delivery.

3.4 Alarm Settings menu

Press the Alarm Settings key, the following menu appears on the screen.

Modes	Monitor Data	Alarms	Configuration	Calibration
		Lower	Higher	
Pressure cmH ₂ O		<input type="text" value="5"/>	<input type="text" value="40"/>	Apnea Time <input type="text" value="15"/>
MV L		<input type="text" value="0"/>	<input type="text" value="40"/>	Loudness <input type="text" value="5"/>
Rate bpm		<input type="text" value="0"/>	<input type="text" value="100"/>	
FiO ₂ %		<input type="text" value="35"/>	<input type="text" value="100"/>	
VTE mL		<input type="text" value="200"/>	<input type="text" value="1000"/>	
<input type="button" value="Alarm Log"/>		<input type="button" value="Auto Set"/>		<input type="button" value="Return"/>

Figure3-7 Alarm settings menu

3.4.1 Setting alarm parameters

There are the following parameters can be set:

- MV: Higher limit and lower limit, unit: L;
- Pressure: Higher limit and lower limit, unit: 1cmH₂O;
- VTE: Higher limit, unit: mL
- Rate: Higher limit, unit: bpm
- Tapnea: Higher limit, unit: second;
- FiO₂ : upper limit and lower limit
- Loudness: 5 rating: 1, 2, 3, 4, 5.

All alarm parameters have a set of presets:

- MV higher limit =40 L,MV lower limit= 0L
- Pressure higher limit = 40cmH₂O, Pressure lower limit = 5cmH₂O
- VTE Higher limit = 600mL,VTE lower limit= 200mL
- Rate higher limit= 5bpm,Rate lower limit= 40bpm
- Tapnea Higher limit = 15s
- FiO₂ higher limit= 100%, FiO₂ lower limit= 21%



CAUTION: When the ventilator restarts,alarm limits will be preset automaticly!
CAUTION: Setting ALARM LIMITS to extreme values that can render the ALARM SYSTEM useless !

Setting method as shown in the following, taking *alarm volume* for example.

<p>Step 1</p> <p>Turn the ComWheel to select loudness button and push it, as shown in the right figure.</p>	<table border="1" style="width: 100%; border-collapse: collapse; background-color: #f0f0f0;"> <tr> <td style="text-align: left;">Modes</td> <td style="text-align: left;">Monitor Data</td> <td style="text-align: left;">Alarms</td> <td style="text-align: left;">Configuration</td> <td style="text-align: left;">Calibration</td> </tr> <tr> <td></td> <td style="text-align: center;">Lower</td> <td style="text-align: center;">Higher</td> <td></td> <td></td> </tr> <tr> <td>Pressure cmH2O</td> <td style="text-align: center;">5</td> <td style="text-align: center;">40</td> <td></td> <td>Apnea Time 15</td> </tr> <tr> <td>MV L</td> <td style="text-align: center;">0</td> <td style="text-align: center;">40</td> <td></td> <td>Loudness 3</td> </tr> <tr> <td>Rate bpm</td> <td style="text-align: center;">0</td> <td style="text-align: center;">100</td> <td></td> <td></td> </tr> <tr> <td>FiO2 %</td> <td style="text-align: center;">35</td> <td style="text-align: center;">100</td> <td></td> <td></td> </tr> <tr> <td>VTE mL</td> <td style="text-align: center;">200</td> <td style="text-align: center;">1000</td> <td></td> <td></td> </tr> <tr> <td colspan="2" style="text-align: center;">Alarm Log</td> <td colspan="2" style="text-align: center;">Auto Set</td> <td style="text-align: center;">Return</td> </tr> </table>	Modes	Monitor Data	Alarms	Configuration	Calibration		Lower	Higher			Pressure cmH2O	5	40		Apnea Time 15	MV L	0	40		Loudness 3	Rate bpm	0	100			FiO2 %	35	100			VTE mL	200	1000			Alarm Log		Auto Set		Return
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Rate bpm	0	100																																							
FiO2 %	35	100																																							
VTE mL	200	1000																																							
Alarm Log		Auto Set		Return																																					
<p>Step 2</p> <p>Turn the comwheel to select appropriate alarm volume and push it. You cannot turn off alarm volume.</p>	<table border="1" style="width: 100%; border-collapse: collapse; background-color: #f0f0f0;"> <tr> <td style="text-align: left;">Modes</td> <td style="text-align: left;">Monitor Data</td> <td style="text-align: left;">Alarms</td> <td style="text-align: left;">Configuration</td> <td style="text-align: left;">Calibration</td> </tr> <tr> <td></td> <td style="text-align: center;">Lower</td> <td style="text-align: center;">Higher</td> <td></td> <td></td> </tr> <tr> <td>Pressure cmH2O</td> <td style="text-align: center;">5</td> <td style="text-align: center;">40</td> <td></td> <td>Apnea Time 15</td> </tr> <tr> <td>MV L</td> <td style="text-align: center;">0</td> <td style="text-align: center;">40</td> <td></td> <td>Loudness 3</td> </tr> <tr> <td>Rate bpm</td> <td style="text-align: center;">0</td> <td style="text-align: center;">100</td> <td></td> <td></td> </tr> <tr> <td>FiO2 %</td> <td style="text-align: center;">35</td> <td style="text-align: center;">100</td> <td></td> <td></td> </tr> <tr> <td>VTE mL</td> <td style="text-align: center;">200</td> <td style="text-align: center;">1000</td> <td></td> <td></td> </tr> <tr> <td colspan="2" style="text-align: center;">Alarm Log</td> <td colspan="2" style="text-align: center;">Auto Set</td> <td style="text-align: center;">Return</td> </tr> </table>	Modes	Monitor Data	Alarms	Configuration	Calibration		Lower	Higher			Pressure cmH2O	5	40		Apnea Time 15	MV L	0	40		Loudness 3	Rate bpm	0	100			FiO2 %	35	100			VTE mL	200	1000			Alarm Log		Auto Set		Return
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Rate bpm	0	100																																							
FiO2 %	35	100																																							
VTE mL	200	1000																																							
Alarm Log		Auto Set		Return																																					

3.4.2 Alarm log submenu

To view the alarm log, turn the knob to select the *Alarm Log* button and press it, the Alarm Log submenu appears. See the following figure.

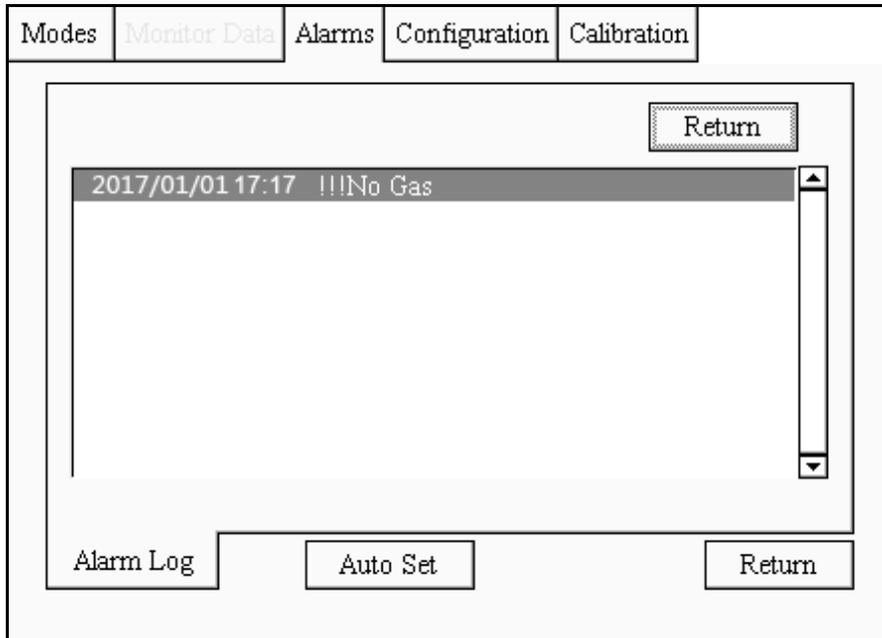


Figure 3-8 Alarm log submenu

The alarm log shows alarm events in order of occurrence, with the most recent event at the top of the list.

View alarm log:

Turn the comwheel to select listbox button and push it, the rectangle frame outside alarm event activated. Then rotate the comwheel to check details up and down.

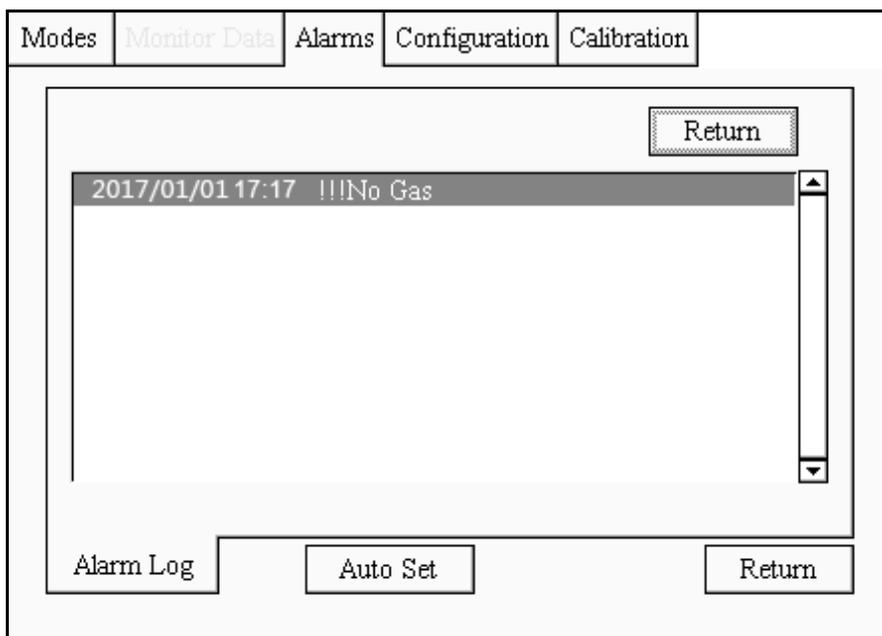


Figure 3-9 Alarm log inquire

NOTE:

The alarm log can store up to 200 of the most recent entries. When the alarms happen, the ventilator saves the alarm type and time automatically.

When ventilator is powered down or experiences a total loss of power for a finite duration, The alarm log will exist continually.

3.5 Patient data

Press the *menu* key, Turn the comwheel to select *data* menu appears on the screen like the following figure.

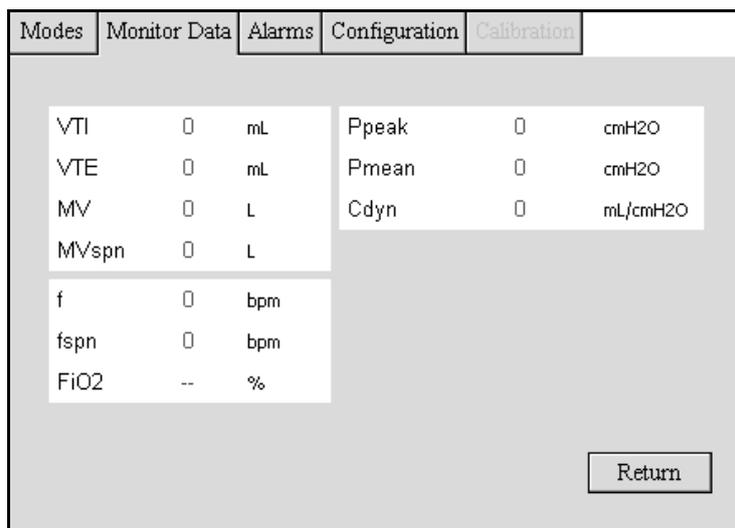


Figure 3-10 Patient data menu

3.6 Configuration menu

Press *menu* key, Turn the comwheel to select *Configuration* menu appears on the screen like the following figure.

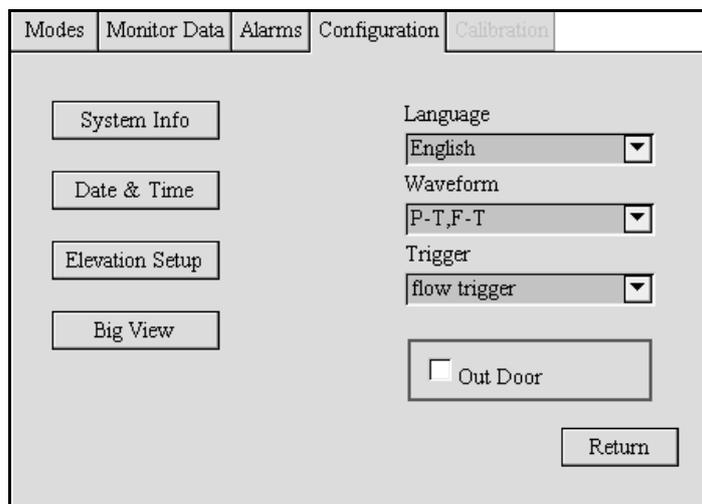
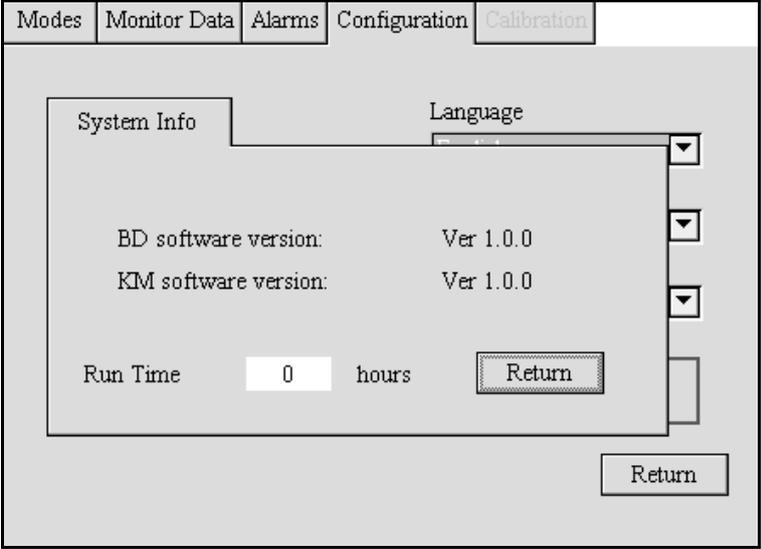
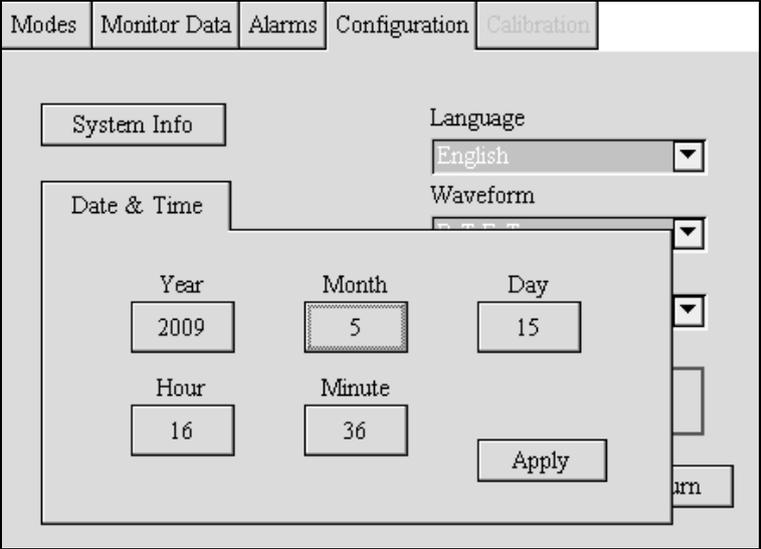
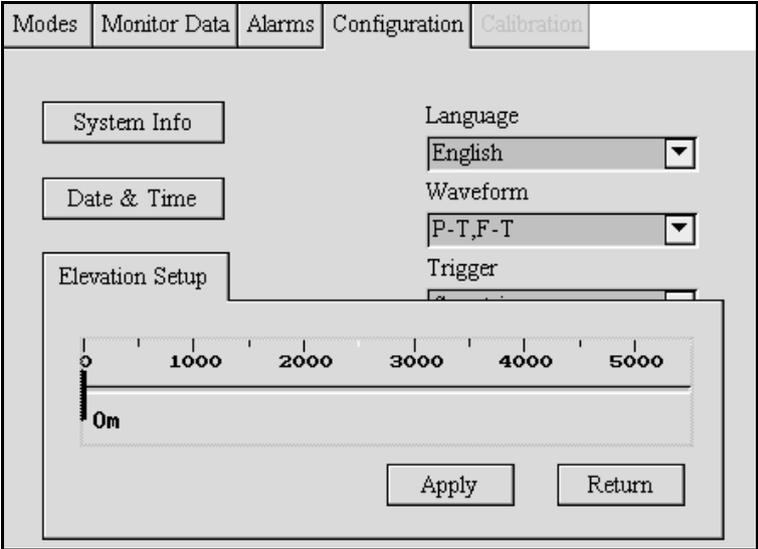


Figure 3-11 Configuration menu

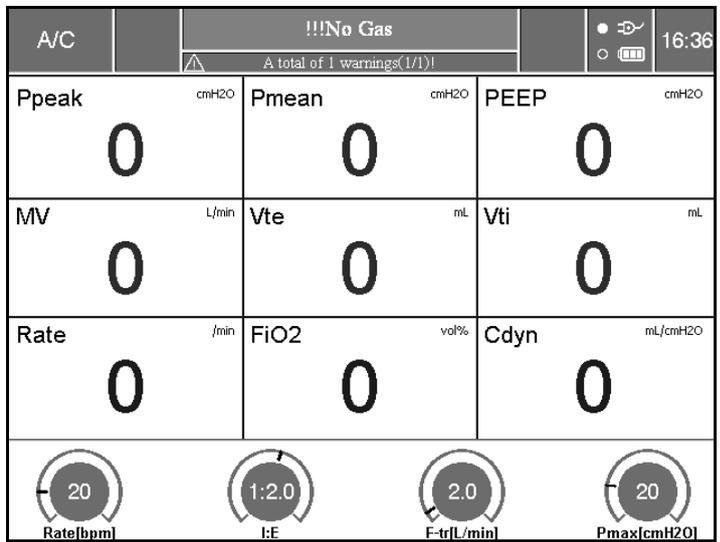
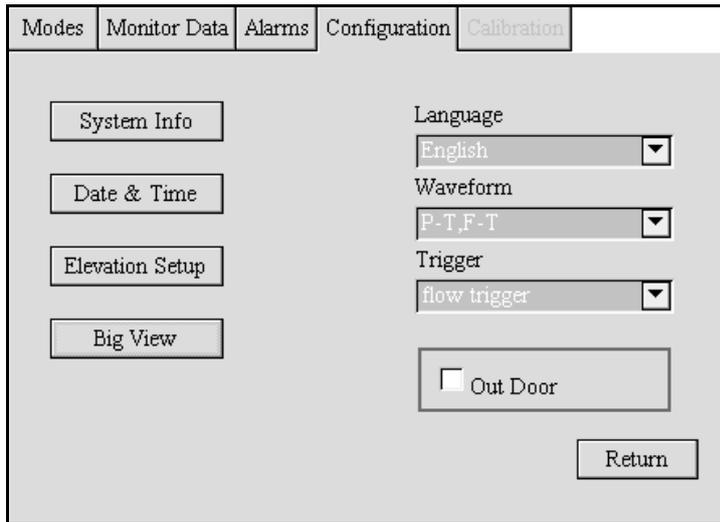
<p>System Info</p> <p>Turn the comwheel,select <i>System Info</i> button,push it and enter into <i>System Info</i> menu.</p> <p>In the <i>System Info</i> menu,the software version of all boards is listed and display the run time of this device.</p>	
<p>Date & Time</p> <p>Turn the comwheel,select <i>Date & Time</i> button,push it and enter into <i>Date & Time</i> menu.</p> <p>In the <i>Date & Time</i> menu, Turn the comwheel to select year,month,day,hour and minute respectively,push button and turn the comwheel to change data,at last,push <i>Apply</i> button to confirm.</p>	
<p>Altitude setting:</p> <p>Set the location of the altitude</p>	

Big View:

Press menu key,

Turn the comwheel to select Configuration menu appears,

Turn the Big View, Main menu on the screen like the following figure.

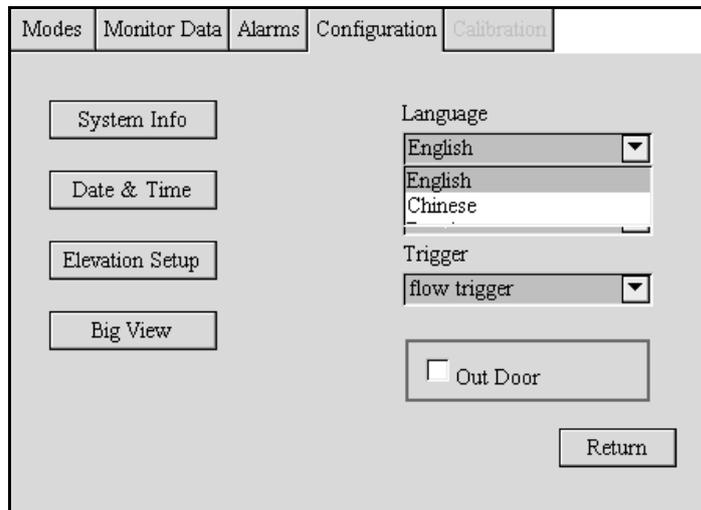


Language:

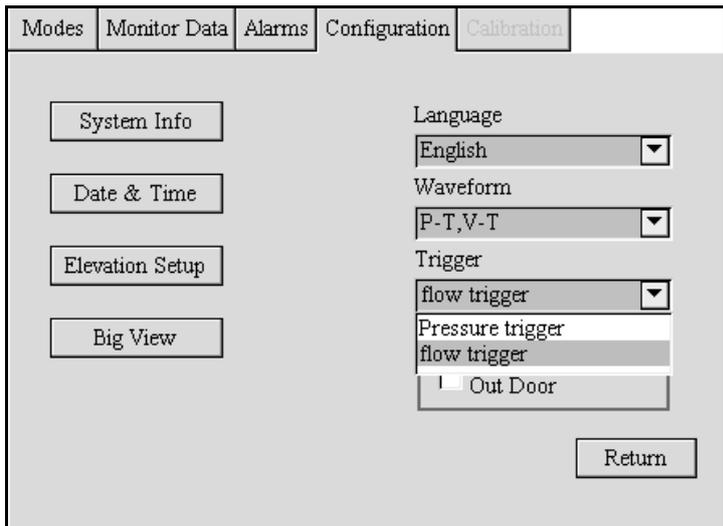
Chinese,English,Russian, Turkish, Spanish, Portuguese

Turn the comwheel to select Language dropdown listbox as right figure.

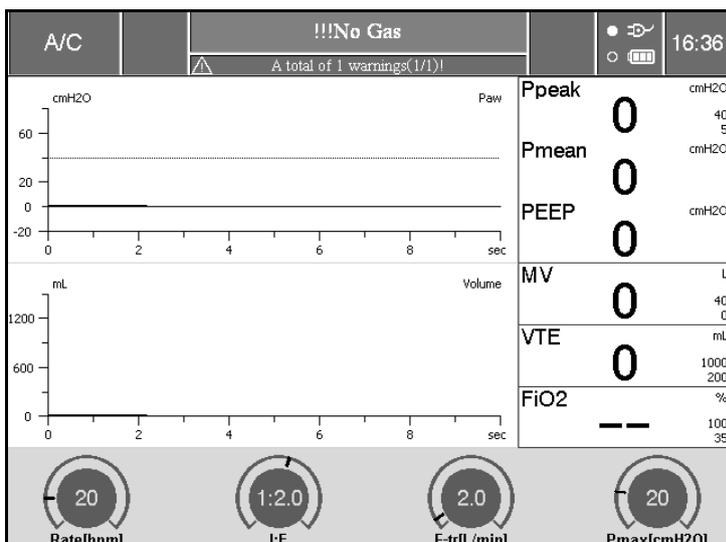
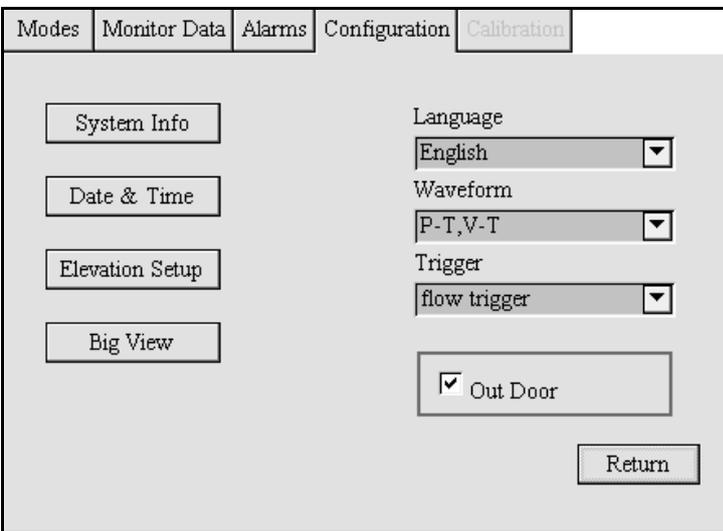
Push it and drop down other options,turn the comwheel to select wanted option and push again to confirm



Waveform:
 Turn the comwheel to select waveform dropdown listbox as right figure.
 It have three choices:
 Paw-t Flow-t waveform
 Paw-t Volume-t waveform
 Volume-t Flow-t waveform



Out Door:
 Press menu key,
 Turn the comwheel to select Configuration menu appears,
 Turn the Out Door, Main menu on the screen like the following figure.



3.7 Ventilation parameters setup

Turn the breath knob in front panel to set *Rate*, *I:E*, *F-tr* and *Pmax* parameters ,as shown in right figure. When setting, the pointer of icon will rotate by your action.

3.8 Main menu

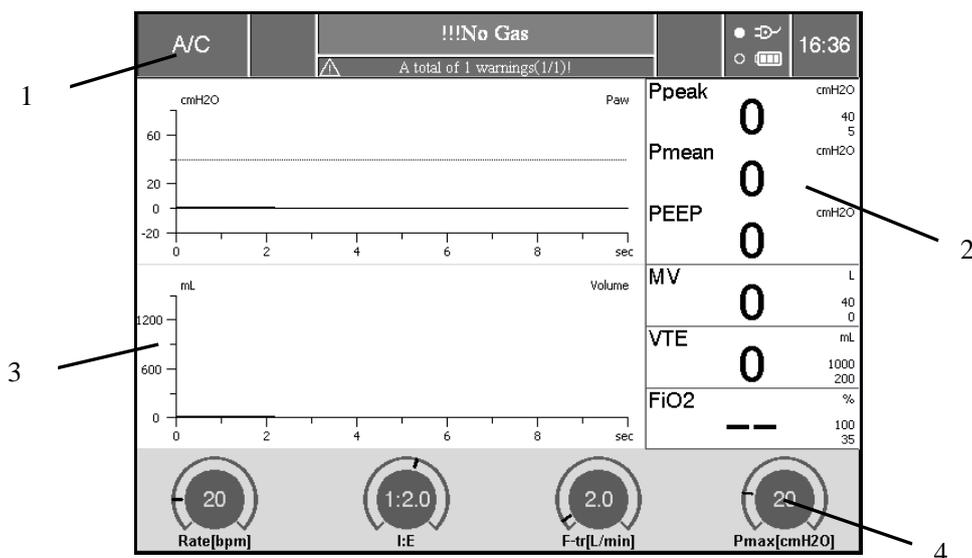


Figure 3-12 Main menu

- 1. Information display area
- 2. parameters monitor area
- 3. waveform display area
- 4. parameters setting area

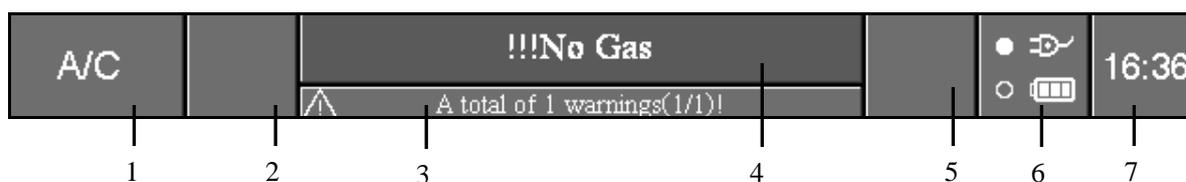


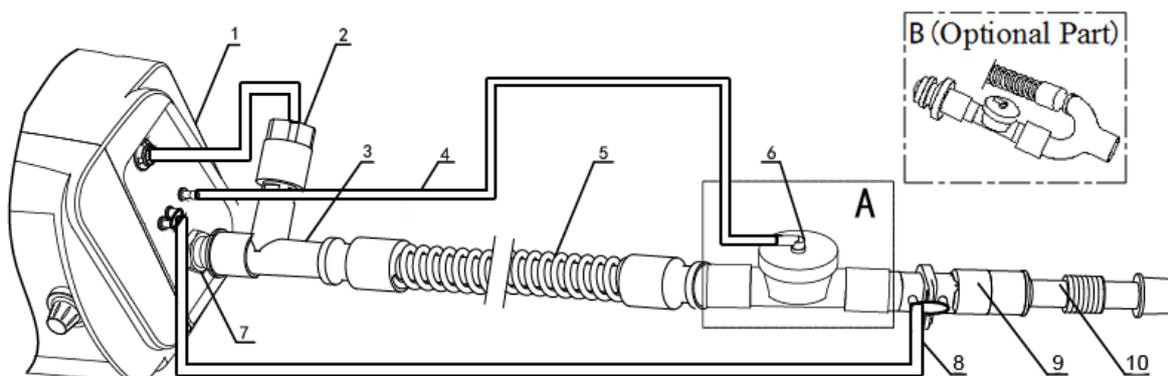
Figure 3-13 Information bar

- 1. modes display area
- 2. trigger symbol display area
- 3. operating information display area
- 4. alarm information display area
- 5. silence symbol display area
- 6. power information display area
- 7. system time

4 Install and Connection

- ⚠ WARNING:** To prevent generating wrong data and malfunction, please use the cables, hoses, and tubes from Eternity.
- ⚠ WARNING:** The operator will have to ensure that the inspiratory and expiratory resistances as shown in section 9.3 are not exceeded when adding attachments or other components or sub-assemblies to the breathing system.
- ⚠ WARNING:** when adding Bacteria Filter or other components or sub-assemblies to the VENTILATOR BREATHING SYSTEM, the pressure gradient across the VENTILATOR BREATHING SYSTEM, measured with respect to the PATIENT CONNECTION PORT, may increase.
- ⚠ WARNING:** Eternity suggests that user should use the breathing tubes, humidifier and bacteria filter that had get CE mark.
- ⚠ CAUTION:** To avoid equipment false alarm caused by high strength electric field:
- Put the electricity surgical conducting wire far from the breathing system.
 - Do not put the electricity surgical conducting wire on any parts of the anesthetic system.
- ⚠ CAUTION:** To protect the patient, as the electricity surgical equipment is being used:
- Monitor and ensure that all the life supporting and monitoring equipment are operated correctly.
 - Never use electrical conduction masks or hoses.

4.1 Connect Patient Circuit and accessories



- | | | | |
|-----------------|--------------------------------|-----------------------|----------------------------------|
| 1. Ventilator | 2. Oxygen sensor | 3. Oxygen sensor seat | 4. Exhalation valve control pipe |
| 5. Silicon hose | 6. Breath valve | 7. Insp hole | 8. Pressure sampling pipe |
| 9. Flow sensor | 10. Durable silicone flex tube | | |

- The first step :connect the end of the oxygen sensor to the insp hole of the ventilator.
- The second step : connect one end of the silicon hose to the oxygen sensor seat, and the other end of the silicon hose is connected to the air inlet end of the breath valve.
- The third step : connect the pressure sampling pipe 1 to the breath valve.
- The fourth step : connect the inlet end of the pressure sampling pipe 2 to the flow sensor.
- The five step: connected to the air outlet end of the breath valve to the air inlet end of the flow sensor, the durable silicone flex tube connection to the flow sensor on the outlet end.
- The six step: connect the pressure sampling pipe 2 to the right side of the ventilator.
- The seven step: connect the test lung or respirator to repeatable flexible patient end.

4.2 Connecting Gas and Electricity

Warning:

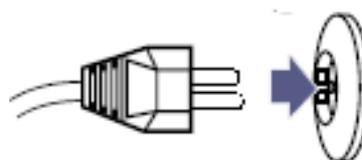
- Put the power cord and screwed tube in a certain place, to avoid apnea the patient.
- Only connect external power adapter with ISO-standard socket. And pay attention to polarity if necessary.
- For two-phase alternating current circuit user, do not attempt to switch earth line and zero line. SH200 ventilator belongs to Class I equipment specified in EN60601-1 *Medical Electrical equipment: Part one: General requirement for safety*.
- Low battery alarm may be occur, if you power on the ventilator with it do not have external power supply for a long time. If this happens, connect the ventilator with the external power supply (use the exclusive power adapter) to charge for 10 hours at least. If the alarm still existed, the internal battery must be replaced. (Please connect qualified technician).

1. Connecting power supply

Plug the power cord to the socket on the rear panel of ventilator, connect the other end of power cord to wall power, and make sure the power supply voltage complying with this manual.

Warning:

If voltage fluctuation exceeds 10 % , Eternity recommends using a AC manostat.



2. Connecting gas supply

SH200 need connect a blender to supply mixed gas from 21% to 100%.

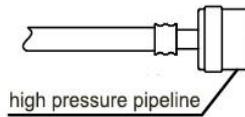
If you don't purchase blender, you can connect oxygen hose to ventilator directly.

The gas connectors designed for non-interchange to avoid man-made mistake.

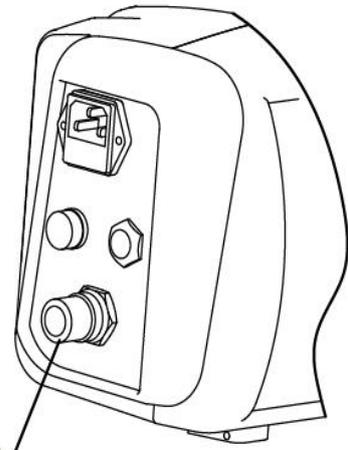
The rated working pressure of gas supply is 0.4MPa.

⚠ Warning:

Use only dry, compressed medical gases.



high pressure pipeline



Oxygen inlet

5 Preoperative Checkout

5.1 Preoperative Checkout procedures

Test interval Preoperative Checkout should be done in the following situation:

- Before use of the first patient each day.
- Before use of each patient.
- After repair or maintenance.

Test schedule is given in the table below:

Before use of the first patient each day	Before use of each patient
System check: Power failure alarm test: Alarm test: Breathing system test:	Breathing system test:

 **WARNING:** Do not use this system before the operation and maintenance manual are read and understood.

- Whole system connection
- All warnings and cautions
- Using guide of each system module
- Testing method of each system module

Before using this system:

- Complete all tests of this section
- Test all the rest of system modules

If test failure, do not use this system. Please contact service representative.

5.2 System Checkout

 **WARNING:** make sure the breathing circuit is connected correctly and in good condition.

Make sure:

- 1 Equipment is in good condition.
- 2 All the components are correctly connected.
- 3 The connection and pressure of pipeline gas supply system are correct.
4. The required emergency device is ready and in good condition.

5. Connect the power cord to the AC power outlet. The power indicator light will light up when power is connected.

If failure, that means no electric power supplying. Exchange other sockets, close breaker, or replace power cord.

5.3 Mains failure alarm test

1. Turn power switch to “

5.4 Test humidifier performance

if SH200 is used in emergency departments and recovery room, humidifier should be connect. At that time, Test about humidifier refer to relative instructions for use.

5.5 Alarm test

1. High pressure alarm test

Set upper limit of P_{aw} to 20cmH₂O. Press standby key to ventilate, and then adjust tidal volume knob make the pressure increasing in the patient circuit, when P_{aw} more than 20cmH₂O, the high pressure alarm generated, and the ventilator switches to expiration phase immediately.

2. Low pressure alarm test

Set pressure low limit to 5 cmH₂O, take away reservoir bag, low pressure alarm occurs.

3. Circuit occlusion alarm test

After high pressure alarm occurs, continue to press the reservoir bag, when high pressure alarm lasting more than 15 seconds, the continuous high pressure alarm occurs.

4. low tidal minute volume test

Set the low limit of MV to 6, and adjust V_t to 200ml, Rate to 20 , one minute later, low tidal minute volume alarm occurs.

5. High tidal minute volume test

Set the upper limit of MV to 6, and adjust V_t to 400ml, Rate to 20 , one minute later, high tidal minute volume alarm occurs.

6. low oxygen concentration alarm test (option)

Setup the lower limit of oxygen concentration to 50%, then use air only for ventilating, 10 breath cycles later, the low FiO_2 alarm appears.

7. High oxygen concentration alarm test (option)

Setup the higher limit of oxygen concentration to 50%, then use oxygen only for ventilating, 10 breath cycles later, the high FiO_2 alarm appears.

8. Apnea alarm test

Set ventilation mode to SPONT, the apnea alarm occurs after a while, and the ventilator turns to A/C mode from SPONT mode.

9. High breath rate alarm test

Set the upper limit of Rate to 20, and adjust Rate to 30 ,one minute later,high breath rate alarm occurs.

10. Low breath rate alarm test

Set the lower limit of Rate to 20, and adjust Rate to 16 ,one minute later,low breath rate alarm occurs.

11. High expiratory tidal volume alarm test

Set the high limit of V_{TE} to 0.6, and adjust V_t to 700ml, high tidal volume alarm occurs.

12. Low expiratory tidal volume alarm test

Set the low limit of V_{TE} to 0.6, and adjust V_t to 500ml, low tidal volume alarm occurs.

5.6 Breathing system test

Warning :

- Failure to make sure of correct setup and operation before use can result in patient injury.

Please follow these steps to do before you begin Ventilator Settings (described in part 3):

1. Gas supply and external power supply

Check the gas supply and external power can supply enough resource for the ventilator. Check the patient circuit for leak, disconnect or connecting mistakes. And make sure all cables, plugs, sockets and screw pipe are accord to safe requirement.

2. Check Apnea Alarm

Set the ventilator to SPONT mode, meanwhile start to time until the alarm is triggered. This period should be about 12 to 18 seconds.

3. Check the work state of the ventilator

This is a standard work state of the ventilator settings:

Ventilation mode:	A/C;
Rates of breath:	20;
I:E	1:2;
Airway pressure upper limit (x0.1kPa):	40;
Airway pressure lower limit (x0.1kPa):	5;
Fsens	2;
V_T :	500;
FiO_2 :	100%;
Gas supply rated pressure	0.4MPa;

Altitude setting

0~500m;

4. Check tidal volume

Cut off the gas supply, turn to the A/C ventilation mode, it should be 0 of the tidal volume monitor. Recover the gas supply and adjust V_t to 700ml, check the tidal volume monitor is at a range of $700 \pm 20\%$.

5. Test high airway pressure alarm:

Adjust the tidal volume to set the airway pressure peak is about 2.5kPa, Then set the Airway Pressure Upper Limit to a numerical value lower than 2.5kPa slightly. The Airway Pressure Upper Limit alarm has been triggered meanwhile the ventilator turn to expiration, the airway pressure decreases.

6. Test low airway pressure alarm:

Set the airway pressure upper limit to 0.1kPa, then disconnect patient pipe, the airway pressure lower limit alarm takes place after 4-15 sec.

7. Test trigger flow sensitivity:

Set the trigger flow at 2l/min, wear the mask and do a inspiration, the inspiration step of the ventilator begins once airway flow is higher than the setting, meanwhile the "trigger" indicator light on the front panel flashes.

8. SIMV

Set ventilation mode to SIMV, change the breathing rates, see the display of " f_{total} " in 1 minute, it should accordant as setting you just made.

9. Sigh

Let the ventilator work at a standard work state, record the tidal volume. Then change ventilation mode to A/C+Sigh, adjust the airway upper limit pressure to maximum, see the display of the tidal volume data, it should 1.5 time as normal the second time respiration takes place. This happens every 100 times, during this ventilation mode.

10. SPONT

Set the ventilation mode to SPONT, adjust the trigger flow with 2l/min, wear mask. The ventilator begins a ventilation when the airway flow is higher than 2 l/min. when the patient spontaneous inspiration finishes or the ventilation time get to the certain time determined by breathing rates and I : E, or the airway pressure up to 6cmH₂O, the ventilator will turn to expiration and waiting for next patient spontaneous inspiration.

6 Cleaning and sterilizing

⚠ WARNING: Use a cleaning and sterilizing schedule that conforms to your institution's sterilization and risk-management policies.

- Refer to the material safety data policy of each agent.
- Refer to the operating and maintaining manual of all the sterilizing equipments.
- Wear safety gloves and safety goggles.

⚠ CAUTION: To prevent damage:

- Refer to the data supplied by the manufacturer if there are any questions about the agent.
- Never use any organic, halogenate or oil base solvent, anesthetic, glass agent, acetone or other irritant agents.
- Never use any abrasive agent to clean any of the components (i.e. Steel wool, silver polish or agent).
- Keep liquids far from the electrical components.
- Prevent liquid from entering the equipment.
- Do not immerse the synthetic rubber components more than 15 minutes: any longer will cause inflation, or accelerating aging.
- The PH value of the cleaning solution must be from 7.0 to 10.5.

⚠ WARNING: Talc, zinc stearate, calcium carbonate, or corn starch that has been used to prevent tackiness could contaminate a patient's lung or esophagus, causing injury.

⚠ WARNING: Check if there is damage in the components. Replace if necessary.

⚠ CAUTION:

- This manual can only give general guidelines for cleaning, disinfecting, and sterilizing. It is the user's responsibility to ensure the validity and effectiveness of the methods used.

Table 6-1 Cleaning, disinfecting, sterilizing

Part	Procedure	Comments
Ventilator external surfaces (exclude LCD screen)	All external surfaces of the ventilator can be wiped clean with a soft cloth using Isopropyl Alcohol and mild soap solution or with one of these chemicals or their equivalents. Use water to rinse off chemical residue as necessary.	Do not allow liquid or sprays to penetrate the ventilator or cable connections. Do not use pressurized air to clean or dry the ventilator,.
	⚠ Warning: <ul style="list-style-type: none"> ● Do not use organic impregnate to clean the ventilator surface. 	

	<ul style="list-style-type: none"> ● If use ultraviolet radiation to disinfect, do not let the time over 1 hour. ● DO NOT submerge the ventilator or pour cleaning liquids over, into or onto the ventilator. 	
Patient circuit tubing	Disassemble and clean, then autoclave, pasteurize, or chemically disinfect.	If submerged in liquid, use pressurized air to blow moisture from inside the tubing before use. Inspect for nicks and cuts, and replace if damaged.
	<p>⚠ Caution:</p> <ul style="list-style-type: none"> ● If users select patient circuit tubing by themselves, Eternity suggests they should use breath tubing that comply with local regulations. 	
Expiratory module	Take off expiratory module, dismantle it and disinfect them respectively to use steaming. Disinfect expiratory module when patient changing.	After disinfecting and airing, install the expiratory module and pay attention to airtightness.
	<p>⚠ Caution:</p> <ul style="list-style-type: none"> ● Make sure that no liquid remains in the pressure measuring canal of the expiratory module, since it might cause malfunction. 	

⚠ Warning:

- Sterilizing after special infection or infectious patient use: use 2% soda water to clean the surface of the ventilator. After that clean it with water.
- After using ventilator on a tuberculosis patient, a special sterilizing is needed. Immerse components in certain disinfection solution over 2 hours. And then put it in a formalin fume box 12 hours for more disinfection.

6.1 Cleaning: general guidelines

Do not clean or reuse single-patient use or disposable products. When cleaning parts, do not use hard brushes or other instruments that could damage surfaces.

1. Wash parts in warm water and mild soap solution.
2. Rinse parts thoroughly in clean, warm water (tap water is fine).
3. Eternity recommends that you inspect all parts at every cleaning. Replace any damaged parts.
4. Whenever you replace parts on the ventilator, make sure it can work in a good condition before connect it to patient.

⚠ Caution:

- Follow the soap manufacturer's instructions. Exposure to soap solution that is more highly concentrated than necessary can shorten the useful life of the products. Soap residue can cause blemishes or fine cracks, especially on parts exposed to elevated temperatures during sterilization.

⚠ Warning:

- To avoid any risk of infection for hospital staff or other patients, clean and disinfect ventilator after use. Follow all accepted hospital procedures for disinfecting contaminated parts (protective clothing, eyewear, etc.).

6.2 Disinfection and sterilization

Do not disinfect, sterilize, or reuse single-patient use or disposable products. When sterilizing tubing, coil it in a large loop, avoiding kinks or crossing tubing. The tubing lumen should be free of any visible droplets prior to wrapping.

6.3 Disinfecting/Cleaning/Sterilizing Schedule

What	How often	How		
		Disinfecting and cleaning		Sterilizing
Reusable components	Recommended cleaning intervals)	Wiping	Immersion	Steam 134 °C, 10 minutes
SH200 ventilator	after each patient	outside	no	no
mobile stand, gas supply hoses	after each patient	outside	no	no
Patient circuit,	as needed	no	yes	yes
Expiratory module	after each patient weekly	Wiping	Immersion	Steam 134 °C, 10 minutes

This table serves as a guideline only. Always follow accepted hospital procedures and guidelines for cleaning and disinfecting.

After disinfecting/cleaning: sterilize at 134 °C. Otherwise risk of malfunction due to residual liquid in pressure measuring line.

7 User Maintenance

⚠ WARNING: Movable components and detachable parts can cause injury. Use caution when system components and parts are being moved or replaced.

⚠ WARNING: Disposal of waste or invalidated apparatus must be in accordance with the relevant policies in local government.

7.1 Repair Policy

Do not use malfunctioning equipment. All repairs must be executed by Eternity's technicians or Service Representative who had get the warranty by Eternity. After repair, test the equipment to ensure that it is functioning properly, in accordance with the manufacturer's published specifications.

To ensure full reliability, all repairs and service should be done by an authorized Eternity's Representative. If this is not possible, replacement and maintenance of parts in this manual should be performed by a competent, trained individual with experience in ventilator Systems repair, and appropriate testing and calibration equipment.

⚠ CAUTION: No repair should ever be undertaken or attempted by anyone without proper qualifications and equipment.

It is recommended that you replace damaged parts with components manufactured or sold by Eternity. After any repair work, test the unit to ensure it complies with the manufacturer's published specifications.

Contact the nearest Eternity Service Center for service assistance. In all cases, other than where Eternity's warranty is applicable, repairs will be made at Eternity's current list price for the replacement part(s) plus a reasonable labor charge.

7.2 Maintaining Outline and Schedule

The following schedule is a recommended minimum standard based upon normal usage and environmental conditions. Frequency of maintenance for the equipment should be higher if your actual schedule is more than the minimum standard.

Frequency	Maintenance
Daily	Clean the outer surface.
Weekly	Perform pressure sensor calibration. Perform flow sensor calibration.
When cleaning and installing	Check if any components are broken, and replace or repair them if necessary.
As required	Replace invalid fuse with new one.

7.3 Useful life estimation

⚠ CAUTION: The useful life of the following parts should be considered in normal environment and operating requirements.

Patient tubing	1 year
Power cord, gas pipe	8 years
Main unit	8 years
Battery	1 year

7.4 Calibrating sensor

Set the ventilator into standby mode, then press the *menu* key and turn the comwheel to select *Calibration* menu, see figure 7-1.

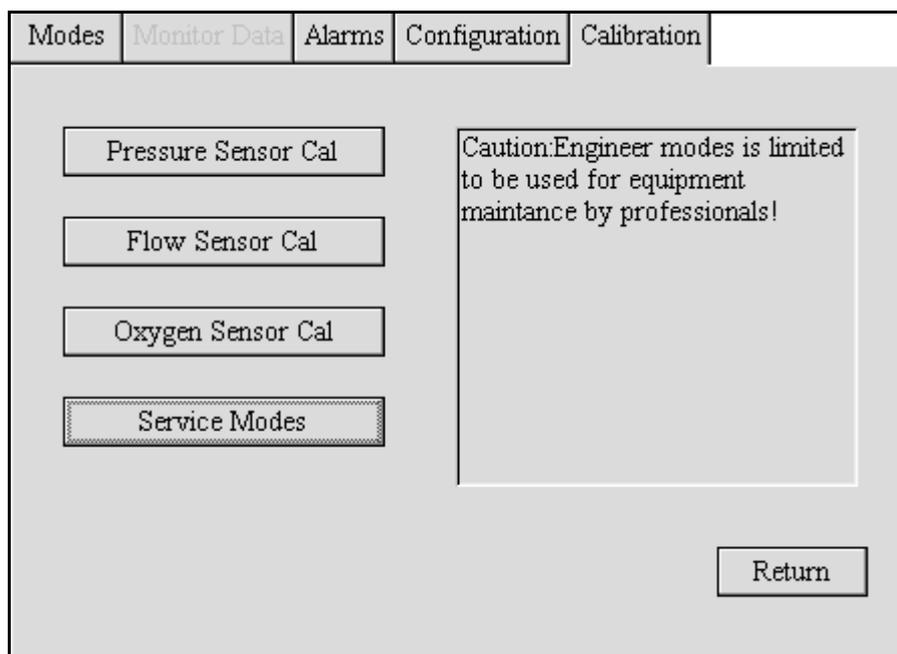
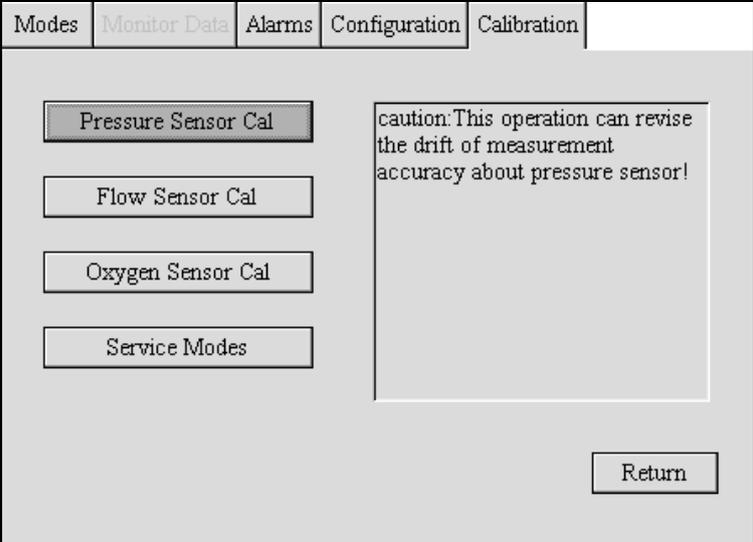
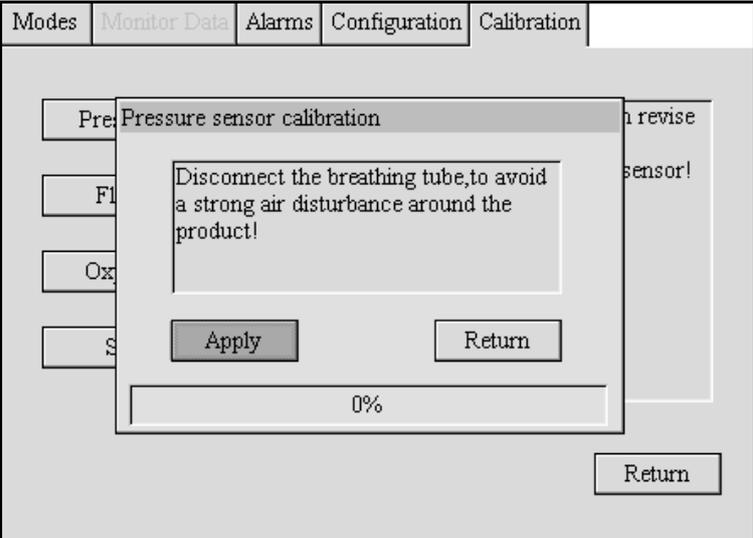
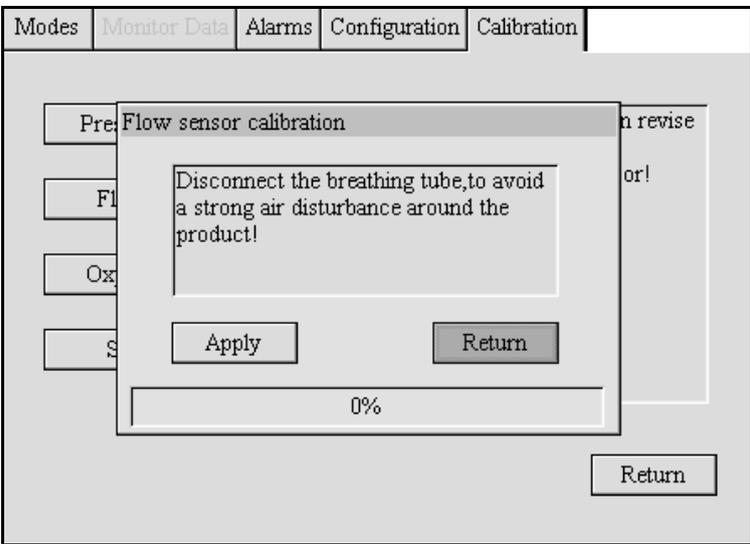


Figure 7-1 Calibration submenu

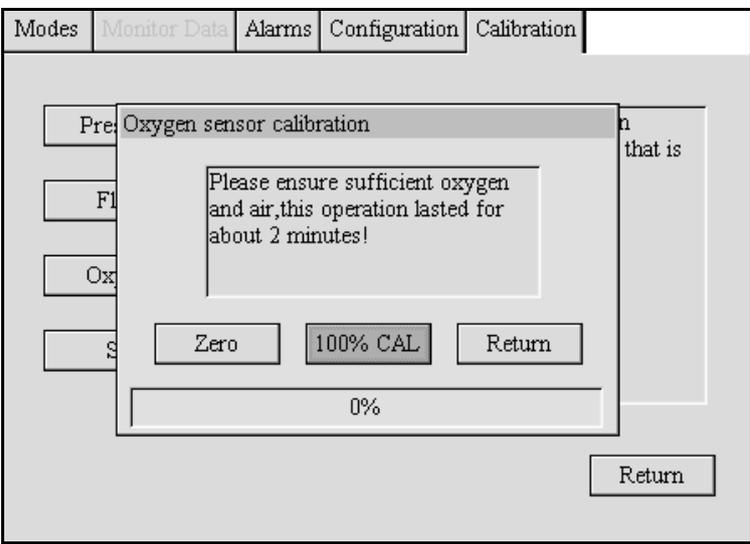
1. Calibrate pressure sensor

<p>Turn the comwheel to select <i>Pressure sensor</i> button, see right figure.</p> <p>Pay attention to prompt on screen.</p>	
<p>push the comwheel, enter into <i>pressure sensor calibration</i> menu. see right figure.</p>	
<p>Select <i>Apply</i> button, push comwheel to calibrate.</p> <p>If succeed, the word <i>Calibration completed</i> will be displayed on the screen</p> <p>If failed, the word <i>Calibration failed</i> will be displayed on the screen. please contact Eternity.</p>	

2. Calibrate flow sensor

<p>Turn the comwheel to select Flow sensor and press it, see right figure.</p> <p>Calibrating procedure refer to <i>Calibrating pressure sensor</i>.</p> <p>Pay attention to prompt on screen.</p>	
---	--

3. Calibrate oxygen sensor (option)

<p>Expose the oxygen sensor into the air, wait for about two minutes, Turn the comwheel to select oxygen sensor and press it, see right figure.</p> <p>Calibrating procedure refer to <i>Calibrating pressure sensor</i>.</p> <p>Pay attention to prompt on screen.</p>	
--	--

7.5 Replacing fuses

- ⚠ WARNING:** Disconnect from power supply before replacing fuses, otherwise that can injure operator, even death.
- ⚠ WARNING:** Replace fuses with only those of the specified type and current rating, otherwise that can damage the equipment.

⚠ CAUTION: The fuse is fragile, so replacement should be carefully. Do not use excessive force.

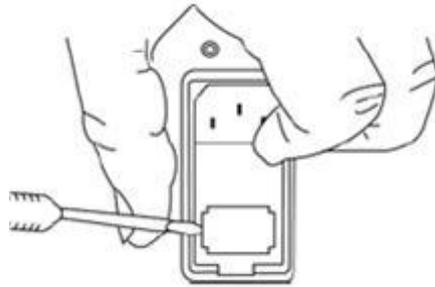


Figure 7-2 Pry out the fuse holder

Replacing steps:

- 1 Using a flat bladed screwdriver, lift open the cover. Using the same screwdriver, loosen and pull out the fuse holder as shown in figure 7-5.
- 2 Remove the fuses from both sides of the fuse holder and replace with fuses indicated by Eternity.
- 3 Push fuse tubes to original place gently.
- 4 Connect mains supply.

7.6 Transport

The machine must be put in proper place for the clinic personnel's convenience during operation. During the up and down-stairs movement one must take care of the ventilation loop and power cables. It's better to take the ventilation loop off prevent damage. Avoid fierce shock and vibration while transport the ventilator.

The transportation environment should be at temperature of $-40^{\circ}\text{C}\sim+55^{\circ}\text{C}$ and relative humidity above 93%.

7.7 Maintaining battery

1 Specification

DC14.8V 5200mAh lithium battery

Charge: 6 hours typically

Temperature protect: 65°C

Overflow protect: 8-10A

2 Cautions

Charge: Once mains supply connects; the system will charge battery automatically. It is recommended that charging time is better than 6 hours.

Discharge: It will last 3 hours generally to use the battery supply.

The alarm "Battery Low!!" should be displayed on the screen when the capacity of battery is not enough until the system shut-off. The user/operator should connect mains supply to charge battery in time and avoid the system shut-off abnormally.

Do not disassemble battery device without valid authorization.

Do not short-circuit between positive plate and negative plate of battery.

3 Storage

The maintenance of charging should be carried out with interval of 3 months at least if storage of battery exceeds 3 months.

Stored environment should avoid dampness, high temperature.

If improper maintenance makes battery damage, replace it in time to avoid liquid of battery corroding the apparatus. Replace the battery, please contact Eternity service representatives.

4 Replacement

Eternity recommends the battery must be provided by Eternity or agency get the warrant.

⚠ CAUTION: An authorized Eternity services representative can replace battery. If not to use the battery for long-time, please contact Eternity service representatives to disconnect battery. The waste battery should be disposed in accordance with the local policies.

⚠ CAUTION: When 'BATTERY DISCHARGED' alarm occurs, charging should be done immediately. Or else, the SH200 Ventilator System will shut off in several minutes automatically.

⚠ WARNING: Comply with the relevant rules about biohazard when to dispose battery.

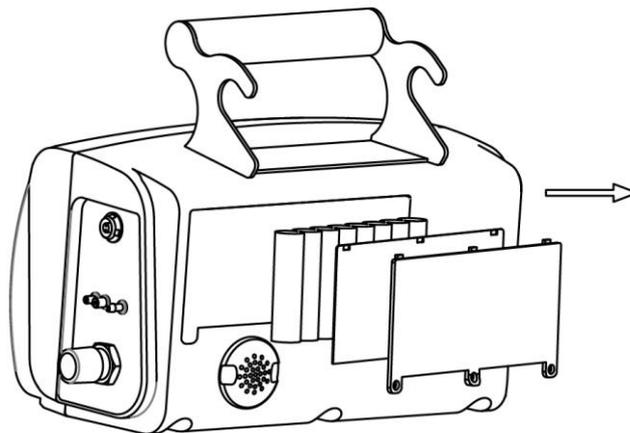


Figure 7-3 replace battery package

Replacing steps:

- 1 Remove the battery package from battery box
- 2 unplug the connector from cable.
- 3 Replace with battery package indicated by Eternity and plug the connector reliable.
- 4 install the battery cover.

7.8 Maintaining Oxygen sensor

The oxygen measurement is based on the principle of a galvanic cell. The monitored gas diffuses through a membrane into the electrolyte in the sensor. The electrolyte contains a working electrode and a reference electrode. The oxygen is reduced electrochemically and the resultant current is proportional to the O₂ partial pressure in the gas.

7.9 Calibrate O₂ sensor



WARNING: Do not perform the calibration steps when the system connected with patient.



WARNING: If operating pressure is not equal with calibrating pressure, the accuracy of reading may exceed range stated.



WARNING: When to calibrate O₂ sensor, ambient pressure must be equal with monitoring pressure of delivering O₂ in the patient circuit.

When the oxygen sensor is expanded or updated, measurement accuracy of the readings is bad, recalibrate oxygen sensor can revise these influence. Refer to 7.4 calibrating O₂ sensor.

7.10 Technical requirements



WARNING: The oxygen monitor is not equipped with automatic barometric pressure compensation. So, if barometric pressure changes, the precision will be influenced.

O₂ sensor belongs to expendable, so the user should pay attention to period of validity, and use it in accordance with performance and requirements.

The technical requirements of O₂ sensor used are the following:

Form and definition of interface: RJ11 interface

Typical input at 21% concentration: 9 to 13 mV

Accuracy in measurement and full scale error: <1% (0 to 100%)

Operating temperature: 0 to 40°C

Response time: not more than 13 seconds

Useful life: not less than 12 months

Accordable standard: ISO 21647 / ISO 7767



CAUTION: More detailed parameters refer to technical data up to date publicized by the manufacturer.

7.11 Replacing filter

Every 500 hours, the fan filter should be checked and cleaned if necessary. The fan filter is located the rear enclosure of display screen. To clean the filter, remove it from its recess and immerse in warm soapy water. Rinse thoroughly and dry thoroughly before replacing in the SH200.

.Replacing steps(Figure 7-4):

1. pull down power cord;
2. get down filter cover from rear enclosure of SH200;
3. take out filter and put into soapy water.
4. Rinse thoroughly and dry thoroughly before replacing

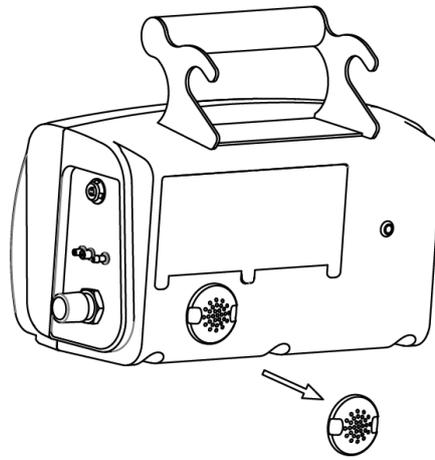


Figure 7-4 replace battery package

8 Alarm and Troubleshooting

⚠ WARNING: No repair should ever be undertaken or attempted by anyone without proper qualifications and equipment.

8.1 About alarm

⚠ CAUTION: If alarm occurs, protect patient safe firstly, and then go to diagnose fault or service it necessarily.

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

Alarm messages displays on the top area of display screen, see figure8-1.



Figure 8-1 Alarm message area

The high priority alarms must be disposed immediately.

Priority	Sound	Silence	Prompt	Alarm lamps
High	5 tones, 2 hurry; Periods: 10 seconds	120 seconds	Red background, “!!!”	Red, blinking
Medium	3 tones Periods: 25 seconds	120 seconds	Yellow background, “!!”	Yellow, blinking
Low	1 tone Once only.	---	Yellow background, “!”	Yellow

⚠ NOTE: If a alarm goes away spontaneously (autoresets), its message remains lit with blue background (not flashing) until you press the alarm reset key.

⚠ NOTE:	When alarm silencing, the alarm bell has dashed “X” in itself and the count down of 120 seconds present underside. At the same time, alarm sound disappears. After 120 seconds, alarm bell turns to original shape and alarm sound reappears.	
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8.2 Alarm message list

Message	Priority	Alarm definition	Operator action
!!VTE HIGH	Medium	V_{TE} greater than high limit for 4 breath cycles continuously.	Check patient and settings. Consider whether the patient's compliance or resistance has changed.
!!VTE LOW	Medium	V_{TE} less than low limit for 4 breath cycles continuously.	Check patient and settings. Consider whether the breath

			tube is leak.
!!!MV LOW	High	MV less than low limit for 10 breath cycles continuously..	Check patient and settings.
!!!MV HIGH	High	MV greater than high limit for 10 breath cycles continuously..	Check patient and settings.
!!!FiO ₂ LOW	High	FiO ₂ less than low limit for 25s continuously..	Check patient, air and oxygen supplies, oxygen analyzer, and ventilator.
!!!FiO ₂ HIGH	High	FiO ₂ greater than high limit for 25s continuously.	Check patient, air and oxygen supplies, oxygen analyzer, and ventilator.
!MAINS FAILURE	Low	No AC power detected after startup.	Prepare for power loss. Check integrity of ac power source
!!RATE HIGH	Medium	Rate greater than high limit for 20 breath cycles continuously.	Check patient and settings.
!!!RATE LOW	High	Rate less than low limit for 3 breath cycles continuously.	Check patient and settings.
!!BATTERY LOW	Medium	Battery capability detected works less than 10 minutes.	Charge the battery quickly. Obtain alternative ventilation if necessary.
!!NO GAS	Medium	O ₂ supply pressure less than 0.28MPa in ventilating process.	Check patient and oxygen source. Obtain alternative ventilation if necessary.
!!!PRESSURE LOW	High	Paw monitored less than low limit, and last more than three breath cycles.	Check patient and settings.
!!!APNEA	High	The set apnea interval has elapsed without the ventilator, patient, or operator triggering a breath. The ventilator has entered apnea ventilation.	Check patient and settings.
!!!PRESSURE HIGH	High	Airway pressure greater than high limit for 2 breath cycles continuously.	Check patient, patient circuit, and endotracheal tube.
!!!CIRCUIT OCCLUSION	High	Paw monitored more than high limit last for 15 seconds in ventilating process.	Check patient, breath tube, and endotracheal tube.
!!!BATTERY DISCHARGED	High	Battery capability detected works less than 5 minutes.	Charge the battery immediately. Obtain alternative ventilation if necessary.

8.3 Troubleshooting

Malfunctions	Possible cause	Recommended action
AC indicator is not bright	Power cord is unplugged. Power cord is damaged. Power socket failure. Fuse is burned.	Plug it firmly. Replace power cord. Turn to other socket. Replace fuse.
Maximum pressure alarm sounds continuously	Patient circuit is occluded; Patient's respiratory tract is occluded; Maximum pressure setting is too low; Ventilator parameters changed.	Check the pipeline leak part; Reset the alarm settings; Check the patient Check the sampling hose
Minimum pressure alarm sounds continuously	Patient circuit leaks; Alarm settings is too high; Patient's co-operation changes; Sampling hose is disconnected or broken	Check the pipeline leak part; Reset the alarm settings; Check the patient Check the sampling hose
Trigger icon blinking	The trigger value may be smaller.	Reset trigger value.

9 Specifications and Operation Theory

9.1 Physical specification

All specifications are approximately, maybe changed at any moment without notice.

 **CAUTION:** Do not put SH200 into the shock environment.

 **CAUTION:** Do not lay the heavy on the top.

Size	350mm(H)×260mm(W)×160mm(D)
Weight	5kg

9.2 Environment requirements

Temperature	Operation:	5°C ~40°C
	Storage:	-40°C ~55°C
Relative humidity	Operation:	30%~80%, non-condensing
	Storage:	≤93%, non-condensing
Atmospheric Pressure	Operation:	70~106kPa

 **CAUTION:** The device should be stored at the room that is drafty and no corrosion gas exists.

 **CAUTION:** When the storage conditions are beyond the requirements of operational environment, and the storage state is transferred into operation state, the product only can be used after being stored in environment for over 8 hours.

9.3 System technical specification

Gas supply	Composition	O ₂
	Pressure	0.28MPa~0.6MPa
	Velocity of flow	≤100L/Min
Power supply	Voltage & Frequency	100V~240V, 50Hz~60Hz
	Power	≤ 50VA
	Fuse	F2AL/250V φ5X20
	Earth resistance	<0.2Ω
Inspiratory and expiratory port	Conical connectors (ISO5356)	
Inspiratory and expiratory resistance	At flow of 60L/min for adult use, inspiratory resistance ≤0.6kPa; expiratory resistance ≤0.6kPa At flow of 30L/min for paediatric, inspiratory resistance ≤0.6kPa; expiratory resistance ≤0.6kPa	
Maximum security pressure	≤ 8kPa	
Compliance	≤ 4mL/100Pa	
Electrical safety	Meet requirements for Class I, type B equipment specified in EN60601-1 <i>Medical Electrical equipment: Part one: General requirement for safety.</i>	
Classification	According to EN 60601-1, SH200 ventilator belongs to the following classifications: Class I, Type B, General, mobile equipment.	
Noise:	≤ 65dB(A)	
The auditory ALARM SIGNAL sound pressure	>65dB	

9.4 Operation principle

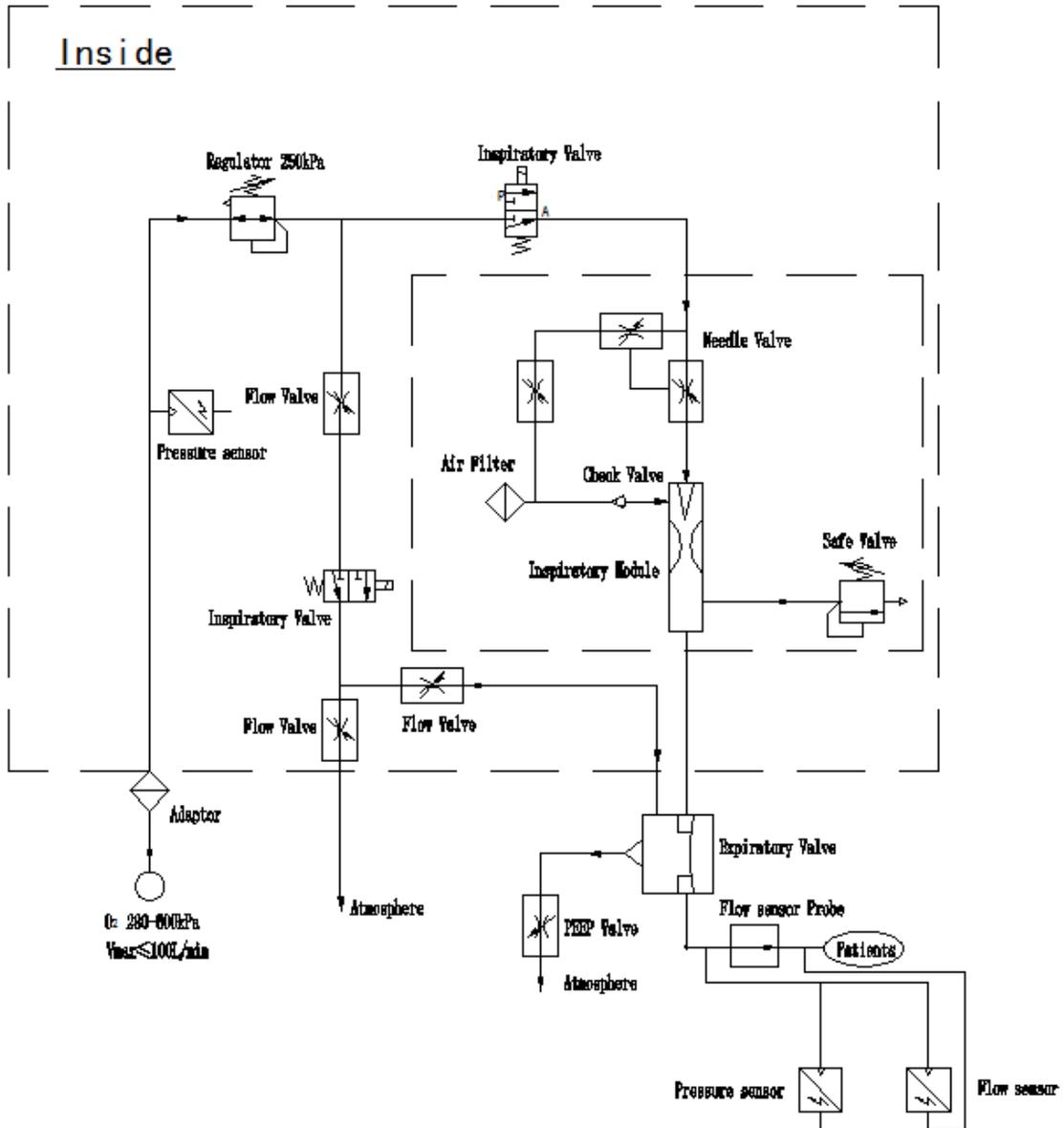


Figure 9-1 SH200 Ventilator System operation principle diagram

9.5 Performance parameters

9.5.1 Setting ventilation mode

Ventilation mode	Adjustable respiratory parameters
A/C mode	V_T , Rate, I:E, Fsens, FiO_2
A/C+Sigh mode	V_T , Rate, I:E, Fsens, FiO_2
SIMV mode	V_T , Rate, T_I , Fsens, FiO_2
SPONT	
Backup mode	V_T , Rate, I:E, Fsens, FiO_2

9.5.2 Setting ventilating parameters

Item	Range
V_T	0~1500ml
Rate	4 ~ 100bpm
Rate in SIMV mode	1 ~ 40bpm
I:E	10:1~1:10
T_I	0.2s~10s
FiO_2	45%~100%
Fsens	1~20 l/min

9.5.3 Monitoring performance

Item	Range
V_{TI}	0~2000 mL
V_{TE}	0~2000 mL
f	0~100 bpm
fspn	0~100 bpm
MVspn	0~99L
MV	0~99L
Pmean	0~80 cmH ₂ O
Ppeak	0~80cmH ₂ O
FiO_2	21%~100%
C	0~200 mL/cmH ₂ O
R	0~200 cmH ₂ O /L/s
PEEP	0~80 cmH ₂ O

9.5.4 O₂ monitoring specification

Response time:	Not more than 15 seconds
Type of O ₂ sensor:	Chemical fuel cell
Useful life:	12 months (normal operating)
Operational principle:	<p>O₂ monitoring modules can monitor and display oxygen concentration of the patient circuit, and contain one oxygen sensor. The O₂ sensor can detect the proportionable voltage on its surface, generated with partial pressure of O₂. The O₂ sensor is chemical fuel cell, and its metal electrode can be oxidated when oxygen diffuses into it. The current generated from oxidation proportion O₂ pressure on the surface of electrode. The electrode will be used up gradually in oxidation process. The voltage of sensor would be affected by the temperature of gas mixture monitored. Thermistor on the shell of sensor will auto-compensate temperature difference inside the sensor. Signal processing and circuit analyzing can be used in the O₂ monitoring modules. So the signal of O₂ sensor could be transformed to O₂ concentration. Besides, the concentration displays on the screen, and compares with alarm limit value saved, if the concentration exceeds the limits, alarm should be occurred.</p>

9.5.5 Setting alarm parameters

Item	Range
MV-upper limit	1~99L
MV-lower limit	0~98L
P _{aw} -upper limit	1 cmH ₂ O~80 cmH ₂ O
P _{aw} -lower limit	0~79 cmH ₂ O
V _{TE} -upper limit	60~2000ml
V _{TE} -lower limit	OFF,50~1990ml
Rate-upper limit	1~100 bpm
Rate-low limit	0~99 bpm
Tapnea	15s~60s
FiO ₂ -lower limit	21%~99%
FiO ₂ -upper limit	22%~100%

**CAUTION:**

All low limits of parameters in above table may not be set up the high limits, nor may the high limits be set below the low limits.

10 Environmental protection.

10.1 Disposal of waste product and component



This symbol means do not dispose of the device as municipal waste, but dispose of at municipal collection points for waste electrical and electronic equipment.



CAUTION: Abandoned electronic components in accordance with local regulations processing.

11 Note on EMC risk for the device function

Changing or reassembling this equipment without Eternity's authorization may cause electromagnetic compatibility problems. Contact with Eternity for assistance. Designing and testing this equipment is in accordance with the following stipulations.

⚠️WARNING: using cell phone or other radio radiant equipment near this product may cause malfunction. Closely monitor the working condition of this equipment if there is any radio radiant supply nearby.

Using other electrical equipment in this system or nearby may cause interference. Check if the equipment works normally in these conditions before using on a patient.

Be careful of the following when SH200 is connected:

Do not put any object which is not in accordance with EN60601-1 in the 1.5M range of patients.

An isolated transformer must be used for alternating current supply (in accordance with IEC60989), or additional protective ground wires are equipped if all the devices (for medical or non-medical use) are connected to SH200 by using signal input/signal output cable.

If a portable all-purpose outlet is used as the alternating current supply, it must be in accordance with EN60601-1-1 and cannot be put on the floor. Using another portable all-purpose outlet is not recommended.

Do not connect the non-medical equipment directly to the alternating current outlet on the wall. Only the alternating current supply of the isolated transformer can be used. Otherwise, the surface leaking current may exceed the range permitted by EN60601-1 under the normal conditions, and misoperation may cause injury to patients or operators.

A complete system current leaking test (according to EN60601-1) must be performed after any equipment is connected to these outlets.

⚠️WARNING: medical electrical equipment operators contact non-medical electrical equipment and patients at same time. It is dangerous of patients or operators.
Guidance and manufacture's declaration – electromagnetic emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The SH200 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of SH200 Ventilator should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SH200 Ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The SH200 Ventilator is suitable for use in all establishments, including domestic 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity –for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The SH200 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of SH200 Ventilator 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%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output 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 differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and	<5% U_T (>95% dip in U_T)	<5% U_T (>95% dip in U_T)	Mains power quality should be that of a

voltage variations on power supply input lines IEC 61000-4-11	for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	typical commercial or hospital environment. If the user of the SH200 Ventilator requires continued operation during power mains interruptions, it is recommended that the SH200 Ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	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 manufacture's declaration – electromagnetic immunity –for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The SH200 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of SH200 Ventilator 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	30 V _{rms} 150 kHz to 80 MHz outside ISM bands ^a 10 V _{rms} 150 kHz to 80MHz	30V 10V	Portable and mobile RF communications equipment should be used no closer to any part of the <i>SH200 Ventilator</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$

Radiated RF IEC 61000-4-3	in ISM band ^a	10 V/m	$d = \left[\frac{23}{E_1} \right] \sqrt{P}$ 800 MHz to 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, ^c should be less than the compliance level in each frequency range. ^d Interference may occur in the vicinity of equipment marked with the following symbol: 
	10 V/m 80 MHz to 2.5 GHz		
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a The ISM (industrial, scientific and medical) bands between 150kHz and 80MHz are 6.765 MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70. ^b The compliance levels in the ISM frequency bands between 150 kHz and 80MHz and in the frequency range 80MHz to 2.5GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. ^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SH200 Ventilator is used exceeds the applicable RF compliance level above, the SH200 Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SH200 Ventilator. ^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM –for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the SH200 Ventilator				
The SH200 Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SH200 Ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SH200 Ventilator as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz	80 MHz to 800MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{12}{V_2} \right] \sqrt{P}$	$d = \left[\frac{1.2}{E_1} \right] \sqrt{P}$	$d = \left[\frac{2.3}{E_1} \right] \sqrt{P}$

0.01	0.035	0.12	0.012	0.023
0.1	0.11	0.38	0.038	0.073
1	0.35	1.2	0.12	0.23
10	1.1	3.8	0.38	0.73
100	3.5	12	1.2	2.3

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 The ISM (industrial, scientific and medical) bands between 150 kHz and 80MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66MHz to 40.70MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80MHz to 2.5GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Statement

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Refer to this manual before any Eternity product is used. The manual includes operating procedures which must be performed with cautiously, operations that may result in non-normal working conditions and the dangers which may damage equipment or cause bodily harm. Eternity is not responsible for the security, reliability and function of the equipments in case that the dangers, damages and non-normal phenomenon mentioned in this manual happen. Free repairs for these malfunctions will not be provided by Eternity.

Eternity have the rights to replace any content in this manual without notice.

Manufacturer Responsibility:

Eternity is responsible for the security, reliability and function of the equipments when to following conditions are adhered to:

- Installation, adjustments, mending and repairs must be performed by individuals authorized by Eternity;
- Necessary electrical equipment and the working environment must be in accordance with the national standards, professional standards and the requirements listed in this manual;
- Equipment must be used as instructed in the operating instructions.

CAUTION: This equipment is not for family use.

CAUTION: Malfunctioning equipment may become invalid and cause bodily injury if a set of effective and approving repairing proposals cannot be submitted by the institution which is responsible for using this equipment.

The paid theoretical framework diagram will be supplied according to customer requirements by Eternity, plus calibrating method and other information to help the customer, under the assistance of qualified technicians, repair the equipment parts where can be done by customer himself based on the stipulation by Eternity.

Warranty:

Manufacturing techniques and materials:

For a period of one year from the date of original delivery, the components and assemblies of this product is warranted to be free from defects manufacturing techniques and materials, provided that the same is properly operated under the conditions of normal use and regular maintenance. The warranty period for other parts is three months. Expendable parts are not included. Eternity's obligation under the above warranties is limited to repairing free of charge.

Free Obligations:

- Eternity's obligation under the above warranties does not include the freight and other fees;
- Eternity is not responsible for any direct, indirect or final product broken and delay which result from improper use, alteration by using the assemblies unratified and maintenance by anyone other than Eternity;
- This warranty does not apply to the followings:

Improper use

Machines without maintenance or machines broken

The label of Eternity original serial number or mark is removed or replaced

Other manufacturers' product

Security, reliability and operating condition:

Eternity is not responsible for the security, reliability and operating condition of this product in case that:

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

Return

Follow the steps in case that the product needs to be returned to Eternity :

1. Obtain the rights of return

Contact with the customer service of Eternity by informing them the number and type of the product. The number is marked on the surface of the product. Return is unacceptable if the number cannot be identified. Enclose a statement of the number, type and the reason of return as well.

2. Transportation charges

Transportation and insurance charges must be prepaid by the user for transporting the product to Eternity for repairing. (Customers charges is added with regard to the products sold to non-Chinese mainland users)

SH200 Emergency Ventilator

User Manual

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