Avante Alta V10 Anesthesia Machine

Operating Manual

Avante | Health Solutions

Preface

Read carefully and understand the contents of this manual before using this equipment.

Intellectual property rights

The company owns the intellectual property rights of this product, this manual must be treated as confidential information. This manual only provides references for the operation, maintenance and repair of our products.

Without our prior written consent, no person shall use, disclose or permit others to obtain this manual by any means, in whole or part of the information and all its intellectual property rights (including copyright) of the Company. No person in any way shall also without prior consent in the whole or part of this manual contents not only limited to photography, reproduction, including copying or translation into another language.

The company holds the final interpretation rights of this manual; without prior notice, the Company alone also reserves the right to modify the contents of this manual.

The Company reserves the right to make technical alterations without prior notice and to modify product specifications.

Liability of manufacturer

The Company is only responsible for the safety, reliability and performance of the equipment in the following circumstances:

- Assembly operation, expansion, re-adjustment, improvement and maintenance by the Company's authorized personnel.
- The supporting electrical equipment and environment conform to national standards, industrial standards, and this manual's requirements.
- Use according to the operation instruction.

⚠WARNING

- Equipment failure and the possible injury to patient's health may occur if the agency responsible for using this equipment does not set out an effective and satisfactory maintenance plan.
- When a central gas supply system is used. The failure of the central gas supply system may cause all the devices connected to the Anesthetics to stop working.
- This system should always be used in conjunction with other vital signs monitoring equipment and / or professional judgment of the patient's condition.
- This equipment should be used together with the use of Anesthetics gas scavenging system, the user should be configured to comply with ISO 80601-2-13 standard Anesthetics gas scavenging system.
- The Anesthetics vaporizers used should be carried out (in accordance with ISO 80601-2-55).

- IEC 60601-1 applies to all medical electrical equipment used or part of the Anesthetics machine in question. Even if the individual components in the device are non-functional when they are connected to an auxiliary power outlet that forms the medical electrical system. The operator must be aware that when the device is connected to the auxiliary power outlet current leakage is an evaluated risk.
- Explosion hazardous. Do not use flammable Anesthetics agent such as Ether or Cyclopropane with this equipment. Only non-flammable Anesthetics agents which meet the requirements specified in ISO 80601-2-13 can be used with this equipment. This Anesthetics workstation may be used with Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane. Only one of these Anesthetics agents may be used at a time.
- In order to avoid false alarms caused by high intensity electric field:
  - Please keep electrical wires away from this system as well as sensitive components, such as flow sensors and oxygen sensors.
  - Do not store/locate electrical wires on any part of this system.
- If the following condition occurs, the company is not responsible for the safety / reliability of this system.

  - This system is not operated correctly in accordance with the "user Manual" and qualified personnel.

Servicing and Repairs

In order to ensure the full operational life of this device, servicing by an engineer trained by the manufacturer should be undertaken periodically.

Always give as much of the following information as possible:

- Type of equipment
- Product name
- Serial number
- Approximate date of purchase
- Apparent fault

Pay Services:

Where regulations beyond the scope of the warranty, the company will implement the fee-based service agreed by both supplier and purchaser.

Even during the warranty period, the system needs to be repaired due to the following causes**:** man-made damage, grid voltage exceeds the device-specified range and natural disasters.

The company is not responsible for the following (including but not limited to) caused by the direct, indirect or final damage:

- Abnormal use.
- Replacement parts without the permission of the Company or by the company without

authorized personnel to repair the machine.

- The original serial number tag or product identification markings have been altered or removed.

Return Policy

If the need arises to return the equipment to the Company, please follow these steps:

Obtain a right of return number, please contact our customer service department, and specify the product series number, this series of numbers has been marked on the outside shipping box or on the equipment, if the series of numbers are non-legible, return will not be accepted. Please mark the model name and serial number at the same time give the reason for the return.

When this system is shipped back for maintenance, users should bear the freight (including customs fees).

Equipment life: 8 years

Company Address

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Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

- Revision number: 1.1
- Release time: 2020-10

Table of Contents

1.1 System Safety

1.1.1 System Terms

User’s manual warnings, cautions, and important issues**.**

⚠ Danger

✧ Indicates risk – harm for the patient or serious consequences, as well as serious damage to property caused by vigilant operation.

⚠ Warning

◆ Alert may have potential risks or unsafe operation, may result in minor injury, product failure or damage to property.

⚠ Caution

● Express the need to comply with instructions or steps, provide a description or explanation, ensuring safe and efficient use of this product.

1.1.2 Warning

◆ This device can only be operated and used by professional well trained authorized medical personnel who must strictly follow the guidelines in this user manual to operate the equipment.

◆ Carefully check the machine, accessories and connections before use to ensure normal and safe operation.

◆ To avoid the risk of electric shock, the device should have the power cable grounded to protect the main power supply outlet.

◆ If the event of any abnormal situation, Anesthetics workstation should be checked immediately. Do not attempt to self-diagnose, otherwise danger of electric shock shall be recognized by the Company's professional and technical personnel.

◆ To ensure patient safety, the audible alarms and the alarm limits are to be set appropriately.

All ventilation alarm parameters are to be set by the clinical anesthetist; other audible alarms are to be adhered to.

◆ All physiological parameters and alarm information that are used as basis for clinical treatment can only be used as a reference for the clinician.

◆ To avoid the risk of fire, keep equipment away from flammable materials.

◆ Follow local regulations when disposing of package materials

1.1.3 Caution

● Use only approved components specified in the user manual to ensure patient safety.

● When worn parts, accessories or the replacement of the equipment expires, disposal in accordance with the hospital protocol and local regulations.

- Electromagnetic field anesthetics workstation performance would adversely affect the use of other devices in the vicinity. Pay attention to the relevant EMC requirements. Mobile phones, MRI equipment, X-ray emitted electromagnetic radiation can impact device and cause interference.
- Assure that the local power supply voltage and frequency are consistent with the requirements of this equipment.
- In the handling and installation process, please ensure that this machine is protected from external damage avoid collisions, dropping etc.

1.1.4 Caution

- For easy operation and observation, ensure that the machine is in an upright correct position.
- User manual should be placed in the Anesthetics workstation for easy observation.

Class I special waste

Depleted batteries must be replaced and disposed of in accordance with local regulations.

Class II special waste

The oxygen concentration sensor must be discarded and replaced according to local regulations. Oxygen concentration sensor should not be handled as a normal waste.

Hazardous waste (infectious)

The apparatus includes some parts of waste that cannot be handled as normal waste.

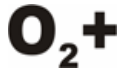
All discarded (disposable) components must be dealt in accordance to hospital regulations and in an environmentally safe manner.

Do not allow excess exhalation fluid to accumulate within the sensor probe, otherwise it will affect the function of the ventilator.

Do not use sharp objects to touch the screen.

It is highly recommended to have at least one spare battery as a backup power source.

1.2 Equipment Symbols

	Alternating current		Fuse
	Dangerous voltage		General warning (yellow background)
	Type BF equipment		Type B equipment
	Battery		Equipotential
	AC power supply (Indicates a connection to mains)		Battery symbol (indicating the battery status, display the current remaining capacity)
	Power On		Power Off
	Lighting		USB interface
 Insp	Inspiratory flow	 Exp	Expiratory flow
	Bag position/ manual ventilation		Mechanical ventilation
	Lock		Unlock
	Flow control		O_2 Flush button
	Oxygen Sensor connector		Bi-directional rotation
	Spare cylinders	O_2 280 ~ 600 kPa (41 ~ 87 PSI) ≤ 100 L/min	O_2 supply connector
N_2O 280 ~ 600 kPa (41 ~ 87 PSI) ≤ 100 L/min	N_2O supply connector	AIR 280 ~ 600 kPa (41 ~ 87 PSI) ≤ 100 L/min	Air supply connector
AGSS	AGSS outlet		Standby button
	Activate alarms（“x” indicates the number of active alarms）		Driver gas(The “x” is the driver gas type:$_2$ or Air)
	Audio Pause		Assisted breathing symbol
	Adjust the lower limit alarm parameters		Alarm parameter adjustment cap

	Caution		The logo appears do not touch the interface
	Do not reuse		Identifies the user needs to perform the operation
	Refer to instruction manual		Operating instructions
	Date Of Manufacture		Manufacturer
SN	Serial Number	EC REP	Authorized Representative In The European Community
LOT	Batch Code	REF	Catalogue Number
CE XXX	CE marking and Notified Body Number (93/42/EEC in accordance with harmonized standards)	IP21	Protected against solid foreign objects of Φ12.5mm and greater 1: Protection against vertically falling water drops
	Contains Or Presence Of Natural Rubber Latex		Keep Dry
	handle with care		Do not roll
	upward		Temperature Limitation
	Class I special waste (Depleted of used batteries must be in accordance with local regulations concerning the replacement and discarded)		Class II special waste (The O_2 sensor must be used in accordance with local regulations concerning the replacement and discarded. Normal waste is not the way to handle the processing of waste O_2 sensor)
	Hazardous waste (infectious) The apparatus includes some parts of the waste is not in a normal manner		Waste not processed properly handle used batteries (in some areas may not provide recycling facilities)
	Call for maintenance	IOIOI	Serial port interface
RS232	RS232 port interface	VGA	VGA output interface
	Do not obstruct-block		Disconnect mains plug from electrical outlet
	Disconnect gas from outlet		Alarm system clear

	Home position		
	Absorbent bypass on		

1.3 Term abbreviation and definition

Abbreviation	Definition
AA	Anesthetics agent
AGSS	Anesthetics Gas Scavenging System
ACGO	Auxiliary Common Gas Outlet
APL	Adjustable Pressure Limit
BTPS	Body temperature, ambient pressure, saturated humidity conditions
BDU	Breath Delivery Unit
Cdyn	Dynamic Compliance
CO_2	Carbon dioxide
DES	Desflurane
ENF	Enflurane
ET	End-tidal concentration
EtAA	End-tidal Anesthetics agent
EtENF	End-tidal Enflurane
EtHAL	End-tidal Halothane
EtDES	End-tidal Desflurane
EtSEV	End-tidal Sevoflurane
EtISO	End-tidal Isoflurane
EtN_2O	End-tidal Nitrous oxide
$EtCO_2$	End-tidal carbon dioxide
Esens	Expiratory Trigger Sensibility
Exp	Expiratory
FI	Fraction of inspired gas
FiO_2	Fraction of inspired oxygen
FiAA	Fraction of inspired Anesthetics agent
FiENF	Fraction of inspired Enflurane
FiHAL	Fraction of inspired Halothane
FiDES	Fraction of inspired Desflurane
FiSEV	Fraction of inspired Sevoflurane
FiISO	Fraction of inspired Isoflurane
FiN_2O	Fraction of inspired Nitrous oxide
$FiCO_2$	Fraction of inspired Carbon dioxide
f	Frequency
ftotal	Total respiratory rate

fspn	Spontaneous respiratory rate
Fsens	Flow Trigger Sensibility
GUI	Graphic User Interface
HAL	Halothane
I:E	Inspiratory-expiratory ratio
Insp	Inspiratory
ISO	Isoflurane
L/min	L/min
kPa	kilopascal
Kg	Kilogram
MAC	Minimum alveolar concentration
Manual	Manual ventilation
MV	Minute volume
N_2O	Nitrous oxide
O_2	Oxygen
Paw	Airway pressure
PCV	Pressure control ventilation
PEEP	Positive end-expiratory pressure
Pinsp	Pressure control level of inspiration
Plimit	Pressure limit level
Pmean	Mean airway pressure
Ppeak	Peak pressure
Pplat	Plateau pressure
Pmin	Minimum pressure
PCV	pressure control ventilation
PRVC	pressure guaranteed ventilation - volume control ventilation
Pause	Inspiratory pause time
Psens	Pressure Trigger Sensibility
PSV	Pressure support ventilation
Psupp	Pressure support level
R	Resistance
SEV	Sevoflurane
SIMV	Synchronized intermittent mandatory ventilation
SIMV-V	Synchronized intermittent mandatory ventilation –volume control ventilation
SIMV-P	Synchronized intermittent mandatory ventilation -pressure control ventilation
SIMV-PRVC	Synchronized intermittent mandatory ventilation -pressure guaranteed ventilation - volume control
SPONT/PSV	Pressure support ventilation with apnea backup
STPD	Standard Temperature and Pressure Dry
Tinsp	Inspiratory time
Tslope	Pressure rise time

Texp	Expiratory time
VT	Tidal volume
Vte	Expired tidal volume
Vti	Inspired tidal volume
VCV	Volume control ventilation

1.4 System information

1.4.1 System classification

This system is classified as follows:

1. Class I Equipment.
2. Type B Equipment.
3. Type BF Equipment.
4. Continuous operation.

1.4.2 Device standards

Devices used with this Anesthetics system shall comply with the following standards where applicable:

1. Breathing system and breathing system components ISO 80601-2-13.
2. Anesthetics gas scavenging systems ISO 80601-2-13.
3. Anesthetics vapor delivery devices ISO 80601-2-13.
4. Oxygen monitors ISO 80601-2-55.
5. Carbon dioxide monitors ISO 80601-2-55.
6. Exhaled volume monitors ISO80601-2-13.
7. Anesthetics agent monitors ISO 80601-2-55.
8. Pulse oximeter monitors ISO 80601-2-61.

1.4.3 Integral system components

This Anesthetics system contains the following integral components, monitoring devices, alarm systems, and protection devices that comply with European, international, and national standards:

Standard：

■Breathing system pressure-measuring device

■Airway pressure-limitation device

■Volume monitor

■Breathing system integrity alarm

■Anesthetics ventilator

■Breathing system

Optional：

■ Oxygen Sensor

■Side stream CO_2 module

■IRMA CO_2/AX+ module

■ SpO_2 module

■Auxiliary Common Gas Outlet(ACGO)

■Anesthetics vapor delivery device.

■Anesthetics gas scavenging systems(AGSS)

■Auxiliary Oxygen

■Suction regulator

■ Driver gas switch valve

2.1 Introduction

2.1.1 Intended use

The Anesthetic machine is intended to provide breathing Anesthetics for adult, pediatric patients during surgery.

The Anesthetics machine must only be operated by qualified anesthesia personnel who have received the correct training for its use.

The anesthesia machine without absolute contraindications.

⚠ Warning

- This Anesthetics machine is intended for use by qualified Anesthetics personnel only or under their guidance. Anyone unauthorized or untrained must not perform any operation on it.
- This product cannot be used under magnetic resonance (MRI) environment.
- Clinical environment is the operating room, emergency room.

2.1.2 Product performance structures

The equipment consists of the Anesthetics host, Anesthetics ventilator, the patient circuit, vaporizer, flow meters and other components.

2.2 Appearance

Front view

1. Frame
2. Anesthesia Vaporizer with Mounting bar
3. Anesthesia Ventilator
4. Handle
5. Drawers
6. Castors
7. ACGO switch
   - When ACGO switch is on: Fresh gas will be delivered to half open breathing system through ACGO outlet.
   - When ACGO switch is off: Fresh gas will be delivered to CO2 Circle Absorber.

8. ACGO port
9. Soda lime chamber
10. CO2 Circle Absorber
11. Airbag port
12. Bellow
13. Pipeline gas pressure gauges

    Displays the pressure value of the pipelines gas or the regulated pressure value of reserve cylinder gas.

14. Fresh gas flowmeter

    Fresh gas flow control knob

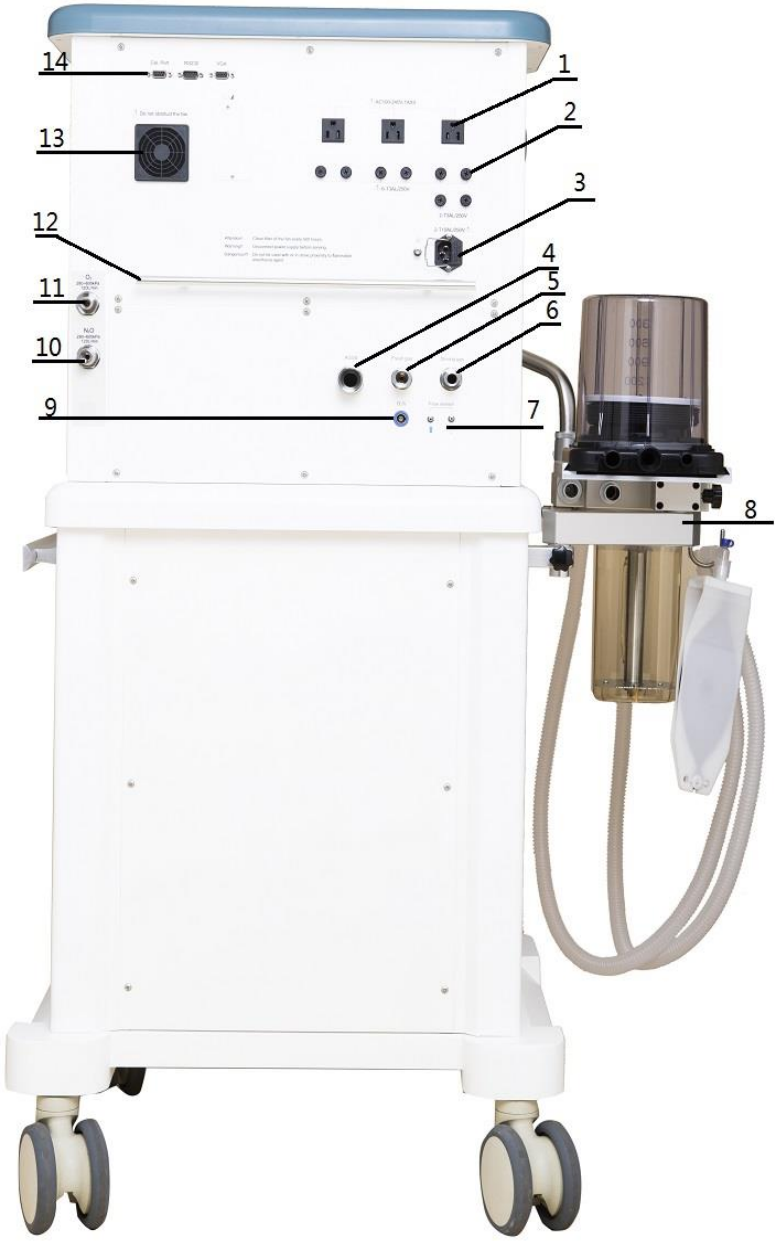
    - Turn flow control counterclockwise to increase gas flow.
    - Turn flow control Clockwise to decrease the gas flow.

15. System switch

    -  : Turn on the Anesthetics workstation system.
    -  : Turn off the Anesthetic workstation system.

16. O_2 flush button
17. Knob
18. Top table

Rear view



1. Auxiliary electrical outlets(3 outlets on back)
2. Fuse
3. Mains inlet
4. AGSS connection
5. Fresh Gas outlet
6. Driving gas
7. Flow sensor connector

8. Arm for CO2 Circle Absorber
9. O2 sensor connector
10. N2O gas source inlet
11. O2 gas source inlet
12. Pole for cable
13. Fan
14. Communication port
15. Battery box cover

Communication port

A. Calibration port (attachment to connect external calibration equipment for the machines calibration. This port can also be used to update the software of main unit.

B. RS232 interface (external multi-gas detection module IRMA CO_2 or IRMA AX .

C. VGA port (to provide external VGA output of the ventilator screen depending upon configuration)

2.3 Anesthesia Ventilator

See 6 Anesthesia Ventilator for details.

2.4 Battery

⚠ Caution

- Run the machine on Battery only at least once every month to extend the batteries life span. When using the Anesthetic machine, always connect to main power to keep the battery charged in case of electricity failure.
- Battery life is dependent on frequency of use. For a properly maintained and stored Nickel-hydrogen battery, its life expectancy is approximately 2 years. For more aggressive use models, life expectancy can be shortened. We recommend replacing Nickel-hydrogen batteries every 2 years.
- The operating times of a battery depends on configuration and operation, for example, starting module monitoring frequently will shorten the operating times of batteries.
- In case of battery failure, contact us or have your service personnel replace it. Don’t replace the battery without permission.
  The Anesthetic machine provides a built-in battery. When the Anesthetic machine is connected to the AC power source, the batteries are charged until it is full regardless of whether the system switch is on. In case of power failure, the Anesthetic machine will automatically be powered by the internal batteries.

Battery charging time / working hours (full charge)

Power Modules	Charging time	Working Hours

One set of batteries	About 4 hours	About 90 minutes

⚠ Caution

- If a battery has been discharged and has been stored for a long time, charging may take longer than the time stated in the table above.

2.4.1 Battery indicator

On-screen the power status indicator as follows:

● 
○  : The AC power is being used. When the battery icon is fluctuating, the battery is charging.

○ 
●  : The battery is being used.

On-screen the battery icon indicator as follows:

 : Indicates that the battery is fully charged.

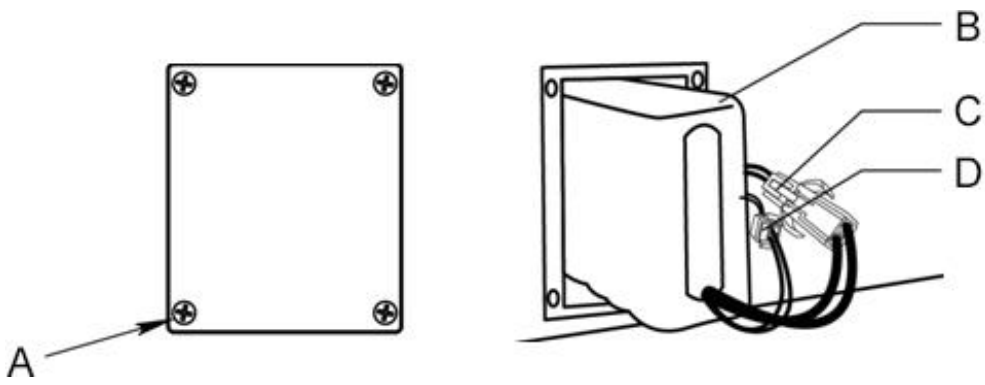
 : Indicates that the battery is normal and need focus on battery status.

 : Indicates low battery and the batteries need to be charged.

 : Indicates too low battery and the batteries need to be charged immediately.

The capacity of the internal battery is limited. If the battery capacity is too low, a high level Alarm [BATTERY LOW] will be triggered. If the [BATTERY DISCHARGED] alarm generated that the Anesthetic machine will soon automatically shut down, you need to immediately connect the AC power.

2.4.2 Installing or Replacing Batteries



A. Battery Cover B. Battery

C. Battery power supply cable C. Battery charging cable

Installing batteries:

1. Connect the battery power supply cable and the battery charging cable to the Anesthetic

machine.

2. Install the battery to the battery compartment as shown in the figure above.
3. Install the battery cover.

Replacing batteries:

Replace batteries with reference to installing batteries.

⚠ Warning

- To ensure that pipeline gas supply hose and breathing circuit components are not toxic, and will not cause allergic reactions to the patient and does not react with the anesthetic substances.
- Continuous use of desiccated soda lime may endanger patient safety. Adequate precautions should be taken to ensure that the soda lime in the absorber canister does not become desiccated. Turn off all gases when finished using the system.
- When using electrical surgical equipment, keep wires away from the breathing circuit, oxygen sensors, flow sensors and other components on the Anesthetic workstation and ensure that the Anesthetic workstation manual ventilation mode can be used at any time in order to avoid interference with electrical surgical equipment. In the meantime, please note that all monitoring and life support equipment are operation ready.
- Never use antistatic or conductive masks with the breathing tubes. They can cause burns if they are used near high frequency electrosurgical equipment.
- This equipment must be installed by the company authorized engineer.
- This Anesthetic machine has waste gas exhaust ports. The operator of the machine should pay attention to the disposal of the residual breathing gas scavenged.
- The Anesthetic workstation and power usage environment must meet environmental specifications B.2 B.3 specifications inside power requirements.
- Before Installing and using the Anesthetic workstation, all packing materials should be removed completely.

3.1 Install CO2 Circle Absorber

⚠ Caution

- Pay attention to the disposal of the breathing system after equipment use, the detection of the soda lime in the canister and the Anesthetic agent in the vaporizer to ensure the normal operation of the equipment.

3.1.1 install the arm

Install the arm on the aluminum piece of the frame and use the black knob to tighten it.

3.1.2 install the CO2 Circle absorber

1.Put the metal body on the arm, and use black knob to tighten.

2.Use 4 screws to secure the aluminum board on the arm, then insert the bellow on the aluminum board.

3.Install the bag arm on the metal body.

4.Install the pressure gauge on the metal body.

5.Install the soda lime chamber on the down of metal body Insert the soda lime chamber.

3.2 Install the Oxygen Sensor

⚠ Warning

- Before installing the O_2 sensor, check that the seal on the sensor is in good condition. Fit a new sensor if the seal is missing or damaged.
- Oxygen sensor must be tightened to avoid breathing system leak.

1. Install the three way connector on the expiration connector and insert the O2 sensor on it.

2. Insert the sensor cable into the O2 sensor.

3. Insert the other end of the cable into the O_2 sensor connector marked O_2% on the rear of the Anesthetic machine frame.

3.3 Install the breath circuit

⚠ Caution

- When installing the breathing tube, hold the tube connector at both ends of the tube to prevent damage of the tube.

1. The two breathing hoses are connected to the breathing system with expiratory and inspiratory connectors.

3.4 Install flow sensor

1.Insert the Flow Sensor between the Y-piece of the breath circuit and the patient connection as **FIGURE 3-1.**The blue tube of flow sensor is closest to the patient.
Connect the blue and colorless tubes to the Flow Sensor connectors in the back of anesthesia machine. The blue tube goes to the connector with blue mark. The colorless tube goes to the connector with colorless mark.

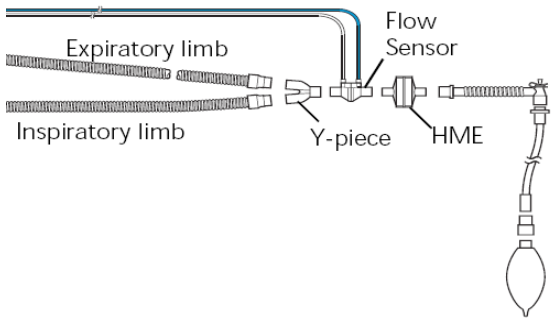


FIGURE 3-1 Installing the Flow Sensor

NOTE:

To prevent inaccurate Flow Sensor readings, make sure the Flow Sensor is correctly installed:

- The blue Flow Sensor tube must be toward the patient.
- The Flow Sensor tubes must be upright.
- The Flow Sensor tubes must not be kinked.
- The Flow Sensor tubes must be secured with clamp (included with Flow Sensor).

3.5 Installation of the Manual Bag

Connect the breathing bag to the manual bag port on the CO2 Circle Absorber system.

3.6 Installation of the Vaporizer

⚠ Warning

- If the vaporizer is incompatible with the Anesthetic machine, the performance of the Anesthetic agent in the vaporizer will be degraded. Use the vaporizer matching the Anesthetic machine.

⚠ Caution

- For details about how to install and use the vaporizer, refer to the Vaporizer Instructions for Use.

Please refer to the user manual of Anesthesia Vaporizer.

3.7 Power connector

⚠ Warning

- Powering additional devices through the auxiliary power outlets can increase the total leakage current. Test for leakage current at regular intervals. To reduce the total leakage current, use devices with an isolation transformer.

3.8 Gas source Connection

This is provision of piped gas Anesthetic workstation source (O_2, N_2O).

Medical gas pipeline connection

Connect the medical gas hose between the central gas supply terminal and the inlet on the Anesthetic workstation.

⚠ Caution

- Gas connections are not interchangeable. Check the label, symbol, and color code while connecting.

⚠ Warning

- Use medical grade gas supplies only. Other types of gas supplies may contain water, oil, or other contaminants.
- Check that cylinders are available as a backup in case of a central gas supply failure.

3.9 Connect the pipeline

Connect the pipeline among CO2 circle absorber, bellow and the body of anesthesia machine.

4.1 Test procedure before the operation

4.1.1 Test Interval

In the following cases, the test should be performed before the operation:

1) preoperative test should be initiated in each patient before the operation.
2) When required after a maintenance or service procedure.

Recommended testing schedule is as follows：

	The first patient daily before use	Each patient before use
System Check	4.2	
Flow control system test	4.3	
O_2 flush test		4.4
Vaporizer test	4.5	
APL Valve Test	4.6	
System Test	4.7	
Alarm Test	4.8	
Preoperative preparations		4.9

⚠ Caution

- Before using this equipment, read user manual to understand the function and operation of each component.
- If the system fails a test, do not use the device. Contact a maintenance engineer.

4.2 System Check

⚠ Warning:

- ◆ Ensure that the Anesthetic machine is not imbalanced and does not tilt more than 10 °
- ◆ Additional equipment placed on the top shelf must be securely attached. Do not install additional equipment on the top shelf heavier than 30 kg or above 450 mm in height.

Make sure that:

1. The Anesthetic machine is undamaged.
2. All components are correctly attached.
3. The breathing system is correctly connected, and the breathing tubes are undamaged.
4. The vaporizers are locked in position and contain sufficient agent.
5. The gas supplies are connected and the pressures are correct.
6. The necessary emergency equipment is available and in good condition.
7. Equipment for airway maintenance and tracheal intubation is available and in good condition.

8. Applicable Anesthetics and emergency drugs are available.
9. The casters are not damaged or loose and the brakes are set and function correctly.
10. Make sure the breathing system is locked in position.
11. The AC main indicator and the battery indicator come on when the power cord is connected to an AC power source. Note that if the indicators are not on, the system does not have electrical power.
12. The anesthetic machine is switched on or off normally.

4.3 Flow Control System Test

1. Connect the central pipeline gas supply.
2. Clockwise turn the flow control (minimum flow).
3. Turn on the system switch to ⊙ position.
4. Test the O_2-N_2O Link system with flow increasing:

Turn the N_2O and O_2 flow controls fully clockwise (minimum flow). Then turn the N_2O flow control counterclockwise and set the N_2O flow control to the rates shown in the table. The O_2 flow must meet the requirement listed in the following table.

Step	N_2O Flow（L/min）	O_2 Flow（L/min）
1	0.6	≥0.2
2	1.5	≥0.5
3	3.0	≥1.0
4	6.0	≥2.0
5	9.0	≥3.0

1. Test the O_2-N_2O Link system with flow decreasing:

Turn the N_2O and O_2 flow controls and set the N_2O flow to 10.0 L/min and the O_2 flow to 6 L/min respectively. Then slowly turn the O_2 flow control clockwise and set the N_2O flow control to the rates shown in the table. The O_2 flow must meet the requirement listed in the following table.

Step	N_2O Flow（L/min）	O_2 Flow（L/min）
1	9.0	≥3.0
2	6.0	≥2.0
3	3.0	≥1.0
4	1.5	≥0.5
5	0.6	≥0.2

1. Turn the N_2O and O_2 flow controls and set the O_2 and N_2O flow to 2.0 L/min. Disconnect the O_2 pipeline supply or close the O_2 cylinder valve, the N_2O flow must drop to 0 L/min.
2. Set the system switch to Ō position.

4.4 Oxygen Flush Test

1. Connect O_2 pipeline.
2. Set the system switch to the ⊙ position.
3. Ensure that the bag/Vent switch is set to vent  position.
4. Connect the patient circuit and seal the Y-piece by test block.
5. Push the O_2 flush button, Check that the bellows fully inflate within 4 seconds. Release the O_2 flush button to stop inflation.

4.5 Vaporizer Test

4.5.1 Vaporizer back pressure test

⚠Warning

- Check that each vaporizer is securely mounted.
- The machine must be connected to an Anesthetic gas scavenging system.
- To prevent damage, turn the flow controls fully clockwise (minimum flow or OFF) before using the system.

1. Connect the O_2 pipeline supply.
2. Set the system switch to the ⊙ position.
3. Set the O_2 flow to 6L / min.
4. Make sure that the O_2 flow stays constant.
5. Set a vaporizer concentration of 1%. Check that the O_2 flow does not decrease more than 1 L/min through the full range.
6. If the vaporizer fails this test, install a different vaporizer and repeat operation 4. If the problem persists, the malfunction is in the Anesthetic system. Do not use the system, contact trained technical personnel.
7. Test each vaporizer as above.

⚠Caution

- Do not test the vaporizer when the concentration control is between “OFF” and the first graduation above “0” (zero).

4.5.2 Vaporizer Interlock System Test

Check that the interlock mechanism of each vaporizer is working correctly, i.e. check that only one vaporizer at a time can be turned on when two vaporizers are fitted. Refer to the vaporizer user manual for additional pre-use checks.

4.6 APL Valve Test

1. Set the system switch to the ⊙ position.
2. Ensure that the bag/Vent switch is set to bag position.
3. Check that the breathing bag and breathing tubes are correctly connected.
4. Connect the Y-piece to the test plug on the breathing system.
5. Adjust APL valve limited pressure.
6. Push and hold the O_2 flush button until system stabilizes (not to exceed 45 cmH_2O).
7. Release the O_2 flush button and verify that pressure does not fall below 15 cmH_2O.

4.7 Alarm test

a) The alarm lamp flashes yellow and red once in turn and an audible beep sounds.

b) The start-up screen is displayed, followed by the standby screen after approximately 15 seconds.

c) Audio and visual alarm indicators are triggered.

4.7.1 Prepare for Alarm Test

1. Connect a test lung or manual bag to the Y-piece patient connector.
2. Set the bag/vent switch to vent.
3. Set the system switch to ON.
4. Set the system to standby mode.
5. Set the ventilator control setting to the follows:
   - Ventilation Mode: Select ventilation mode [VCV].
   - Tidal volume [VT]: 500mL.
   - Respiratory rate [Freq]: 15BPM.
   - Breathing ratio [I: E]: 1:2
   - PEEP: OFF
6. Push the O_2 flush button to fill the bellows.
7. Set the flowmeter to 0.5-1L/min.
8. Press the standby key to exit to standby mode.
9. Check that the ventilator displays the correct data, and that the bellows inflates and deflates normally during mechanical ventilation.

4.7.2 Minute Volume(MV) Low Alarm Test

1. Set the MVlow alarm limit to 10.0 L.

2. Check that a MV low alarm is triggered.
3. Set the MV low alarm limit to 2.0 L/min and check that the alarm is cancelled.

4.7.3 PRESSURE HIGH Alarm Test

1. Set the pressure high alarm limit to 30cmH_2O.
2. Check the Peak reading. Adjust the tidal volume until the reading is higher than the pressure high alarm limit.
3. Check that a PRESSURE HIGH alarm triggered.

4.7.4 Continuous Pressure High Alarm Test

1. Connect the manual bag.
2. Set the flowmeter to minimum.
3. Set the APL valve to 30 cmH_2O position.
4. Set the bag/Vent switch to bag.
5. Press and hold the O_2 flush button to fill bag until the reading on the airway pressure gauge is approximately 30 cmH_2O.
6. After 15 seconds, check that a continuous pressure high alarm is triggered.

4.7.5 PRESSURE LOW Alarm Test

1. Set the bag/Vent switch to vent.
2. Set the Paw low alarm limit to 5 cmH_2O.
3. Disconnect the test lung from the Y piece patient connection.
4. Check that a PRESSURE LOW alarm triggered.
5. Connect the test lung to the Y piece port.
6. Make sure the low Paw alarm is cancelled.

4.8 Preoperative preparations

1. Check that the ventilator parameters and alarm limits are set to applicable clinical levels. For details, refer to section 7 Operations and Ventilation Setup.
2. Check that the system is Standby.
3. Check that the equipment for airway maintenance, manual ventilation and tracheal intubation, and applicable Anesthetic and emergency drugs are available.
4. Set the bag/Vent switch to the bag.
5. Connect the manual bag to the bag port.
6. Turn off all vaporizers.
7. Turn the APL valve control to fully open the APL valve (MIN position).

8. Turn all flow controls to set all gas flows to minimum.
9. Check that the breathing system is not damaged and correctly connected.

⚠Warning

- Before connecting a patient, flush the Anesthetic machine with 5 L/min of O_2 for at least one minute. This removes unwanted gas mixtures from the system.

5.1 Turn on the System

1. Plug the power cord into an AC mains power outlet. The mains indicator is lit when the AC power is connected. The battery will be charged (if it is not already fully charged).
2. Check that the breathing system is properly connected.
3. Turn the system switch to ON position.

5.2 Standby Mode

1. Set the system switch to ON.

2. To return to standby mode during mechanical ventilation, press the standby key, and in the pop up menu select the ‘Activate Standby Mode’ button.

3. In standby mode, press the standby key, the system enters operating mode.

5.3 Turn the System Off

When a clinical procedure is completed:

1. Check that the vaporizer is in the OFF position, and all gas flow controls are set to off.

2. Turn the system switch to the OFF position.

5.4 Using the Touch Screen

This system uses touch screen technology, hard keys, and a control knob to access system functions, menus, and setting. The touch screen allows easy access to menus and settings.

Touch only one touch point at a time to check the correct selection is made.

⚠ Caution

- Do not apply excessive force to the touch screen; damage may occur.

5.5 System Settings

This chapter only describes the basic settings.

5.5.1 Alarm volume

1. Select [System] -> [Settings] -> [Loudness].
2. Select [Loudness]: 20% (minimum), 40%, 60%, 80%, 100% (maximum).

5.5.2 System time

1. Select the [System] -> [Date & Time].
2. Set [Time] and [Date].
3. Select [Apply].

5.5.3 Sign Breath Internal

1. Select the [System] -> [Settings] -> [Sigh Breath Every].
2. In the [Sigh Breath Every] menu, set 50-100 breaths.

5.5.4 Set the Language

1. Select the [System] -> [Settings] -> [Language].
2. In the [Language] menu, select the required language.

5.5.5 Set O_2 monitoring switch

If the anesthetic machine is not configured with an O_2 sensor or the O_2 sensor is depleted, the oxygen monitor can be set to OFF to prevent the occurrence of an O_2 sensor alarm.

1. Select [System] -> [Settings] -> [O_2].
2. Set the oxygen monitor to [ON] or [OFF].

5.5.6 Set patient trigger type

In the [SIMV-V], [SIMV-P] and [PSV] mode, the patient trigger is permitted. Trigger sensitivity can be set in flow triggering or pressure triggering. Normally flow triggering is preferable as this enables the patient to breathe with less effort.

1. Select the [System] -> [Settings] -> [Trigger Type].
2. Select the desired trigger type.

6.1 Set up

1. Connect the machine to the AC Power.

2. Connect the machine to the pressure gases (280 - 600 kPa).

3. Assemble the breathing system and bellows with anesthesia machine.

4. Connect the flow sensor and oxygen sensor etc.

⚠WARNING

- Position the Flow Sensor with the small tubing upright to prevent kinking and moisture buildup. Use the tubing clip to secure the Flow Sensor tubes to the patient circuit.

6.2 Powering on the System

1. Set the system switch to ON. Make sure that all the operating state LED and alarm lamp are illuminated.

2. The display shows the start-up screen and a start-up music is given at the same time, then enter the standby screen.

6.3 Patient Setup

6.3.1 Select patient type

Patient type can only be changed when the current ventilation mode is **Standby** mode.

1. Select **Standby** mode.

2. Select the Patient type: **Adult**, **Pediatric**, or **Neonatal**.

4. Select the Gender type: **male** or **female**. This step can be conducted when patient type is adult or pediatric only.

6.3.2 Setting Patient Height

Patient height determines the ideal body weight (IBW), which is used in calculations for ventilator start-up settings.

1. Select patient type and gender type.

2. Adjust the patient height setting and confirm the setting. The ideal bodyweight (**IBW**) and start-up settings are automatically calculated and displayed.

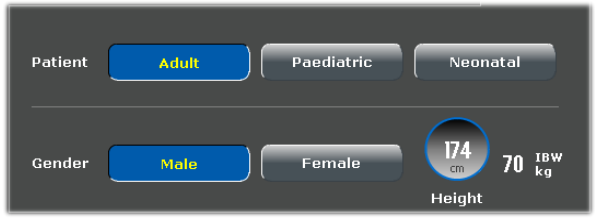


FIGURE 6-1 patient setup

6.4 Standby Mode

Standby Mode is the operating mode in which all the systems functionality are idle. It is the default system startup operating mode and is used between ventilation operations. During Standby, the user can adjust some settings in any ventilation mode, but no ventilation mode is enabled.

6.4.1 To Enter Standby Mode:

1. Select the **Standby key** on the front panel. A confirmation dialog box opens.

2. Select **Accept** to confirm entering **Standby** mode.

NOTE: In Standby mode, automatic ventilation and parameter monitoring are disabled.

6.4.2 To Exit Standby Mode:

Push the **start ventilation** button on the screen.

6.5 Set Ventilation Mode

6.5.1 Volume Control Ventilation (VCV)

6.5.1.1 Description

Volume control ventilation (referred to as VCV) mode is a basic fully-mechanical

ventilation mode. In the VCV mode, ventilator delivers the preset tidal volume with a constant flow or decelerating flow(depending on flow pattern setting)during the preset inspiratory time with the preset pause time and at the preset respiratory rate.

The peak pressure can vary from breath to breath if the patient's compliance and/or resistance change.

In the VCV mode, as long as airway pressure is less than upper pressure limit and the gas flow will be delivered.

To ensure the set tidal volume gas delivery, the ventilator adjusts gas flow based on the measured inspiratory volume, dynamically compensates for the loss of tidal volume arising from breathing system compliance and system leakage and eliminates the effect of fresh gas as well.

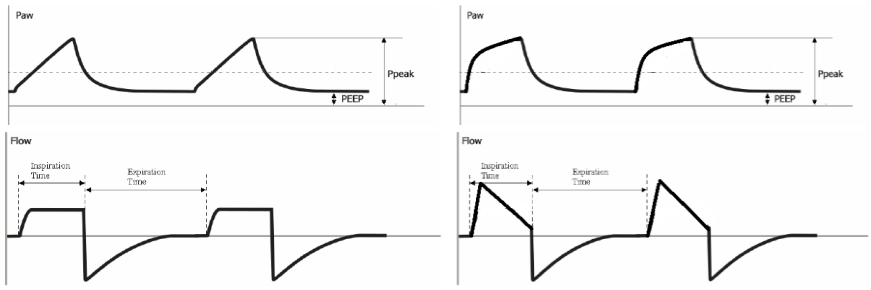


FIGURE 6-2 flow and paw waveform in VCV mode

The ventilator can deliver constant flow or decelerating flow by the flow pattern setting in the [**controls**] menu.

Although patients may be safely ventilated utilizing a constant flow pattern, the decelerating flow pattern does provide other benefits in addition to minimizing pressures. A decelerating flow waveform pattern has been shown to reduce peak inspiratory pressures, dead space, and alveolar-arterial gradients while increasing mean airway pressures and improving patient to ventilator synchrony.

6.5.1.2 Start VCV Mode

1. Push the [**Modes**] button to open the [**Modes**] menu.

2. Push [**VCV**] in the [**Modes**] menu, then the [**controls**] menu for VCV mode is opened.

3. Adjust appropriately parameter settings for the patient and then confirm the settings so as to start VCV mode.

6.5.1.3 Parameter Setup Area in VCV Mode

When VCV mode is confirmed, Key parameters are automatically switched over to the parameter setup area in this mode. It is convenient to monitor and set.

The following figure shows these parameters to be set in VCV mode.

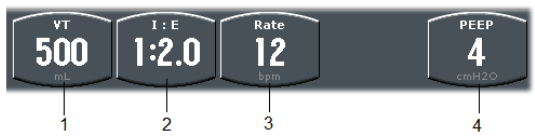


FIGURE 6-3 Key parameters in VCV mode

1. [VT]: Tidal volume
2. [I:E]: Ratio of inspiratory time to expiratory time
3. [Rate]: Breath rate
4. [PEEP]: Positive end-expiratory pressure

6.5.1.4 Set Parameters in VCV Mode

You can push the [**controls**] button or push the parameter in the parameter setup area directly, the [**controls**] menu is opened, select the parameter that you want to adjust in VCV mode. The

following takes setting of **VT** as an example.

1. Push the [**VT**] button.
2. turn control knob to set [**VT**] to the desired value.
3. Push the control knob or the [**VT**] button to confirm the setting.
4. Set other parameters in this mode in the similar way.

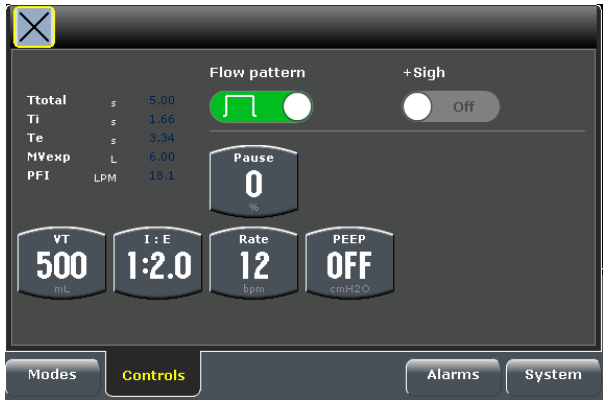


FIGURE 6-4 All parameters in VCV mode

6.5.2 Pressure Control Ventilation (PCV)

6.5.2.1 Description

Pressure control ventilation (hereinafter referred to as PCV) mode is a basic fully-mechanical ventilation mode. In the PCV mode, ventilator delivers a flow at the preset pressure throughout the preset inspiratory time at the preset respiratory rate.

During the inspiratory time, the pressure is constant and the flow is decelerating. The peak pressure (Peak) is the sum of the settings for PEEP and PC above PEEP. If for any reason pressure decreases during inspiration, the flow from the ventilator will immediately increase to maintain the set inspiratory pressure.

The volume may vary from breath to breath if the patient’s compliance and/or resistance change.

In the PCV mode, you need to set upper pressure limit to prevent high airway pressure from injuring the patient.

The following figures show the Paw waveform and flow waveform in the PCV mode.

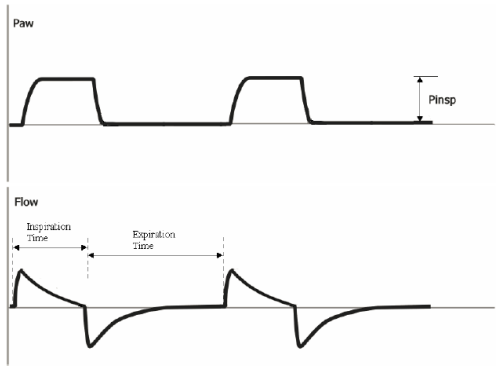


FIGURE 6-5 The paw and flow waveforms in PCV mode

Generally, in the PCV mode, the Paw waveform rises sharply during inspiration and stays at the plateau for a relatively long time without peak. The flow waveform declines in the same period.

In the PCV mode, tidal volume is measured instead of preset.

6.5.2.2 Start PCV Mode

1. Push the [**Modes**] button to open the [**Modes**] menu.
2. Push [**PCV**] in the [**Modes**] menu, then the [**controls**] menu for PCV mode is opened.
3. Adjust appropriately parameter settings for the patient and then confirm the settings so as to start PCV mode.

6.5.2.3 Parameter Setup Area in PCV Mode

When PCV mode is confirmed, Key parameters is automatically switched over to the parameter setup area in this mode. It is convenient to monitor and set.

The following figure shows all related parameters to be set in PCV mode.

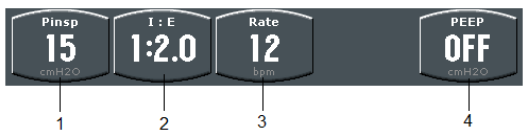


FIGURE 6-6 Key parameters in PCV mode

1. [Pinsp]: Pressure control level
2. [I:E]: Ratio of inspiratory time to expiratory time
3. [Rate]: Breath rate
4. [PEEP]: Positive end-expiratory pressure

6.5.2.4 Set Parameters in PCV Mode

The same method as 6.5.1.4

FIGURE 6-7 All parameters in PCV mode

6.5.3 Pressure Regulated Volume Control (PRVC)

6.5.3.1 Description

PRVC is a controlled mode of ventilation which combines the advantages of volume controlled and pressure-controlled ventilation. The ventilator delivers the preset tidal volume with the lowest possible pressure.

The first breath delivered to the patient is a volume controlled breath. The measured plateau pressure is used as the pressure level for the next breath. For the following breath, this pressure is constant during the set inspiratory time and the flow is decelerating.

The set tidal volume is achieved by automatic, breath-by-breath regulation. The ventilator adjusts the inspiratory Pressure Control level to the lowest possible level to guarantee the preset tidal volume, in accordance with the mechanical properties of the airways/lungs/thorax.

The following figures show the Paw waveform and flow waveform in the PRVC mode.

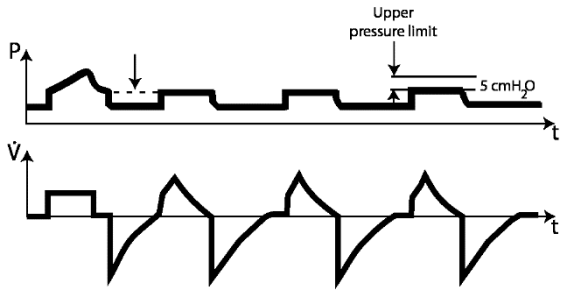


FIGURE 6-8 The paw and flow waveforms in PRVC mode

WARNING

PRVC is not recommended when there is a leakage in the patient´s breathing circuit.

6.5.3.2 Start PRVC Mode

1. Push the [**Modes**] button to open the [**Modes**] menu.
2. Push [**PRVC**] in the [**Modes**] menu, then the [**controls**] menu for PRVC mode is opened.
3. Adjust appropriately parameter settings for the patient and then confirm the settings so as to start PRVC mode.

6.5.3.3 Parameter Setup Area in PRVC Mode

When PRVC mode is confirmed, Key parameters is automatically switched over to the parameter setup area in this mode. It is convenient to monitor and set.

The following figure shows these parameters to be set in PRVC mode.

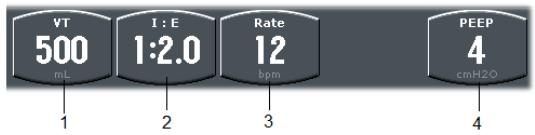


FIGURE 6-9 Key parameters in PRVC mode

1. [VT]: Tidal volume
2. [I:E]: Ratio of inspiratory time to expiratory time
3. [Rate]: Breath rate
4. [PEEP]: Positive end-expiratory pressure

6.5.3.4 Set Parameters in PRVC Mode

The same method as 4.5.1.4

FIGURE 6-10 All parameters in PRVC mode

6.5.4 Pressure Support Ventilation(PSV)

6.5.4.1 Description

Pressure Support is a spontaneous mode of ventilation. The patient initiates the breath and the ventilator delivers support with the preset pressure level. With support from the ventilator, the patient also regulates the respiratory rate and the tidal volume. In Pressure Support, the patient triggers all breaths, the preset inspiratory Pressure Support level is kept constant and there is a decelerating flow. The peak pressure (Peak) is the sum of the settings for PEEP and Pressure Support above PEEP.

Any change in the mechanical properties of the lung/thorax and/or patient effort will affect the delivered tidal volume. If this occurs, the Pressure Support level must be adjusted to ensure the desired ventilation.

Inspiration starts when the patient triggers a breath and gas flows into the patient's lungs at a constant pressure. Since the pressure provided by the ventilator is constant, the flow will decrease until the inspiratory cycle off is reached, when the expiration starts.

If no breath is detected within the interval determined by the apnea time setting, a apnea alarm will be activated and the ventilator will go to backup ventilation to ensure breath delivery to the patient.

Expiration starts:

1. when the inspiratory flow decreases to the preset inspiratory cycle off level [**Esens**].

2. if the pressure increases 3 cmH2O above the Pressure Support level.

3. if the upper pressure limit is exceeded.

4. if the inspiration exceeds 2 s for adults and 1.5 s for infants.

The following figures show the Paw waveform and flow waveform in the PSV mode.

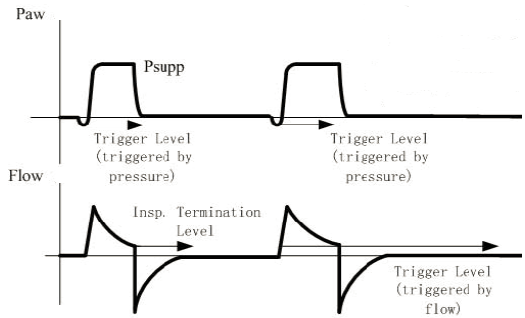


FIGURE 6-11 The paw and flow waveforms in PSV mode

6.5.4.2 Start PSV Mode

1. Push the [**Modes**] button to open the [**Modes**] menu.

2. Push [**PSV**] in the [**Modes**] menu, the [**controls**] menu for PSV mode is opened.

3. Adjust appropriately parameter settings for the patient and then confirm the settings to start PSV mode.

6.5.4.3 Parameter Setup Area in PSV Mode

When PSV mode is confirmed, Key parameters is automatically switched over to the parameter setup area in this mode. It is convenient to monitor and set.

The following figure shows these parameters to be set in PSV mode.

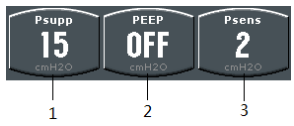


FIGURE 6-12 Key parameters in PSV mode

1. [Psupp]: Pressure support level above PEEP
2. [PEEP]: Positive end-expiratory pressure
3. [Psens] or [Fsens] Pressure trigger sensitivity or flow trigger sensitivity

6.5.4.4 Set Parameters in PSV Mode

The same method as 6.5.1.4

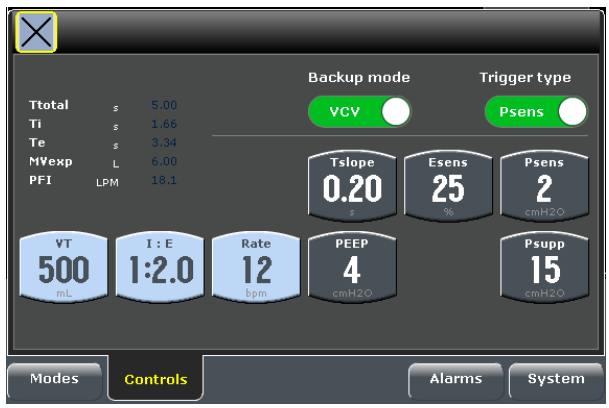


FIGURE 6-13 All parameters in PSV mode

6.5.4.5 Set Backup Mode

There are two different Backup modes, relevant parameters are shown in a kind of different color.

1. push [**Backup mode**] button, select VCV or PCV.
2. Adjust these relevant parameters to desired value.

6.5.5 Synchronized Intermittent Mandatory Ventilation (SIMV)

6.5.5.1 Description

During SIMV the patient receives mandatory breaths that are controlled or assisted by the ventilator. These mandatory breaths are synchronized with the breathing efforts of the patient who can breathe spontaneously between the mandatory breaths.

The mandatory breath is defined by the basic settings (ventilation mode, breath cycle time,

respiratory pattern and volumes/pressures).The SIMV rate is the rate of the mandatory breaths per minute.

The spontaneous/pressure-supported breath is defined by setting the Pressure Support level above PEEP. When the user gradually decreases the SIMV rate, the patient has more and more time for the spontaneous/pressure-supported breaths.

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

As Figure 4-15 shows, each SIMV breath cycle (Tb) has two parts: the first part of the cycle is the mandatory interval (Tm) and is reserved for a PIM. If a PIM is delivered, the Tm interval ends and the ventilator switches to the second part of the cycle, the spontaneous interval (Ts), which is reserved for spontaneous breathing throughout the remainder of the breath cycle. At the end of an SIMV breath cycle, the cycle repeats. If a PIM is not delivered, the ventilator delivers a VIM at the end of the mandatory interval, then switches to the spontaneous interval.

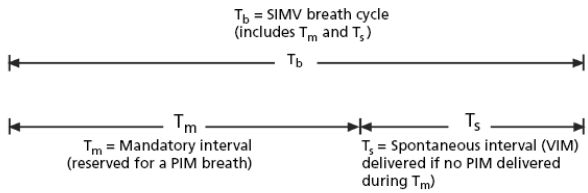


Figure 6-14 SIMV breath cycle

There are three different SIMV modes:

- SIMV (VC) + Pressure Support
- SIMV (PC) + Pressure Support
- SIMV (PRVC) + Pressure Support

6.5.5.2 Start SIMV Mode

You can select [SIMV-VC], [SIMV-PC] or [SIMV-PRVC] as required.

To start SIMV-VC mode, do as follows:

1. Push the [Modes] button to open the [Modes] menu.
2. Push [SIMV-VC] in the [Modes] menu, then the [controls] menu for SIMV-VC mode is opened.
3. Adjust appropriately parameter settings for the patient and then confirm the settings to start SIMV-VC mode.

To start SIMV-PC or SIMV-PRVC mode, take the above description as an example.

6.5.5.3 Parameter Setup Area in SIMV Mode

When SIMV mode is confirmed, Key parameters is automatically switched over to the parameter setup area in this mode. It is convenient to monitor and set.

- The following figure shows these parameters to be set in SIMV-VC mode.

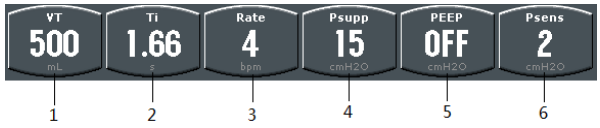


FIGURE 6-15 Key parameters in SIMV-VC mode

1. [VT]: Tidal volume
2. [Ti]: Inspiratory time
3. [Rate]: Breath rate
4. [Psupp]: Pressure support level above PEEP
5. [PEEP]: Positive end-expiratory pressure
6. [Psens] or [Fsens] Pressure trigger sensitivity or flow trigger sensitivity

- The following figure shows these parameters to be set in SIMV-PC mode.

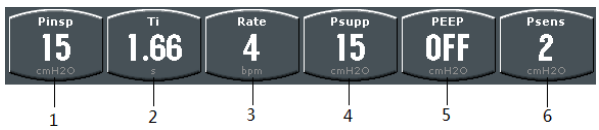


FIGURE 6-16 Key parameters in SIMV-PC mode

1. [Pinsp]: Pressure control level above PEEP
2. [Ti]: Inspiratory time
3. [Rate]: Breath rate
4. [Psupp]: Pressure support level above PEEP
5. [PEEP]: Positive end-expiratory pressure
6. [Psens] or [Fsens] Pressure trigger sensitivity or flow trigger sensitivity

- The following figure shows these parameters to be set in SIMV-PRVC mode.

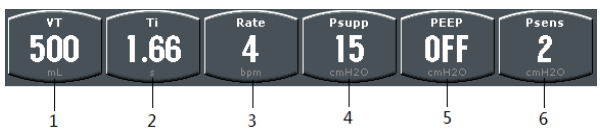


FIGURE 6-17 Key parameters in SIMV-VC mode

1. [VT]: Tidal volume
2. [Ti]: Inspiratory time
3. [Rate]: Breath rate
4. [Psupp]: Pressure support level above PEEP

5. [PEEP]: Positive end-expiratory pressure

6. [Psens] or [Fsens] Pressure trigger sensitivity or flow trigger sensitivity

6.5.5.4 Set Parameters in SIMV Mode

The same method as 4.5.1.4

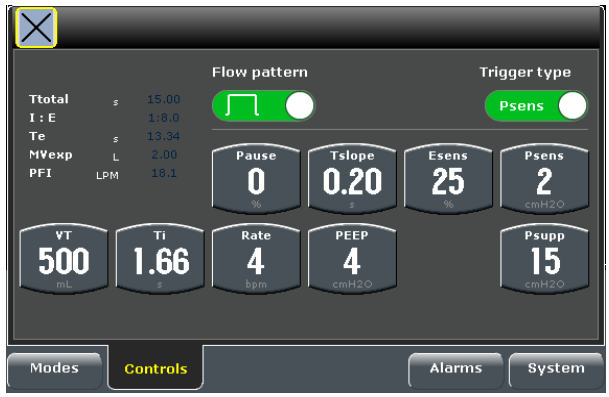


Figure 6-18 All parameters in SIMV-VC mode

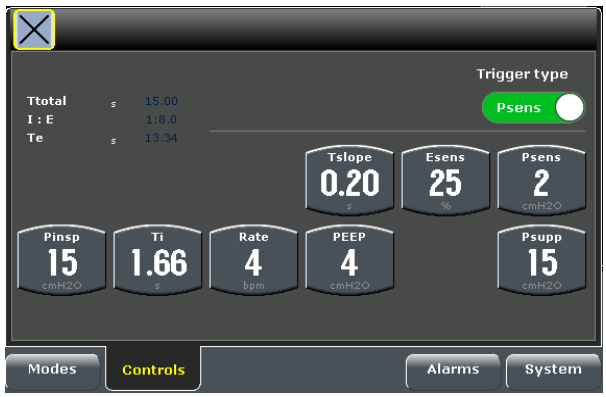


Figure 6-19 All parameters in SIMV-PC mode

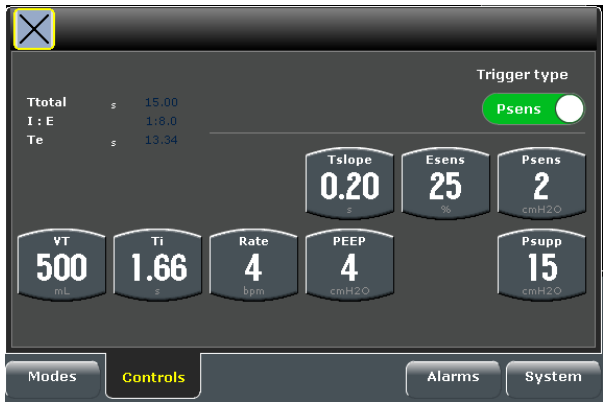


Figure 6-20 All parameters in SIMV-PRVC mode

6.5.6 Manual/Spontaneous Mode

Manual/spontaneous ventilation mode is the operating mode used for manually ventilating a patient or to let a patient breathe spontaneously. To use the manual/spontaneous ventilation mode, the user must first set the APL valve in breath system to the appropriate pressure value and then select **MAN./SPONT** mode from [**modes**] menu.

In **MAN./SPONT** mode, no parameters need to be set. No parameter in the key parameters area and the [**controls**] menu is not visible either.

6.6 Operation of stopwatch

1. Start the stopwatch by pressing the stopwatch button. Then the color of the button will change from grey to green and the stopwatch will start to count.
2. The Stop the stopwatch by pressing the stopwatch button again, and the button will change from green to grey and the stopwatch will stop counting.
3. Reset the stopwatch by pressing the stopwatch button continuous more than three seconds. This can only be done when the stopwatch is stopped.

6.7 User Menus

Anesthesia ventilator has a number of menus that can be accessed by the user:

- Standby screen
- Normal screen
- Modes menu
- Controls menu
- Monitoring menu
- Alarms menu
- System menu

6.7.1 Standby Screen

When the anesthesia ventilator is not in use for a short period of time, entering standby status can help save power and extend service life of the machine.

The ventilator enters standby status automatically after start-up. To enter standby status, you can push the ⏻ key and then select [Accept] from the pop-up menu. The following figure shows the standby screen.

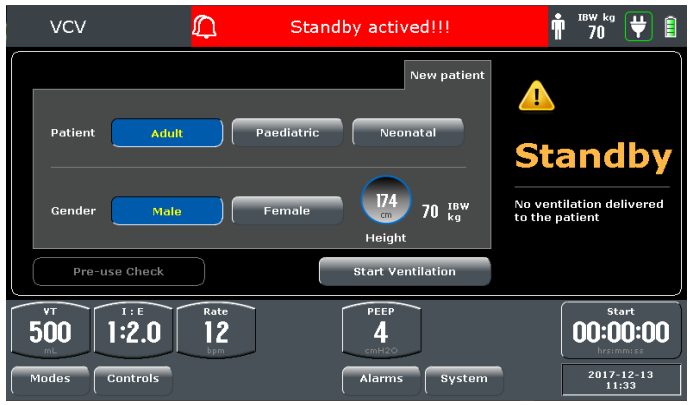


Figure 6-21 Standby screen

In standby status, the following changes occur to the system:

- Displaying monitored parameters and waveforms is disabled. The system is in standby status.
- The ventilator stops to deliver gases.
- The parameters can be set. When the standby status exits, the system will operate based on the final settings in standby status.
- The patient data can be defined, When the patient height and type have been defined, the ventilator settings of tidal volume, minute volume and respiration rate will change, in accordance with the patient data.

There are three kinds of patient size to select:

- Adult
- Pediatric
- Neonatal(optional)

To exit standby, push the [Start Ventilation] button in standby mode.

NOTE

- The patient type and height can be changed when the anesthesia ventilator is in standby mode only.

6.7.2 Normal Screen

The following figure shows the normal screen.

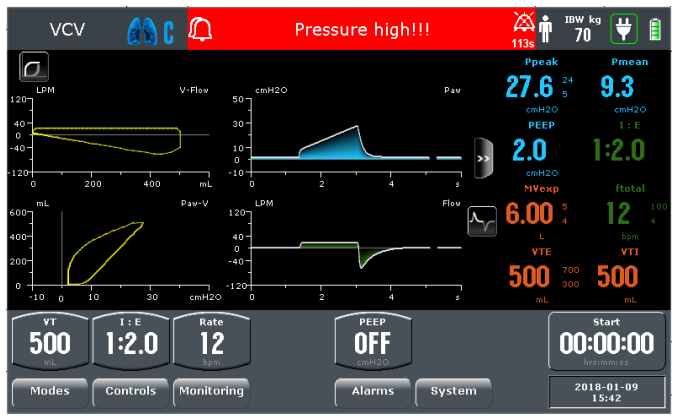


Figure 6-22 Normal screen

6.7.2.1 Waveform

The waveform combinations vary depending on the configurations. The waveforms displayed include:

- Paw waveform
- Flow waveform
- Volume waveform
- CO2 waveform
- Pleth waveform
- Volume-Flow loop
- Pressure-Flow loop
- Pressure-Volume loop

Push button to open or close spirometry loop display and push button to open the loop selection menu, Volume-Flow loop or Pressure-Flow loop can be selected.

Push button to open the waveform selection menu, flow waveform, volume waveform, Pleth waveform(optional) or CO_2 waveform(optional) can be selected.

6.7.2.2 Parameter Monitoring

The parameter combinations displayed vary depending on the configurations.

6.7.3 Modes Menu

When pressing [Modes] button, the modes menu appears. There are eight kinds of ventilation modes to select:

- VCV
- PCV
- PRVC(optional)
- SIMV-VC
- SIMV-PC
- SIMV-PRVC(optional)
- PSV
- MAN./SPONT

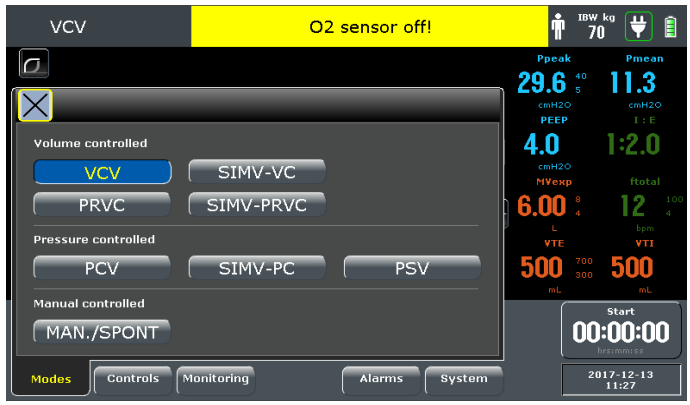


Figure 6-23 Modes screen

6.7.4 Controls Menu

When pressing [Controls] button, the controls menu appears. The parameter combinations displayed vary in controls menu depending on mode setting.

6.7.5 Monitoring Menu

When pressing [Monitoring] button, the monitoring menu appears. All monitoring parameters are displayed in this menu, two sub-menus are displayed.

- Ventilation parameters in values 1 sub-menu.
- CO_2 parameters and SpO_2 parameters in values 2 sub-menu. When the CO2 module or SpO2 module exists,CO_2 parameters and SpO_2 parameters will be displayed.

The following figure shows monitoring menu.

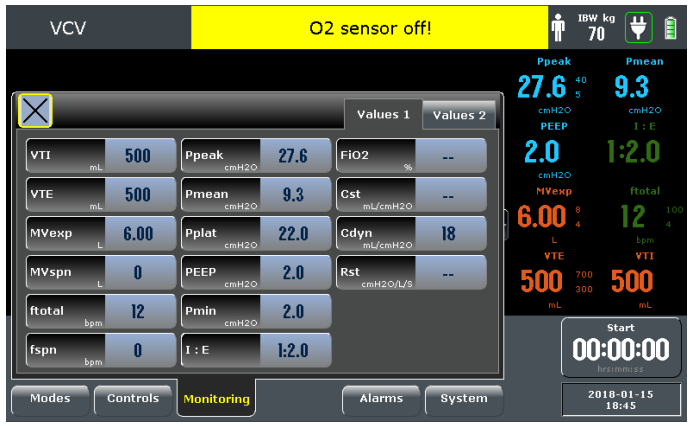


Figure 6-24 Values 1 sub-menu in the monitoring menu

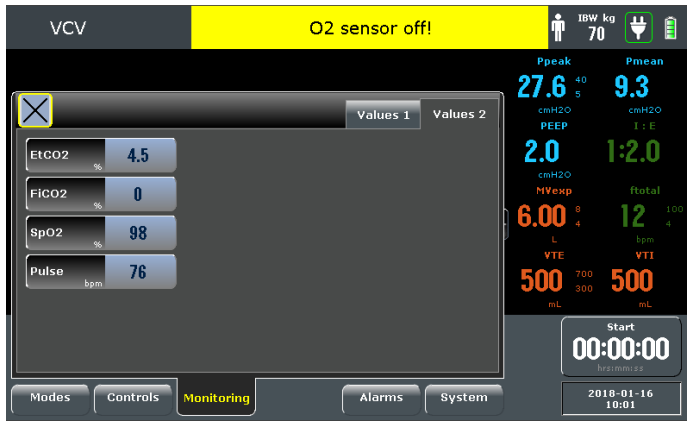


Figure 6-25 Values 2 sub-menu in the monitoring menu

6.7.6 Alarms Menu

When pressing [Alarms] button, the alarms menu appears. The alarms menu has three sub-menus:

- Limits 1
- Limits 2
- Alarm log

Activate the setting by pressing control knob or pressing desired setting button. Several alarm settings can be changed immediately, by turning the control knob, and press control knob or button to confirm. The setting will not change, before entering is pressed on the control knob or button is pressed again. For high and low alarm limits, the value of the lower limit is always less than the higher limit.

You can access the Alarms menu and change alarm settings at any time, without affecting ventilation.

6.7.6.1 Alarm limits 1

The ventilation alarm settings can be accessed in the limits 1 sub-menu. The following figure shows limits 1 sub-menu in the alarm menu.

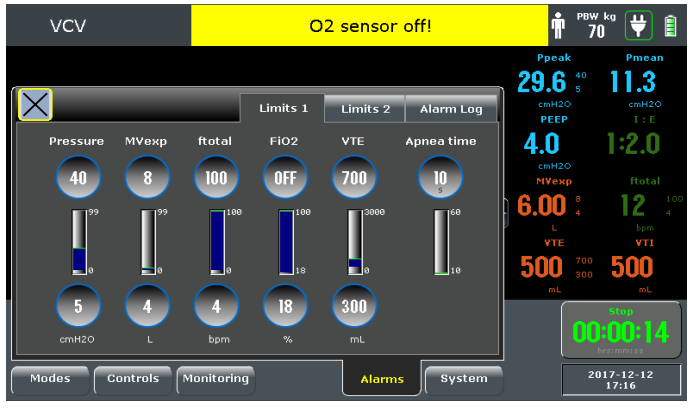


Figure 6-26 Alarm limits 1 sub-menu

The following alarm settings can be accessed in this menu:

- High pressure
- Low pressure
- High MVexp (expiratory minute volume)
- Low MVexp (expiratory minute volume)
- High ftotal (respiratory rate)
- Low ftotal (respiratory rate)
- High VTE (Expiratory tidal volume)
- Low VTE (Expiratory tidal volume)
- High FiO2 (only if O2 sensor is installed)
- Low FiO2 (only if O2 sensor is installed)
- Apnea time

6.7.6.2 Alarm limits 2

The ventilation alarm settings can be accessed in the limits 2 sub-menu. The following figure shows limits 2 sub-menu in the alarm menu.

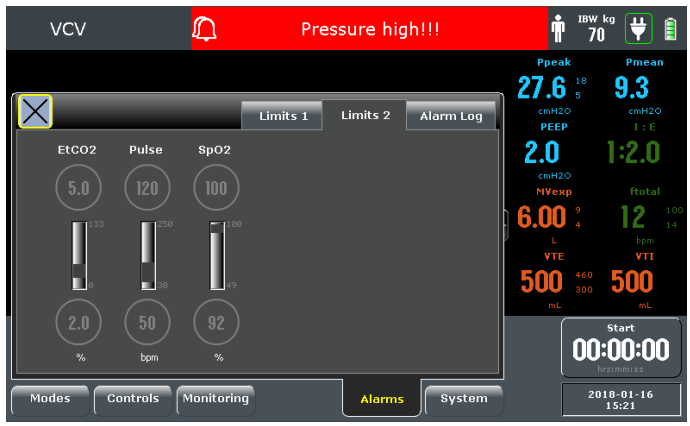


Figure 6-27 Alarm limits 2 sub-menu

The following alarm settings can be accessed in this menu:

- High $EtCO_2$ (only if CO_2 module is installed)
- Low $EtCO_2$ (only if CO_2 module is installed)
- High Pulse Rate (only if SpO_2 module is installed)
- Low Pulse Rate (only if SpO_2 module is installed)
- High SpO_2 (only if SpO_2 module is installed)
- Low SpO_2 (only if SpO_2 module is installed)

If the CO2 module or SpO2 modules are not installed, CO2/SpO2 alarm settings can not be set.

⚠WARNING:

The alarms should be adjusted according to the patient and should not be adjusted to extreme settings.

6.7.6.3 Alarm Log

Two hundred recent alarms can be stored in the alarm log. If the alarm log is full, the oldest alarm record will be overwritten. The following figure shows alarm log sub-menu.

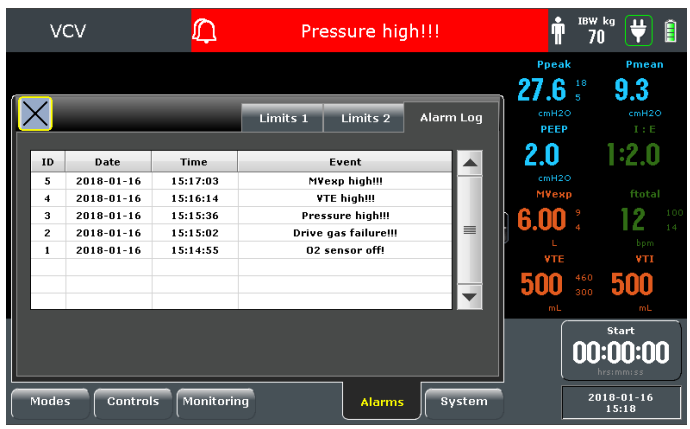


Figure 6-28 Alarm log sub-menu

6.7.7 System Menu

When pressing [System] button, the system menu appears. The following sub-menus can be accessed in the system menu:

- Information
- Setup
- Date & Time
- Calibration
- Service Modes

6.7.7.1 Information Menu

The following information can be viewed in this menu:

- Model
- Software Version
- Options Installed

- Runtime (Ventilator Operating Hours)
- Barometric Pressure
- Gas supply Pressure

When the option is installed, the option icon is active. The following figure shows the information sub-menu.

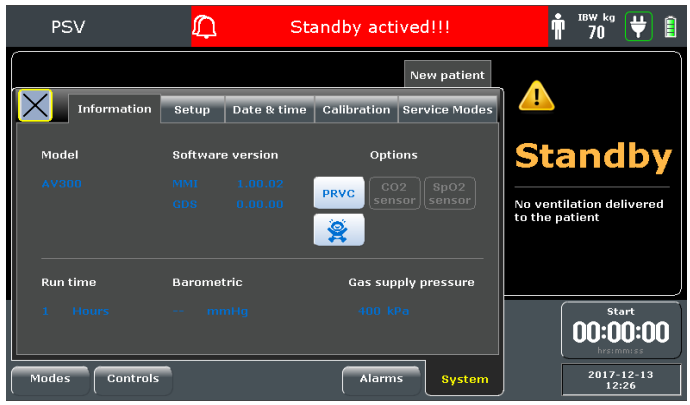


Figure 6-29 Information menu

6.7.7.2 Setup Menu

The following settings can be accessed in this menu:

- Loudness
- Language
- Units
- Sensor on/off

Figure 6-30 Setup Menu

6.7.7.2.1 Set Alarm Loudness

Adjust the alarm loudness as follows:

1. Push the [loudness] button, turn the control knob and adjust the loudness value as desired according to test voice.
2. Push the [loudness] button again or push the control knob to confirm.

6.7.7.2.2 Set Language

Set the language as follows:

1. Select the current language pop-up window opens.
2. Select the desired language or push the control knob to confirm selection.
3. After confirmation, the language for screen display is update automatically.

6.7.7.2.3 Set Units

Set units as follows:

1. Press [units] button to open units setting menu (**Figure 6-31**).
2. Press a parameter and turn the control knob to select the desired unit. The change takes effect immediately. Repeat for any other desired parameters.
3. Press [Exit] button to return setup menu.

Figure 6-31 Units menu

6.7.7.2.4 Sensor on/off

When O_2 sensor, CO_2 module or SpO_2 module are installed, the monitoring switch is active. Select a monitoring switch to enable or disable these monitoring functions as desired.

When O_2, SpO_2 or CO_2 monitoring is disabled, the appropriate “Alarms Off” message is displayed in the alarm state area.

6.7.7.3 Setting System time

1. Open the **System -> Date & time** menu (**Figure 6-32**).
2. Select and adjust a parameter. Repeat as necessary. **Apply** the changes.
3. Select [**Date Format**] and toggle between [**YYYY-MM-DD**], [**MM-DD-YYYY**] and [**DD-MM-**

YYYY].

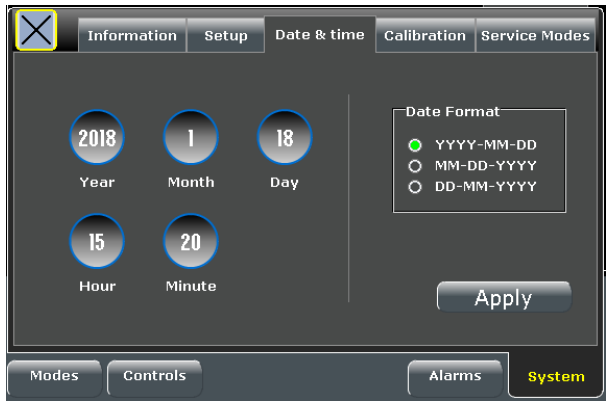


Figure 6-32 Data & Time Menu

6.7.8 Calibration

Touch the [**Calibration]** window (**Figure 6-33**) to view and access the calibrations.

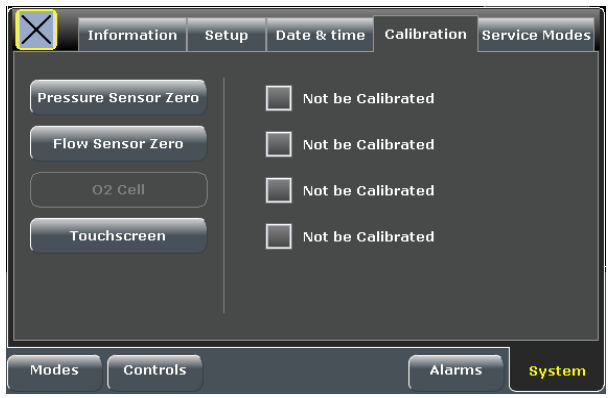


Figure 6-33 Calibration menu

6.7.8.1 Pressure Sensor Zero Calibration

1. Touch [**Pressure Sensor Zero**] button, the calibration menu appears.
2. Follow the instructions displayed, disconnect the breathing circuit at the patient side of the flow sensor, touch [**Start**] button.
3. When calibration is complete, verify that the message bar displays "**Calibration Completed!".**

6.7.8.2 Flow Sensor Zero Calibration

1. Touch [**Flow Sensor Zero**] button, the calibration menu appears.
2. Follow the instructions displayed, disconnect the flow sensor from breathing circuit ,touch [**Start**] button.
3. When calibration is complete, verify that the message bar displays "**Calibration**

Completed!”.

6.7.8.3 O_2 Cell Calibration

NOTE:

- The O_2 cell calibration requires that an O_2 cell be installed, monitoring enabled, and oxygen be available.

1. Touch [**O_2 cell**] button, the calibration menu appears.
2. Follow the instructions displayed, disconnect the O_2 sensor from breathing circuit, touch [**100%**] button or [**21%**] button respectively.
3. When calibration is complete, verify that the message bar displays “**Calibration Completed!”.**

6.7.9 Service Modes Menu

Touch the [**Service Modes]** window (**Figure 6-34**) to view and service. Service is only accessible when the correct password has been given.

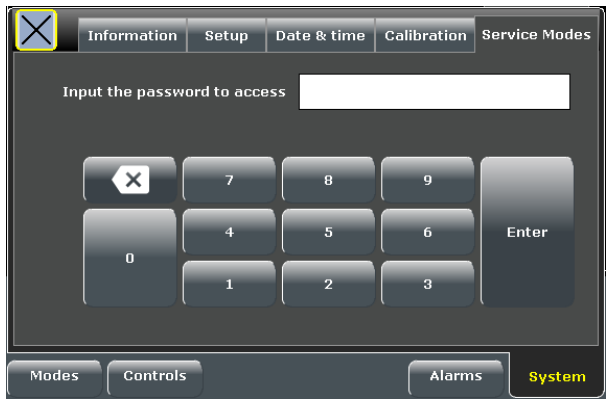


Figure 6-34 Service Modes Menu

⚠ Warning

- Before clinical use, check that all connections are secure and the pre-operation tests are completed. If any tests failed, do not use the system. Contact the service engineer for repair.

7.1 Input Fresh Gas

7.1.1 N_2O, O_2, Air Input Settings

1. Check each gas supply connection and pressure.

2. Gas flow values are shown on the respective flow meter.

3. The O_2 and N_2O flow controls are linked:

a) Increase the N_2O flow. The O_2 control will increase the O_2 flow, to maintain the O_2 concentration in the mixed gas above 25%.

b) Decrease the O_2 flow. The N_2O flow will decrease, to maintain an O_2 concentration greater than 25% in the mixed gas.

7.1.2 Vaporizer and Anesthetic Agent Setting

Follow the instructions in the vaporizer user manual.

7.2 Set Ventilation Mode

7.3 Ventilator Settings

7.3.1 Set Tidal Volume

1) Select [VT] hotkey.
2) Press the control knob; turn the knob to set the required VT value.
3) Press the control knob to confirm and activate the change.

⚠ Caution

- Confirm the new setting before adjusting another parameter. If confirmation is not given, the ventilator reverts to the pre-set value.

7.3.2 Set Respiratory Rate

1) Select the [FREQ] hotkey.
2) Press the control knob, turn the knob to set the required FREQ value.
3) Press the control knob to confirm and activate the change.

7.3.3 Set Inspiratory Time

1) Select the [TI] hotkey.
2) Press the control knob; turn the knob to set [TI] is set to an appropriate values.
3) Press the control knob to confirm and activate the change.

7.3.4 Set Inspiratory & Expiratory Ratio

1) Select [I: E] hotkey.
2) Press the control knob, turn the knob to set the required I: E value.
3) Press the control knob to confirm and activate the change.

7.3.5 Set Pressure Limit Level

1) Select [Alarms] ->[Limit 1].
2) Press the control knob, and turn the knob to set the upper and lower limits [pressure] to the required values.
3) Press the control knob to confirm and activate the change.

7.3.6 Set PEEP

1) Select the [PEEP] hotkey.
2) Press the control knob and turn the knob to set PEEP to the desired value.
3) Press the control knob to activate and confirm the change.

7.3.7 Set Pressure Control Level

1) Select the [Pinsp] hotkey.
2) Press the control knob and turn the knob to set Pinsp at the desired value.
3) Press the control knob to confirm and activate the change.

7.3.8 Set Pressure Support Level

1) Select the [Psupp] hotkey.
2) Press the control knob and turn to set [Psupp] at the desired value.
3) Press the control knob to confirm and activate the change.

7.3.9 Set Apnea Time

If SPONT / PSV mode is used, the system is provided with a backup ventilation mode.

If an Apnea situation occurs, and there is no spontaneous breathing, or spontaneous breathing and an inspiratory trigger condition is not reached, the system in accordance with the set ‘Apnea time', automatically enters backup ventilation mode.

Apnea Time in a no-breath conditions is set as follows:

1) Select [Alarm] -> [Apnea time].
2) Turn the control knob to set the Apnea time to the desired value.
3) Press the button to confirm and activate the change.
4) Closing the window or returning to the main screen will cancel the setting.

7.3.10 Set Inspiratory Pause

1) In VCV mode, select the [Pause] hotkey.
2) Set the pause at the desired value:0, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%.
3) Press the control knob to confirm and activate the change.

7.3.11 Set Rise Time

In pressure mode, rise time is available.

1) Select [Tslope] hotkey.
2) Set the [Tslope] at the desired value, namely 0-2s, 0.1s increments.
3) Press the control knob again to activate the change.

7.3.12 Set Expiratory trigger sensibility

1) In the SIMV-V, SIMV-P, SPONT / PSV mode, select [Control] - [Esens] hotkey.
2) With the control knob pressed, turning the knob to set Esens to the desired value, (5% to 80% with increments of 5%).
3) Press the control knob to confirm the change.

7.4 Start Mechanical Ventilation

To exit Standby mode and start mechanical ventilation, press the Standby key.

⚠ Caution

- Check the parameters are set to appropriate values before starting ventilation.

7.5 Parameters Monitoring

7.5.1 FiO_2 monitoring

If the system is configured with an O_2 module or an oxygen sensor, FiO_2 values are displayed.

⚠ Caution

- If an oxygen sensor is used, oxygen concentration monitoring may be inaccurate. Calibrate the oxygen sensor if the inaccuracies are large.

7.5.2 Pressure Monitoring

Pressure related parameters are measured as shown below.

【PEEP】

【Ppeak】

【Pplat】

【Pmean】

7.5.3 Tidal Volume Monitoring

⚠ Caution

- The tidal volume values on the bellows housing give an approximate indication, and may be inconsistent with the actual measured volumes. This is a normal phenomenon.
- International standards require that the user must monitor tidal volume during a clinical procedure.

Volume related parameters are measured as shown below.

【VTI】

【VTE】

【MV】

【MVspn】

7.5.4 Breath Rate Monitoring

Breath rate related parameters are measured as shown below.

【ftotal】

【fspn】

7.5 Pulmonary Function

The system displays dynamic compliance monitoring, static resistance, and spirometry loops to reflect the patient's pulmonary function.

The system provides two spirometry loops: Paw-V (Paw-volume) loop and V- Flow (volume-flow) loop. The scales of volume flow and Paw are adjusted automatically.

7.6 Alarm Setup

Use the Alarm setup menu to set and adjust alarm limits and to view alarm history.

See section 6.2.5 for alarm descriptions.

Set alarm limits：

1. Select the [Alarms] hotkey and select the [limits 1] /[limits2]/ [limits 3] page.
2. Set upper and lower limit respectively for each parameter.
3. Exit the menu.

Chapter 8 Alarms

8.1 Introduction

Alarms are triggered by a vital sign that appears abnormal, or by a technical condition within the Anesthetic machine. Alarms are indicated to the user by visual and audible alarm indicators.

8.2 Alarms

The anesthesia ventilator System provides alarms and messages that are indicated to the user by visual and audible alerts. Alarms and messages appear in the alarm state area. Users can adjust alarm properties, which include setting alarm limits to trigger alarm conditions, adjusting alarm volume, and silencing alarms.

⚠WARNING:

An audible alarm indicates an anomalous condition that may result in damage to the equipment or injury to the patient. The cause of each alarm should be investigated and any necessary measures taken to remove the alarm condition.

When an alarm is activated:

- an audible warning sounds;
- a message appears in the alarm state area if the alarm priority is highest;

- the alarm is added to the list of alarms in the alarm log.

Only the highest priority alarm message is displayed in the alarm state area. If more than one alarm is activated, the icon  is displayed. If the alarm condition is removed during this time, the alarm is automatically cleared from the list, but for the last alarm, the alarm message will continue until the silence key is pressed.

8.3 Alarm Levels

By severity, the ventilator's alarms fall into three categories: high level alarms, medium level alarms and low level alarms.

1. High level alarms

Indicates that the patient is in a life threatening situation and an emergency treatment is demanded.

2. Medium level alarms

Indicates that the patient's vital signs appear abnormal and an immediate treatment is required.

3. Low level alarms

Indicates that the patient's vital signs appear abnormal and an immediate treatment may be required.

The level for all alarms are preset before the ventilator leaves the factory and cannot be changed.

8.4 Alarm Indicators

The anesthesia ventilator provides the following alarm indicators:

- **An alarm LED located on top of the key area.** The LED can illuminate red, yellow or OFF depending on the alarm condition.

  If multiple alarms occur simultaneously, the audio and LED behavior will follow the highest priority active alarm.
- **Colored alarm messages displayed on the Main Screen.** High priority messages are red. medium priority messages and low priority messages are yellow. If more than one alarm is activated, only the highest priority alarm message is displayed.
- **Alarm audio through the system alarm speaker.** Table 6-1 lists the audio behavior for each type of alarm.

Alarm Priority	Audio Behavior	Message Behavior	Alarm Led Color
High	Play high priority alarm sound, the interval between each play is 10 sec.	white text red background, high priority mark !!!	Red
Medium	Play medium priority alarm sound, the interval between each play is 25 sec.	black text yellow background, medium priority mark !!	Yellow

Low	Only play low priority alarm sound one time	black text yellow background, low priority mark !	Yellow

TABLE 8-1 Alarm indicators

8.5 Silencing Alarms

When an alarm condition occurs and the alarm audio is sounded, the user can select the Silence key to silence the alarm audio. In silenced status, all the alarm indicators work normally except audible alarm tones.

When the Silence key is selected, all active alarms are silenced and the icon on the left side of the alarm message changes to indicate that the alarm is silenced. When the 120 second silence icon appears, the audio alarms are silenced for 120 seconds, after which the audio alarms resume.

NOTE: A new alarm will sound if that alarm occurs while the system is in a silenced state. If this occurs, you can select the Silence key again to silence the new alarm and reset the silence countdown timer to 120 seconds.

8.6 Alarm Messages

This section lists the following alarms messages:

For each alarm message, corresponding actions are given instructing you to troubleshoot problems.

If the problem persists, contact your service personnel.

information	**Alarm conditions**	**Alarm level**
Apnea	No breath has been detected within the set apnea time	High priority
MVexp high	Minute volume is higher than minute volume upper-limit-set-value, in continuous 10 respiration cycles	High priority
MVexp low	Minute volume is lower than minute volume lower-limit-set-value, in continuous 10 respiration cycles	High priority
Pressure high	Peak is higher than airway pressure upper limit-set-value, in continuous 2 respiration cycles	High priority
Pressure low	Peak is lower than airway pressure lower limit-set-value, in continuous 3 respiration cycles	High priority
Continuous pressure high	Airway pressure in the breathing circuit is greater than PEEP setting +15CMH2O for 15 seconds in continuous	High priority
Rate low	Total respiratory frequency monitored values are lower than the respiratory frequency lower limit set value for all 3 continuous respiratory cycles.	High priority
Battery discharged	Battery power supplying time is less than 5 minutes.	High priority
FiO2 high	The oxygen concentration monitored value are higher than the oxygen concentration upper limit set value for all continuous 10 respiratory	High priority

	cycles.	
FiO2 low	The oxygen concentration monitored value are lower than the oxygen concentration lower limit set value for all continuous 10 respiratory cycles.	High priority
Pulse rate high	When pulse rate monitored value is higher than pulse upper limit value for continuous 10 cycles.	High priority
Pulse rate low	When pulse rate monitored value is lower than pulse lower limit value for continuous 10 cycles.	Medium priority
SpO_2 high	SpO_2 monitored value is higher than SpO_2 upper limit value for continuous 10 cycles.	Medium priority
$EtCO_2$ high	$EtCO_2$ monitored value is higher than the $EtCO_2$ upper limit value for continuous 3 cycles	High priority
$EtCO_2$ low	$EtCO_2$ monitored value is lower than the $EtCO_2$ lower limit value for continuous 3 cycles	Medium priority
$EtCO_2$ sampling tube obstruction	$EtCO_2$ three consecutive cycles detected sampling tube obstruction	Medium priority
SpO_2 sensor disconnected?	SpO_2 sensor disconnected	Low priority
Standby	Return to standby mode.	High priority
V_{TE} high	Expiratory tidal volume monitored value is higher than the tidal volume upper limit set-value for 4 continuous respiration cycles	High priority
V_{TE} low	Expiratory tidal volume monitored value is lower than the tidal volume lower limit set-value for 4 continuous respiration cycles	Medium priority
Battery low	when battery supplying time is less than 10 minutes,	High priority
Driving gas failure	Driving gas source pressure is lower than 0.28MPa for 10 seconds	High priority
Rate high	Total respiration frequency monitored value is higher than the respiratory frequency upper-limit set-value for all continuous 20 respiratory cycles	Medium priority
Mains failure	AC power disconnected	Low priority

Table 8-2 Alarm messages

Chapter 9 Cleaning and Disinfection

⚠ Warning

- Obey applicable safety precautions.
- Read the material safety data sheet for each cleaning agent.
- Read the operation and service manual for all disinfection equipment.
- Wear gloves and safety glasses. A damaged O_2 sensor can leak and cause burns (contains potassium hydroxide).
- Reuse of non-disinfected breathing system or reusable accessories may cause cross-contamination.
- The operations described in Preoperative Test must be performed before patient use every time the Anesthetic machine has been disassembled for cleaning and disinfection or has been reassembled.
- To prevent leaks, avoid damaging any component in case of disassembling and reassembling the breathing system. Ensure the correct installation of the system, especially of the seal. Make sure of the applicability and correctness of the cleaning and disinfection methods.
- Disassemble and reassemble the breathing system as described in this manual. For further disassembly and reassembly, contact us. Improper disassembling and reassembling may cause breathing system leak and compromise normal system use.

⚠ Caution

- Clean and disinfect the equipment as required before it is put into use for the first time.
- To help prevent damage, refer to the manufacturer’s data if you have questions about a cleaning agent.
- Do not use organic, halogenated, or petroleum-based solvents, Anesthetic agents, glass cleaners, acetone, or other harsh cleaning agents.
- Do not use abrasive cleaning agents (such as steel wool, silver polish or cleaner).
- Keep all liquids away from electronic parts.
- Do not permit liquid to go into the equipment housings.
- Do not soak synthetic rubber parts for more than 15 minutes. Swelling or faster aging can occur.
- Cleaning solutions must have a pH of 7.0 to 10.5.

9.1 Clean and Disinfect the Anesthetic Machine Housing

1. Clean the surface of the Anesthetic machine housing with a damp cloth soaked in mild detergent (such as 70% ethanol).
2. After cleaning the housing, remove the remaining detergent by wiping with a dry lint free cloth.

⚠ Warning

- Seeping liquid into the control assembly can damage the equipment or cause personal injury. When cleaning the housing, make sure that no liquid flows into the control assemblies and always disconnect the equipment from the AC mains. Reconnect the AC mains after the cleaned parts are fully dry.

⚠ Caution

- Use only soft dry and lint free cloth to clean the display. Do not use any liquid for display cleaning.

9.2 Disassembling the Breathing System

You need to disassemble the breathing system cleanable parts first before cleaning the system.

9.2.1 Remove the oxygen sensor

Take the O2 sensor from the 3 way connector.

9.2.2 Remove the flow sensor

Take away the flow sensor from the Y connector of breath circuit.

9.2.3 Remove the breath circuit

Take away the breath circuit from the CO2 Circle Absorber

⚠ Caution

- When disassembling the breath circuit, hold the tube connectors at both ends of the tube to prevent damage to the tube.
- Do not reuse the filter. Follow local regulations regarding disposal of hospital waste when the filter is discarded.

9.2.4 Remove the Bag Arm

1. Loosen the locking nut counterclockwise.
2. Remove the bag arm from the CO2 Circle Absorber.

9.2.5 Remove the bellows Assembly

1. take away the silicon connection tube on the bellow.
2. take back from the metal board to take away the bellow.
3. rotate the plastic cover of bellow and take away it.
4. Move the folding bag from the bellows base.
5. Uninstall the bellows base
6. Remove locking tabs and ring from the bellows base.

9.2.6 Remove the absorber canister

1. Hold the canister’s handle, press the knob and take down the small arm, and remove it.

⚠ Warning

- Soda lime is a caustic substance and is a strong irritant to eyes, skin and respiratory system. Affected parts should be flushed with water. If irritation continues after flushed by water, seek medical assistance immediately.
- After removing the CO_2 absorber canister, by-pass assembly can prevent the system from

gas leakage. It's dangerous to patient if the canister is not installed in a long time.

9.3 Cleaning& disinfection and Re-install the CO2 Circle Absorber and bellow

Parts marked are autoclavable. Metal and glass parts can be steam autoclaved. Maximum commended temperature is 134ºC. By using autoclave to solidify bacterioprotein rapidly, quick and reliable disinfection can be achieved. Suffered from 15 to20 minutes of 1.05 kg/cm$_2$ steam pressure and 121ºC temperature, all bacteria and most blood cells are killed.

Such parts are washable by hand. Rinse and dry all parts of the breathing system except the O_2 sensor completely by using mild detergent (pH ranging from 7.0 to 10.5).

⚠ Warning

- Do not use talc, zinc stearate, calcium carbonate, corn starch or equivalent materials to prevent tackiness. These materials can go into the patient's lungs and airways and cause irritation or injury.
- Do not put both of the breathing system and the O_2 sensor in liquid or autoclave them.
- Inspect all parts for deterioration. Replace them if necessary.

All parts of the breathing system can be cleaned and disinfected. The cleaning and disinfection methods are different for different parts.

You need to select the appropriate method to clean and disinfect the parts based on the actual situations to avoid cross-contamination.

This table is our recommended cleaning and disinfection methods for all parts of the breathing system.

The following is our recommended disinfection method:

- Patient breath circuit and Y piece(reusable)：

First flush off by water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol or autoclave under maximum temperature 134℃.

- Flow sensor：

First flush off by water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol.

- Bellows assembly:

First flush with water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol.

- Check valve assemblies：

First flush with water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol or autoclave under maximum temperature 134℃.

- Oxygen sensor：

Clean with a damp cloth soaked in mild detergent and then wipe off the remaining detergent with a dry lint free cloth.

- Absorber canister assembly :

First flush with water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol or autoclave under maximum temperature 134℃.

- Reusable manual bag:

First flush with water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol or autoclave under maximum temperature 134℃.

- CO2 circle absorber:

First flush with water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol or autoclave under maximum temperature 134℃.

- Bag Arm:

First flush with water, then soak it in solution mixed by water and detergent 30 minutes, the suggested temperature is 30-41 ℃, after that treat by clean water, finally wipe by using 70% medical use alcohol or autoclave under maximum temperature 134℃.

9.3.1 Re-install the CO2 Circle Absorber

Make sure that all components of breathing system are fully dry before installing it.

9.3.2 Re-install the bellows assembly

1. Make sure that all components of bellows are fully dry.

2. Install the ring, then push the latch toward the center and attach the locking tabs. Install the pressure-relief valve.

3. Push the latch toward the center and install the rim. A “Double Click” should be heard when the rim is installed. Pull up on the rim to make sure it’s locked.

4. Install the folding bag and bellows housing.

5.install the plastic cover on the base.

9.3.3 Re-install the Bag Arm

When the bag arm is fully dry, Install the Bag Arm.

9.3.4 Re-install the Airway Pressure Gauge

When the airway pressure gauge is fully dry, Install the Airway pressure gauge.

9.3.5 Re-install the Oxygen Sensor

1. Make sure that all components of oxygen sensor is fully dry.

2. Install the three way again and insert the O2 sensor on the it.

3. Install the oxygen sensor cable.

9.3.6 Re-install the Absorber Canister

When the absorber canister is fully dry, install absorber canister on the CO2 circle absorber.

9.3.7 Re-Install the Flow Sensor

⚠ Caution

Flow sensor temperature will be heated to 35-40 º C or so, this is a normal phenomenon, not an indication of machine failure.

1. Make sure that all components of flow sensor are fully dry.

2. Connect Flow sensor and inspiratory connector or expiratory connector. Insert the inspiratory connector or expiratory connector into flow sensor and turn around clockwise until connector and sampling holes are in the same direction.

3. Keep the sampling port of flow sensors up and plug flow sensors into the sampling holes.

4. Install the locking nuts, and tighten the locking nuts clockwise.

⚠ Warning

While replacement of the flow sensor, please consider calibration of the flow sensor, thus ensuring tidal volume measurement accuracy (see flow sensor calibration).

10.1 Maintenance policy

⚠ Warning

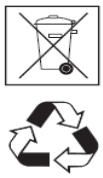
- Only use lubricants approved for Anesthetic and O_2 equipment. Do not use lubricants containing oil or grease that may burn or explode in high O_2 concentrations.
- Follow infection control and safety procedures to prevent cross-infection. After clinical procedures, equipment may be contaminated with blood and body fluids.
- Movable parts and removable components may present a hazard. Use care when moving or replacing system assemblies and components.
- Check correct operation of the system after servicing and repair.
- All maintenance, repairs, cleaning and disinfection must only be carried out when the unit is non-operational.
- Devices connected to the auxiliary outlets may increase leakage currents. Check the total leakage current every six months.
- All repairs, servicing, and the replacement of components must be undertaken by a trained engineer.
- After repair, carry out a pre-use test (Section 4). Do not use a malfunctioning Anesthetic machine.

⚠ Caution

- Test the unit to ensure that it complies with the manufacturer's specification.
- Replace damaged parts with components manufactured or sold by us. Then test the unit to make sure that it complies with the manufacturer's published specifications.
- Please contact our sales department to obtain support services.

⚠ Caution

Class I special waste



Depleted and used batteries must be in accordance with local regulations concerning the replacement.

Class II special waste

The O_2 sensor must be discarded according to local regulations.

Parts that can be discarded

All disposable components must be disposed of by hospital regulations and in an environmentally safe manner.

10.2 Maintenance Schedule

⚠ Caution

- This schedule is based on a maximum total annual usage time of 2000 hours per year. If the actual annual usage exceeds 2000 hours, maintenance must be increased accordingly.
- Local policies or regulations may require that maintenance be performed more frequently than stated here.

Minimum Frequency	Maintenance
Daily	• Clean external surfaces. • Perform a flow sensor and pressure sensor calibration.
Monthly	•Perform 21% and 100% O_2 cell calibrations. • Drain the vaporizers. •Clear water build up inside the water traps of CO_2 module.
Yearly	•Replace O-ring on the patient circuit port and the vaporizer manifold. • Perform CO_2 module Calibration. • Perform AG module Calibration.
Every two years	•Replace every filter in the gas inlet. • Replace with new built-in battery
During of Cleaning and setup	•Inspect parts for damage. Replace/repair as necessary.
As necessary	•Install new cylinder gaskets on cylinder yokes. •Empty the water collection cup If there is water build up in it. •Empty and clean the overflow trap on the optional suction regulator. •Replace the soda lime in the canister if soda lime color change is detected. •Replace the O_2 sensor if a great deviation of the measured value by the O_2 sensor occurs and the problem persists after multiple calibrations. •Replace the flow sensor if the seal for the flow sensor is damaged, the membrane inside the flow sensor is cracked or distorted. •Replace the transfer tube if damaged.

10.3 Pressure Sensor Zeroing

⚠ Caution

- Do not perform calibration while the unit is connected to a patient.
- During calibration, do not operate the flow meter or ventilator systems. Do not move or compress the breathing tubes.

Procedure

1. Stop manual or mechanical ventilation.
2. Open the breathing tube patient connection to air. Check that the bellows falls to the bottom.
3. Turn the flow meter to minimum.

4. In standby mode, touch the [System] hotkey -> [Calibration] hotkey ->[Pressure Sensor Cal]. Pressure sensor zero calibration will start automatically.

10.4 Flow Sensor Zeroing

1. Stop manual or mechanical ventilation. If a breathing tube is connected to the breathing system, then open the breathing tube patient connection to air. Check that the bellows falls to the bottom.
2. Turn off the flowmeter.
3. In standby mode, touch the [System] hotkeys -> [Calibration] hotkey ->[Flow Sensor Cal]. Flow sensor zero calibration will start automatically. Do not touch the breathing tubes during calibration.

10.5 Oxygen Concentration Calibration

⚠ Caution

- Calibrate the O_2 sensor at the same ambient pressure in which it will be used to monitor oxygen delivery in the breathing system.
- Disassemble the O_2 sensor for calibration If needs. Re-install the O_2 sensor after making sure that there is no water build-up in the O_2 sensor and its installation Part.
- The O_2 calibration is not required if no O_2 sensor is configured or used.
- Check that the oxygen sensor cables are connected correctly.
- With ACGO port to calibrate, remember turn off ACGO after calibration is finished.

10.5.1 21% O_2 Calibration

⚠ Caution

- Perform O_2 calibration when the measured value of O_2 concentration has a great deviation or when the O_2 sensor is replaced.
- If the calibration fails, check for technical alarm. Then do the calibration again.
- In case of repeated calibration failures, replace the O_2 sensor and do the calibration again. If it continues to fail, contact your service personnel.
- Obey the relevant stipulations about biohazard when disposing the discarded O_2 sensor. Do not burn it.

To calibrate at 21% O_2, do as follows:

1. Return to the standby mode.
2. Turn off all of gas flow from flowmeter.
3. Touch [System] hotkeys -> [Calibration] -> [Oxygen Cell Cal]->[21%].
4. Make sure that the patient or test lung is disconnected from the system.
5. Follow the prompts [Before O_2 21% calibration requests supply 10L/min of Air through or expose in air > 2 minutes].
6. Push the [Enter] hotkey to start calibration.

7. After a successful calibration, the screen shows [Calibration Completed!]. Otherwise the message [Calibration Failure!] is displayed. In this case, you need to do the calibration again.

10.5.2 100% O_2 calibration

⚠ Caution

- If the calibration fails, check for technical alarm. Then do the calibration again.
- In case of repeated calibration failures, replace the O_2 sensor and do the 21% O_2 calibration again. Calibrate at 100% O_2 again after 21% O_2 calibration is completed. If it continues to fail, contact your service personnel.

To calibrate at 100% O2, do as follows:

1. Make sure that 21% O_2 calibration is already completed successfully and that no [O_2 Supply Failure] alarm occurs.
2. Make sure that the system is Standby. If not, press the key and then select [Ok] from the pop-up menu to enter standby status.
3. Turn off all of gas flow from flowmeter.
4. Touch [System] hotkeys -> [Calibration] -> [Oxygen Cell Calibration]->[100%].
5. Make sure that the patient or test lung is disconnected from the system.
6. Follow the prompts [Before O_2 100% calibration requests supply 10L/min of O_2].

10.6 Touchscreen Calibration

⚠ Caution

- Calibrate touchscreen if the touchscreen focus is offset.

Procedure

1. In the standby mode, select the [system] hotkeys -> [Calibration] hotkey ->[Touchscreen Cal.].

NOTE

If the touch screen can't be used normally, you can double-click the control knob to enter the touchscreen calibration during start-up.

2. Click the cursor center until the calibration is complete and return to standby.

10.7 Fault Diagnosis and Troubleshooting

Fault	Cause	Action
Ventilation system leak	APL is not closed during manual mode	Turn the APL valve to the appropriate position
	Absorber canister is not installed correctly	Reinstall
	Damaged or loose breathing tube connector	Refit or renew the breathing tube
	A loose check valve	Reinstall
	Bag/vent switch failure	Contact a service engineer
Bellows does not	The respiratory rate is set to fast and	Set respiratory rate to a

inflate completely	expiratory time is too short.	reasonable value
	The breathing system leaks	Carry out a system leak test
	Flowmeter is closed	Reset the flowmeter
During the in-spiratory phase, the bellows is not compressed	Bag/vent switch is still in the bag position.	Turn the Bag/vent switch to vent
	Flow control valve has failed; no drive gas is delivered.	Contact a service engineer
	Bellows housing is damaged	Replace the bellows housing
	During inhalation, the PEEP valve cannot be closed.	Contact a service engineer
Manual breathing airway pressure is too high	APL valve is set too high.	Reset the APL valve.
Power indicator is not lit	Power cord is not connected System and ventilator switch is not turned on Power cord is damaged Mains power outlet is faulty Fuse has blown.	Connect the power cord. Turn the switch to On Replace the power cord. Switch to another power outlet. Contact a service engineer
No power at aux-iliary outlet	Fuse has blown.	Contact a service engineer Replace the fuse
No airway pressure waveform	There is a disconnect between the pressure sensor and the sample tube, or Gas source is exhausted.	Reconnect. Check the gas supply

⚠ Warning

- Use only accessories specified in this chapter. Using other accessories may cause incorrect measured valued or equipment damage.
- Disposable accessories can't be reused. Reuse may degrade performance or cause cross-contamination.
- Check the accessories and their packages for damage. Do not use them if any sign of damage is detected.
- Parts which are intended to be in contact with patients must comply with the biocompatibility requirement of ISO10993-1 to prevent any adverse reactions arising from such contact.
- Disposal of the accessories shall comply with the applicable waste control regulations.

Gas Supply Hoses	
Air gas supply hose, DISS	301000101
Air gas supply hose, NIST	301009816
N_2O gas supply hose, DISS	301009796
N_2O gas supply hose, NIST	301000272
O_2 gas supply hose, DISS	301000153
O_2 gas supply hose, NIST	301009815
Vaporizer	
X60 anesthesia vaporizer	301000100
O_2 sensor	
O_2 sensor cable	301009913
O_2 sensor, MOX-4, Build-in berating system	101090006
Breathing System	
Absorber canister assembly	301009782
Bellows assembly	301000588

Product Specifications

A.1 Safety Standards

Type of protection against electric shock	Class I, with internal power supply. When the integrity of the external protective earthing equipment or protective ground conductor generates doubt, the device must be replaced by: Internal power supply (battery).
Applied part	Type B: Breathing tubes.
Operating Mode	Continuous
Explosion Protection	Does not provide explosion protection (common equipment), cannot use flammable Anesthetics
Degree of protection against harmful ingress of water	Ordinary equipment, without protection against ingress ofwater. IP21
Devices and electrical connection between the patient	Non-electrical connections
Move Level	Mobile equipment
Disinfection	Autoclave or disinfectant

A.2 Environmental Specifications

Work Environment	Temperature	10~40 ℃
	Humidity	5~95%,non-condensing
	Barometric pressures	70~106 KPa
Storage environment	Temperature	-20~55 ℃
	Humidity	5~95%, non-condensing
	Barometric pressures	50~106 KPa

A.3 Pneumatic Specifications

Gas supplies	
Pipeline gases	O_2,N_2O,Air
Cylinder gases	Option
Cylinder connections	Option
Primary regulator output pressure	Less than 400kPa
Pipeline connections(filtered)	DISS, NIST. All fittings available for O_2,Air and N_2O
Pressure displays	Pressure gauges
Pipeline inlet pressure	280-600kPa(41-87)psi
Flush flow	25L/min to 75L/min

N_2O Cut-off pressure	Internal O_2 supply pressure less than 90 kPa
ACGO	
Connector	Male 22 mm conical connector incorporating a coaxial female 15mm conical connector. Shared with inspiratory port.
Fresh gas	
6 tubes flowmeter	O_2 range: 0 to 10 L/min N_2O range: 0 to 12 L/min Air range: 0 to 15 L/min Accuracy: ±10% of reading value or ± 200 ml/min, whichever is greater
O_2-N_2O link system	Mechanical device for hypoxic guard,O_2 concentration not lower than 25%
Auxiliary O_2 supply	
Gas supply	O_2 in the system
Flow range	0 to 10 L/min/0 to 15L/min
Accuracy	±5% of full range

A.4 Power Specifications

Parameter	Specification
External AC power	
Input Voltage	100-240V
Input Frequency	50/60Hz
Input Power	<150 VA
System leakage current limit-do not exceed	Less than 500 uamps for the system and all systems connected to electrical outlets.
Resistance to ground	Less than 0.2Ω
Fuse	T10AL/250V
Power cord	3M
Auxiliary output supply	
Output voltage	100-240V
Output frequency	50/60Hz
Max power for each output	240W
Internal Battery	
Number of batteries	one battery
Battery Type	Li-ion Battery
Rated battery voltage	12VDC
Battery capacity	5200mAh;
Shutdown Delay	Less than 10min (powered by new fully-charged battery after thefirst low-power alarm)

Shortest supply time	90min;
Charging time	4h;

A.5 Physical Specifications

Technical parameters	Specification
Machine	
Size	1370× 950 × 650 (H × W × D)
Weight	Approximately100kg
Maximum bearing weight of the top cover	30kg
Display	
Type	Color TFTLCD (touch screen)
Size	10.4 inches
Resolution	800 × 480 pixels
Brightness	Fixed
Audio instruction	
Speaker	Alarm sounds, tone: supports multi-level volume, alarm tone meet IEC60601-1-8 standards.
Control	
Knobs	1. Support clockwise/ counterclockwise rotation and pressing operation
Button	4.Alarm pause, alarm reset, standby, back to the main screen
Interface	
Power supply	An AC power inlet Three auxiliary output outlets
Monitor	A standard color VGA monitor connector ,15-PIN D-sub socket
Equipotential	An equipotential ground terminal
Moving means	
Roller	4 castors, diameter 125mm
Brake	
Brake plate	Standard: Brakes for two casters
Toolbox	
Drawer	Standard:3 drawers 170 × 392 × 398 (H × W × D)

A.6 Breathing System Specifications

Bellows volume	About 1600mL
Absorber canister volume	About 1600mL

Connector	ACGO ports: standard OD 22mm, ID 15mm, tapered connector; Inhalation and exhalation ports: standard OD22mm, ID 15mm, tapered connector Manual bag port: standard OD22mm, ID 15mm, tapered connector
System leaks	In any mode, the system is not greaterthan140ml/min leakage
System compliance	Volume of gas lost due to internal compliance (Manual mode only): ＜3.0 ml/0.098 kPa (1 cmH_2O) ＜120 ml/3 kPa (30 cmH_2O)
APL valve	Approximately 0 to 70 cmH_2O
Airway pressure gauge	-20 to +100 cmH_2O

A.7 Ventilator Specifications

⚠ Caution

All technical specifications are ratings are subject to change without Caution.

Basic description		
Parameter		Description
Drive gas	Gas type	O2 or Air
	Inlet pressure	280-600 kPa.
	Max flow	≤ 120 L / min.
Operating Mode		VCV,PCV,SIMV-VC,SIMV-PC,PSV,Manual/SPONT. Optional: SIMV-PRVC, PRVC
Waveform		Waveform: Pressure,Flow-rate,Volume,CO2(optional),Pleth(optional) Loop:PV loop, PF loop,FV loop
Safety Pressure		System pressure does not exceed 10 KPa.

Parameters setting range	
Parameter	description
Tidal volume	Range: 50 - 1500ml; optional 10 - 1500ml Increment: 10 ~ 100 mL: 5mL; 100 ~ 1500 mL: 10mL;
Respiratory rate	Range: 1 ~ 100 bpm; increment: 1 bpm.
Inspiratory time	Range: 0.1 ~ 10.0 s; increments: 0.1 s.
Respiratory ratio	Range: 4:1 to 1:10; increments: 0.5.
Percentage of inspiratory pause	Range: 0 to 50%; Increment: 5%
PEEP	Range: OFF, 3 ~ 20 cmH2O; Increment: 1 cmH2O.
Pressure Support	Range: 0 ~ 70 cmH2O; Increment: 1 cmH2O.
Pressure Control	Range: 5 ~ 70 cmH2O; Increment: 1 cmH2O.
Flow trigger	Range: 0.5 ~ 20L/min; increments: 0.1L/min.

Pressure Trigger	Range: 0 ~ 20 cmH2O; increments: 0.1 cmH2O.
PSV Insp Termination Level	Range: 5 ~ 80%; increments: 5%.

monitored parameters	
Parameter	Description
Inspiratory tidal volume	Range: 0 ~ 2500 mL; Resolution: 1 mL. Error of ± 20mL or actual value ± 15%, whichever is greater.
Expiratory tidal volume	Range: 0 ~ 2500 mL; Resolution: 1 mL. Error of ± 20mL or actual value ± 15%, whichever is greater.
Minute ventilation	Range: 0 ~ 60 L / min; Resolution: 0.1 L / min. Error of ± 1L/min or actual value ± 15%, whichever is greater
Spontaneous minute ventilation	Range: 0 ~ 60 L / min; Resolution: 0.1 L / min. Error of ± 1L/min or actual value ± 15%, whichever is greater.
Respiratory rate	Range: 0 ~ 100 bpm; Resolution: 1 bpm. Error of ± 2 beats / min or actual value ± 10%, whichever is greater.
Spontaneous breathing frequency	Range: 0 ~ 100 bpm; Resolution: 1 bpm. Error of ± 2 beats / min or actual value ± 10%, whichever is greater.
Respiratory ratio	Range: 30:1 to 1:150; resolution: 0.1. Error of ± 20%,
Peak airway pressure	Range: 0 ~ 100 cmH2O; Resolution: 1 cmH2O. Error of ± (2% + 4% of full scale actual reading)
Mean airway pressure	Range: 0 ~ 100 cmH2O; Resolution: 1 cmH2O. Error of ± (2% + 4% of full scale actual reading)
PEEP	Range: 0 ~ 100 cmH2O; Resolution: 1 cmH2O. Error of ± (2% + 4% of full scale actual reading)
Inspiratory plateau pressure	Range: 0 ~ 100 cmH2O; Resolution: 1 cmH2O. Error of ± (2% + 4% of full scale actual reading)
FiO2(optional)	Range: 15 to 100%; Resolution: 1%. Error is ± (2.5% +2.5% of full scale actual reading)
Compliance	Range: 0 ~ 300 mL/cmH2O; resolution: 1 mL/cmH2O. Error of ± 20% or ± 5 mL/cmH2O, whichever is greater.
Airway resistance	Range: 0 ~ 600 cmH2O / (L / S); Resolution: 1 cmH2O / (L / S). Error of ± 20% or ± 5 cmH2O, whichever is greater.
EtCO2 (optional)	Range: 0 ~ 100 mmHg; Resolution: 1 mmHg. Error is ± (0.43% of the volume percentage + 8% of the gas concentration) is equivalent to the range of optional units to monitor KPa and mmHg.
Inhalation of carbon dioxide (optional)	Range: 0 ~ 100mmHg; Resolution: 1 mmHg. Error is ± (0.43% of the volume percentage + 8% of the gas concentration) is equivalent to the range of optional units to monitor KPa and mmHg.

Alarm settings		
Alarm type		Range
Tidal volume	High	20 ~ 3000 mL
	Low	OFF,10 ~ 2990 mL

Minute ventilation	High	1 ~ 99 L
	Low	0 ~ 98 L
Respiratory rate	High	1 ~ 100bpm
	Low	OFF,1 ~ 99 bpm
FiO2(optional)	High	19 ~ 100%, OFF
	Low	18 ~ 99%
Airway pressure	High	6 ~ 99 cmH2O
	Low	0 ~ 98 cmH2O
SpO2(optional)	High	50 ~ 100 %
	Low	49 ~ 99 %
Pulse(optional)	High	31 ~ 250 bpm
	Low	30 ~ 249 bpm
ETCO2 (optional)	High	0.1 to 13.3%;
	Low	0 to 13.2%
Apnea alarm		Setting time is 10 ~ 60 s, in increments of 1 s.
Drive gas failure alarm		Drive gas pressure is less than 280 kPa.
AC power failure alarm		The mains breaks down or the power cord disconnects
Low battery alarm		Alarm battery time is 20 min.
Battery discharged alarm		Alarm battery time is 10 min.
O2 sensor failure		FIO2 <15% Vol.
Silent Alarm		≤ 120 s

A.8 Anesthetic Vaporizer (optional)

Anesthetic vaporizer (for details, refer to the vaporizer Instructions for Use)	
Vaporizer position	double vaporizer positions
Mounting mode	with interlocking function
Applicable standard	ISO 80601-2-13

H EMC

⚠ Warning

- The devices need to be installed and used in compliance with the electromagnetic environment.
- Portable and mobile RF communications equipment can affect the equipment
- Pins of connectors identified with the ESD warning symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.
- The use of accessories, sensor and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment.
- The equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

The equipment cannot be used magnetic resonance (MRI) environment.

<table>
<tr><td colspan="3">Guidance and manufacture’s declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">The Anesthetic Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of ANESTHETIC MACHINE should assure that it is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Anesthetic Workstation uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The Anesthetic Workstations suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

<table>
<tr><td colspan="4">Guidance and manufacture’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The Anesthetic Workstation intended for use in the electromagnetic environment specified below. The customer or the user of ANESTHESIA MACHINE should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Electrostatic</td><td>±6 kV contact</td><td>±6 kV contact</td><td>Floors should be wood, concrete</td></tr>
</table>

discharge (ESD) IEC 61000-4-2	±8 kV air	±8 kV air	or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) line(s) ±2 kV line(s) to earth	±1 kV line(s) line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of The Anesthetic Workstation requires continued operation during power mains interruptions, it is recommended that Anesthetic Workstation be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTEU_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Anesthetic Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of ANESTHESIA MACHINE should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RFIEC 61000-4-3	3Vrms 150kHz to 80MHz outside ISM bands[a] 10Vrms 150kHzto 80MHz In ISM bandsa 10V/m	3V 10V 10V/m	Portable and mobile RFcommunicationsequipment should be used no closer to any part ofthe system, including cables, than the recommended separation distance calculated fromthe equationappropriate for the frequency of thetransmitter. **Recommended separation distances:** $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$

	80 MHz to 2.5 GHz		$d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz～800 MHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz～2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c]should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the followingsymbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the Anesthetic Workstation	
The Anesthetic Workstation is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of The Anesthetic Workstation can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The Anesthetic Workstation recommended below, according to the maximum output power of the communications equipment.	
Rated	Separation distance according to frequency of transmitter /m

maximum output power of transmitter W	150 kHz to 80 MHz outside ISM Bands $d = \left[\frac{12}{V1}\right]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \left[\frac{12}{V2}\right]\sqrt{P}$	80Mhz to 800MHz $d = \left[\frac{12}{E1}\right]\sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

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

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

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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

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