SH300 Ventilator System

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 /or 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.

NOTE:

Each Eternity product has a serial number, such as

SH300 xx xx xxx

SH300: Ventilator model

E: English version

the first xx : the year of manufacturing

the second xx : the month

the xxx : equipment number

Contents

1 Introduction 1

1.1 What's SH300? 1
1.1.1 Intended Use 1
1.2 Symbols 1
1.3 Definitions, Acronyms, and Abbreviations 3

2 Structure 5

2.1 Frontview 5
2.1.1 Front panel 5
2.1.2 LCD screen 8
2.1.3 Expiratory module 9
2.2 Back panel 9

3 Operating Guide 10

3.1 Starting System 10
3.2 Setup ventilation mode 11
3.3 Ventilation mode introduction 12
3.3.1 VCV 12
3.3.2 VCV+SIGH 13
3.3.3 SIMV 13
3.3.4 CPAP/PSV 14
3.3.5 PCV 15
3.3.6 APRV 15
3.3.7 BIPAP 16
3.3.8 PRVC 17
3.3.9 SynchronizedNebulizer 17
3.4 Alarm Settings menu 18
3.4.1 Setting alarm parameters 18
3.4.2 Alarm log submenu 19
3.5 Monitor data 20
3.6 Configuration menu 20
3.7 Ventilation parameters setup 23
3.8 Main menu 23
3.9 Assist function operating 24
3.9.1 Freeze 24
3.9.2 Insp Hold 24
3.9.3 Exp Hold 24
3.9.4 Manual Insp 24
3.9.5 O_2 Suction 24
3.9.6 Lock 24

4 Install and Connection 25

4.1 Assembling the ventilator 26
4.2 Assemble of the cart 26
4.3 Connect tube 27
4.4 Connecting Gas and Electricity 27

5 Preoperative Checkout 29

5.1 Preoperative Checkout procedures 29

5.2 System Checkout 29
5.3 Mains failure alarm test 30
5.4 Test humidifier performance 30
5.5 Alarm test 30
5.6 Breathing system test 31

6 Cleaning and sterilizing 33

6.1 Cleaning and sterilizing 33
6.1.1 Cleaning: general guidelines 34
6.1.2 Disinfection and sterilization 35
6.1.3 Disinfecting/Cleaning/Sterilizing Schedule 35
6.1.4 Cleaning Method for the Exhalation Valve Assembly 36
6.1.5 Method of Sterilization for the Exhalation Valve Assembly 36

7 User Maintenance 37

7.1 Repair Policy 37
7.2 Maintaining Outline and Schedule 37
7.2.1 User maintenance 37
7.2.2 Useful life estimation 38
7.2.3 Calibrating sensor 38
7.3 Assembling the expiratory module 42
7.4 Replacing fuses 43
7.5 Transport 43
7.6 Maintaining battery 44
7.7 Maintaining Oxygen sensor 45
7.7.1 Replace O_2 sensor 45
7.7.2 Calibrate O_2 sensor 46
7.7.3 Technical requirements 46
7.7.4 Recommended O_2 sensor 46
7.8 Replacing fan filter 47

8 Alarm and Troubleshooting 48

8.1 About alarm 48
8.2 Alarm message list 49
8.3 Troubleshooting 50

9 Specifications and Operation Theory 51

9.1 Physical specification 51
9.2 Environment requirements 51
9.3 System technical specification 52
9.4 Operation principle 53
9.5 Performance parameters 54
9.5.1 Setting ventilation mode 54
9.5.2 Setting ventilating parameters 54
9.5.3 Monitoring performance 56
9.5.4 O_2 monitoring specification 57
9.5.5 Assistant performance 57
9.5.6 Setting alarm parameters 58
9.6 Order information 58
9.7 Electromagnetic Compatibility 59

Foreword

Thank you for purchasing and utilizing Eternity equipment.

For using the apparatus rightly and effectively, please read the User Manual through and carefully 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.

Users are welcome to contact the following contact information.

Name:	Beijing Eternity Electronic Technology Co. Ltd.
Address:	F2-3， Building 2,No.17,Xijing Road,Shijingshan District,100041, Beijing, PEOPLE'S REPUBLIC OF CHINA
Tel:	0086- 010-68813220
Fax:	0086-010-68827023
URL:	http://www.yshmed.com

Manufacturer: Beijing Eternity Electronic Technology Co. Ltd.

European Representative:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537　Hamburg，Germany

CE 0123

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

1 Introduction

1.1 What's SH300?

The SH300 Ventilator System 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 10.4' TFT screens that display monitored data separately from ventilator settings for easy assessment of your patient's condition.

⚠**WARNING: The user of SH300 must be professional and trained.**

⚠**WARNING: SH300 is unsuitable for use in a magnetic resonance imaging (MRI) environment.**

⚠**WARNING: SH300 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.**

1.1.1 Intended Use

The SH300 Ventilator System 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. It can be used in ICU, respiration and emergency room.

⚠**WARNING: SH300 is not to be used with infant.**

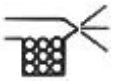
1.2 Symbols

⚠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）		Warning or Caution, ISO 7000-0434
	Standby		NOTE: refer to the manual
	Alternating Current		Buzzer silence
	Alternating Current		Battery
	Protectively earth		Assist breath
	Equipotential		Address of manufacture
SN	Serial Number		Date of manufacture
	Screen Unlock		Screen lock
	Freeze function Activated		NEBULIZER
	Child mode		Adult mode

1.3 Definitions, Acronyms, and Abbreviations

CPAP	Continuous Positive Airway Pressure
Rate	Respiratory rate.breath 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
Pinsp	Inspiratory airway pressure in PCV
Pmean	Mean airway pressure is updated every at the end oflast breath cycle, i.e. a running mean
Ppeak	Maximum patient airway pressure during a patient breath
Pplat	Patient airway pressure measured at the end of inspiratory pause time
Ptr	Pressure sensitivity
Ftr	Flow sensitivity
Psupp	Pressure support
TI	Inspiration time
Pause	Inspiratory pause time; increase inspiration time to facilitate increased patient oxygenation
Volume	Real time gas volume
VT	Tidal volume of mechanically delivered breaths
VTE	Exhaled tidal volume
VTI	Inhaled tidal volume
Phigh	High pressure level
Plow	Low pressure level
Thigh	High pressure level time
Tlow	Low pressure level time
VCV	Volume control ventilation

PCV	Pressure control Ventilation
PRVC	Pressure Regulated Volume Control
SIMV-V	Synchronized Intermittent Mandatory Ventilation,mandatory type is VCV
SIMV-P	Synchronized Intermittent Mandatory Ventilation,mandatory type is PCV
SIMV-PRVC	Synchronized Intermittent Mandatory Ventilation,mandatory type is PRVC
APRV	Airway pressure release ventilation
BIPAP	Bilevel Positive Airway Pressure
PSV	Pressure support ventilation
INSP HOLD	Manual closure of inspiration and expiration valves after inspiration
EXP HOLD	Manual closure of inspiration and expiration valves after expiration
O_2 SUCTION	100% oxygen gas deliver two minute

2 Structure

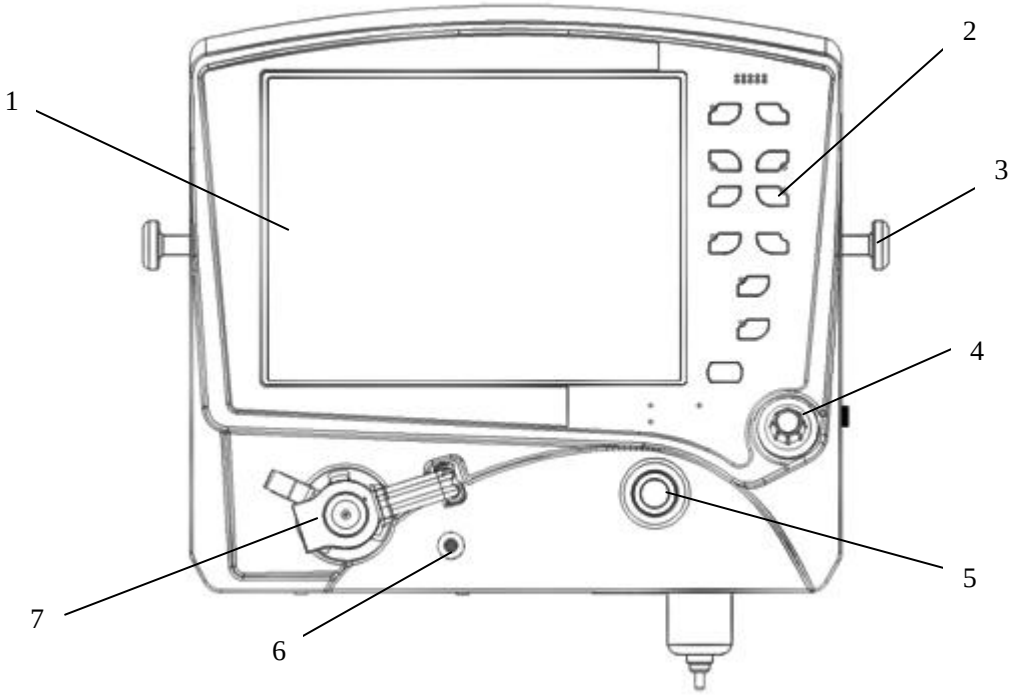
2.1 Frontview

⚠**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 SH300 Ventilator System is in use.**

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

2.1.1 Front panel



1.Display 2.Controls and Indicators3.Holder4.Knob
5. Inspiratory port 6.Nebulizer7.Expiratory valve module

Figure 2-1Frontview of SH300

1. Ventilator display

it displays the most information including alarm message, patient data, waveform monitored etc. More details refer to section 2.1.2.

2. controls and indicators

	Alarm silence	Alarm silence key. Turns off alarm sound for 2 minutes .In this within two minutes , press this key to restore the alarm sounds again, and Again thetiming.
	Alarm reset	Clears inactive alarms
	Screen lock	When the yellow light on the screen lock key is lit, pressing other keys (including the Knob) has no effect until you press the screen lock key again. The screen lock key allows you to clean the LCD screen and prevents inadvertent changes to settings and displays.
	Return	Return to main interface 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 system setting menu. The yellow light on the menu key lights during menu operating period.
	Freeze	freezes the current screen and suspends real-time update of data until pressed again
	Inspiratory hold	Causes the ventilator to seal the patient's breathing circuit after the end of the gas delivery phase of a designated, volume-or pressure-based mandatory inspiration.
	Expiratory hold	Causes the ventilator to seal the patient's breathing circuit when the expiratory phase of a designated breath, mandatory or spontaneous, is followed by a mandatory inspiration.
	Manual inspiratory	Delivers one manual breath to the patient according to the current mandatory settings
	O_2 Suction	Push to deliver 100% O2 for 2 minutes. The yellow light on the O2 suction key lights during 100% O2 delivering period.
	AC power indicator lamp	When the ventilator connected ac power, the lamp lights.
DC	DC power indicator lamp	When the battery supplying power, lamp lights beside DC.

DC STATUS	Charge lamp	When the battery charging, orange lamp lights beside DC STATUS.when the battery is full，the lamp off
	Knob	Push to select a menu item or confirm a setting. Turn clockwise or counterclockwise to scroll menu items or change settings.

2.1.2 LCD screen

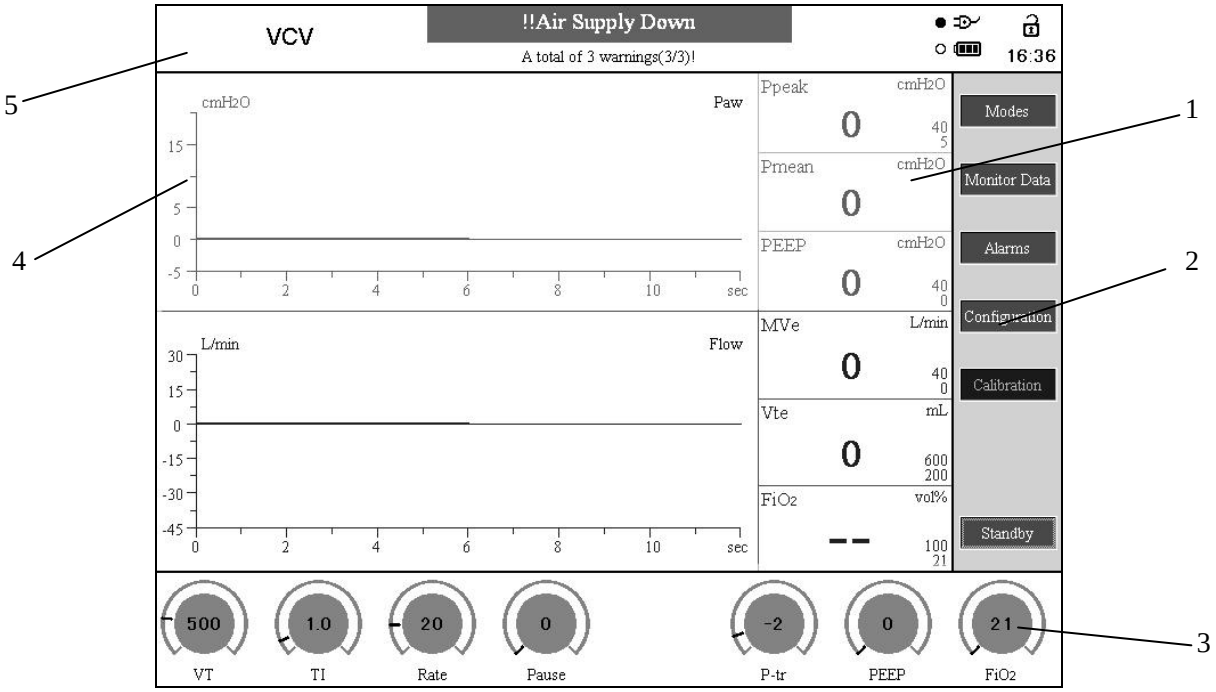


Figure 2-2 main interface

1. Parameters monitored area

   Parameters monitored on the main interface are: MV, VTE, PEEP, FiO_2.etc.the upper and lower limit can be set on the alarm settings menu.

2. Menu bar

   Turn the knob or touch the screen to setting Modes,Monitor Data,Alarms,Configuratian,Calibration,Start/by

3. Parameters setting bar

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

4. Waveforms

   In this area ,it display two types of waveform .More types of waveform can be set on the system configure menu.

5. 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 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 state. from full to empty .when mains fails, the internal battery will supply to ventilator automatically.
- means Child mode; means Adult mode.

2.1.3 Expiratory module

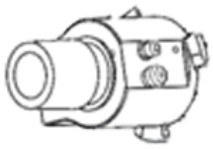


Figure 2-3 Expiration module of SH300

Pressing down the lock locking device on the exhalation valve seat, it is in the unlocked state, and rotate it counter clockwise about ten degrees to take off expiratory module, and then disinfect it. When disinfecting finished, rotate the expiratory module to the original position rightly and then the locking switch returns to locked status automatically.

Make sure the installation must be right, or else leakage may occur. And test the ventilator before putting into operation.

2.2 Back panel

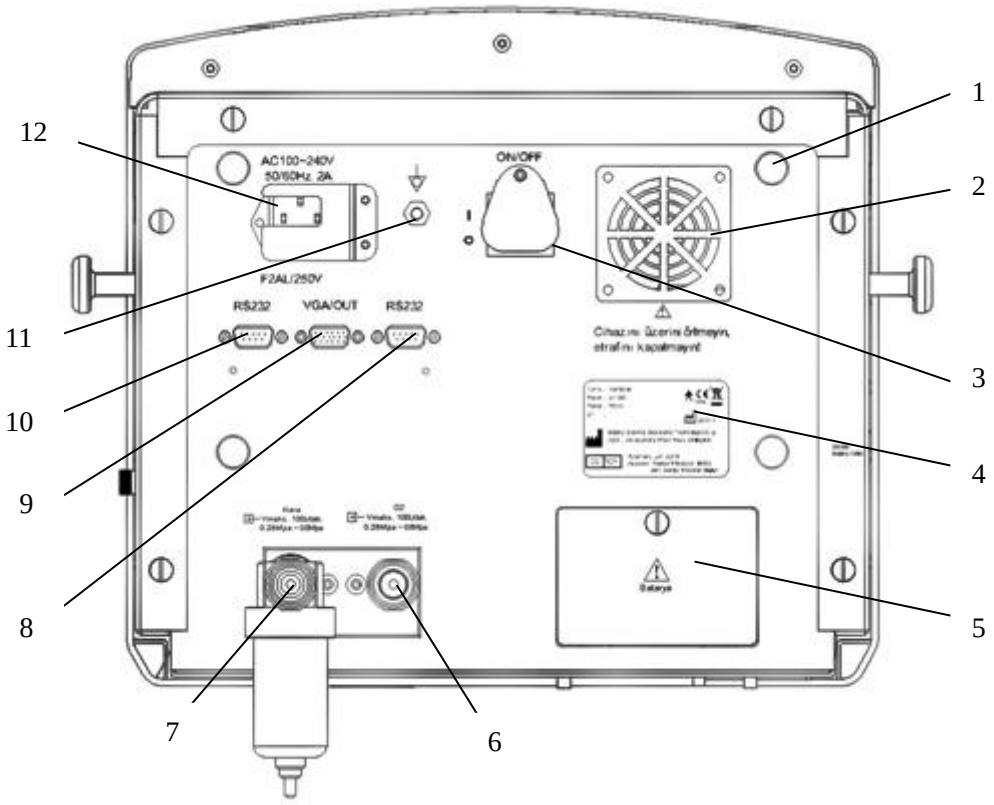


Figure 2-4 back panel of SH300

1. Winding base 2. Fan and fan filter3. Power switch4.Nameplate label
5. Battery box 6. O_2 inlet 7. Air inlet 8. RS232 interface
9. VGA interface 10. RS232 interface11.Potential equalization terminal
12. Power cord socket

3 Operating Guide

3.1 Starting System

Step 1 Connect power supply

Plug the power cord into AC power outlet. The power indicator light will be light when power is connected and the swith turn on

Step 2 Power On

Set power switch to ON (“⊙”).

The ventilator startup, the display screen lights and shows startup interface, see figure 3-1.

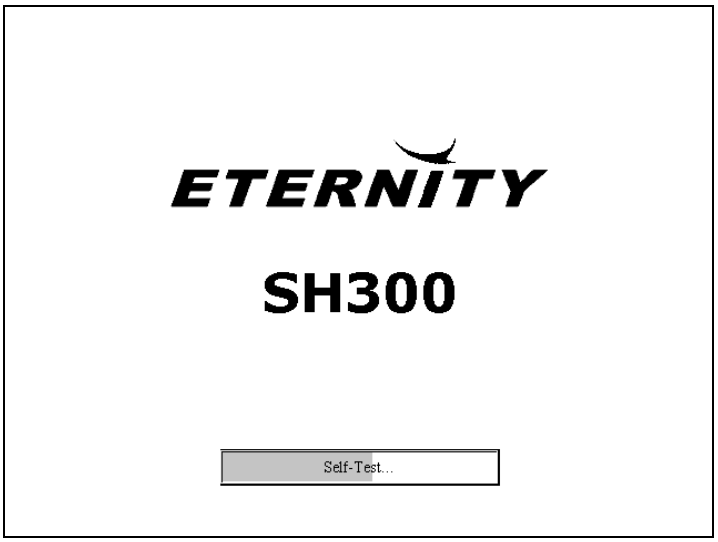


Figure 3-1 Startup interface

Step 3 Patient Setup

Choose your type to be supplied to the patient’s use. Turn the knob to select the desired patient mode, push down to confirm the selection.

After confirming the change option to display a blue background,

Turn the knob to make blue cursor to elevation options dialog, push the knob to confirm , enter into the elevation data to adjust window. Press the knob, when the data to adjust area into a light blue, which can adjust the data.

When the set value, press the button to confirm, then move the blue cursor to "Apply", and press the knob to return the interface.

see figure 3-2

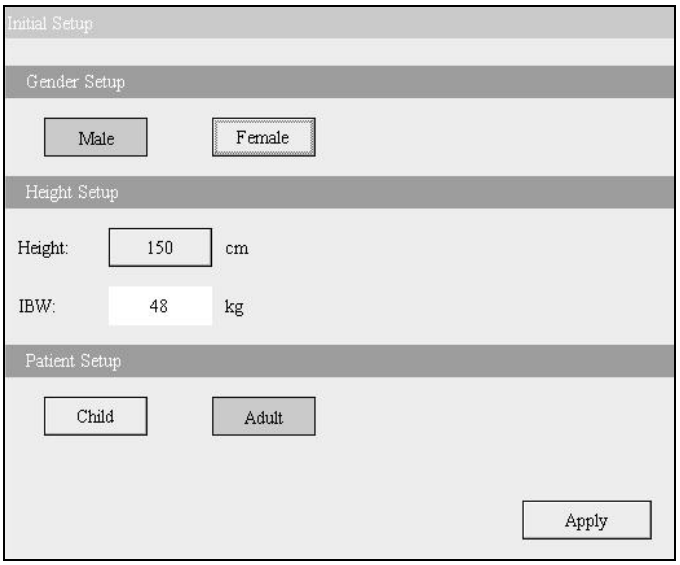


Figure 3-2 Initial Steup interface

Move the blue cursor to "Apply", and press the knob the display screen switches to main interface,

see figure 3-3

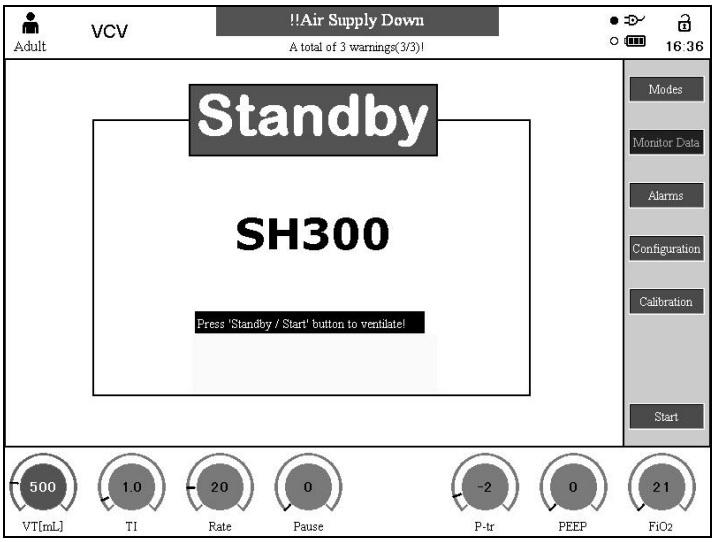


Figure 3-3 Standby interface

NOTE: If you want to change the Patient mode , please TURN OFF the ventilator and then turn on.

3.2 Setup ventilation mode

Step 1

Turn the knob or touch the screen to select "modes" in the upper right corner of the screen, the ventilation mode menu appears on the screen as showed right figure, the mode of focused item is current ventilation mode.

see figure 3-4

.

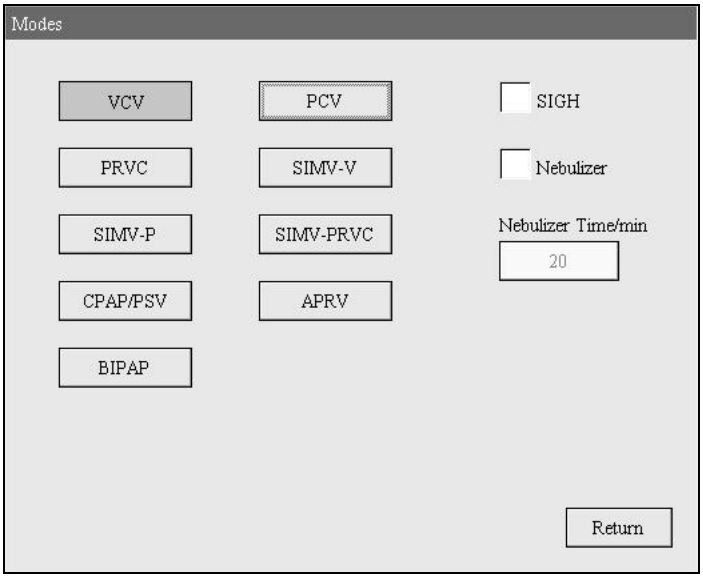
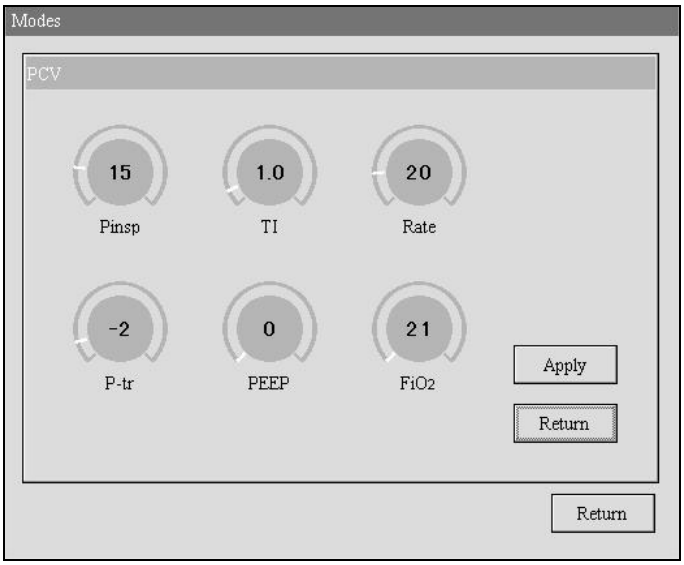


Figure 3-4 Modes interface

Step 2 Turn the cursor will move by selected item. Push the Knob, selected item will be focused to display like right figure. In the pop-up menu , you can set the required parameter values see figure 3-5	 Figure 3-5 Parameter interface

Setting other ventilation mode is similar to the above.

3.3 Ventilation mode introduction

3.3.1 VCV

In VCV 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)breathe(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 VCV mode.

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

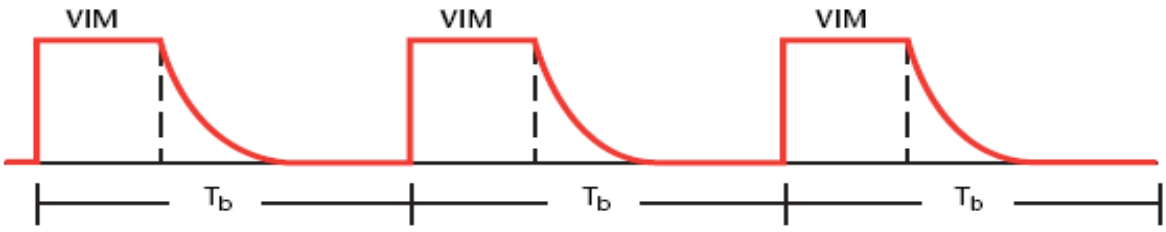


Figure 3-6 VCV mode, no patient effort detected

Figure 3- shows VCV breathe delivery when patient inspiratory effort is detected. The ventilator delivers PIM breathes at a rate more than the set respiratory rate. And Tb is the breath period in seconds.

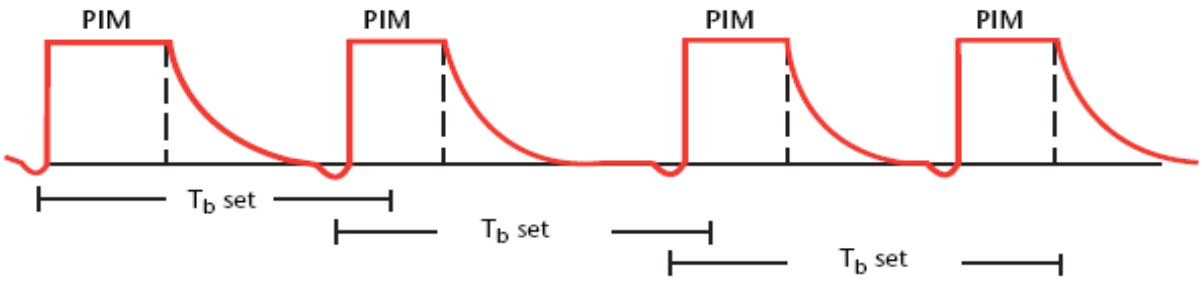


Figure 3-7 VCV mode, patient effort detected

Figure 3-8 shows VCV breath delivery when there is a combination of VIM and PIM breaths. And Tb is the breath period in seconds.

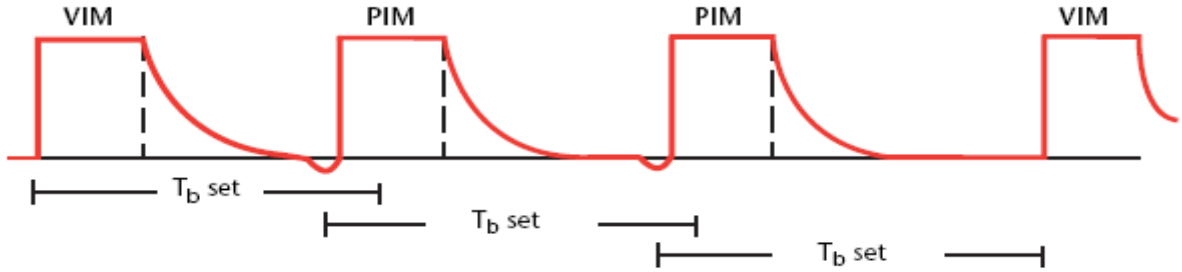


Figure 3-8 VCV mode VIM and PIM breaths

⚠ Caution ：

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

3.3.2 VCV+SIGH

VCV+SIGH, base on VCV 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 volume(**SIMV-V**) or pressure-based(**SIMV-P**) or PRVC(SIMV-PRVC), and the spontaneous breaths can be pressure-assisted (for example, when pressure support is in effect.) You can select pressure-triggering or flow-triggering in SIMV.

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 inspriratory effort is not sensed within the breath cycle).

As Figure 3-9 shown, each SIMV breath cycle (Tb) has two parts: the first part of the cycle is the mandatory interval (Tm) and is reserved for a PIM. If a PIM is delivered, the Tm interval ends and the ventilator switches to the second part of the cycle, the spontaneous interval (Ts), 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.

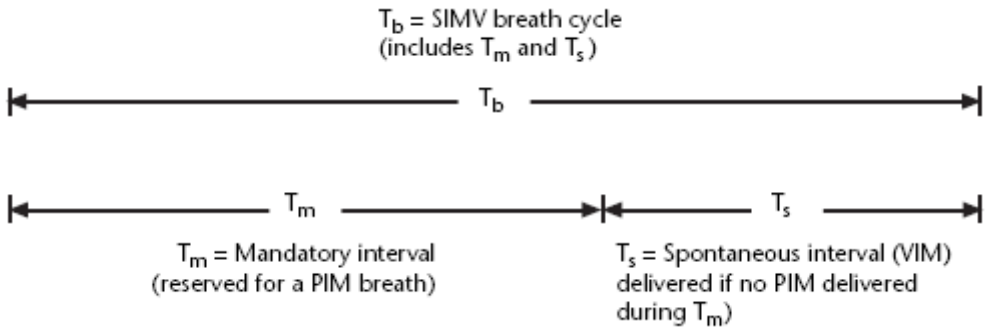


Figure 3-9 SIMV breath cycle (mandatory and spontaneous intervals)

⚠Warning

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

3.3.4 CPAP/PSV

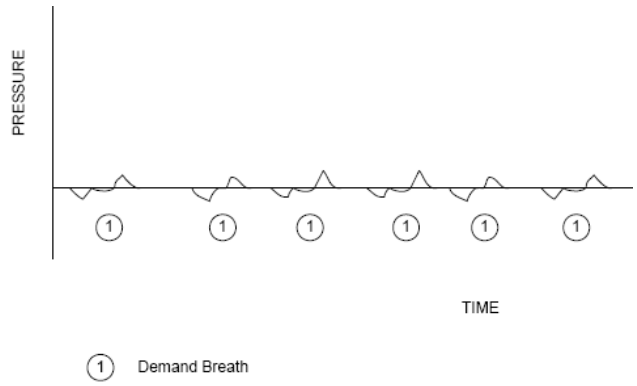


Figure 3-10 CPAP Waveform

In CPAP/PSV mode, inspiration is usually initiated by patient effort. Breaths are initiated via pressure or flow triggering, whichever is currently active. An operator can also initiate a manual inspiration during CPAP/PSV. An operator can also initiate a manual inspiration during CPAP/PSV . VIM breaths are not possible in CPAP/PSV mode.

Apnea Backup ventilation is active in CPAP/PSV 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.

A PSV (Pressure Support Ventilation) breath is a demand breath where the pressure level during inspiration is a preset PSV level plus PEEP. PSV breaths are:

• Controlled by pressure (preset PSV level + PEEP);

• Limited by pressure (preset PSV level + PEEP + margin)

• Cycled by time (PSV Tmax) or flow (PSV Cycle).

Pressure Support is active when CPAP/PSV mode is selected

⚠Warning

Volume breathes is offered for apnea backup delivery.

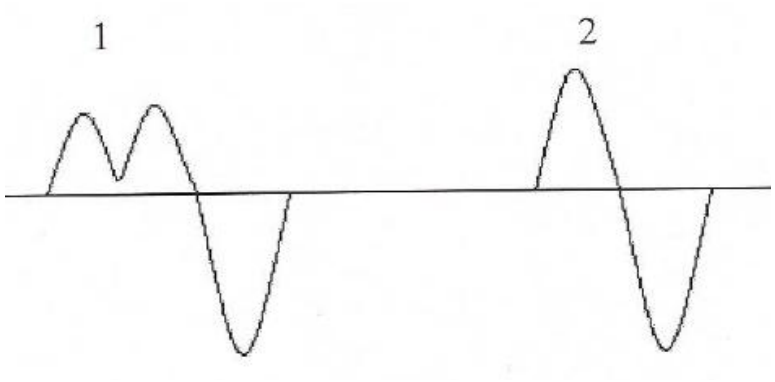


Figure 3-11 PSV Waveform

In figure 3-11 breath number 1 represents the flow tracing which occurs when the PSV level is insufficient to meet the patient demand. Breath two shows resolution after increasing the PSV level slightly.

3.3.5 PCV

PCV (Pressure Control Ventilation) is mandatory ventilation with preset respiratory frequency and pressure limit. The main difference between PCV and VCV is controlled object.Operation theory refers to VCV mode.

3.3.6 APRV

APRV is a Time Cycled Pressure mode in which the ventilator cycles between two different baseline pressures based on time, which can be synchronized with patient effort. Controlled ventilation can be maintained by timed cycling the transitions between baseline pressures. Additionally, CPAP can be added to improve comfort for the spontaneous breathing patient

In this mode, the patient is allowed to breathe spontaneously at two preset pressure levels. These are set using the Phigh and Plow controls. The maximum durationat each pressure during time cycling is set with the Thigh and Tlow controls

The ventilator synchronizes the change from Pressure Low to Pressure High with the detection of inspiratory flow orthe first inspiratory effort detected within the T Low Sync window. Transition from Pressure High to Pressure Low occurs with the first end of inspiration detected after the T High Sync window opens.

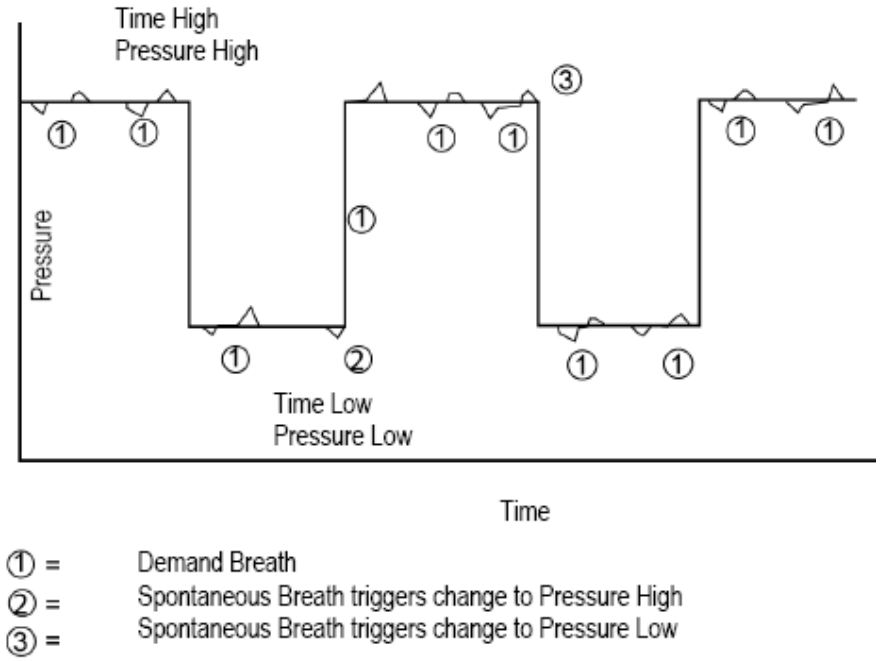


Figure 3-12 APRV Waveform

3.3.7 BIPAP

BIPAP mode is a mixed mode of ventilation that combines the attributes of mandatory and spontaneous breathing. In BIPAP mode, mandatory breaths are always pressure-controlled, and spontaneous breaths can be pressure-supported. In the absence of spontaneous breathing, BIPAP resembles A/C mode, except that BIPAP establishes two levels of positive airway pressure, similar to having two levels of PEEP. Cycling between the two levels can be triggered by BIPAP timing settings or by patient effort. These pressure levels are called low PEEP(Plow)and high PEEP(Phigh). At either pressure level, patients can breathe spontaneously, and spontaneous breaths can be assisted with pressure support. BIPAP monitors mandatory and spontaneous tidal volumes separately.

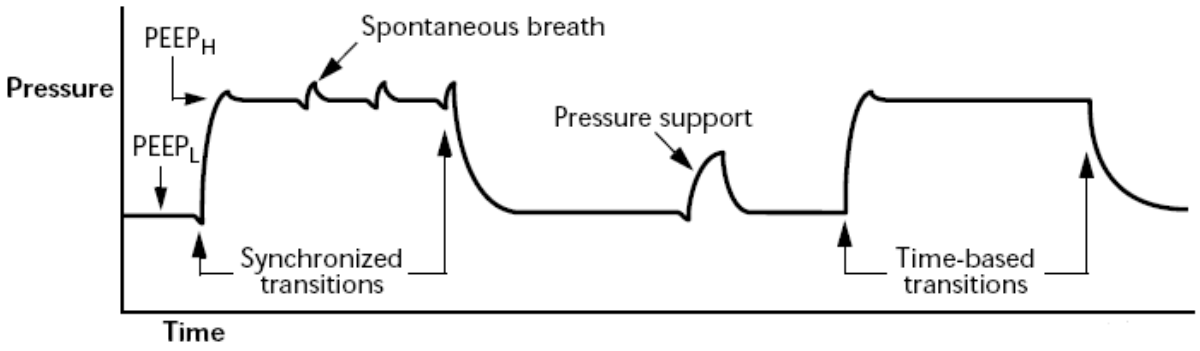


Figure 3-13 BIPAP mode

3.3.8 PRVC

Pressure Regulated Volume Control (PRVC) breaths are pressure breaths where the pressure level is automatically modulated to achieve a preset volume. PRVC breaths are:

Controlled by pressure (inspiratory + PEEP) and volume;

Limited by pressure (inspiratory + PEEP + margin);

Cycled by time.

PRVC breath operation is as follows:

When PRVC is selected, a decelerating flow, volume controlled test breath, to the set tidal volume to the patient. The demand system is active during
this test breath.

The ventilator sets the target pressure at the end inspiratory pressure of the test breath for the first pressure control breath.

The next breath and all subsequent breaths are delivered as pressure control breaths.

The inspiratory pressure is based on the dynamic compliance of the previous breath and the set tidal volume.

The maximum step change between two consecutive breaths is 3 centimeters of water pressure.

The maximum tidal volume delivered in a single breath is determined by the volume limit setting.

3.3.9 SynchronizedNebulizer

When an in-line nebulizer is attached and the Nebulizer button is pressed, the ventilator supplies nebulized gas to the patient at 6 L/min.

The standard in-line nebulizer is powered by 100% oxygen for delivery of prescribed medications in the ventilator circuit. When nebulization is active, the nebulizer flow is synchronized with the inspiratory phase of each breath and can be adjusted in increments of 1 minute for a maximum of 60 minutes.

Nebulization model activate, when into the standby mode the mark nebulization don 't disappear and nebulization time to stop. After working and the nebulization timing to continue.

You may end the nebulization period early by pushing the Nebulizer button again

⚠**CAUTION**：Use of an external flow meter to power the nebulizer is not recommended.

⚠**WARNING** ：Using the nebulizer may impact your patient’s volumes.

3.4 Alarm Settings menu

Turn the knob or touch the screen to select “Alarms”, the following menu appears on the screen.

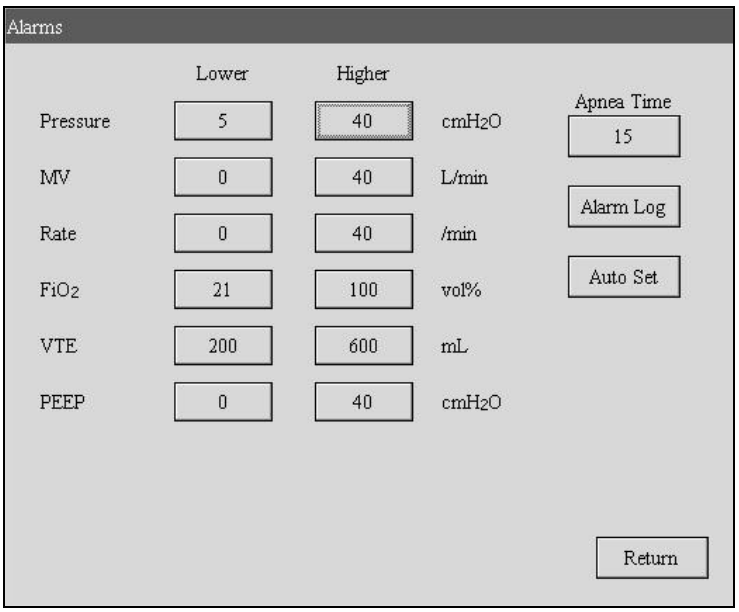


Figure 3 -14 Alarm settings interface

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: cmH_2O;

VTE: Higher limit, unit: L

Rate: Higher limit, unit: bpm

Tapnea time, unit: second;

FiO_2 : upper limit and lower limit

All alarm parameters have a set of presets:

MV higher limit =40 L,MV lower limit= 0L

Pressure higher limit = 40cmH_2O,Pressure lower limit = 5cmH_2O

VTE Higher limit = 600mL,VTE lower limit= 200mL

Rate higher limit= 40bpm, Rate lower limit= 0bpm

Tapnea time = 15s

FiO_2higher limit= 100%,FiO_2 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 SYSTEMuseless！**

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.

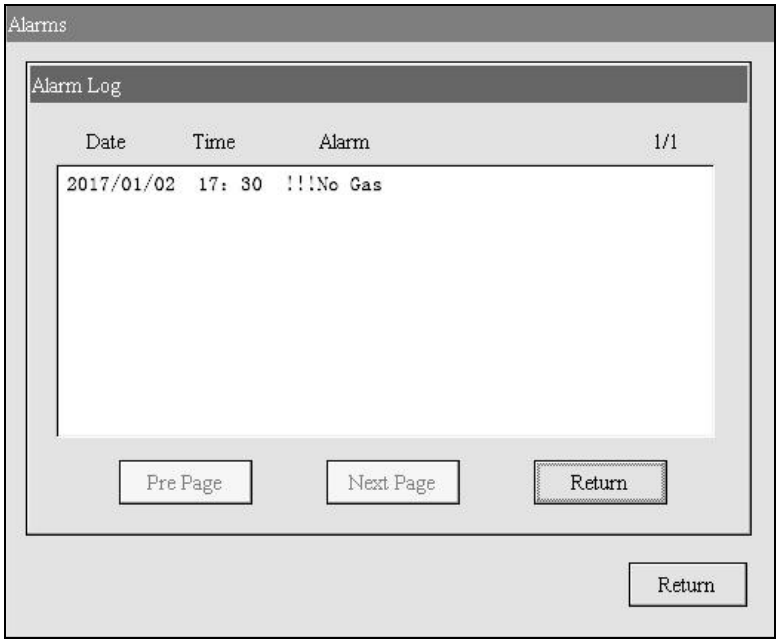


Figure 3-15 Alarm log submenu

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 Knob to s check details up and down.

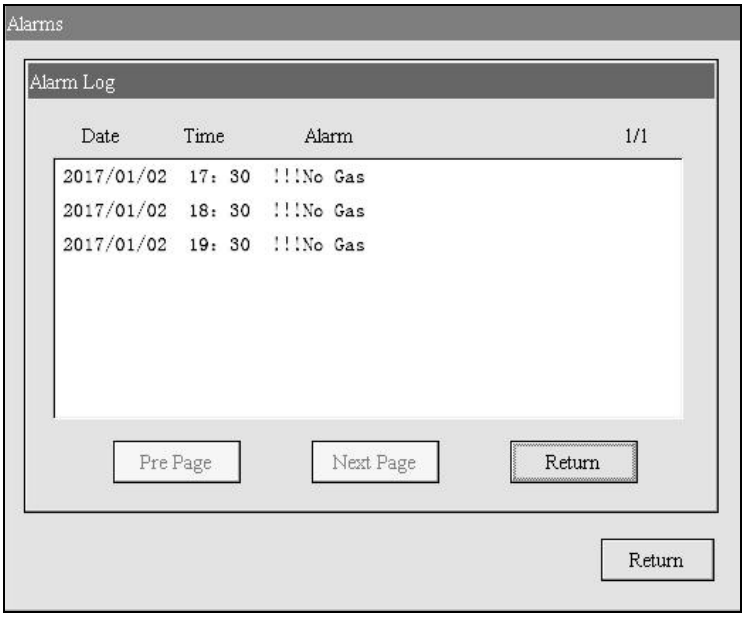


Figure 3-3 Alarm log interface

NOTE:
The alarm log can store up to 100 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 continuely.

3.5 Monitor data

Turn the knob or touch the screen to select “Monitor Data”, the screen like the following figure.

Figure 3-17 Monitor Data interface

3.6 Configuration menu

Turn the knob or touch the screen to select “Configuration”, on the screen like the following figure.

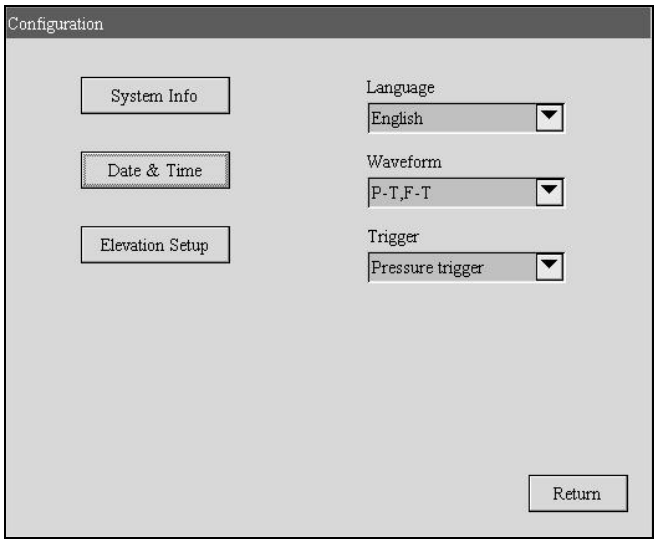


Figure 3-18 Configuration interface

1.System Info

Turn the knob or touch the screen, select System Info button, push it and enter into System Info menu.
In the System Info menu, the current software version of all boards is listed and display the run time of this device.

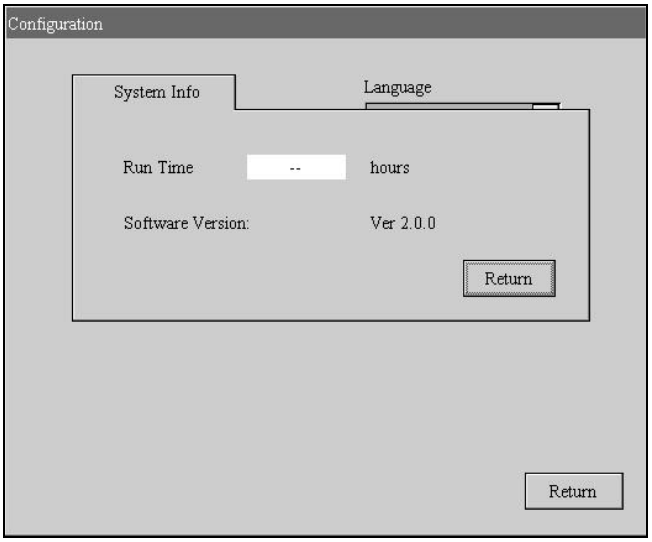


Figure 3-19 System Info interface

2.Date and Time

Turn the knob or touch the screen, select System Info button, push it and enter into System Info menu.
In the System Info menu, set year, month, day and time

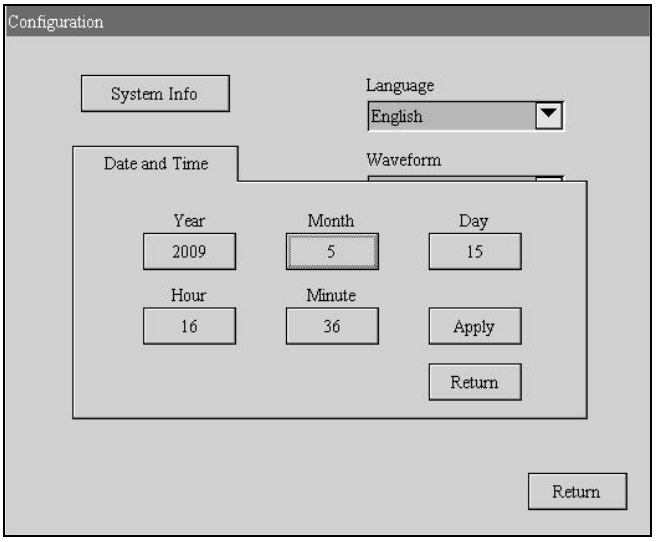


Figure 3-20 Date and Time interface

3.Elevation Setup

Turn the knob or touch the screen to make blue cursor to elevation options dialog, push the knob to confirm , enter into the elevation data to adjust window.
Press the knob, when the data to adjust area into a light blue, which can adjust the data.

After setting the data , and then press the knob to confirm, then move the blue cursor to "Apply".press the button to confirm.

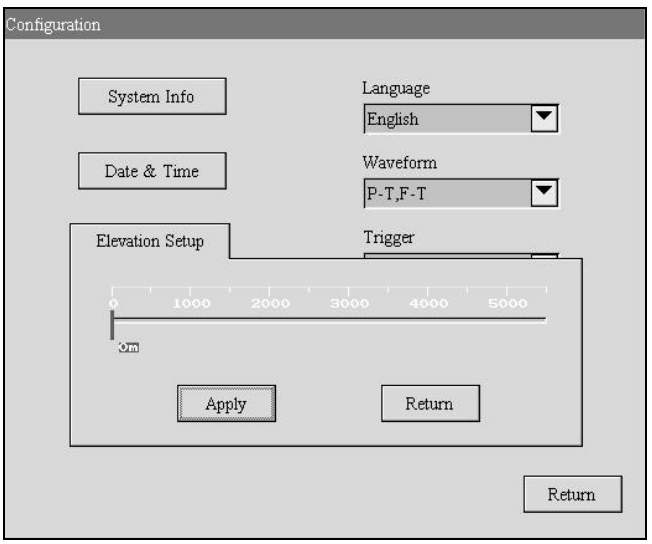


Figure 3-21 Elevation Setup interface

4.Language

Turn the knob or touch the screen to select Language dropdown listbox as right figure.

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

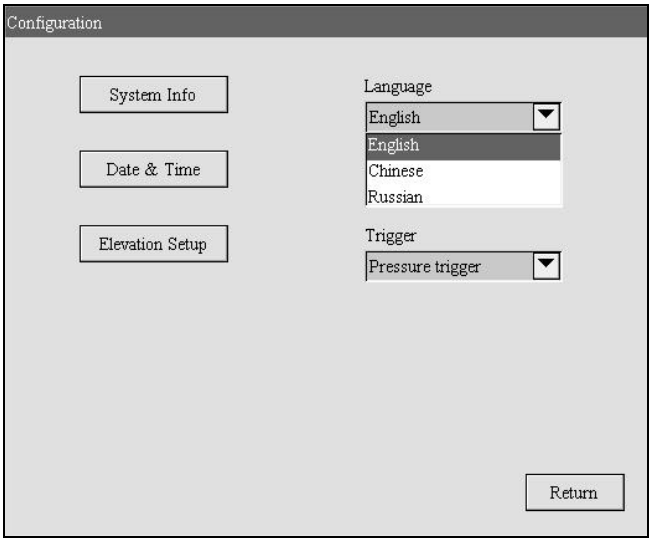


Figure 3-22 Language interface

5.Waveform

Turn the knob or touch the screen to select waveform dropdown listbox as right figure.

It have five choices.

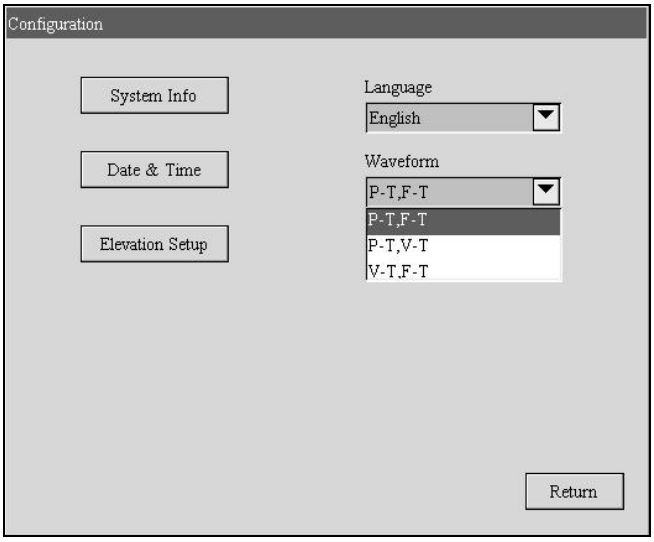


Figure 3-23 Waveform interface

6.Trigger Type

pressure trigger and flow trigger
If trigger typed changed, the relative parameter on the parameter bar changed in-phase and keep identical.

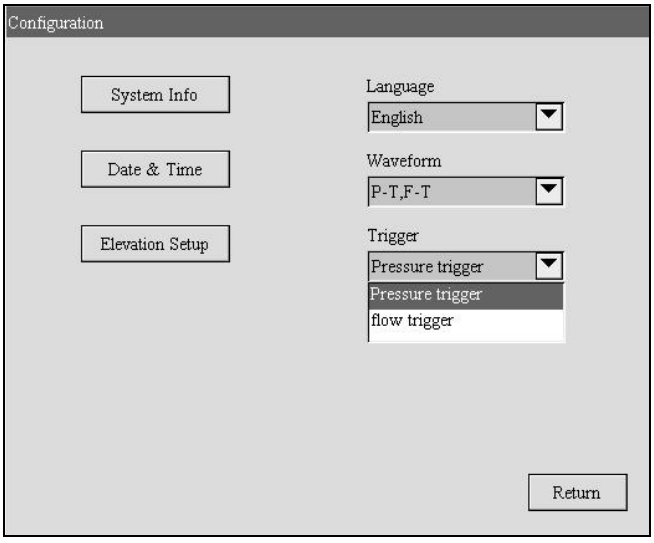


Figure 3-24 Trigger Type interface

3.7 Ventilation parameters setup

Turn the Knob in main windows to select VT button as shown in right figure. Press the Knob and rotate it to adjust VT value until the wanted, and then press it again to confirm. When TI is adjusted, the limit by VT, Rate and Pause is considered, if the set is limited, please check those parameters.	 Figure 3-25 Ventilation parameters setup interface

Setting procedure about other parameters is similar to one above.

3.8 Main menu

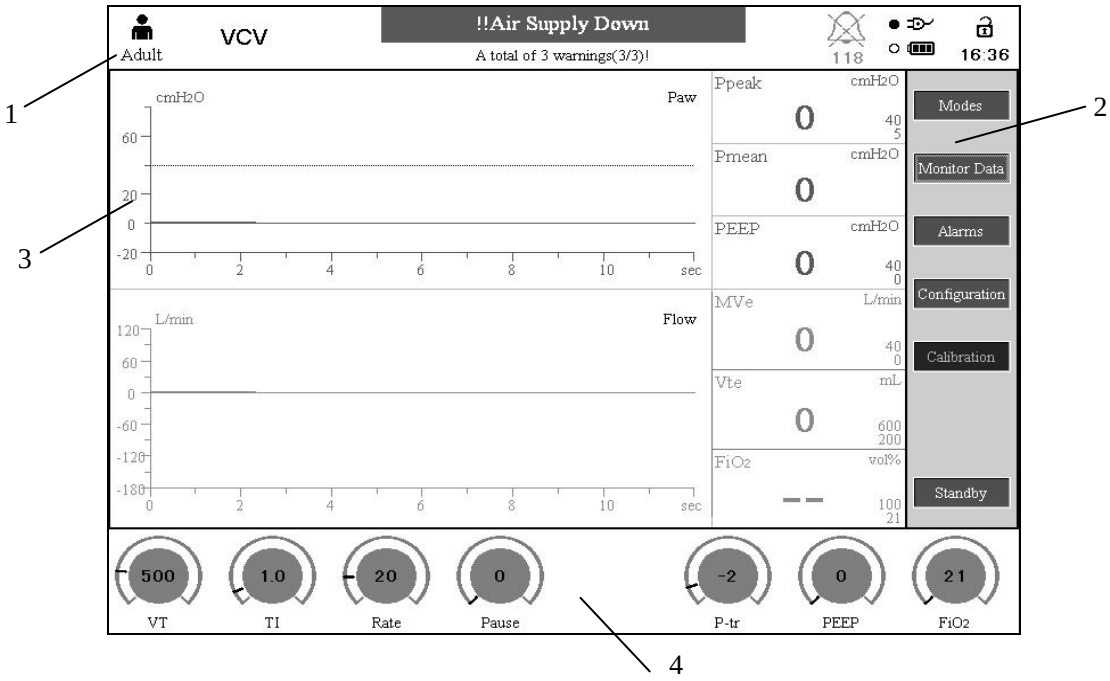


Figure 3-26 Main menu

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

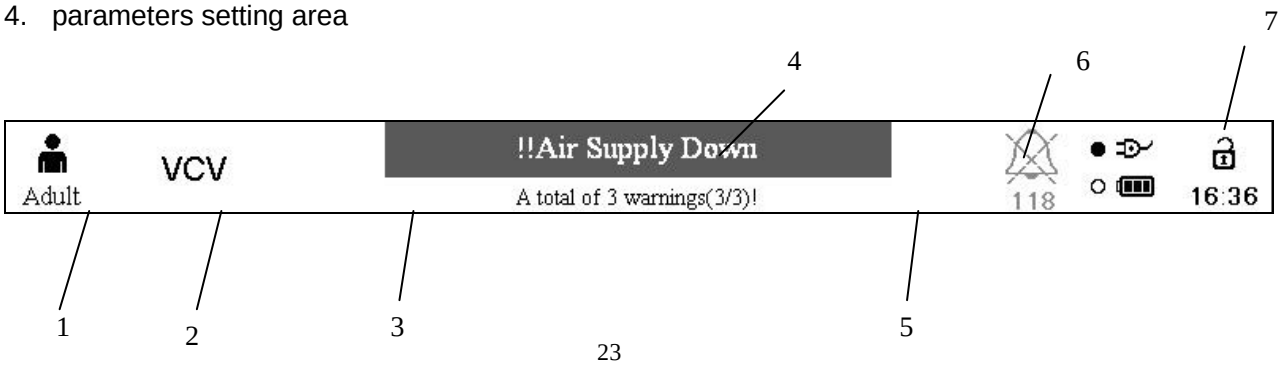


Figure 3 -27 Information bar

1. modes display area
2. Trigger and Nebulizer 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 and lock state

3.9 Assist function operating

3.9.1 Freeze

The FREEZE button freezes the current screen and suspends real-time update of data until pressed again. This function is only valid in main menu.

3.9.2 Insp Hold

When the Insp Hold button is pressed and held, once the preset volume of a volume breath has been delivered, the patient is not allowed to exhale for a maximum of 15 seconds.

3.9.3 Exp Hold

When the Exp Hold button is pressed and held, at the start of the next breath interval the ventilator does not allow the patient to inspire or exhale for a maximum of 15 seconds.

3.9.4 Manual Insp

Pressing this button during the expiration phase of a breath delivers a single mandatory breath at current ventilator settings. No breath is delivered if the button is pressed during inspiration.

3.9.5 O_2 Suction

When this button is pressed, the ventilator increases the oxygen concentration delivered to the patient to 100% for 2 minutes. If the 100 %O2 button is pressed again within the three-minute period, themaneuver is cancelled and the ventilator returns to the prior settings for FiO2.

3.9.6 Lock

When press down this button, all the key can not use. If press down this button again, you can use all key.

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 section9.3 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 VENTLATOR BREATHING SYSTEM, measured with respect to the PATIENTCONNECTIONPORT, 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 Assembling the ventilator

Assemble your SH300 ventilator’s cart using the following instructions. The ventilator body is easily attached to the base by means of four thumbscrews.

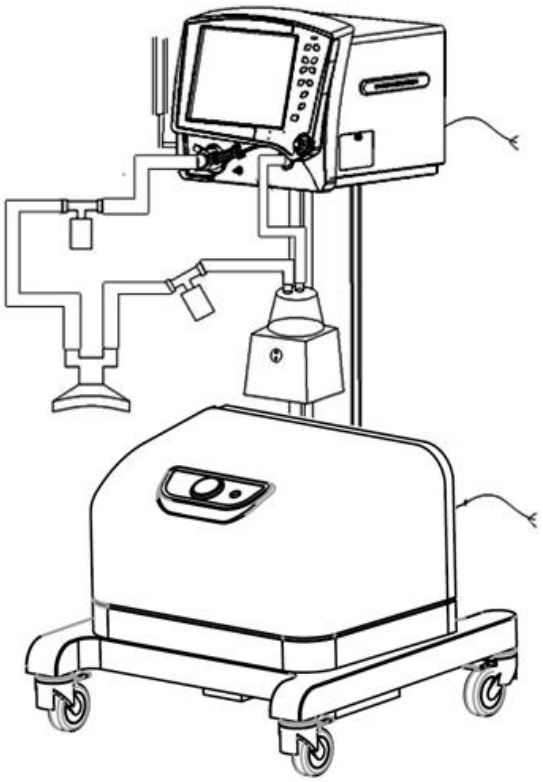


Figure 4-1 Ventilator

4.2 Assemble of the cart

You should assemble the cart and ventilator before use., install the ventilator onto the connecting plate with four screws(see figure 4-3).

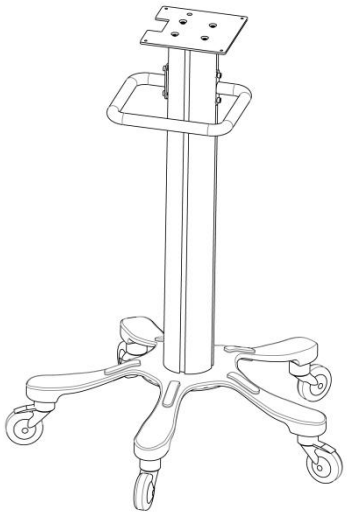


Figure 4-2 connection for pillar

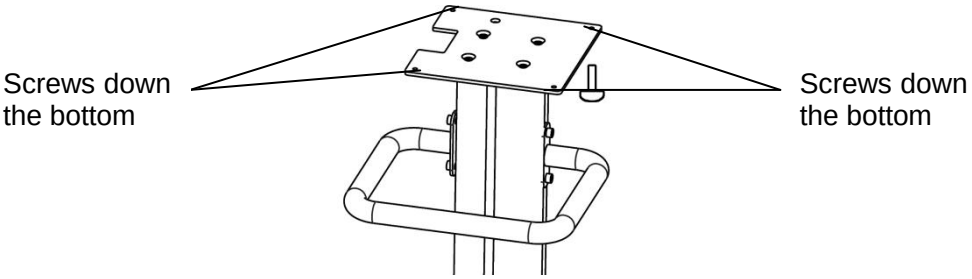


Figure 4-4connection for the Ventilator

4.3 Connect tube

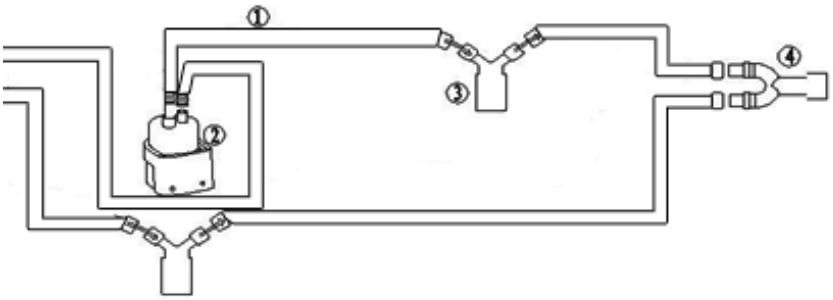


Figure 4-5 connection for patient tubing

You can connect the patient tubing as figure 4-5, and then connect it with ventilator.

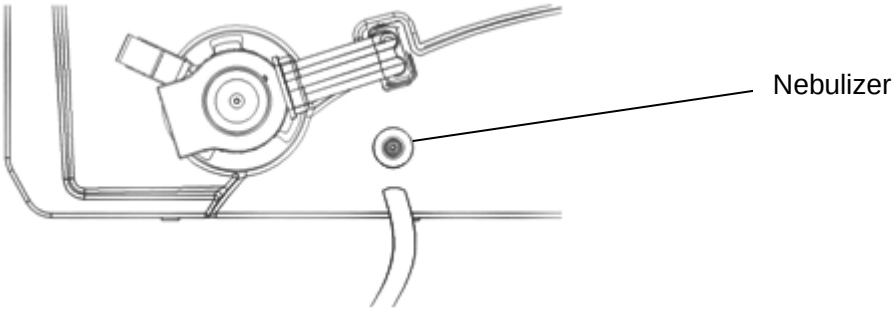


Figure 4-6 Attaching a Nebulizer

You can use an in-line nebulizer with the Vela ventilator. To use a nebulizer you must have a high-pressure oxygen source attached to the ventilator. Attach the nebulizer tubing as shown in figure 4-6.

4.4 Connecting Gas and Electricity

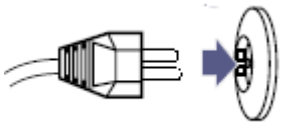
⚠ Warning：

- 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

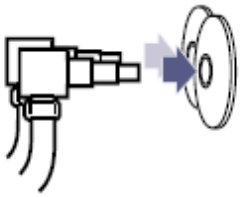
necessary.

- For two-phase alternating current circuit user, do not attempt to switch earth line and zero line. SH300 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

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.	

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:	Breathing system test:
Power failure alarm test:	
Alarm 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 “ ⊙ ”, stand-by interface appears after a while.
2. After operating for 5 minutes, pull out power cord.
3. Make sure that power off failure alarm occurs , which has the following characteristics:
   Alarm sound;
   “!MAINSFAILED” message displays on the alarms information display area;
4. Connect power cord again.
5. Make sure the alarm eliminate.

5.4 Test humidifier performance

Test about humidifier refer to relative instructions for use.

5.5 Alarm test

1. High pressure alarm test

   Set Vt to 500, upper limit of Paw to 20cmH_2O. Press standby key to ventilate, and then press the reservoir bag to make the pressure increasing in the patient circuit, when Paw more than 20cmH_2O, 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 Vt 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 Vt to 400ml, Rate to 20 ,one minute later, high tidal minute volume alarm occurs.

6. low oxygen concentration alarm test

   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

   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 Vt 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 Vt 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:	VCV;
Rates of breath:	20;
T_I:	1.0;
T_P	0;
Airway pressure upper limit (×0.1kPa)：	40;
Airway pressure lower limit (×0.1kPa)：	5;
PEEP	0;
P-tr	-2;
V_T:	500;
FiO_2:	21%;
Gas supply rated pressure	0.4MPa

4. Check tidal volume

Cut off the gas supply, turn to the VCV ventilation mode, it should be 0 of the tidal volume monitor. Recover the gas supply and adjust Vt to 700ml, check the tidal volume monitor is at a range of 700±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 pressure sensitivity:

Set the trigger pressure at -0.1kPa, wear the mask and do ainspiration, the inspiration step of the ventilator begins after airway pressure lower 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 pressure with -0.2kPa, wear mask. The ventilator begins a ventilation when the airway pressure lower than -0.2kPa. 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 6cmH_2O, 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.

6.1 Cleaning and sterilizing

⚠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

<table>
<tr><th>Part</th><th>Procedure</th><th>Comments</th></tr>
<tr><td rowspan="2">Ventilator external surfaces（ exclude LCD screen）</td><td>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.</td><td>Do not allow liquid or sprays to penetrate the ventilator or cable connections. Do not use pressurized air to clean or dry the ventilator,.</td></tr>
<tr><td colspan="2">⚠ Warning：
● Do not use organic impregnate to clean the ventilator surface.
● 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.</td></tr>
<tr><td rowspan="2">Patient circuit tubing</td><td></td><td>Breath tubing supplied by Eternity is disposable, do not try to sterilize.</td></tr>
<tr><td colspan="2">⚠ Caution：
● If users select patient circuit tubing by themselves, Eternity suggests they should use breath tubing that gets CE mark.</td></tr>
<tr><td rowspan="2">Expiratory module</td><td>Take off expiratory module, dismantle it and disinfect them respectively to use steaming.
Disinfect expiratory module when patient changing.</td><td>After disinfecting and airing, install the expiratory module and pay attention to airtightness.</td></tr>
<tr><td colspan="2">⚠ Caution：
● Make sure that no liquid remains in the pressure measuring canal of the expiratory module, since it might cause malfunction.</td></tr>
</table>

⚠ **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. Immersecomponents in certain disinfection solution over 2 hours. And then put it in a formalin fume box 12 hours for more disinfection.

6.1.1 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.).

6.1.2 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.

6.1.3 Disinfecting/Cleaning/Sterilizing Schedule

What	**How often**	**How**		
Reusable components	Recommended cleaning intervals)	**Disinfecting and cleaning**		**Sterilizing**
		Wiping	Immersion	Steam 134 °C, 10 minutes
SH300ventilator	after each patient	outside	no	no
mobile stand, circuit support arm, gas supply hoses	after each patient	outside	no	no
Patient circuit, Y-piece, water traps, collecting jar	as needed	no	yes	yes
Expiratory module	after each patient weekly	no	yes	yes

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.

6.1.4 Cleaning Method for the Exhalation Valve Assembly

Remove the Exhalation Valve Assembly for Cleaning

1. Press and hold the release latch on the lower right left of the exhalation valve housing.
2. Grasp the exhalation valve body, and then gently pull it free from the housing.
3. rotate platen counter-clockwise until it is removed, Grasp the exhalation valve diaphragm and remove it from the exhalation valve body.
4. Using a clean soft cloth and Isopropyl Alcohol, wipe all exposed surfaces around the exhalation valve housing. Do not allow cleaning fluid to spill into the opening in the exhalation valve housing.

To Clean the Exhalation Valve Body and Diaphragm:

1. Soak in Klenzyme solution for 5 minutes. Klenzyme bath may be heated to a maximum of 67 °C (152 ºF).
2. Rinse in distilled water. After cleaning the surfaces, make sure all excess cleaning solution is completely removed to prevent residue buildup. Dry with a soft cloth or allow to air dry.

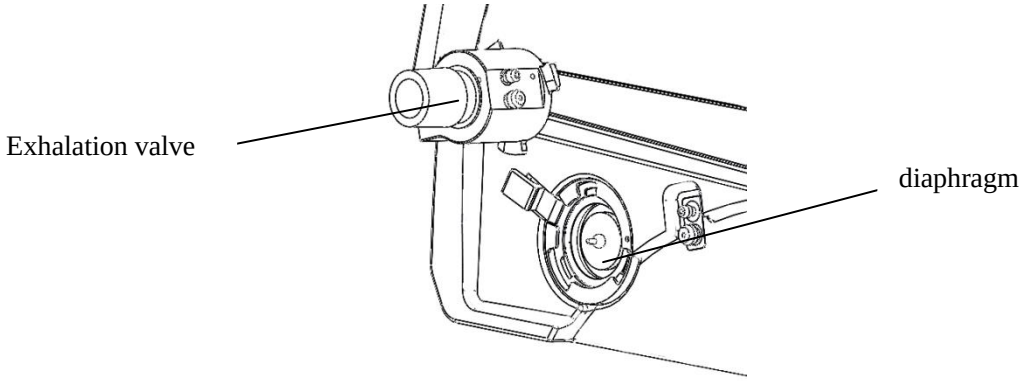


Figure 6-1 Removing of Exhalation Valve

6.1.5 Method of Sterilization for the Exhalation Valve Assembly

The preferred method of sterilization is Steam Sterilization (autoclave), minimum 132° C (270° F) maximum temperature 134 ºC (273 ºF). It is recommended that the accessories listed above be replaced after 30 cleaning and sterilization cycles.

1. After cleaning the surfaces, make sure all excess cleaning solution is completely removed toprevent residue buildup.
2. Sterilize the exhalation valve body and diaphragm using steam autoclaving within the guidelines stated above.
3. Using a low flow gas source (less than 10 L/min) ensure the differential pressure tubes are free of moisture and debris.
4. To avoid possible damage to elastomeric components, the peak temperature for Respiratory Care accessories should not exceed 275 °F (135 °C) for steam autoclave.
5. Steam autoclave at 0 gravity cycle time is 15 minutes. At HiVac (20 psi) cycle time is 7 minutes and drying time is 10 minutes.

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 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.

7.2.1 User maintenance

Frequency	**Maintenance**
Daily	Clean the outer surface.
Weekly	Perform pressure sensor calibration.
Monthly	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.

7.2.2 Useful life estimation

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

Note: if the Exhalation valve diaphragm, oxygen sensor, the respiratory pipe over the use of time, there will be service tips, please contact the nearest Eternity customer service center.

Face mask, Patient circuit	Single use
Power cord, gas pipe	8 years
Main unit	8 years
Battery	1 year
Exhalation valve diaphragm	6 months
oxygen sensor	12 months
breathing pipeline	18 months

7.2.3 Calibrating sensor

Set the ventilator into standby mode, Turn the knob or touch the screen to select "Calibration", see figure7-1.

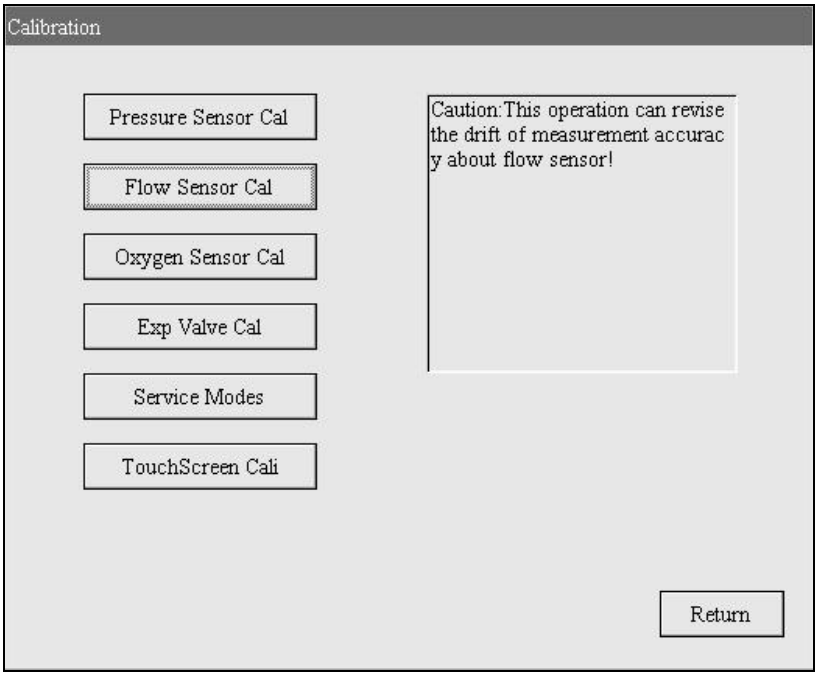


Figure 7-1 Calibration menu

1.Calibrate Press sensor

Turn the Knob to select Pressure sensor button, see right figure.

push the Knob, enter into pressure sensor calibration menu.
see right figure.

Select do button, push Knob to calibrate
If succeed, the word Calibration completed will be displayed on the screen

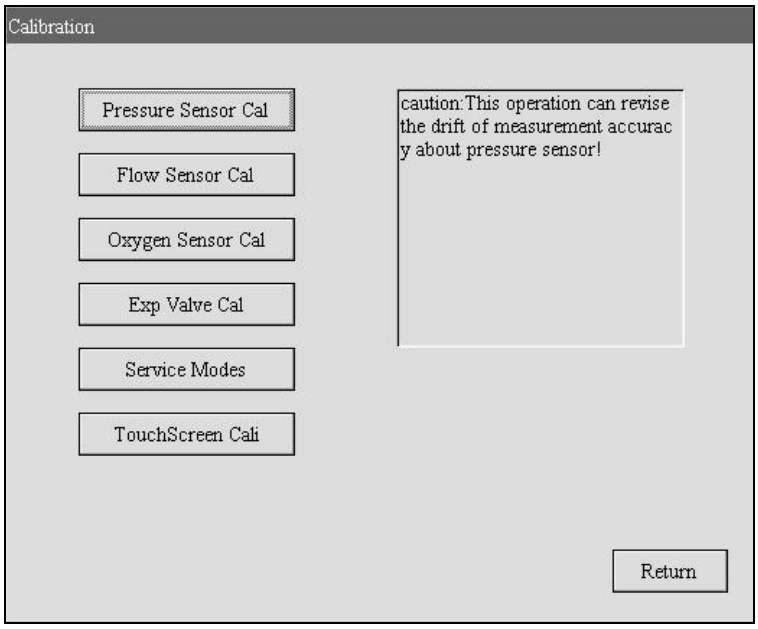


Figure 7-2 Calibrate Press sensor interface

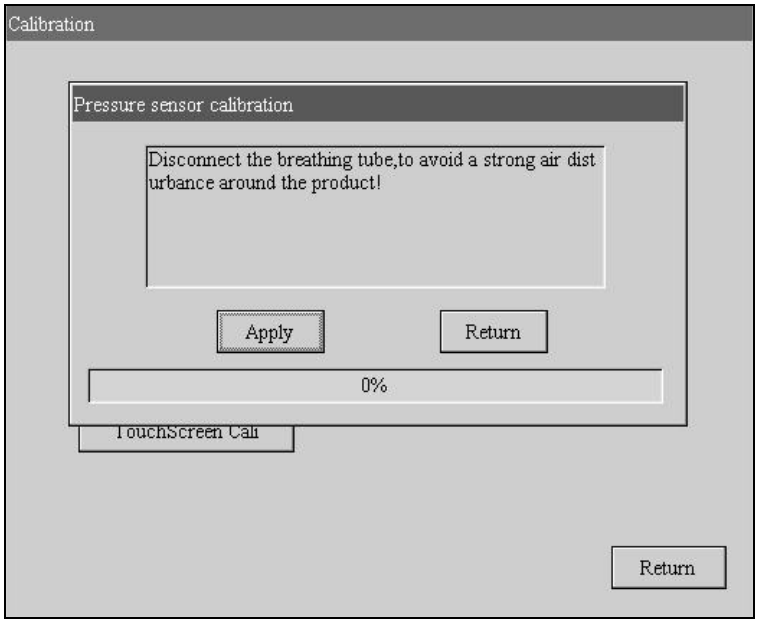


Figure 7-3 Calibrate Press sensor interface

2.Calibrate flow sensor

Turn the Knob to select Flow sensor and press it, see right figure.
The other operation like the press sensor calibrate.

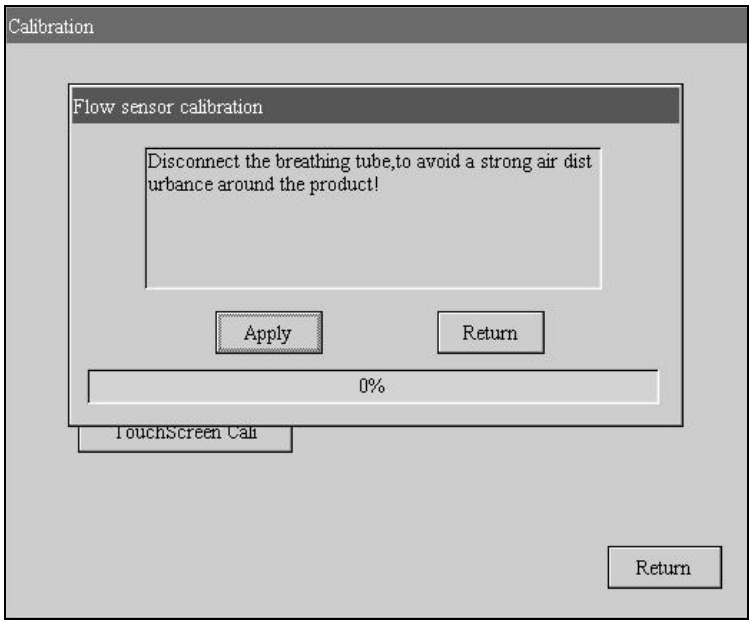


Figure 7-4 Calibrate flow sensor interface

3.Calibrate oxygen sensor

Turn the Knob to select *oxygen sensor* and press it, see right figure.
The other operation like the press sensor calibrate.

NOTE: Make sure the ventilator connect enough air and oxygen.

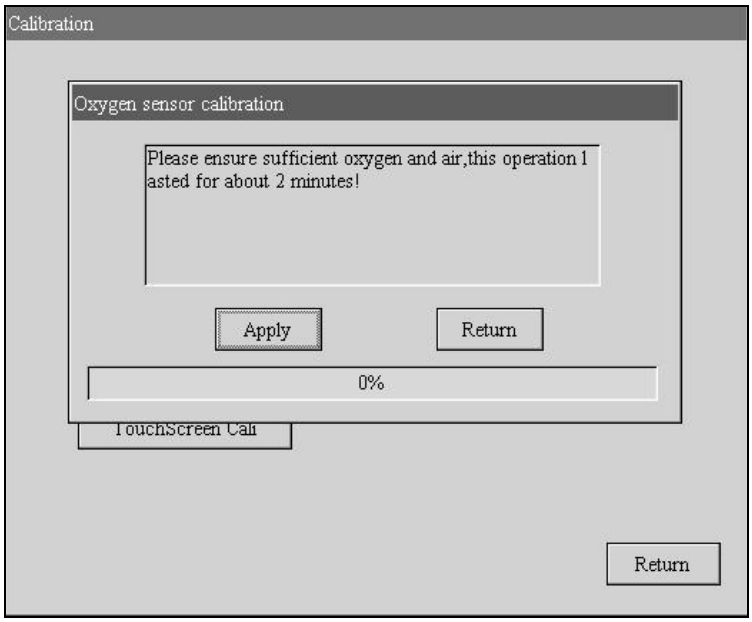


Figure 7-5 Calibrate oxygen sensor interface

4.Calibrate Exp. Valve

Turn the Knob to select Exp Valve Cal and press it, see right figure.
Calibrating procedure refer to Calibrating pressure sensor.
The other operation like the press sensor calibrate.

NOTE: Before calibrating expiratory valve, ensure no leakage!

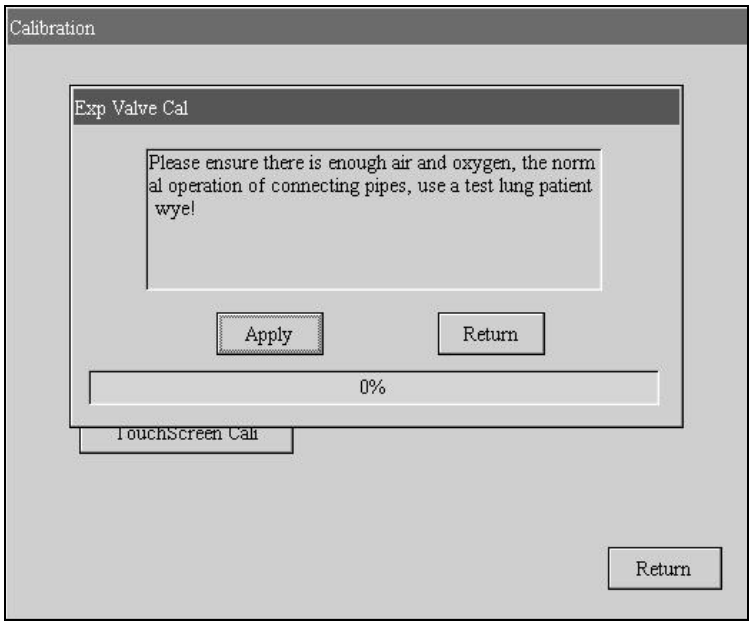


Figure 7-6 Calibrate Exp. Valve interface

5.Service Modes

Used by after-sales engineers to verify machine use

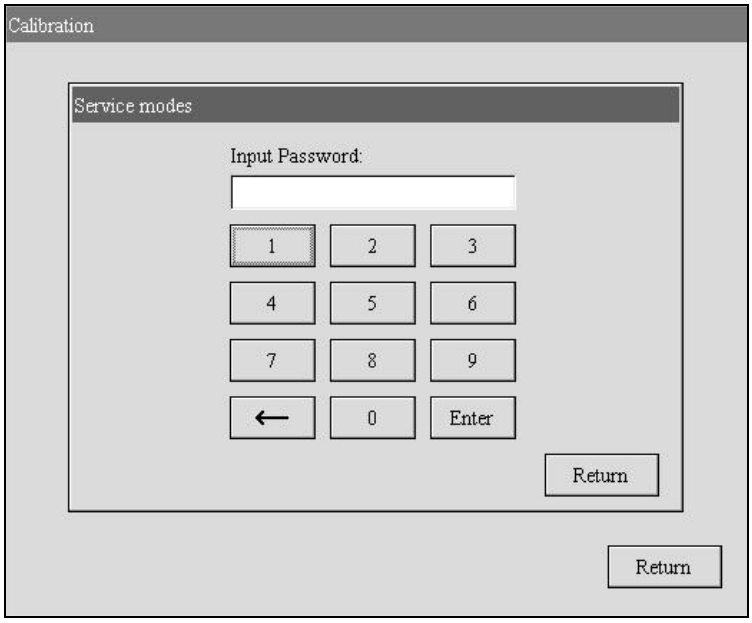
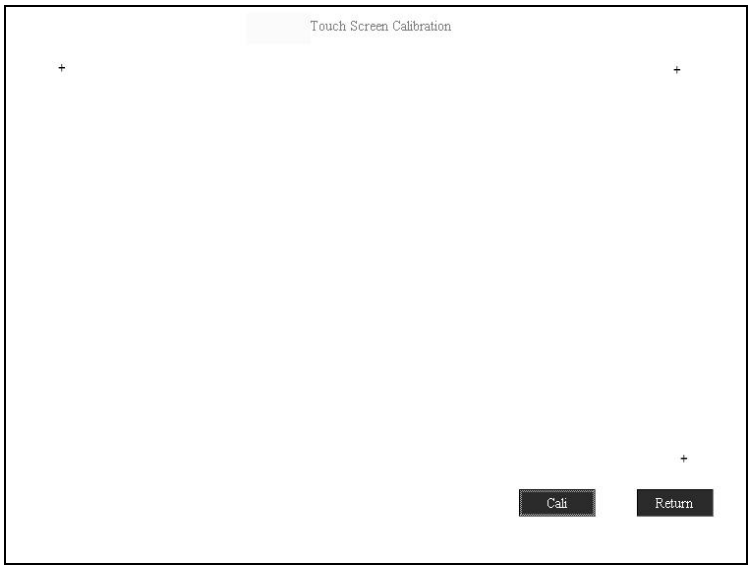


Figure 7-7 Service Modes interface

6.Touch Screen Cali For touch screen verification	 Figure 7-8 Touch Screen Cali interface

7.3 Assembling the expiratory module

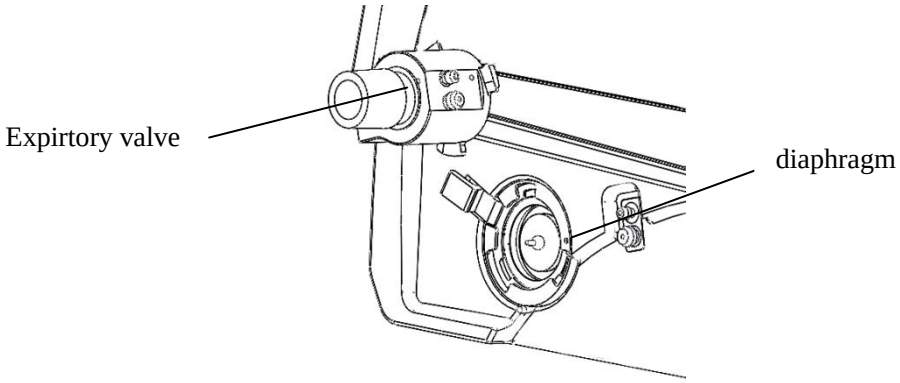


Figure 7-9 assembling for expiratory valve body

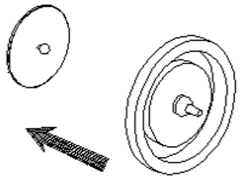


Figure 7-10 assembling for diaphragm

Assembling steps:

1. Insert the support plate into diaphragm.
2. Diaphragm placed in the installation of the exhalation valve seat internal.
3. Pressing down the locking device on the exhalation valve seat. Alignmenton the exhalation valve to exhalation valve seat mounting location, rotate it clockwise take off expiratory module. then the locking device returns to locked status automatically.

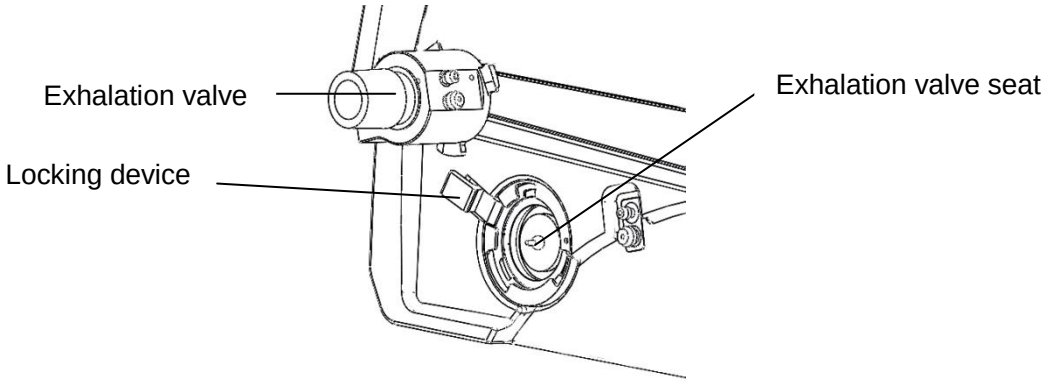


Figure 7-11 installing expiratory module

⚠**CAUTION: If the diaphragm damages, please contact Eternity.**

7.4 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.**

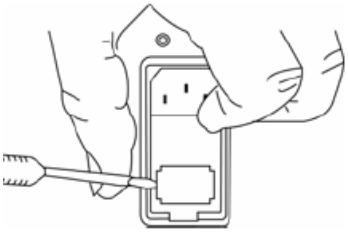


Figure 7-12 Pry out the fuse holder

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.

7.5 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℃～+50℃ and relative humidity above 90%.

7.6 Maintaining battery

1 Specification

DC16.2 VDC，6900mAh;Lithium battery package.

Charge: 6 hours typically

Temperature protect: 65℃

Overflow protect:6A

2 Cautions

Charge: Once AC supply connects and turn on the swith; the system will charge battery automatically. It is recommended that charging time is better than 6 hours.

Discharge: It will last 60 minutes 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 SH300 Ventilator System will shut off in several minutes automatically.

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

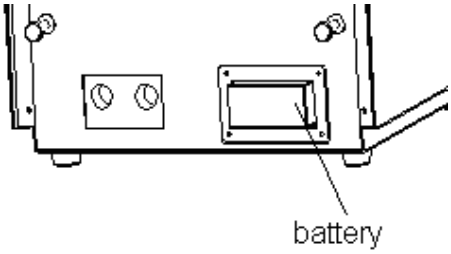


Figure 7-13 replace battery package

Replacing steps:

1 Using a cross screwdriver, lift open the battery box cover.
2 Remove the battery package from battery box and unplug the connector from cable.
3 Replace with battery package indicated by Eternity and plug the connector reliable.
4 Using the same cross screw driver, screw in tightly.

7.7 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 aworking electrode and a reference electrode. The oxygen is reduced electrochemically and the resultant current is proportional to the O2 partial pressure in the gas.

7.7.1 Replace O_2 sensor

WARNING: Comply with the relevant rules about biohazard when to disposesensor.

Replacement steps:

1 Using a cross screwdriver, open the oxygen sensor box cover.
2 Disconnect the cable and unscrew oxygen sensor from inspiratory module.
3 Replace it with a new one, and connect the cable to O_2 sensor.
4 Using the samescrewdriver,install the oxygen sensor box cover.

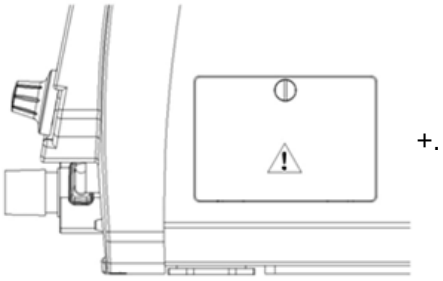


Figure 7-14 replace oxygen sensor

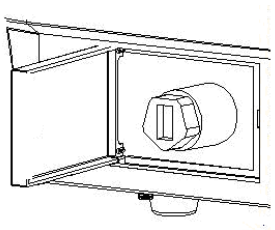


Figure 7-15 unscrew oxygen sensor box cover

7.7.2 Calibrate O_2 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 O_2 sensor, ambient pressure must be equal with monitoring pressure of delivering O_2 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 7.2.3 calibrating oxygen sensor.

7.7.3 Technical requirements

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

O_2 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 O_2 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℃

Response time: not more than 13 seconds

Useful life: not less than 12 months

Accordable standard: ISO 21647 / ISO 7767

7.7.4 Recommended O_2 sensor

Type	OOM102-1	OOM103-1
Manufacturer	ENVITEC	ENVITEC
Response time (second)	<13 seconds	<5 seconds
Useful life(month)	12	12
Current applied	Yes	Yes

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

7.8 Replacing fan 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 SH300.

.Replacing steps:
1. pull down power cord;
2. get down fan cover from rear enclosure of SH300;
3. take out fan filter and put into soapy water.
4. Rinse thoroughly and dry thoroughly before replacing

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 serviceit 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, when you press down the alarm silence button again, the alarm sound again .After 120 seconds, alarm bell turns to original shape and alarm sound reappears.

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.
!!BATTERYLOW	Medium	Battery capability detected works less than 10 minutes.	Charge the battery quickly. Obtain alternative ventilation if necessary.
!!AIRSUPPLY DOWN	Medium	Air supply pressure less than 0.25MPa in ventilating process.	Check patient and air source. Obtain alternative ventilation if necessary.
!!O_2SUPPLY DOWN	Medium	O_2 supply pressure less than 0.25MPa in ventilating process.	Check patient and oxygen source. Obtain alternative ventilation if necessary.
!!!PRESSSURE 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.
!!!NO GAS	High	O_2 and air supplies pressure both less than 0.25Mpa in ventilating process	Check patient, air and oxygen source. Obtain alternative ventilation if necessary.
!!!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 SH300 into the shock environment.**

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

Size	400mm(H)×303mm(W)×250mm(D)
Weight	Approximately 15kg
Power cord	Rating voltage: 100 to 240VAC; Capacity of current: 220 to 240VAC 10A; Type: Three-core cable (Medical level)
Gas pipe	Compression resistance: 1MPa
Patient circuit	Single use
Face mask	Single use
Screen	10.4’ TFT LCD, touch screen

9.2 Environment requirements

Temperature	Operation:	10℃～40℃
	Storage:	-20℃～55℃
Relative humidity	Operation:	≤80%, non-condensing
	Storage:	≤93%, non-condensing
Atmospheric Pressure	Operation:	70～106kPa
	Storage:	50~ 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 ,Air (All gas must be medical level)
	Pressure	0.28MPa～0.6MPa
	Velocity of flow	≤100L/Min
	Connector	DISS-male，DISS-female，NIST（ISO 5359）
Power supply	Voltage & Frequency	110V～240V，50Hz～60Hz
	Power	≤2A
	Fuse	250V 2A φ5X20（T）
	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	≤12.5kPa	
Compliance	≤ 4mL/100Pa	
Electrical safety	Meet requirements for Class I, type B equipment specified in EN60601-1 *Medical Electrical equipment: Part one: General requirement for safety*.	
Classification	According to EN 60601-1, SH300ventilator belongs to the following classifications: Class I, Type B, General, mobile equipment.	
Noise:	≤ 65dB(A)	
The auditory ALARM SIGNAL sound pressure	>65dB(A)	

9.4 Operation principle

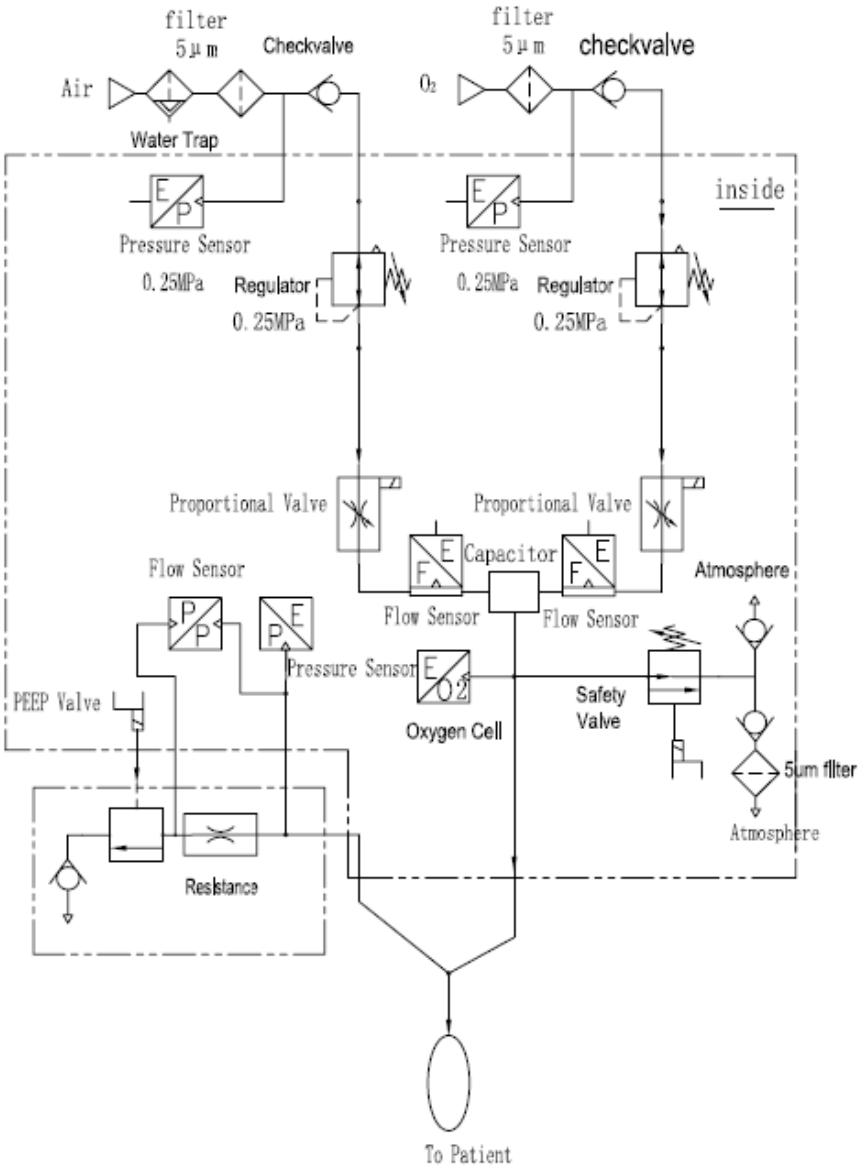


Figure 9-1 SH300 Ventilator System operation principle diagram

9.5 Performance parameters

9.5.1 Setting ventilation mode

Ventilation mode	Adjustable respiratory parameters
VCV mode	VT, TI, Rate, Pause, P-tr/F-tr,PEEP, FiO_2
VCV+Sigh mode	VT, TI, Rate, Pause, P-tr/ F-tr,PEEP, FiO_2
PCV mode	Pinsp, TI, Rate, P-tr/ F-tr,PEEP, FiO_2
SIMV（VCV） mode	VT, TI, Rate, Psup, P-tr/ F-tr,PEEP, FiO_2
SIMV（PCV） mode	Pinsp, TI, Rate, Psup, P-tr/ F-tr ,PEEP, FiO_2
CPAP/PSV mode	VT, TI, Rate, Psup, P-tr/ F-tr ,PEEP, FiO_2
BIPAP mode	Phigh ,Thigh,Rate, Psup,P-tr/ F-tr,PEEP, FiO_2
APRV mode	Phigh ,Thigh, Tlow,P-tr/ F-tr ,Plow, FiO_2
Backup mode	V_T, Rate, T_I,P-tr/ F-tr, PEEP, FiO_2
PRVC mode	VT, TI, Rate, Pause, P-tr/ F-tr,PEEP, FiO_2
SIMV PRVC mode	VT, TI, Rate, Psup, P-tr/ F-tr,PEEP, FiO_2

9.5.2 Setting ventilating parameters

Child mode				
Item	**Range**	**Resolution**	**Accuracy**	**Remark**
VT	20~500ml	10ml	±20 ml or ±15%,	
Rate	4 ~ 100bpm	1bpm	±1bpm (≤10bpm); ±10% (other)	-----
RateinSIMV mode	1~ 40bpm	1bpm	±1bpm (≤10bpm); ±10% (other)	-----
TI	0.1s~12s	0.1s	±0.1s (0～1s); ±10％ (other)	----
Pause	0~50%	5%	±0.1s（0～1s）; ±10％ (other)	Limited by T_I, the maximum of Tp is 50%T_i.
FiO_2	21%~100%	1%	±6％	Invalid when single gas supply operated.
P-tr	0~ -20cmH_2O	-1cmH_2O	±1 cmH_2O（0～5 cmH_2O）; ±20％（other）	----
F-tr	1~20LPM	0.5LPM	±1LPM(1～5LPM); ±20％（other）	----
PEEP	0 ~ 10 cmH_2O	1 cmH_2O	±2 cmH_2O	----
Psup	0 ~ 30 cmH_2O	1 cmH_2O	±2 cmH_2O（≤10 cmH_2O）; ±10％（other）	Based on PEEP
Pinsp	5 ~ 30 cmH_2O	1 cmH_2O	±2 cmH_2O（≤10 cmH_2O）; ±10％（other）	Based on PEEP
Thigh	0.1s~30s	0.1s	±0.1s (0～1s); ±10％ (other)	----
Tlow	0.5s~30s	0.1s	±0.1s (0～1s); ±10％ (other)	----
Phigh	5 ~ 30 cmH_2O	1 cmH_2O	±2 cmH_2O（≤10 cmH_2O）; ±10％（other）	----
Plow	0 ~ 10 cmH_2O	1 cmH_2O	2 cmH_2O	----

Adult mode				
Item	**Range**	**Resolution**	**Accuracy**	**Remark**
VT	50~2500ml	10ml	±20 ml or ±15%,	
Rate	4 ~ 100bpm	1bpm	±1bpm (≤10bpm); ±10% (other)	-----
Rate in SIMV mode	1~ 40bpm	1bpm	±1bpm (≤10bpm); ±10% (other)	-----
TI	0.1s~12s	0.1s	±0.1s (0～1s); ±10％ (other)	----
Pause	0~50%	5%	±0.1s（0～1s）; ±10％ (other)	Limited by T_I, the maximum of Tp is 50%T_i.
FiO_2	21%~100%	1%	±6％	Invalid when single gas supply operated.
P-tr	0~ -20 cmH_2O	-1 cmH_2O	±1 cmH_2O（0～5 cmH_2O）; ±20％（other）	----
F-tr	1~20LPM	1LPM	±1LPM(1～5LPM)； ±20％（other）	----
PEEP	0 ~ 50 cmH_2O	1 cmH_2O	2 cmH_2O（≤10 cmH_2O）; ±10％（other）	----
Psupp	0 ~ 70 cmH_2O	1 cmH_2O	----	Based on PEEP
Pinsp	5 ~ 70 cmH_2O	1 cmH_2O	±2 cmH_2O（≤10 cmH_2O）; ±10％（other）	Based on PEEP
Thigh	0.1s~30s	0.1s	±0.1s (0～1s); ±10％ (other)	----
Tlow	0.5s~30s	0.1s	±0.1s (0～1s); ±10％ (other)	----
Phigh	5 ~ 70 cmH_2O	1 cmH_2O	±2 cmH_2O（≤10 cmH_2O）; ±10％（other）	----
Plow	0 ~ 50 cmH_2O	1 cmH_2O	±2 cmH_2O（≤10 cmH_2O）; ±10％（other）	----

9.5.3 Monitoring performance

Item	Range	Resolution	Accuracy
V_{TI}	0~4000 mL	1 mL	±20 mL or ±15% (other)
V_{TE}	0~4000 mL	1 mL	±20 mL or ±15% (other)
f	0～100 bpm	1 bpm	±2 bpm (≤20 bpm); ±10% (other)
fspn	0~100 bpm	1 bpm	±2 bpm (≤20 bpm); ±10% (other)
MVspn	0～40L	1L	±0.5L or ±15% (other)
MV	0～40L	1L	±0.5L or ±15% (other)
Pmean	0～80cmH_2O	1cmH_2O	±2 cmH_2O or ±10%
Pplat	0～80cmH_2O	1cmH_2O	±2 cmH_2O or ±10%
Ppeak	0～80cmH_2O	1cmH_2O	±2 cmH_2O or ±10%
Pmin	-20～80cmH_2O	1cmH_2O	±2 cmH_2O or ±10%
FiO_2	18%～100%	1%	±3%
C	0～150 mL/cmH_2O	----	----
R	0～200 cmH_2O /L/s	----	----
PEEP	0～50 cmH_2O	----	----
Waveform monitor	Supply Paw-t curve, Flow-t curve, V-t curve, P-V loop and F-V loop.	----	----

9.5.4 O_2 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:	O_2 monitoring modules can monitor and display oxygen concentration of the patient circuit, and contain one oxygen sensor. The O_2 sensor can detect the proportionable voltage on its surface, generated with partial pressure of O_2. The O_2 sensor is chemical fuel cell, and its metal electrode can be oxidated when oxygen diffuses into it. The current generated from oxidation proportion O_2 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 O_2 monitoring modules. So the signal of O_2 sensor could be transformed to O_2 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.

9.5.5 Assistant performance

Item	Description
Freeze	freezes the current screen and suspends real-time update of data
Inspiratory Hold	Manual closure of inspiration and expiration valves after inspiration
Expiratory Hold	Manual closure of inspiration and expiration valves after expiration
O2 suction	100% oxygen gas deliver two minute
Manual Insp	during the expiration phase of a breath delivers a single mandatory breath at current ventilator settings.

9.5.6 Setting alarm parameters

Item	Adult Range	Child Range	Accuracy
MV-upper limit	0～99L	1～20L	±0.5L or ±15%
MV-lower limit	0～98L	0～19L	±0.5L or ±15%
P_{aw}-upper limit	1 cmH_2O ～ 80 cmH_2O	1 cmH_2O～40 cmH_2O	±2 cmH_2O or ±10%
P_{aw}-lower limit	0～79 cmH_2O	0～39 cmH_2O	±2 cmH_2O or ±10%
V_{TE}-upper limit	50ml～2000ml,	50ml～600ml	±20mL or ±15%
V_{TE}-lower limit	OFF,40～1990ml	OFF,40ml～590ml	±20mL or ±15%
Rate-upper limit	1～100 bpm	1～70 bpm	±2 bpm（0～20bpm）; ±10%（other）
Rate-low limit	0～99bpm	0～69bpm	±2 bpm（0～20bpm）; ±10%（other）
Tapnea	15s～60s	15s～60s	±1s or ±10%
FiO_2-lower limit	21%~99%	21%~99%	±3%
FiO_2-upper limit	22%~100%	22%~100%	±3%

⚠**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.**

9.6 Order information

Description	specification	Stock number
Exhalation valve diaphragm		SH300-30-03
Exhalation valve		SH300-30-00
One-way membrane		SH300-30-05
Filter		VS-21-01
O_2 pipeline	5m	GYG-01A
Air pipeline	5m	GYG-03B
Power cord	3m	ES-03
O_2 sensor	---	EK-12
Silicon corrugated hose	---	ACC-27
Manual gasbag	3L	ACC-02
Cleat gasbag	---	ACC-05
Face mark	---	ACC-04

9.7 Electromagnetic Compatibility

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 SH300 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 SH300by 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 SH300 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of SH300 Ventilator should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SH300 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 SH300 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 SH300 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of SH300 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±1 kV differential mode ±2 kV common	Mains power quality should be that of a typical commercial or

	mode	mode	hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) 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	<5% U_T (>95% dip in U_T) 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SH300Ventilatorrequires continued operation during power mains interruptions, it is recommended that the SH300Ventilatorbe 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.
NOTEU_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 SH300 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of SH300 Ventilatorshould 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_{rms} 150 kHz to 80 MHz outside ISM bands [a] 10 V_{rms}	3 V 10V	Portable and mobile RF communications equipment should be used no closer to any part of the *SH300 Ventilator*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz

Radiated RF IEC 61000-4-3	150 kHz to 80MHz in ISM band [a] 10 V/m 80 MHz to 2.5 GHz	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: 

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 theSH300 Ventilator is used exceeds the applicable RF compliance level above, the SH300 Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating theSH300 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 *SH300 Ventilator*

The SH300 Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SH300Ventilatorcan help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SH300Ventilatoras 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 $d = [\frac{3.5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800MHz** $d = [\frac{1.2}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{2.3}{E_1}]\sqrt{P}$
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

Beijing Eternity Electronic Technology Co, Ltd. (Eternity for short) holds the copyrights to this manual, which is non-public published, and reserves the rights to keep it as a secure document. Refer to this manual when operating, maintaining and repairing Eternity products only. Anyone other than Eternity may not make it known to others.

Proprietary materials protected by the copyright law are included in this manual. Any section of it cannot be reproduced, copied, or translated into other languages without any prior written approval from Eternity who reserves the copyright.

Everything written in this manual is considered to be correct. Eternity is not legally responsible for any mistakes printed within and any damages caused by incorrect installation and operation. Eternity does not supply privileges endowed by the patent law to any other parties. Eternity is not legally responsible for the results caused by patent law breaking and any rights of the third party violating.

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 equipment 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 equipment 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)

SH300 Ventilator System

User Manual

Version：19.01
Modified date: Aug. 2019
Printed for the first time in 2019