Anesthetic Apparatus

Typ Anastazja 7500

CE 0297

User's Manual

01/2008

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Each FARUM S.A. product has a serial number, such as

Anastazja7500 xxxx-xxxxx

ANASTAZJA 7500: machine model

the first xxxx : the year of manufacturing

the second xx : the month

the third xxx : equipment number

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  The label of FARUM S.A. original serial number or mark is removed or replaced

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2. Transportation charges

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

Contents

1 Introduction

1.1 What's ANASTAZJA 7500?

ANASTAZJA 7500 is a compact and integrated anesthesia transmitting system. The breathing machine not only provides patients in operation with auto ventilation, but also monitors and displays the patient's various parameters. The ventilator used in the system is controlled by a microprocessor.

The anesthetic ventilator controlled by microprocessor of ANASTAZJA 7500 includes monitor internally, volume mode, and other functions optional. It can be used for communication with cardiac blood vessel and monitor of breathing gas by serial interface.

Not all the optional functions available may be included in the manual. It is also possible to add other equipment to the top or middle of this system for added functions. For more information with respect to the existing product, please feel free to contact the local representatives.

⚠ **WARNING:** **The user of ANASTAZJA 7500 must be professional and trained.**

⚠ **WARNING:** **ANASTAZJA 7500 is unsuitable for use in a magnetic resonance imaging (MRI) environment.**

1.1.1 Range for used

ANASTAZJA 7500 is applicable for patients of over 25 Kg with standard set and for child of over 12 Kg with cycles and CO_2 monitoring device of child.

⚠ **WARNING:** **ANASTAZJA 7500 is not to be used with infant.**

Figure 1-1 ANASTAZJA 7500

1.2 Symbols Used in the Manual and in the Equipment

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

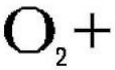
⚠ **WARNING**: indicates potential hazards to operators or patients

⚠ **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:

⚠ **CAUTION:** **This manual complies with EN 1041.**

	ON（Power）		Type B equipment
	OFF（Power）		Type BF equipment
	Stand-by		Type CF equipment
	Stand-by or preparatory state for a part of the equipment		Warning or Caution, ISO 7000-0434
	ON only for part of the equipment		NOTE: refer to the manual, IEC601-1
	OFF only for part of the equipment		This way up
	Direct Current		Dangerous Voltage
	Alternating Current		Input
	Protectively earth		Output
	Earth	EC REP	CE Representative
	Frame or chassis ground	**SN**	Serial Number
	Date of manufacture		Address of manufacture

	Equipotential		View the reading on the top of float
	Alarm Silence		Reservoir bag location/manual ventilation
	Movement in one direction		Movement in two directions
	Lock		Unlock
	Close drain valve		Open drain valve (release liquid)
	Inspiration flow		Expiration flow
134°c	Autoclavable		Oxygen flush
	Auto ventilation		CE Representative
	Gas cylinder		The system, with this label under the stipulations in the operating manual, complies with the requirements related from 93/42/EEC. xxxx is the certificate number used by FARUM S.A. quality system to certify authorizations

2 Anesthetic System Control

2.1 Anesthetic system

⚠ **CAUTION:** **The anesthetic system is intended to be used with the following monitoring devices, alarm systems, and protection devices:**

-- pressure measuring in accordance with 8.1 of ISO 8835-2;

-- pressure limitation device in accordance with 51.101.1 of IEC60601-2-13;

-- exhaled volume monitor in accordance with 51.101.4 of IEC60601-2-13;

-- breathing system integrity alarm system in accordance with 51.101.5 of IEC60601-2-13;

-- continuing pressure alarm in accordance with 51.101.6 of IEC60601-2-13;

-- O_2 monitor in accordance with ISO 9918.

⚠ **WARNING:** **To avoid explosion hazards, flammable anesthetic agents such as ether and cyclopropane shall not be used in this anesthetic workstation. Only anesthetic agents which comply with the requirements for non-flammable anesthetic agents as specified in this manual.**

Halothane, desflurane, sevoflurane, enflurane,and isoflurane have been found to be non-flammable agents.

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

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

⚠ **WARNING:** **Leakage and douse of liquid, such as anesthetic agent, bring on dangerous states or malfunctions inside device.**

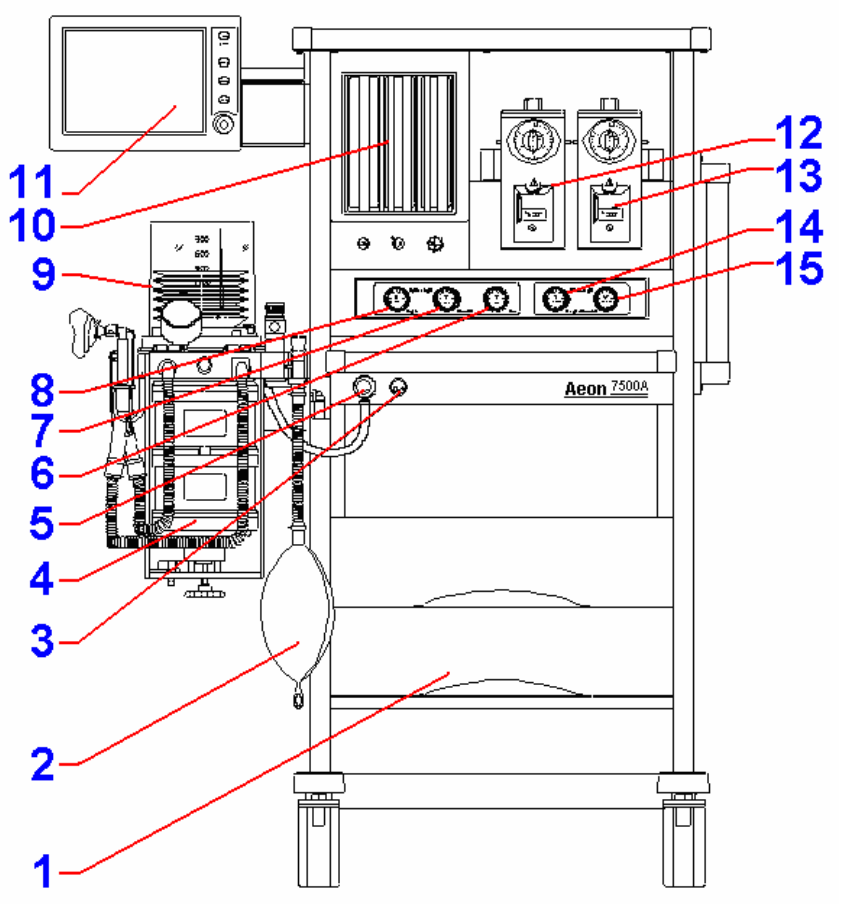
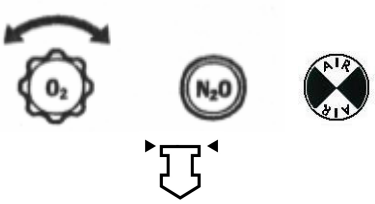


Figure 2-1 ANASTAZJA 7500 (front view)

1	Drawer	2	Reservoir Bag
3	Oxygen Flush	4	Absorber cycle
5	Common Gas Outlet	6	Air pipeline pressure gauge
7	N_2O pipeline pressure gauge	8	O_2 pipeline pressure gauge
9	Autoclavable Bellows Assembly	10	Flowmeters
11	Display Screen of anesthetic ventilator	12	Enflurane Vaporizer
13	Isoflurane Vaporizer	14	O_2 cylinder pressure gauge
15	N_2O cylinder pressure gauge		

Figure 2-1 each control function on the front view of Anastazja7500

Item		Diagram	Description
3	Oxygen Flush		Press Oxygen Flush button to supply O_2 to the breathing system with high flow rate
5	Common gas outlet		connects the anesthesia machine to the breathing system

10	Flow Control		Turn the knob counterclockwise to increase the flow; turn clockwise to decrease the flow. Read top of float when the flowmeter is being read.

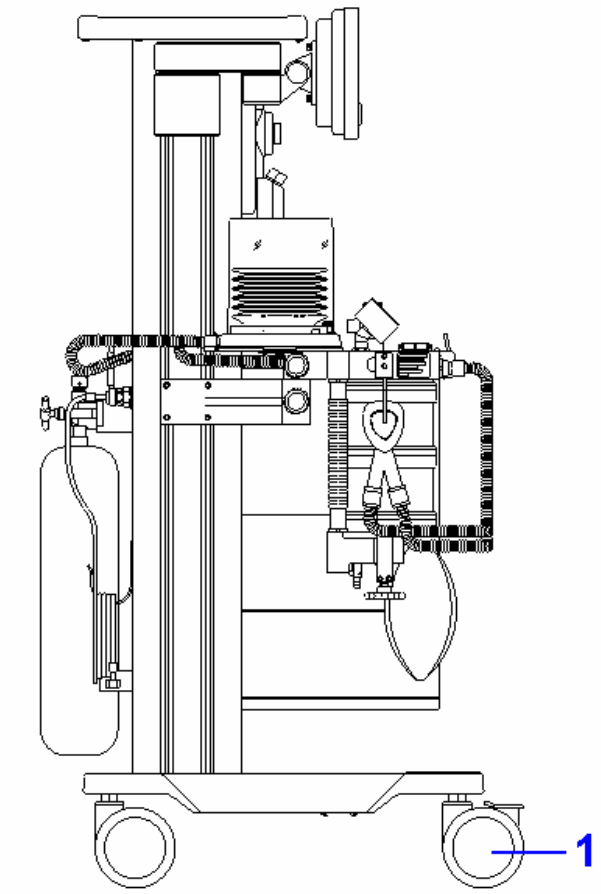


Figure 2-2 ANASTAZJA 7500 (side view)

Figure 2-2 each control function on the side view of Anastazja7500

Item		Diagram	Description
1	Castor（with break）		Push down to lock, and pull up to unlock.

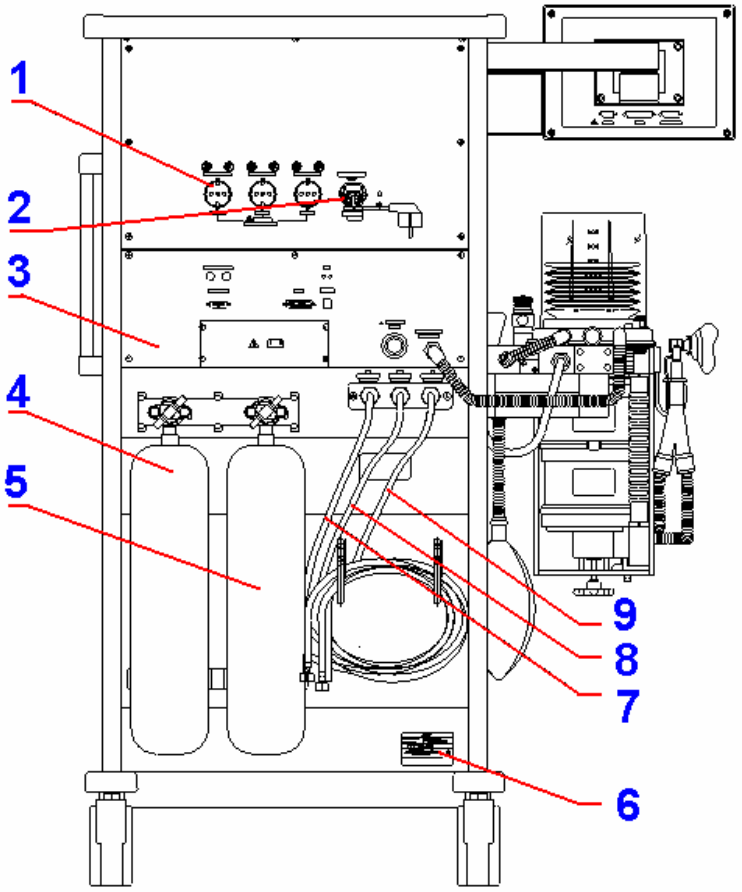


Figure 2-3 Anastazja7500 (back view)

1	Auxiliary mains socket outlet	2	Power socket
3	Anesthetic ventilator unit	4	N_2O cylinder
5	O_2 cylinder	6	Nameplate
7	Air pipeline	8	N_2O pipeline
9	O_2 pipeline		

2.2 The Breathing system module

⚠ **CAUTION:** **Any adult anesthetic ventilator system used together with the anesthetic gas supply system must be in accordance with ISO 8835-2.**

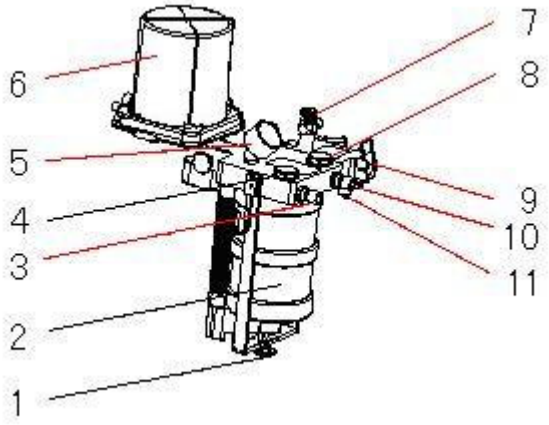
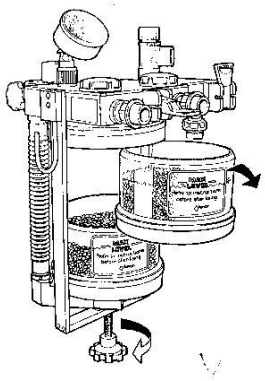
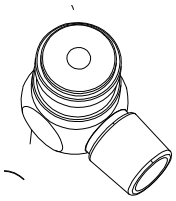
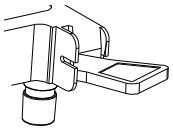
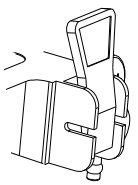


Figure 2-4 Breathing system module

1 Absorber mount release handle
2 Absorber (Carbon dioxide absorbent)
3 Exhalation Port / patient circuit connector
4 Exhalation valve
5 Airway pressure gauge
6 Bellows assembly (auto ventilation)
7 APL (adjustable pressure limit) valve
8 Inhalation valve
9 Manual reservoir bag/auto ventilation switch
10 Inhalation Port/Patient circuit port
11 Manual reservoir bag port

Figure 2-4 the breathing system components function control

Item		Diagram	Description
2	Absorber mount release	 Two soda lime canisters are applied with a volume of 1500 ml for each so that it can be continuously used for 6-8 hours at full load. The water from the reaction is drained via the water collector underneath.	
7	APL valve		Adjust the pressure limit of the breathing system during the manual ventilation process. The readings are approximate. The colors represent different pressure zones. Green represents safety zone; yellow represents transition zone; red represents high pressure zone. Adjusting ranges between 0.19-6 kPa.
9	Manual bag/auto switch	reservoir ventilation  Auto ventilation “off” gas into reservoir bag  Auto ventilation “on” gas into bellows	Select manual ventilation (reservoir bag) or auto ventilation (ventilator).

2.2.1 Absorber cycle

2.2.1.1 Structure

The functions of absorber cycle: absorb carbon dioxide; vent exhaust gas; assistant respiration; monitor airway pressure; drain water generated by chemistry etc.

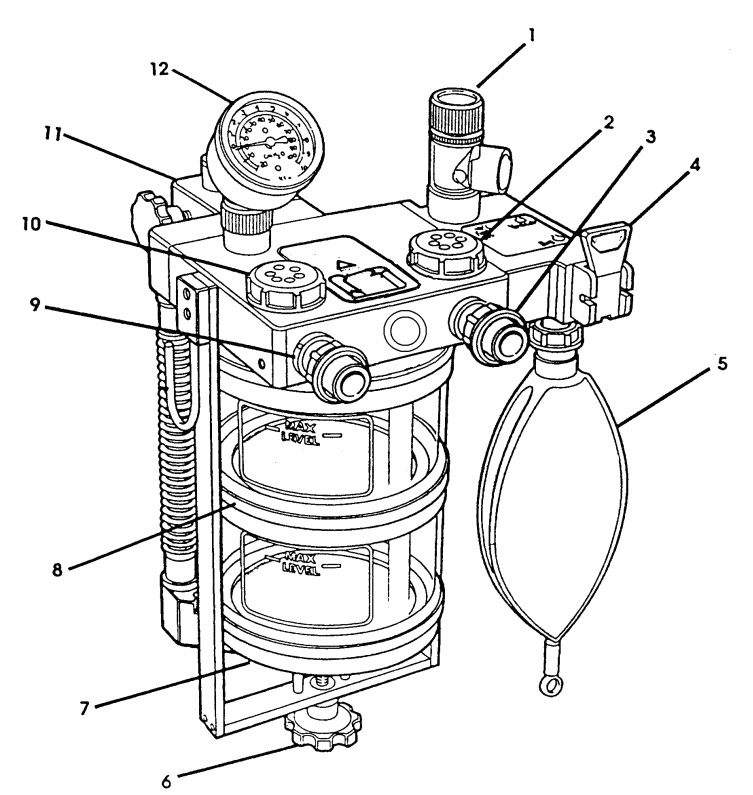
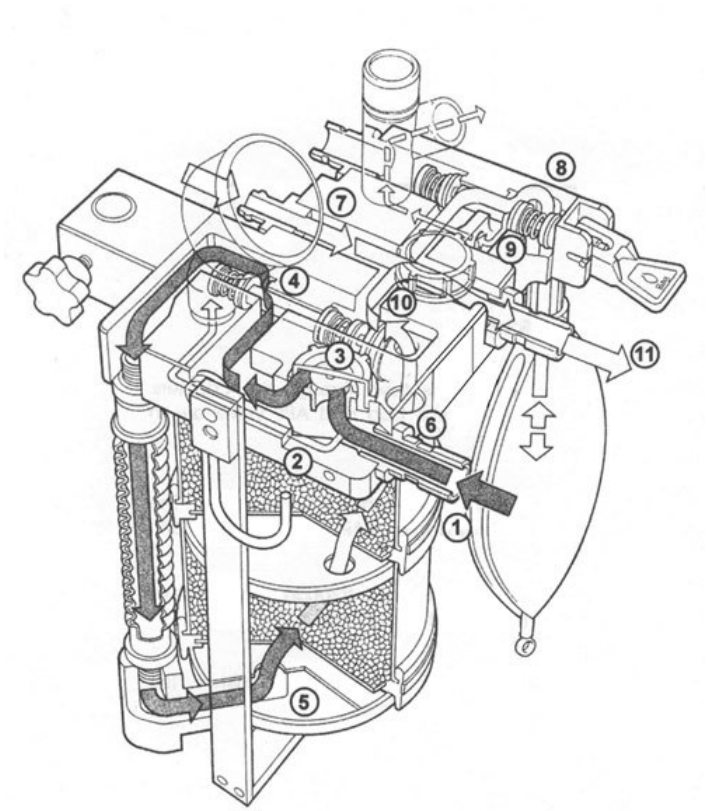


Figure 2-5 Absorber cycle

1. APL valve
2. Inhalation valve
3. Inspiratory port
4. Bag/Ventilator Switch
5. Reservoir Bag
6. Handle
7. Lower absorber
8. Upper absorber
9. Expiratory port
10. Exhalation valve
11. Fixation module
12. Airway Pressure Gauge

2.2.1.2 Principle

Gas flow schematic diagram, see Figure 2-6.



Bag operating

1-Expiratory gas of patient;
2-Sampling airway pressure;
3-via exhalation valve
(unidirectional);
4-bypass switch (normal close);
5-enter into absorber;
6-leave absorber;
7-fresh gas compensation;
8-Bag/Ventilator (Bag ”ON”);
9-APL valve sampling path;
10- via exhalation valve;
(unidirectional);
11-Inspiratory gas

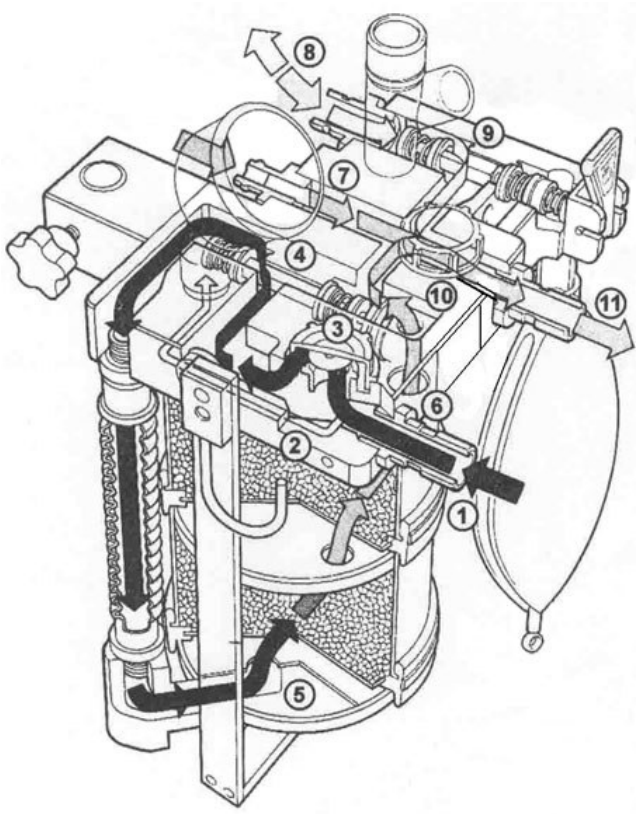


Figure 2-6 Gas flow schematic diagram

Ventilator operating

1-Expiratory gas of patient;
2-Sampling airway pressure;
3-via exhalation valve
(unidirectional);
4-bypass switch (normal close);
5-enter into absorber;
6-leave absorber;
7-fresh gas compensation;
8-gas of patient
9- Bag/Ventilator (Bag ”OFF”);
10- via exhalation valve;
(unidirectional);
11- Inspiratory gas

2.2.2 Bellows Assembly

2.2.2.1 Ports

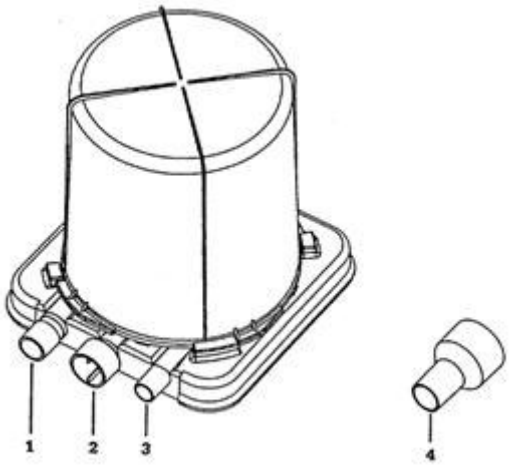


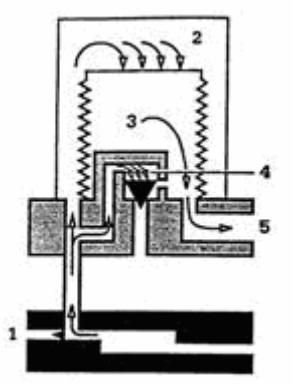
Figure 2-7 Ports of bellows assembly

1 Breathing system connector 2 Exhaust gas port 3 Driven gas connector 4 Adapter

⚠ **WARNING:** **Never connect exhaust gas port with sub-atmospheric system directly. Or else leakage of breathing system generates.**

The adapter can be used to connect the waste gas scavenging system to the bellows assembly if the standard pipeline is used in the waste gas scavenging system.

2.2.2.2 ventilating circulation



Inhalation primary phase:

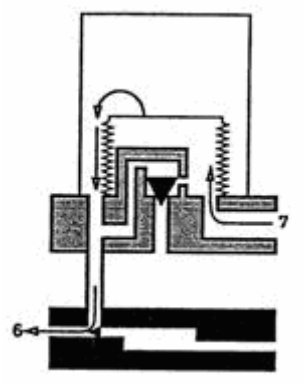
1 Exhalation valve

2 Driving gas

3 Gas of patient circuit

4 Spill-over valve

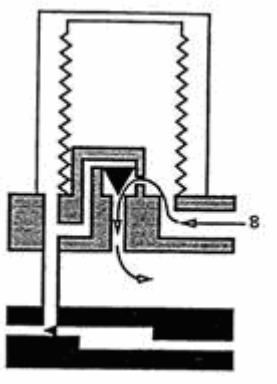
5 To patient circuit



Exhalation primary phase:

6 Driving gas

7 From patient circuit



Exhalation end phase:

8 Excess gas of patient circuit

2.3 Vaporizer Control

Refer to operating and maintenance manual of vaporizer for more details.

⚠ **WARNING:** **Anesthetic vapour delivery device used with anesthetic system must be in accordance with ISO 8835-4.**

2.4 Ventilator Control

⚠ **CAUTION:** **Anesthetic ventilator accords with ISO 8835-5.**

⚠ **CAUTION:** **Monitoring conditions of this system: Ambient temperature: 29℃;**

Air temperature: 30℃;Air humidity: 30%; Gas component: Oxygen.

⚠ **CAUTION:** **If the temperature of sensor is lower than dew point of breathing gas, vapour may coagulate on the surface of sensor, and oxygen concentration monitored may be lower than practice value.**

Optional function: SIMV mode, P-V loop and V-Flow loop can be added by code.

2.4.1 Front Panel

Front panel consists of display screen, keys, indicators, and a knob.

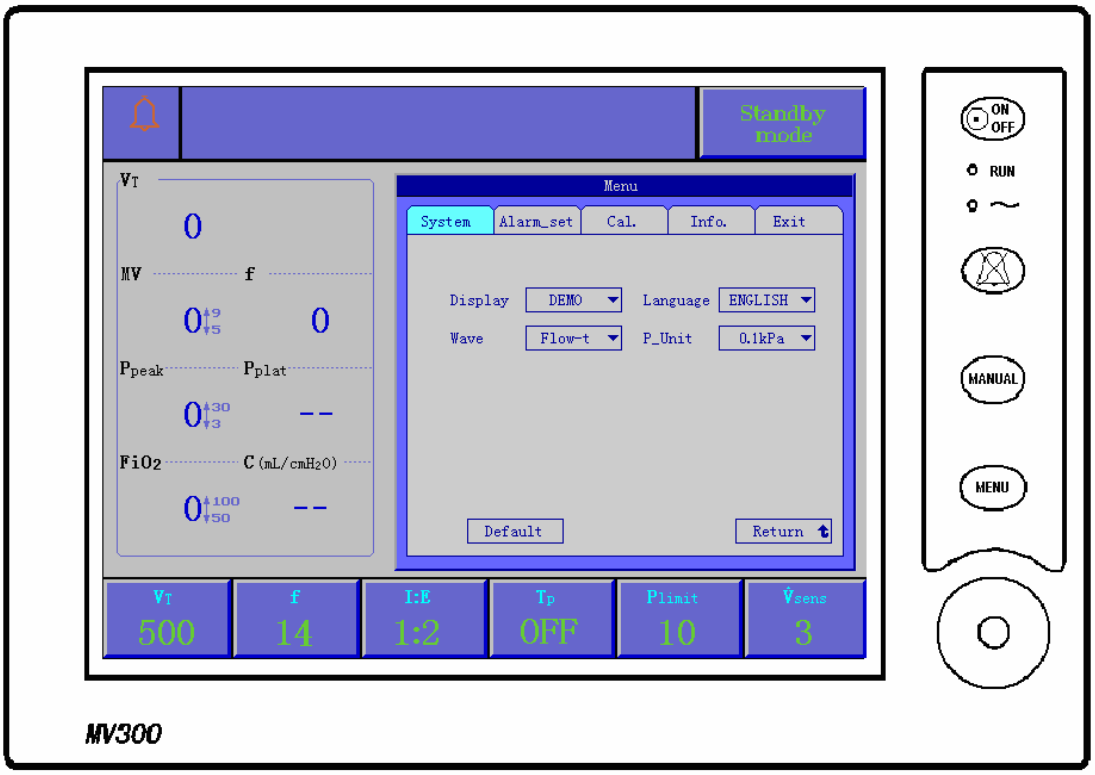


Figure 2-8 Front Panel

2.4.2 Keys

	Mains switch key	Press the key and hold on for 2 second, you can start or shut off ventilator.
	Alarm silence key	Press the key, alarm mutes for 110 seconds.
	Manual mode key	Press the key, change original ventilation mode to manual mode; Press again, back to the original ventilation mode.
	Menu key	Press the key, a “Menu” window appeared on the display screen, more details refer to section 2.5.

2.4.3 Indicators

	Running Indicator	The indicator brightly as ventilator operating.
	AC Indicator	The indicator brightly as AC power effectively; The indicator dark as AC power failure.

2.4.4 Knob

The user may use the rotary knob to select the menu item and modify the setup. It can be rotated clockwise or counter-clockwise and pressed like other buttons. The user may use the knob to realize the operations on the screen and in the system menu and parameter menu.

The rectangular mark on the screen that moves with the rotation of the knob is called “cursor”. Operation can be performed at any position at which the cursor can stay.

Operating method:

- Move the cursor to the item where the operation is wanted
- Press the knob
- One of the following four situations may appear:
  - The background color of cursor may become into the contrast color, which implies that the content in the frame can change with the rotation of the knob.
  - Pull down menu or dialogue box may appear on the screen, or the original menu is replaced by the new menu.
  - Save setup.

2.4.5 Display Screen

The display of the ventilator is a color TFT, which can display the monitoring and setting parameters, waveforms, alarm information as well as displayed on the screen. See Figure 2-9.

The screen has three areas: information area (1), monitoring area (2), and parameter setup area (3).

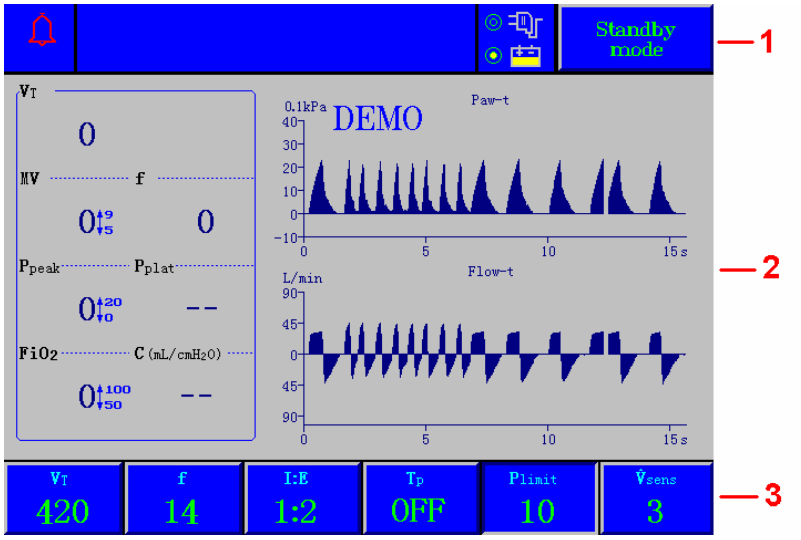


Figure 2-9 Display Screen

2.4.5.1 Information area

Information area lies on the top part of the screen, which is used to display the current status of the ventilator and the patient. The information area contains following components:

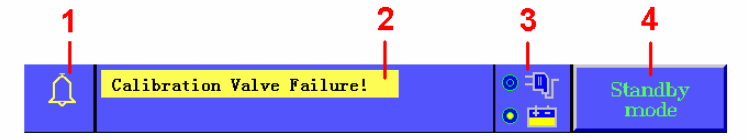


Figure 2-10 Information area

1 Alarm bell

When alarm appears, the color of alarm bell accords with the background color of the upper prior alarm message; press alarm silence key, “X” dashed line appears on the alarm bell, and 110 seconds counts down. More details refer to section 8.1.

2 Alarm messages

Technical alarm and functional alarm supplied by the system, and not more than two alarm messages displayed on the top of the screen. More details refer to section 8.2.

3 Power supply

Two kinds of power supply: AC power external and internal battery.

4 Ventilation mode

Five ventilation modes: VCV mode, Pressure mode, SIMV mode, Manual mode, and Standby mode.

Turn and press the knob to setup ventilation mode required, and press again to save it.

2.4.5.2 Monitoring area

Monitoring area has two parts: Patient parameter and waveform.

Patient parameter is fixedly displayed in the left side of the monitoring area. It includes seven parameters:

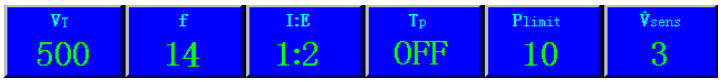
V_T:	Tidal volume	MV:	Minute volume
f:	Respiratory frequency	P_{peak}:	Peak value of airway pressure
P_{plat}:	Pressure at the end of inspiratory pause time	FiO_2:	Oxygen concentration
C:	compliance		

Waveform is displayed in the right side of the monitoring area. It has four types:

Flow-t waveform, V-t waveform, Paw-V loop and V-FLOW loop.

More details refer to section 3.5.

2.4.5.3 Parameter setup area



Parameter setup area lies on the bottom part of the screen. It includes:

V_T:	Tidal volume	f:	Breaths per minute
I:E:	Inspiration to expiration time	T_P:	Inspiratory pause time
P_{limit}:	Maximum airway pressure limit setting	V_{sens}:	Triggering flow sensitivity

2.4.6 Rear Panel

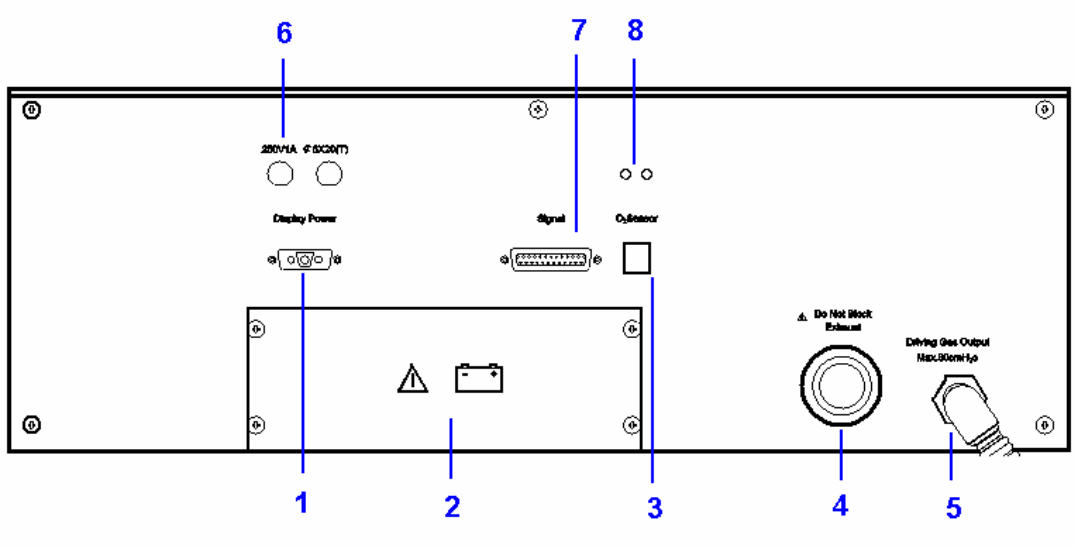


Figure 2-11 Rear Panel

1 Display Power interface
2 Battery
3 O_2 Sensor interface
4 Exhaust Port
5 Driven Gas Outlet
6 Fuse
7 Signal interface
8 P&V interface of sampling parallel line

Item		Description
1&7	Display Power interface and Signal interface	Use display power cable and signal cable to connect relevant interface of rear panel with interfaces on rear of display screen respectively. Display power interface and signal interface: provide power supply and signal to the display.
2	Battery	Refer to section 7.6
3	O_2 Sensor Interface	RJ 11 standard interface. Use oxygen sampling line to connect O_2 sensor with O_2 sensor interface. Oxygen concentration value measured by O_2 sensor is transmitted to the ventilator through O_2 sensor interface. If no O_2 sensor in the breathing system, the alarm message “No O_2 sensor!” will be shown in the display screen.

4	Exhaust Port	Don't block exhaust port. It is only a outlet of driven gas. Safety valve inside exhaust port may be used to limit maximum of airway pressure. When airway pressure exceeding the maximum, the safety valve will open and exhaust for protecting airway of patient. The maximum airway pressure is 6 kPa.
5	Driven Gas Outlet	Size: male 16 mm taper Use thread-tube to connect driven gas outlet with driven gas inlet of bellows. Inspiratory phase: gas from ventilator drives bellows to make fresh gas enter into the airway; Expiratory phase: return gas from the airway drives bellows to make gas from ventilator exhaust through exhaust port.
6	Fuse	250V 1A ∅5X20(T), more details refer to section 7.5.3
8	P&V interface	Connect sampling parallel line to P&V interface, the other end to probe. It provides basis for monitoring and troubleshooting that the real time airway pressure is transmitted to the ventilator. Parameter monitored such as V_T and MV, are calculated by ventilator basing on the flow via the probe. ⚠ **CAUTION** **Ensure sampling line and probe connect right, avoid liquid entering and leakage.**
Accessory relatively		—— Probe of sampling and sampling parallel line Flow of breathing cycle is measured by means of pressure difference. Avoid water entering into the probe and sampling parallel line in the process of operating, otherwise parameter monitored will be affected. Ensure airtightness of sampling system, if sampling device is aging, please replace it. Sterilization: cleaning it with sterilizing agent, then swing it mechanically. The formation and preparation of the agent must be done in accordance with the direction given by the manufacturer. —— O_2 Sensor Operation condition: 0.5 to 2.0 Bar. More details refer to section 7.4

2.5 Menu

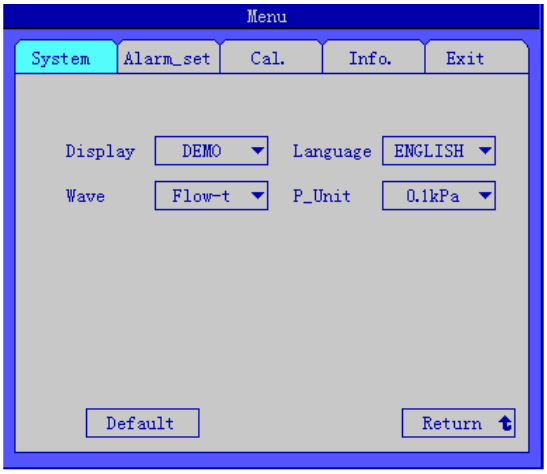
2.5.1 Operating Guide

Calibrate or carry out other process, explanation will be displayed on the screen.

A demonstration like the following steps:

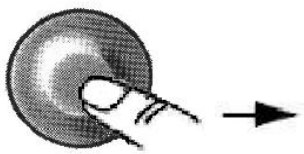
Step 1

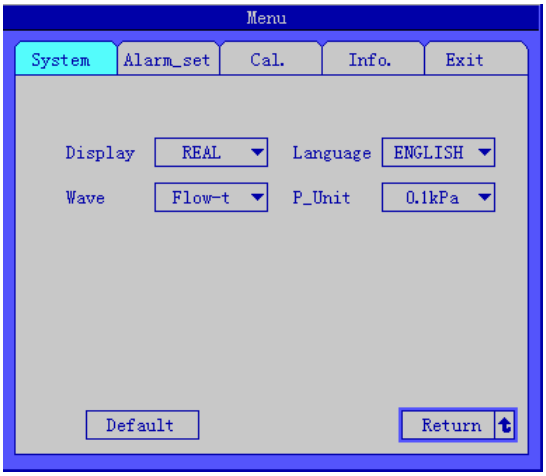
Press ”MENU” key, then display a menu window on the screen.



Step 2

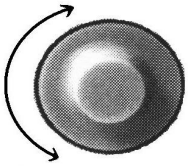
Press knob to select “Return”.

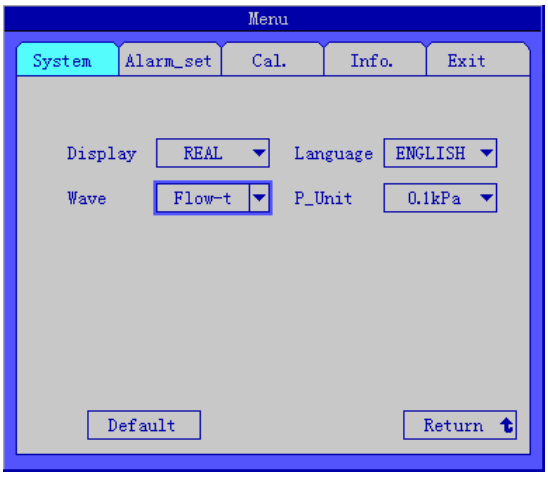




Step 3

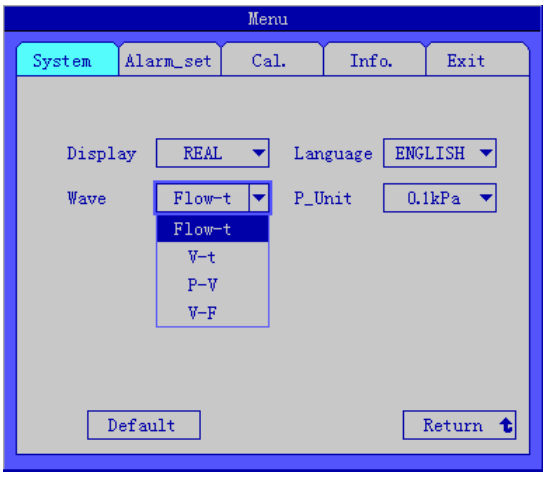
Turn the knob to select option required such as “Wave”.





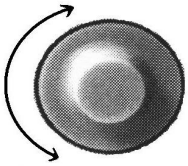
Step 4

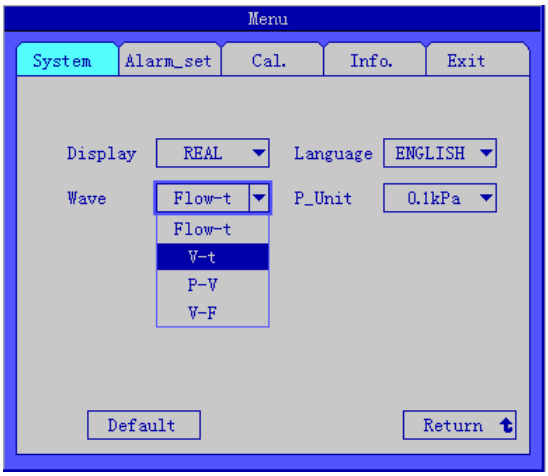
Press the knob, then a pull down menu appears.



Step 5

Turn the knob to select option required.

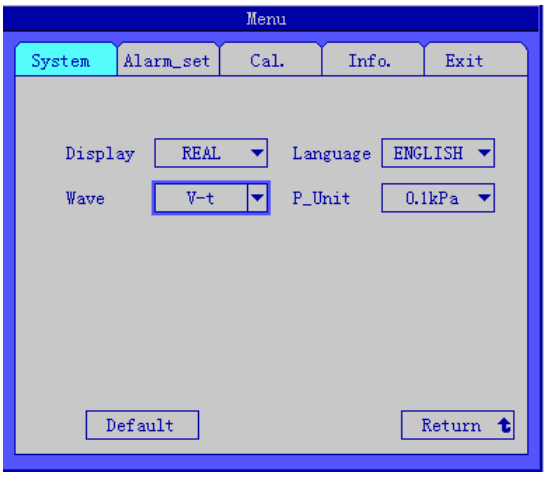




Step 6

Press the knob to save new setup.

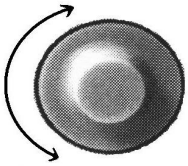
Go to next setup or exit “System” menu.

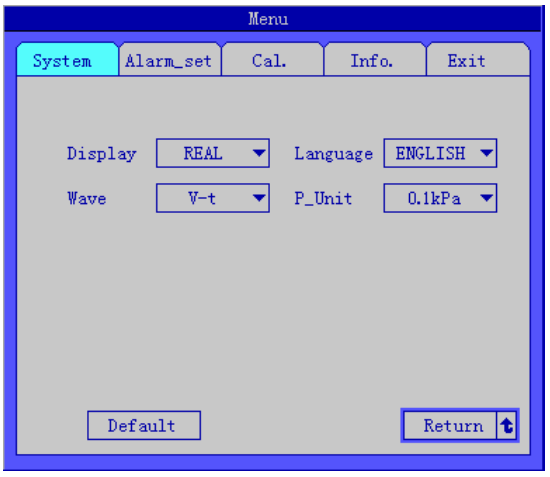


Step 7

Exit “System” menu:

Turn the knob to select”Return”, and then press it.



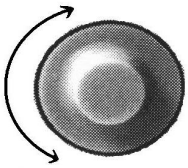


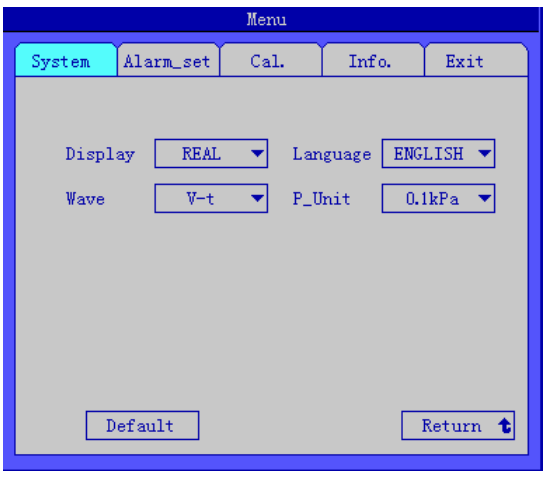
Step 8

Exit “Menu”:

1. Turn the knob to select “Exit” menu, and then press it, or

2. Press “MENU” key directly.

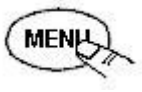




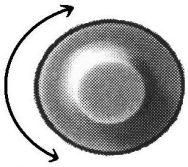
2.5.2 Menu diagram

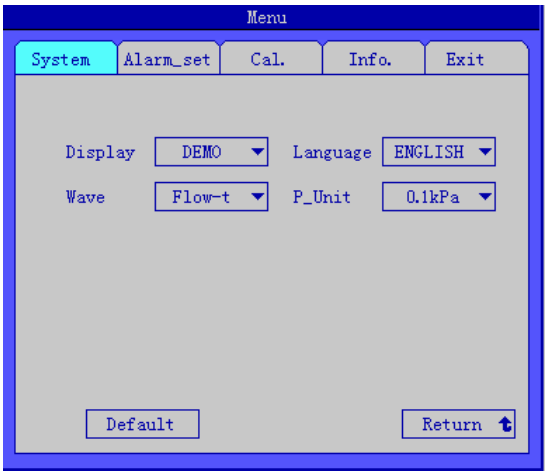
See Figure 2-12. Some functions are optional.

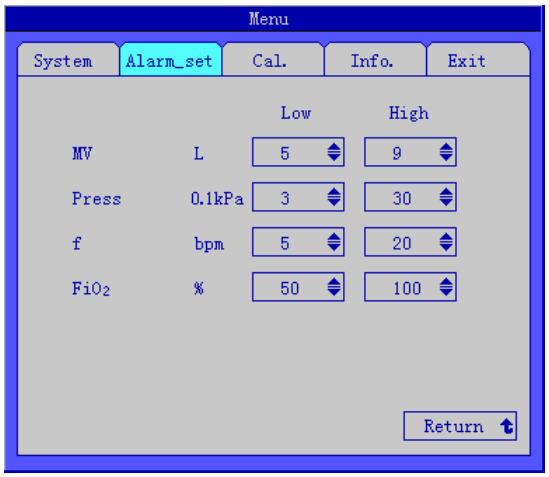
Press ”MENU” key, the Menu window displaying on the screen.



Turn the knob to select a submenu.







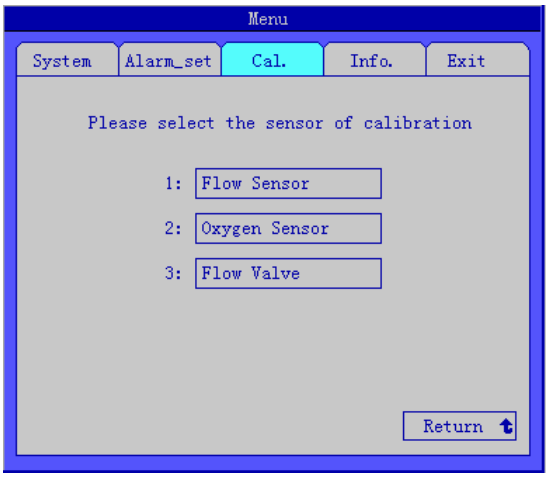
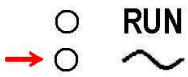


Figure 2-12 Menu diagram

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 bright when power is connected.

Step 2 Power-on self-test

Press power ON/OFF key and last 2 seconds:

Display start, “RUN” indicator light brightly, and enter LOGO interface; See Figure 3-1

Later, self-testing interface appears. See Figure 3-2

If self-testing succeeds, the display works normally and the system is situated stand-by mode.

If failure, alarm message is displayed on the screen. Please carry out operation in accordance with the prompt information.

Figure 3-1 LOGO interface

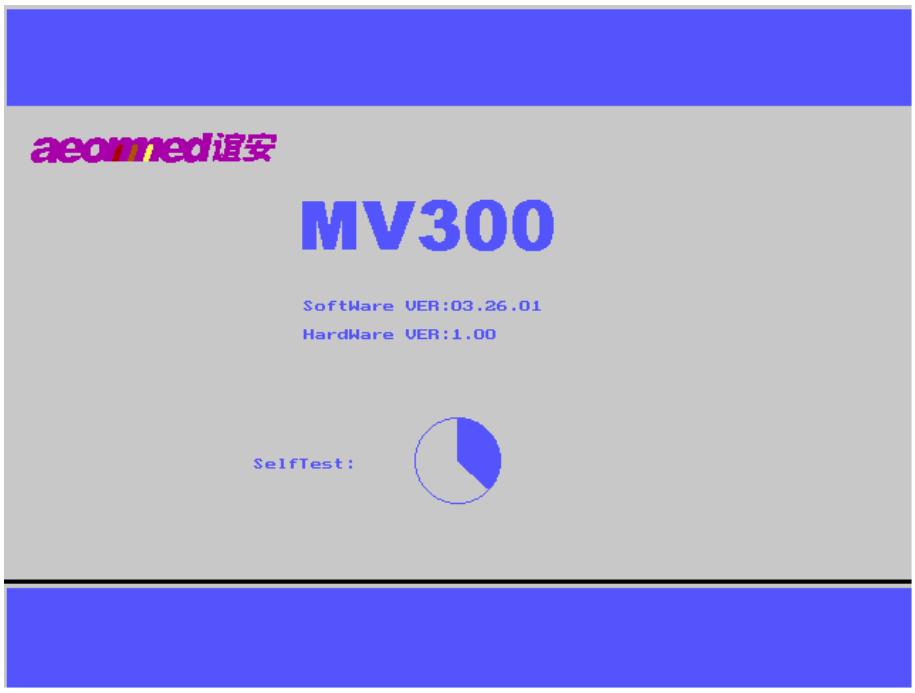


Figure 3-2 Self-testing

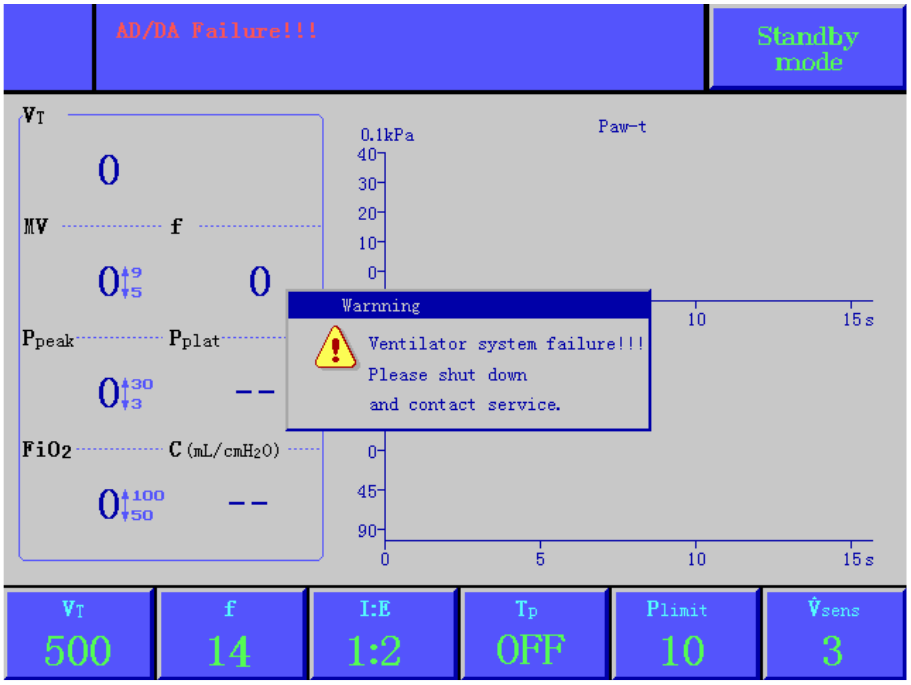


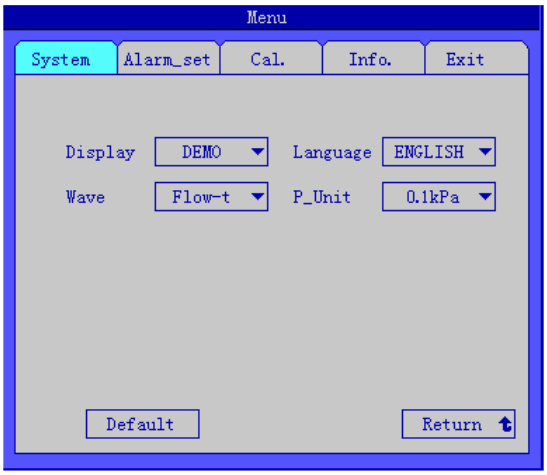
Figure 3-3 Self-test failure

⚠ **WARNING** **if any unwonted malfunction appears, change bag / ventilator switch to manual mode, stop mechanical ventilating.**

3.1.1 Alarm Limit Set

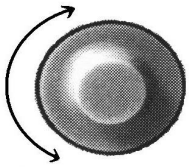
Step 1

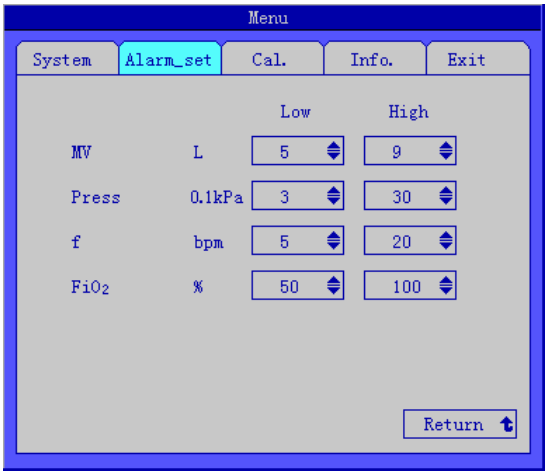
Press ”MENU” key, then display a menu window on the screen.



Step 2

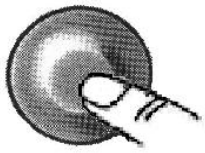
Turn the knob to select “Alarm_set” submenu.

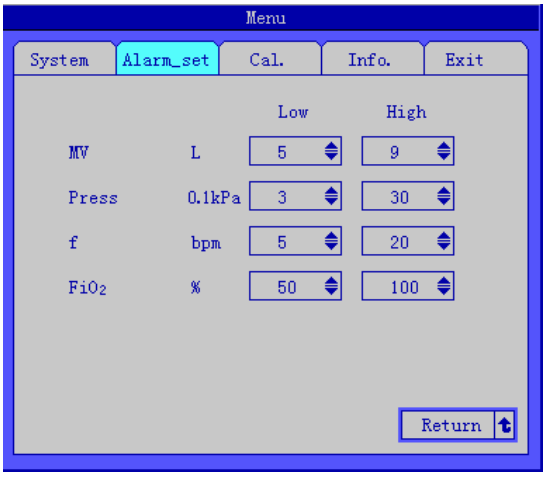




Step 3

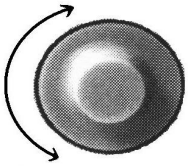
Press the knob to select “Return”.

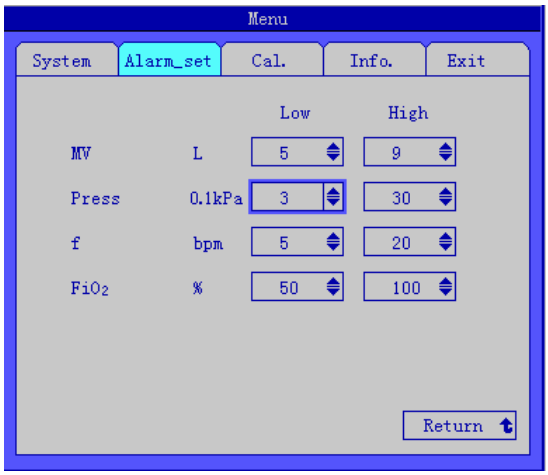




Step 4

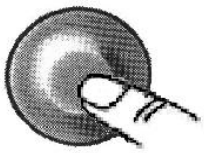
Turn the knob to select option required.

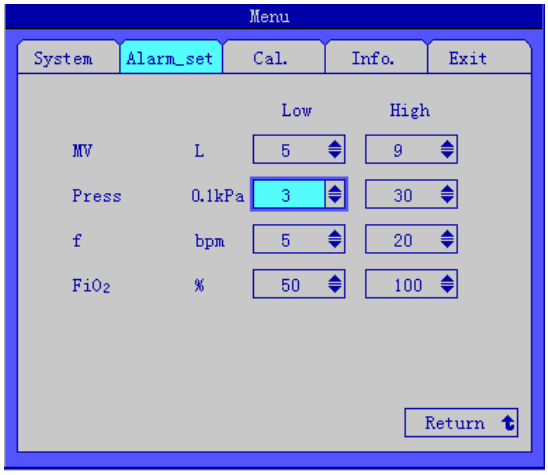




Step 5

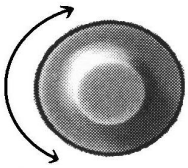
Press the knob, the grounding of option displays different color and high brightness.

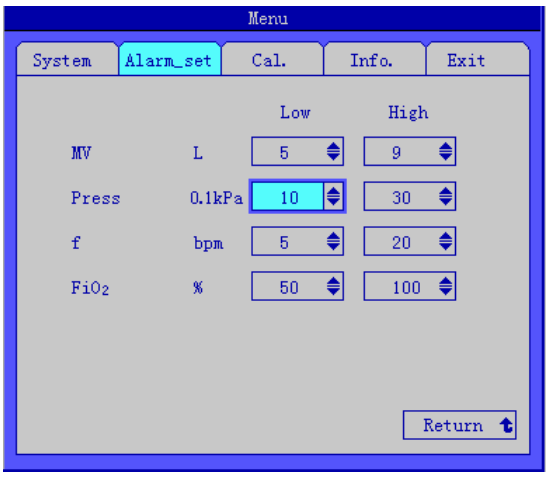




Step 6

Turn the knob to adjust the value.

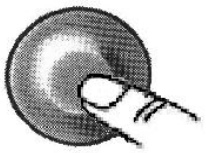


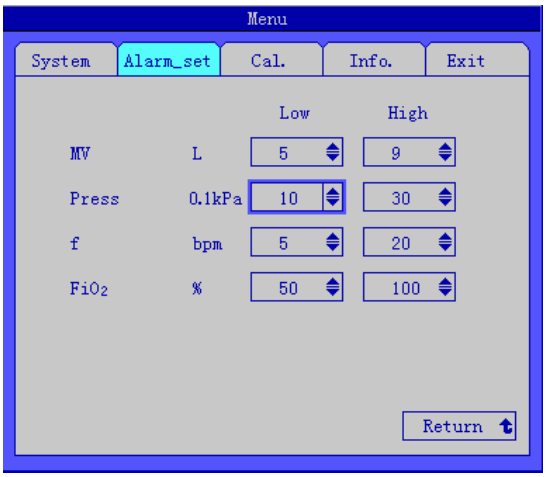


Step 7

Press the knob to save the new adjustment.

Go to next setup or exit “Alarm_set” menu.

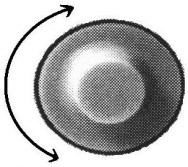


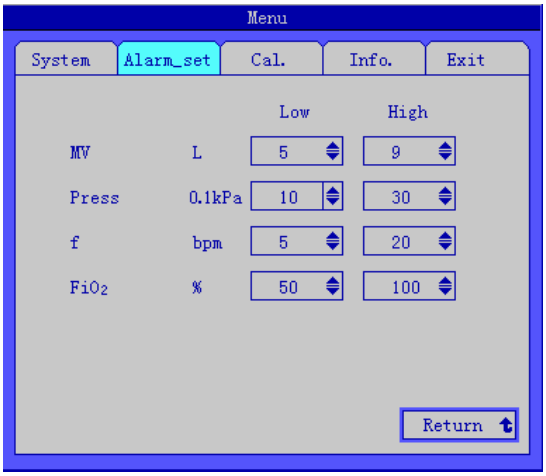


Step 8

Exit “Alarm_set” menu:

Turn the knob to select ”Return”, and then press it.



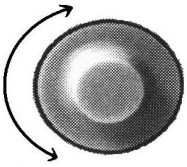


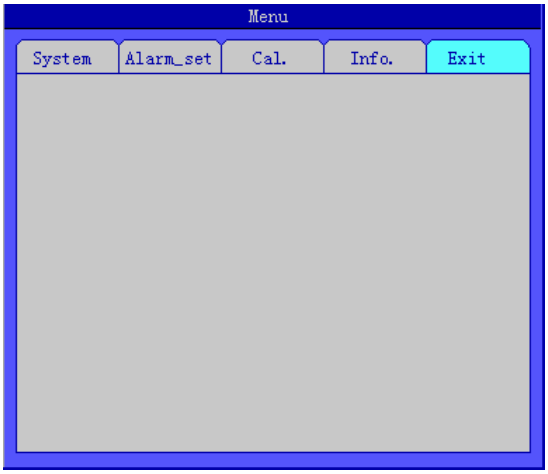
Step 9

Exit “Menu”:

1. Turn the knob to select “Exit” menu, and then press it, or

2. Press “MENU” key directly.





3.1.2 Restore Default Set

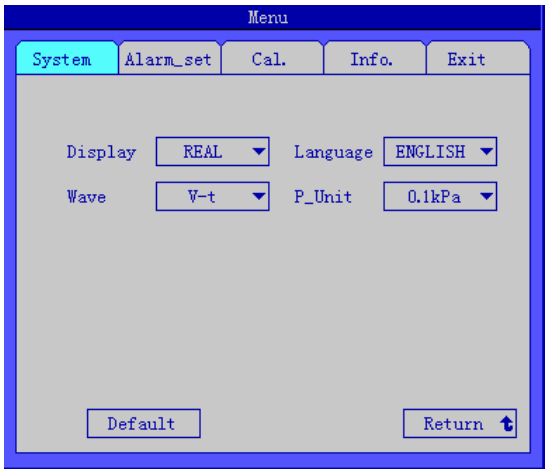
Restore default setting includes:

- Wave and P_unit items in the system submenu;
- All items in the alarm_set submenu.

In a state of default, waveform display and pressure unit is “Flow-t” and ” 0.1kPa” respectively; about details of alarm setting refer to section 8.4.

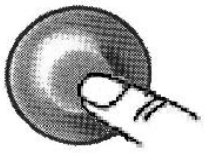
Step 1

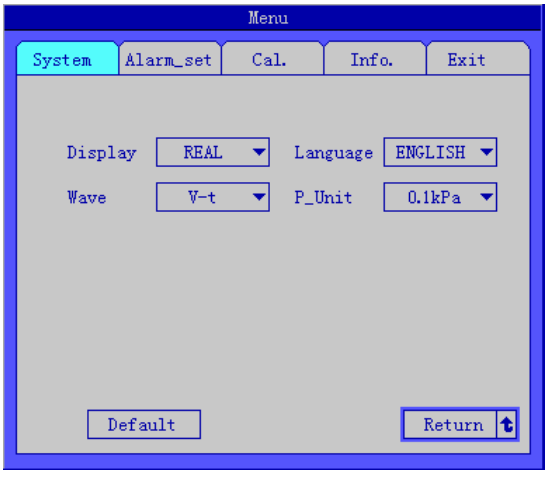
Press ”MENU” key, then display a menu window on the screen.



Step 2

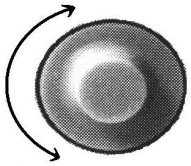
Press the knob, the cursor point to “Return” automatically.

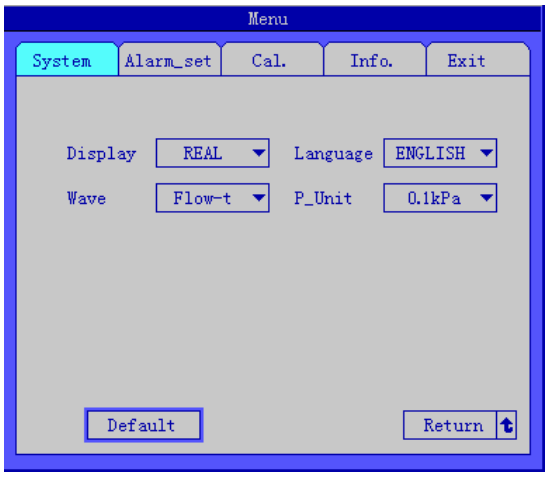




Step 3

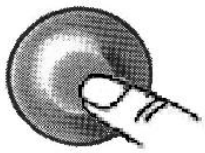
Turn the knob to select “Default”.

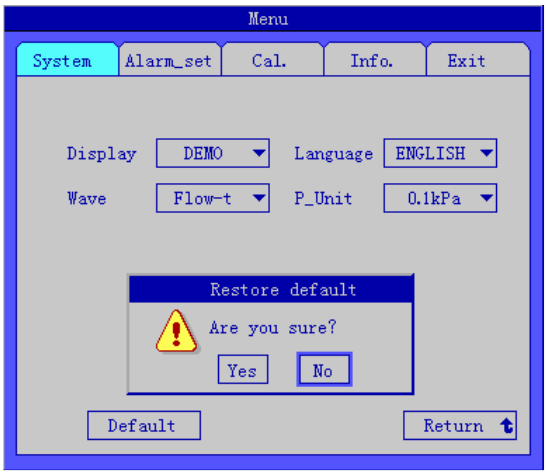




Step 4

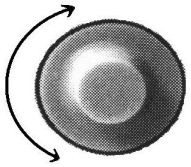
Press the knob, and then display a dialogue box on the menu.

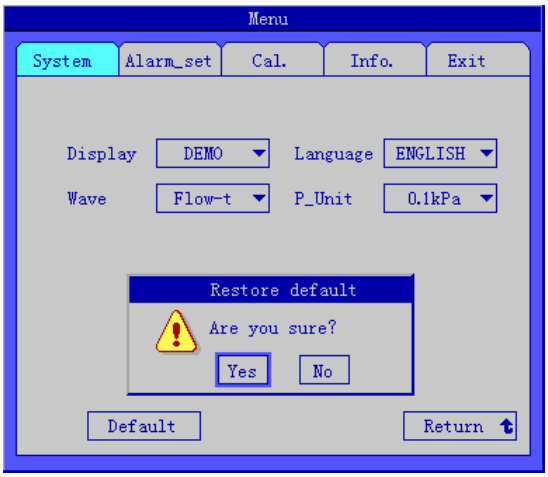




Step 5

Turn the knob to select “Yes”, and then the state of “Wave” and “P_Unit” restore default setup. See section 8.4.

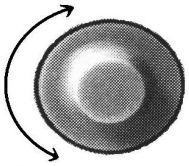


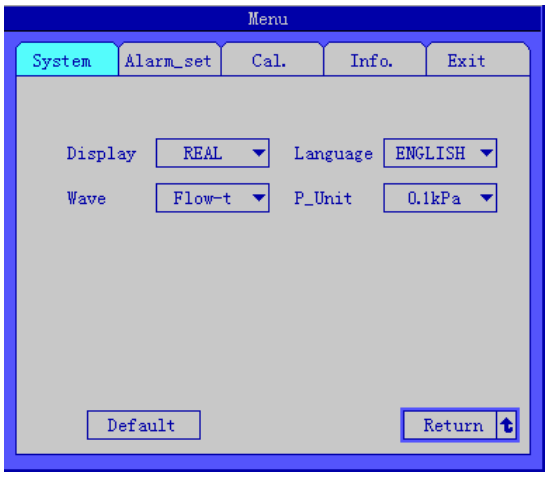


Step 6

Exit “System” menu:

Turn the knob to select ”Return”, and then press it.



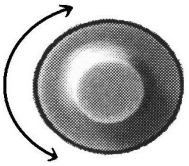


Step 7

Exit “Menu”:

1. Turn the knob to select “Exit” menu, and then press it, or

2. Press “MENU” key directly.



3.1.3 Ventilation Mode Set

Current ventilation mode shown at top right corner of the display, with arrow pointed up. See figure 3-4.

Standby mode

VCV mode

Pressure mode

SIMV mode

Manual mode

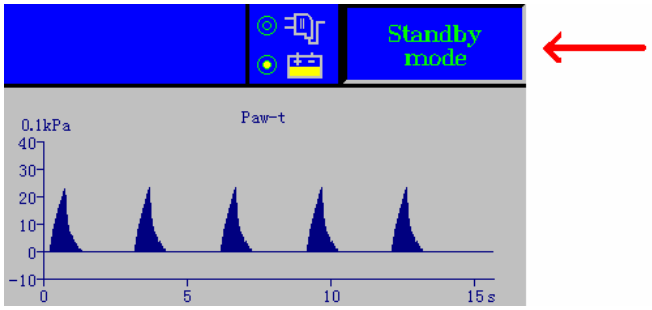


Figure 3-4

Step 1

Turn the knob; make cursor point to the current ventilation mode.

⚠ **CAUTION** **Exit the menu before carrying out this step.**

Step 2

Press the knob to make sure the grounding changed.

Step 3

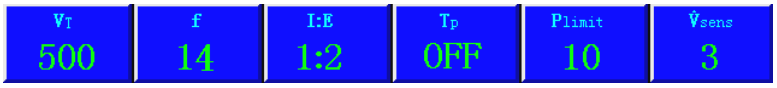
Turn the knob to select ventilation mode required.

Step 4

Press the knob to save the setup.

3.1.4 Ventilator Control Set

1. Standby mode: all parameters can be adjusted.

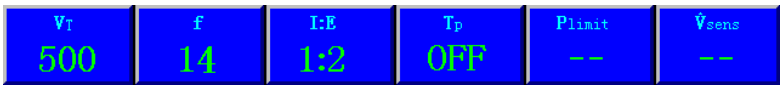


2. SIMV mode: f_{IMV} replace f; T_P and Plimit displays "- -", it means unadjusted.

Adjustable range:

- V_T: 0, 50 ~ 1500 mL
- f_{IMV}: 1 ~ 40 times
- T_I: 0.5 ~ 4.0s
- Vsens: 1 ~ 30L/min

3. VCV mode: Plimit and Vsens displays "- -", it means unadjusted.



According to V_T, f, I:E, T_P, the flow of inspiratory phase can be calculated by the following formula:

$$\text{Flow} = V_T \times (I+E) \times f/(1000*I)(L/min)$$

Gas flow limit: lower: 5L/min; upper: 75L/min

4. Pressure mode: T_P and Vsens displays"- -", it means unadjusted.

5. Manual mode: all parameters displays"- -", it means unadjusted.

Steps of setting refer to section 3.1.3.

3.2 Starting Auto Ventilation

⚠ **WARNING:** **Before getting started, make sure to set the patient circuit installing and controlling correctly.**

The following procedures assume that the system is in on position and manual reservoir gas ventilating mode.

Step 1

Make sure the control settings coincide with the clinical settings.

Step 2

Set the reservoir bag / ventilator switch to auto ventilation position.

Auto ventilation ON (gas goes to the bellow)

Step 3

Select auto ventilation. Refer to section 3.1.3.

Step 4

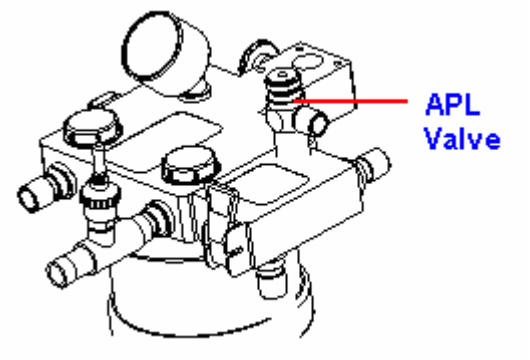
Fill the bellows with O_2 flush if necessary.

3.3 Shutting Off Auto Ventilation

Step 1

Before stopping the auto ventilation, make sure the setting of manual circuit is complete, and the setting of APL valve is correct.

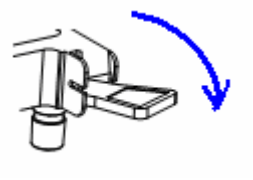
This valve is used to adjust the pressure limit of the breathing system during the manual ventilation period.



Step 2

Set the reservoir bag / ventilation switch to reservoir bag position

Select Manual ventilation, stop auto ventilation (ventilator).



Auto ventilation OFF (gas goes to the reservoir bag)

⚠ **CAUTION: Take the monitoring reading of the anesthetic ventilator rather than the observed reading of the bellows.**

3.4 Alarm

Alarm message displays on the top of screen.

The grounding of top prior alarms is red, but the grounding of middle prior and the lowest prior ones are yellow.

3.4.1 Alarm tone

Judging prior level from the tone of alarms:

Top prior: 5 tones, 2 hurry, 9 seconds interval, repeat

Middle prior: 3 tones, 6 seconds interval, repeat

Low prior: 2 tones

3.4.2 Alarm Silence

When alarming, press alarm silence key, eliminate sound for 110 seconds.

During the silence, spare time displayed on the screen.

Details about alarm messages refer to chapter 8.

3.5 Waveform

1 Paw-t waveform

Y-Axis: airway pressure; X-Axis: time. More details refer to section 10.8.8.

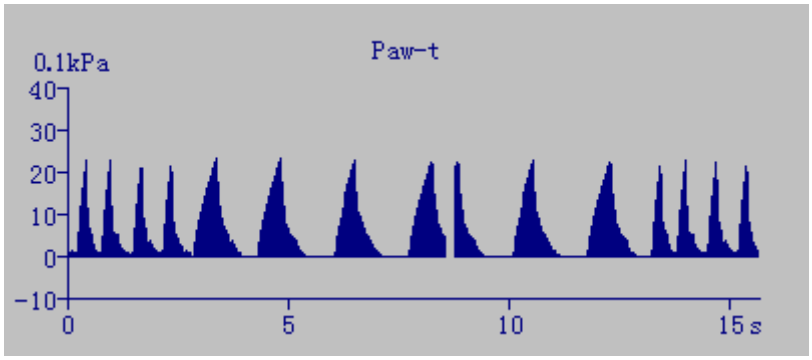


Figure 3-5 Paw-t waveform

2 Flow-t waveform

Flow scale: -90 to 90L/min. Time scale: 0 to 15s.

Time-Axis: Positive inspiratory direction above 0L/min level; minus expiratory direction below 0L/min level; no gas flow on 0L/min level.

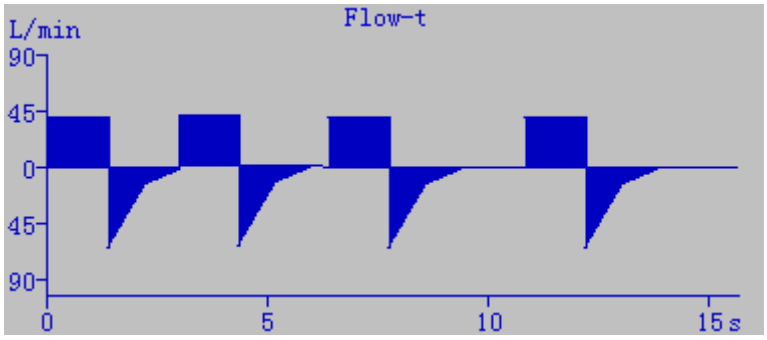


Figure 3-6 Flow-t waveform

3 V-t waveform

Y-Axis: Tidal volume, range: 0 to 1.2L.

Waveform of respiratory phase presents saw-shaped.

See Figure 3-7, (1) inspiratory phase; (2) expiratory phase.

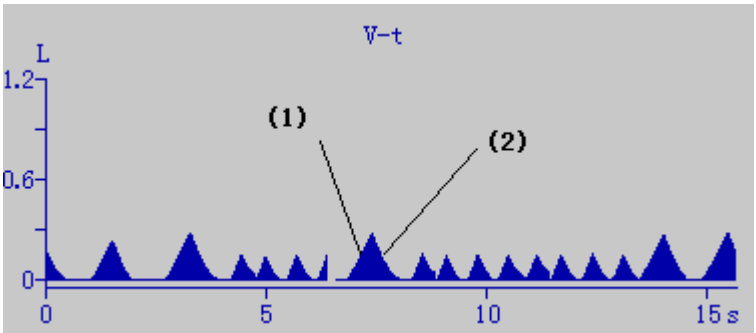


Figure 3-7 V-t waveform

4 Paw-V Loop (Optional)

Y-Axis: pressure; X-Axis: tidal volume. See Figure 3-8.

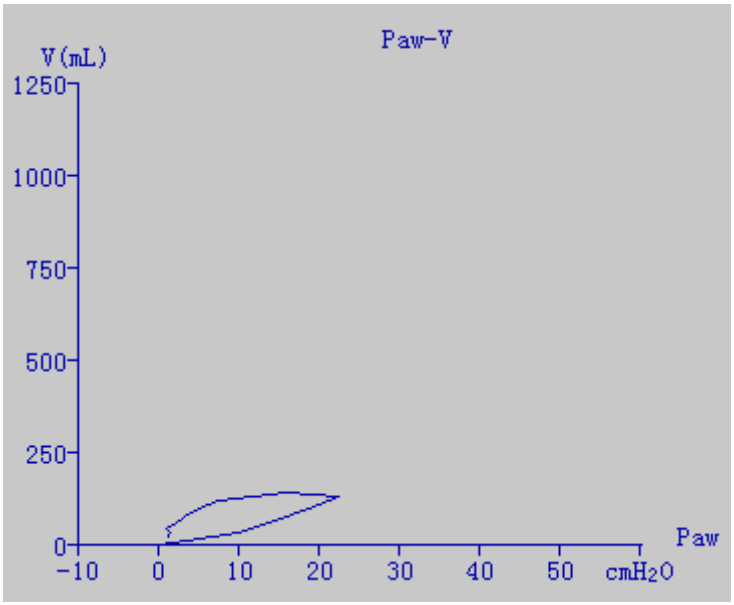


Figure 3-8 Paw-V loop

5 V-FLOW Loop (Optional)

Y-Axis: flow; inspiratory flow above 0L/min level; expiratory flow below 0L/min level.

X-Axis: tidal volume. See Figure 3-9.

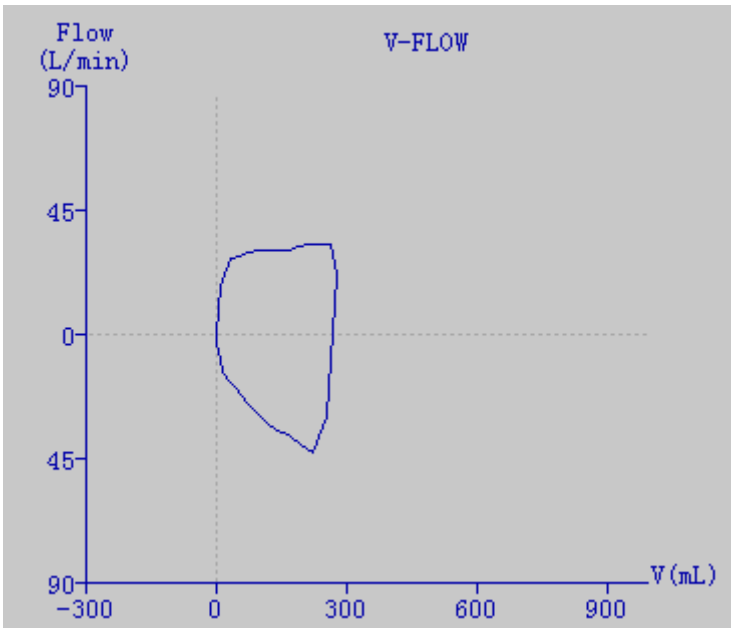


Figure 3-9 V-FLOW loop

4 Preoperative Checkout

4.1 Anastazja7500 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:	Ventilator test:
Gas pipeline and gas cylinder test:	
Flow control test:	
Vaporizer installation and test	
Alarm test:	
Breathing system test:	
Ventilator 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.

4.1.1 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 Breathing circuit is correctly connected and in good condition; there is sufficient absorbent in the breathing system.

4 Vaporizer is in lock position and is filled with sufficient anesthetic.

5 The connection and pressure of pipeline gas supply system are correct.

6 The connected cylinder valve should be closed if there are backup cylinders.

⚠ **WARNING: Do not leave the cylinder valves open during pipeline gas supply period; otherwise, cylinder gas supply will be used up and lead to insufficient supply in case of pipeline malfunction.**

7. The required emergency device is ready and in good condition.
8. The device for airway maintenance, organ cannula are ready and in good condition.
9. The applicable anesthetic and emergency medicine are ready.
10. Make sure the truckles are tight and locked and free of motion.
11. 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.

4.1.2 Mains failure alarm test

1 Press power ON/OFF key lasting 2 seconds, stand-by interface appears after self-test.

2 After operating 5 minutes, pull out power cord.

3 Make sure that power off failure alarm occurs, it has the following characteristics:
- Alarm sound;
- “Mains Failure!” message displays on the screen;
- Mains icon flickering.

4 Connect power cord again.

5 Make sure the alarm eliminate.

4.2 Testing the gas supply pipeline and the gas cylinder

⚠ **CAUTION:** **A user must confirm that gas supply is connected correctly; there is no any disconnection, leakage, faulty connection in gas circuits and pressure indicates correctly. Stop using and check gas connections if abnormal.**

⚠ **CAUTION:** **To prevent from damage:**

Open cylinder valve slowly.

Never control the flow with excessive force.

Skip step 2 if the system is not using cylinder gas supply.

1 Disconnect all pipeline gas supply and close all the cylinder valves.

- If the readings of the pipeline pressure gauge and cylinder pressure gauge are not zero.
- switch on O_2 supply.
- Adjust flow control to middle range.
- Make sure all the pressure gauges are reset to zero except the O_2 pressure gauge.
- Switch off O_2 supply.
- Make sure the O_2 pressure gauge is reset to zero. The low O_2 supply alarm should be on when pressure drops.

2 Make sure cylinders are fully filled:

- Open each cylinder valve.
- Make sure the pressure of each cylinder is high enough. In case the pressure is insufficient, close the corresponding cylinder valve and install a fully filled cylinder.

3 Test cylinder high pressure leak one by one.

4 Close flowmeters.

5 Open the cylinders.

6 Record the cylinder pressures.

7 Close the cylinder valves.

8 Begin to record the pressures after one minute. If O_2 pressure drops to 5000kPa, it means there is a leakage:

- If leakage exists, according to direction of section 5.5, replace a new sheet gasket, and then tighten T handle.
- Perform this step again. If leakage exists all the same, do not use this system.

9 Step 5 ~ 7 should be repeated for all the cylinders. N_2O pressure drop in one minute should not exceed 700kPa.

10 Close all the cylinder valves.

⚠ **CAUTION:** **Do not leave the cylinder valves open during pipeline gas supply period; otherwise, cylinder gas supply will be used up and lead to insufficient supply in case of pipeline malfunction.**

11 Connect pipeline gas supply.

12 Check pipeline pressure according to the table below:

ANSI (U.S. and International), Australia, Canada, France and Japan	345kPa (50psig)
ISO, Italy, Scandinavia, South Africa, Spain and Switzerland	414kPa (60psig)
Austria and Germany	500kPa (75psig)

4.3 Monitoring Flow Control

⚠ **WARNING:** **Refer to Step 1 to 13 of *monitoring without oxygen* for monitoring without oxygen.**

Refer to Step 1 to 13 of *monitoring with oxygen* for monitoring with oxygen.

4.3.1 Monitoring without oxygen

⚠ **WARNING:** **The monitoring system cannot be replaced by link system. The fresh gas containing enough oxygen may not avoid the existence of low oxygen mixture in the breathing circuit.**

If N_2O exists, it will pass through the system during the test, which should be securely collected and removed.

Patients may be injured by improper gas mixture. The link system should not be used if a proper ratio of O_2 and N_2O is not possible.

The following procedures can test whether the link system has serious malfunction; however, it cannot determine whether the calibration is correct.

⚠ **CAUTION:** **The gas flow switch should be adjusted slowly. Do not turn it hard when the reading of the flowmeter goes beyond the maximum or minimum flow rate; otherwise, the control valve can be damaged and the control will not work.**

Follow the steps to test the flow control:

1. Connect the pipeline gas supply or open the cylinder valves slowly.
2. Turn clockwise all the flow control till the end (minimum flow).
3. Turn on mains switch.
4. Do not use this system if the battery is not fully charged or other ventilator failure alarm occurs.
5. Make sure:
   - The oxygen flow is between 25mL/min and 75mL/min.
   - No gas flowing in any other flow tube.
   - Step 6 and step 7 are only applicable for the N_2O system test.

⚠ **WARNING:** **During Step 6 to Step 7, keep link systems working state.**

Only adjust testing of control (N_2O in step 6 and O_2 in step 7).

Adjust flow according to order (N_2O firstly O_2 secondly).

If adjustable range exceeds, please adjust flow control to the nearest place and perform this step again.

6. To test the flow increase of the link system:
   - Turn clockwise the N_2O and O_2 flow control till the end (minimum flow).
   - Turn counterclockwise the N_2O flow control slowly.
   - Set N_2O flow control to the rate described in the following table. The O_2 flow must be higher than the minimum flow limit.

Set N_2O flow to (liters per minute)**:**	**O_2 flow must be higher than the minimum flow** (liters per minute):
0.6	0.2
1.5	0.5
3	1.0
7.5	2.5

7. This step tests the function of the Link System when flow is reduced, you should:

Set N_2O flow to (liters per minute)**:**	**O_2 flow must be higher than the minimum flow** (liters per minute):
6.0	2.0
3.0	1.0
0.6	0.2

8. Adjust full flow of all the gas to ensure that the flowmeter float must move smoothly.
9. Shut off the oxygen supply either by closing the oxygen cylinder valve, or by disconnecting the oxygen pipeline supply.
10. Make sure:
    - As pressure decreases, the oxygen-supply failure alarm must continuously sound.
    - Disconnect the flow of nitrous oxide and oxygen to be sure that the oxygen flow will be the last to stop.
    - Air flow remains.
    - If the oxygen is the driving gas of the ventilator, the oxygen-supply failure alarm must continuously sound.
11. Turn all of the flow control valve knobs completely clockwise to the minimum flow.
12. Reconnect oxygen pipeline supplies or slowly open the oxygen cylinder valve.
13. Turn off mains supply.

4.3.2 Monitoring with Oxygen

⚠ **WARNING:** **The monitoring system cannot be replaced by link system. The fresh gas containing enough oxygen may not avoid the existence of low oxygen mixture in the breathing circuit.**

If N_2O exists, it will pass through the system during the test, which should be securely collected and removed according to safe and eligible methods.

Patients may be injured by improper gas mixture. The link system should not be used if a proper ratio of O_2 and N_2O is not possible.

⚠ **CAUTION:** **Before continuous testing, perform test of the O_2 monitoring device according to step 8 in section 4.6.**

Follow the steps to test the flow control:

1. Connect the pipeline gas supplies, or slowly open the cylinder valve.
2. Turn all of the flow control valve knobs completely clockwise to the minimum flow.
3. Turn on mains switch.
4. Do not use this system if the battery is not fully charged or other ventilator failure alarms occur.
5. Make sure:
   - The oxygen flow is between 25mL/min and 75mL/min.
   - No gas flowing in any other flow tube.
   - Step 6 and step 7 are only applicable for the N_2O system test.

⚠ **WARNING:** **During Step 6 to Step 7, keep link systems working state.**

Only adjust testing of control (N_2O in step 6 and O_2 in step 7).

Adjust flow according to order (N_2O firstly O_2 secondly).

The oxygen sensor being used must be calibrated correctly.

6 To test the flow increase of the link system:
   - Turn clockwise the N_2O and O_2 flow control till the end (minimum flow).
   - Turn counterclockwise the N_2O flow control slowly.
   - Make sure that the oxygen flow is increasing. The concentration of the oxygen tested must ≥ 21% during the complete process.

7 To test the flow increase of the link system:

- Set the nitrous oxide flow to 9.0L/min.
- Set the oxygen flow to 3/min or higher.
- Turn the flow control valve knob of the oxygen clockwise slowly.
- Be sure that the oxygen flow is getting reduced. The concentration of the oxygen tested must ≥ 21% during the complete process.

8 Adjust all of the gas full flow to ensure that the flowmeter floats must move smoothly.

9 Shut off the oxygen supply either by closing the oxygen cylinder valve, or by disconnecting the oxygen pipeline supply.

10 Make sure:

- As pressure decreases, the oxygen-supply failure alarm must continuously sound.
- Disconnect the flow of nitrous oxide and oxygen to be sure that the oxygen flow will be the last to stop.
- Air flow remains.
- If oxygen is the driving gas of the ventilator, the oxygen-supply failure alarm must continuously sound.

11 Turn all of the flow control valve knobs completely clockwise to the minimum flow.

12 Reconnect oxygen pipeline supplies or open the oxygen cylinder valve slowly.

13 Turn off mains supply.

4.4 Installing and testing of vaporizer

4.4.1 Installation

⚠ **WARNING:** **Do not take the vaporizer away from the bypass valve with its locking lever locked.**

Do not use more than one vaporizer at the same time in this system.

Install vaporizers in accordance with the following steps:

1. The vaporizer must be disassembled and reinstalled if its top is not horizontal.
2. Set the locking lever of the vaporizer so that it is locked.
3. Try to lift the vaporizer directly upwards so as to separate itself from the bypass valve, but do not pull the vaporizer forwards. Be careful not to rotate it on the bypass valve.
4. As the vaporizer is taken away from the bypass valve, reinstall the vaporizer and then follow step 1 to step 3. Do not use this system if you cannot put return the vaporizer to a horizontal position on the bypass valve.
5. Try on opening two vaporizers at the same time.
   - Testing any possible instance of each combination.
   - If more than one vaporizer can be opened at the same time, disassemble and reinstall them, then perform step 1 to step 5.

4.4.2 Testing Vaporizer Back Pressure

⚠ **CAUTION:** **About performance testing of vaporizer refer to relevant instruction for use.**

4.5 Testing alarm

1 Connect reservoir bag to patient end.

2 Set bag/ventilator switch to ventilator control.

3 Turn on mains switch.

4 Set control options:

Ventilation mode:	VCV mode
Ventilator:	V_T: 700ml
	f: 20bpm
	I:E: 1:2
	Plimit：40cmH_2O
Anesthetic machine:	O_2 flow: minimum flow (25-75mL/min)
	All other gas: close
	Press O_2 flush button to inflate bellows.

5 Set bag/ventilator switch to bag control, and then set to ventilator control again. Make sure:

- Auto ventilation start.
- Display right data on the screen.
- Bellow assembly up and down during auto ventilation.

6 Adjust O_2 flow to 5L/min.

7 Make sure:

- Pressure at the end of expiration is 0cmH_2O approximately.
- Right data displayed on the screen.
- Bellow assembly up and down during auto ventilation.

8 Test O_2 monitoring and alarm:

- Remove O_2 sensor from the absorber cycle, and confirm that O_2 concentration measured in the room air is about 21%.
- Adjust lower limit of O_2 concentration to 50%, and confirm that “FiO_2 low!!” alarm occurs.
- Adjust lower limit of O_2 concentration to 21% again, and confirm that the alarm eliminates.
- Put O_2 sensor back to the absorber cycle.
- Adjust upper limit of O_2 concentration to 50% again.
- Press O_2 flush to charge the breathing system, and confirm that “FiO_2 high!!” alarm occurs.
- Adjust upper limit of O_2 concentration to 100%, and conform that the alarm eliminates.
- Let O_2 sensor pass pure O_2 for 2 minutes, and conform that O_2 concentration measured is about 100%.

9 Test low minute volume alarm:

- Turn to “Alarm_set” menu.
- Adjust lower limit of MV to 6L/min, and conform that “Minute Volume Low!!” alarm occurs.
- Turn to “Alarm_set” menu again.
- Adjust lower limit of MV to 10L/min, and conform that the alarm eliminates.

10 Test high airway pressure alarm:

- View P_{peak} on the screen.
- Adjust lower limit of Paw to below P_{peak}, and conform that “Paw high!!!” alarm occurs.
- Adjust lower limit of Paw to above P_{peak}, and conform that “Paw high!!!” alarm eliminates.

11 Test low airway pressure alarm:

- Remove reservoir bag form the absorber cycle.
- Other alarm occurs, such as “Minute volume low!!”.
- Make sure that “Paw low!!” alarm occurs.

12 Test continuous high airway pressure alarm:

- Set control options:

  APL valve: Set to the maximum value

  Bag / Ventilator switch: Bag

- Set bag / ventilator switch to bag control, auto ventilation should stop.
- Block up patient end and press O_2 flush button.
- Make sure that “Paw continuous high!!!” alarm occurs after 15 seconds approximately.

13 Turn off mains supply.

4.6 Testing the Breathing System

Refer to the operating manual and:

Verify the non-return valve in the Breathing circuit module works normally:

The non-return exhalation valve will ascend during the exhalation period while it will descend during the inhalation period.

⚠ **WARNING:** **Objects in the breathing system can interrupt or disrupt the delivery of breathing system gas, resulting in possible patient death or injury:**

Do not use any testing plug small enough to slip completely into the breathing system.

4.6.1 Checking Oxygen flush Switch

Press the oxygen flush button (the sound of gas should be heard from the fresh gas outlet) then release. The button must immediately drop back to its position and stop delivering the gas.

4.6.2 Testing Breathing System

Turn the switch of the anesthesia machine to Manual Bag. Pressure gauge is zeroed. APL Valve knob should be fully clockwise to the maximum. Connect the wye connector to the test lung.

Occlude the manual reservoir bag on the port below the switch. Press the oxygen flush button or open the flowmeter to make the indication of the pressure gauge achieve 3KPa, then release the button and close the flowmeter. After 20 seconds observation, the pressure indicated by the pressure gauge must not exceed 0.3KPa.

4.6.3 Testing APL Valve

Adjust the positions of every switch and knob according to the method of testing Breathing System Leak. Open the oxygen flow to 5 liters per minute. Adjust the APL valve to position the pressure of the pressure gauge in different places respectively. The common gas outlet must overflow some gas as the pressure is stable.

⚠ **WARNING:** **Be sure that there is no any testing plug or foreign objects in the Breathing System.**

4.7 Testing Ventilator

1 Connect the test lung to the patient circuit port.

2 Set the Reservoir bag / Ventilator switch to the Reservoir bag position.

3 Turn on mains switch.

4 Set control options:

Ventilation mode:	VCV mode
Ventilator:	V_T: 700ml f: 20bpm I:E: 1:2 Plimit：40cmH_2O
Anesthetic machine:	O_2 flow: less than 200mL All other gas: close Press O_2 flush to charge bellows.

5 Set the bag / Ventilator switch to ventilator control.

6 Press the Oxygen flush button to inflate the bellows.

7 Ensure:

- Auto ventilation start.
- No low pressure alarm.
- Ventilator displays the correct data.
- The bellows ascend and descend during the period of auto ventilation

8 Set the O_2 flow control to 5L/min.

9 Ensure:

- Ending expiratory pressure is about 0 cmH_2O.
- Ventilator displays the correct data.
- The bellows inflate and scavenge during the period of auto ventilation.

10 Set the ventilator control and alarm limits to the proper clinical level.

11 Turn off mains supply and close all valves of gas cylinders if not to use the system.

12 Ensure that the things in the following table should be prepared completely.

Apparatus:	Airway maintenance Manual ventilation Organ cannula
anesthesia and emergent drugs applicably	

13 System preparation:

- Close all vaporizers.
- Open the APL valve.
- Set the bag / ventilator switch to bag control.
- Set all the flow controls to the minimum.
- Be sure that the breathing system connects correctly

⚠ **WARNING: Be sure that the breathing system connects correctly.**

⚠ **WARNING: Flush the anesthesia machine for at least one minute by using O_2 with 5L/min flow speed to remove unnecessary mixed gas and objects in the system before connecting the equipment to the patient end.**

⚠ **WARNING: Anesthesia equipment must be connected to the waste gas scavenging system to outlet the waste gas to prevent the staff working in the operating rooms from injury.**

This requirement must be followed in the testing and clinical application.

5 Installing and Connecting

⚠ **CAUTION**: **O_2 monitoring must be used on this equipment. For the related stipulations, refer to local standards.**

⚠ **CAUTION**: **According to the European standard EN 740 and International Standard IEC 60601-2-13 / ISO 8835-1, this equipment must use expiratory volume monitoring, O_2 monitoring (in accordance with EN 12342 or ISO 7767) and CO_2 monitoring (in accordance with EN 864 or ISO 9918).**

⚠ **CAUTION**: **Anesthetic monitoring (in accordance with ISO 21647:2004) must be made as the anesthetic vaporizer is being used according to the European standard EN 740 and International Standard IEC 60601-2-13 / ISO 8835-1.**

⚠ **WARNING**: **Operating room environment can be influenced by the expiratory gas. Some unexpected dangers may occur if the anesthetic has been not tested for a long time. The operator must dispose of expiratory gas in a timely fashion according as required, and examine other items to minimize the chances of danger and malfunction.**

⚠ **WARNING**: **Be sure the gas pipeline supply hoses and the breathing circuit components are non-poisonous, do not cause patient allergy, and do not create dangerous by-product through reaction with the anesthesia gas or the anesthetic.**

⚠ **WARNING**: **To prevent generating wrong data and malfunction, please use the cables, hoses, and tubes from FARUM S.A..**

⚠ **CAUTION**: **It is dangerous if there is anesthetic in the absorber. Measures must be made to prevent the soda lime in the absorber from drying. Turn off all the gas supplies after finishing using the system.**

⚠ **CAUTION**: **This system can be operated correctly under IEC 60601-1-2 interference. Higher-level interference may cause alarm and result in auto ventilation suspension.**

⚠ **CAUTION**: **To avoid equipment false alarm caused by high strength electric field:**

- **Put the electricity surgical conducting wire far from the place where the breathing system and the O_2 sensor are put on.**
- **Do not put the electricity surgical conducting wire on any parts of the anesthetic system.**

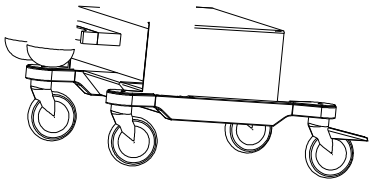
⚠ **CAUTION:** **To protect the patient, as the electricity surgical equipment is being used:**

- **Monitor and ensure that all the life supporting and monitoring equipment are operated correctly.**
- **Ensure that the backup manual ventilator can be used immediately in case that electricity surgical equipment cannot secure the use of ventilator.**
- **Never use electrical conduction masks or hoses.**

5.1 Installing Product

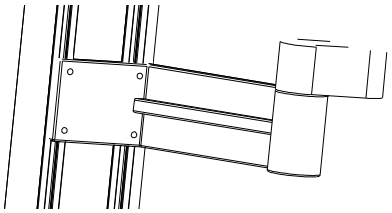
5.1.1 Shelf

Unpack the bottom package, take out the shelf and lock its truckles so it cannot move freely.



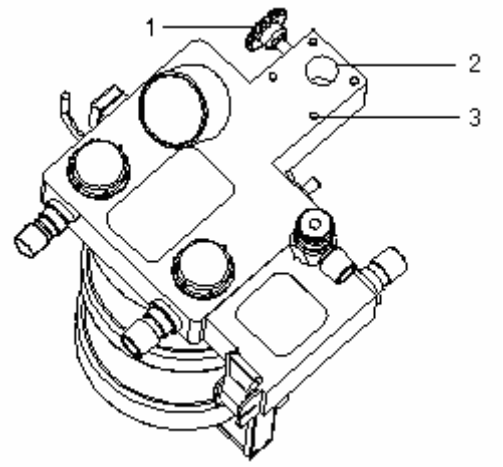
5.1.2 Breathing circuit limb

Connect the breathing circuit limb to its mounting tracks, then tighten the screws.



5.1.3 Absorber cycle

When installing, hold the top plate of the breathing circuit with both hands, connect the position fixing hole to the limb post, sit it on the limb post, then tighten the knob .



1 knob
2 fixing hole
3 bolt hole

5.1.4 The bellows Assembly base

Connect the bellows assembly base to the bolt hole (3) of the absorber cycle, then tighten the screws.

5.2 Installing Absorber

⚠ **CAUTION:** **The ANASTAZJA 7500 shall comply with configurations and conditions under which clause 24 of the General Standard IEC 601-1.**

⚠ **WARNING:** **Follow the proper security measures:**

- **Do not use the absorber if the anesthetic is chloroform or trichloroethylene.**
- **Avoid to let the skin or eyes touch the materials in the absorber. Clean the affected part immediately and seek medical attention if materials come in contact with skin or eyes.**
- **Do not replace absorber during the period of ventilating.**
- **Replace the absorbent often to prevent the deposition of non-metabolism gas as the system is not on.**
- **Check the color of the absorbent after finishing each case. The original color of the absorbent may be restored when not in use. Refer to the labels of the absorbent for the details.**
- **Carbon monoxide is released if completely dried absorbent contact with the anesthetic. Replace the absorbent for security.**
- **Perform leakage testing of breathing system in bag control mode after disassembling the absorber.**

The absorber in this system can be used repetitious.

The capacity of each absorber is 1500mL. It is recommended to use Medisorb absorbent.

Only air, oxygen, carbon monoxide, halothane, enflurane, isoflurane, sevoflurane and can desflurane be used for the absorber.

5.2.1 When to replace absorbent

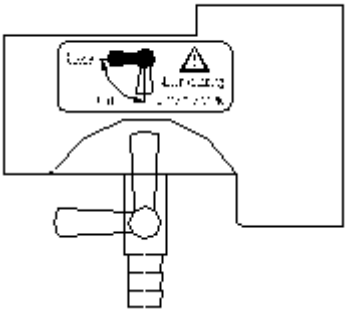
Changed color of the soda lime in the absorbent indicates that it has absorbed the carbon dioxide; however, this color is not 100% accurate. To decide whether to replace the absorbent, use CO_2 monitoring machine.

Remove the changed-color absorbent immediately. The soda lime will restore its original color several hours later and that may mislead the operator.

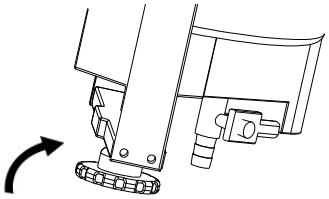
5.2.2 Disassembling Absorber

The absorber is reusable. Follow the disassembling procedures:

1 Turn on drain valve to get rid of water generated by chemical reaction.



2 Rotate the handle clockwise to disassemble the absorber.



5.2.3 Filling Absorbent

1 Remove the absorbent of absorber.

2 Cleaning and sterilization refer to section 6.3.

3 Fill the absorber with fresh absorbent after dryness. Wipe soda lime fell on the edge of absorber, and then install it back. Make sure the airtightness is well, and that no leakage and spillage.

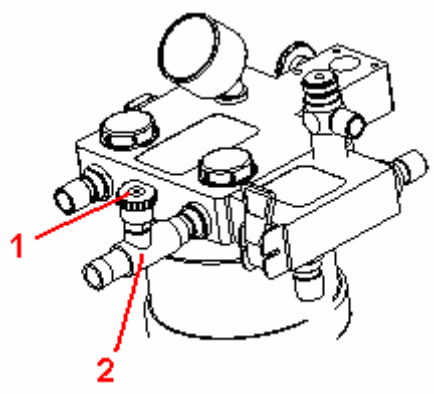
5.3 Connecting tubes and lines

⚠ **CAUTION:** **CO_2 monitor (in accordance with ISO 9918) should be connected at elbow bend of patient end.**

⚠ **CAUTION:** **Anesthetic agent monitor (in accordance with ISO 21647:2004) should be connected at pipe T installed inspiratory port.**

⚠ **CAUTION:**

O_2 sensor should be connected at pipe T installed inspiratory port.



1 O_2 sensor connector

2 pipe T

5.4 Connecting Gas and Electricity

⚠ **WARNING: IEC 60601-1-1 applies both for combination of items of medical electrical equipment and for combinations of at least one item of medical electrical equipment with one or more items of non-medical electrical equipment. Even if there is no functional connection between the individual pieces of equipment, when they are connected to an auxiliary mains socket outlet they constitute a medical electrical system. It is essential that operators are aware of the risks of increased leakage currents when equipment is connected to an auxiliary mains socket outlet.**

⚠ **WARNING: The equipment connected to the power outlet will increase electric current leakage. Test electric current leakage regularly.**

⚠ **WARNING: A malfunction of the central gas supply system may cause more than one or even all devices connected to it to stop their operation simultaneously.**

⚠ **CAUTION: Disconnect the anesthetic workstation from the gas supply after use to prevent contamination or pollution of the pipeline system.**

⚠ **CAUTION: Only the medical gas supply should be used. Other types of gas supply may contain water, oil or other pollutants.**

⚠ **WARNING: All connectors of gas supply have different dimensions and structures. It can avoid wrong operation occurs.**

5.4.1 AC inlet

AC Power:

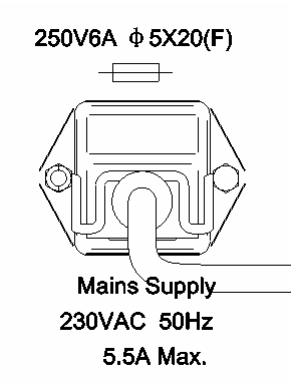
230VAC 50Hz;

5.5A Max.

Fuse:

250V6A, ∅5X20（F）

Clasp can stop power cord breaking off.



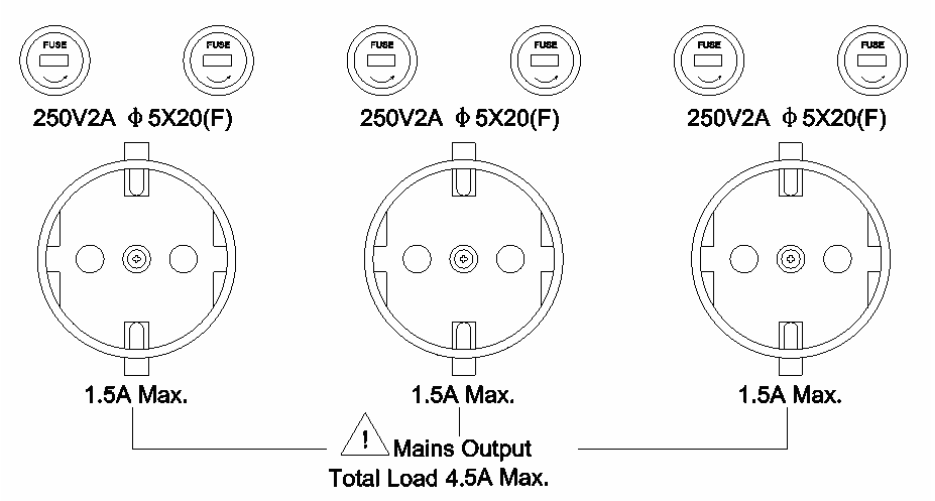
⚠ **WARNING Switch the anesthesia machine to backup battery in case of AC failure alarm, and prompt alarm message displaying on the screen.**

5.4.2 Auxiliary mains socket outlet

⚠ **CAUTION** **Auxiliary mains socket outlets operator- accessible should be not more than four when in use ANASTAZJA 7500.**

This label displays the voltage of the power supply and the rated ampere value of the circuit breaker.

Fuse: 250V 2A ϕ5X20(F)
Maximum current outlet: 1.5A (each); 4.5A (total)



5.4.3 Serial Port

RS-232 port on the rear of display can permit serial inlet and outlet of command and data.

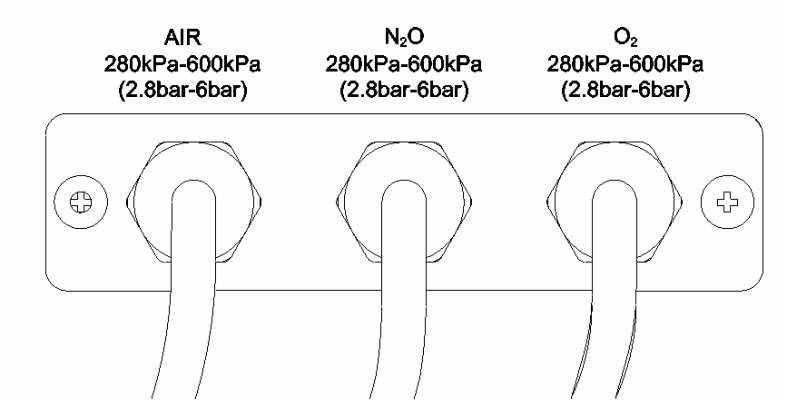
Signal Standard: RS232C (EIA-574)

Signal Definition: DTE configuration

Interface: DB9/M

DB-9 Connector Pin Out		
Pin #	**Signal Name**	**Signal Description**
1	CD	Carrier Detect
2	RXD	Receive Data
3	TXD	Transmit Data
4	DTR	Data Terminal Ready
5	GND	Signal Ground / Common
6	DSR	Data Set Ready
7	RTS	Request To Send
8	CTS	Clear To Send
9	RI	Ring Indicator

5.4.4 Pipeline gas supply inlet

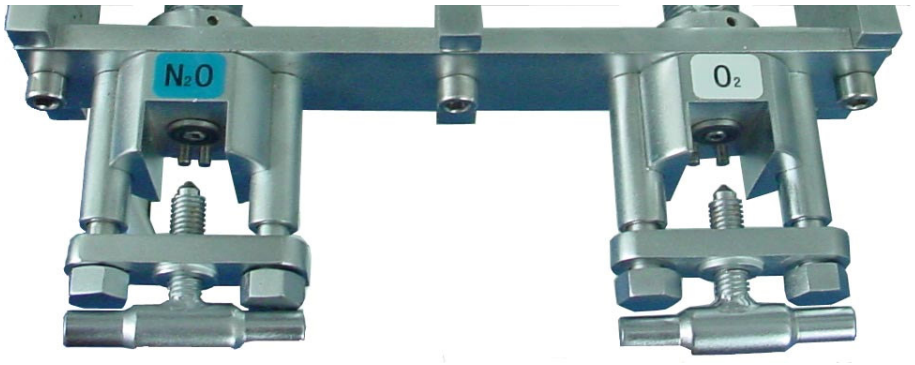


Pressure inlet: 280 to 600 kPa

Pipeline connector: DISS (Diameter-indexed safety system) and NIST (non-interchangeable screw-threaded).

It can prevent wrong connection generating.

5.4.5 Cylinder gas supply inlet



Cylinder connector: PISS (Pin-indexed safety system)

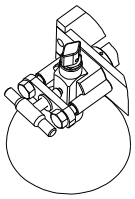
It can prevent wrong connection generating.

⚠ **WARNING: The connecting procedures of O_2 and N_2O to the rear of the anesthesia system have been provided. Each has a different dimension to avoid user's misoperation. A continuous pressure monitoring device is installed in the front of the anesthesia system to monitor each gas that connects with hospital supply pipelines.**

5.5 How to install gas cylinder (Testing high pressure leak)

⚠ **CAUTION:** **Do not turn the cylinder valve on when the pipeline gas supply is being used. The gas supply of the cylinder may be used out in case of pipeline failure so that the backup supply may be insufficient.**

1 Turn the handle T of the cylinder valve clockwise until it is tight. Close the valve of the cylinder to be changed.



2 Release the yoke piece, then disassemble the cylinder.

3 Remove the valve cap from the new cylinder.

4 Keep the cylinder inlet away from all the objects which could be damaged by the release of high pressure gas.

5 To clear the cylinder valve of any debris, use the cylinder wrench to briefly open, then close the cylinder.

6 Install the cylinder.

- Align index pin with the basic hole of the gas cylinder.
- Close yoke piece and screw handle T.

7 Perform the high pressure leak test:

- Disconnect the pipeline gas supply.
- Close flowmeter.
- Open the cylinder.
- Close the cylinder.
- Record the pressure of the cylinder.
- If the pressure of the O_2 cylinder drops more than 5000 KPa (725PSi) after one minute, the high pressure circuit has an unacceptable leak.
- If the pressure of the N_2O cylinder drops more than 690 KPa after one minute, the high pressure circuit has an unacceptable leak.

Repairing gas leak

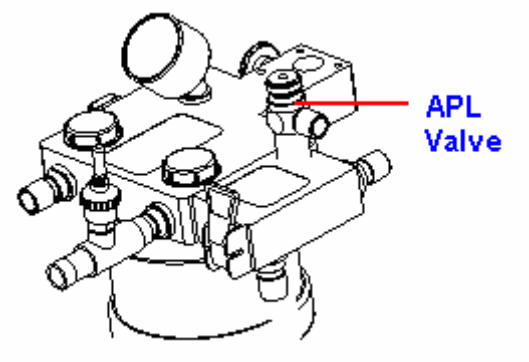
Install a fresh cylinder gasket and tighten the connector.

Repeat this step. Do not use this system in case of continuous gas leak.

5.6 Connect gas scavenging transfer & receiving system

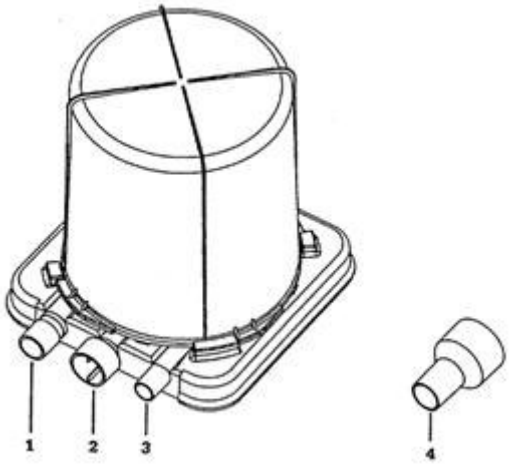
There are two ports releasing exhaust gas in this system. Connect the two ports to gas scavenging transfer and receiving system with tubes.

1. APL valve



2. Exhausting port of bellows assembly

See the following figure; number 2 is the exhausting port.



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. The O2 sensor may leak and burn (by Chlorine Potassium Oxide) if damaged. Do not inhale fumes.**
- **Do not inhale fume.**

⚠ **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, acestone 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.**
- **Only the components marked 134□ are pressure-resistant and heat-resistant.**
- **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.**

⚠ **CAUTION:** **Never immerse the circuit O_2 sensor or flow sensor connector in the liquid.**

Never dispose the circuit O_2 sensor connector by using hot press.

Do not clean the inner surface of the flow sensor. Clean the outer surface by using a damp cloth.

Check if there is damage in the components. Replace if necessary.

6.1 Cleaning and sterilization of pre-use first

Main unit	Clean the machine's panel and all surfaces with soft cloth soaked with the water soluble sterilizing agent. Sterilize main unit with ultraviolet radiation. Do not use acetic hyctro peroxide or formaldehyde steaming.
Breathing system components	Refer to section 6.2
Absorber cycle	Washing, refer to section 6.4
Bellows assembly	Washing refer to section 6.5.4

6.2 Cleanable Breathing System Components

Threaded tubes (contacted with patient),mask, Y piece connector, elbow bend, reservior bag	Designed for using only once, not need to sterilize. The waste should be recovered. When to replace these expendable, products with medical level and equal specification should be selected to use.
Threaded tubes and bag (repetitious)	Washing to sterilize
Pipe T	Washing to sterilize
Sampling probe and parallel lines of flow	Clean with soap before use of each patient, and then washing in disinfecting solution after airing.

Components marked 134□ are pressure-resistant and heat-resistant and can be cleaned by hand or by machine (by using the mild agent with PH < 10.5). Scrub them thoroughly, then air out to dry.

Clean the bellows assembly by disassembling them, or they will take longer to dry. To dry, hang the bellows by from its top disk while spread fully. Moisture remaining in the folds of the bellows may make the bellows tacky.

Reassemble the bellows assembly prior to the hot-press disposal. Put the bellows assembly up side down when the hot-press disposal is being processed.

6.3 Absorber

Refer to “Disassembling the Absorber” in the section 5.2.2

⚠ **WARNING: The dry absorber may be very dangerous with the presence of any anesthetic. Take proper measures to avoid dry soda lime in the absorbent. Switch off all gas supplies after use.**

6.3.1 Auto cleaning with agent or disinfector

Clean the absorber in the agent or disinfector according to the cleaning procedure.

Put the absorber in the heat-up room with the maximum temperature as 80ºC or with the room temperature.

Higher-level sterilization is recommended if the agent and disinfector cannot sterilize equipment.

6.3.2 Manual cleaning

Rinse the absorber.

Immerse the absorber completely in the sink with water and agent about three minutes at a temperature of 40 ºC (104).

Rinse the absorber.

Higher-level sterilization must be performed after cleaning by hand.

6.3.3 Advanced Sterilizing

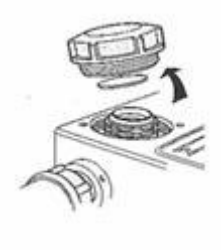
The absorber must be cleaned before advanced sterilizing.

The absorber can be placed in high temperature and high pressure conditions. The maximum temperature recommended is 134ºC (273).

Put the soda lime into the absorber after being dried, and then tighten the knob. Clear all soda lime debris.

6.4 Absorber assembly

1 Inhalation valve and exhalation valve



Dismount the cover of the inspiration and expiratory valves by rotating it counter clockwise, then clean all parts of them with the gauze soaked with water soluble sterilizing agent, after all parts cleaned and dried recover it in original integration. Then one must check the leakage and the movement of the inspiration and expiration valves in accordance with the required regulation and checking procedure. Please handle all parts with care preventing any damage.

2 Absorber module

Either vapouring (not more than 50ºC) or immersion sterilization can be used in practice, in case of immersion all sterilized parts must be dried with the high pressure air or oxygen before reuse.

6.5 The Bellows Assembly

This section is about disassembling, assembling, cleaning and sterilizing the bellows assembly. Read all content of this section before disassembling, assembling, cleaning and sterilizing the bellows assembly to avoid equipment malfunction and patient injury.

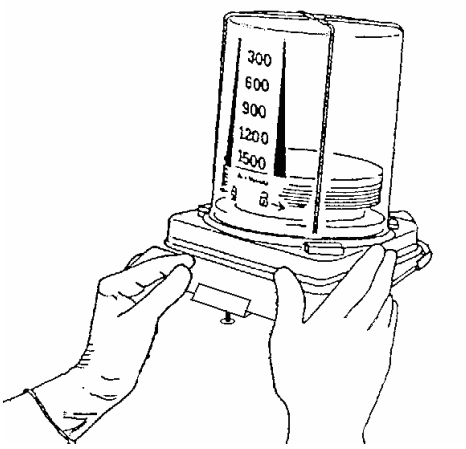
⚠ **CAUTION: The material of the bellows is made of latex.**

6.5.1 Disassembling

To disassembling the bellows assembly:

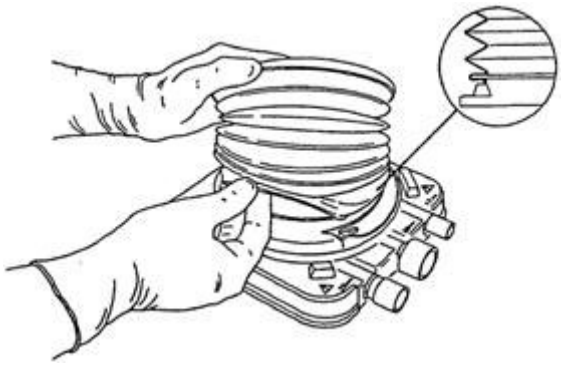
(To assemble the bellows assembly, perform the steps in “Disassembling the bellows assembly” in reverse order):

1 Loosen the screws from the bellows assembly base, then remove the bellows assembly.

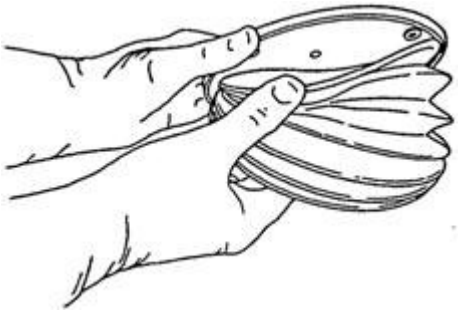


2 Turn counterclockwise and remove the bellows housing.

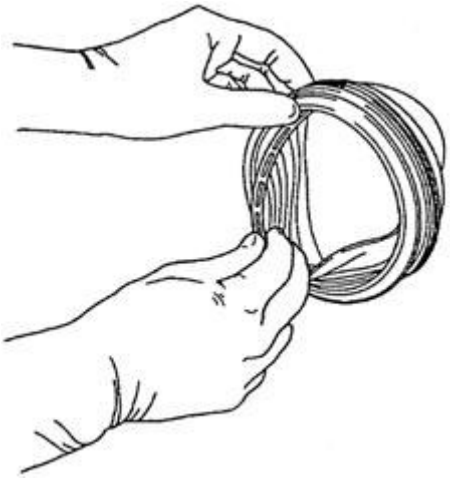
3 Detach the bellows from the base plate.



4 Detach the top plate from the bellows.

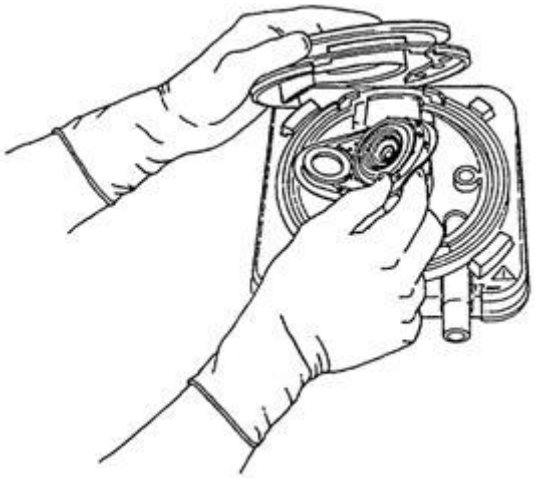


5 Remove the bellows assembly's adapter ring.



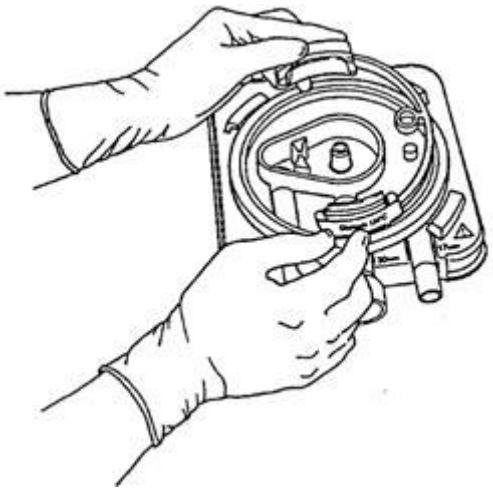
6 Push the locking spring to the center, and then remove the plate.

7 Remove the pop-off valve diaphragm and the pop-off valve seat.

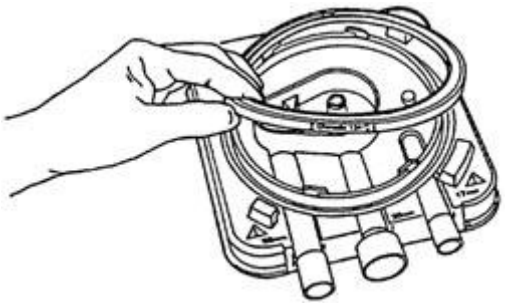


⚠ **WARNING**: **Do not remove bellows assembly seat from diaphragm of the pressure relief valve. This can distort the seat or diaphragm and cause injury to the patient.**

8 Push to the center, then remove the locking spring.



9 Remove the seal.



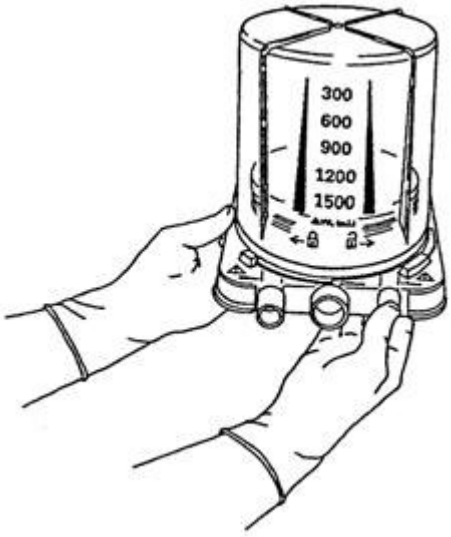
6.5.2 Testing Function

⚠ **WARNING: Do not use any object small enough to slip completely into the system when occluding the breathing system for test purposes.**

⚠ **WARNING: Always check the breathing system components for foreign objects before using on a patient.**

This test is to ensure all the components are installed correctly. It cannot replace the system test. The bellows assembling can be installed in case they requirement testing. Otherwise, they need to be disassembled to check and replace broken components, then reassembled and tested.

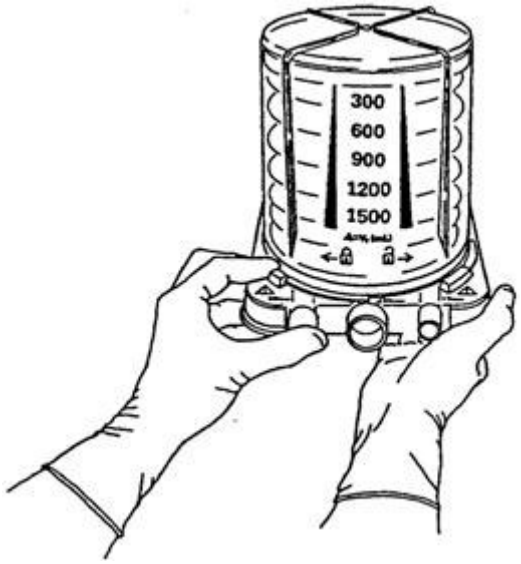
Hold the bellows assembly in hands vertically upwards to occlude the driving gas port before installing.



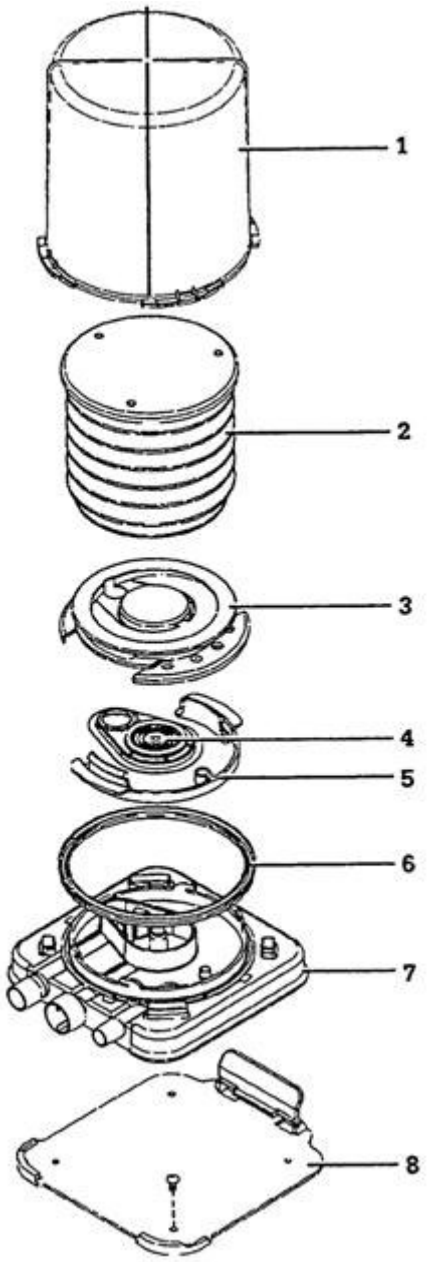
Invert the bellows assembly. If the descending velocity of the bellows top is no more than 100 ml/min, this could be because the driving gas port is not properly sealed, bellows or seal is not installed correctly or other component are broken and that the descending velocity exceeds the limit.

Open the driving gas port to make the bellows fully spread, and then occludes the breathing system connector.

Turn the bellows assembly so it faces vertically upwards. If the descending velocity of the bellows top is no more than 100 ml/min this could be because the bellows or pop-off valve is not installed correctly or other component are broken and the descending velocity exceeds the limit.



6.5.3 Assembly lists



1. housing	5. locking spring
2. bellows	6. seal
3. rim	7. bellows base
4. spill-over valve	8. holder

6.5.4 Cleaning and Sterilizing

Follow the machine and sterilizer manufacturer's cleaning recommendations.

1 Cleaning

1) Disassembling.

⚠ **WARNING: Never separate the diaphragm and the valve seat in a pop-off valve.**

2) To prevent component damage, clean them lightly. Put the recommended nonenzyme mild agent used for latex and plastic in hot water.

⚠ **CAUTION: Do not immerse them more than 15 minutes to prevent inflation or aging.**

3) Rinse using clean hot water, and then dry.

⚠ **CAUTION: Dry by hanging while fully spread. If moisture is left in the bellows, they may become tacky.**

4) Check the components if they are broken or damp, then perform the assembling and function test.

5) Connect the bellow assembly, ventilator and breathing system.

6) Perform the preoperative check.

2 Sterilizing

Cleaning and sterilizing must be performed at the same time. Follow instructions for the common bellows assembly sterilization methods.

Sterilizing after general patient use:

Clean the inner and outer parts of the bellows assembly in a soap-and-water solution. Rinse thoroughly in cold water, and dry with soft cloth. Immerse plastic and latex instruments in 70-80% ethyl alcohol for half an hour. Take them out using the aseptically transmits pliers, then store in clean containers. Repeat this step before next use. Components made of metal and glass can be sterilized with high pressure steam. When the steam pressure is increased by the autoclave, the rising temperature can concrete the bacterium protein rapidly to kill bacteria. In 1.05 KG/CM2 steam pressure, the temperature rises to 121C. All bacteria and most sorus can be killed if this temperature is maintained for 15-25 minutes.

Sterilizing after special infection or infectious patient use:

Open pulmonary TB, pulmonary abscess, pseudomonas, tetanus aeruginosa infection, gas gangrene or infectious hepatitis is included. Used bellows assembly components must be completely sterilized according to preliminary and final disposal procedures.

1) Preliminary disposal: Perform in accordance with the isolated disposal stipulation. Collect and leave all the used bellows assembly components during the operation process in the operating room. Immerse the bellows assembly components in the 1:1000 benzalkonium bromide or 1-5% cresol for 30 minutes after finishing the operation.

2) Final disposal: perform the final sterilizing disposal after the bellows assembly components are processed by the above-mentioned preliminary disposal:

- Scrub the bellows assembly in a soap-and-water solution. Thoroughly rinse in cold water, and dry;
- If conditions permit, suffocating the components directly contacted with patients with formald or oxirane is preferred, or perform immersing sterilization respectively. For example: the components used by open pulmonary TB patients must be immersed in 3% cresol for 30 minutes; the components used by tetanus aeruginosa infection patients must be immersed in 0.2% potassium permanganate for 30 minutes; the components used by gas gangrene patients must be immersed in 0.1% chlorhexidine for 30 minutes; the components used by pulmonary abscess patients must be immersed in 0.1% benzalkonium bromide for 60 minutes; the components used by pseudomonas patients must be immersed in 0.1% benzalkonium bromide for 120 minutes;
- the components being immersed need to be rinsed by water and dried for next use;
- scrub and rinse the components indirectly contacted with patients with 1-3% phenol solution or soap-and-water solution and water. Irradiate them by using the ultraviolet ray for 30 minutes if necessary.

6.5.5 Regular Maintenance

⚠ **WARNING: Do not perform any tests and repairs when the equipment is being used to avoid patient injury.**

Perform the following check every 30 days to be sure that component worn by use and daily cleaning are replaced in time.

Test by eyes
Separate the bellows assembly and anesthesia machine
Disassemble the bellows assembly

⚠ **WARNING: Never separate the diaphragm and the valve seat in a pop-off valve**

Check each component carefully to check for cracks, distortion, dissolution, inflation and other physical changes. Replace them if necessary.

Assemble the bellows assembly, and then perform the leak test.

7 User Maintenance

⚠ **WARNING:** **To avoid fire:**

- **Use the lubricant approved for anesthesia or O_2 equipments' use.**
- **Never oil or grease any anesthesia or O_2 equipment. In general, oils and greases oxidize readily, and – the presence of O_2 – are highly flammable.**
- **All the covers or housings for the system use must be made of static proof material, as static material may cause fire.**

⚠ **WARNING:** **Follow sterilizing control and security stipulations because used equipment may contain blood and body fluids.**

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

⚠ **WARNING:** **No shock and strong vibration should happen during transportation because the glass cover of flowmeter is fragile.**

⚠ **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. Make all necessary repairs, or have the equipment serviced by an authorized FARUM S.A. Service Representative. After repair, test the equipment to ensure that it is functioning properly, in accordance with the manufacturer's published specifications.

To ensure full reliability, have all repairs and service done by an authorized FARUM S.A. 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 Anesthesia Systems repair, and appropriate testing and calibration equipment.

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

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

Contact the nearest FARUM S.A. Service Center for service assistance. In all cases, other than where FARUM S.A. warranty is applicable, repairs will be made at FARUM S.A. 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

Minimum maintaining Standard	Planned maintaining Standard
Daily	Clean the outer surface.
weekly	Perform 21% O_2 sensor calibration. Ventilate the system, open flowmeter, and make sure that the float move up and down smoothly. It can prevent blocking and clinging.
monthly	Perform 100% O_2 sensor calibration. Test leakage of bellows assembly. (refer to section 6.5.2)
When cleaning and installing	Check if any components are broken, and replace or repair them if necessary.
As required	Replace new gasket of cylinder gas supply. Perform flow sensor calibration when flow waveform is unusual. Replace O_2 sensor (one year generally). Open the drain valve and replace absorbent in the absorber.

7.2.2 Permissive Repairing

Minimum maintaining Standard	Planned maintaining Standard
6 months	Test electric current leakage.
6 months	Test mechanical safety valve.
12 months	Perform the maintenance, checking, testing, calibrating and replacing of the components stipulated in this manual by qualified individuals. Notes: This is the recommended minimum maintaining level. Perform the local policies if they are equal to or higher than those in this manual.

7.2.3 Useful life estimation

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

Sampling probe and parallel lines	1500 times
Threaded tubes used repetitiously	Not less than 1 year
Power cord, cables, sampling line of O_2 sensor	8 years
Bellows assembly (except bellows)	1500 times
Drain valve	5000 times
Battery	1 year
Lamp tubes of display	50,000 hours
Pipelines, pipe T	8 years
Main unit	8 years

7.3 Maintaining the Breathing System

Parts that are broken, crushed, worn or distorted must be replaced immediately when cleaning the breathing system.

Refer to the sections corresponding to reassembly and testing.

7.3.1 Replace O_2 sensor

⚠ **WARNING: Comply with the relevant rules about biohazard when to dispose sensor. No burning.**

Replacement steps:

1 Pull out the connector of sampling line from O_2 sensor.

2 Pull out the O_2 sensor from the pipe T.

3 Replace it with a new one, and connect the sampling line to O_2 sensor.

7.3.2 Calibrate O_2 sensor

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

When to calibrate O_2 sensor, ambient pressure must be equal with monitoring pressure of delivering O_2 in the patient circuit.

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

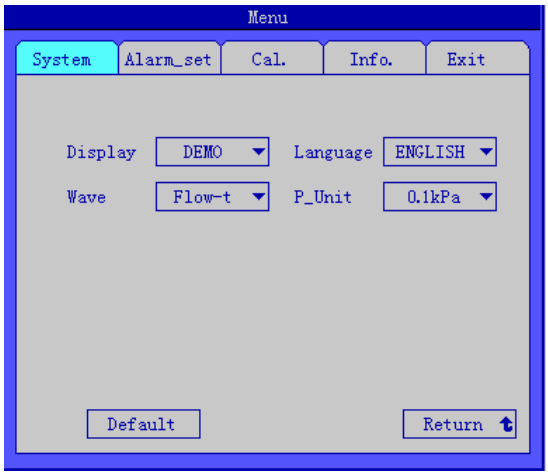
7.3.2.1 Calibrate 21% O_2 sensor

It will cost more than 3 minutes to perform 21% O_2 sensor calibration.

Before performing 100% O_2 sensor calibration, 21% O_2 sensor calibration must be finished.

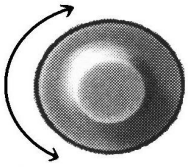
Step 1

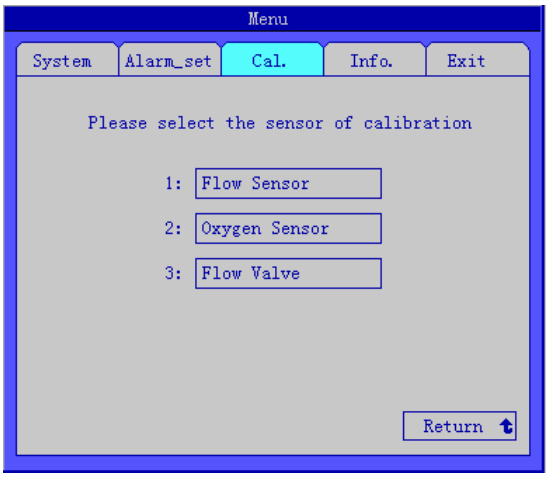
Press “MENU” key, a menu window appears on the screen.



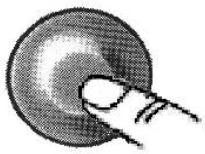
Step 2

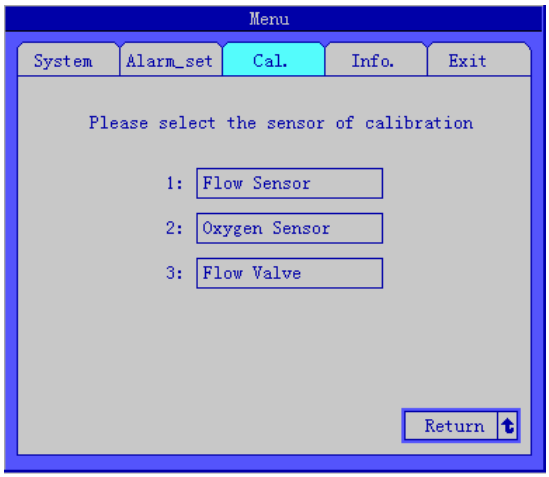
Turn the knob to select “Cal.” submenu.





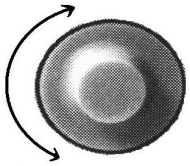
Press the knob, the cursor appears on the “Return”.

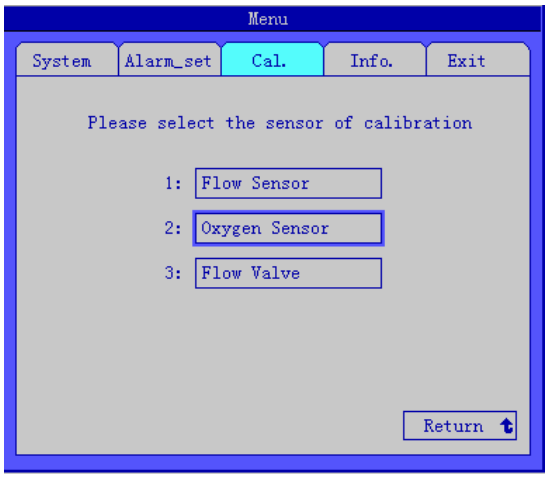




Step 3

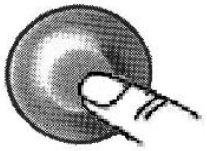
Turn the knob to select “Oxygen Sensor”.

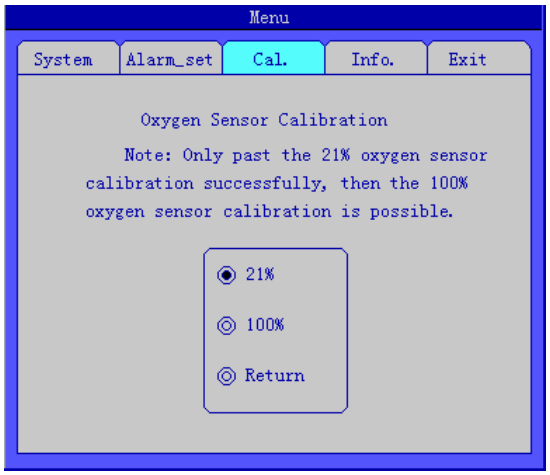




Press the knob, a new menu named “Oxygen Sensor Calibration” cover the original.

Please attention to the message on the menu.



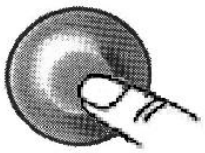


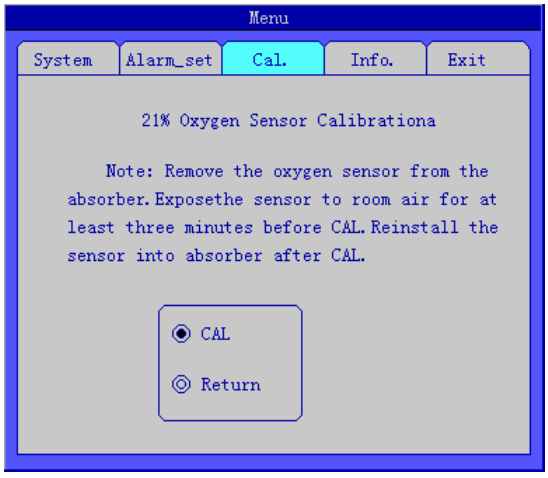
Step 4

Press the knob, a new window named “21% Oxygen Sensor Calibration” cover the original.

Perform the operation in accordance with the prompt on the screen.

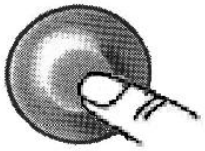
Disassemble O_2 sensor from absorber cycle, and put it in the air not less than 3 minutes.



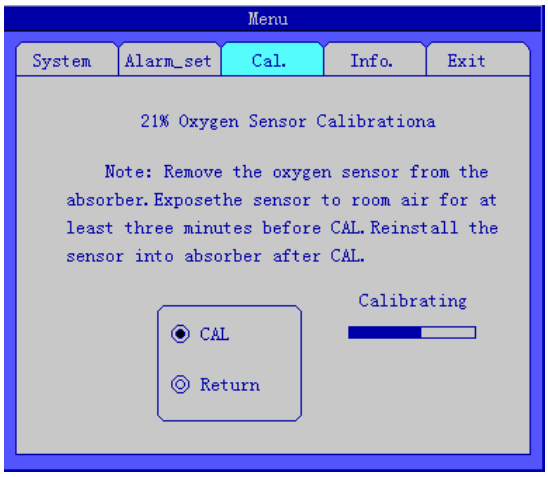


Step 5

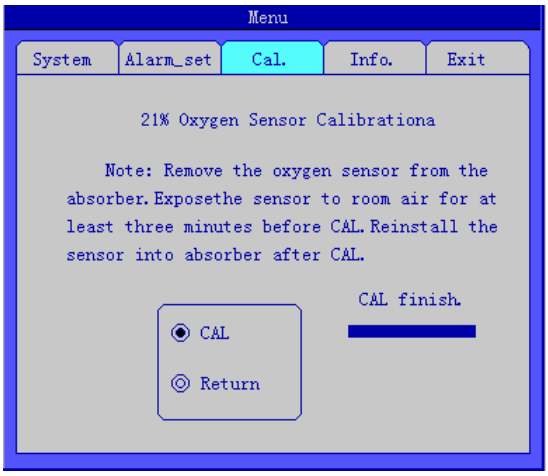
Press the knob to perform the calibration.



In the process of calibration, the word “Calibrating” displays on the screen.



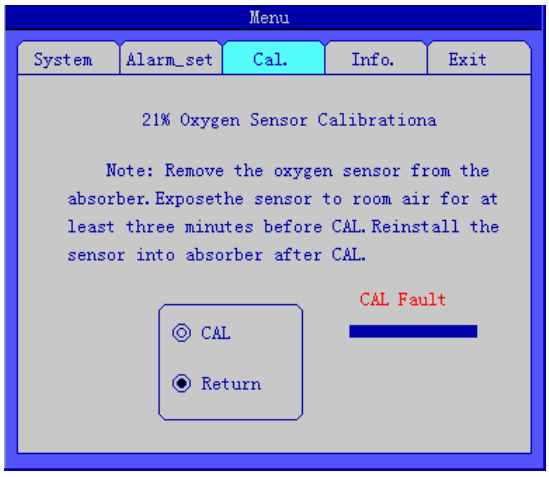
“CAL. finish.” will be displayed on the window after the calibration succeed. Then put O_2 sensor back to the patient circuit according to the prompt on the window, and perform 100% calibration.



If 21% calibration failure, the word “CAL fault” displays on the window.

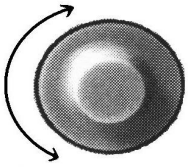
If the calibration failure occurs:

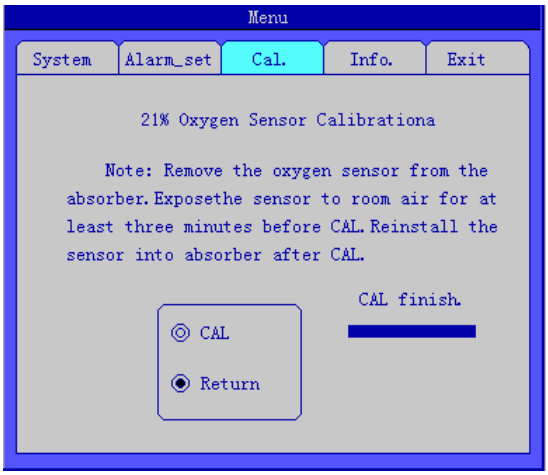
- Repeat these steps to calibrate it again.
- If still failure, perform 100% oxygen sensor calibration (step 7). And then calibrate 21% O_2 sensor again when the 100% calibration succeeded. If not, replace O_2 sensor and then recalibrate it.



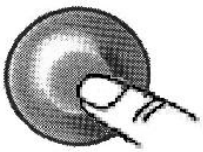
Step 6

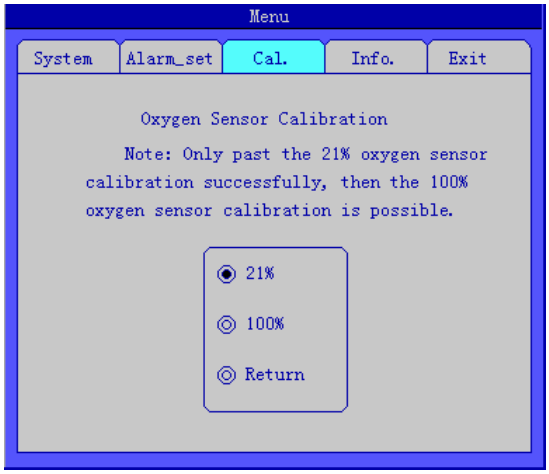
Exit to “21% Oxygen Sensor Calibration” menu; please turn the knob to select “Return”.





Press the knob, back to ” Oxygen Sensor Calibration” menu.





7.3.2.2 Calibrate 100% O_2 sensor

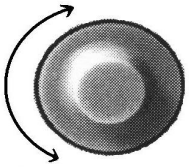
It will cost more than 3 minutes to perform 21% O_2 sensor calibration.

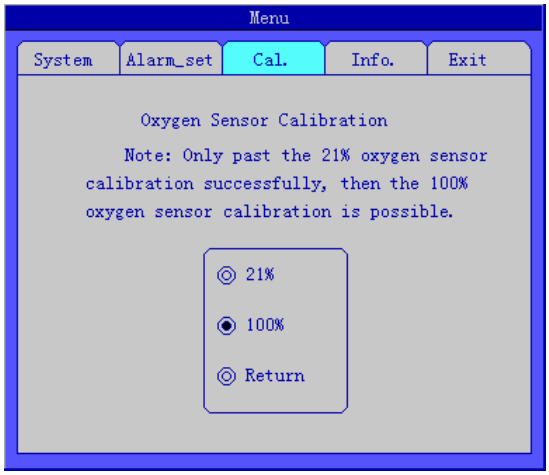
Before performing 100% O_2 sensor calibration, 21% O_2 sensor calibration must be finished.

⚠ **WARNING: Never to perform the calibration when the system connected with patient.**

Step 7

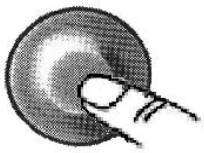
Turn the knob to select ”100%” option.

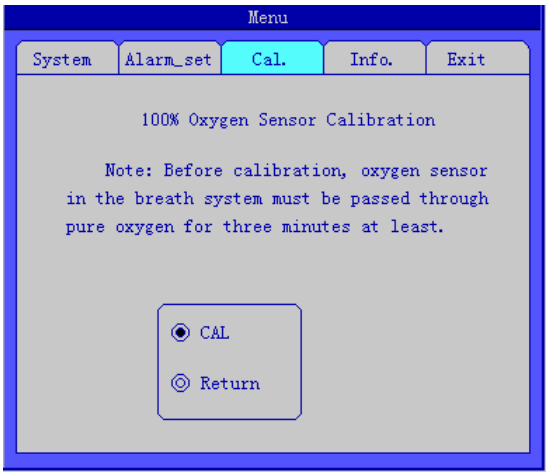




Press the knob, a new window named “100% Oxygen Sensor Calibration” cover the original.

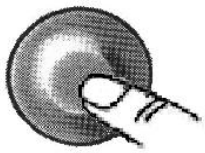
Perform the operation in accordance with the prompt on the screen.



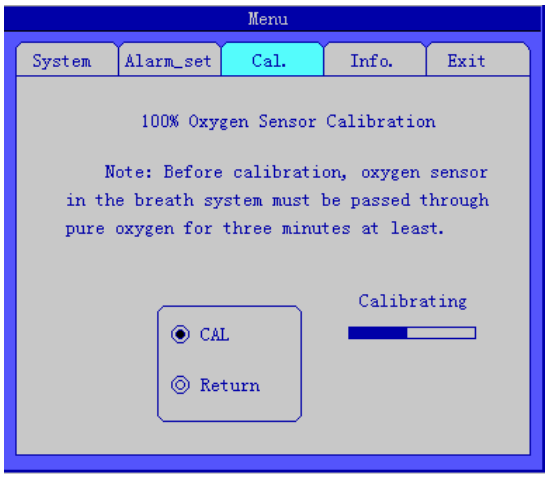


Step 8

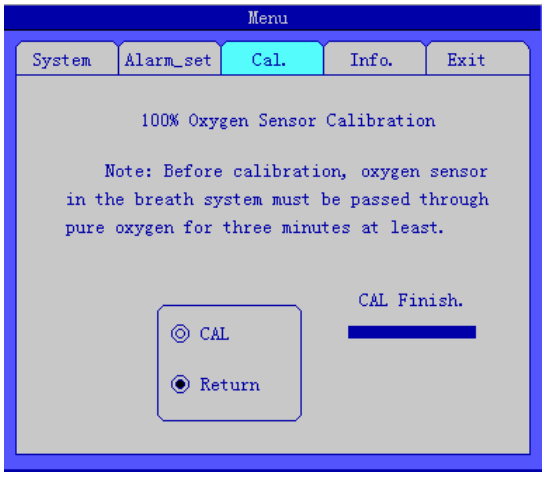
Press the knob to perform the calibration.



In the process of calibration, the word “Calibrating” displays on the screen.



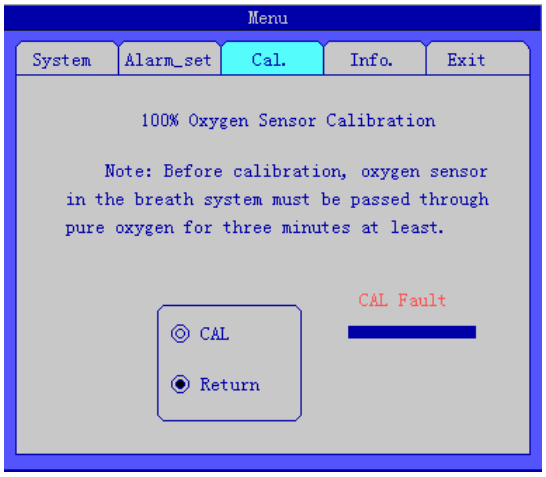
“CAL. finish.” will be displayed on the window after the calibration succeed.



If 100% calibration failure, the word “CAL fault” displays on the window.

If the calibration failure occurs:

- Recalibrate it.
- Reduce airway pressure and try it again.
- If failure still exists, replace O_2 sensor and perform 21% calibration.



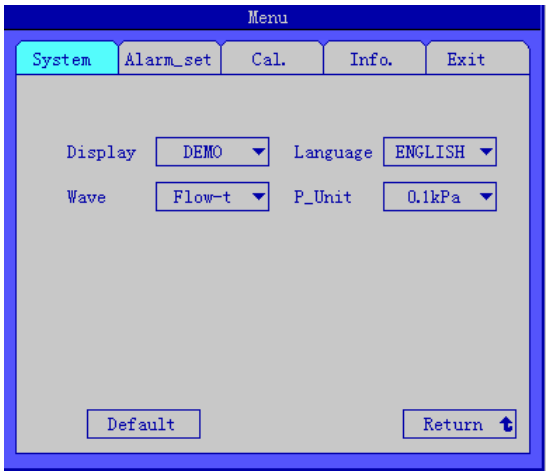
Step 9

Press “MENU” key to exit directly.

7.3.3 Calibrate flow sensor

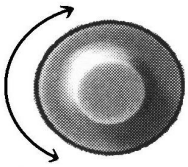
Step 1

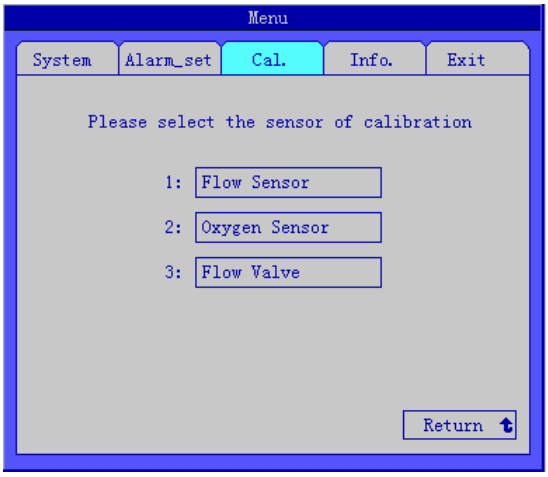
Press “MENU” key, a menu window appears on the screen.



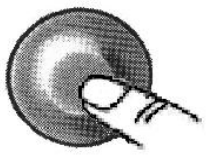
Step 2

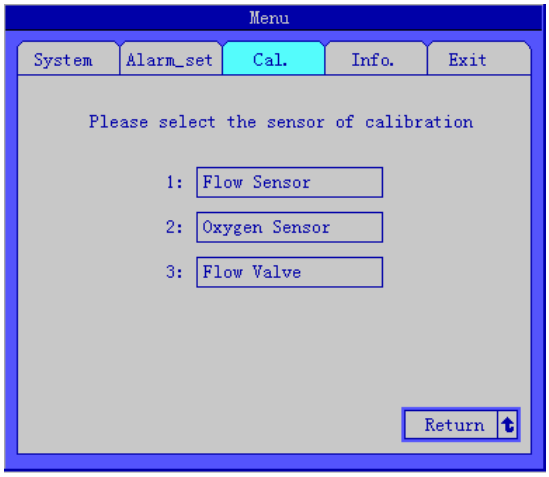
Turn the knob to select “Cal.” submenu.





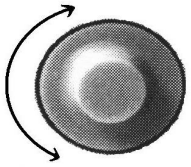
Press the knob, the cursor appears on the “Return”.

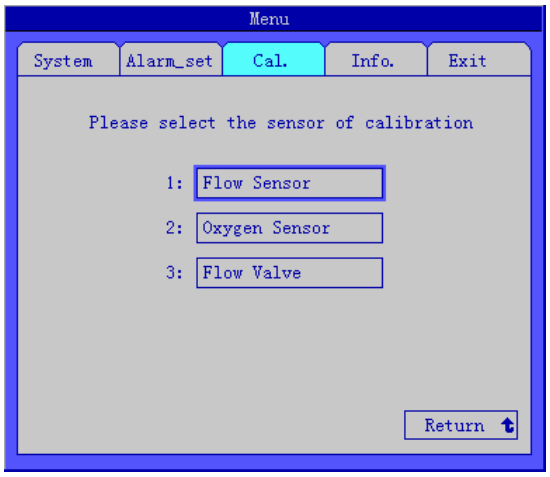




Step 3

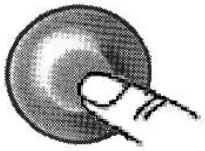
Turn the knob to select “Flow sensor”.

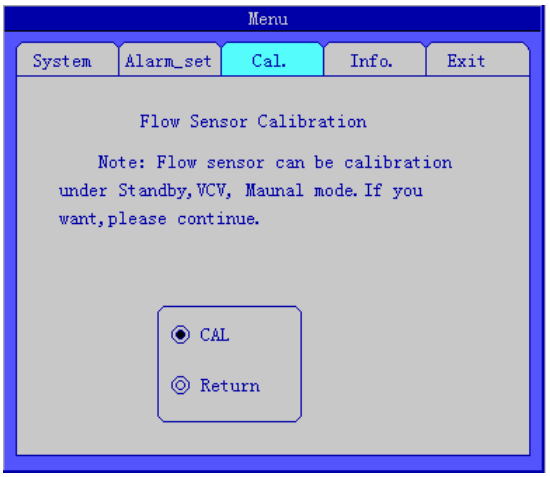




Press the knob, a new window named “Flow Sensor Calibration” covers the original.

Pay attention to the prompt on the screen.

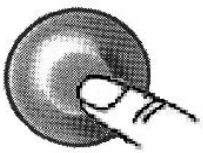


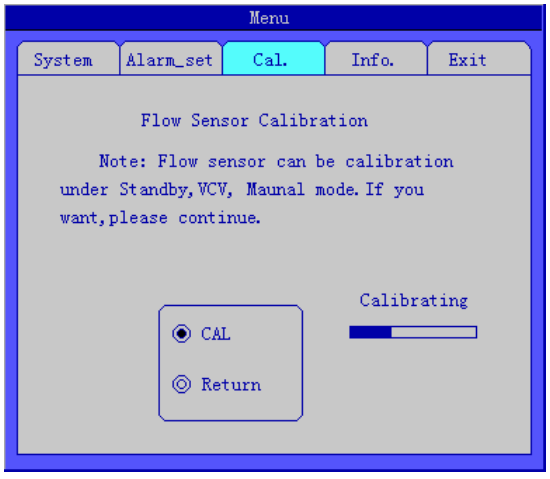


Step 4

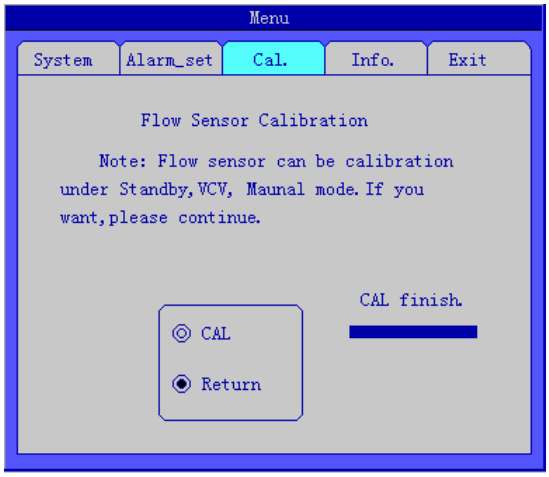
Press the knob to perform the calibration.

In the process of calibration, the word “Calibrating” displays on the screen.



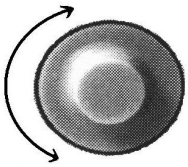


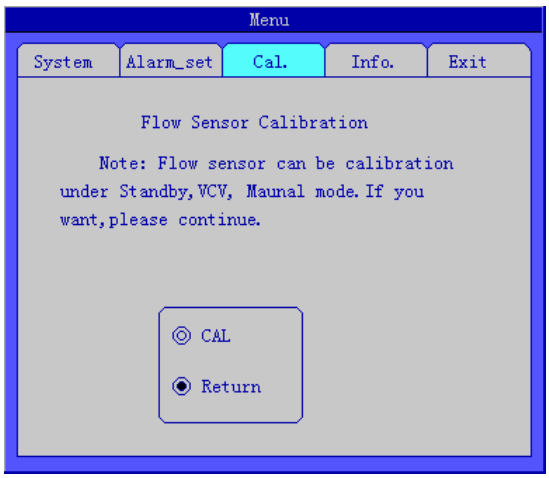
"CAL. finish." will be displayed on the window after the calibration succeeds.



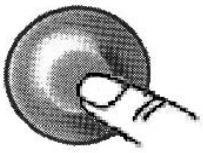
Step 5

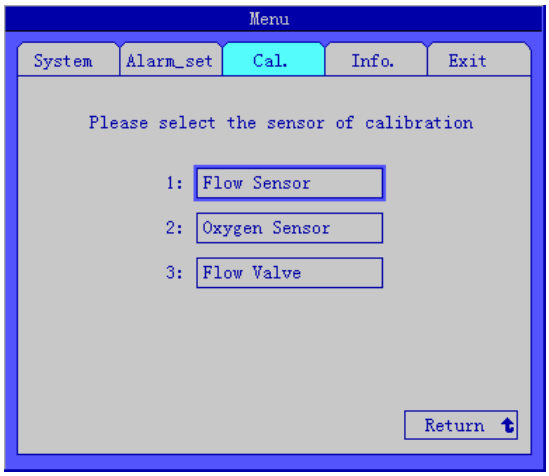
Turn the knob to select "Return" option.





Press the knob, back to "Cal." menu.





Step 6

Exit: Select "Return" and press knob, then turn to "Exit" menu and press it again; or press the "MENU" key directly.

7.3.4 Calibrate flow valve

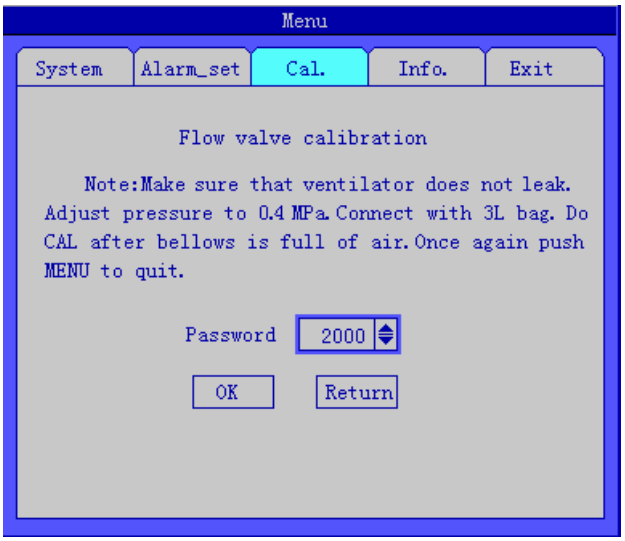
Make sure:

- Pressure range of driven gas (oxygen): 280 to 600kPa
- All connections of tubes and lines should be correct
- Leakage of breathing system should comply with the requirements in section 4.6
- Operating 5min. at least in VCV mode: Vt＝500, f＝20, I:E＝1:2, Tp＝OFF

Calibrating:

Press “MENU” key, and perform flow sensor calibration according to the steps of section7.3.3.

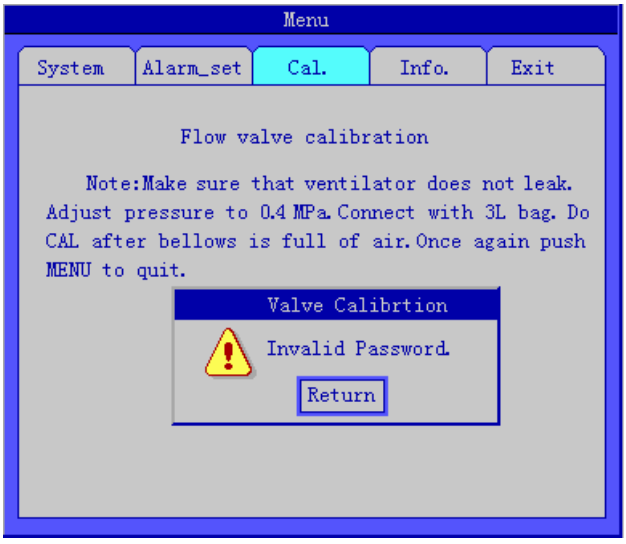
Input “2020” on the following figure, and press “OK”, then the calibrating starts until “Calibration finish” displays on the window. And the ventilation mode becomes standby.



During the calibrating process, press the “MENU” key to exit and the calibrating will cease.

If the calibration failure, it may be because the increase of tidal volume monitored is non-linear, just contact eligible service representative.

If password is wrong, see the following figure.



To calibrate flow valve when there be a difference of 30% between the value of tidal volume monitored and the settings.

7.4 Maintaining oxygen sensor

Perform the calibration periodically, interval refer to section 7.2.1.

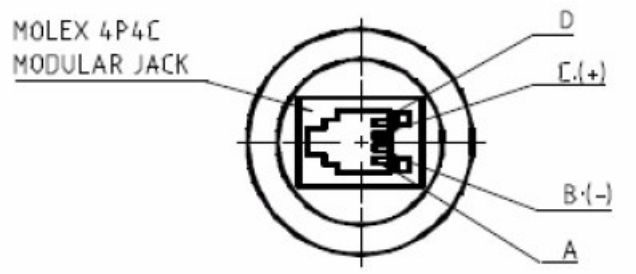
7.4.1 Technical requirements

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 in the ANASTAZJA 7500 are the following:

Maximum input of interface: 0 to 500mV DC

Form and definition of interface: FCC-68 4 cores telephone plug (RJ11-4), see the following figure.



Typical input at 21% concentration: 5 to 20mV

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

Operating temperature: 0 to 40□

Response time: not more than 15 seconds

Useful life: not less than 12 months ()

Accordable standard: EN12598 / ISO7767

7.4.2 Recommended O_2 sensor

Type	V-03A	OOM-105	M-07	MOX-4
Manufacturer	Ventrex	AnviteC	International Technologies	City-Technology
Response time (second)	7	5	8	15
Useful life (month)	12	--	16	12
Current applied	Yes	Yes	No	No

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

7.5 Replacing fuses

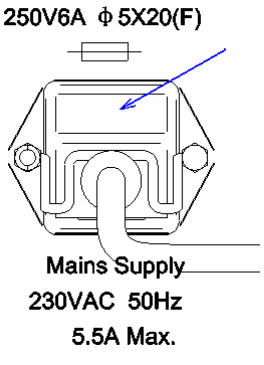
⚠ **WARNING:** **Disconnect from power supply before replacing fuses, otherwise that can injure operator even death.**

⚠ **WARNING:** **Replace fuses with only those of the specified type and current rating, otherwise that can damage the equipment.**

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

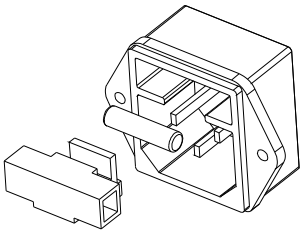
7.5.1 Replacing fuse of mains supply

The location of fuse as shown in the following figure with arrow pointed up.



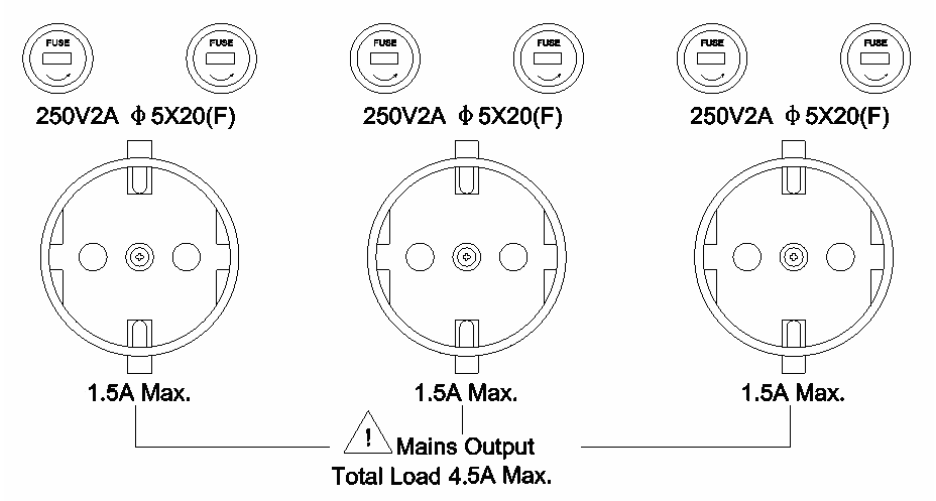
Replacing steps:

1 Insert the screwdriver into the groove on the top of fuse box.
2 Prize up gently.
3 The cover of fuse box springs lightly.
4 Take off the cover.
5 Take out fuses.
6 Enclose the new ones.
7 Push the cover to original place.
8 Connect mains supply.



7.5.2 Replacing fuse of auxiliary mains socket outlets

The location of fuse is in the rear panel of the machine, see Figure 2-3. The specification is shown in the following figure.

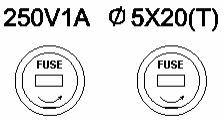


Replacing steps:

1 Plug the screwdriver to groove on the end of fuse box.
2 Turn counterclockwise 3 to 5 circles then pull out fuse tubes lightly.
3 Take off fuse tubes.
4 Enclose the new ones.
5 Push fuse tubes to original place gently.
6 Turn clockwise 3 to 5 circles with screwdriver to tighten.
7 Connect mains supply.

7.5.3 Replacing fuse of ventilator

The location of fuse is in the rear panel of the ventilator. See Figure 2-11 (6). The specification is shown in the following figure.



Replacing steps:

1 Plug the screwdriver to groove on the end of fuse box.
2 Turn counterclockwise 3 to 5 circle then pull out fuse tubes lightly.
3 Take off fuse tubes.
4 Enclose the new ones.
5 Push fuse tubes to original place gently.
6 Turn clockwise 3 to 5 circles with screwdriver to tighten.
7 Connect mains supply.

7.6 Maintaining battery

1 Specification

DC 24V 2.3 AH; 12V lead-acid battery, two in serial.

Charge: 8 hours typically

2 Cautions

Charge: Connect mains supply; the system will maintain auto-charging battery. It is recommended that charging time is better than 8 hours.

Discharge: It will last 90 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 corrading the apparatus. Replace the battery, please contact FARUM S.A. service representatives.

FARUM S.A. is not legally responsible for the damage caused by improper maintenance or operation.

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

8 Alarm and Troubleshooting

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

8.1 About alarm

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

Alarm messages displays on the top area of display screen. See Figure 8-1.

Figure 8-1 Alarm message area

The high priority alarms must be disposed immediately.

Priority	Volume	Silence	Prompt	Alarm bell
High	5 tones, 2 hurry; Periods: 9 seconds	110 seconds	Red background, 3 “!” Displaying frequency: 2Hz	Red, flickering
Medium	3 tones Periods: 6 seconds	110 seconds	Yellow background, 2 “!” Displaying frequency: 0.5Hz	Yellow, flickering
Low	2 tones Periods: 27 seconds	110 seconds	Yellow background, 1 “!” Displaying all the time until alarm disappears.	Yellow

⚠ **CAUTION:** **There are two alarm display areas, and the array of alarms is according to priority from high to low.**

⚠ **CAUTION:** **When alarm silencing, the alarm bell has dashed “X” on itself, and the color of bell accords with of which the higher priority alarm.**

8.2 Alarm message list

⚠ **CAUTION: Operation instruction is not included in the alarm message list.**

8.2.1 Technical alarm

Message	Priority	Condition	Operator Action	Repair
AD/DA Failure!!!	High	Picking card failure Zero wander	Ventilator failure; Switch to bag mode, manually bag (ventilate) patient. Monitoring is non-effective.	Please contact eligible service representative.
Exhaust Valve Failure!!!	High	Chip failure Cables fall off	Switch to bag mode, manually bag (ventilate) patient. Monitoring still available.	Please contact eligible service representative.
Flow Valve Failure!!!	High	Flow valve failure Cables fall off	Switch to bag mode, manually bag (ventilate) patient. Monitoring still available.	Please contact eligible service representative.
Flow Sensor Failure!!!	High	The 25 pin cable falls off 2. Sampling circuit break off	Switch to bag mode, manually bag (ventilate) patient. Monitoring is non-effective.	Please contact eligible service representative.
Calibration Valve Failure!	Low	Self-tuning valve blocked	Switch to bag mode, manually bag (ventilate) patient. Monitoring is non-effective.	Please contact eligible service representative.
No Driver Gas Supply!!!	High	Gas exhausted Central gas supply ceasing or lack	Check pipeline gas supply or Replace O_2 cylinder.	----
Mains Failure!	Low	Connection failure Power failure	Check connection Check mains supply Check fuses	Replace fuses when melted.
Battery Low!	Low	Used out. Battery failure.	Resume to use mains supply immediately; Charging; Switch to bag mode.	Maintain battery periodically, and ensure it full charged.
No O_2 Sensor!	Low	Connection failure	Set lower O_2 limit to “OFF”	----
Communication Failure!	Low	Cables fall off Defective circuit	Ventilator failure, monitoring is non-effective.	Please contact eligible service representative.
DC Power Failure!!!	High	Power board failure.	Ventilator failure, stop using.	Please contact eligible service representative.

8.2.2 Functional alarm

Message	Priority	Condition	Operator Action	Repair
Paw continuous High!!!	High	Pressure sensor failure Channel of sampling blocked Resistance of exhalation is too high or channel of exhalation blocked	Switch to bag mode, manually bag (ventilate) patient. Check tubes and sampling lines, and dispose block existed.	If the alarm still exists, please contact eligible service representative.
Paw High!!!	High	Paw greater than upper limit. Settings of V_T higher. Patient airway blocked. Exhalation valve blocked.	Reset upper limit of Paw. Check expiratory cycle, and dispose block existed. Check V_T settings. Check airway of patient, and dispose block existed.	----
Paw Low!!	Medium	No driven gas. Sampling lines fall off or blocked. Respiratory frequency lower.	Reset lower limit of Paw	Check the parallel sampling lines.
Vt Low!!	Medium	Measuring value is under half of settings. Seeper in the sampling line occurs. Calibrating value excursion of flow valve occurs.	Operation can be continuous. Swing the sampling lines automatically.	If excursion occurs, please contact eligible service representative.
FiO_2 Low!!	Medium	FiO_2 less than lower limit. Compensation of air or N_2O overmuch. O_2 sensor non-calibrated. O_2 sensor failure.	Reset lower limit of FiO_2. Reduce compensation. Perform the calibration. Replace O_2 sensor.	----
FiO_2 High!!	Medium	FiO_2 greater than upper limit.	Reset upper limit of FiO_2.	----
Minute Volume High!!	Medium	MV greater than upper limit.	Reset upper limit of MV.	----
Minute Volume Low!!	Medium	MV less than lower limit. Leakage occurs.	Reset lower limit of MV. Check patient end.	----

Frequency High!!	Medium	f greater than upper limit. The patient has independent respiration.	Reset upper limit of f. Examine the patient and confirm independent respiration exists or otherwise.	----
Frequency Low!!	Medium	Monitoring value not more than settings. Wye pipe falls off.	Check the connection and leakage of patient end.	----

8.3 Troubleshooting

8.3.1 Anesthesia machine troubleshooting and analyzing

Symptom	Possible Cause	Recommended Action
Patient breathing circuit gas leak	APL valve is on	Turn APL valve to off
	soda lime in the cylinder port is not sealed very well	Reinstall or remove the natrium calcareousness grains at the joint
	Screw tubes are broken or the connector loosens	Replace or reinstall
	valves loosen	Tighten them
	Bag / ventilator switch failure	Please contact eligible service representative.
Excessive pressure caused by manual ventilation	APL valve is adjusted incorrectly	Adjust it properly
Switch to bag control, bellows charging; switch to ventilator control, bag charging.	Leakage occurs at bag / ventilator switch.	Please contact eligible service representative.
APL valve doesn't work normally	APL valve failure	Please contact eligible service representative.

8.3.2 MV300 Troubleshooting and Analyzing

Symptom	Possible Cause	Recommended Action
The digital tube has no power, and ventilator does not work	Power supply cable is unplugged Power switch is off Fuse is burned	Plug in power supply cable Turn on power switch Replace with a new one
Ventilator stops operating suddenly, indicator light turns off, and sounds alarm	Power supply is interrupted	Use manual ventilation
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 and adjust patient circuit Check the patient Readjust the alarm setting Recalculate the ventilator parameter
Minimum pressure alarm sounds continuously	Patient's pipeline 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
No indication from the airway pressure gauge	Sampling hose is disconnected; Gas supply drains	Reconnect the sampling hose; Replace the gas supply
Tidal volume readings does not display normally	Flow sensor is unplugged; The inner and outer O rings of bellows base are broken; Bellows is broken; Pop-off valve is broken	Plug in the flow sensor; Reassemble the bellows assembly
The bellows is inflated excessively	Gas scavenging port is occluded Malfunctioning waste gas scavenging system creates excessive resistance or vacuum	Remove the occlusion; Repair waste gas scavenging system
The bellows does not expand during ventilation or tends to collapse	Breathing resorption interface is unplugged; Bellows base is broken; Tear or leak in the bellows; Exhalation diaphragm is broken; O rings are broken	Reconnect breathing resorption interface; Check and replace a bellows base; Check and replace a bellows; Check and replace an exhalation diaphragm; Check and replace O rings

8.4 Default setting

Setting	Range	Increment	Default
Lower limit－MV	0 to 20L/min	1 L/min	5 L/min
Upper limit－MV	1 to 25L/min	1 L/min	9 L/min
Lower limit－Paw	0 to 2 kPa	0.1 kPa	3 kPa
Upper limit－Paw	0 to 8 kPa	0.1 kPa	30 kPa
Lower limit－f	4 to 100 bpm	1 bpm	5 bpm
Upper limit－f	4 to 100 bpm	1 bpm	20 bpm
Lower limit－FiO_2	OFF, 21 to 100％	1%	50%
Upper limit－FiO_2	OFF, 21 to 100％	1%	100%
Vt	See section 10.8.4		500 mL
f			14
I:E			1:2
T_P			OFF
Plimit			10 cmH_2O
Vsens			3 L/min

9 Accessories

9.1 The breathing System

Description	Stock Number
Bellows housing	BA100-6
Bellows	BA100-5
Base plate	BA100-10
Pop-off valve	BA100-4
Locking spring	BA100-11
Seal	BA100-2
Bellows base	BA100-1

9.2 The Absorber Assembly

Description	Stock Number
Absorber cycle	AC100
APL valve assembly	AC100.3
Oxygen flush	235-895
Exhalation valve	AC100.1-6
Gas pressure gauge	AC100.7
Handle	AC100.6
Water scavenging valve module	AC100.11
Reusable absorber	AC100.9
O ring	AC100.8-3
Manual reservoir bag/ventilator switch assembly	AC100.4

9.3 Others

Description	Specification	Stock Number
O_2 pipeline	5m	CA034
N_2O pipeline	5m	CA035
Air pipeline	5m	CA056
Power cord	5m	WD0128
Probe	----	WJ156
Pipe tee	----	WJ088
Sampling parallel lines	3m	CA040
Anesthetic cycle for adult	One-off	WJ194
Power cable	1.5m	MV300 (E) JL.1
Signal cable	1.5m	MV300 (E) JL.2
O_2 sensor sampling line	3m (expanded)	MV300 (E) JL.3
Lead-acid battery assembly	----	CA058
Reusable thread tube	ϕ22×600 mm	WJ196
Reusable thread tube	ϕ15×600 mm	WJ198
Reusable thread tube	ϕ22×450 mm	WJ195
Reservoir bag	3L	WJ023
O_2 cylinder	4L	WJ048
N_2O cylinder	4L	WJ049
Castor	ϕ125 mm	WJ035
Castor (with break)	ϕ125 mm	WJ036

10 Specifications and Operation Theory

10.1 Gas circuit of ANASTAZJA 7500

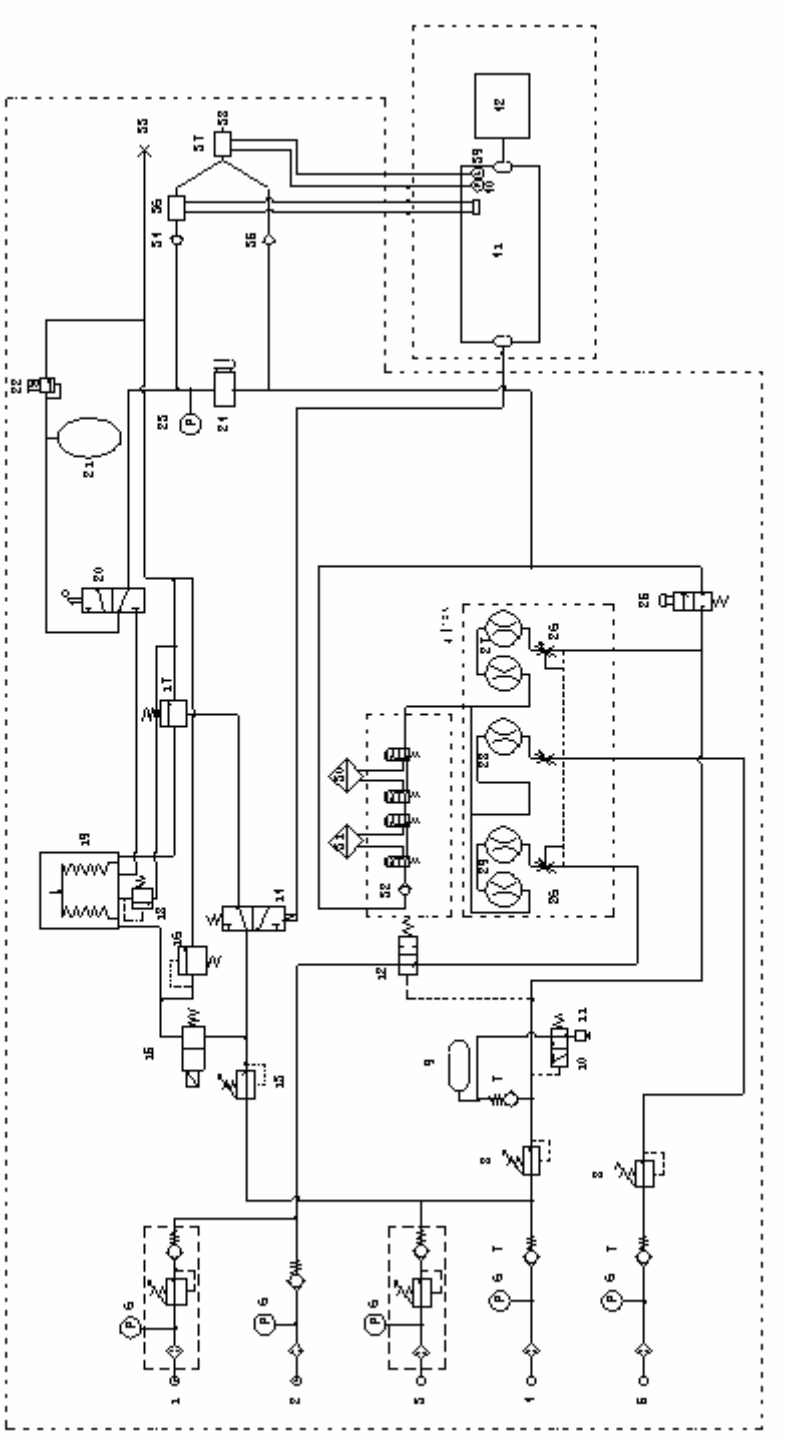


Figure 10-1 Gas circuit diagram

See Figure 10-1

1. N_2O cylinder
2. N_2O Pipeline
3. O_2 cylinder
4. O_2 pipeline
5. Air pipeline
6. Gauge
7. Checkvalve
8. Reducer (400kPa)
9. O_2 reservoir
10. Reversal valve (100 to 220kPa)
11. Whistle
12. N_2O cut-off (20 to 200kPa)
13. Reducer (250kPa)
14. Magnetic valve
15. Flow valve
16. Safety valve (6kPa)
17. Exhaust valve
18. Spill-over valve (0.1 to 0.3kPa)
19. Bellows
20. Manual reversal valve
21. Manual reservoir bag
22. APL valve (0.19 to 0.6kPa)
23. Airway gauge
24. Absorber
25. O_2 flush
26. N_2O-O_2 linkage
27. O_2 flowmeter
28. Air flowmeter
29. N_2O flowmeter
30. Vaporizer 1
31. Vaporizer 2
32. Micro-checkvalve
33. To air
34. Exhalation valve
35. Inhalation valve
36. O_2 sensor
37. Probe
38. Patient
39. Flow sensor
40. Pressure sensor
41. Ventilator
42. Display screen

⚠ **CAUTION:** **Follow all instructions on how to operate all equipment in the anesthesia system including monitoring equipment, alarm systems and protecting equipment.**

10.2 System technical specification

10.2.1 Drive

Gas supply:

Pipeline:	O_2, Air, N_2O
Cylinder:	O_2, N_2O
Connect to cylinder:	PISS (pin-indexed safety system)
Reducer:	400kPa
Connect to pipeline:	DISS-male, DISS-female, NIST (ISO 5359) All fittings used to connect O_2, Air and N_2O pipeline gas supply are all ready.
Display pressure:	Gauges with color coded
Input pressure at pipeline inlets	280 to 600kPa

⚠ **WARNING: All gas supplies must be in accordance with medical level.**

⚠ **CAUTION: Pressure at pipeline inlets must be according to 280 to 600kPa when delivering ceases in the anesthetic gas delivering system.**

10.2.2 Flow

Gas component	Scale (thin tube)	Scale (thick tube)
O_2	0.05 to 1 L/min	1.1 to 10 L/min
N_2O	0.05 to 1 L/min	1.1 to 10 L/min
Air	----	0.1 to 10 L/min

Accuracy: With regard to the flow between ±10% of full scale or 300 ml/min (higher is preferred) and full scale under the condition of 20C, 101.3 kPa, flow meter precision is within the ±10% of indicated values. The precision is 4 degree when the flow is lower than 10% of full scale or 300 ml/min (higher is preferred).

Adjust O_2 and Nitrous oxide proportionally to ensure the O_2 concentration is no less than 25%.

O_2 flush: 35 to 75 L/min

O_2 failure alarm and the associate cut-off device

	O_2 pressure
O_2 failure alarm:	20 to 200kPa
N_2O cut-off:	50 to 220kPa

⚠ **CAUTION:** **O_2 failure alarm takes precedence of N_2O cut-off.**

10.2.3 Classification

According to IEC60601-1, ANASTAZJA 7500 belongs to the following classifications:

- Class I equipment
- Type B equipment
- General equipment
- Mobile equipment
- Flammable anesthetic cannot be used
- Operate continuously

10.3 Power supply

Voltage:	230VAC 50Hz
Input power:	Not more than 50VA
Maximum input current:	5.5A
Fuse at mains supply inlet:	250V 6A ∅5X20 (F)
Fuse above auxiliary mains socket outlets outlet:	250V 2A ∅5X20 (F)
Maximum output current of auxiliary mains socket outlets:	1.5A (each); 4.5A (total)
Fuse in rear of ventilator:	250V 1A ∅5X20 (T)
Earth resistance:	<0.2Ω

⚠ **WARNING:** **Then connection of equipment to the auxiliary mains socket outlets can increase the patient leakage currents to values exceeding the allowable limits in the event of a defective protective earth conductor.**

10.3.1 Power cord

Length:	5 meters
Rating voltage:	90 to 264VAC
Capacity of current:	220 to 240VAC 10A
Type:	Three-core cable (Medical level)

10.4 Electromagnetic Compatibility

Changing or reassembling this equipment without FARUM S.A. authorization may cause electromagnetic compatibility problems. Contact with FARUM S.A. 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 ANASTAZJA 7500 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 ANASTAZJA 7500 by using signal input/signal output cable.

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

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

ANASTAZJA 7500 is equipped with all-purpose alternating current outlet for connecting other medical equipments. Do not connect non-medical equipment to these outlets. Otherwise, the surface leaking current may exceed the range permitted by EN60601-1 under normal conditions and misoperation may be dangerous 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 ANASTAZJA 7500 Anaesthetic Workstation is intended for use in the electromagnetic environment specified below. The customer of the user of the *ANASTAZJA 7500 Anaesthetic Workstation* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *ANASTAZJA 7500 Anaesthetic Workstation* 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 *ANASTAZJA 7500 Anaesthetic Workstation* 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 *ANASTAZJA 7500 Anaesthetic Workstation is* intended for use in the electromagnetic environment specified below. The customer or the user of *ANASTAZJA 7500 Anaesthetic Workstation* 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 mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and 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 *ANASTAZJA 7500 Anaesthetic Workstation* requires continued operation during power mains interruptions, it is recommended that the *ANASTAZJA 7500 Anaesthetic Workstation* be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity

The *ANASTAZJA 7500 Anaesthetic Workstation is* intended for use in the electromagnetic environment specified below. The customer or the user of *ANASTAZJA 7500 Anaesthetic Workstation* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz outside ISM bands [a]	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the *ANASTAZJA 7500 Anaesthetic Workstation*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{12}{V_2}\right]\sqrt{P}$
		10V	
	10 V_{rms} 150 kHz to 80MHz in ISM band [a]		$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
		1 V/m	$d = \left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	10 V/m 80 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 the *ANASTAZJA 7500 Anaesthetic Workstation is* used exceeds the applicable RF compliance level above, the *ANASTAZJA 7500 Anaesthetic Workstation* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *ANASTAZJA 7500 Anaesthetic Workstation*.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 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 *ANASTAZJA 7500 Anaesthetic Workstation*

The *ANASTAZJA 7500 Anaesthetic Workstation is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *ANASTAZJA 7500 Anaesthetic Workstation* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *ANASTAZJA 7500 Anaesthetic Workstation* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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.

10.5 Physical specification

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

⚠ **CAUTION: Do not put ANASTAZJA 7500 into the shock environment.**

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

System	Height	1350mm
	Width:	656mm
	Depth:	622mm
	Weight:	148kg
Castor	125mm (5 in.), with breakers on the front castors.	
Drawer	130mm (H) ×465mm (W) ×360mm (D)	
Display	10.4’ TFT LCD	
Cylinder gauge	Scale: 0 to 25MPa. Resolution: 50kPa. Accuracy: ±2.5% of full scale.	
Pipeline gauge	Scale: 0 to 1MPa. Resolution: 1MPa. Accuracy: ±2.5% of full scale.	
Airway gauge	Scale: -2 to 10kPa. Resolution: 200Pa. Accuracy: ±2.5% of full scale.	

10.6 Environment requirements

Temperature	Operation:	10 to 40 ℃
	Storage:	-10 to 40 ℃
Relative Humidity	Operation:	Not more than 80%, non-condensing
	Storage:	Not more than 90%, non-condensing
Atmospheric pressure	Operation:	86 to 106 kPa
	Storage:	86 to 106 kPa
Height	Operation:	500 to 800 mmHg （3565 to -440m）
	Storage:	375 to 800 mmHg （5860 to -440m）

10.7 Breathing system technical specifications

Compensation of fresh gas	Flow compensation range: 0 to 10 L/min Gas components: O_2, N_2O, air, anesthetic agent
Absorbent	Capacity: 1500 ml (each)
Connection	Common Gas Outlet: ISO 5356 connector
Leakage of breathing system	At pressure of 3 kPa: Leakage of flow: ≤150 ml/min
Resistance of breathing system	At flow of 60L/min: Resistance of exhalation: ≤0.6 kPa; Resistance of inhalation: ≤0.6 kPa. At flow of 30L/min: Resistance of exhalation: 2.2 kPa; Resistance of inhalation: 2.2 kPa. Patient cycle of small resistance should be used in accordance with the relevant standard.
Resistance of APL valve	At flow of 60L/min, resistance of flow: 0.05 to 3 kPa; At flow of 30L/min, resistance of flow: 0.1 to 0.5 kPa.
Leakage of connector	Resistance of flow: ≤50 ml/min. (APL valve close fully)
Resistance of checkvalve	Dryness: ≤0.15 kPa

The pressure generated by a wet unidirectional valve: <0.14 kPa;
The pressure to open a wet unidirectional valve: <0.1 kPa

Compliance of absorber	<50 ml/ kPa

10.8 Anesthesia Ventilator

10.8.1 Operation Theory

The high-pressure oxygen enters the pressure reduction valve I, and the output pressure from the pressure reduction valve I is stabilized at 0.25MPa (already adjusted before ex-factory). The output gas from the pressure reduction valve I enters the electromagnetic valve. In inspiring, the electromagnetic valve is open; the two-way outputs enter the flow valve and the pressure reduction valve II respectively. The one entering the pressure reduction valve II presses on the diaphragm in the expiration valve by means of the gas pressure to control the opening and closing of the expiration valve, and the output pressure is stabilized at 0.05MPa (already adjusted before ex-factory). The other one enters the flow valve; the tidal volume value could be changed through adjusting the flow valve. The pure oxygen entering the gas line is mixed in accordance with a certain proportion in the gas room. The air enters from the venturi-type valve, and a unidirectional valve is installed in the venturi-type valve to prevent the gas overflowing.

The sponge gas entrance is adopted for the unidirectional valve to reduce noise and filtrate the gas to be breathed in. A safety valve is installed on the side face of the gas room to prevent that the air pressure is too high and will make hurt to a patient. When the air pressure exceeds the set value of the safety valve (6kPa), the safety valve can open automatically and the gas will be discharged from the safety valve. The electromagnetic valve will be closed in expiration, the pressure exerted on the diaphragm of the expiration valve will disappear, and the diaphragm will loose. Thus the gas room connects with the atmosphere directly. The gas compressed in the bellows by the ventilator will discharge to the atmosphere through the expiration valve. The process above will be repeated along with the breath rhythm.

During the above procedures, it is the electromagnetic valve that controls the gas flowing direction, and is controlled by the mainframe board. In inspiration the electromagnetic valve will be opened while in expiration it will be closed. In the Figure 10-2, the display plate is used for the digital display for the respiration rate, breath frequency, the tidal volume and the oxygen concentration, the display of the corresponding display lamps and the display of the luminous line of the pressure. The mainframe board is the central processing unit of the ventilator circuit part. It not only controls the opening and closing of the electromagnetic valve, but also receives and processes the pressure signal, the flow signal. It receives the inputs from the panel and sends the signal that will be outputted to display to the display plate. The voltage stabilizing power supply provides the circuit needed voltages. The functions of the subsystems above are set and adjusted by the keys on the panel.

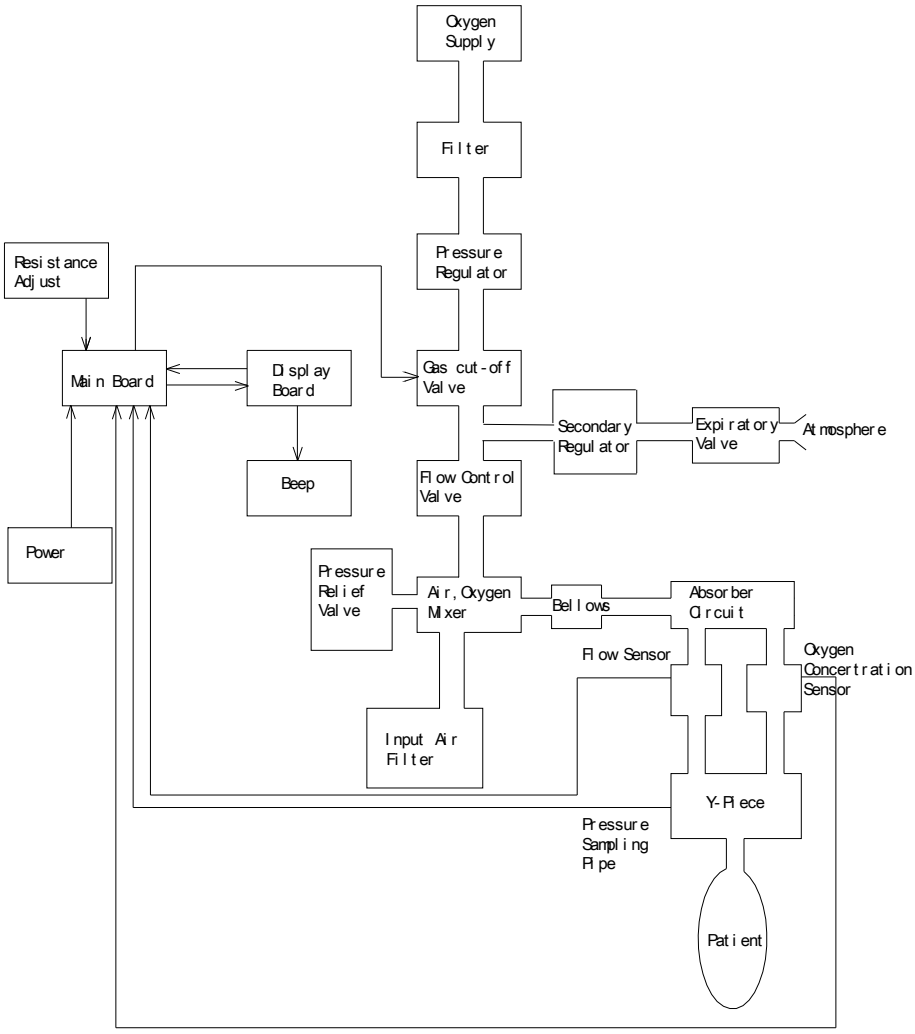


Figure 10-2 Operation principle sketch diagram of ventilator

10.8.2 Performance of ventilator

Maximum security pressure of airway system	Not more than 6 kPa
Compliance:	Not more than 40 mL/kPa
Electrical safety:	Meet requirements for Class I, type B equipment specified in EN60601-1 *Medical Electrical equipment: Part one: General requirement for safety*.
Noise of whole unit:	Not more than 65dB(A)

10.8.3 Setting ventilation mode

Ventilation mode	Adjustable respiratory parameters
VCV mode	V_T、f、I：E、T_P（inspiratory pause）
Pressure mode	V_T、f、I：E、Plimit（maximum airway pressure limit setting）
SIMV mode	V_T、f_{IMV}、T_I、Vsens（trigger sensitivity of volume）
Manual mode	----

10.8.4 Setting ventilating parameters

	Range	Resolution
V_T:	0, 50 to 1500 mL	10 mL
	Maximum V_T output limited by 75L/min (see 10.8.5 flow valve)	
f:	4 to 100 bpm	1 bpm
I：E:	1:0.5 to 1:8	0.5
T_P:	5% to 50%, OFF (only available in VCV mode);	5%
P_{limit}:	0.5 to 7 kPa (only available in Pressure mode);	0.1 kPa
V_{sens}:	1 to 30 L/min (only available in SIMV mode);	1 L/min

10.8.5 Gas dynamics performance

Gas source:	Anesthetic system
Gas component:	O_2
Rating pressure:	250 kPa
Input pressure range:	280 to 600 kPa
Flow valve range:	5 to 75 L/min
Output:	Pressure range: 0 to 6 kPa; flow range: 0 to 75 L/min

10.8.6 Setting alarm parameters

Item	Limit	Range	Resolution
MV (minute volume)	Lower	0 to 20 L/min	1 L/min
	Upper	1 to 25 L/min	1 L/min
Paw (airway pressure)	Lower	0 to 2 kPa	0.1 kPa
	Upper	2 to 8 kPa	0.1 kPa
f (respiratory frequency)	Lower	0 to 100 bpm	1 bpm
	Upper	4 to 110 bpm	1 bpm
FiO_2 (Oxygen concentration)	Lower	OFF, 21% ~ 100%	1%
	Upper	21% ~ 100%, OFF	1%

⚠ **CAUTION:** **If the alarm limits of FiO_2 are OFF, and O_2 sensor not connected, the "No O_2 sensor!" alarm will cancel.**

⚠ **CAUTION:** **All lower limits of parameters in above table may not be set up the upper limits, nor may the upper limits be set below the lower limits.**

10.8.7 Volume

Type of volume sensor	Pressure difference
Physiological dead space of sampling probe	9.5 mL

10.8.8 Monitoring performance

Item	Range	Resolution	Accuracy
V_T:	0 to 2000 mL	1 mL	±30 mL (below 200 mL); ±15% (other)
MV:	0 to 30 L/min	1 L/min	±15%
f:	0 to 100 bpm	1 bpm	±5% (above 20 bpm); ±1 bpm (other)
P_{peak}:	0 to 8 kPa	0.1 kPa	±200 Pa (below 2 kPa); ±10% (other)
P_{plat}:	0 to 8 kPa	0.1 kPa	±200 Pa (below 2 kPa); ±10% (other)
FiO_2:	14 to 105%	1%	±3%
C:	0 to 99 mL/cmH_2O	1 mL/cmH_2O	±2 mL/cmH_2O (below 10 mL/cmH_2O) ±20% (other)

Electric quantity: 100%, 75%, 50%, 25%, 0%. If 0% displays, and mains supply not connected, the system will shut down.

Paw-t waveform: Pressure monitoring range:-20 to 80 cmH_2O。Paw-t waveform display pressure axis varies with the upper alarm limit of Paw:

0 to 30 cmH_2O	-10 to 40 cmH_2O
31 to 50 cmH_2O	-15 to 60 cmH_2O
51 to 80 cmH_2O	-20 to 80 cmH_2O

Paw-t waveform display time axis varies with the f setting:

0 to 20 bpm	0 to 15 sec.
21 to 40 bpm	0 to 10 sec.
41 to 100 bpm	0 to 5 sec.

Flow-t waveform: Flow scale: -90 to 90L/min. Time scale: 0 to 15s.

V-t waveform: Y-Axis: Tidal volume, range: 0 to 1.2L.

Paw-V loop: Y-Axis: pressure; X-Axis: tidal volume.

V-FLOW loop: Y-Axis: flow; X-Axis: tidal volume.

10.8.9 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 partial 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.