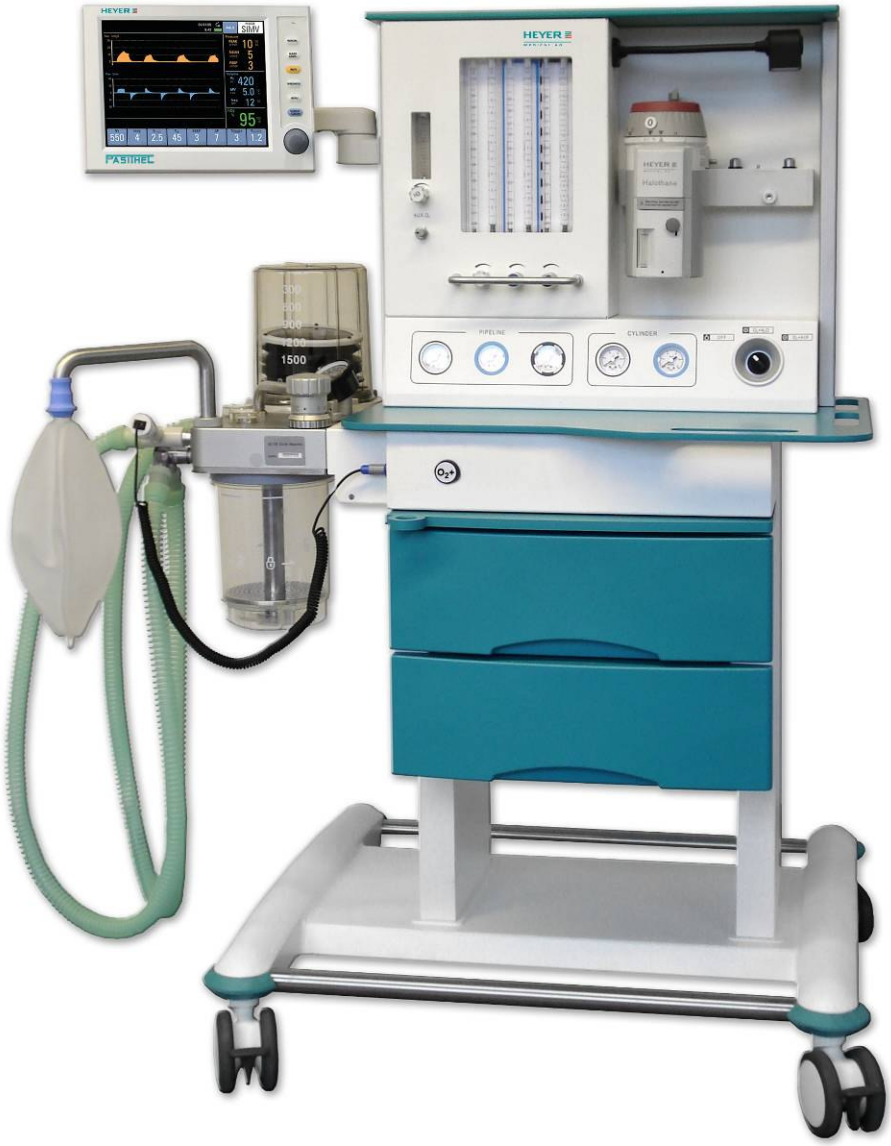
PASIHEL

Anesthesia System

Operator's Manual

Rev. 0.2 Draft – 12/09



HEYER MEDICAL AG

INNOVATION IN DESIGN AND TECHNOLOGY

Contents

1 Statement

HEYER Medical AG ("HEYER") holds the copyright to this manual, which is not publicly published, and reserves the right to maintain it as a secure document. Refer to this manual when operating, maintaining and repairing products only. Releasing information contained within the manual is prohibited.
Proprietary materials protected by copyright law are included in this manual. No section of it can be reproduced, copied, or translated into other languages without prior written approval from HEYER.
All instructions in this manual are considered to be correct. HEYER is not legally responsible for damages caused by incorrect installation or operation. HEYER does not supply privileges endowed by patent law to any other parties. HEYER is not legally responsible for the consequences of breaking the patent law or of a third party violation.
Refer to this manual before using the product. The manual includes: Operating procedures which must be performed with caution; information on actions and situations that may result in damage to the equipment, and actions and situations that may cause bodily harm. HEYER is not responsible for the security, reliability, and/or function of the equipment in the event that damage or other irregular actions occur. Repairs for these malfunctions are not covered by the warranty.
HEYER has the rights to replace any content in this manual without notice.

1.1 Manufacturer Responsibility

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

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

CAUTION: This equipment is not for family use.

CAUTION: Malfunctioning equipment may cause damage and/or bodily injury if repair request are not submitted in a timely manner by the company or organization using the equipment.

The paid theoretical framework diagram, calibrating method, and other instructions will be supplied to the customer upon request. With the assistance of qualified technicians and when stipulated by HEYER, specific equipment parts can be repaired by the customer.

1.2 Security, Reliability and Operating Conditions

HEYER is not responsible for the security, reliability and operating conditions of this product when:

- The assemblies are disassembled, extended, or readjusted
- The product is not operated correctly in accordance with the manual instructions; the power supply that is used is incorrect, and/or the product is operated in an environment other than optimal conditions per this manual.

1.3 Return

In the event a product needs to be returned to HEYER, please follow these steps:

1. Obtain the right of return.
Contact our customer service department with the product number and type. The number is marked on the surface of the product and is **required** for a return. Enclose a letter containing the product number, type, and the reason for the return.

2. Transportation charges
Transportation and insurance charges must be prepaid by the user prior to shipping the product to HEYER for repair.

1.4 Details of the Manufacturer

Apparatus: Anesthesia System HEYER Pasithec

Manufacturer:
HEYER Medical AG
Carl-HEYER-Strasse 1-3
D-56130 Bad Ems / Germany
Tel.: +49 (0) 2603 / 791-3
Fax: +49 (0) 2603 / 70424
E-Mail: info@heyermedical.de
Internet: http://www.heyermedical.de

2 Introduction

2.1 Intended Use

The HEYER Pasithec is a compact and integrated anesthesia transmitting system. The anesthetic ventilator not only provides patients undergoing operations with auto ventilation, but also monitors and displays the patient's various parameters.
The anesthetic ventilator used in the system is controlled by a microprocessor, which internally configures the monitor and the volume mode; other functions are optional.
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 contact your local representatives.

⚠ **WARNING: All Pasithec users must be trained.**

⚠ **WARNING: HEYER Pasithec is not suitable for use in an MRI environment.**

2.1.1 Range of Use

Pasithec is applicable for patients of over 2 kg with standard configuration. Pasithec is for use in the Operating Room and/or Emergency Room of a hospital, drug addiction treatment center, or other medical facilities where anesthesia is used.

2.1.2 Contraindication

Pasithec is not suitable for pneumothorax patients

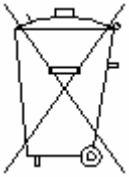
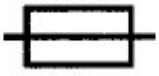
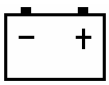
2.2 Symbols

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

⚠ **WARNING**: Indicates potential hazards to operators or patients.

⚠ **CAUTION**: Indicates potential damage to equipment.

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

	AC: Alternating current		Type B Applied Part
	DC: Direct current		Attention: consult accompanying document
	Protective earth		Dangerous Voltage
	Equipotentiality		Rotation in two directions
	Movement in one direction		Movement in two directions
	Right-turning movement		Left-turning movement
	Lock		Unlock
 Insp.	Inspiration flow	 Exp.	Expiration flow
SN	Serial Number	O_2+	O_2 flush
	Reservoir bag port		Do not dispose in garbage basket.
	Fuse		View the reading on the top of the float.
	Recyclable		Battery

	Bell cancel		Variability of rotational adjustment
	Bell		Non-ionizing electromagnetic radiation
△!	Alarm, general		Date of manufacture
△!!	Urgent alarm		Address of manufacturer
EC REP	EC Representative	CE PENDING	The system, with this label under the stipulations in the operating manual, complies with the requirements related from 93/42/EEC.

2.3 Definition, Abbreviation

AC135	Anesthetic Breathing System
AGSS	Anesthetic Gas Scavenging Transfer & Receiving System
APL	Adjustable Pressure Limit
BDU	Basic Data Unit
C	Compliance
C·G·O	Common Gas Outlet
cmH_2O	Centimeters of Water
IPPV	Intermittent Positive Pressure Ventilation
EEPROM	Electrically Erasable Programmable Read Only Memory
FiO_2	Fraction of Inspired Oxygen
Flow-t	Flow-time Waveform
Freq	Frequency
$Freq_{MIN}$	Minimum Frequency in PS Mode
GUI	Graphical User Interface
I:E	Inspiratory to Expiratory Ratio
L	Liter
L/min	Liters Per Minute
Manual	Manual ventilation
ml	Milliliter
MRI	Magnetic Resonance Imaging
MV	Minute Volume
Paw	Airway Pressure
Pb	Plumbum
PEAK	Peak Pressure
PLAT	Plat Pressure
MEAN	Mean Pressure
Paw-t	Pressure-time Waveform
PCV	Pressure Control Ventilation
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
PS	Pressure Support Ventilation
P_{TARGET}	Target Pressure
SIMV	Synchronized Intermittent Mandatory Ventilation
T_{INSP}	Inspiratory Time
T_P	Inspiratory Pause Time
Trigger	Flow Trigger
T_{SLOPE}	Inspiratory Slope Time
UI	User Interface
V_T	Tidal Volume
WDT	Watch Dog Timer
ΔP	Differential Pressure
Enf.	Enflurane
Hal.	Halothane
Iso.	Isoflurane
Sev.	Sevoflurane
Des.	Desflurane
$ETCO_2$	End-Expiratory CO_2 Concentration
$INSCO_2$	Inspiratory CO_2 Concentration
MAC	Minimum Alveolar Concentration

3 System Components

3.1 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;**
- **+ system is to be equipped with an ANESTHETIC GAS SCAVENGING TRANSFER and RECEIVING SYSTEM complying with ISO 8835-3 before being put into service.**
- **+ 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 21647.**
- **+ CO_2 monitor in accordance with ISO 21647.**
- **+ ANESTHETIC monitor in accordance with ISO 21647.**

⚠ **WARNING:** **To avoid explosion hazards, flammable anesthetic agents such as Ether and Cyclopropane shall not be used in the anesthetic workstation. Only use anesthetic agents that 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:** **Contact with a liquid, such as anesthetic agent, results in damage within the device.**

⚠ **WARNING:** **The incline angle should not exceed 10 degrees whenever the anesthetic system is in use.**

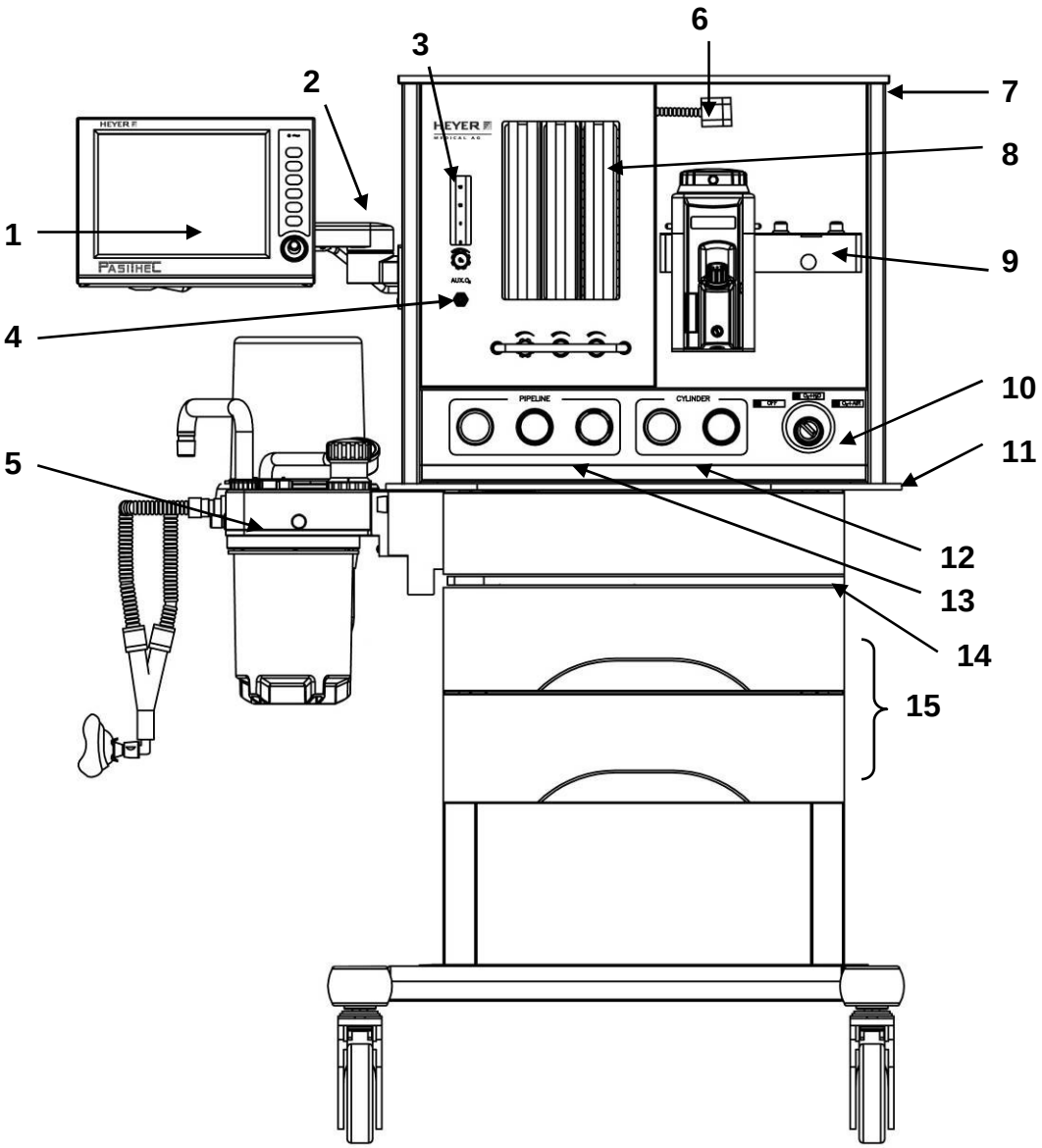


Figure 3-1 Front View

Legend:

1	User Interface (UI)	2	Arm
3	Aux. O_2 Flowmeter	4	Aux. O_2 Outlet
5	Breathing System	6	Flexible Top Light
7	Top Board	8	Flowmeter
9	Vaporizer Mount	10	Pneumatic and Electronic Switch
11	Main tray	12	Cylinder Pressure Gauges
13	Pipeline Pressure Gauges	14	Pull-out Writing Board
15	Drawers		

Descriptions of each control function at the front of Pasithec:

	Item	Description
3	Aux. O_2 Flowmeter	Provides O_2 with a maximal flow of 15 L/min to Aux. O_2.
8	Flowmeter with Flow Control Knobs	Turn the knob counterclockwise to increase the flow; turn clockwise to decrease the flow. Reading point is top of float inside flow tube.
6	Top Light	The top light will illuminate if top light is switched on. The top light switch has two settings: on and off.
10	Pneumatic and Electronic Switch	The switch can control electricity and gas and has three settings. Electricity main switch: OFF, ON, ON; gas way main switch: OFF, O_2+N_2O, O_2+Air. Function of electricity main switch: When system is shut off, the assistant power and controller are started with the main switch. The machine performs a system self test, and after the test, the startup is complete. While system is in startup state, turn off the main switch and be sure the main unit system is closed completely. Function of gas way main switch: when switch is in the OFF position, O_2, N_2O and AIR cannot enter the flowmeter. When switch is in O_2+N_2O position, O_2 and N_2O can enter into flowmeter. When the switch is in O_2+Air position, O_2 and AIR can enter.
14	Writing Board	The writing board can hold up to 10 kg and can be used by a doctor during an anesthesia operation.

⚠ **WARNING:** **When performing closed or semi-closed ventilation with breathing system, the Fresh gas switch should be placed to Circle Absorber. Otherwise, there will be anesthetic gas leakage and abnormal operation of the machine.**

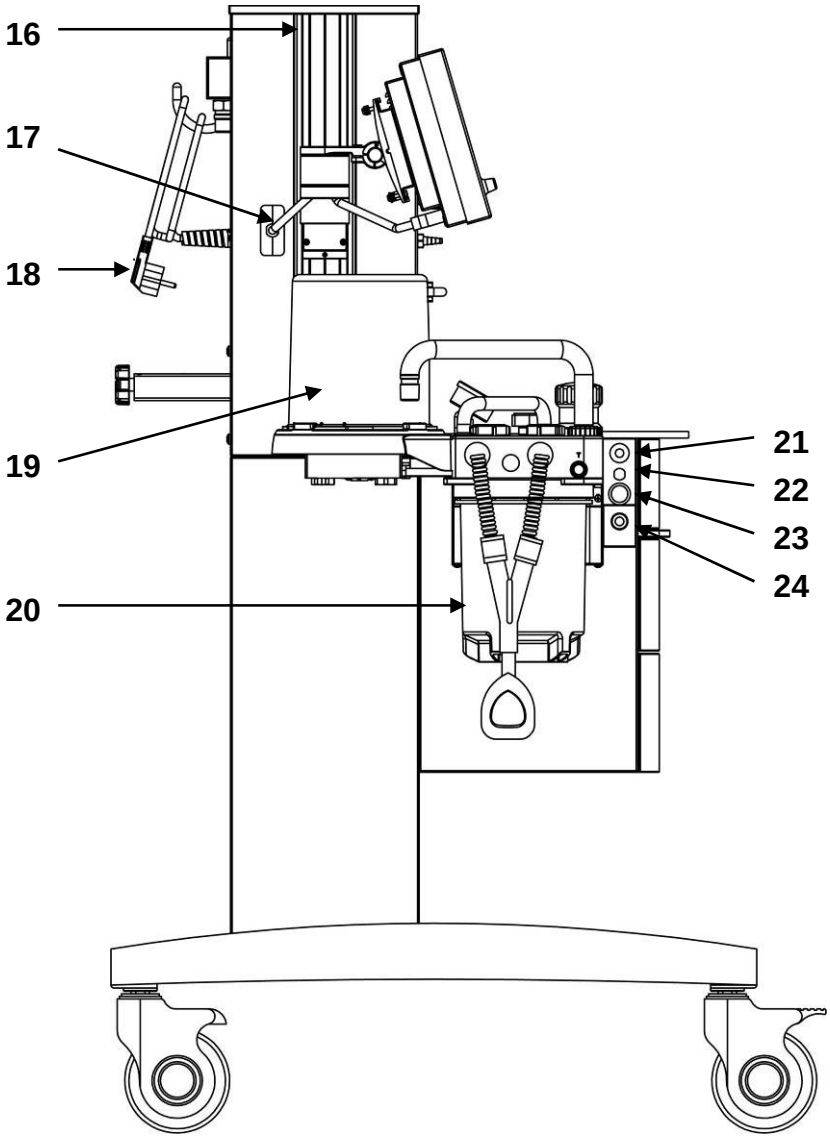


Figure 3-2 Side view

Legend:

16	GCX Mounting Rail	17	UI Signal Cable
18	Power Cable	19	Bellows Assembly
20	Absorber Circle Assembly	21	O_2 Flush (O_2+)
22	O_2 Sensor Socket	23	Driving Gas Outlet – Switch
24	Driving Gas Outlet (CGO)		

Descriptions of each control function at the side view of Pasithec:

	Item	Description
21	O_2 Flush (O_2+)	Press the O_2 Flush (O_2+) button to supply the breathing system with O_2 at a high flow rate.
22	O_2 Sensor Socket	Socket to connect Oxygen Sensor for monitoring oxygen concentration of absorber circle. When monitoring patient oxygen concentration in inspiratory gas at the back of inspiratory valve, the socket can be selected.
23 / 24	Driving Gas Outlet (Switch)	Provide driving gas to other equipment. Pressure: 280 kPa~600 kPa, flow: max. 90 L/min.

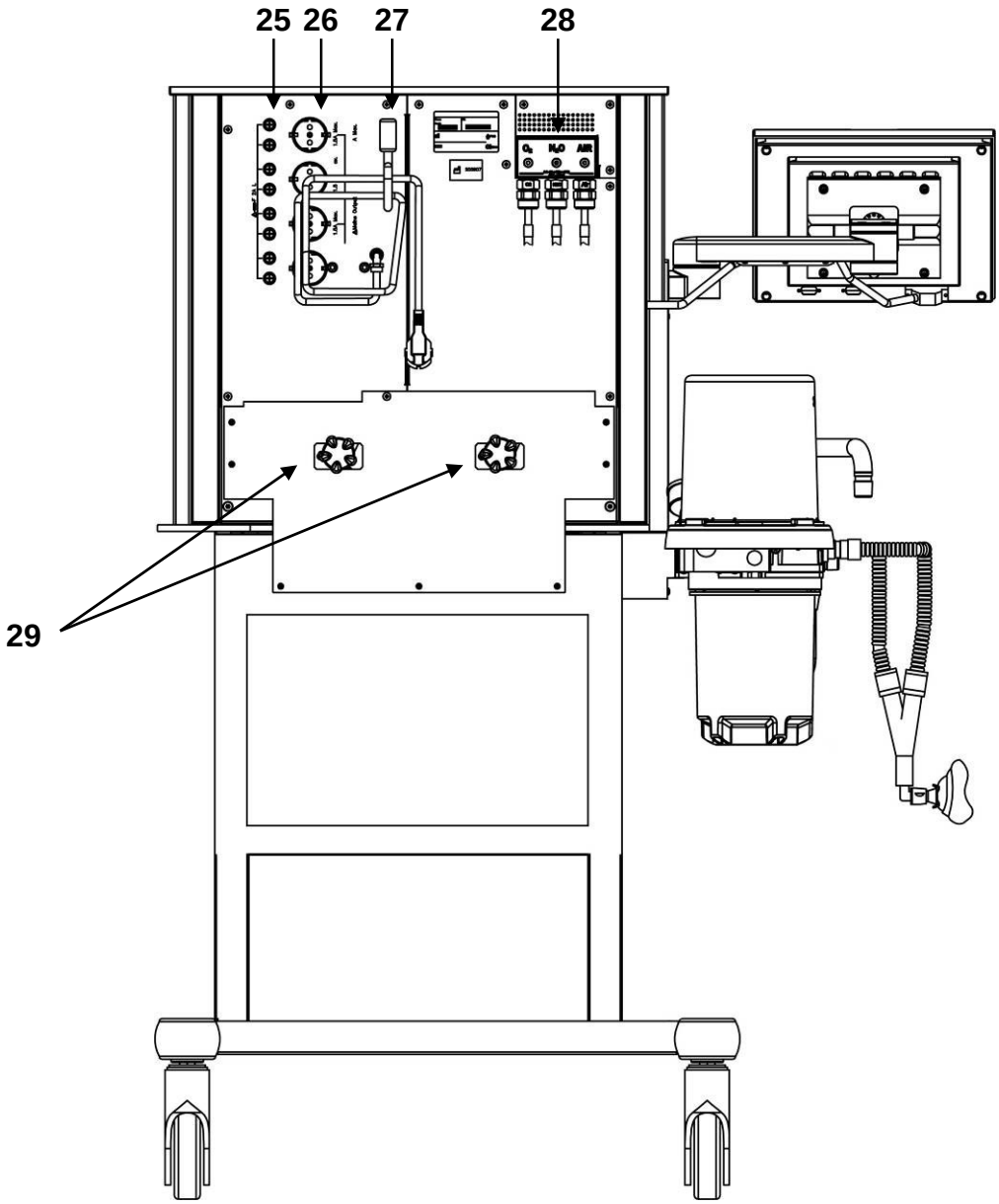


Figure 3-3 Rear View

Legend:

25	Fuses	26	Aux. Power Sockets
27	Power Cable	28	Pipeline Gas Inlet Module
29	Gas Cylinder Yokes		

3.2 Breathing System

⚠ **CAUTION:** **The breathing system used together with the anesthetic gas supply system shall be in accordance with ISO 8835-2.**

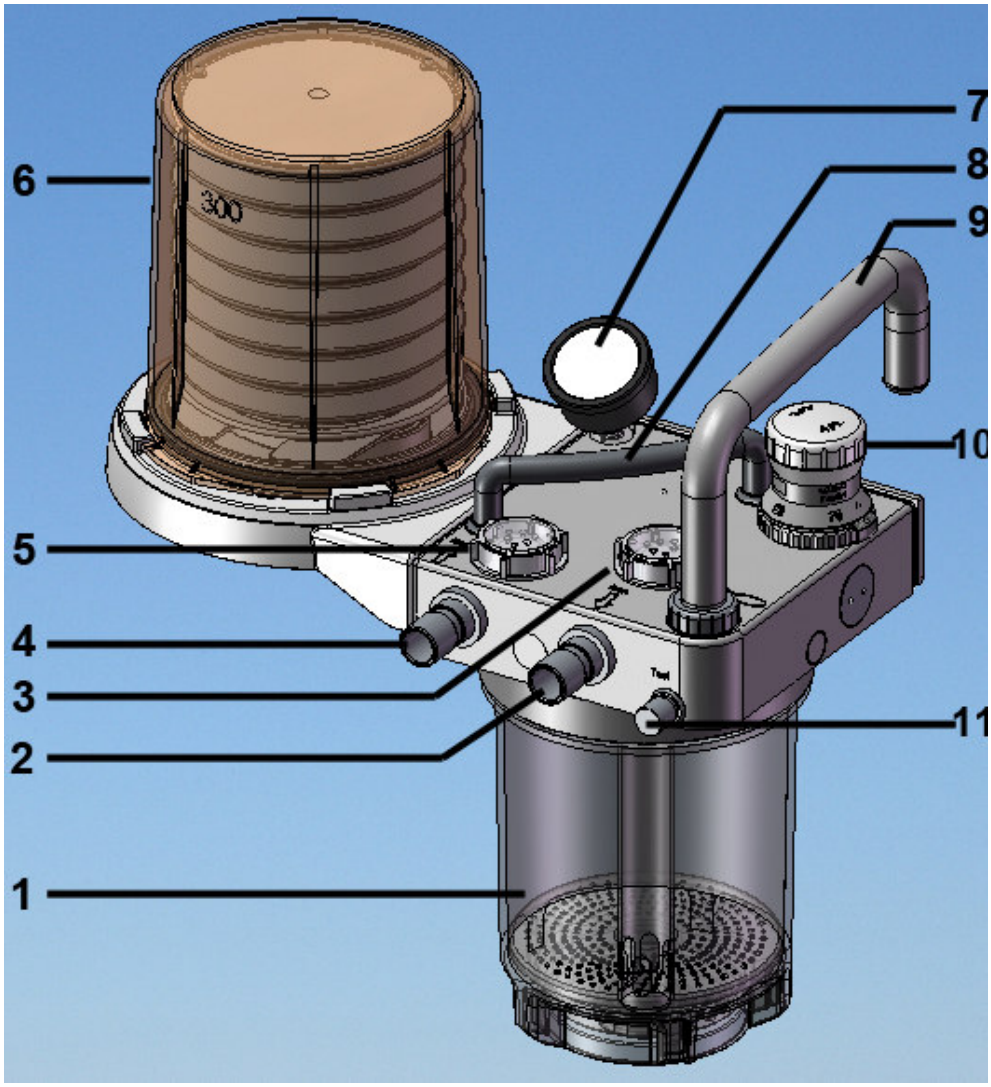


Figure 3-4 Breathing System

Legend:

1	Absorber Canister	2	Inspiratory Port
3	Inspiratory Valve	4	Expiratory Port
5	Expiratory Valve	6	Bellows
7	Airway Pressure Gauge	8	Handle
9	Bag Arm	10	APL valve
11	Test Block		

3.2.1 Bellows Assembly Ports

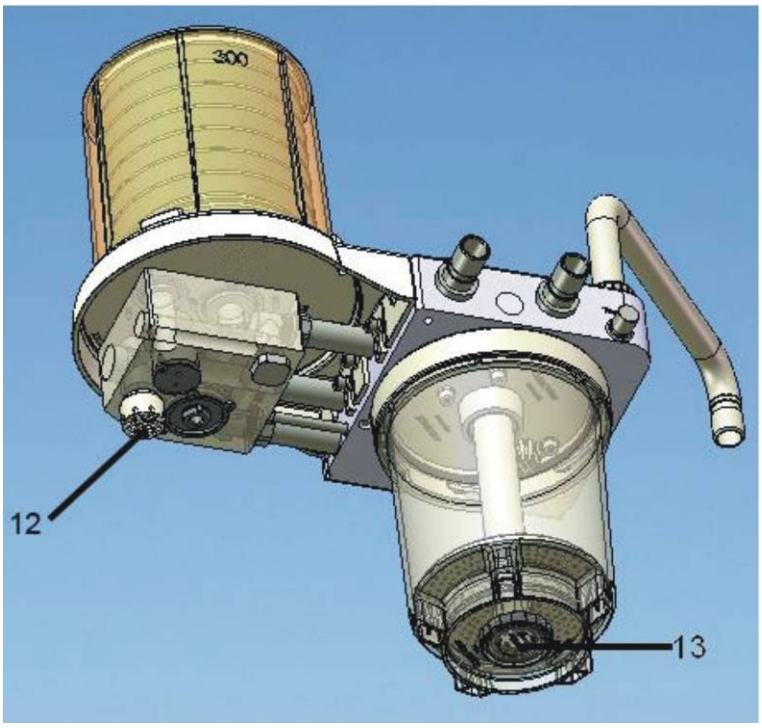


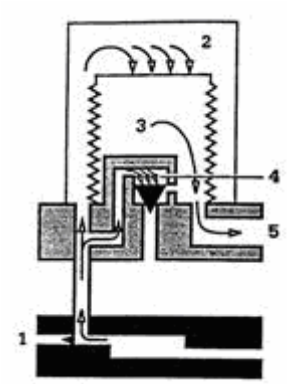
Figure 3-5 Ports of bellows assembly

12 Exhaust Gas Port

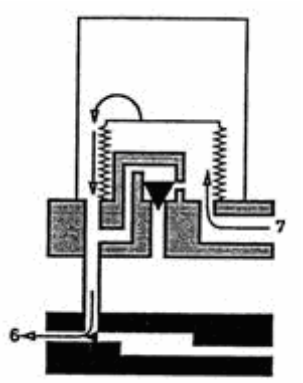
13 Nut (drain plug): Loosen the nut to drain the water when absorbent (natrium lime) in absorber has been commixed with water.

⚠ **WARNING:** **Never connect exhaust gas port with sub-atmospheric system directly, as it results breathing system leakage.**
Do not block exhaust gas port.

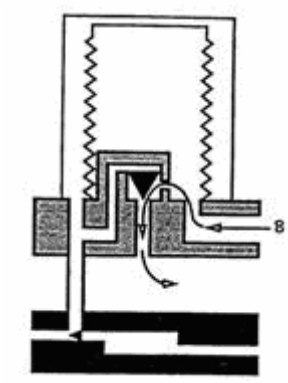
3.2.2 Ventilating Circulation



Inhalation Primary Phase:
1 Exhalation Valve
2 Driving Gas
3 Gas of Patient Circuit
4 Pressure-Relief Valve
5 To Patient Circuit



Exhalation Primary Phase:
6 Driving Gas
7 From Patient Circuit



Exhalation End Phase:
8 Excess Gas from Patient Circuit

3.3 Vaporizer

⚠ **CAUTION:** **The vaporizer used with the anesthetic system shall comply with ISO 8835-4.**

A checklist for the assembly of the anesthetic system from individual components shall be provided by the assembler of the anesthetic system.

For more detailed information about the vaporizer, please refer to the instructions for the vaporizer when used in the anesthetic system.

3.4 Anesthetic Ventilator

⚠ **CAUTION:** **Anesthetic ventilator used in anesthetic system shall comply with ISO 8835-5.**

⚠ **CAUTION:** **Monitoring conditions of this system: Ambient temperature: 25℃; Air temperature: 25℃; Air humidity: 30%; Gas component : O_2.**

⚠ **CAUTION:** **If the temperature of O_2 sensor is lower than dew point of breathing gas, vapor may coagulate on the surface of the sensor and oxygen concentration on the monitor may be lower than the practice value.**

3.4.1 Front Panel

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

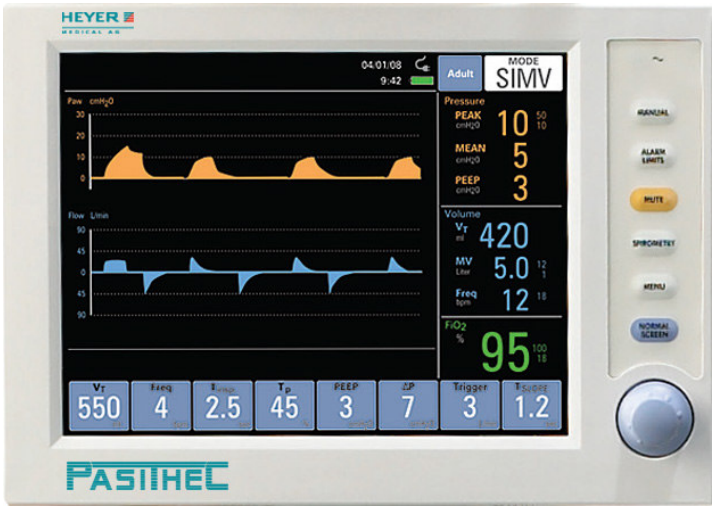


Figure 3-6 Front Panel

3.4.2 Keys

MANUAL AUTO	Manual Key	Press the key to change original ventilation mode to manual mode; Press again to change back to the original ventilation mode.
ALARM LIMITS	Alarm Limits Key	Press the key to open alarm window on the screen; Press again to close the alarm window.
MUTE	MUTE Key	Press the key to mute the alarm for 110 seconds. New alarms shall override the mute.
SPIROMETRY	Spirometry Key	This key shall toggle the display between the waveform window and the two loop display configurations of the Spirometry Loop Window described in section 4.5. The first key press shall display the “Pressure-Volume” loop display configuration. The second key press shall display the “Flow-Volume” loop display configuration. After both configurations have been cycled through the display, a third key press shall return the display to the Normal Screen.
MENU	MENU Key	Press the key and a “Menu” window appeared on the display screen; for more details refer to section 3.5. The first menu key press after the initial power up will display the calibrate menu, with “Start Calibration” highlighted.
NORMAL SCREEN	Normal screen Key	The key closes the “Spirometry” and other windows and returns the screen to pressure and flow waveforms. If the “Spirometry” and all other windows are already closed when the NORMAL SCREEN key is pressed again, no action shall occur.

3.4.3 Indicator

	AC indicator	The indicator lights up when AC power is in use; the indicator is dark when the AC power fails.

3.4.4 Navigator Knob

The user can adjust 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 knob may be used to select options on the screen, in the system menu, and in the parameter menu.

The rectangular mark on the screen that moves with the rotation of the knob is the “cursor”. The cursor can be used to select any menu item on which it lands.

Operating method:

- Move the cursor to the item you wish to select
- Press the knob
- One of the following four situations will happen:
  - If the background color of the cursor becomes a contrasting color, the content in the frame can change with the rotation of the knob.
  - A pull down menu or dialogue box may appear on the screen
  - The original menu will be replaced by the new menu.
  - Save setup

3.4.5 Screen Layout

The display of the ventilator is a color TFT, which can display the monitoring and setting parameters, waveforms, and alarm information on the screen. See Fig. 3-7.

The screen has three areas: information area, monitoring area, and parameter setup area.

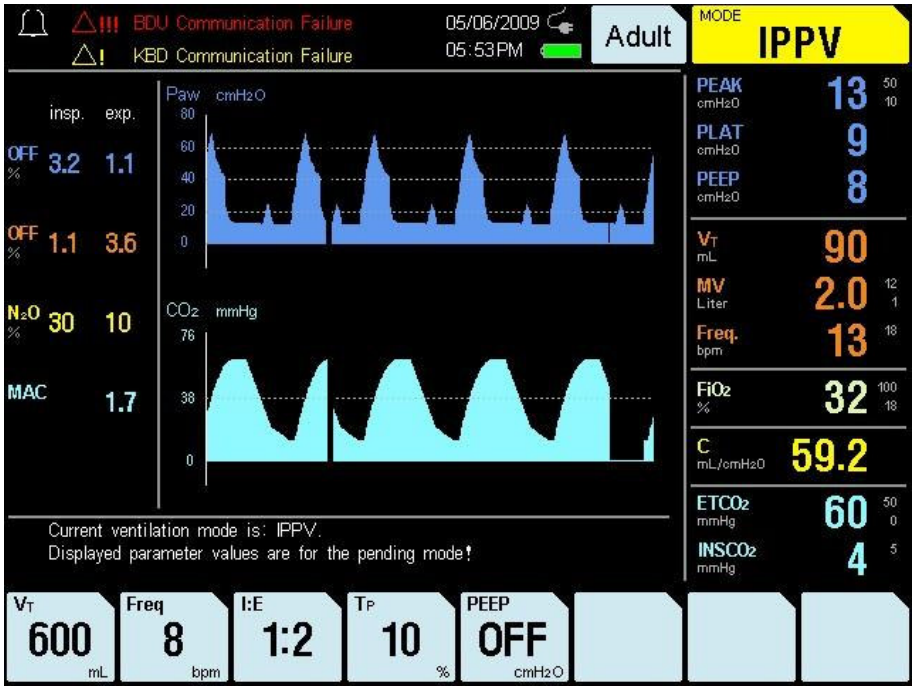


Figure 3-7 Display screen layout

3.4.5.1 Information Area

The information area is divided into seven areas: Alarm Indication, Alarm Messages, Date, Time, Power Source, Patient Type and Ventilation Mode.

3.4.5.1.1 Alarm Indication

The bell icon is displayed when an alarm is present. When it appears, the color of alarm bell is white. Pressing the alarm mute key places an “X” on the alarm bell icon for 110 seconds. Displayed below the bell icon is a countdown timer that will display remaining silence time.

3.4.5.1.2 Alarm Messages

Technical Messages and Functional Alarm will be displayed in the alarm message area. High priority alarms will be red. Mid- and low-priority alarms will be yellow. Up to 2 alarm messages can be displayed on the screen. For more details, refer to Chapter 9.

3.4.5.1.3 Power Source

Located the left of Ventilation Mode tile are two icons: AC and Battery. The display status of the Battery includes: Full, Charging and Exhausted. The display status of the AC includes: AC power up and AC power down.

AC power up: (1) The Battery icon is solid and at 100% capacity when fully charged. (2) If in charging, the Battery icon shows capacity alternately.

AC power down: (1) The Battery icon shows the current capacity. (2) The Battery can supply power for the machine for about 15 minutes when the low battery alarm sounds.

3.4.5.1.4 Date

The display mode of Date has three types: MM/DD/YY, DD/MM/YY or YY/MM/DD.

3.4.5.1.5 Time

The display mode of Time has 2 types: 12 hour or 24 hour format.

3.4.5.1.6 Patient Type

The patient type shall be displayed as Adult or Child. By highlighting (black text on white background) the Patient type tile and pressing, the navigator knob shall toggle the patient type between Adult and Child. Changing patient type is possible in STANDBY mode only. The default patient type when the machine is powered up is Adult.

3.4.5.1.7 Ventilation Mode

Pressing the navigator knob when the Mode tile is highlighted displays the current ventilation mode in white text on a black background, and the “MODE” label remains displayed in black text on a green background. Rotating the navigator knob clockwise allows the user to scroll through the ventilation mode selections: STANDBY, IPPV, PCV, SIMV, PS and MANUAL. Rotating the navigator knob counterclockwise allows the user to scroll through the settings in the reverse order. The default mode when the machine is powered up is standby.

3.4.5.2 Monitoring Area

The monitoring area has two parts: Patient waveform and parameters. See Fig. 3-7.

3.4.5.3 Parameters Setup Area

The parameter setup area contains 8 tiles of fixed vertical height and fixed horizontal width; each tile contains the tile's parameter value.

Each tile represents a location that may be highlighted by the navigator knob. Current parameter settings are displayed in reverse video in the parameter window when a parameter tile is highlighted (black text on white background). Rotating the navigator knob clockwise allows the user to increase the setting while rotating the knob counterclockwise decreases the setting. When the selection reaches its maximum or minimum setting, the minimum or maximum setting is displayed.

Pressing the navigator knob selects the parameter setting which is displayed as white text within a black field. Parameter settings shall be in normal video unless the parameter tile has been selected or highlighted. Parameter tiles are populated per table 3-1 below.

A timeout shall occur when a parameter tile is selected or changed but not confirmed for 15 seconds. Upon a timeout, the parameter setting reverts back to the previously confirmed value.

The parameter timeout shall be available for the following items:

- Ventilation Mode
- Patient Type

Table 3-1

In the following table "Para." is equated with "Parameter".

Vent Mode	**Para. Setup 1**	**Para. Setup 2**	**Para. Setup 3**	**Para. Setup 4**	**Para. Setup 5**	**Para. Setup 6**	**Para. Setup 7**	**Para. Setup 8**
STANDBY	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank
IPPV	V_T	Freq.	I:E	T_P	PEEP	Blank	Blank	Blank
PCV	P_{TARGET}	Freq.	I:E	Blank	PEEP	Blank	Blank	T_{SLOPE}
SIMV	V_T	Freq.	T_{INSP}	T_P	PEEP	ΔP	Trigger	T_{SLOPE}
PS	Blank	$Freq_{MIN}$	Blank	Blank	PEEP	ΔP	Trigger	T_{SLOPE}
MANUAL / AUTO	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank

3.4.6 Rear Panel

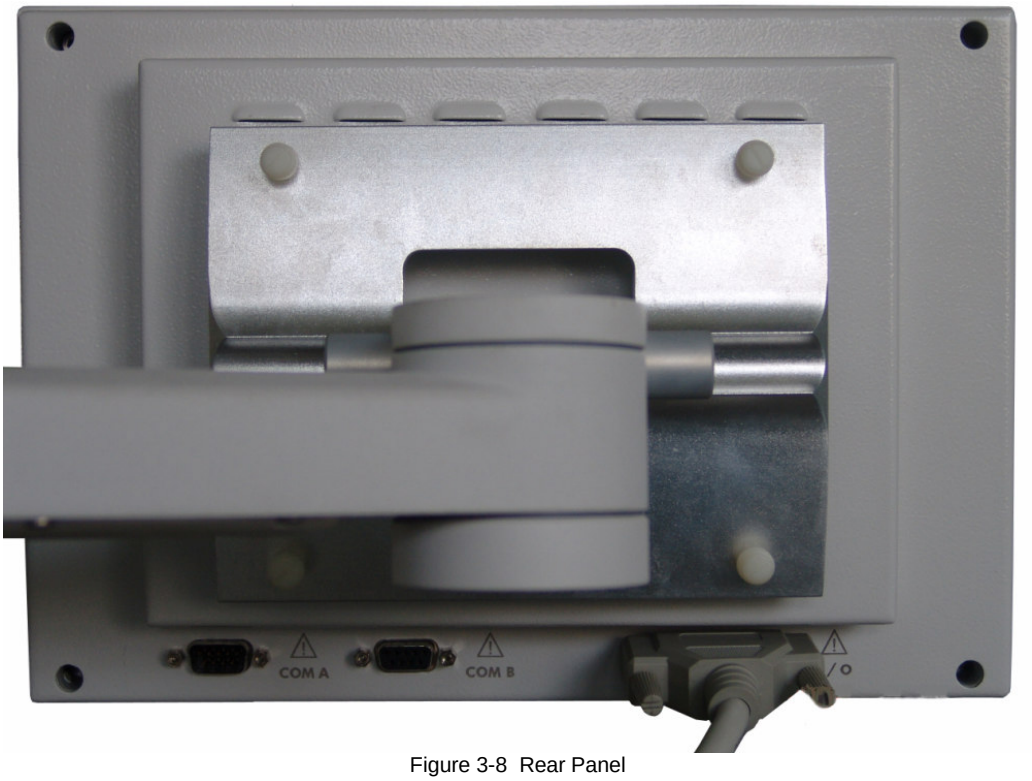


Figure 3-8 Rear Panel

Legend:

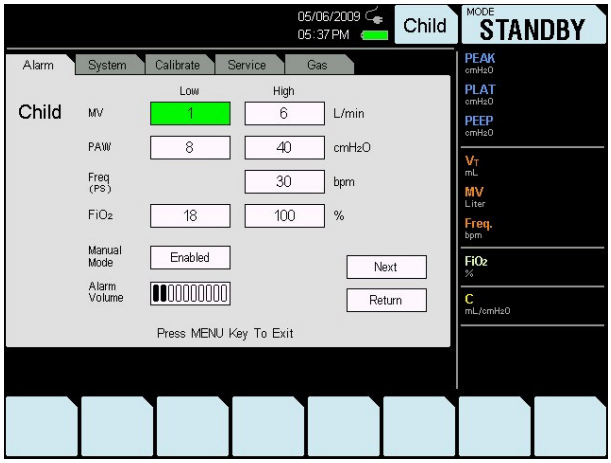
COM A Interface	Communication extension interface communicates with the IRMA.
COM B Interface	Communication extension interface is used for connecting external communication equipment (RS232 interface).
SIGNAL Interface	Signal interface is used for connecting display screen to main unit.

3.5 Menu

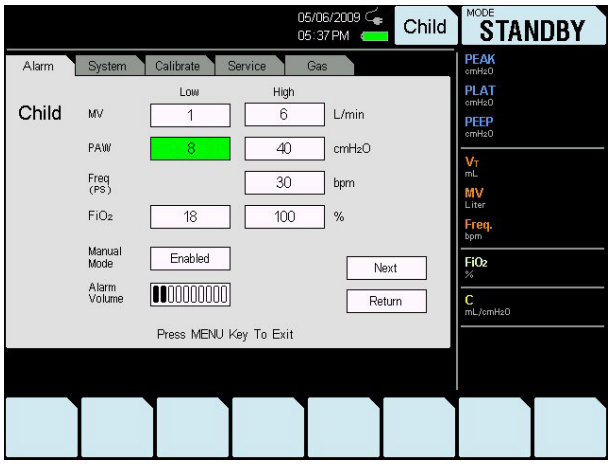
3.5.1 Operating Guide

When calibrating or carrying out other functions, an explanation of the process will be displayed on the screen.
The following diagram is an example.

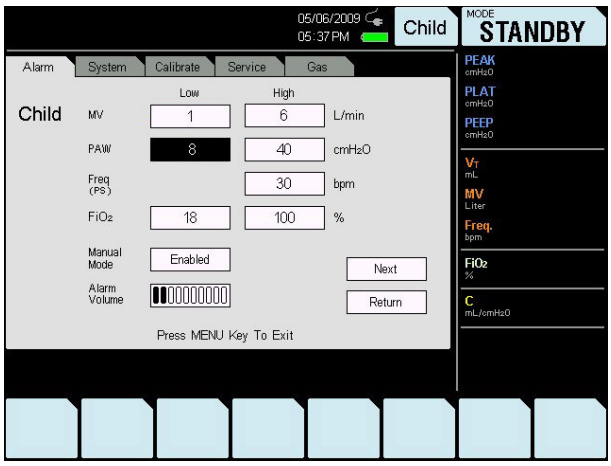
Step 1
When the MENU key is pressed, a “Menu” window is displayed on the screen.
Note: The “Menu” window opens in the last viewed menu.
The following example illustrates how to operate the settings.



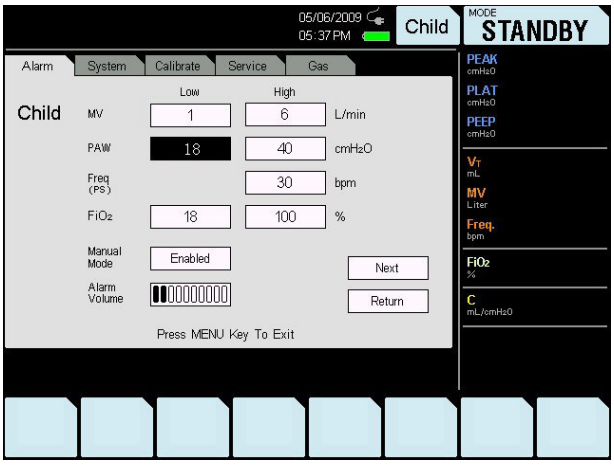
Step 2
Turn the knob to select the Paw-Low option; the selected option will appear as black text on a green background.



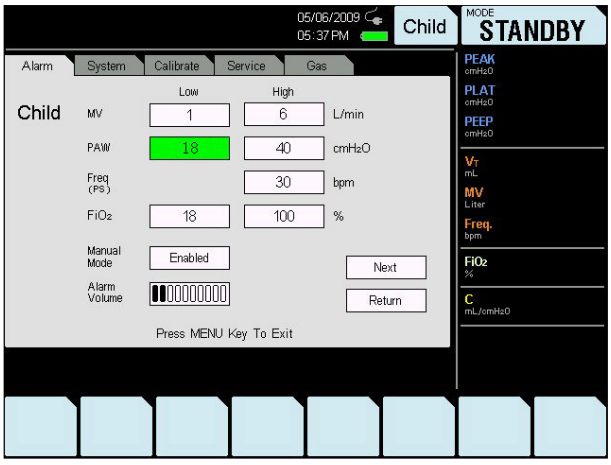
Step 3
Press the knob to enter the setting; the background will appear as white text on a black background.



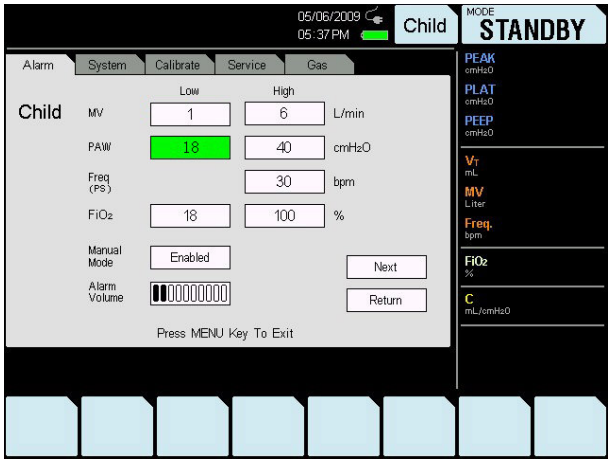
Step 4
Turn the knob to select the setting.



Step 5
Press the knob to save the setting; the background will appear as black text on a green background.

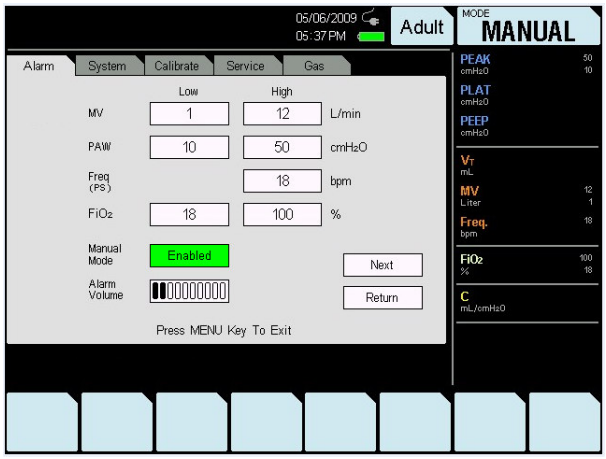


Step 6
Turn the knob and select “Return” to set other parameters. Follow the above directions to select the corresponding submenu.
Press the MENU key to exit the screen.

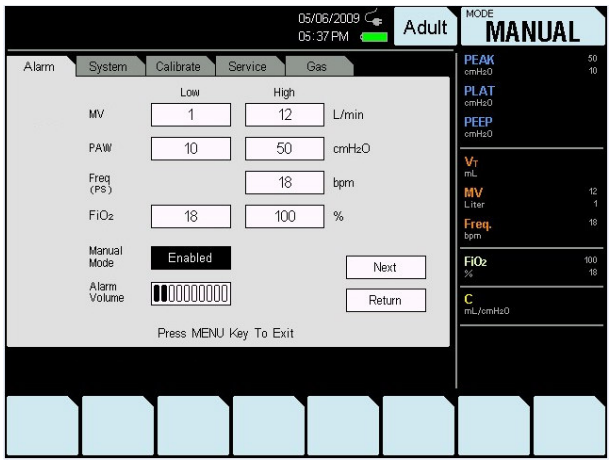


The default alarm setting in the manual mode is “Enabled”. To adjust the setting:

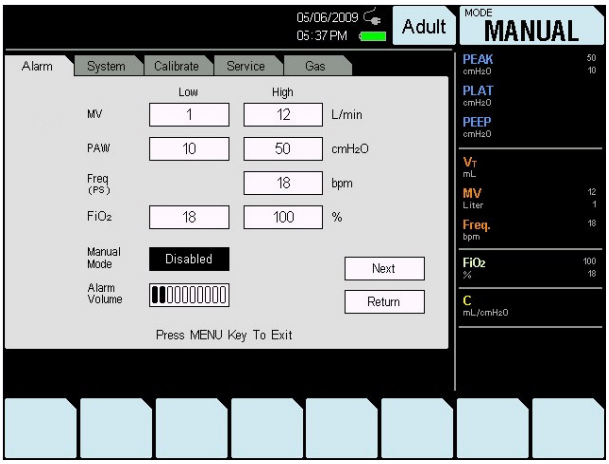
Step 1: Select “Manual Mode.”



Step 2: Press the knob.



Step 3: Turn the knob to display “Disabled.”



Step 4: Press the knob to save the “Disabled” setting.

The patient’s pressure, tidal, and asphyxiation alarms will not be displayed.

3.5.2 Menu Diagram

Figure 3-9 to
Figure 3-13 displays each submenu in the Menu window. Some functions are optional.

When you press the MENU key, the “Menu” window is displayed on the screen.

Turn the knob to select a submenu.

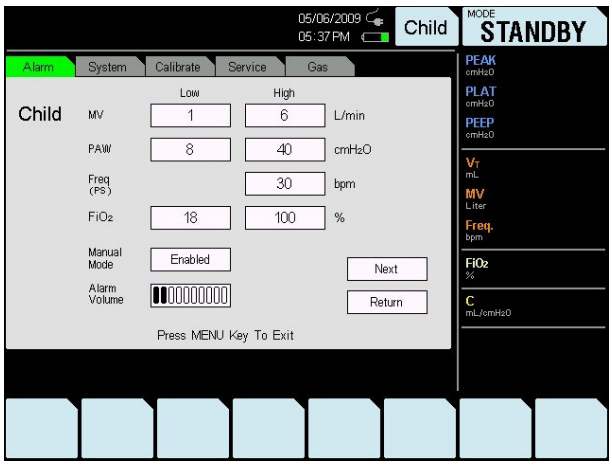


Figure 3-9 Alarm submenu (Page 1)

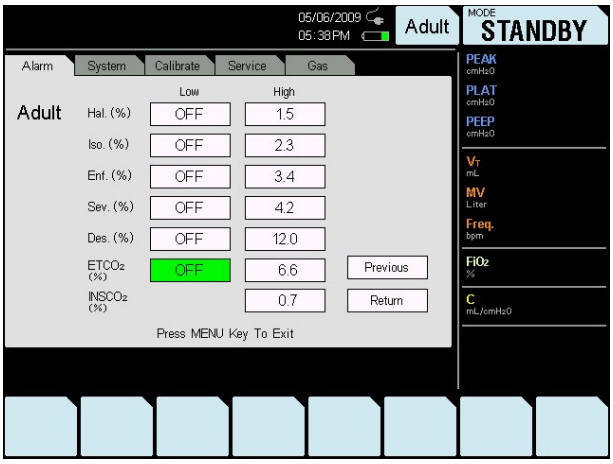


Figure 3-10 Alarm submenu (Page 2)

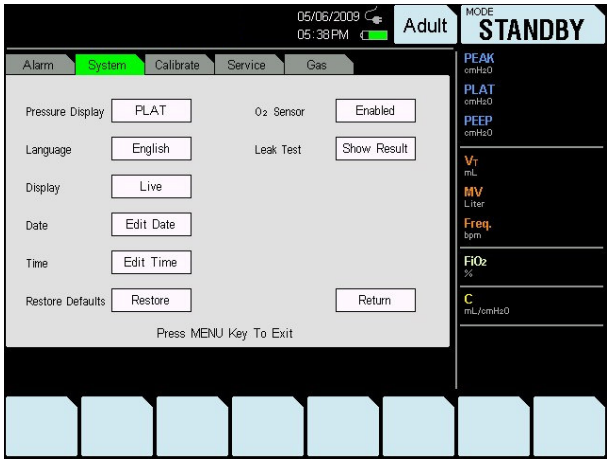


Figure 3-11 System submenu

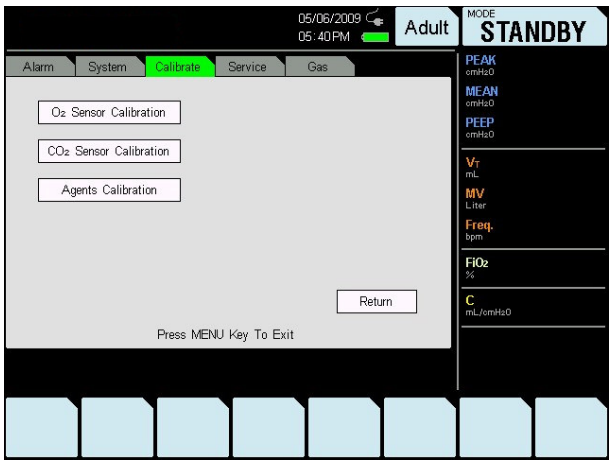


Figure 3-12 Calibrate submenu

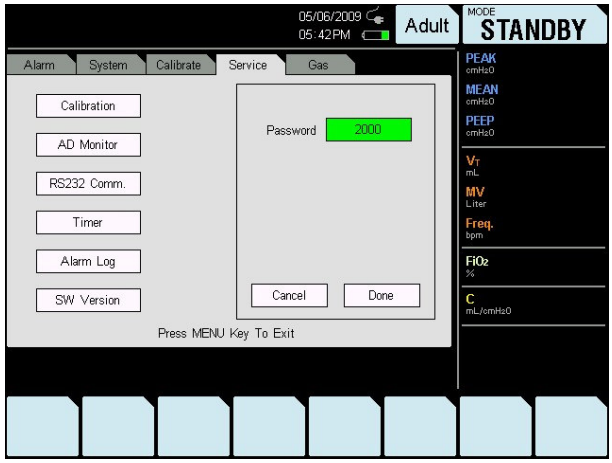


Figure 3-13 Service submenu

⚠ CAUTION: A password is needed for the Service submenu. Only an authorized engineer can access this submenu.

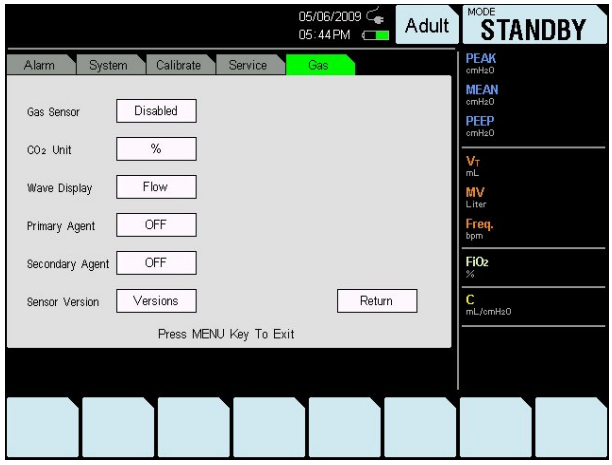


Figure 3-14 Gas submenu

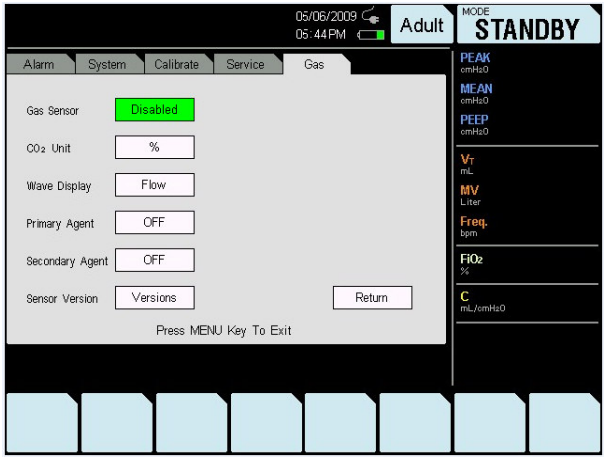
Gas Sensor

When the gas sensor is in “Enabled” mode, the sensor was properly connected to the machine and can be used.

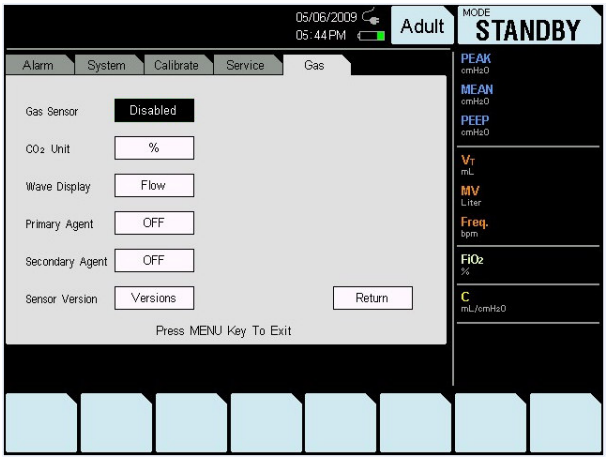
When the gas sensor is in “Disabled” mode, it was not properly connected prior to starting the machine and cannot be used.

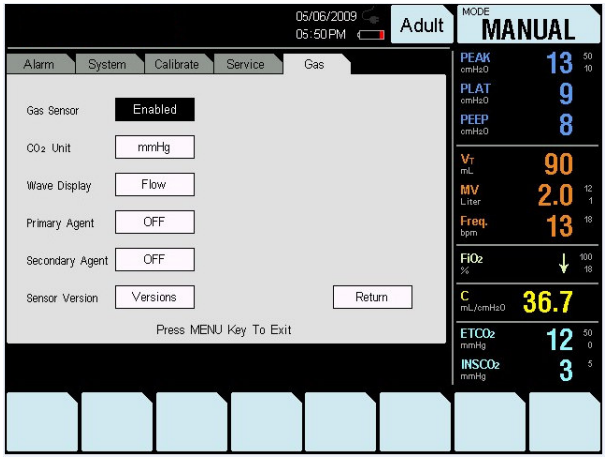
The Gas Sensor settings can be adjusted by following these instructions:

Step 1: Turn the knob to select “Gas Sensor.”

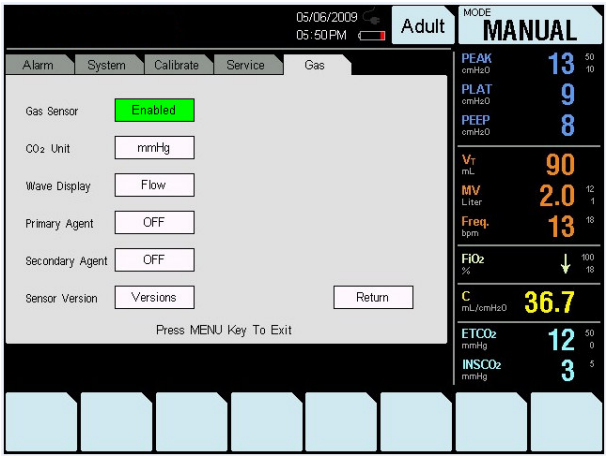


Step 2: Press the knob, and then turn it to change the settings.



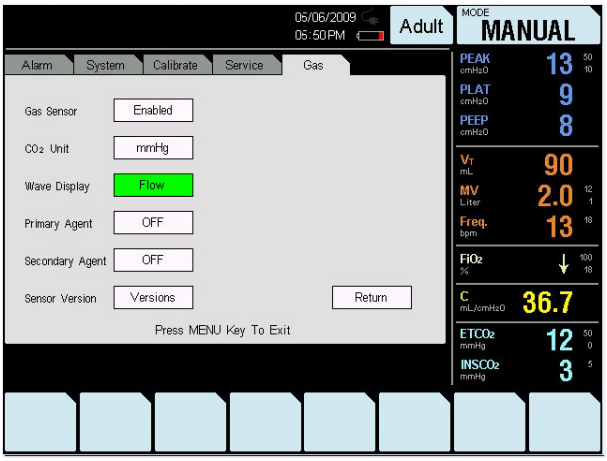


Step 3: Press the knob to save the setting.

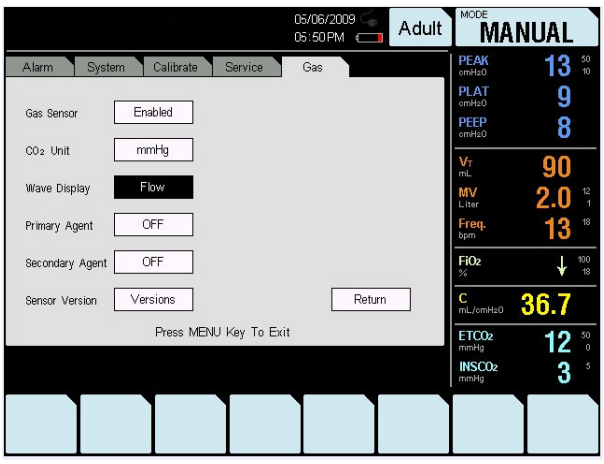


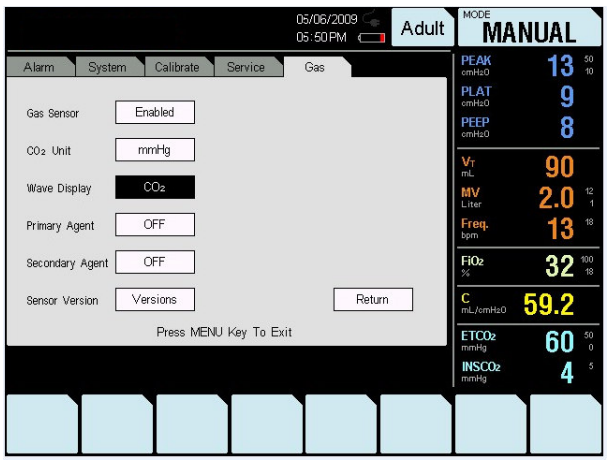
When the Wave Display is in “Flow” mode, flow-time wave is displayed.
When the Wave Display is in “CO_2” mode, CO_2-time wave is displayed.
The Wave Display default setting is “Flow” when the machine is turned on.
To adjust Wave Display settings, follow these instructions:

Step 1: Turn the knob to select “Wave Display.”

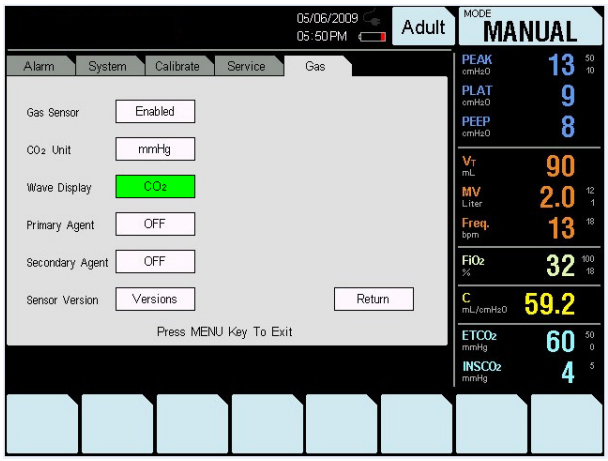


Step 2: Press the knob, and then turn it to change the setting.





Step 3: Press the knob to save the setting.



4 Operating Guide

4.1 Startup

Step 1: Connect Main Supply and Gas Supply
Plug the power cord into the AC power outlet and connect the pipeline gas supply and standby gas supply. Turn on the cylinder valve of the standby gas supply and turn off the flowmeters of O_2, N_2O, Air, and Aux. O_2.

Step 2: Turn on the Power Switch
Turn the Power Switch to “ON”. The UI will power on and perform a System Self Test.

4.1.1 System Self Test

When the UI is powered on, the startup interface is displayed, followed by the LOGO interface.

Figure 4-1 LOGO Interface

The System Self Test interface will appear after the LOGO interface.

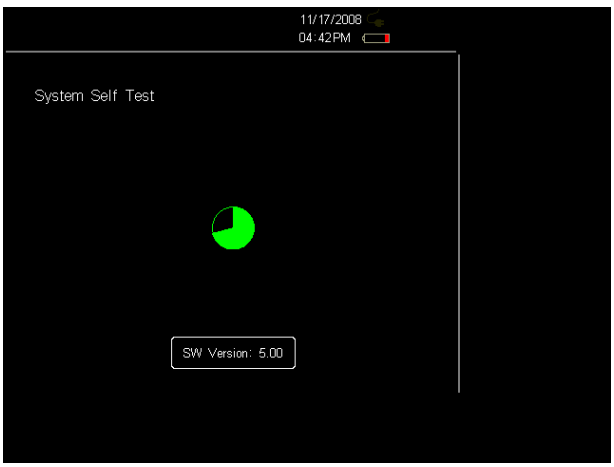


Figure 4-2 System Self Test Interface

The System Self Test Complete interface will appear when the self test is complete.

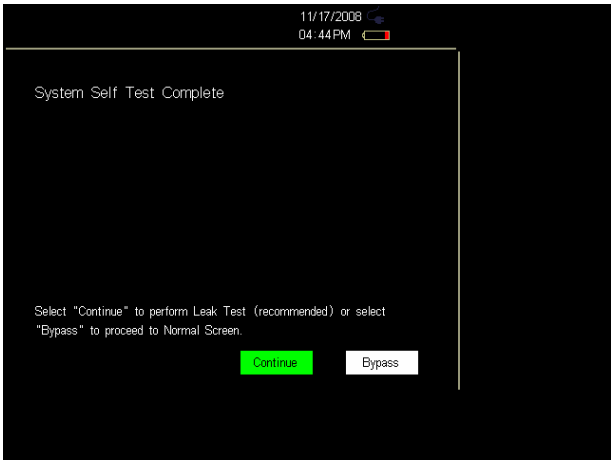


Figure 4-3 System Self Test Complete interface

Select the “Continue” option to perform the Leak Test procedure.
Select “Bypass” to enter the STANDBY interface.
If the self test fails, please contact a service representative.

4.1.2 Manual Leak Test

The Leak Test includes verification of APL valve and Flowmeter. Click “Continue” to begin the leak test. See Figure 4-4 below.

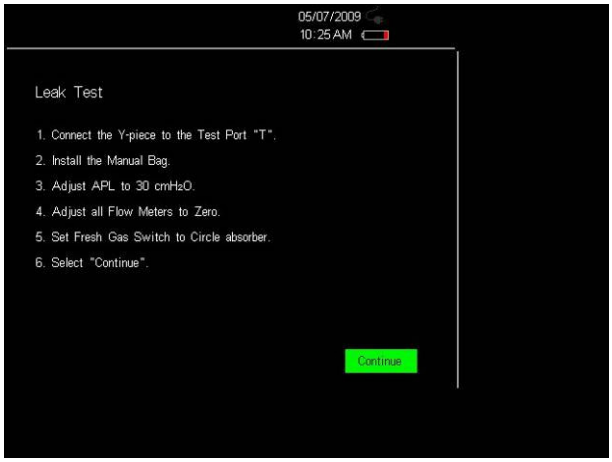


Figure 4-4 Setup before Manual Leak Test

Perform the following according to the prompts in the above figure:
1. Connect the Y-piece to Test Port “T”.
2. Install the Manual Bag.
3. Adjust APL valve to 30 cmH_2O.
4. Adjust all flowmeters to zero.
5. Set Fresh Gas switch to Circle absorber.
6. Select “Continue”.

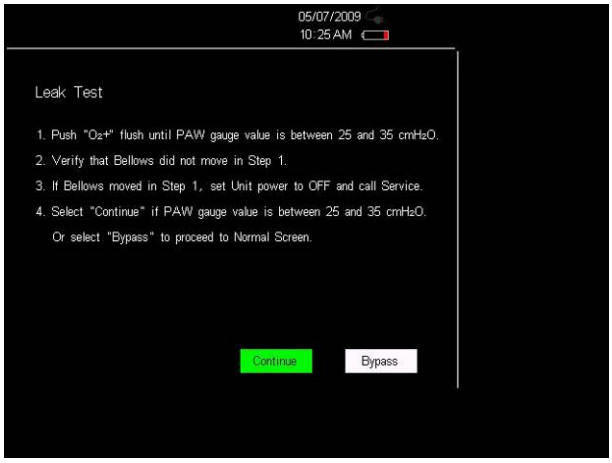


Figure 4-5 Manual Leak Test

Perform the manual leak test according to the instructions pictured in Figure 4-5:
1. Push O_2 flush button until Paw gauge value is between 25 cmH_2O and 35 cmH_2O.
2. Verify that bellows did not move while performing step 1.
3. If bellows moved during step 1, turn off Power Supply and contact manufacturer.
4. Select “Continue” if Paw gauge index is between 25 cmH_2O and 35 cmH_2O.

4.1.3 Safety Valve Test

Click the “Continue” to perform Safety Valve Test as shown in Figure 4-6:

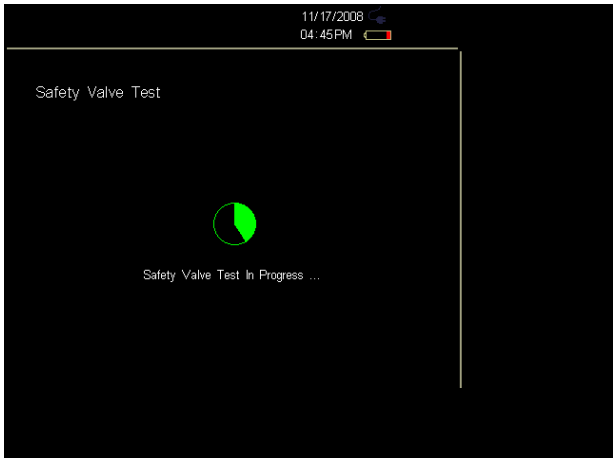


Figure 4-6 Safety Valve Test in progress.

When test is complete, screen will display the following:

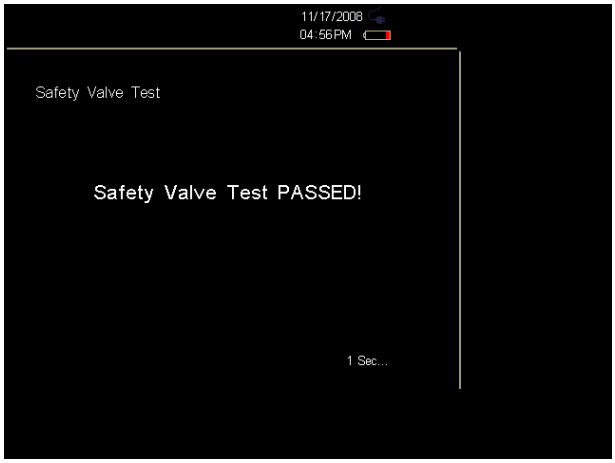


Figure 4-7 Safety Valve Test Pass interface

4.1.4 Automatic Leak Test

When the Safety Valve Test is complete, the Automatic Leak Test is displayed on the screen.

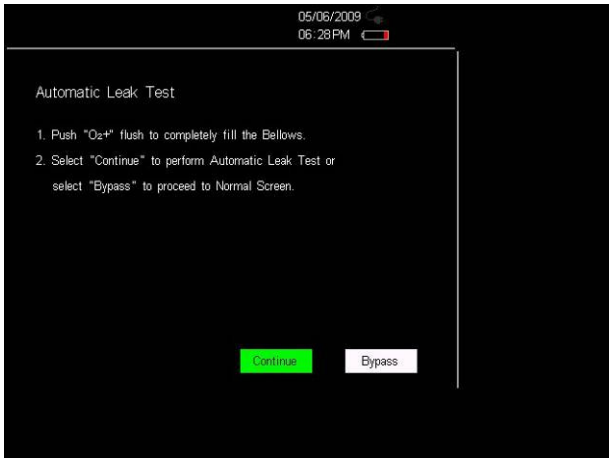


Figure 4-8 Automatic Leak Test

Click “Continue” to perform the Leak Test.

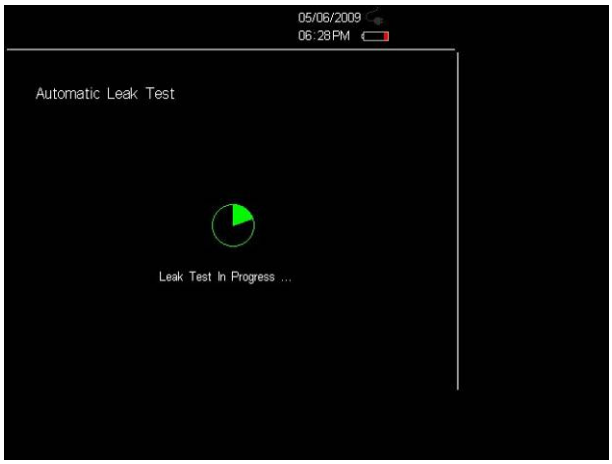


Figure 4-9 Automatic Leak Test in progress

When the leak test is complete, the following is displayed:

Figure 4-10 Automatic Leak Test Pass interface

4.1.5 Compliance Test

Click “Continue” to perform the Compliance Test.

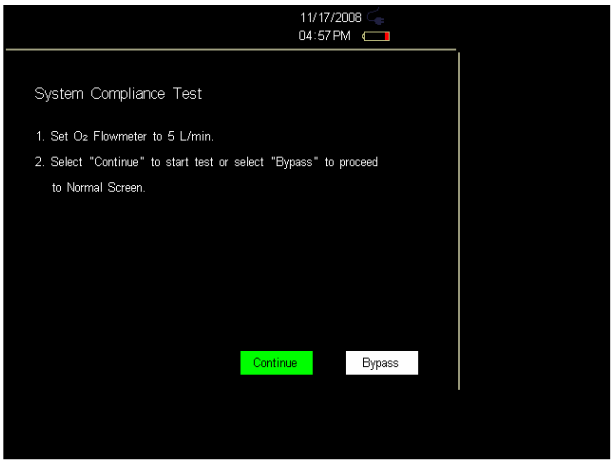


Figure 4-11 Compliance Test

Perform the Compliance Test according to the instructions pictured in Figure 4-11:
1. Set O_2 flow to 5 L/min.
2. Select “Continue” to start test or select “Bypass” to proceed to Normal Screen.

Click “Continue” option to perform the Compliance Test.

Figure 4-12 Compliance Test in Progress

The following will appear after the Compliance Test is complete:

Figure 4-13 Compliance Test Complete interface

Complete the Compliance Test according to the instructions shown in Figure 4-13:
1. Set O_2 flowmeter to zero.
2. Select “Continue” to proceed to Normal Screen.

Click “Continue” and the STANDBY screen will appear:

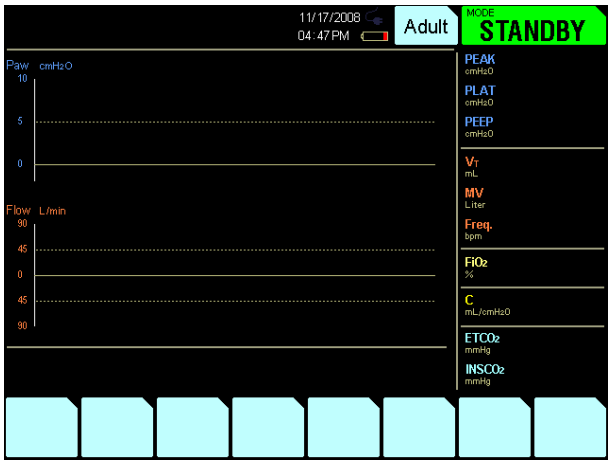
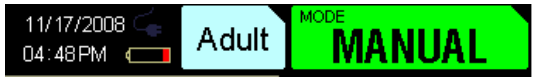


Figure 4-14 STANDBY interface

4.1.6 Ventilation Mode Setup

The current Ventilation mode is shown at top right corner of the display, with the arrow pointed up.



STANDBY mode
IPPV mode
PCV mode
SIMV mode
PS mode
Manual mode

Step 1: Turn the knob and point the cursor to the current ventilation mode.

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

Step 2: Press the knob to ensure the grounding changed.

Step 3: Turn the knob to select the required ventilation mode.

Step 4: Press the knob for the pre-election state; setting parameters can then be changed.

Step 5: Point cursor to the ventilation mode and press the knob to save the setup.

4.1.7 Breathing Parameters Setup

Step 1: Turn the knob and point the cursor to the corresponding parameter.

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

Step 2: Press the knob to ensure the grounding changed.

Step 3: Turn the knob to select the required ventilation mode.

Step 4: Press the knob to save the setup.

4.2 Start Mechanical Ventilation

⚠ **WARNING: Before beginning, set the patient circuit installing and controlling correctly. The following procedures assume that the system is on and the manual reservoir gas is in ventilating mode.**

Step 1: Check that the control settings coincide with the clinical settings.

Step 2: Select “Auto Ventilation”. To adjust settings, refer to section 4.1.6.

Step 3: If necessary, push the O_2 flush button to inflate the bellows.

4.2.1 Stop Mechanical Ventilation

Set ventilation mode to Manual or STANDBY mode.

4.3 Start Manual Ventilation

Step 1: Before starting manual ventilation, connect the reservoir bag to the gas operation port and ensure the APL valve setting is correct. The APL valve is used to adjust the pressure limit of the breathing system during the manual ventilation period.

Step 2: Set the ventilation mode to “Manual”, or press the “MANUAL/AUTO" key. To use the reservoir bag to perform manual ventilation if necessary, push the O_2 flush button to inflate the reservoir bag.

4.3.1 Stop Manual Ventilation

Set Ventilation Mode to STANDBY mode.

Manual ventilation can also be stopped by not pinching the reservoir bag or by pressing the “MANUAL/AUTO" key, which will revert the system to mechanical ventilation.

4.4 Shutdown

Turn off gas supply and set the ventilation mode to “Standby” after the gas within the system is emptied. Turn off the power.

4.5 Waveforms

1. Paw-t Waveform

Y-Axis: airway pressure; X-Axis: time. For more details, refer to section 10.8.6.

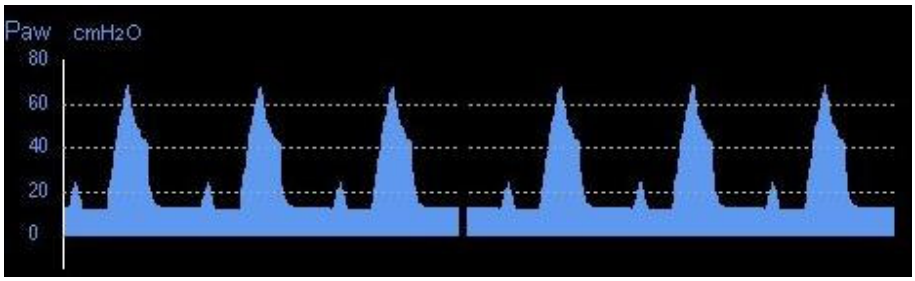


Figure 4-15 Paw-t waveform

2. Flow-t Waveform

Flow scale: -90~90 L/min.
Time-Axis: Positive inspiratory direction above 0 L/min level; minus expiratory direction below 0 L/min level; no gas flow on 0 L/min level.

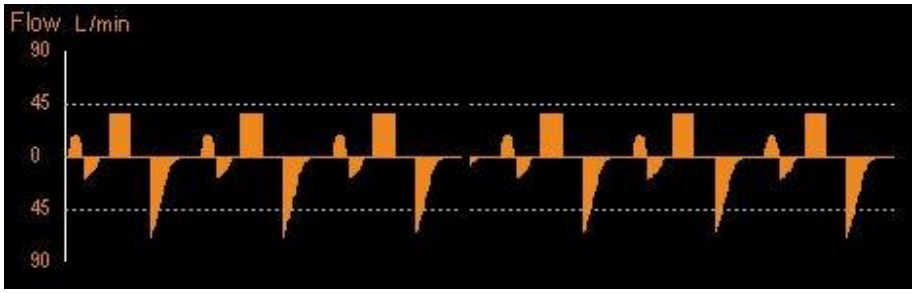


Figure 4-16 Flow-t waveform

3. CO_2- t Waveform

Y-Axis: CO_2; X-Axis: time.

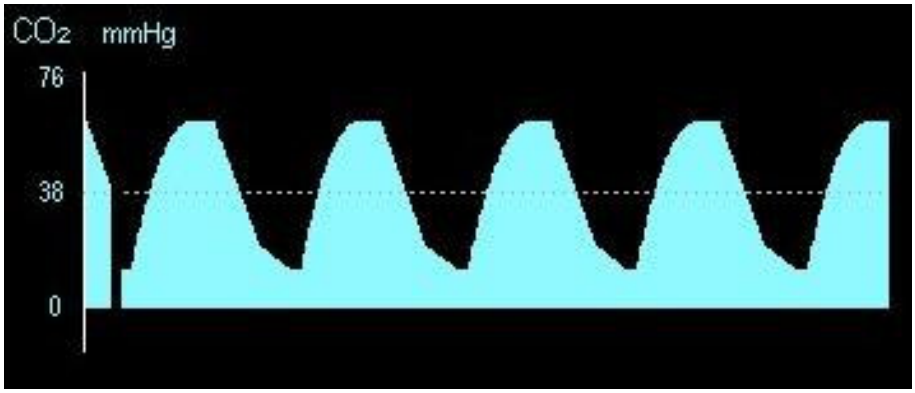


Figure 4-17 CO_2- t waveform

4. Pressure-Volume Loop

Y-Axis: tidal volume; X-Axis: pressure.

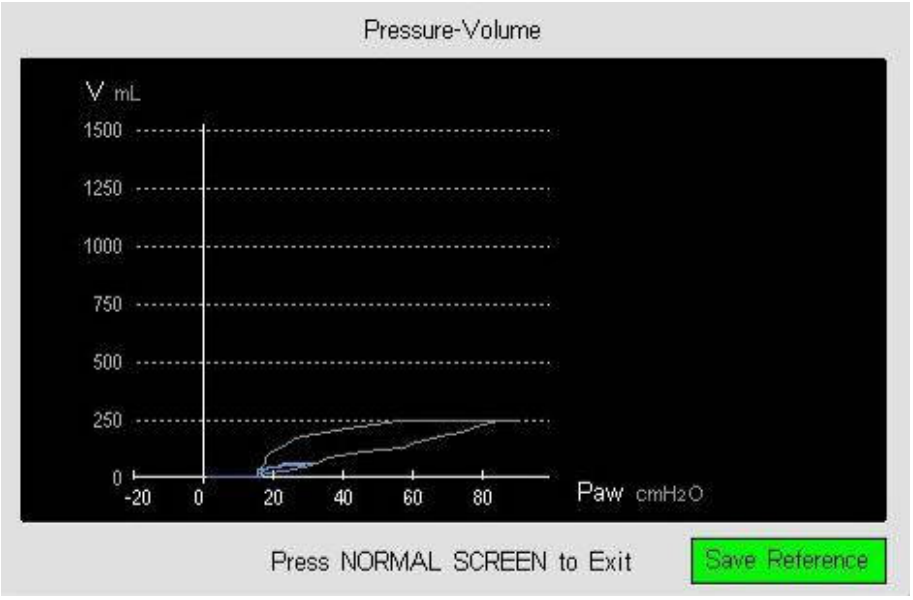


Figure 4-18 Pressure-Volume Loop

5. Flow-Volume Loop

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

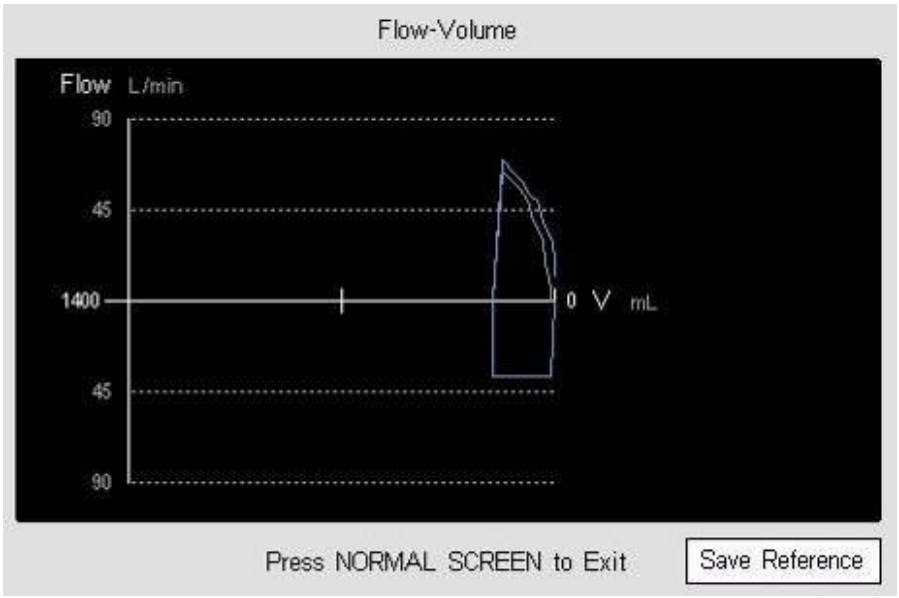


Figure 4-19 Flow-volume Loop

The “Save Reference” option can be used to preserve a loop for future reference. When a loop is currently being displayed, or no loop is currently being displayed, Press “Save Reference” when either a loop is currently being displayed or no loop is being displayed, and the next complete loop (inspiration and expiration) will be saved as a reference.
After “Save Reference” is pressed down, the Pressure-Volume loop and Flow-Volume loop are simultaneously preserved.
When “Save Reference” is pressed again, the system immediately deletes the current preserved Pressure-Volume loop and Flow-Volume loop and preserves the two new reference loops.
When a user exits the loop function, the preserved loops are saved. When the working mode is STANDBY, the two function loops are deleted.

5 Pre-use Check List

5.1 Pre-use Check List Procedure

Test interval: Pre-operative Checkout should be done each day prior to use by the first patient; prior to the use of each subsequent patient, and after repair or maintenance.

The test schedule appears in the table below:

Prior to use by the first patient each day	**Prior to use by 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 until the operation and maintenance manuals have been read and understood.**

- Whole system connection
- All warnings and cautions
- User guide for each system module
- Testing method for each system module

Before using this system:

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

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

5.1.1 Check System

⚠ **WARNING:** **Ensure 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 and the breathing system contains sufficient absorbent.
4 Vaporizer is in lock position and is filled with sufficient anesthetic.
5 The connection and pressure of pipeline gas supply system are correct.

⚠ **WARNING:** **Do not leave the cylinder valves open during pipeline gas supply period. The cylinder gas supply could be emptied and lead to insufficient supply in case of pipeline malfunction.**

6 The required emergency device is ready and in good condition.
7 The device for airway maintenance and organ cannula are ready and in good condition.
8 The applicable anesthetic and emergency medicine are ready.
9 Tighten and lock the truckles to ensure they are free of motion.
10 Connect the power cord to the AC power outlet. The power indicator light will glow when power is connected. If the indicator does not glow, power is not being supplied to the machine. Plug the power cord into a different socket, close the breaker, or replace the power cord.

5.1.2 Main Failure Alarm Test

1 Turn on the power. Screen will display the stand-by interface after running the self-test.
2 After 5 minutes, unplug the power cord.
3 Check the “Power Off Failure Alarm”; it has the following characteristics:
   a) Alarm sounds
   b) “Mains Failure!” message displays on the screen
   c) Mains icon flickers
4 Reconnect power cord.
5 Alarm will stop.

5.2 Test Gas Supply Pipeline

⚠ **CAUTION:** **A user must confirm that gas supply is connected correctly. The pressure should be correct and there should be no leakages or faulty connections in the gas circuits. Stop using immediately and check gas connections if any of the above occur.**

Disconnect all pipeline gas supplies if the reading of the pipeline pressure gauge is not zero.

- Switch on O_2 supply.
- Adjust flow control to middle range.
- Make sure the N_2O pressure gauge is reset to zero.
- Switch off O_2 supply.
- Make sure the O_2 pressure gauge is reset to zero. The low O_2 supply alarm should sound when pressure drops.

5.3 Monitoring Flow Control

⚠ **WARNING:** **Refer to Step 1 to 14 of *Monitoring without Oxygen* for monitoring without oxygen.**
Refer to Step 1 to 13 of *Monitoring with Oxygen* for monitoring with oxygen.

5.3.1 Monitoring without Oxygen

⚠ **WARNING:** **The monitoring system cannot be replaced by a link system. A fresh supply of gas that contains oxygen may not sufficiently increase the level of oxygen 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 control valve should be adjusted slowly. Do not turn it quickly when the reading of the flowmeter goes beyond the maximum or minimum flow rate; the control valve could be damaged and/or break.**

Follow the steps to test the flow control:

1. Connect the pipeline gas supply or open the cylinder valves slowly.
2. Turn counter-clockwise O_2, N_2O, AIR flow control valve.
   Make sure no gas flows in the flowmeter.
3. Turn on the Pneumatic and Electronic Switch and choose the "O_2+N_2O" option.
4. Do not use this system if the battery is not fully charged or other ventilator failure alarm occurs.
   - Step 5 and step 6 are only applicable for the N_2O system test.

⚠ **WARNING:** **During Step 5 and Step 6, continue to use the link systems.**
Only adjust control test (N_2O in step 5 and O_2 in step 6).
Adjust flow according to order (N_2O first, O_2 second).
If adjustable range is exceeded, adjust flow control and perform this step again.

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

N_2O flow (liters per minute)**:**	**O_2 flow (must be higher than the minimum flow)** (liters per minute):
1.5	0.5
3	1
6	2
9	3

6. Test the function of the link system when flow is reduced.

N_2O flow (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

7. Adjust full flow of all gases to ensure that the flowmeter float moves smoothly.
8. Shut off the oxygen supply by closing the oxygen cylinder valve or by disconnecting the oxygen pipeline supply.
9. When using the flow control:
   - 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.
   - If the oxygen is the driving gas of the ventilator, the oxygen-supply failure alarm must continuously sound.
10. Turn all flow control valves completely clockwise to close.
11. Change the Pneumatic and Electronic Switch to "O_2+AIR".
12. Adjust full flow of O_2 and AIR to ensure that the flowmeter float moves smoothly.
13. Adjust the knob of the N_2O flowmeter and ensure that there is no gas in the flowmeter.
14. Turn off the Pneumatic and Electronic Switch.

5.3.2 Monitoring with Oxygen

⚠ **WARNING:** **The monitoring system cannot be replaced by a link system. A fresh supply of gas that contains oxygen may not sufficiently increase the level of oxygen in the breathing circuit.**
If N_2O exists, it will pass through the system during the test, which should be securely collected and properly disposed of.
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 testing, perform test of the O_2 monitoring device according to step 8 in section 5.3.1.**

Follow the steps to test the flow control:
1. Connect the pipeline gas supplies, or slowly open the cylinder valve.
2. Turn all flow control valves completely clockwise to the end.
3. Turn on the Pneumatic and Electronic Switch.
4. Do not use this system if the battery is not fully charged or other ventilator failure alarms occur.
5. While testing the flow control, be sure gas is not flowing through any flow tubes. Step 6 and step 7 are only applicable for the N_2O system test.

⚠ **WARNING:** **During Step 6 and Step 7, continue to use link systems.**
Only adjust testing of control (N_2O in step 6 and O_2 in step 7).
Adjust flow according to order (N_2O first, O_2 second).
The oxygen sensor must be calibrated correctly.

6 To test the flow increase of the link system:
- Turn the N_2O and O_2 flow control clockwise to the end.
- Turn the N_2O flow control slowly counterclockwise.
- Check that the O_2 flow is increasing. The concentration of the oxygen tested must ≥ 25% during the complete process.

7 To test the flow increase of the link system:
- Set the N_2O flow to 9 L/min.
- Set the O_2 flow to 3 L/min or higher.
- Turn the O_2 flow control valve slowly clockwise.
- Check that the O_2 flow is being reduced. The FiO_2 tested must ≥ 25% during the complete process.

8 Adjust the gases to full flow to ensure that the flowmeter floats moves smoothly.
9 Shut off the O_2 supply by closing the O_2 cylinder valve or by disconnecting the O_2 pipeline supply.
10 While testing, be sure:
- As pressure decreases, the oxygen-supply failure alarm sounds continuously.
- 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 sound continuously.

11 Turn all flow control valves completely clockwise to the close.
12 Reconnect O_2 pipeline supplies or open the O_2 cylinder valve slowly.
13 Turn off the Pneumatic and Electronic Switch.

5.4 Installing and Testing Vaporizer

5.4.1 Installation

⚠ **WARNING:** **Do not remove the vaporizer from the bypass valve with its locking lever locked.**
Do not use more than one vaporizer simultaneously with this system.

Install vaporizers by following these 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. Lift the vaporizer straight up to separate it from the bypass valve, but do not pull the vaporizer forward. Be careful not to rotate it on the bypass valve.
4. As the vaporizer separates from the bypass valve, reinstall the vaporizer and then follow step 1 to step 3. Do not use this system if it is not positioned horizontally on the bypass valve.
5. Attempt to open two vaporizers at the same time. If more than one vaporizer can be opened at the same time, disassemble and reinstall them. Then perform step 1 to step 5.

5.4.2 Testing Vaporizer

⚠ **CAUTION:** **Refer to relevant instructions for use regarding the performance testing of the vaporizer.**

5.5 Alarm Test

1 Connect simulation lung to patient.
2 Turn on power switch.
3 Set control options:

Ventilation mode:	CMV mode
Ventilator:	V_T: 700 ml f: 20 bpm I:E: 1:2 P_{limit}: 40 cmH_2O
Anesthetic machine:	All gases: closed Press O_2+ button to inflate bellows.

4 Set ventilation mode to manual ventilation, and reset to CMV control.
- Be sure: Auto ventilation starts.
- Correct data is displayed on the screen.
- Ventilator should bellow up and down during auto ventilation.

5 Adjust O_2 flow to 5 L/min.
6 Be sure:
- Pressure at the end of expiration is between 2~3 cmH_2O.
- Correct data is displayed on the screen.
- Ventilator bellows up and down during auto ventilation.

7 Test O_2 monitoring and alarm:
- Remove O_2 sensor and confirm that O_2 concentration measured in the room is about 21%.
- Adjust lower limit of O_2 concentration to 50%; the "Low FiO_2!!" alarm should sound.
- Adjust lower limit of O_2 concentration to 21% again; the alarm should stop.
- Adjust O_2 sensor back to AC110.
- Adjust upper limit of O_2 concentration to 50% again.
- Press "O_2 Flush" to charge the breathing system; the "High FiO_2!!" alarm should sound.
- Adjust upper limit of O_2 concentration to 100%; the alarm should stop.
- Let O_2 sensor pass pure O_2 for 2 minutes; O_2 concentration should measure about 100%.

8 Test low minute volume alarm:
- Turn to "Alarm" submenu.
- Adjust lower limit of MV to 16 L/min; the "Low Minute Volume!!" alarm should sound.
- Turn to "Alarm" submenu again.
- Adjust lower limit of MV to 10 L/min; the alarm should stop.

9 Test high airway pressure alarm:
- View PEAK on the screen.
- Adjust lower limit of Paw to below PEAK; the "High Airway Pressure!!!" alarm should sound.
- Adjust lower limit of Paw to above PEAK; the "High Airway Pressure!!!" alarm should stop.

10 Test low airway pressure alarm:
- Remove reservoir bag from the absorber circle.
- An alarm, such as "Low Minute Volume!" alarm should sound.
- "Low Airway Pressure!!" alarm should sound.

11 Test continuous high airway pressure alarm:
- Set control options:
  APL valve: Set to the maximum value
  Ventilation mode: Bag
- Set ventilation mode to Manual Mode and auto ventilation should stop.
- Block patient end and press O_2+ button.
- "Continuous Pressure!!!" alarm should sound after 15 seconds.

12 Turn off the Pneumatic and Electronic Switch.

5.6 Breathing System Test

Confirm the non-return valve in the Breathing Circuit module works normally:
The non-return exhalation valve will ascend during the exhalation period and 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 a testing plug small enough to slip completely into the breathing system.

5.6.1 Check O_2+ Button

Press the O_2+ button (the sound of gas should be heard from the fresh gas outlet) then release. The button should immediately drop back to its normal position and stop delivering gas.

5.7 Ventilator Test

1 Connect the simulation lung to the patient end.
2 Turn on Power Switch.
3 Set control options:

Ventilation mode:	CMV mode
Ventilator:	V_T: 700 ml f: 20 bpm I:E: 1:2 P_{limit}: 40 cmH_2O
Anesthetic machine:	O_2 flow: less than 200 ml All other gas: closed

4 Press the O_2+ button to inflate the bellows.
5 Be sure:
- Auto ventilation starts.
- No low pressure alarms sound.
- Ventilator displays the correct data.
- The bellows ascend and descend during auto ventilation.

6 Set the O_2 flow control to 5 L/min.
7 Ensure:
- Ending expiratory pressure is between 2~3 cmH_2O.
- Ventilator displays the correct data.
- The bellows inflate and scavenge during auto ventilation.

8 Set the ventilator control and alarm limits to the proper clinical level.
9 Turn off main supply and close all gas cylinder valves if not using the system.
10 Ensure that the following items are complete:

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

11 System preparation:

- Close all vaporizers.
- Open the APL valve.
- Set the bag / ventilator switch to “Bag Control”.
- Set all flow controls to minimum.

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

⚠ **WARNING: Flush the anesthesia machine for at least one minute by using O_2 with 5 L/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 prevent the bodily injury. This must be followed during testing and clinical application.**

6 Installation and Connection

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

⚠ **CAUTION:** **According to the 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 done while the anesthetic vaporizer is being used according to the European standard EN 740 and International Standard IEC 60601-2-13 / ISO 8835-1.**

⚠ **WARNING:** **The operating room environment can be affected by expiratory gas. To prevent damage and/or injury, the anesthetic must be tested regularly. The operator must dispose of expiratory gas in a timely fashion and examine all parts to minimize damage and malfunction.**

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

⚠ **WARNING:** **To prevent data reporting errors and malfunction, use cables, hoses, and tubes supplied by HEYER.**

⚠ **CAUTION:** **Anesthetic in the absorber is dangerous. Ensure the soda lime in the absorber does not dry out. Turn off all gas supplies when finished 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:**

- **Keep the electricity surgical conducting wire away from the breathing system and the O_2 sensor.**
- **Do not put the electricity surgical conducting wire on any parts of the anesthetic system.**

⚠ **CAUTION:** **To protect the patient while the electrical surgical equipment is being used:**

- **Monitor and ensure that all life supporting and monitoring equipment are working correctly.**
- **Ensure that the backup manual ventilator can be used immediately if the electrical surgical equipment fails.**
- **Never use masks or hoses that can conduct electricity.**

6.1 Install the Absorber Canister

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

- **Do not use the absorber if the anesthetic is chloroform or trichloroethylene.**
- **The materials in the absorber are dangerous; avoid contact with the skin or eyes. If contact occurs, clean the affected area immediately and seek medical attention. Do not replace absorber during ventilation.**
- **Do not replace the absorber if the Breathing System is in operation.**
- **Replace the absorbent often to prevent the deposits of non-metabolic gas when the system is turned off.**
- **Check the color of the absorbent after each use. The original color of the absorbent may be restored when not in use. Refer to the labels on the absorbent for additional details.**
- **Carbon monoxide is released if completely dried absorbent comes into contact with the anesthetic. Replace the absorbent for security.**
- **Perform leakage testing of the breathing system in manual mode after installing the absorber.**

The absorber in this system can be used repeatedly.
The capacity of each absorber canister is 1500 ml.
Only Air, Oxygen, Nitrous Oxide, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane are used for the absorber.

6.1.1 When to Replace Absorbent

Change in color of the soda lime in the absorbent indicates that it has absorbed carbon dioxide; however, this color is not 100% accurate. To decide whether to replace the absorbent, use the CO_2 monitoring machine.
Immediately remove absorbent that has changed color. Soda lime sometimes reverts to its original color several hours after use.

6.1.2 Disassembling Absorber

The absorber is reusable. Follow the disassembling procedures:

1 Turn the absorber clockwise and then disconnect it according to directions on the absorber. Turn the absorber counter-clockwise to re-install.

6.1.3 Filling Absorbent

1. Remove the absorbent from the absorber.
2. Clean and sterilize according to section 7.3.1.1.
3. Fill the absorber with fresh absorbent once the canister is dry. Wipe soda lime off the edge of the absorber, and then re-install it. Ensure the canister is airtight and that there is no leakage or spillage.

6.2 Connecting Tubes and Lines

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

⚠ **CAUTION:** **Anesthetic machine should be used with anesthetic agent monitor. Anesthetic agent monitor (e.g. Datex-ohmeda S/5 Anesthetic gas monitor) should be used in accordance with ISO 21647:2004 and should be connected at the Y-piece installed at the inspiratory port.**

⚠ **CAUTION:** **O_2 sensor should be connected at inspiratory port of anesthetic absorber circle.**

Step 1: Connect breathing tube.
Connect the two tubes on the inspiratory and expiratory ports, respectively. Connect the Y-piece to the patient end.

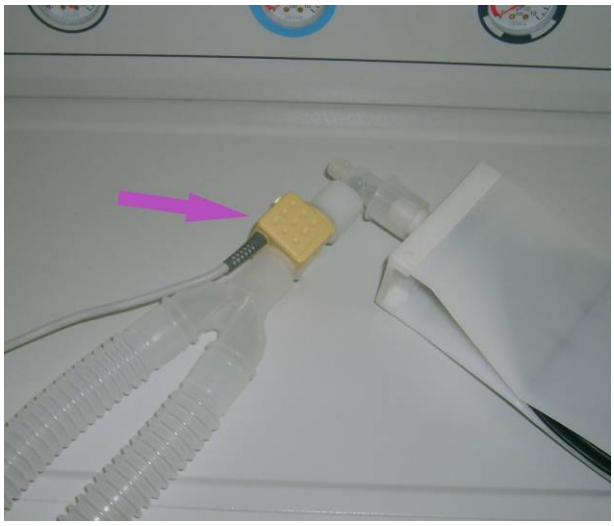
Step 2: Connect reservoir bag.
Connect the reservoir bag onto the bag arm port of the breathing system.

Step 3: Connect oxygen sensor.
Connect the oxygen sensor between the inspiratory port of the breathing system and patient system. Turn and insert the oxygen sensor vertically in the connector.

Step 4: Connect the oxygen sensor cable.
Connect one end of the cable (RJ11 connector) to the bottom of the oxygen sensor. Connect the other end of the cable (round connector) to the oxygen sensor port at the side of the machine.

6.2.1 Connect CO_2 Monitor

Step 1
Connect one end of the CO_2 monitor to the Y-piece of the patient end and the other end to the reservoir bag.



Step 2
Plug the data connecter into the COM A port at the back of ventilator.

6.2.2 Connect Anesthetic Agent Monitor

Step 1
Connect one end of the anesthetic agent monitor to the Y-piece of the patient end and the other end to reservoir bag.

Step 2
Plug the data connecter into the COM-A port of the back of ventilator.

6.3 Connecting Gas and Electricity

⚠ **WARNING:** **IEC 60601-1-1 applies to combining 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 main 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 main 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 one or more devices connected to it to shut down 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:** **Note that all gas supply connectors have different dimensions and structures.**

6.3.1 AC Inlet

AC Power: 100~240 VAC 50/60 Hz; 8A Max.
Fuse: 250V / 10A, ∅5X20 (F)
Power cable is fixed on the mainframe.

Refer to section 8.5 for replacing the fuse.

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

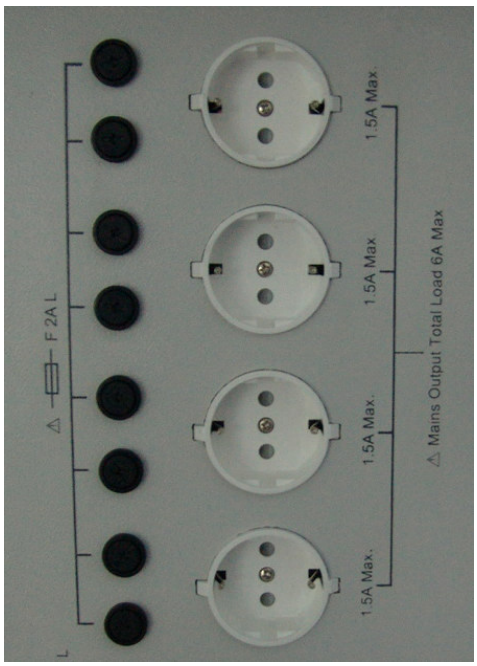
6.3.2 Aux. Mains Outlet

⚠ CAUTION **No more than four auxiliary mains socket outlets should be used when HEYER Pasithec in use.**

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

Fuse: 250V / 2A, ∅5X20 (F)
Maximum current outlet: 1.5A (each); 6A (total)

Refer to section 8.5 for replacing the fuse.



6.3.3 Communication Port

Two RS-232 ports (COM-A and COM-B) on the rear of the display are communicating ports. The connection of RS-232 permits serial inlet and outlet of command and data.
The interface of COM-A port is a DB9/M needle connector and is used for data communication or to connect the gas monitor module. The Signal Definition of the port is DTE.

Pin #	Signal Name	Signal Description
2	RXD	RS232 Receive Data, input of the machine.
3	TXD	RS232 Transmit Data, output of the machine.
5	GND	Signal Ground / Common
9	5V	DC5V power, provide output power in gas monitor module, <200mA. In data communication, this pin and the RI output signal of RS232C indicates electrical compliance.
Other	NC	Not connected.

The interface of COM B port is a DB9/M hole connector and is used for data communication. The Signal Definition of the port is DCE.

Pin #	Signal Name	Signal Description
2	TXD	RS232 Transmit Data, output of the machine.
3	RXD	RS232 Receive Data, input of the machine.
5	GND	Signal Ground / Common
Other	NC	Not connected.

6.3.4 Gas Inlet Module

The Gas Inlet Module includes pipeline gas supply and standby gas supply.
The pipeline connector and standby gas supply connector all adopt DISS (Diameter-indexed safety system), which can prevent wrong connections.

7 Cleaning and Disinfecting

⚠ **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 operation and maintenance manual of all sterilizing equipment.**
- **Wear safety gloves and safety goggles. The O_2 sensor may leak and burn (by Chlorine Potassium Oxide) if damaged. Do not inhale fumes.**
- **Do not inhale fumes.**

⚠ **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 solvents, anesthetics, glass agents, acestone, or other irritating agents.**
- **Never use an abrasive agent to clean any of the components (i.e., steel wool, silver polish, etc.).**
- **Keep liquids away from the electrical components.**
- **Do not allow liquids to enter the equipment.**
- **Do not immerse the synthetic rubber components more than 15 minutes; any longer will cause inflation or accelerate aging.**
- **Only the components marked 134℃ are pressure-resis tant 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 could cause injury to a patient's respiratory system or esophagus.**

⚠ **CAUTION:** **Never immerse the circuit O_2 sensor or flow sensor connector in liquid.**
Do not clean the inner surface of the flow sensor. Clean the outer surface with a damp cloth.

Check for damage to the components. Replace if necessary.

7.1 Cleaning and Disinfecting prior to first Use

Complete 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 hydro peroxide or formaldehyde steaming.
Breathing system components	Refer to section 7.2.
Breathing System	Wash, refer to section 7.3.
Bellows	Wash, refer to section 0.

7.2 Cleanable Breathing System Components

Corrugated tubing (contacted with patient), face mask, Y-piece connector, L-piece, reservoir bag	Designed for using only once, no need to sterilize. The waste should be recovered. When replacing, ensure new products have the same specifications.
Corrugated tubing and bag (repetitious)	Wash to sterilize

7.3 Absorber Circle

Component	Wiping method Soap water	Cleaning method Soap water	Chemicals Cidex	Sterilization Steam autoclave	Maximum temperature (℉/℃)
Absorber canister	yes	yes	yes	no	
Airway pressure gauge	yes	no	no	no	
APL valve	yes	yes	yes	no	
Valve cover and valve patch	yes	yes	yes	no	
Absorber circuit integration (without the above mentioned)	yes	yes	yes	yes	273℉/134℃

7.3.1 Disassembling Absorber Circle

Step 1
Lock the castors of the machine to prevent movement.

Step 2
Turn the handle (arrow pointed) of absorb circle 90° counter-clockwise from closed state.

Step 3
Hold the handle (see arrow) of absorb circle with two hands and then pull it out horizontally from the supplying board of absorb circle.
The red part of the supplying board is a heater. Do not touch it!

7.3.1.1 Absorber Canister

Refer to “Disassembling the Absorber” in section 6.1.2.

- **Auto cleaning with agent or disinfector**

Clean the absorber in the agent or disinfector according to the specified cleaning procedure.
Put the absorber in the heat-up room and set at room temperature or a maximum temperature of 80℃.
Higher-level sterilization is recommended if the agent and disinfector cannot sterilize equipment.

- **Manual cleaning**

Rinse the absorber.
Immerse the absorber completely in the sink filled with water and cleaning agent for three minutes at a temperature of 40℃.
Rinse the absorber.
Higher-level sterilization must be performed after cleaning by hand.

- **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 80℃ (176℉).
Put the soda lime into the absorber after drying; tighten the knob. Clear all soda lime debris.

7.3.1.2 Airway Pressure Gauge

Clean the Airway pressure gauge with a soft cloth soaked with a water soluble sterilizing agent.

7.3.1.3 APL Valve

Clean APL valve with soft cloth soaked with a water soluble sterilizing agent. Dip in soap water or cidex solution to clean and disinfect.

7.3.1.4 Inspiratory Valve and Expiratory Valve

Dismount the cover of the inspiratory and expiratory valves by rotating them counter-clockwise.
Remove the valve patch, clean the valve seat and put back together.
Clean cover of the inspiratory and expiratory valves and valve patch with gauze soaked in a water soluble sterilizing agent.
After all parts are cleaned and dry, replace them.
Check for leakage and the movement of the inspiration and expiration valves according to instructions in the manual.
Handle all parts with care to prevent damage.

7.3.1.5 Absorber Circle Integration

Steam (not more than 50℃) or immersion disinfectio n can be used. In case of immersion, all sterilized parts must be dried with high pressure air or oxygen before reuse.

7.3.1.6 Installing Absorber Circle

When installing, pull the supply board of the absorber circle as far as it will go. Hold the handle (see arrow) of absorb circle with two hands and insert it in the supply board. Push the supply board and absorber circle together to ensure a tight seal with seat module.

Turn the handle (see arrow) of absorber circle 90° clockwise from open to lock the circle.

7.3.2 Bellows Assembly

This section covers disassembling, assembling, cleaning and sterilizing the bellows assembly. Read all parts of this section before disassembling, assembling, cleaning and sterilizing to avoid equipment damage and/or patient injury.

⚠ **CAUTION: Only the folding gasbag is made of latex.**

7.3.2.1 Disassembling

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

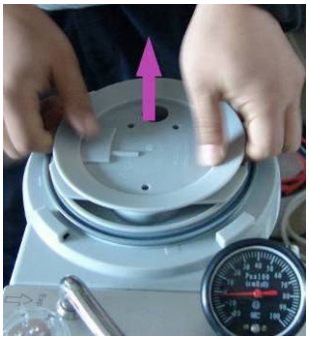
1. Bellows assembly is fixed on the absorber cycle. Turn counterclockwise and remove the bellows housing.

2. Detach the folding gasbag.

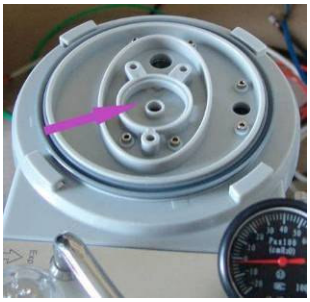
3. Detach the top plate from the folding gasbag, and remove inner ring from the top of folding gasbag.

4. Turn counter-clockwise and remove the three black handles from the rim.

5. Remove the rim.



6. Remove the pressure-relief valve diaphragm and the seal.
   Note: Install pressure-relief valve diaphragm on tray, then attach to the base of the bellows.



7.3.2.2 Cleaning and Sterilizing

Follow the machine and sterilizer manufacturer's cleaning recommendations.

Cleaning

1) Disassembling.

⚠ **WARNING:** **Never separate the diaphragm and the valve seat in a pressure-relief valve.**

2) To prevent component damage, clean lightly with recommended non-enzyme mild agent for use with latex and plastic in hot water.

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

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

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

4) Check the components if they are broken or damp, and then perform the assembling and function test.
5) Connect the bellow assembly, ventilator and breathing system.
6) Perform the preoperative check.

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/cm^2 steam pressure, the temperature rises to 121℃. 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 that had indirect contact 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.

7.3.3 Regular Maintenance

⚠ **WARNING:** **To avoid patient injury, do not perform any tests or repairs when the equipment is in use.**

Perform the following check every 30 days to ensure that component worn by use and daily cleaning are replaced in a timely manner.

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 pressure-relief 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.

8 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 in 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: Shock and strong vibration during transportation can break the fragile glass cover of the flowmeter.**

⚠ **WARNING: Disposal of waste or invalidated apparatus must be in accordance with local laws.**

8.1 Repair Policy

Do not use malfunctioning equipment. Make all necessary repairs, or have the equipment serviced by an authorized HEYER Service Representative. After repair, test the equipment to ensure that it is functioning properly and in accordance with the manufacturer's published specifications.
To ensure full reliability, have all repairs and service done by an authorized 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 damaged parts be replaced with components manufactured or sold by HEYER. After any repair work, test the unit to ensure it complies with the manufacturer's published specifications.
Contact the nearest HEYER Service Center for service assistance. In all cases, other than where our warranty is applicable, repairs will be made at current list price for the replacement part(s) plus a reasonable labor charge.

8.2 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.

8.2.1 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 moves up and down smoothly. It can prevent blocking and clinging.
Monthly	Perform 100% O_2 sensor calibration. Test leakage of bellows assembly.
When cleaning and installing	Check if any components are broken, and replace or repair them if necessary.
As required	Replace O_2 sensor (one year generally). Open the drain valve and replace absorbent in the absorber.

8.2.2 Useful Life Estimation

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

Main unit	5 years
Components	5 years
Vaporizer	5 years
Absorb circle	5 years

8.2.3 Replacement of Consumable Parts

Parts are replaced at multiple intervals from the date of installation.

Consumable parts	6 months	12 months	36 months
Check/replace internal battery (3 years)	Not needed	Check	Replace
Check/replace folding bag	Not needed	Check	Replace
Check/replace U-shaped ring (U-ring)	Not needed	Check	Replace
Check/replace O-shaped silicone airtight ring ∅6X1.8 (for micromanometer)	Check	Replace	Replace
Check/replace O-shaped silicone airtight ring ∅4X1.8 (for micromanometer)	Check	Replace	Replace
Check/replace O-shaped rubber airtight ring 14×2.65 (on by-pass valve).	Check	Replace	Replace
Replace O_2 sensor	Check	Replace	Replace

8.3 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.

8.3.1 Replace O_2 Sensor

⚠ **WARNING: Follow local laws when disposing of biohazardous materials. Do not burn.**

Replacement steps:

1 Pull out the connector of sampling line from O_2 sensor.
2 Replace it with a new one, and connect the sampling line to O_2 sensor.

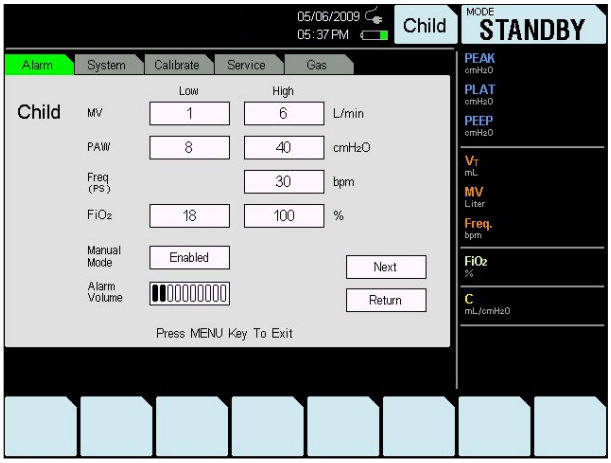
8.3.2 Calibrate O_2 Sensor

⚠ **WARNING: Do not perform the calibration steps when the system is connected to a patient.**
When calibrating 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.

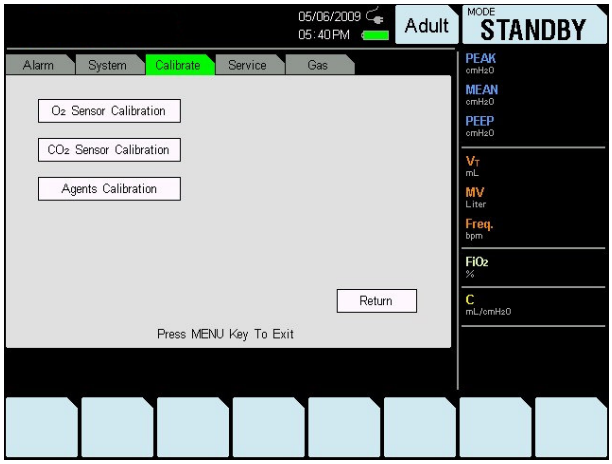
8.3.2.1 Calibrate 21% O_2 Sensor

It takes 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.

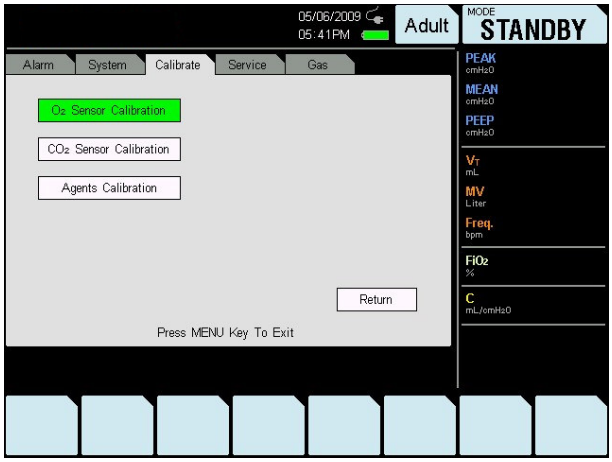
Step 1
Press MENU key and a menu window appears on the screen.



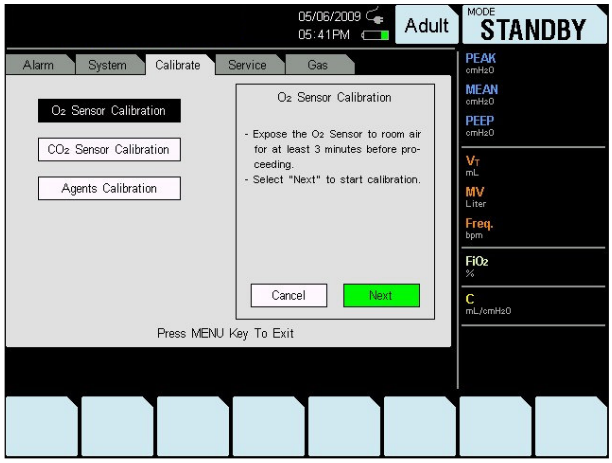
Step 2
Turn the knob to select “Calibrate” submenu.



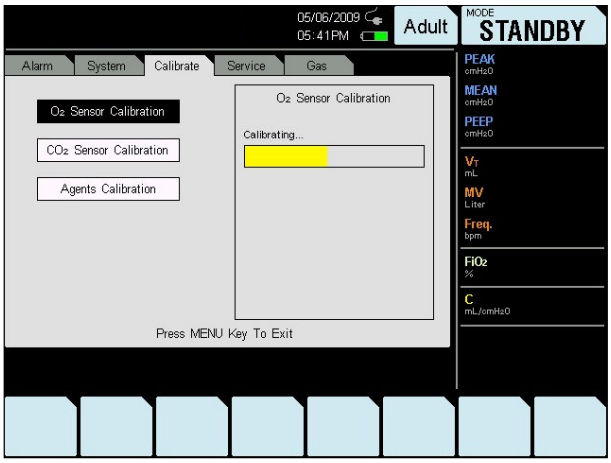
Press the knob and the cursor appears on the O_2 Sensor Calibration option.



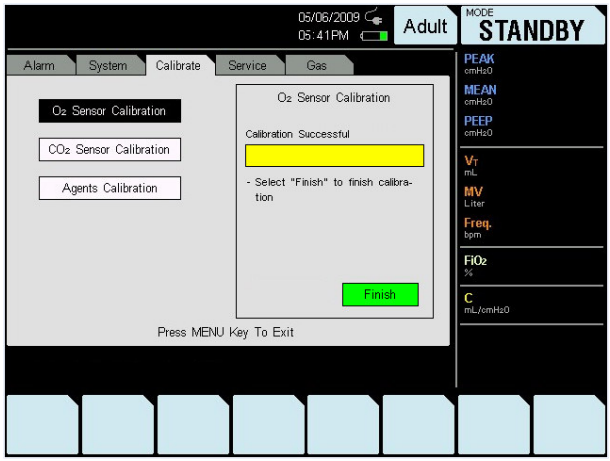
Step 3
Press the knob and a new window appears right side.
Perform the operation in accordance with the prompt on the screen.
Disassemble O_2 sensor from the Y-piece and place it in the air for more than 3 minutes.



Step 4
Press the knob to perform the calibration.
In the process of calibration, the word “Calibrating” displays on the screen.

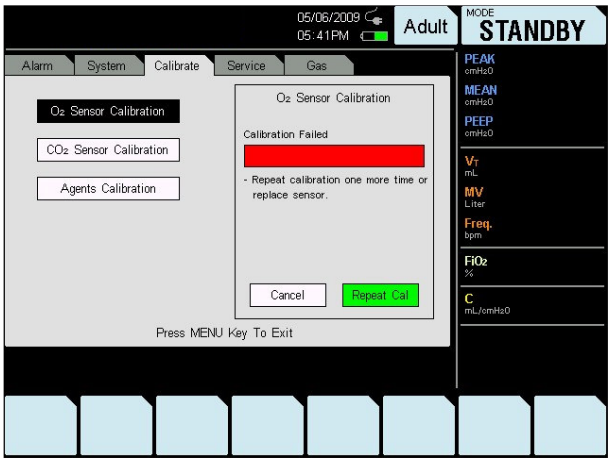


“Calibration successful” will be displayed on the window after the O_2 Sensor calibration is successfully completed. Replace the O_2 sensor and press “Finish” to continue.



If 21% calibration fails, the word “Calibration failed” is displayed in the window.
If calibration fails:

- Repeat these steps to calibrate it again.
- If it fails again, replace the O_2 sensor and recalibrate it.

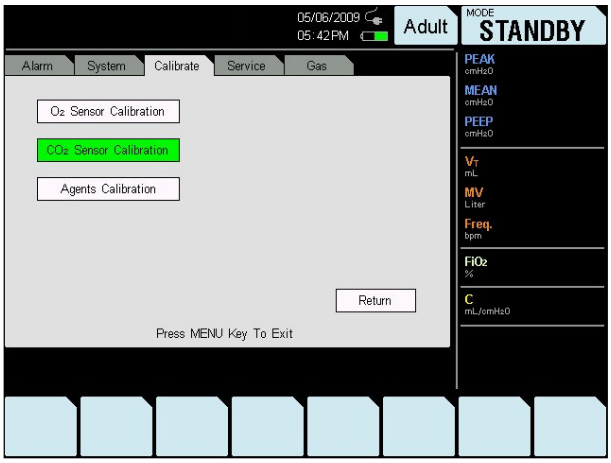


8.3.2.2 Calibrate 100% O_2 Sensor

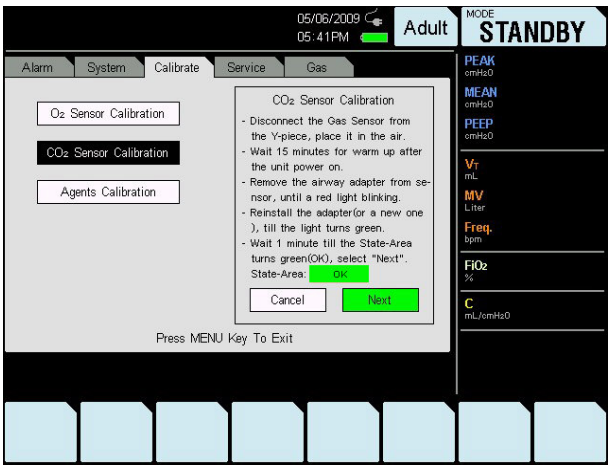
This item must be performed by an authorized service engineer.

8.3.3 Calibrate CO_2 Sensor

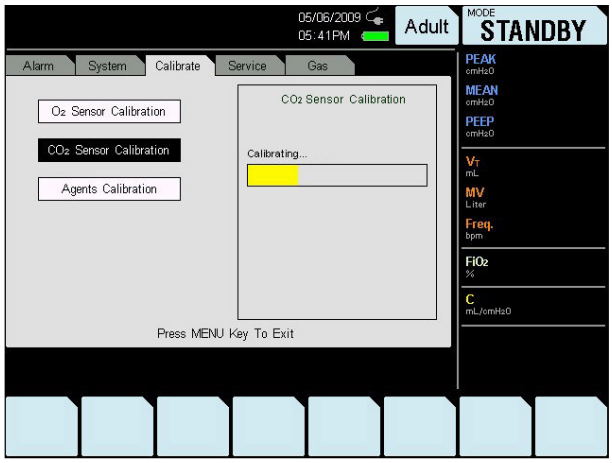
Step 1
Turn the knob to select "CO_2 sensor Calibration" in the "Calibrate" submenu.



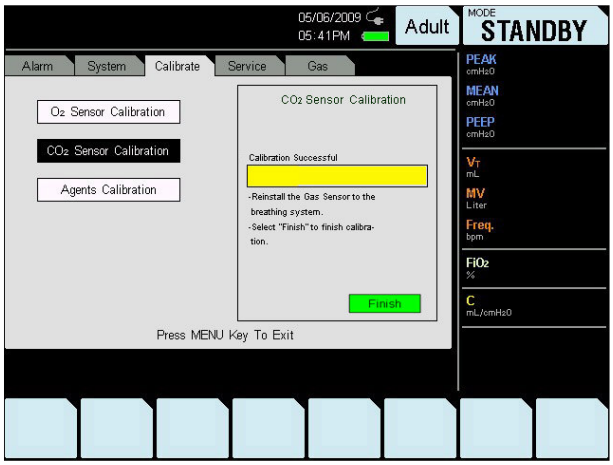
Step 2
Press the knob and a new window appears on the right side.
Perform the operation according to the prompts on the screen.
Disconnect the Gas sensor from the Y-piece, and place it in the air for no less than 15 minutes.
Remove the airway adapter (or a new one) until the light turns green.
Wait 1 minute till the State-Area turns green (OK) and select it.



Step 3
Press NEXT to perform the calibration.
In the process of calibration, the word “Calibrating” displays on the screen.

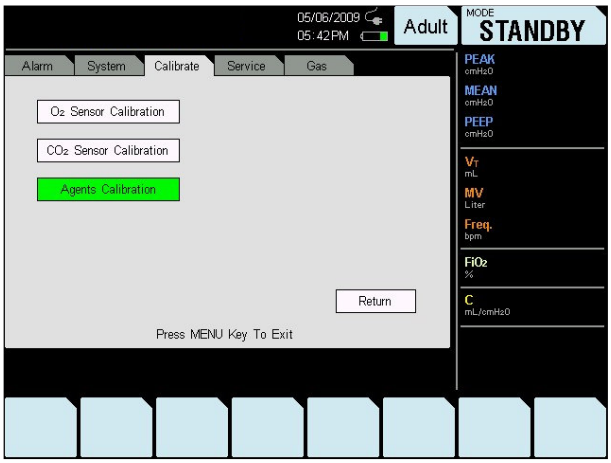


“Calibration successful” will be displayed on the window after the calibration is completed successfully. Reinstall the Gas Sensor to the breathing system. Select “Finish” to complete the calibration.



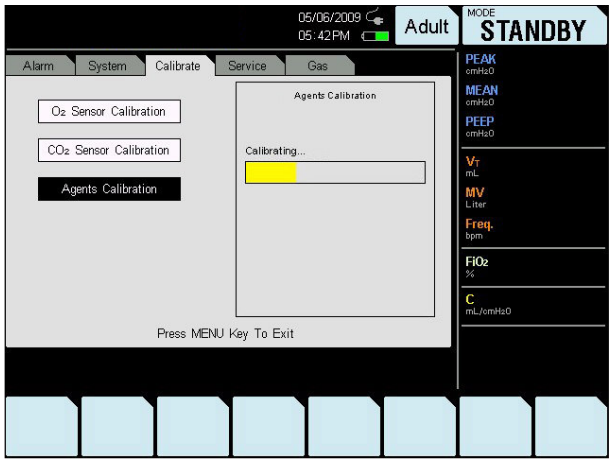
8.3.4 Calibrate Agents

Step 1
Turn the knob to select “Agents Calibration” in the “Calibrate” submenu.

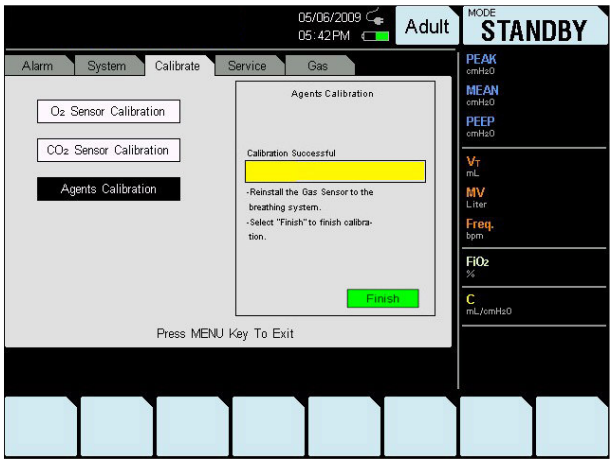


Step 2
Press the knob and a new window appears on the right side.
Perform the operation according to the prompt on the screen.
Disconnect the Gas Sensor from the Y-piece and place it in the air for no less than 15 minutes.
Remove the airway adapter (or a new one) until the light turns green.
Wait 1 minute till the State-Area turns green (OK) and select NEXT.

Step 3
Press the NEXT knob to perform the calibration.
During calibration, the word “Calibrating” displays on the screen.



“Calibration successful” will be displayed in the window after the calibration is completed successfully. Reinstall the Gas Sensor to the breathing system. Select “Finish” to complete the calibration.



8.4 Maintaining O_2 Sensor

Perform the calibration periodically; refer to section 8.2.1.
When the machine is not in operation, avoid placing the O_2 sensor in a high oxygen concentration to increase its life.
The O_2 sensor’s useful life is 12 months.
SV-03A is the O_2 sensor recommended by the manufacturer.

⚠ **CAUTION: For more detailed information, refer to technical data that is regularly updated by the manufacturer.**

The effect of temperature on the performance of a capillary barrier O_2 sensor is relatively small. Changing the temperature from +20℃ to -20℃ will t ypically result in 10% loss of the output signal. In contrast, temperature has a much greater effect on solid membrane O_2 sensors. The diffusion of gas across the membrane is an activated process and as a result has a large temperature coefficient. Typically a 10℃ change of temperature doubles the output signal from the sensor. Solid membrane O_2 sensors require temperature compensation as a result, and many have thermistors in them.

8.5 Replace the Fuses

⚠ **WARNING:** **To prevent injury or death, disconnect the system from the power supply before replacing fuses.**

⚠ **WARNING:** **Replace fuses with only those specified type to prevent damage to the equipment.**

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

Replacing steps:

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

8.6 Maintaining Battery

- **Specification**

24V, lead-acid battery.
Charge: 8 hours typically

- **Cautions**

Charge: Connect mains supply; the system will maintain auto-charging battery. Charging time is more than 8 hours.
Battery supply will last 120 minutes.
The alarm “Low Battery!” should be displayed on the screen when the battery is nearly drained. The user/operator should connect mains supply to charge battery and avoid the system shut-off.
Do not disassemble battery device without valid authorization.
Do not short-circuit the battery between the positive plate and the negative plate.

- **Storage**

Batteries should be charged every 3 months if battery power exceeds 3 months.
Store batteries in a dry, cool place.
If battery is damaged, it must be replaced to avoid damage. Contact a service representative.

⚠ **CAUTION:** **Only an authorized services representative can replace the battery. If the battery will not be used, contact a service representative to disconnect the battery. Dispose used batteries in accordance with local laws.**

8.7 The IRMA Probe

The IRMA probe is intended for monitoring CO_2. It has two airway adapters, one for an adult and one for a child.

Never sterilize or immerse the IRMA airway adapters in liquid. They can be cleaned using a cloth moistened with ethanol or isopropyl alcohol. Replace every two weeks.

Figure7-1：IRMA child adapter

Figure 7-2：IRMA adult adapter

Figure 7-3：IRMA CO_2 gas module

Figure 7-4：IRMA AX+gas module

9 Alarm and Troubleshooting

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

9.1 About Alarm

CAUTION: **If alarm occurs, ensure the patient safe before attempting to diagnose the problem.**

Alarm messages display on the top of the screen.

Figure 9-1 Alarm message area

The high priority alarms must be attended to immediately.

Priority	Volume	Silence	Prompt	Alarm bell
High	5 tones, 2 hurry; Every 8 seconds	110 seconds	Red background, 3 "!" Display frequency: 2Hz	Red, flickering
Medium	3 tones Every 10 seconds	110 seconds	Yellow background, 2 "!" Display frequency: 0.5Hz	Yellow, flickering
Low	2 tones Non-repeat	----	Yellow background, 1 "!" Display until alarm stops.	Yellow

When two or more alarms with equal priority are generated at the same time, the signals will be displayed in turn.
The operator can hear the alarm sound or distinguish the priority of alarm from at least 4 meters. The alarm message is visible from more than 1 meter away.

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

CAUTION: **When the alarm is silenced, the alarm bell has dashed "X" on it.** 

CAUTION: **A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area.**

CAUTION: **The auditory alarm signal sound pressure range is between 62dB and 75d (measured from a distance of 1 meter).**

9.2 Alarm Message List

CAUTION: **Patient safety comes first during an operation. Repair the problem once the operation is finished.**

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

9.2.1 Technical Alarm

Message	Priority	Cause of Alarm	Machine Mode When Checked (Startup / Run)	Operator Action	Repair
BDU EEPROM Data Failure	- -	Incorrect checksum during EPROM check	Startup only	Call Service Representative	Service Rep needed.
EEPROM IC Failure	- -	EEPROM cannot read/write	Startup only	Call Service Representative	Service Rep needed.
WDT Failure	- -	Incorrect Watchdog state.	Startup only	Call Service Representative	Service Rep needed.
AD/DA failure	- -	Incorrect D/A A/D data	Startup only	Call Service Representative	Service Rep needed.
PEEP failure	- -	PEEP valve data incorrect	Startup	Mechanical ventilation failed.	Service Rep needed.
Inspiration Valve Failure	- -	Monitor sensor ZERO state incorrect.	Startup	Mechanical ventilation failed.	Service Rep needed.
Vent/ Manual Valve Failure	- -	Valve state incorrect.	Startup only	Call Service Representative	Service Rep needed.
Expiration Sensor Failure	- -	Sensor Data incorrect	Startup only	Call Service Representative	
O_2 Supply Failure	High	Drive gas pressure is lower than 2.9 psi ± 15%	Startup and Runtime	Check pipeline gas supply	Replace O_2 cylinder.
Power Fail	Low	The AC Power Fail Alarm shall occur when there is a failure of the AC Mains.	Startup and Runtime	Check connection	Check mains supply. Check fuses. Replace fuses when blown.
Low Battery	Med	With no AC, battery voltage is lower than 22V.	Runtime	Resume AC power immediately; if 10 minutes remaining until shutting down, switch to Bag mode	Maintain battery periodically, and ensure it is fully charged.
O_2 Sensor Failure	High	Check the oxygen sensor state by the AD input data and judge whether Oxygen has failed or not.	Startup and Runtime	Use external measuring system	Replace the oxygen sensor.
BDU Communication Failure	High	If the GUI cannot send or receive data from the BDU Unit for more than 0.5s.	Startup and Runtime	Switch to bag mode and manually ventilate patient. Monitoring still available.	Service Rep needed.
Speaker Failure	- -	Lack of Main alarm Feedback	Startup only	Ventilator working normally. Abort or ignore.	Please contact eligible service representative.

Message	Priority	Cause of Alarm	Machine Mode When Checked (Startup / Run)	Operator Action	Repair
O_2 Cal Due	Low	72 hours has elapsed since last 21% O_2 Calibration	Runtime only		
Software Version Error	- -	BDU, UI, and Keyboard software versions are inconsistent with released set.	Startup only	Call Service Representative	Service Rep needed.
Keyboard Communication Failure	Low	No communication between UI and Keyboard.	Startup and Runtime		
Pressure Sensor Failure	- -	Pressure sensor data incorrect.	Startup only	Call Service Representative	Service Rep needed.
Inspiration Sensor Failure	- -	Inspiration sensor data incorrect	Startup only		Ventilator failure; switch to bag mode and manually ventilate patient. Monitoring is not available.

9.2.2 Functional Alarm

Message	Priority	Condition	Disabled In Manual Mode	Operator Action	Repair
Continuous Pressure	High	If the value of airway pressure is greater than 10 cmH_2O in Manual mode and lasts more than 10 seconds, machine generates continuous high airway pressure alarm. In other modes, if current value of airway pressure (PEEP value set + 10 cmH_2O) lasts more than 10 seconds, machine generates continuous high airway pressure alarm. This alarm is decided by upper machine and displayed in any mode other than STANDBY mode.	No	Switch to bag mode, manually ventilate patient. Check tubes and sampling lines and clear any blockages.	If the alarm continues, please contact eligible service representative.
High Airway Pressure	High	Paw greater than upper limit for 2 consecutive breath cycles. Settings of VT higher. Patient airway blocked. Exhalation valve blocked. Machine response: Immediately enter expiratory cycle.	Yes	Reset upper limit of Paw. Check expiratory cycle, and clear any blockages. Check VT settings. Check airway of patient, and clear any blockages.	----
Low Airway Pressure	Mid	SW417.2 For Freq >= 4: Airway pressure below pressure alarm low limit for > 15 seconds. For Freq < 4: Airway pressure below pressure alarm low limit for > 30 seconds.	Yes	Reset lower limit of Paw	Check the parallel sampling lines.
Low FiO_2	High	FiO_2 less than lower limit. Over-compensation of air or N_2O. O_2 sensor non-calibrated. O_2 sensor failure.	No	Reset lower limit of FiO_2. Reduce compensation. Perform the calibration. Replace O_2 sensor.	----
High FiO_2	Mid	FiO_2 greater than upper limit.	No	Reset upper limit of FiO_2.	----

Message	Priority	Condition	Disabled In Manual Mode	Operator Action	Repair
High Minute Volume	Mid	MV greater than upper limit.	Yes	Reset upper limit of MV.	----
Low Minute Volume	Mid	MV less than lower limit. Leakage occurs.	Yes	Reset lower limit of MV. Check patient end.	----
High Breath Rate	Mid	F greater than upper limit. The patient has independent respiration.	N.A.	Reset upper limit of f. Examine the patient and confirm independent respiration exists.	----
APNEA	High	The measured expiratory tidal volume is: <20 ml (for patient Type = Child) or <150 ml (for patient Type=Adult) For a period of: >60 seconds (Vent Mode = MANUAL) or >35 seconds (Vent Mode=(SIMV or PS) and Breathing Frequency setting < 6) or >30 seconds (all other automatic ventilation modes and Breathing Frequency settings) The Minute Volume (MV), Tidal Volume (VT) and Breathing Frequency measurements are blanked during the APNEA condition and resume after the condition is resolved. Ventilation mode changes (excluding STANDBY) during an APNEA condition shall not restart the apnea timing. Breathing circuit disconnects during automatic ventilation shall cause an apnea alarm.	Yes		
APNEA Backup	Mid	FreqMIN in PS mode triggers the ventilator.	N.A.		

Message	Priority	Condition	Disabled In Manual Mode	Operator Action	Repair
High PEEP	Mid	Exp pressure 5 cmH_2O above PEEP for 2 breaths, or Exp. Pressure 5 cmH_2O above PEEP in pressure support mode for more than 30 seconds.	N.A.		
Negative Pressure	High	Negative Airway Pressure of -2 cmH_2O or less for greater than 4 seconds.	No		

9.3 Troubleshooting

Symptom	Possible Cause	Recommended Action
Breathing System leak	APL valve is on	Turn APL valve to off
	Canister is not sealed well	Reinstall or remove the natrium calcareousness grains at the joint
	Corrugated tubing is broken or the connector is loose	Replace or reinstall
	Valves loose	Tighten them
Excessive pressure caused by manual ventilation	APL valve is adjusted incorrectly	Adjust it properly
APL valve doesn't work normally	APL valve failure	Please contact eligible service representative.
The AC indicator has no power, and ventilator does not work	Power supply cable is unplugged Power switch is off Fuse burned out	Plug in power supply cable Turn on power switch Replace with a new one
Ventilator stops operating suddenly, indicator light turns off, and alarm sounds	Power supply is interrupted	Use manual ventilation
Maximum pressure alarm sounds continuously	Breathing System is occluded Patient's respiratory tract is occluded Maximum pressure setting is too low Ventilator parameters changed	Check and adjust Breathing System Check the patient Readjust the alarm setting Recalculate the ventilator parameter
Minimum pressure alarm sounds continuously	Breathing System leaked Alarm settings are too high Patient's compliance changed Pressure sampling pipe is disconnected or broken	Check the pipeline for leak Reset the alarm settings Check the patient Check the pressure sampling pipe
No indication from the airway pressure gauge	Pressure sampling pipe is disconnected Gas supply exhausted	Reconnect the pressure sampling pipe Replace the gas supply
Tidal volume readings do not display normally	Flow sensor is disconnected The sealing ring of bellows base is broken Bellows base is broken	Reconnect the flow sensor Check the bellows and replace the broken parts, then reassemble it and carry out testing procedure according to section 6.2.5
The folding gasbag is inflated excessively	Gas scavenging port is occluded Malfunctioning waste gas scavenging system created excessive resistance or vacuum	Remove the occlusion Repair waste gas scavenging system

10 Specifications and Operation Theory

10.1 Physical Specification

All specifications are approximate and may be changed without notice.

⚠ **CAUTION: Do not use the Pasithec in a volatile environment.**

⚠ **CAUTION: Do not place heavy objects on the top of the machine or in the draws. The top board and working table can bear 25kg, and the drawer can bear 10kg.**

System	Dimensions:	1400 mm (H) × 1000 mm (W) × 770 mm (D)
	Weight:	148 kg (without vaporizer and cylinder)
	Load for top plate	25 kg
Castor	125 mm, with breakers on the front castors.	
Drawer	115 mm (H) × 485 mm (W) × 325 mm (D)	
Display	10.4' TFT LCD	
Cylinder gauge (O_2)	Scale: 0 to 25 MPa (0 to 3500 psi). Resolution: 1 MPa. Accuracy: ±2.5% of full scale.	
Cylinder gauge (N_2O)	Scale: 0 to 10 MPa (0 to 1400 psi). Resolution: 0.4 MPa. Accuracy: ±2.5% of full scale.	
Pipeline gauge (Air & O_2 & N_2O)	Scale: 0 to 1 MPa (0 to 145 psi). Resolution: 0.05 MPa. Accuracy: ±2.5% of full scale.	
Airway pressure gauge	Scale: -10 to 100 cmH_2O. Resolution: 200 Pa. Accuracy: ±2.5% of full scale.	

10.2 Environment Requirements

Temperature	Operation:	10~40℃
	Storage:	-20~55℃
	Transport	-20~55℃
Relative Humidity	Operation:	Not more than 80%, non-condensing.
	Storage:	Not more than 93%, non-condensing.
	Transport	Not more than 93%, non-condensing.
Atmospheric pressure	Operation:	70~106 kPa
	Storage:	70~106 kPa
	Transport	70~106 kPa

⚠ **CAUTION: Store in a room free from drafts and corrosive gases.**

10.3 System's Technical Specifications

10.3.1 Gas Supply

Pipeline Supply:	O_2, N_2O, Air
Connect to pipeline:	DISS-male, DISS-female, NIST (ISO 5359) All fittings used to connect O_2, N_2O and Air pipeline gas supply should be ready.
Input pressure at pipeline inlets:	280~600 kPa（2.8~6 bar）

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

Pressure at pipeline inlets must be 280~600 kPa when gas flow stops in the anesthetic gas delivering system.

10.3.2 Flowmeter

Flow rate

Gas component	Scale (thin tube)	Scale (thick tube)
O_2	0.05~1 L/min	1.1~10 L/min
N_2O	0.05~1 L/min	1.1~12 L/min
Air	0.05~1 L/min	1.1~15 L/min

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

Accuracy: ±10% of full scale under the condition of 20℃, 101.3 kPa,

10.3.3 Classification

According to IEC60601-1, HEYER Pasithec belongs to the following classifications:

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

10.4 Input/Output

10.4.1 Electrical

Voltage:	100~240 VAC, 50/60 Hz
Maximum input current:	10A
Fuse of AMSO:	250V/10A, ∅5X20 (F)
Socket of AMSO:	4
Fuse above AMSO:	250V/2A, ∅5X20 (F)
Maximum output current of AMSO:	1.5A (each); 6A (total)
Earth resistance:	<0.2Ω

⚠ **WARNING:** **The 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.**

10.4.2 Pneumatic

Pipeline supply:	O_2, Air, N_2O
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:	Color coded gauges
Connect vaporizer:	Two Selectatec®-type interface vaporizers
Input pressure at pipeline inlets:	280~600kPa
Connect to Breathing System:	Insp. Port connector: ∅22 OD /∅15 ID Exp. Port connector: ∅22 OD /∅15 ID Breathing System to AGSS: ∅30 OD

10.5 Electromagnetic Compatibility

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

⚠ **WARNING:** **Using cell phones or other radio equipment near this product may cause malfunctions. Closely monitor the working condition of this equipment if radio equipment is in close proximity.**

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 HEYER Pasithec is connected:

Do not put any object which is not in accordance with EN60601-1 within 1.5 meters of patients.

An isolated transformer must be used for alternating current supply (in accordance with IEC60989). Additional protective ground wires are equipped if all the devices (for medical or non-medical use) are connected to Pasithec 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 other portable all-purpose outlets are 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 equipment malfunction may cause injury to patients or operators.

HEYER Pasithec is equipped with all-purpose alternating current outlet for connecting to other medical equipment. Do not connect non-medical equipment to these outlets, or the surface leaking current may exceed the range permitted by EN60601-1 under normal conditions and the equipment may malfunction and cause injury to patients or operators.

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

⚠ **WARNING: Medical electrical equipment operators should avoid non-medical electrical equipment and patients.**

10.6 Operation Theory

The HEYER Pasithec is a continuous flow anesthetic system. It is equipped with an airway which can transfer O_2, N_2O, AIR and inhalation anesthetic drugs. Airway parts can use O_2, N_2O and AIR, and the O_2, N_2O and AIR which is needed reduce to 280 kPa~600 kPa can enter into the machine through a high pressure pipeline. Once through the protective pressure reducer in the machine, O_2 and Air enter into Pneumatic and Electronic Switch, while N_2O-cut valve can only open when the pressure of O_2 more than 50kPa (the FiO_2 LOW alarm will be active when the pressure of O_2 is less than 0.2MPa in the state of startup) and the N_2O can enter into Pneumatic and Electronic Switch. Otherwise, N_2O can not enter the airway of the machine. The state of gas entering into flowmeter can set to three states with the Pneumatic and Electronic Switch: OFF, O_2+ N_2O, and O_2+Air. The flow of O_2, N_2O and AIR can be adjusted by the knob of the flowmeter. Adjust O_2 and N_2O proportionally to ensure the O_2 concentration is no less than 25%. O_2, N_2O and AIR are mixed in the flowmeter; the mixed gas in the anesthetic drug vaporizer can take away part of anesthetic drug. Fresh gas can be transferred to the patient breathing cycle or C.G.O by the fresh gas selection switch. The O_2 from O_2 flush is transferred to the patient breathing cycle or C.G.O directly without going via the flowmeter and vaporizer. The mixer gas or O_2 in the patient breathing cycle can maintain the breathing of a patient by setting ventilation parameters and ventilation mode via machine or manually. The mixed gas or O_2 transferring to C.G.O can be used to maintain patient breathing via Maishi circle.

10.6.1 Pneumatic System

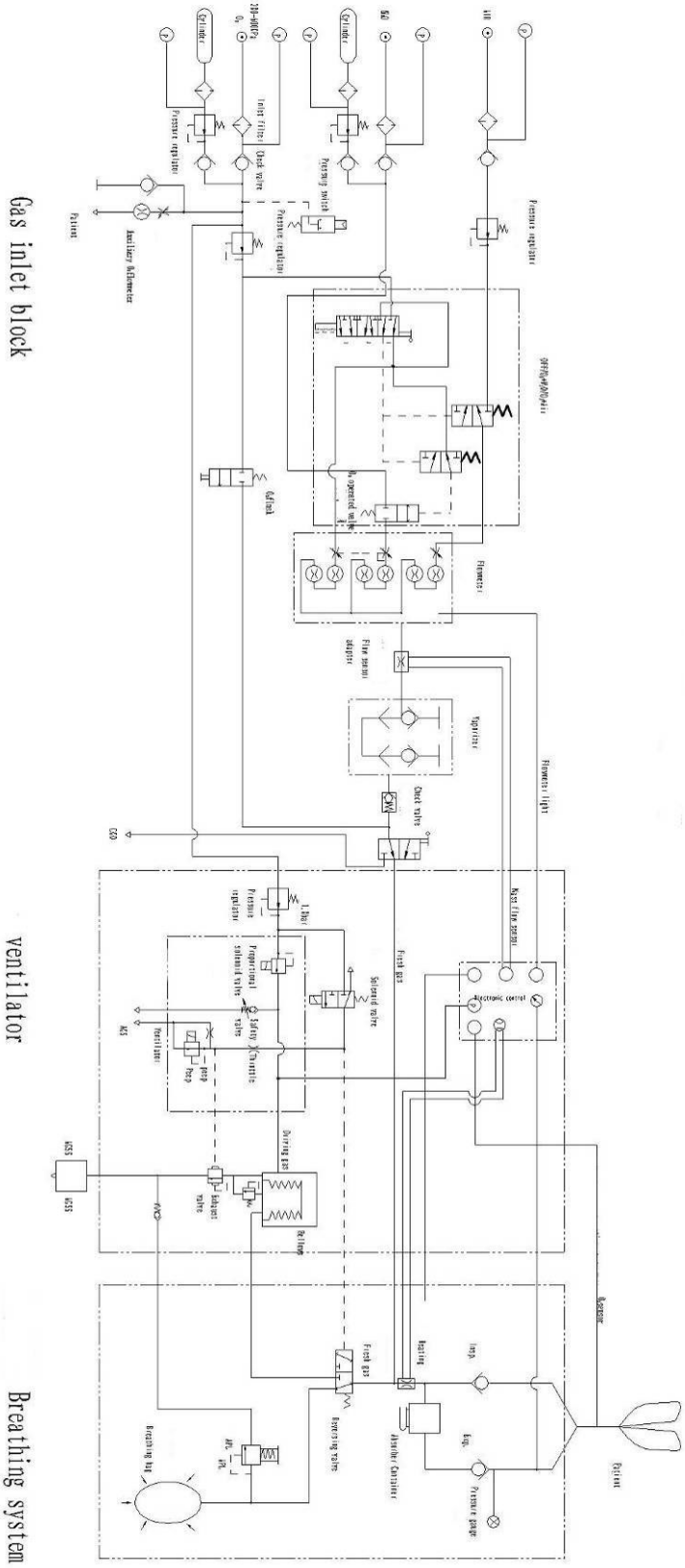


Figure 10-1 Operation principle diagram of system

10.7 Breathing System Technical Specification

Compensation of fresh gas	Flow compensation range: 1 to 10 L/min
	Gas components: O_2, N_2O, Air, Anesthetic Agent
Absorbent	Capacity: 1800 ml
Connection	Common Gas Outlet: ISO 5356 connector
Leakage of breathing system	At pressure of 3 kPa (0.4psi): Leakage of flow: ≤150 ml/min
Resistance of breathing system	At flow of 60 L/min: Resistance of exhalation: ≤0.6 kPa; Resistance of inhalation: ≤0.6 kPa. At flow of 30 L/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 3 L/min, resistance of flow: 0.05 to 3 kPa; At flow of 30 L/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 check valve	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
Internal volume	2.5 L approximately
O_2 flush	25 to 75 L/min
O_2 failure alarm and the associate cut-off device:	
	O_2 pressure
O_2 failure alarm	200 kPa
N_2O cut-off	50 kPa

10.8 Anesthetic Ventilator Specifications

10.8.1 Ventilator Performance

Maximum security pressure of airway system:	80 cmH_2O
Noise of whole unit:	Not more than 60 dB(A) in normal operation (not including alarm voice)
Warm-up time:	More than 5 minutes
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*.
Minute volume:	Max 20 L/min
Inspiratory flowrate:	Max 75 L/min
Pressure transmission range:	5~80 cmH_2O

10.8.2 Ventilation Mode Settings

Ventilation mode	Adjustable respiratory parameters
IPPV	V_T, Freq, I:E, T_P, PEEP
PCV	P_{TARGET}, Freq, I:E, PEEP, T_{SLOPE}
PS	$Freq_{MIN}$, PEEP, ΔP, Trigger, T_{SLOPE}
SIMV	V_T, Freq, Tinsp, T_P, PEEP, ΔP, Trigger, T_{SLOPE}
Manual mode	----

10.8.3 Ventilating Parameters Settings

Item	Range	Resolution	Default	Remark
V_T	20~1500 ml	10 ml	120 ml (Child); 600 ml (Adult)	Unavailable for SIMV & IPPV mode.
Freq.	4~100 bpm	1 bpm	20 bpm (Child); 8 bpm (Adult)	Unavailable for SIMV, PCV & IPPV mode.
I:E	4:1, 3.5:1, 3:1, 2.5:1, 2:1, 1.5:1, 1:1, 1:1.5, 1:2, 1:2.5, 1:3, 1:3.5, 1:4, 1:4.5, 1:5, 1:5.5, 1:6, 1:6.5, 1:7, 1:7.5, 1:8	0.5	1:2	Unavailable for SIMV & IPPV mode.
T_{INSP}	0.2~5.0sec	0.1 sec	1 sec (Child); 2 sec (Adult)	Only available for SIMV mode.
PEEP	Off, 3~30 cmH_2O	1 cmH_2O	Off	Unavailable for SIMV, PCV, PS & IPPV mode.
$Freq_{MIN}$	2~60 bpm	1 bpm	4 bpm (Child); 2 bpm (Adult)	Only available for PS mode.
T_P	Off, 5~60%	5%	10%	Only available for IPPV and SIMV mode.
Trigger	1~15 L/min	1 L/min	2 L/min (Child); 3 L/min (Adult)	Only available for SIMV, PS mode.
P_{TARGET}	5~70 cmH_2O	1 cmH_2O	10 cmH_2O (Child); 20 cmH_2O (Adult)	Only available for PCV mode.
ΔP	3~50 cmH_2O	1 cmH_2O	5 cmH_2O	Only available for SIMV, and PS mode.
T_{SLOPE}	0~2 sec	0.1 sec	0.5 sec	Available for PCV, SIMV, and PS mode.

10.8.4 Gas Dynamics Performance

Gas source	Anesthetic system
Gas component	O_2
Rating supply pressure	400 kPa
Inlet pressure range	280 kPa ~ 600 kPa
Flow valve range	5~75 L/min
Output	Pressure range: 0 ~ 6 kPa; Flow range: 0 ~ 75 L/min

10.8.5 Setting Alarm Parameters

Item	Range	Resolution	Default	Remark
MV Low	0~20 L/min	1 L/min	0.5 L/min (child); 1 L/min (adult)	Unavailable for STANDBY mode
MV High	1~25 L/min	1 L/min	6 L/min (child); 12 L/min (adult)	Unavailable for STANDBY mode
Paw Low	0~70 cmH_2O	1cmH_2O	8 cmH_2O (child); 10 cmH_2O (adult)	Unavailable for STANDBY mode
Paw High	10~80 cmH_2O	1cmH_2O	40 cmH_2O (child); 50 cmH_2O (adult)	Unavailable for STANDBY mode
Freq. High	4~100 bpm	1bpm	30 bpm (child); 18 bpm (adult)	Only available in PS mode mode.
FiO_2 Low	18%~99%	1%	18% (child); 18% (adult)	Unavailable for STANDBY mode
FiO_2 High	21%~100%	1%	100% (child); 100% (adult)	Unavailable for STANDBY mode
$ETCO_2$ Low	0~9% or 0~74 mmHg	1% or 1 mmHg	-----	Unavailable for STANDBY mode
$ETCO_2$ High	1~10% or 1~75 mmHg	1% or 1 mmHg	6% or 50 mmHg	Unavailable for STANDBY mode
$INSCO_2$ High	1~10 mmHg	1 mmHg	5 mmHg	Unavailable for STANDBY mode
Hal. Low	0~8.3%	0.1%	-----	Unavailable for STANDBY mode
Hal. High	0.1~8.4%	0.1%	1.5%	Unavailable for STANDBY mode
Iso. Low	0~8.3%	0.1%	-----	Unavailable for STANDBY mode
Iso. High	0.1~8.4%	0.1%	2.3%	Unavailable for STANDBY mode
Enf. Low	0~9.8%	0.1%	-----	Unavailable for STANDBY mode
Enf. High	0.1~9.9%	0.1%	3.4%	Unavailable for STANDBY mode
Sev. Low	0~9.8%	0.1%	-----	Unavailable for STANDBY mode
Sev. High	0.1~9.9%	0.1%	4.2%	Unavailable for STANDBY mode
Des. Low	0~21.8%	0.1%	-----	Unavailable for STANDBY mode
Des. High	0.1~21.9%	0.1%	12.0%	Unavailable for STANDBY mode

⚠ **CAUTION:** **All lower limits of parameters in above table may not be set to the upper limits, nor may the upper limits be set below the lower limits.**
The operator should check that the current alarm preset is appropriate prior to use on each patient.
Do not set alarm limits to extreme values that can render the alarm system useless.

10.8.6 Monitoring Performance

Item	Range	Resolution	Accuracy
V_T	0 ~ 3000 ml	1 ml	Child: ±10%, at least 10 ml; Adult: ±10%
MV	0.1 ~ 30 L	0.1 L	±15%
Freq.	0 ~ 110 bpm	1 bpm	±1 bpm
PEAK	-20 ~ 99 cmH_2O	1 cmH_2O	±5%, at least 1 cmH_2O
MEAN	-20 ~ 99 cmH_2O	1 cmH_2O	±5%, at least 1 cmH_2O
PLAT	-20 ~ 99 cmH_2O	1 cmH_2O	±5%, at least 1 cmH_2O
FiO_2	18 ~ 100%	1%	±3%
C	0~100 ml/cmH_2O	1 ml/cmH_2O	±2 ml/hPa (≤10mL/hPa); ±20% (other)
PEEP	-20 ~ 99 cmH_2O	1 cmH_2O	±2 cmH_2O

Battery capacity indication:	100%, 75%, 50%, 25%, 0%. When using the battery, the icon displays the remainder battery capacity; when connected with the AC, the icon displays charging.
Paw-t waveform:	Pressure monitoring range: 0 to 80 cmH_2O. Paw-t waveform display pressure axis varies with the upper alarm limit of Paw: Range — Gain 0 to 10 cmH_2O — 5 cmH_2O 0 to 30 cmH_2O — 10 cmH_2O 0 to 80 cmH_2O — 20 cmH_2O Time axis is not only a fixed range but also same scale for Flow-t and Paw-t waveforms. Range: 0 to 15 seconds (gas module open). Range: 0 to 20 seconds (gas module close).
Flow-t waveform:	Flow scale: -90 to 90 L/min; gain: 45 L/min. Time scale: 0 to 15 s (gas module open); 0 to 20 s (gas module close).
CO_2-t waveform:	CO_2 scale: 0 ~ 76 mmHg; gain: 38 mmHg. Time scale: 0 to 15 s (gas module open); 0 to 20 s (gas module close).
Pressure-Volume loop:	X-Axis: pressure; fixed range: -20 to 80 cmH_2O; gain: 20 cmH_2O. Y-Axis: tidal volume; fixed range: 0 to 1500 ml; gain: 250 ml.
Flow-Volume loop:	X-Axis: tidal volume; fixed range: -1400 to 0 ml/min; gain: 700 ml. Y-Axis: flow; fixed range: -90 to 90 ml; gain: 45 ml.

10.9 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 proportionate voltage on its surface, generated with partial pressure of O_2. The O_2 sensor is a 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 an electrode. The electrode will be used up gradually during the oxidation process. The voltage of the sensor will be affected by the temperature of the gas mixture monitored. Thermistor on the shell of the 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. The concentration is displayed on the screen and should be comparable with the alarm limit value saved. If the concentration exceeds the limits, the alarm should be sound. The effect of disturbance gas (CO_2, N_2O, anesthetic gas) on the concentration of the O_2 sensor is less than 0.5%VOL.

10.10 IRMA Probe Specification

Model of Sensor:	IRMA CO_2 or IRMA AX+
Interface :	RS232, 9600 bps
Useful time:	Replace it every two weeks.
Accessory:	Airway adapter, adult/infant Never sterilize or immerse the IRMA airway adapters in liquid. They can be cleaned using a cloth moistened with ethanol or isopropyl alcohol.
Principle of IRMA:	It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and emergency medicine settings for adult, pediatric, and infant patients. The IRMA probe adopts infrared measurement technology to measure the concentration of different gases in the breathing gas mixture, which is based on the fact that the different gas components absorb infrared light at specific wavelengths. Integrated with RS-232 digital interface, it supplies the universal serial interface communication protocol and is easy to connect.

10.10.1 Intended Use

The IRMA main stream multi-gas probe is intended to be connected to other medical devices for display of real time and derived monitoring data of CO_2, N_2O, and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.
It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and emergency medicine settings for adult, pediatric and infant patients.

10.10.2 Technical Specification

General	
Description	Extremely compact infrared mainstream multi-gas probe.
Dimensions(W×D×H)	IRMA CO_2 38×37×34 mm (1.49”×1.45”×1.34”) IRMA AX+: 38×29×31 mm (1.49”×1.14”×1.22”)
Cable length	2.50 mm ± 0.02 m
Weight	<30g (cable excluded)
Operating temperature	IRMA CO_2: 0~40℃, 32~104℉ IRMA AX+: 10~40℃, 50~10?4F
Storage and transportation temperature	IRMA Probe: -20~50℃, -4~122℉
Operating humidity	10-95% RH, non-condensing
Storage and transportation humidity	5~100% RH, condensing
	IRMA CO_2 525~1200 hPa (525 hPa corresponding to an altitude of 4572 m / 15000 feet) IRMA AX+; 700~1200 hPa (700 hPa corresponding to an altitude of 3048 m / 10000 feet)
Storage and transportation pressure	500 to 1200 hPa
Mechanical strength	Withstands repeated 1m (IRMA CO_2 1.8 m) drops on a hard surface. Complies with requirements for road ambulances according to prEN1789:2004 (clause 6.4) and requirements for shock and vibration according to EN ISO 21647:2004 (clause 21.102, transport).
Power supply	IRMA CO_2 4.5~5.5 VDC, max 1.0 W (power on surge @5V less than 350 mA during 200 ms): IRMA AX+: 4.5~5.5 VDC, max 1.4W (power on surge @5V less than 350 mA during 200 ms)
Surface temperature (at ambient temp.23℃)	IRMA CO_2 Max 41℃/106℃ IRMA AX+ Max 55℃/131℉
Interface	Modified RS-232 serial interface operating at 9600bps
Airway adapters	Disposable adult/pediatric: -Adds less than 6 ml dead space -Pressure drop less than 0.3cmH_2O @ 30 LPM Disposable infant: -Adds less than 1 ml dead space -Pressure drop less than 1.3 cmH_2O @ 10 LPM

Note1: After being in a condensing atmosphere, the unit shall be stored for more than 24h in an environment equivalent to the operating humidity.

Data output	
Fi and ET	Fi and ET are displayed after one breath and have a continually updated breath average. IRMA CO_2: CO_2 IRMA AX+: CO_2, N_2O, primary and secondary agents (HAL, ISO, ENF, SEV, DES)
Automatic agent identification	IRMA AX+: Primary and secondary agent.

Gas analyzer	
Calibration	Zeroing recommended when changing Airway adapter
Warm-up time	Concentrations are reported and the automatic agent identification is running within 10 seconds. Full accuracy within 1 minute.
Rise time (@10 l/min)	CO_2 ≦ 90 s N_2O ≦ 300 s HAL, ISO, ENF, SEV, DES ≦ 300 s
Agent identification time	<20 seconds (typically <10 seconds)
Total system response time	<1 second

Accuracy specifications-during standard conditions			
	Range		
Gas	CO_2	AX+	Accuracy
CO_2	0~15 15~25	0~10 10~20	±(0.2 vol% + 2% of reading) Unspecified
N_2O		0~100	±(0.2 vol% + 2% of reading)
HAL, ISO, ENF		0~8 8~12	±(0.15 vol% +5% of reading) Unspecified
SEV		0~10 10~15	±(0.15 vol% + 5% of reading) Unspecified
DES		0~22 22~25	±(0.15 vol% + 5% of reading) Unspecified

Note1: Gas concentration reported in units of volume percent.

Accuracy specifications-during all conditions	
Gas	Accuracy
CO_2	±(0.3 vol% + 4% of reading)
N_2O	±(2 vol% + 5% of reading)
Agents	±(0.2 vol% + 10% of reading)

Note1: The accuracy specification is valid for all specified environment conditions, except for interference specified in the table “Interfering gas and vapor effect” below.

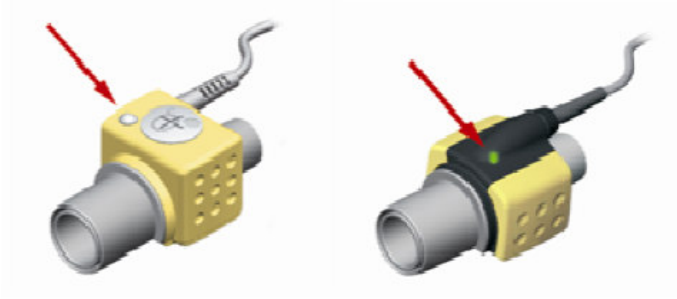
Note2: The accuracy specification for IRMA AX+ is not valid if more than two agents are present in the gas mixture.

10.10.3 System Assembly Instruction

10.10.3.1 Set-up

1. Connect the IRMA connector (RS-232 serial interface) with the COM-A below the UI.
2. Snap the IRMA sensor head on top of the IRMA airway adapter; it will click into place when properly seated.

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



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

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

10.10.3.2 Placement of IRMA Probe

When connecting IRMA probe to an infant patient circuit, avoid direct contact between the IRMA probe and the patient's body.

If the IRMA probe comes into direct contact with any parts of the infant's body, an insulation material shall be placed between the IRMA probe and the body.

⚠ **WARNING:** The IRMA probe is not intended to come into long-term skin contact.

10.10.3.3 Pre-use Check

Always verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

Perform the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter.

10.10.4 Zeroing Procedure

⚠ **WARNING:** Incorrect probe Zeroing will result in false gas readings.
In order to secure high precision IRMA probe measurements, the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe without connecting the airway adapter to the patient circuit. Use the host instrument to transmit a Zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter is of crucial importance for a successful Zeroing. If a "ZERO-REQ" alarm appears after a Zeroing procedure, the procedure has to be repeated.

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

IRMA CO_2 probes:

Zeroing needs to be performed ONLY when an offset in gas values is observed, or when an unspecified accuracy message is displayed.
Allow 10 seconds for the IRMA CO_2 probes to warm up after powering on the machine before proceeding with the Zeroing Procedure.

Allow the IRMA probe to warm up for at least 10 seconds after changing the IRMA airway adapter before transmitting the Zero reference command.

IRMA AX+ probes:

Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy messages is displayed.

Allow 1 minute for warm up of the IRMA AX+ probes after powering on the machine and after changing the IRMA airway adapter before proceeding with the Zeroing. The green LED on the probe will blink for approximately 5 seconds while Zeroing is in progress.

10.10.5 Alarms

Include a description of the host alarm system, including the gas reading alarm limit range, its discrimination, and the implementation of alarm and status information transmitted by the IRMA probe.

Include a description of the status LED situated on the IRMA probe:

Steady green light	System OK
Blinking green light (IRMA AX+)	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check adapter

10.10.6 Cleaning

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

⚠ **CAUTION:** The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.

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

10.10.7 Preventive Maintenance Instructions

Gas span check:
Gas readings should be verified at regular intervals with a reference instrument.
Replace the IRMA airway adapter every two months.

10.10.8 Warnings

The IRMA probe is intended for use by authorized and trained medical personnel only.
The IRMA probe must not be used with flammable anesthetic agents.
Disposable IRMA airway adapters shall not be reused. Used disposable airway adapter shall be disposed of in accordance with local regulations for medical waste.
Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6ml dead space to the patient circuit.
Do not use the IRMA Infant/Pediatric airway adapter with adults as this may cause excessive flow resistance.
Measurements can be affected by mobile and RF communications equipment. The IRMA probe should be used in the electromagnetic environment specified in this manual.
Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.
To keep secretions and moisture from pooling on the windows or oxygen sensor port,a lways position the IRMA probe in a vertical position with the LED pointing upwards.
Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.
Incorrect probe zeroing will result in false gas readings.
Replace the adapter if condensation occurs inside the airway adapter.
The IRMA probe is not intended to be in long term contact with skin.

10.10.9 Cautions

Never sterilize or immerse the IRMA probe in liquid.
Do not apply tension to the probe cable.
Do not operate the IRMA probe outside the specified operating temperature environment.

11 Warranty

Warranty declaration by HEYER Medical AG

In addition to the legal warranty acc. to HBG §377, HEYER MEDICAL AG shall grant a warranty of 12 months for the purchase of a new apparatus from the HEYER product range. The warranty period begins with the date of invoice and is subject to the following conditions:

1. Within the warranty period we will eliminate free of charge any defects or damages on the device that are shown to be caused by a manufacturing or material error. The warranty does not include easily breakable parts, e.g. glass or consumable parts.

2. Warranty services can only claimed upon submission of a delivery note (bill of delivery or invoice); the type and method of damage remedy (repair or replacement) shall be at the discretion of HEYER MEDICAL AG. Warranty services do not result in an extension of the warranty period, nor do they entail a new warranty being granted. There is no independent warranty period for installed spare parts.

3. Excluded from the warranty are: Damages caused by improper use, operating errors, mechanical stress or non-observance of the operating instructions, as well as damages caused by force majeure or by extraordinary environmental conditions.

4. Warranty services may only be claimed if proof is submitted to confirm that all service and maintenance work has been carried out by authorized staff.

5. The warranty includes all faults that impair a faultless functioning of the device on the basis of technical defects of individual components. The warranty obligation can only be recognized by us if the device has been used properly and according to its intended use and no repair attempts have been undertaken by the client himself or by third parties. The warranty claim does not include faults caused by mechanical damages or if the device is being operated with accessories originating from third parties.

6. The warranty is also void if changes, alterations or repairs are made to the device by persons not authorized to do this.

7. The warranty claim only applies to customers of HEYER MEDICAL AG; it cannot be transferred to third parties.

8. The rejected device is to be shipped back to our plant postage free. In case of a request by our customer service department, the costs for shipping to the plant are to be initially generally borne by the customer. After successful repair, we will send the device back freight collect. If HEYER MEDICAL AG confirms the existence of a warranty claim, the customer will receive reimbursement for the costs of delivery and/or transport of the apparatus. Repair parts that do not fall under the warranty claim will be billed by us. The shipping of the device to us always counts as a complete assignment to eliminate all faults and/or replace missing parts, unless the customer expressly excludes partial services. Additional claims to transfer or reduce and replace damages of any kind in particular also of damages not incurred on the object of delivery itself are excluded.

Our service address: HEYER Medical AG
Carl-Heyer-Straße 1-3
D-56130 Bad Ems
Tel.: (02603)791-3
Fax: (02603)70 424

Subject to technical changes!
Rev. No.: 0.2 – dated 18.12.2009

NOTES

NOTES

HEYER
MEDICAL AG
Carl-Heyer-Str. 1/3
D-56130 Bad Ems
Tel.: +49 (0) 2603 / 791-3
Fax: +49 (0) 2603 / 70424
E-Mail: info@heyermedical.de
www.HeyerMedical.de