# ACM812A

## 呼吸机

*航天品质 军工技术*

国食药监械（准）字2009

ISO9001/13485

CE 0197

# ACM812A

## 呼吸机

- 航天品质，军工技术，时尚机型
- 轻便易携，防潮，防震，防盐雾
- 是有创、无创、手动三种通气功能的完美结合
- 容量控制，压力限制，时间切换，充分体现肺保护策略
- 呼气暂停方便吸痰，防止交叉感染
- 气动电控、提供交流、直流、车载三种工作电源
- 适用于成人、儿童等不同人群

### 呼吸模式

| | |
|---|---|
| 辅助/控制 | A/C |
| 同步间歇指令 | SIMV |
| A/C+叹息 | A/C+SIGH |
| 手动通气 | MANUAL |
| 自主呼吸: | SPONT |
| 无创通气: | A/C+持续气流 |

### 控制部分

| | |
|---|---|
| 潮气量: | 0mL～1500mL |
| 分钟通气量: | 0升/分 ～ 20升/分 |
| 吸呼比: | 1:0.3、1:0.5、1:0.7、1:1、1:1.5、1:2、1:2.5、1:3、1:3.5、1:4 |
| 呼吸频率: | 4次/分 ～ 80次/分 |
| 压力限止: | 1kPa～5kPa |
| 触发压力调节: | -2kPa～2kPa |
| 连续气流: | 3LPM～5LPM |
| 吸气暂停: | 20秒 |
| 吸入氧浓度: | 48%～100%可调 |
| 安全阀限压: | 6kPa±15% |

### 监测部分

液晶屏显示
气道压力波形
吸入潮气量
分钟通气量
总计呼吸频率
气道峰压
触发指示
交直流电源指示
电池电量指示
手动通气模式下可监测所有参数和波形

### 声光报警部分

气源不足报警
气道压力上、下限报警
断电报警
电池低压报警

### 其他

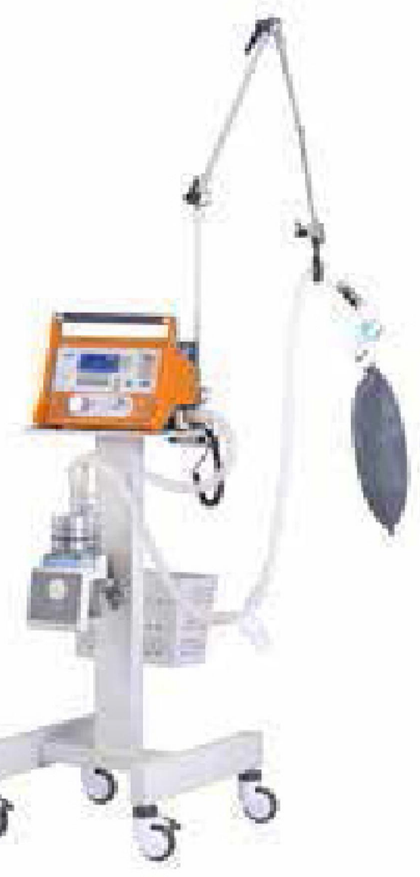
| | |
|---|---|
| 电源: | AC 100V～240V， 50/60Hz，<br>12V车载电源<br>内置电池≥2小时 |
| 气源压力: | 280kPa～600kPa |
| 自备气瓶气源连续工作: | ≥30分钟 |
| 呼吸机系统顺应性: | ≤4×10$^{-2}$ml/100pa |

### 标配

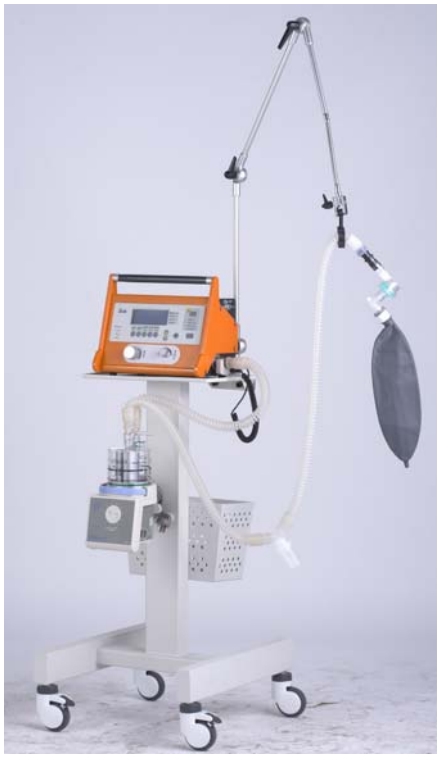
| | |
|---|---|
| 多功能主机挂架 | 1套 |
| 储气瓶 | 1只 |
| 氧桥 | 1个 |
| 扳手 | 1个 |
| 附件及附件包 | 1个 |

### 选配

| | |
|---|---|
| PEEP(0～1kPa) | 1个 |
| 机械手 | 1个 |
| 仪器台车 | 1个 |
| 湿化器 | 1个 |



# ACM812A Ventilator



- Suitable for adult and child
- For various treatment environments such as emergency room, operating theater, ambulance, patient transfer and first-aid
- Unique invasive and non-invasive ventilation modes to meet the different patients' needs
- Inspiration halt, convenient for sucking phlegm
- Oxygen mixing technique to adjust oxygen concentration and meet the oxygen therapy need
- Alarm and monitoring system which meet the international safety standard
- TFT screen, displaying various respiration parameters and waveforms
- With built-in battery and on-vehicle power connector for A/C and D/C power supply
- PEEP valve, humidifier, trolley, supporting arm and other accessories as optional

## Main parameters

| | |
|---|---|
| Applications | Adult, child |
| Control mode | Pneumatic driven and electric controlled, time switch, pressure limit, volume control, apnea ventilation |
| Ventilation modes | A/C, SIMV, SPONT, SIGH, NIPPV, manual |
| Respiratory rate | 4bpm～80bpm |
| Tidal volume | 0，50ml～1500ml |
| I:E ratio | 1: 0.3, 1: 0.5, 1: 0.7, 1: 1, 1: 1.5, 1: 2, 1: 2.5, 1: 3, 1: 3.5, 1: 4 |
| Trigger sensitivity | -2kPa～2kPa,continuously adjustable |
| Oxygen concentration | 48-100% |
| Display mode | LCD screen display |
| Waveform | Airway pressure waveform display |

### Monitoring parameters

Tidal volume, Minute volume, Respiratory rate, Peak airway pressure

### Alarm parameters

Upper airway pressure limit Lower airway pressure limit

Low battery alarm

Power supply failure

Silence for alarm

**Note: This machine can be a portable one with oxygen cylinder.**

# EC Certificate

## Directive 93/42/EEC Annex II, excluding Section 4
## Full Quality Assurance System
## Medical Devices

**Registration No.:** HD 60130281 0001

**Report No.:** 16802111 006

**Products:** Medical devices

(see attachment for site and products included)

Replaces Certificate, Registration no.: HD 60124191 0001

**Expiry Date:** 2023-07-11

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-07-12

Date: 2018-06-13

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to**
**Certificate**
**Registration No.:** HD 60130281 0001
**Report No.:** 16802111 006

Products:

- Anaesthetic Units
- Anaesthetic Vaporizers
- Ventilators
- Medical Ultrasound Diagnostic Systems

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

Date: 2018-06-13

ACM PRODUCT SERIES

CE 0197

# ACM812

# Operation Manual

# List Of Contents

# Cautions

⚠ **Refer to the attached files!**

**Before connecting to the patient, please read this manual carefully. The user must check the safe performance to keep it in a right status.**

**This manual is for the complete configuration. The parts' usage can be referred to it,too.**

Warning:

Blast caution**: the machine can't be used near to the flammable anesthetic gas!**

- **Only the trained staff can operate this machine.**
- **The machine can't be used in a flammable anesthetic gas environment, or there may be blast.**
- **If there is liquid coming into the machine, the machine may be destroyed or there will be the risk of electric shock.**
- **If connected with patient, no maintenance, cover or movement is allowed. And we suggest the special staff supervise the machine all the using time to deal with any warnings or other problems.**
- **If there is any abnormal about warning performance, no usage of this machine. Or it may cause injury even death to the patient, or the damage to the machine.**
- **Don't open the cover without indications, or there will be risk of electric shock.**
- **Although the manufacturer has considered the clinical safety completely, the operator should supervise the machine and patient during the usage.**
- **Please be noted not to collide or shake violently.**
- **Be careful about the arrangement of cables and tubes to avoid wrap the patient to apnea.**
- **If the measuring value is not accurate enough, please examine the syndrome of patient by other methods, then check whether the machine is working normally.**
- **The machine can't be used for neonate.**
- **The sensor's probe can't be fell or collided to avoid damage.**
- **Only the hospital's standard socket can be connected with the machines' power.**
- **When the voltage fluctuating is over 10%, please use the AC regulator.**
- **If the user doesn't have ground wire system, please be noted not to connect 0 wire with ground wire. And since the machine is BF type, Class I, so the three phase socket must be used and the ground wire must be connected well.**
-  **This signal means BF type, Class I**

**Note :**

**1)"warning" : If the user doesn't operate in accordance with the indications, the machine may be damaged, or the operator or the patient may be injured.**

**2)"note" : used to stress the important information!**

**warning**：

**Please read each chapters carefully before operating!**

# User Responsibility

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, ASCF recommends that a telephonic or written request for service advice be made to the nearest ASCF Field Service Support Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by ASCF and by ASCF trained personnel. The Product must not be altered without the prior written approval of ASCF's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper sue, faulty maintenance, improper repair, damage, or alteration by anyone other than ASCF.

⚠ **Caution Please refer to the local regulations when selling or purchasing the mentioned product at anywhere in the world.**

All the other branded products used in this manual belong to their own commercial label.

# Preface

## About ACM812A:

ACM812A is mainly used for first-aid respiratory or anesthesia respiratory, etc. Normally it is installed on the ambulance or other wrecking cars. It is also used for portable environment.

Since some parts may be configured or designed specially under the requirement of the customer, this manual may not be completely right for that usage, please refer to the special products under such conditions.

We undertake: if necessary, we will supply the necessary electric diagrams, list of parts, explanations or revise principles, or other information to the authorized maintain.

**Warning** Please read this manual carefully before operating.

**Warning** Be assure the nontoxic of gas supply tube, bag, and breathing tubes, and not be:

- anaphylactoid in the patient.
- act with the anesthetic gas or anesthetics and bring out byproduct.

**Warning** The machine's gas storage bag and breathing tube should be in accordance with ISO5362 AND yy0461.

**Warning** When the machine is connected with the central gas supply system, whose troubles may cause to working stop not only for one machine, but all the machines connected to it.

**Warning** No usage of anti-static breathing tube and mask. If you use this kind of tube or mask near to the high frequency surgical device, it may cause to flam.

**Warning** The machine can't be used in a dangerous or flammable environment.

**Warning** In order to avoid false alarm because of high intensity electric field:

- please keep the electric surgical lead far away from the anesthetic ventilation system , flow sensor and oxygen sensor.
- Don't put the electric surgical lead at anywhere on the anesthesia machine.

**Warning** The machine can't be used in the MRI environment.

**Warning** In order to protect patient, when using the electric surgical devices, please

- Assure all the life support and supervising devices work normally.
- In case the electric surgical devices can't assure the safe usage of ventilator, please be sure the manual ventilation can be used at any time.

**Warning** In order to protect patient, at any time during usage, please be sure that the machine has independent ventilation mode.( For instance, easy aspirator with mask)

**Warning** About the built-in battery

• The lifespan of the built-in battery is two year. Please change it in time through manufacturer, or there will be dangerous.

• When change the battery, please open the bottom panel and take out the battery, then unscrew the screw and change the battery. Be careful about the anode and cathode.

• If the machine is not used often, please charge the battery every three month, or the lifespan of the battery will be shorten.

**Warning** The inspiratory and expiratory resistance of the machine is 60L/min( adult), 30L/min(child), 5L/min(neonate), not over 0.6kPa. If the user add any breathing accessories to the system, please be sure that the resistance is still not over 0.6kPa.

**Warning** If the pressure at the patient connector is changing, the supplying tidal volume and oxygen concentration is changed, too. Please adjust in time according to the patient status and SP02.

**Warning** This machine is applicable to the patient from 6kg to 125kg.

# 1. General

## 1.1 Introduction

ACM812A Microcomputer controlled ventilator is developed and produced by It, which is a pneumatic driven and electric controlled and time switching ventilator on the principle, is mainly used for post-operation resuscitation, drowning, toxicosis, electric shock, sudden stop of heartbeat and respiration, and etc.. It can also be used for patient with acute respiratory failure.

## 1.2 System components

It is composed of multi-function rack, ventilator, gas cylinder, pipeline and accessories.

## 1.3 Characteristics

### 1.3.1 Ventilation mode

A/C, SIMV, SIGH, SPONT, Non-invasive， A/C + continuous current

### 1.3.2 Power supply

External power supply: AC 100V-240V , 50/60Hz

External power supply: DC 12V±1V

Built-in battery: provide a more than 2-hour power supply when power supply fails
Size: 98mm×60mm×46mm

When break off the main power, it will change to built-in battery automatically.

### 1.3.3 Gas source

When full of oxygen (>= 13MPa), 3.2L cylinder equipped on this system can work more than 1 hour at below status:

Gas input range: 280kPa～600kPa

Tidal volume: 500ml

I/E radio: 1:2

Respiratory rate: 12

Ventilation mode: A/C

Oxygen concentration: 48%

## 1.4 Operational environment requirements

Ambient temperature: 5~40℃;

Relative humidity: no more than 80%;

Atmospheric pressure: 96~104KPa.

**Warning:** if the environment is different from the above requirements, the machine may work abnormally.

# 2. OPERATION PRICIPLE AND STRUCTURAL CHARACTERISTICS

2.1.1 The ventilator block diagram of ACM812A

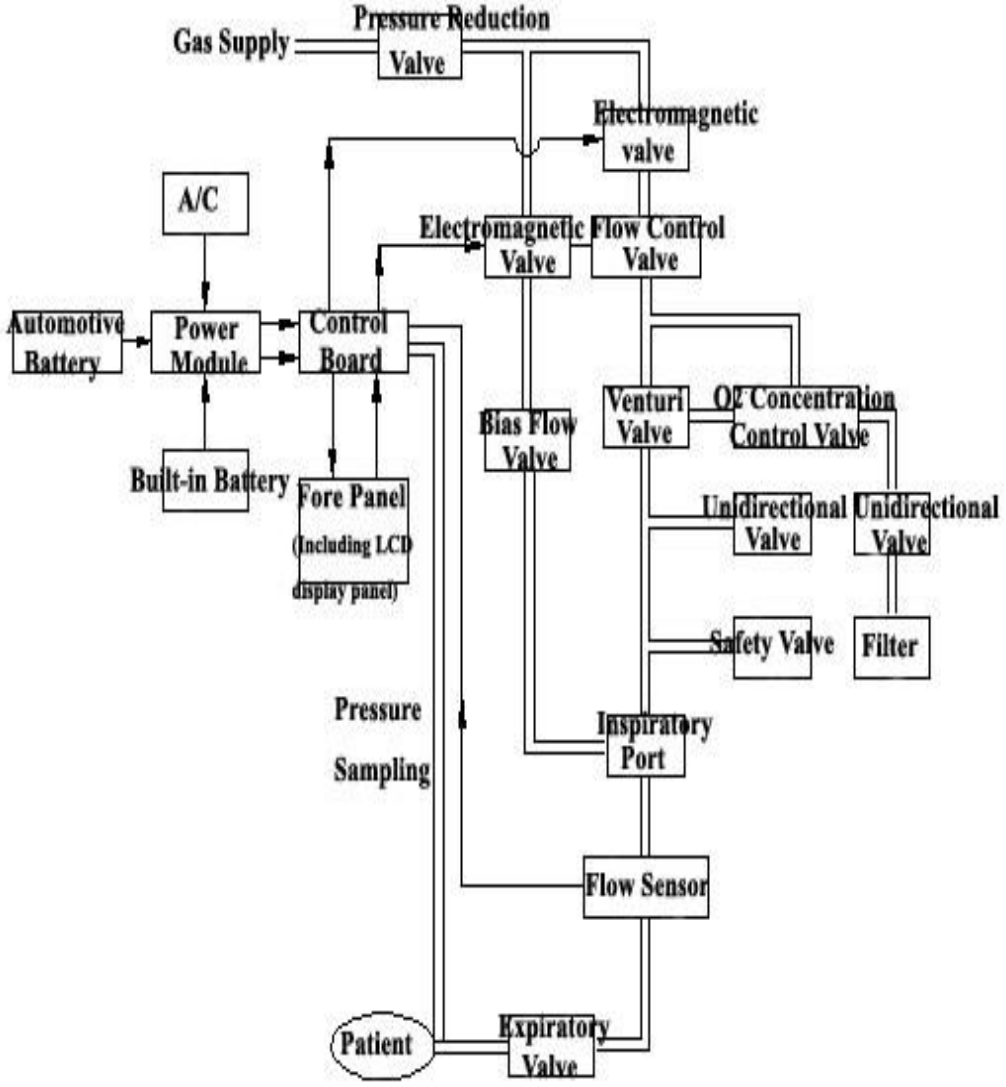



Figure 2.1 block diagram of ventilator

2.1.2 Operation principle

The ventilator-block-diagram is shown in Fig. 2.1, the block connected by pipeline is gas passage part, the block connected by arrow is the electronic control part. Gas enters the pressure reduction valve, and the airway can work normally only when the output pressure from the pressure reduction valve I is stabilized at 0.24MPa ~0.26 MPa (already adjusted before ex-factory). The output gas from the pressure reduction valve enters the inspiratory control electromagnetic valve Y1 and base flow control electromagnetic valve Y2.

In inspiring, the electromagnetic valve Y1 is open, and gas enters the flow control valve; adjusting the flow control valve can change the tidal volume. Gas inhaled by the patient is of

a certain O2 concentration, thus the pure O2 that enters the gas passage passes the O2 concentration control valve and can make the output O2 concentration adjust from 48% to 100% by adopting Venturi principle. Inspiratory unidirectional valve' s function is: when the ventilator's battery exhausts or its power or gas supply fails, it can ensure that patient can inhale air. When the airway pressure exceeds the preset safety pressure (not more than 6kpa), the safety valve in the expiratory valve will open automatically, and gas will be discharged from the safety valve. Finally, gas from the inspiratory port reaches to the patient through outer airway. The electromagnetic valve Y1 will be closed in expiration, the pressure exerted on the diaphragm of the expiration valve will disappear, and the diaphragm will loose. The patient's expiratory gas should be discharged to atmosphere. The process above will be repeated along with the breath rhythm.

In noninvasive and SPONT mode, when airway pressure is less than 0.3kPa, electromagnetic valve Y2 will open and provide a 3-5L/min gas current to the airway to reduce the patient's inspiring work.

During above process, inspiration, expiration and base flow is controlled by the electronic circuit. In Fig.1, circuit part provides all rhythms of whole set operating, including breath frequency and I:E ratio, and at the same time receive and manage pressure and flow signal and the relevant orders put in by the operator, and analyze, manage and display the relevant parameters, so that the operate can observe them and monitor the patient's condition.

The machine can connect with 110V A/C to provide the needed power supply; at the same time charge the storage battery to make the machine go on working if without A/C power. It can also provide DC 12V power socket and on-vehicle wire to make it work normally with the vehicle's power.

## 2.3 STRUCTURE CHARACTERISTICS

### 2.3.1 Introduction of the front panel

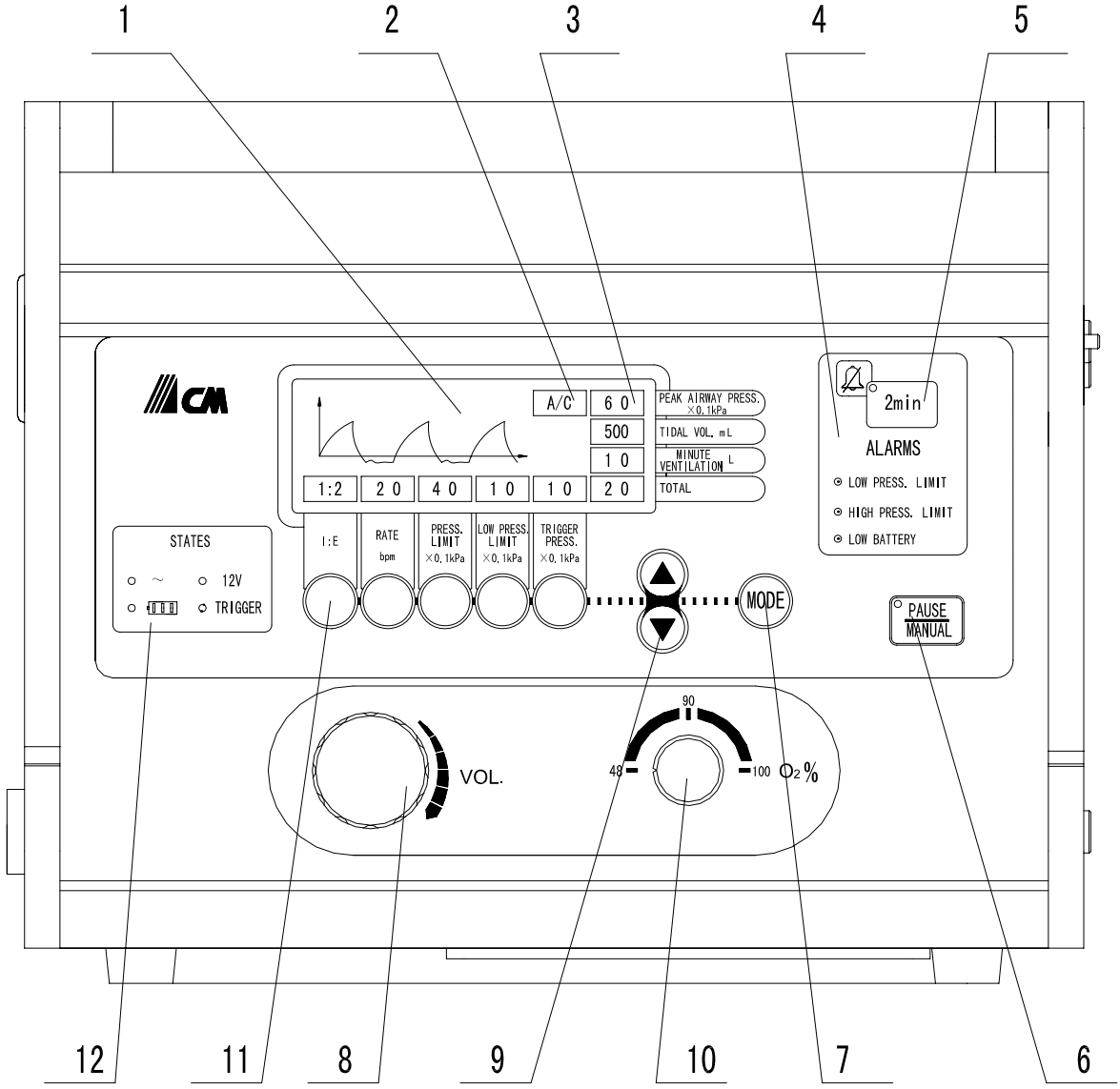



Figure 2.1 **Control function of the front panel**

1. Pressure waveform
2. Ventilation mode display
3. Test area
4. Alarm indication area
5. Silence key
6. Pause/manual key
7. Mode set key
8. Tidal volume adjust knob
9. Up-and-down adjusting key
10. O2 concentration adjusting key
11. Parameter setting area
12. Status indication

2.3.2 Various function of the side panel

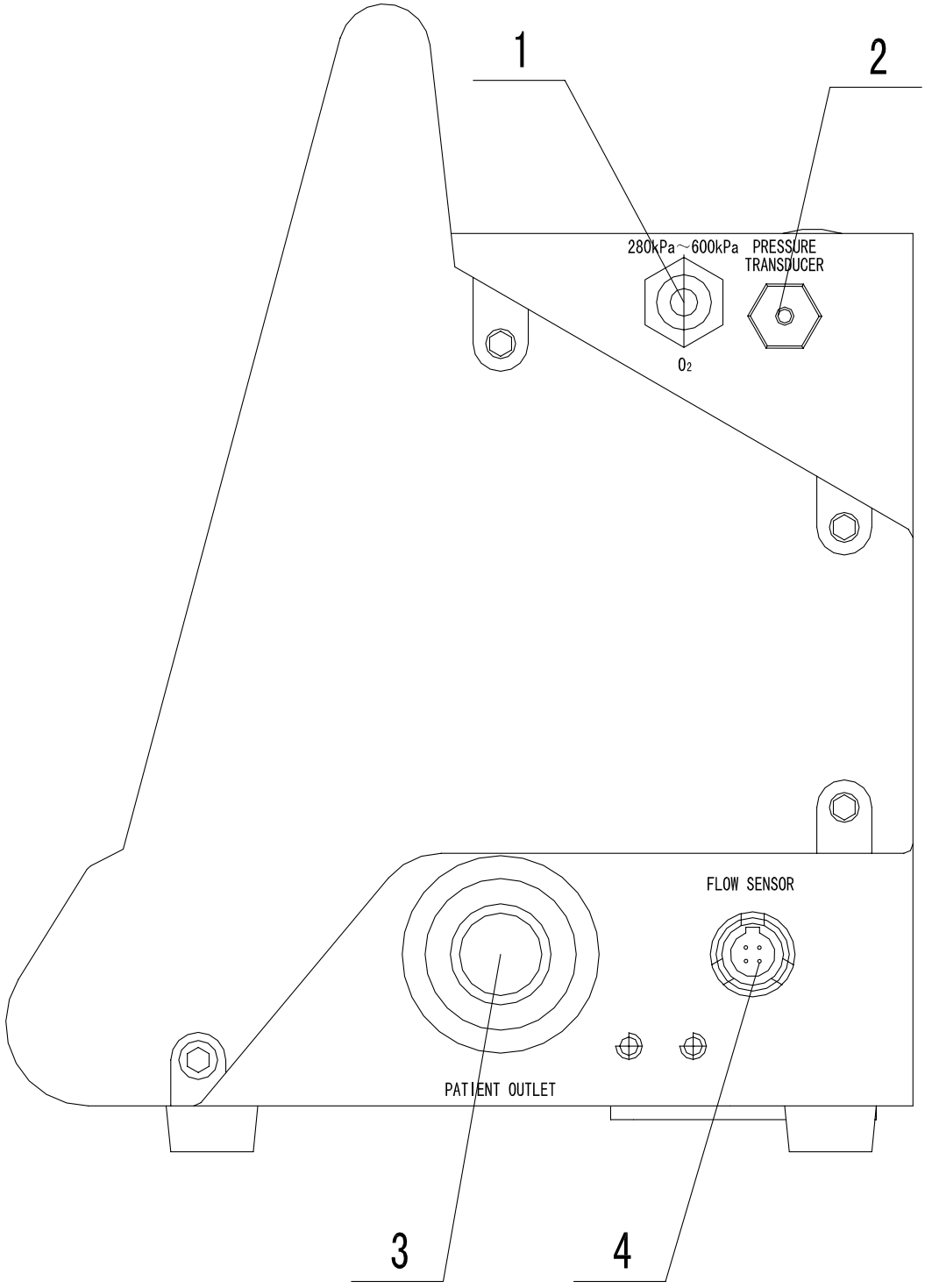



**Fig. 2.3 Various function of the side panel**

1. Gas source inlet
2. Pressure sample port
3. Expiratory port
4. Flow sensor port

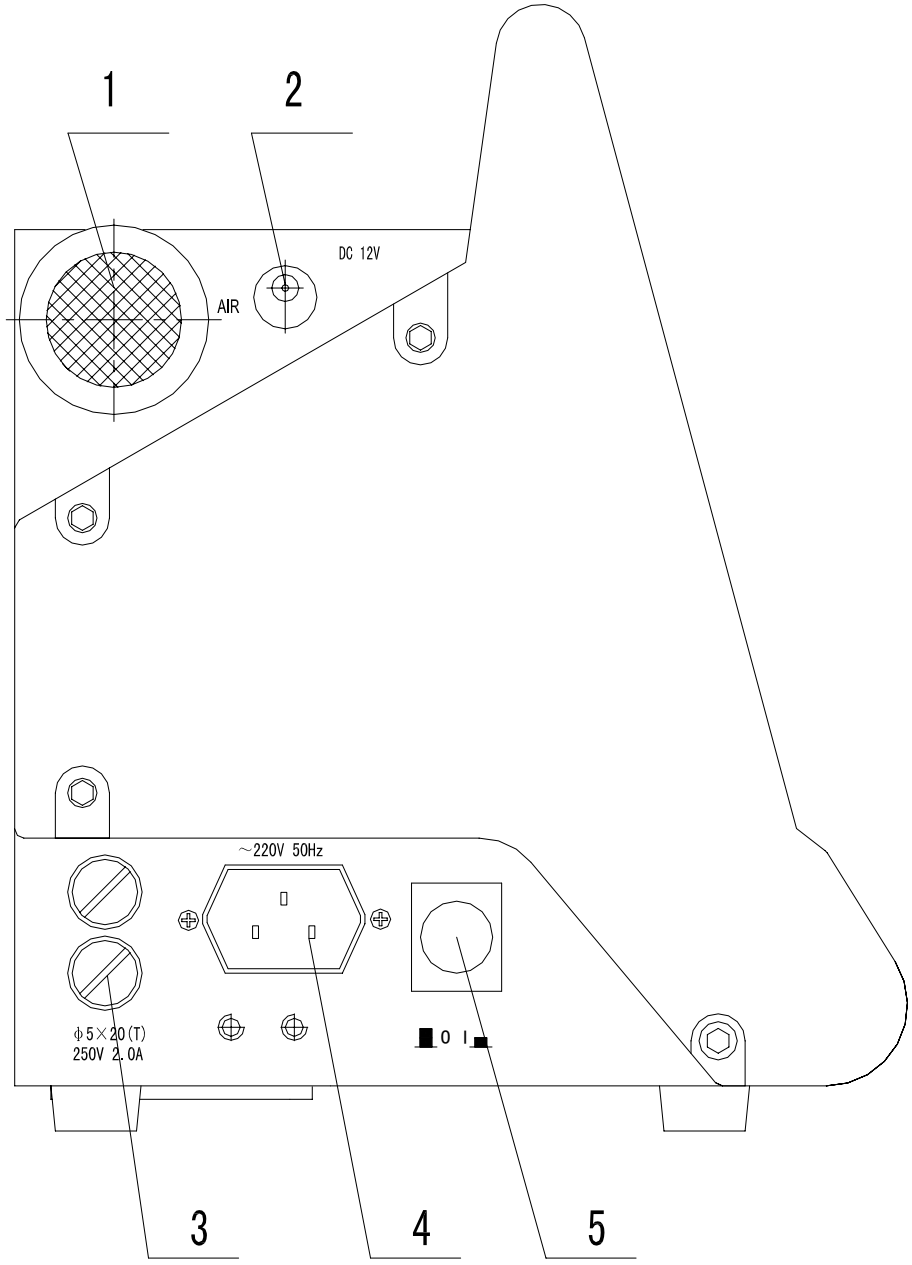
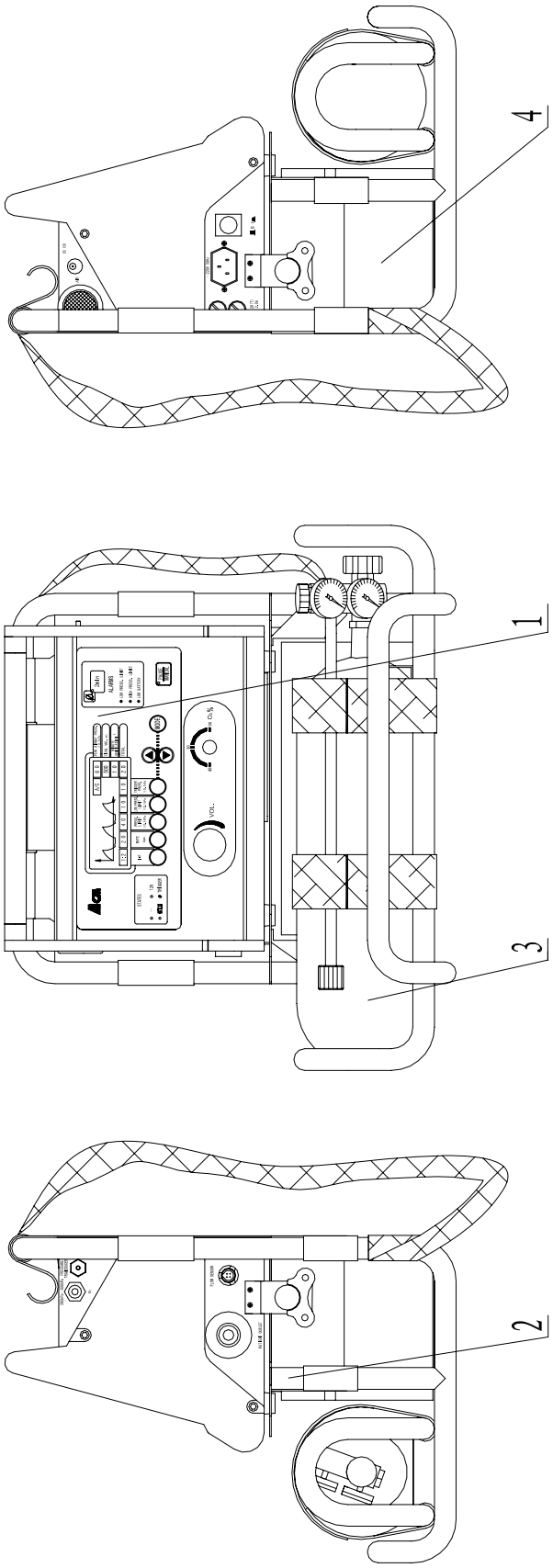



**Fig. 2.4 Ventilator's general diagram**

1. Air inlet
2. DC 12V Power port
3.Fuse Sockt
4.AC 220V Power port
5. Power switch

2.3.3 Ventilator's general diagram




1. Main unit
2. Multi-function shelf
3. Gas cylinder
4. Accessories package

**Fig. 2.5 Ventilator's general diagram**

# 3. TECHNICAL SPECIFICATIONS

3.1 The performance of Airway System

Safety pressure of the airway system: no more than 6kPa±15%.

3.2 Ventilation mode

A/C, SIGH, SIMV, SPONT, Non-invasive—A/C + continuous current, MANUAL

3.3 Ventilation Performance

a) Respiration frequency f: 4~80times/min;

b) I:E: 1:4, 1:3.5, 1:3, 1:2.5, 1:2, 2:3, 1:1, 1:0.7, 1:0.5, 1:0.3, error±10%;

c) Inspiratory tidal volume Vti: 100~1500ml when less than 200Ml and with error of±30ml; the other ranges error is ±10%.

d) Trigger sensitivity $P_T$: ~2~+2kPa, when the pressure is within ~0.5~+0.5kPa, the error is±50kPa, other ranges error is±10%;

e) Inspired oxygen concentration $O_2$%：48~100%，ranges error is±8%

3.4 Monitor Performance

a) Total ventilation frequency $f_{total}$: when $f_{total}$≥60 times/min, the error is ±5%; other error is ±1 time/min;

b) Minute volume MV: display range is from 0L/min to 20L/min, the error is±20%;

c) Inspiratory tidal volume Vti: digital display with error of ±20%;

d) Airway pressure: the luminous line display, the range of monitor is ~2kPa~+6kPa, when the pressure is within ~2kPa~+2kPa, the error is±300Pa, when the pressure is within +2kPa~+7kPa, the error is±15%.

e) Peak pressure value: monitor range is within 0kPa~+6kPa, when the pressure in no more than 3kPa, the error is ±0.5kPa; when peak pressure is more than 3kPa, the error is ±15%.

3.5 Alarm performance

a) Airway pressure upper limit alarm: the range for adjusting is 2kPa~6kPa, the error is±10%;

c) Airway pressure lower limit alarm: the range for adjusting is 0kPa~2kPa, when the pressure is within 0kPa~0.5kPa, the error is ±100Pa; when the pressure is within 0.5kPa~2kPa, the error is±20%. When the sound alarm happens when delay of 4s~15s, light indication appears;

d) Silence: no more than 120s;

f) Asphyxia ventilation: the time of the asphyxia ventilation is 10s~20s. When the

asphyxia ventilation happens, light indication appears;

3.6 Performance of the whole set

a) Compliance of ventilator system: ≤4ml/100Pa；

b) Noise of the whole set: ≤65dB(A)；

c) Electrical safety: meet requirements for I type BF mode equipment specified in GB9706.1~1995 “Medical Electrical equipment: Part one: General requirement for safety;

d) Power: no more than 50VA。

3.7 Requirements for Gas Source and Power Supply

3.7.1 Gas source

The system is equipped with a 3.2L gas cylinder in steel bottle, and can be filled with no more than 14.7KPa medical oxygen; and also can connect to compressed air and compressed oxygen with pressure of 280kPa~600kPa.

3.7.2 Power supply

Power supply:

a) AC100V~240V 50Hz/60Hz

b)DC12V±1V

c)Battery

3.8 Physics parameters

a) Volume: 307mm×204mm×222mm；

b) Weight: 5.8kg.

# 4. INSTALLATION AND CHECK

## 4.1 Installation

### 4.1.1 Connect the power socket

Connect the power socket on the side of the machine. The power on-off is on the right side of socket; and when it is in “I” position, machine is turned on; when in “O” position, machine is turned off.

**CAUTION:** The power cable of ACM812A ventilator can only be connected to the standard plugs in hospital.

Recommendation:

1) When voltage of power system waves exceeds 10%, user should use transformer.

2) When use external 12V power and UPS power, the power on-off can be used normally.

### 4.1.2 Connect the gas inlet pipeline

Connect the gas inlet pipeline to gas inlet port of ventilator, or connect one end of the gas inlet pipeline into gas inlet of ventilator and the other end into multi-tube connector.

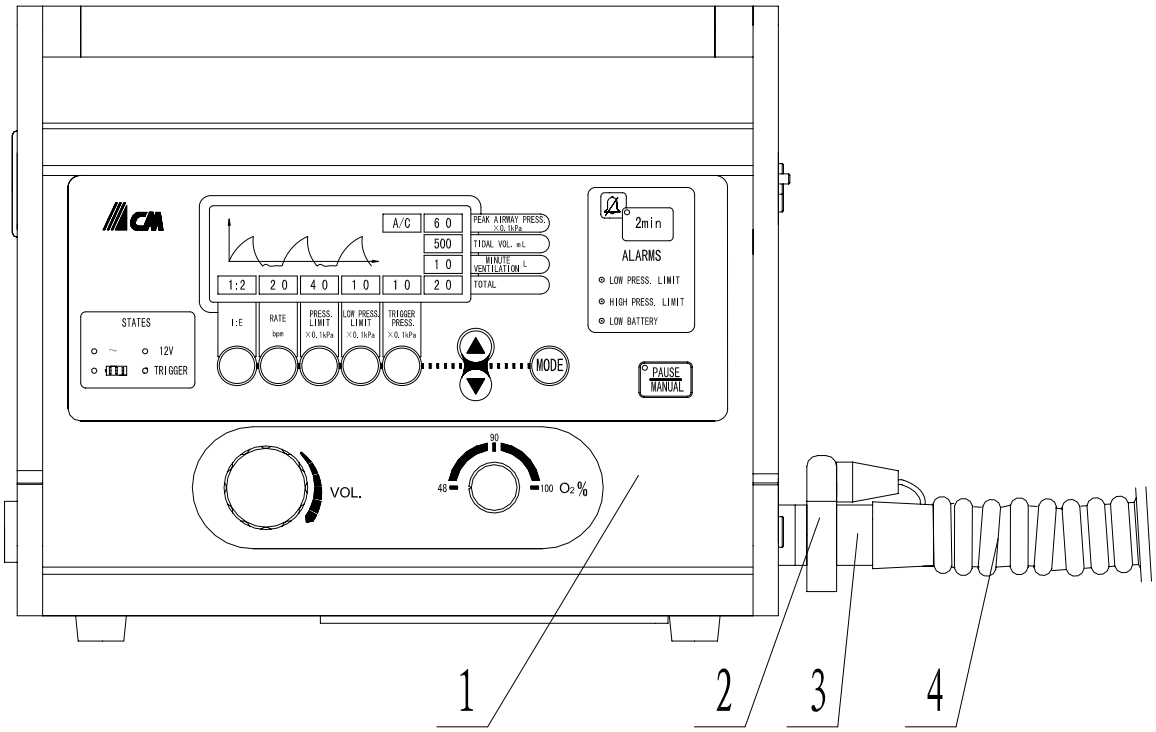
### 4.1.3 Connect the flow sensor

Connect one end of the flow sensor into the socket of flow sensor. Fix the flow sensor on the inspiratory inlet and fix the probe on the flow sensor. (Fig. 4.1)

**CAUTION:** The flow sensor and the probe are precision instrument, and do not break or touch them.

4.1.4 Connect the silica gel pipeline

Connect one end of the silica gel pipeline into the outlet of flow sensor, and the other end into transfer joint. (Fig. 4.1)

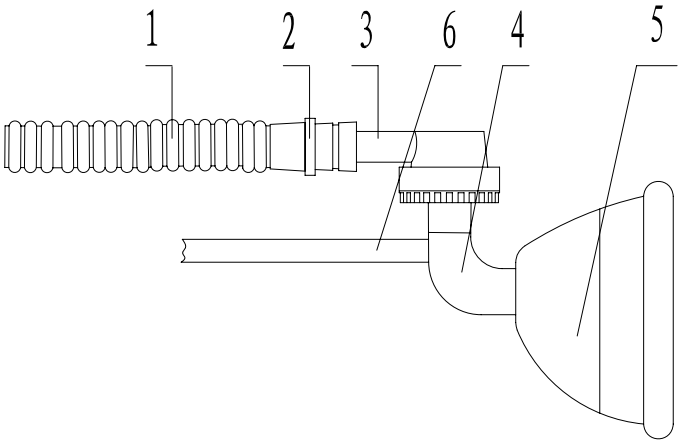



1. Ventilator
2. Probe of flow sensor
3. Flow sensor
4. Silicon tube

Fig. 4.1

4.1.5 Connect expiratory valve and mask

Connect one end of expiratory valve into transfer joint, and the other end into mask or endotracheal intubation. (Fig. 4.2)



1. Silicon tube
2. Inhaling unidirectional valve
3. Expiratory Valve
4.Pressure stomata straight connector
5. Face mask
6.Pressure sampling tube

Fig. 4.2

4.2 Check

After installation and before use ventilator for patient, other than necessary cleaning and disinfection, there should be special doctor and nurse who charge of electrifying and ventilating for machine and simply functional check. After ensure there is no trouble in the machine, the ventilator can be used for patient. The steps of the function check are given as follow.

**WARNING:** If some problems are found during check, do not use the ventilator for patient!

4.2.1 Connect the power supply and the gas source, and check if they are normal or not.

4.2.2 Turn-on: turn on the power switch, the screen will display pressure wave, the ventilator is workable.

4.2.3 Break-off alarm check

Turn on the power supply of ventilator, and turn off it 10 seconds later, there should be audio alarm.

4.2.4 Standard situation check

Open the power and gas source switches, the ventilator is working under the standard situation

a) Ventilation mode: A/C;
b) The preset value of frequency: 12 (times/min);
c) I:E: 1:2;
d) Airway pressure upper limit(×0.1kPa): 60;
e) Airway pressure lower limit(×0.1kPa): 5;
f) Trigger pressure(×0.1kPa): －3;
g) Tidal volume: 500ml;

4.2.5 Tidal volume check:

After opening the machine, connect the simulation lung, observe the tidal volume displayed in the parameter monitor area in the front panel, the display value here should be the same with the set value of the tidal volume in the parameter setting area.

4.2.6 Airway pressure upper limit alarm function check

Adjust the tidal volume to make the peak value of the airway pressure indicated about 0.25kPa, adjust the pressure upper limit value in the setting alarm area, when the pressure upper limit value a litter lower than 0.25kPa, there should be audio and video alarm, at this time, the ventilation mode switches to expiration and the airway pressure decrease follows.

4.2.7 Airway pressure lower limit alarm function check

Adjust the airway pressure lower limit value to make the value displayed 0.1kPa. After picking off the inspiratory pipe, there should be video and audio alarm about 4~15 seconds later.

4.2.8 Trigger pressure function check

Set the trigger pressure to－0.1kPa, wear the mask and gently inspire, When the airway pressure a little lower than this preset value, inspiration begins, at the same time, “trigger indicator light” flashes once.

4.2.9 SIMV mode check

Set the ventilation mode to SIMV, wear the mask and inspire, when airway pressure reaches mandatory ventilation, there is a A/C respiratory cycle.

4.2.10 SPONT mode check

Set the ventilation mode to SPONT, wear the mask and inspire, when the airway pressure a little lower than preset trigger pressure, at this time, ventilator have a continuous airflow.

4.2.11 SIGH mode check

Set the ventilation mode to A/C mode, and after turn the tidal volume knob to 400mL～500mL, choose the ventilation mode as SIGH. Observe how much the simulation lung is expanded and the peak value of airway pressure. From the second breath after setting, the simulation lung appears 1.5 times tidal volume sigh once, under this situation, the sigh appears once every 100 times.

# 5. OPERATIONS

5.1 Pre-use preparative

5.1.1 Carry out the connect procedure given in section 4 of this operation manual to connect the parts of ventilator and then check if they are connected correctly.

5.1.2 Familiarize the operations of this ventilator, check every function and affirm if the device works normally.

5.1.3 The doctor and nurse using ventilator for treatment should have the essential qualifications as follow:

a) Possess the supernal responsibility and sympathism and highly answer for the safety of the patients;

b) Have extensive knowledge, know the respiratory physiology and the respiratory failure pathology and physiology; understand all the operation principles, performances and characteristics of the ventilator and can correctly adjust it; comprehend the signification and clinic application of the respiration monitor.

c) Possess well diathesis, prompt reaction and strong capability to deal with an emergency.

5.2 Panel operation

5.2.1 Parameter setting area operation

Ventilation mode setting

The ventilation mode of the ACM812A ventilator can be chose in accordance with patient status.

a) Control respiration: or called C (Control) [in the A/C mode]

In this mode, patient cannot control the gas venting. Ventilator supplies the intermission positive ventilation for patient according to the pre-adjust ventilation parameters in spite of the patient spontaneous breath. This mode is mainly used for the patient without spontaneous breath or the one whose spontaneous breath is very weakness, and also used for the patient used muscle loosen juice under narcotism.

**Characteristics:**

1) The inspiratory tidal volume should be invariable, the value has to be preset according to the patient status;

2) Preset respiratory frequency;

3) Need to preset I:E;

4) The time switch is used when expiration converts to inspiration.

The waveform of the C mode is shown in Fig. 5.1:

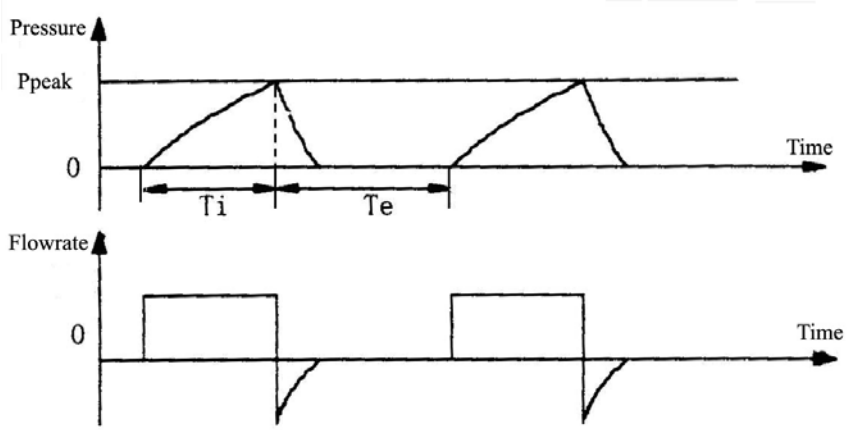



Fig. 5.1 The waveform of the C mode

b) Assistant respiration: or called A (Assist) [In the A/C mode]

Its characteristic is that the patient can control the respiratory frequency, but the respiratory tidal volume and I:E are still controlled by ventilator. This mode is used for the patient who is in his sense and has the capability of spontaneous breath but cannot bring enough breath power. Comparatively with A/C, the different characteristics of A mode is given as follow:

1) Pre-adjust trigger pressure;

2) When the pressure of the patient spontaneous breath reaches the trigger pressure, the device ventilates for patient according to the preset parameters;

3) The preset value of the control ventilation frequency f should be lower several times/min than $f_{total}$;

**CAUTION:** If the trigger pressure is set improperly or patient's capability of spontaneous breath is increased, this mode may cause the ventilation volume excessive. The sketch map of the assistant respiration waveform is shown in Fig. 5.2

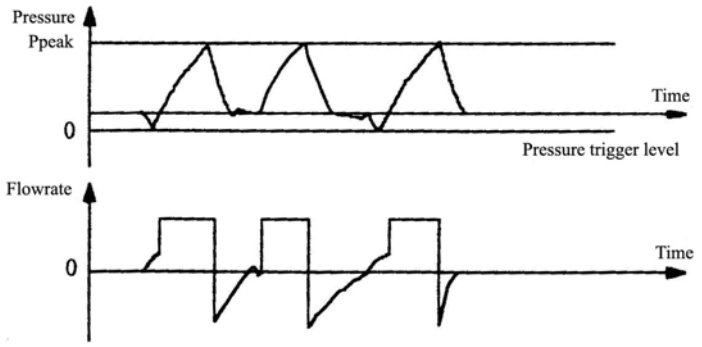



Fig. 5.2 The waveform of the A mode

c) SIGH

SIGH means on the basis of A/C, add the deep breath of 1.5 times tidal volume once every 100 times. It fits the patient who needs machine ventilation for a long time, and also can be used for “extend lung” of the chest surgery. During “extend lung”, because there are several times continuous sigh, at this time doctor and nurse should switch the ventilation mode come-and-go between A/C and SIGH. When sigh, the peak value of the airway pressure will increase as a result of tidal volume doubling, so the preset value of the airway pressure upper limit should be increased too, that is, the pressure peak value should be 1kPa higher than the value in sigh, and the other parameters are the same with the A/C mode.

d) Synchronized intermittent mandatory ventilation (SIMV)

This is a mode combined by patient spontaneous breath and machine command ventilation. Command ventilation is triggered synchronously by patient. It is mainly used for the transition from compelling ventilation to spontaneous breath before removing the ventilator.

If in the previous SIMV cycle, there is no trigger to arouse ventilation, then at the beginning of this cycle, it will provide a mandatory ventilation; in a SIMV cycle, the first trigger provide 1 assisted ventilation, and during the left time, patient will breathe spontaneously if there is trigger.

**NOTE: When using SIMV, the command ventilation and the spontaneous respiration are triggered synchronously by patient, so the trigger lever should be set. In SIMV mode, the inspiration time of mandatory ventilation is the same as that in A/C mode, so it is necessary to set the respiration frequency and I:E ratio in A/ mode.**

**WARNING: When using this mode, if the patient is in a bad way, the abrupt stop of the spontaneous respiration may cause the insufficient ventilation or oxygen lack.**

The sketch map of the SIMV waveform is shown in Fig. 5.3

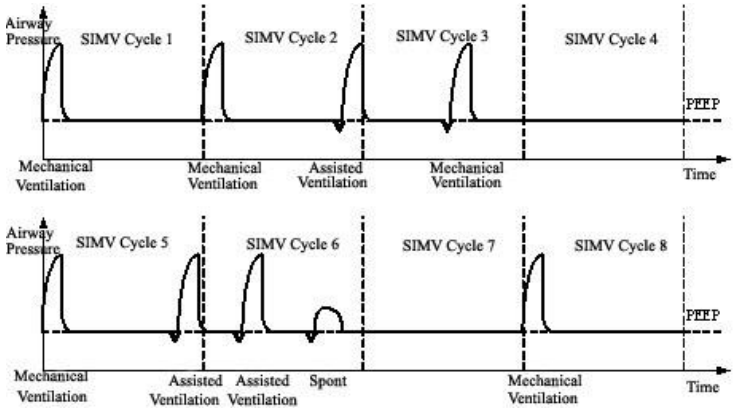



Fig. 5.3 The sketch map of the SIMV waveform

e) Spontaneous respiration mode (SPONT)

The patient spontaneously respires by means of positive pressure gas flow system. In this mode, the patient has come back to spontaneous respiration, at this time, the ventilator only supplies a continuous positive pressure gas flow. During respiration, patient controls the tidal volume, respiration frequency and I:E by himself. Inspiratory flowrate is controlled by the tidal volume knob, when patient stops inspiration, airway pressure arises; when arises to around PEEP+0.6kPa, ventilation will switch to expiration and wait for the patient's next spontaneous inspiration.

**WARNING:** In this mode, the tidal volume, I:E, and respiratory frequency all should be preset in A/C mode besides trigger pressure to prevent patient from dangerous once patient has no spontaneous respiration and the mode of ventilator changes to A/C automatically.

SPONT waveform is shown in Fig. 5.4

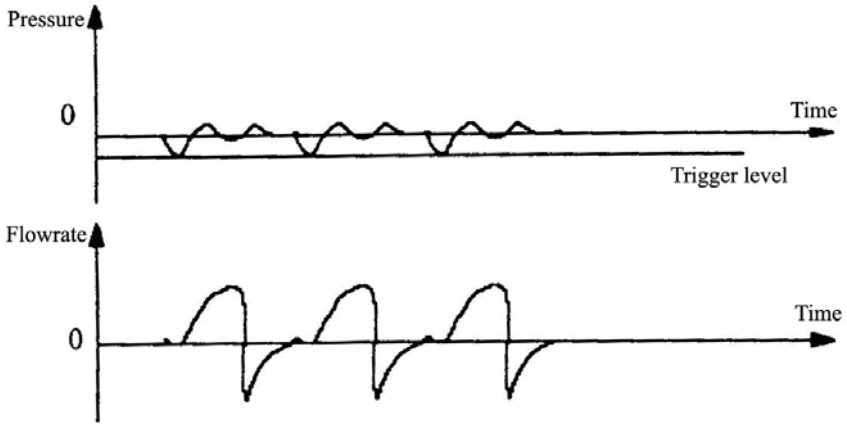



Fig. 5.4 SPONT waveform

f) Noninvasive ventilation

This is a kind of ventilation of A/C with side stream. Under this ventilation mode, the ventilator supplies continuous positive pressure and supply gas to the patient in accordance with the preset parameters.

g) Manual ventilation:

Chooses manual ventilation, and when presses the "MANUAL" key, ventilator will deliver continuous flow (flowrate is the adjusted tidal volume's flowrate). When undo the MANUAL key, ventilator stops ventilation.

**Characteristics: Doctor can give mechanical ventilation according to patient status if patient's disease is complicated.**

**WARNING: When choosing SPONT and Noninvasive mode, oxygen concentration will increase.**

5.3 LCD monitoring, setting and other function area

LCD screen monitoring: tidal volume, airway pressure waveform, Ppeak, ventilating volume and total respiration frequency, I:E ratio, pressure limit, lower pressure limit and trigger pressure. When setting parameters, press corresponding parameter key and the parameter will flash, At this time use ▲, ▼ key to adjust to the suitable value and again press the corresponding parameter key to confirm. The setting is finished then.

When setting ventilation mode, first press mode key and the display part will flash, then press ▲, ▼ key to choose ventilation mode and again press this key to confirm.

See Table 5-1

| Parameter key | Operating method |
|---|---|
| Tidal volume （L） | Rotate the tidal volume regulating knob to regulate the tidal volume value, and the display of the tidal volume changes relatively. Clockwise rotation means value increase, and anticlockwise rotation—decrease of value. |
| I:E ratio | When pressing I:E key, its display part of flashes. At this moment press Δ or ∇ key, and set the I:E mode and press it again to confirm the setting. |
| RATE (Times/min) | Respiratory frequency setting: When pressing RATE key, its display part flashes. At this moment press Δ or ∇ key, and set the respiratory frequency and press it again to confirm the setting. |
| Pressure limit （×0.1kPa） | Press this key and Pressure limit's display part flashes. At this moment press Δ or ∇ key, and set the pressure limit and press it again to confirm the setting. |
| Lower pressure limit （×0.1kPa） | Press this key and Lower pressure limit's display part flashes. At this moment press Δ or ∇ key, and set the lower pressure limit and press it again to confirm the setting. |
| Trigger pressure （×0.1kPa） | Press this key and Trigger pressure's display part flashes. At this moment press Δ or ∇ key, and set the trigger pressure and |

| | |
|---|---|
| | press it again to confirm the setting. |
| Mode | Press this key and Mode's display part flashes. At this moment press Δ or ∇ key, and set the mode and press it again to confirm the setting.. |
| O2 concentration | Rotate the O2 concentration regulating knob to the needed concentration. |
| Silence for 2min | When alarming, press the key to eliminate alarm for 2 minutes. |
| Trigger (indication light) | Display the trigger status, and when triggering this light is bright. |
| Power failure | When the power supply is insufficient, the indication light is bright with audio alarm. |
| Power supply (indication light) | Connect to A/C power, A/C indication light is bright. Connect to 12V power or use built-in battery, DC indication light is bright. |

5.4 Monitoring ventilator during operation

5.4.1 Ventilator always plays a key role in cure respiration failure. So if it is used in wrong way or its troubles cannot be checked and resolved, severe damages will be induced. Therefore, the doctors and nurses with high sense of responsibility and skilled professional knowledge and advanced monitor instrument are desirable.

5.4.2 User should monitor the status of patient and ventilator once every 2 hours (At the beginning, the interval should be shorter.). The serious patient should be monitored once every 1 hour, and the chronic stable patient only need be monitored once every 4 hours.

5.5 Monitor items for ventilator

5.5.1 Check if any preset parameters change or not;

5.5.2 Measure if respiratory frequency is accurate or not directly;

5.5.3 Measure if inspiration time is accurate or not directly;

5.6 Monitor items for patient

5.6.1 Measure spontaneous breath frequency and heart rate;

5.6.2 Measure blood pressure;

5.6.3 Measure data of hemodynamics;

5.6.4 Measure the tidal volume of spontaneous breath. Best measure 10 times to evaluate the average.

## 5.7 Battery recharge

Connecting to the AC power, then the recharge starts. The recharge time should be more than 5 hours.

# 6. USE OF CYLINDER

6.1 Check oxygen pressure

Turn off the cylinder's flow regulating switch (clockwise means close. the same below), open the cylinder's high pressure switch (anticlosewise means open. The same below). Observe the high pressure oxygen meter's indication, you will know the oxygen pressure in the cylinder.

After check, turn off the oxygen supply switch. Open the flow regulating switch to discharge gas, when the high pressure oxygen gauge and the low pressure oxygen gauge are both point to "0", turn off the switch. When the pressure is less than 2MPa, fill oxygen in time.

8.5 Oxygen filling (see fig. 6.1)

a) Open the cylinder's high pressure switch and flow regulating switch, and screw off the oxygen filling plug with special spanner.

b) Open the oxygen supply (big oxygen cylinder) valve to discharge gas, and blow off the outlet end of cylinder and then close it.

c) Take off the plastic protective cap on the 2 ends of the oxygen cylinder, and put the oxygen cylinder on cylinder's oxygen filling end and tighten it with special spanner. Then put the other side of oxygen cylinder on cylinder's oxygen outlet end and tighten it with special spanner.

d) Open oxygen supply valve, and then slowly open cylinder's high pressure switch, and begins to fill oxygen to oxygen cylinder. Observe cylinder's high pressure gauge indication; when the pointer stops rising, gas flowing sound will disappear, which means that the O2 cylinder is basically full. Then go on 1-2 minutes, it can totally full.

e) First turn off the cylinder switch and then the oxygen supply valve. Dissemble the oxygen cylinder and oxygen bridge with special spanners. Put the oxygen filling plug on the oxygen filling end and tighten. Screw the protective cap on the oxygen cylinder.

**NOTE:** during oxygen filling, it is normal for the cylinder's surface to become warm or hot. And if leakage happens, must turn off the cylinder switch and oxygen supply valve.

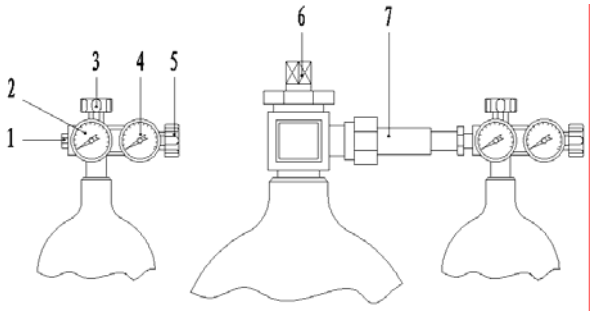



**Fig. 6.1 cylinder filling**

1. Oxygen filling plug
2. Cylinder’s high pressure gauge
3. Cylinder’s high pressure switch
4. Cylinder’s low pressure gauge
5. Cylinder’s flow regulating switch
6. Oxygen supply valve
7. Oxygen bridge

# 7 TROUBLSHOOTING

7.1 Technical fault

7.1.1 Power fault (See table 7-1)

Table 7-1

| Fault phenomena | Possible reason | Measures adopted |
|---|---|---|
| Ventilator inoperative | The power supply cable is not connected, battery no electricity, the fuse is burned out, or the power supply switch is not turned on. | Connect the cable, charge the battery, change the fuse, and turn on the switch. |
| The ventilator stops during operation, the indicating lamp goes out, and audible alarm sounds. | AC power interruption<br>battery no electricity | Manual ventilation and check the AC and DC power |
| The power supply indicating lamp is sometimes on sometimes off, and at the same time, the sound stops. | The power supply plug looses. | Re-plug it. |

7.2 Clinical judgment

7.2.1 Triggered pressure indicating lamp flashing (See table 7-2)

Table 7-2

| Cause | Symptom and diagnosis | Recommended treatment method |
|---|---|---|
| Patient triggered spontaneous respiration | The preset value of the trigger pressure is too small so the patient triggers spontaneous respiration easily. | Reset the trigger pressure value |

7.2.2 Airway pressure upper limit alarm (See table 7-3)

Table 7-3

| Cause | Symptom and diagnosis | Recommended treatment method |
|---|---|---|
| Close end pressure measure pipe or patient respiratory pipeline bend or block | Under material block condition, flow and airway pressure reading will indicate that the resistance in airway is increased. At the same time, the elastic resistance increases (low compliance). | Check the patient pipeline and repair. |
| Mucus accumulated in airway causes airway block | There is gong sound and chest sniffing quiver while auscultation. | Sucking phlegm, getting rid of phlegm, and physical therapy. |
| Airway pressure upper limit is low | | Reset the alarm value according to the patient status. |
| Patient compliance and resistance change | | Recalculate the patient ventilation parameters. |

| | | |
|---|---|---|
| Patient muscular tension and cough | Sometimes the mucus generated by phlegm sucking may cause counteraction between patient and ventilator | |

7.2.3 Airway pressure lower limit alarm (See table 7-4)

Table 7-4

| Cause | Symptom and diagnosis | Recommended treatment method |
|---|---|---|
| Patient pipeline leakage | The gas leakage can be detected through palpating or auscultation of trachea | Check the pipeline and repair the leakage part |
| Alarm value is set too high | | Reset the alarm value according to the patient status |
| Patient compliance change | | Examine the patient status. |
| Insufficient patient spontaneous respiration during SIMV or SPONT | The minute volume and total frequency in monitor area becomes low | Readjust the patient ventilation mode and ventilation parameters. |

# 8 CLEANING AND MAINTENANCE

The purpose of cleaning and maintenance is to avoid cross infection and to extend the usage life of the ventilator and make the device into well standby situation.

8.1 Cleaning and sterilization

8.1.1 Cleaning and sterilization the whole set

Clean the machine's panel and all surfaces with soft cloth soaked with the water-soluble sterilizing agent in common used. One must prevent the sterilizing agent drops from entering the anaesthetic machine and the misusage of organic agent for cleaning the machine.

The whole set can be sterilized by irradiating with ultraviolet ray for 1 hour.

**CAUTION:** When s sterilization the whole set, do not use Acidum Peroxyaceticum, formaldehyde to fumigate.

8.1.2 For respiratory tract infective patient

If the device is used by respiratory tract infective patient, the parts not easily disinfected, such as the machine's panel and all surfaces, should be wiped by 2% Soda Water, and then be cleaned by rinsing.

The things used by tuberculous patient should be used only by himself or be sterilized in especially way, the dunking time should be prolongated to over 2 hours according to the situation. After that, flush them by rinsing, and then put them into formalin fumigate box to disinfect for 12 hours.

8.1.3 Cleaning flow sensor and the probe

The flow sensor and the probe should not fall off as they are precision and damageable parts. For the principle of the sensor is measuring the number of circles turbine rotating with photoelectricity sensor, the result of counter will be inaccurate if the flow sensor and the probe are abraded excessively or too dirty. So try to avoid scratching the flow sensor. If flow sensor and the probe are too dirty, use soft cloth soaked with the water-soluble sterilizing agent to clean. For example, use 70% alcohol tampon to gently wipe cleanlily.

**WARNING:** Strictly prohibit the sterilizing agent dropping into probe.

8.1.4 Sterilization expiratory valve

Take off the valve and the diaphragm and clean and dipped in clear water; after removing the patient’s expired residue in the breathing tubes, dip and sterilize in the disinfecting liquid. If used by tuberculous patient, put them into formalin fumigate box to disinfect for 12-24 hours.

8.1.5 Sterilization outer respiratory pipeline

After patient using, the outer respiratory pipeline should be cleaned and sterilized thoroughly once every time. Normally, flush and dunk them by rinsing. After remove the scrap patient expired in respiratory pipeline, dunk them into disinfection liquid for sterilization. If the device is used by infective patient, use formalin to fumigate for about 12~24 hours.

**NOTICE:** After disinfection by fumigating box, the pipeline should be flushed by high-pressure gas so as to eliminate the peculiar smell.

8.1.6 Cleaning air inlet

Sponge of air inlet on the back panel is used to filter and insulate. When too dirty, it will need replace or clean, or will influence air to enter. Please screw off the back cover of air inlet and take out the sponge, clean it with suds and airing it, and then reinstall it into back panel. Pay attention to the order of installation.

8.1.7 Sterilization, cleaning, drying and correct installation of easily-pollutable items

The tube system that connects patient and this machine is easy to be polluted, so it needs sterilization, and the method is as above-mentioned. After sterilization, tubes, flow sensor and connector should be installed correctly to prevent leakage. After installation, it should go through a trial operation, and only after the machine's normal working can it be connected to the patient. Pay special attention to the airtightness of the expiratory valve. Flow sensor should be vertical to the machine's panel to prevent its loosening and dropping.

8.2 Maintenance

8.2.1 Replacing the fuse tube of the ventilator

There are two fuse tubes in this ventilator connected respectively to ground wire and live wire circuit on the rear panel of the ventilator (Fig. 3).

The fuse tube of live wire circuit stands in the power supply socket. Before replacing, firstly pull out the power line from the power socket, insert a little "–" mode screwdriver into the notch locating the topmost of power socket inside, gently draw out the fuse tube base, and take out of the bad fuse tube from the base, replace the new one, and then gently push the fuse tube base into original position.

The fuse tube of ground wire circuit stands in the round fuse tube base. When replace, insert a little "–" mode screwdriver into the notch locating fuse tube base and contrarotate the screw cap. After screw off it, take out of the bad fuse tube from the base, replace the new one, and then use a little "–" mode screwdriver to screw the cap tightly.

**WARNING:** When replacing the fuse tube, the power must be cut off. Otherwise, there is a possibility of injury or death to patient or the others.

**NOTICE:** When replacing the fuse tube, the type and the dimension of the new fuse tube should be the same as the old one. Otherwise, there is a possibility of damage to equipment.

8.2.2 Maintenance during operation and transportation

The location of the machine at the operation place should be appropriate, so that the doctor or nurse may not touch the machine during operation, therapy or nursing of the patient. Especially the airway pipeline and power supply cable on the ground should not affect walking of person so as to avoid them being contacted and causing gas and electricity failure. The knob on the panel should not be misplaced due to involuntary contact to make the set value abnormal. In transporting the machine, especially going up and down the stairs, it should be protected to avoid the cart from dumping and damaging the valuable machine.

# 9 TRANSPORTATION AND STORAGE

## 9.1 Transportation

The packed product is allowed to be transported by air, highway or railway itself. The product should be free from shock, violent vibration and moisture during transportation (other requirements are met according to order contract).

## 9.2 Storage

The product should be stored in the room with temperature of 0 ~ 40°C, relative humidity of no more than 80%, good ventilation and without corrosion gas.

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

# 10 Information on electromagnetic compatibility

Portable and mobile RF communications equipment can affect ventilator.

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the ventilator as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ventilator。

The ventilator should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ventilator should be observe to verify normal operation in the configuration in which it will be used.

Note: Beijing aerospace chang feng co., ltd. Medical device branch can not guarantee that accessories, lines and transformers not delivered by beijing aerospace chang feng co., ltd. Medical device branch will correspond with EMC requirements of EN 60601-1-2.

| Accessory part/name | Article number | Length/dimensions |
|---|---|---|
| | | |
| | | |

**Note:**

The ventilator is exclusively intended for use by medical professionals. In residential areas, the ventilator may cause radio interference in certain circumstances so that it may be necessary to undertake suitable measures such as realigning, rearranging or screening the ventilator, or filtering the connection with the public power supply.

1.1 Emitted electromagnetic interference

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

| Emissions test | Compliance | Electromagnetic environment – guidance |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 1, Class B | The ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |

1.2 Electromagnetic immunity

| Emissions test | Compliance | Electromagnetic environment – guidance |
|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2<br>6 kV contact<br>8 kV air | ±2 kV, ±4 kV, ± 6 kV contact<br>±2 kV, ±4 kV, ± 8 kV air discharge | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity |

| | | |
|---|---|---|
| | | should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 ±2 kV for power supply lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 ±1 kV Line to line ±2 kV Line to earth | ±1 kV Line to line ±2 kV Line 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 % UT(>95 % dip in UT) for 0,5 cycle 40 % UT(60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery. |
| Conducted RF IEC 61000-4-6 3 Vrms 150 kHz to 80 MHz | 3 Vrms 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter |
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2,5 GHz | |

| | | |
|---|---|---|
| | | manufacturer and d is the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | |
| a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to verify<br>normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.<br>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m. | | |

1.3 Recommended safe distance

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

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | $d = [\frac{3,5}{V_1}]\sqrt{P}$ | $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz | $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.33 |
| 10 | 3.70 | 3.70 | 7.37 |
| 100 | 11.70 | 11.70 | 23.30 |
| For transmitters rated at a maximum output power not listed above, the recommended | | | |

separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# Operation Manual
# For ACM812A Ventilator

**EDITION： 00. 10**

**REVISED IN APRIL, 2008**