

Oxygen Concentrator User's Manual

A5L

- A WARNING-Please read this User's Manual carefully and understand it before using the oxygen concentrator.
- (R) DANGER-Fire is strictly prohibited.

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• Important Safety Information

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Please read this User's Manual before using the oxygen concentrator.

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In order to prevent power outages or possible malfunctions of the oxygen concentrator, those who are in urgent need of oxygen and critically ill patients must be provided with other backup oxygen sources.



This oxygen concentrator is not intended to sustain or prolong life.

The important information in this manual is highlighted using the following terms:

DANGER: Emergency safety information, and may cause injury or death if ignored.

WARNING: Important safety information, and may cause serious injury if ignored.

CAUTION: Information aimed to prevent damage to the product.

NOTE: Information to which special attention must be paid.

⚠ NOTE: Important safety information is indicated in this manual. Please pay special attention to all safety information.

ODANGER-Fire is strictly prohibited.

NOTE: Please keep this Manual properly.

⚠WARNING: In some cases, oxygen therapy can be dangerous. Consult your physician before using an oxygen concentrator.

Symbols and Definitions

| Symbols | Definitions | Symbols | Definitions |
|-------------|--|----------|--------------------|
| \triangle | NOTE! Check the accompanying document. | | Class II equipment |
| ~ | AC | ^ | Type BF equipment |
| ® | Fire is strictly prohibited. | | Up |
| | No rain | | Fragile |
| I | On | 0 | Off |

Overview

This Manual helps you to get familiar with how to use the oxygen concentrator. Please make sure that you have read and understood this User's Manual before using the oxygen concentrator. Important safety and maintenance information is indicated in the instructions. Please pay special attention to all safety information. If your oxygen concentrator is in fault, please contact a dealer authorized.

⚠ Danger: Oxygen can aid combustion. Do not smoke when the oxygen concentrator is turned on or near someone who is working on it.

Do not use if there is any object with high temperature, sparks and open flames within 1.6 m.

• Reason for a Physician to Choose Oxygen Therapy

Nowadays, many people suffer from heart, lung and other respiratory diseases. Your body needs a steady supply of oxygen to keep certain organs' function. Your physician may ask you to supplement oxygen because you cannot get enough oxygen from the indoor air. Supplementing oxygen can increase the total amount of intaking oxygen in your body.

Scope of Application

It is designed for oxygen making and oxygen therapy for patients with hypoxia at medical institutions and families.

• Principle for Oxygen Concentrating

This machine is driven by \sim 220 V 50Hz power. By using air as the raw material and a high-quality molecular sieve, it produces high-purity oxygen conforming to medical oxygen standard by pressure swing adsorption (PSA method) at normal temperatures.

• Contraindications, Precautions, Warnings, and Instructions

MWARNING

- > Do not unplug the oxygen concentrator when the power switch is not turned off.
- > Do not use the oxygen concentrator while bathing.
- > Do not place or store the oxygen concentrator next to a bathtub or sink.
- > Do not touch the oxygen concentrator after it falls into water or liquid, and immediately unplug the power. Do not use the oxygen concentrator again after it falls into water or liquid, and notify a dealer authorized.
- > Do not place or store the oxygen concentrator in a kitchen or bathroom.
- ➤ The oxygen concentrator should be placed away from pollution and smoke.

- > The air inlet of the oxygen concentrator should be located in a well-ventilated place.
- ➤ It takes 5 minutes for the oxygen concentrator to start to reach the specified performance.
- > The oxygen concentrator should not be lubricated with oil, grease or other lubricants.
- > The performance of oxygen concentrator may be affected if any non-specified wetting bottles or drug administration accessories are used.
- > The humidification bottle of oxygen concentrator shall be mounted at the optimal position for the drug administration accessories. It shall be directly mounted at the outlet of the oxygen concentrator.

⚠ NOTES:

- > It is recommended to assign a person to maintain the oxygen concentrator when using it.
- > Do not block the air inlet and outlet of the oxygen concentrator.
- Do not disassemble the oxygen concentrator to prevent electric shock. If the oxygen concentrator is in fault, please contact a dealer authorized timely.
- ➤ When the oxygen concentrator is not in use, please unplug the oxygen concentrator from the power socket.

Main Structure

The oxygen concentrator is composed of a mainframe, a flow controller, a humidification bottle and an oxygen concentration status indicator.

• Important Spare parts of Oxygen Concentrator

⚠NOTE: Please get familiar with the oxygen concentrator before using it.

| 1 | Power switch | 2 | Oxygen outlet | 3 | Nebulizing port | 4 | Humidification bottle |
|----|---|----|--|----|------------------------------------|----|-----------------------------|
| 5 | Air filter cotton cover | 6 | Power cord | 7 | Overload protector | 8 | Caster |
| 9 | Power indicator light | 10 | Normal working indicator | 11 | Low oxygen concentration indicator | 12 | Maintenance indicator |
| 13 | Reminder indicator for filter replacement | 14 | Timing + | 15 | Timing - | 16 | ON / OFF Button |
| 17 | Voice on and off | 18 | Nebulizing/oxygen concentrating switching button | 19 | Nebulizing indicator | 20 | Flow regulating valve |
| 21 | Oxygen concentration indicator | 22 | Timing display | 23 | Cumulative time display | 24 | Flow display |

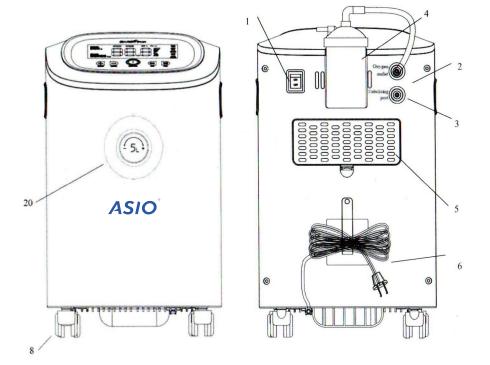
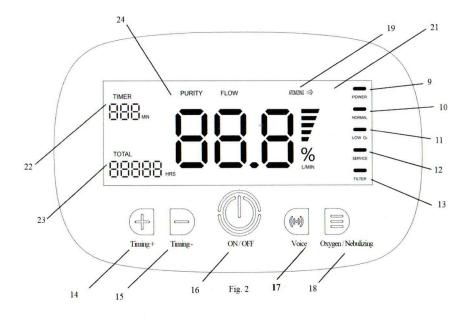
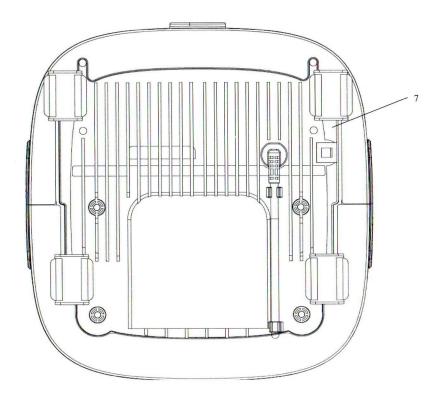


Fig. 1





• Installation of Oxygen Concentrator

- I. Put the oxygen concentrator in the place where you spend the longest time and near the socket. It can be the living room, study, bedroom, etc. But please do not place or store it in the kitchen or bathroom.
- DANGER: Do not put the oxygen concentrator at a place if there is any object with high temperature, sparks and open flames within 1.6 m.
 - NOTE: Do not connect it to a wall outlet controlled by a switch. Do not have other appliances plugged into the same wall outlet.
- II. Place the oxygen concentrator at least 50 cm away from the wall, fabric or other objects. This will ensure that a proper flow of air enters and leaves the oxygen concentrator. The oxygen concentrator should be kept away from pollutants, smoke, and humidity.
- III. It is recommended to use a nasal oxygen tube longer than 2 meters.

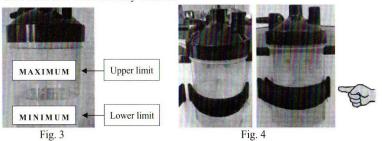
Preparation before Operating the Oxygen Concentrator

- I. Please check whether the air filter cotton (in the air filter cover of the oxygen concentrator) is clean before using the oxygen concentrator every time. Please clean the air filter cotton every week when the oxygen concentrator runs. It is recommended to shorten the cleaning time appropriately. How to properly clean the air filter cotton is discussed on Page 12 of this Manual.
- II. Please install the oxygen concentrator accessories following the steps below.

1. Connection of humidification bottle (model: SH-2):

Install the oxygen humidification bottle as follows:

- a) Add purified water (or distilled water) to the upper and lower limits of the humidification bottle (Fig. 3), and tighten the bottle cap.
- b) Put the humidifier on the humidifier connection base of this product and tie up the magic stick (Fig. 4). Please make sure that it is firmly installed.



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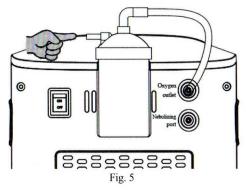
NOTE: The amount of water added to the humidification bottle is between the maximum and minimum water level marks.

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Note: If you need to replace the humidification bottle, please contact a distributor authorized for purchasing and replacing.

2. Nasal oxygen tube connection:

Connect the nasal oxygen tube to the oxygen outlet (Fig. 5).



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Note: The nasal oxygen tube and nebulizing device adopt 5-7 mm tubaeform interface.

- ⚠ It
 - It is recommended to use a nasal oxygen tube and nebulizing device with a medical device registration certificate.
- III. Take out the power cord completely from the strap, make sure that the "power switch" is off (Fig. 6), and then insert the plug into the wall outlet (Fig. 7).

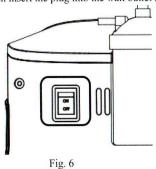




Fig. 7

MARNING: Improper power cords and plugs may cause burns, fire, or other electric shock hazards. Do not use an oxygen concentrator with a damaged power cord.

• Operation Instructions

Danger: Oxygen can aid combustion. Do not smoke when the oxygen concentrator is turned on or near someone who is working on it.Do not use the oxygen concentrator if there is any object with high temperature, sparks and open flames within 1.6 m.

I. Turn the "power switch" to the On (]) position (Fig. 8), and then the power indicator will light up; after pressing the "ON / OFF" button on the panel (Fig. 9) once more, the oxygen concentrator will start and the normal operation indicator will light up.

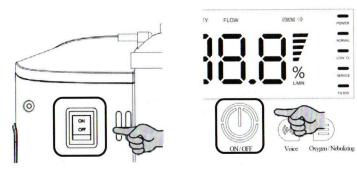


Fig. 8

Fig. 9

- If the oxygen concentrator does not operate normally, please refer to "Identifying and Removing Failures" on Page 13 of this Manual. If necessary, please contact a dealer authorized.
- II. Check the displayed flow (Fig. 10). If it is not the desired flow, you can press the flow + or keys to get the required oxygen flow (The maximum flow recommended by P3W is 3 L/min., and that recommended by P5W is 5 L/min.)

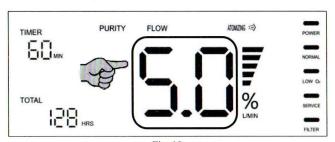


Fig. 10

⚠NOTE: Please adjust the oxygen flow following the doctor's advice.

III. In order to ensure the oxygen concentration and oxygen flow, this oxygen concentrator will undergo quality inspection before delivery. As long as the cumulative time displayed (Fig. 11) is less than 10 hours, it is a normal new machine.

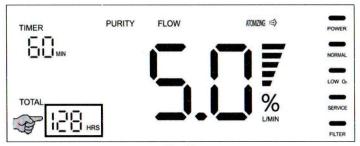


Fig. 11

IV. When the machine is in the running or standby state, press the "Timing +" or "Timing -" button on the panel (Fig. 12) to make the machine in timing status (Fig. 13). Each time you press the "Timing +" button, the timing time increases by 10 minutes; each time you press the "timing-" button, the timing time reduces by 10 minutes. The maximum set time is 240 minutes. After the set time is over, the machine enters the standby state. Press "ON / OFF" on the panel to restart it.

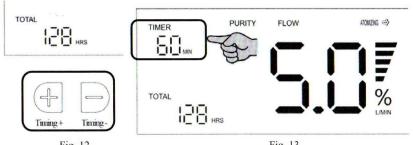


Fig. 12 Fig. 13

Remarks: If there is no operation for more than 10 minutes, the digital display will automatically reduce the brightness. Touch any button again to restore the normal brightness.

V. When the machine is running, press the "ON / OFF" button on the panel (Fig. 14). After that, the whole machine will enter the standby state and the display screen will be off.



Fig. 14

VI. When the oxygen concentrator is not in use, please turn off the "power switch" (The power switch is in O state) (Fig. 15) and unplug the power from the socket.

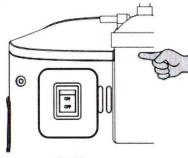


Fig. 15

Alarm

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WARNING: When the oxygen concentration status indicator indicates an abnormal oxygen concentration, please contact a dealer authorized .

I. Alarm classification:

The oxygen concentrator is designed with audible and visual alarm functions, which can alert you to situations that require your attention.

1. There are two levels of alarms: high-level and medium-level.

High-level alarms indicate the most dangerous conditions for critically ill patients and are the most serious warnings.

Medium-level alarms are serious warnings.

The alarm characteristics are shown in Table 1 below.

2. Priority level of alarms: high-level alarm> medium-level alarm, that is, when two levels of alarms exist at the same time, the alarm signal is the sound of high-level alarm.

II. Audible alarm indication:

When an alarm is detected, the oxygen concentrator will make a "drip" alarm sound (The sound pressure range is 60dB (A) \sim 120dB (A)). Different levels of audible alarms are of different sound frequencies.

- 1. High-level alarm: Pause after the "Drip-Drip-Drip ----- Drip-Drip" sound. It will sound 5 seconds later.
 - 2. Medium-level alarm: Pause after the "Drip-Drip-Drip" sound. It will sound 10 seconds later.
- 3. Priority level of alarms: high-level alarm> medium-level alarm, that is, when two levels of alarms exist at the same time, the alarm signal is a high-level alarm indicator.

III. Visual alarm indication:

When an alarm event occurs, the alarm indicator will light up.

Table 1 Alarm characteristics

| Alarm classification | Indicator light color | Flashing frequency | Duty ratio |
|-----------------------|-----------------------|-----------------------|------------|
| High-level alarm | Red | 1.4Hz∼2.8Hz | 20%~60% |
| Medium-level alarm | Yellow | 0.4Hz~0.8Hz | 20%~60% |

Priority level of alarms: high-level alarm> medium-level alarm, that is, when two levels of alarms exist at the same time, the alarm signal is a high-level alarm indicator.

IV. Measures to be taken when an alarm occurs:

- 1. Identify the status represented by the alarming signal
- 2. Exam the patient's condition
- 3. Identify the cause of the alarm
- 4. Take corresponding measures

V. Definition of alarm:

| No. | Alarm | Level | Audible alarm | Visual alarm | Alarm status | Rem ark |
|-----|---|------------------|--|-----------------|---------------------------|------------|
| E1 | The oxygen concentration is lower than 73% five minutes after the oxygen concentrator is turned on. | High-leve | Pause after the "Drip-Drip-Drip- Drip-Drip" sound. It will sound 5 seconds later. | Red light | Technical alarm status | |
| E2 | The oxygen concentration is higher than 73% but lower than 82% five minutes after the oxygen concentrator is turned on. | Medium-l evel | Pause after the "Drip-Drip-Drip- Drip-Drip" sound. It will sound 10 seconds later. | Yellow light | Technical alarm status | |
| E3 | The system pressure is greater than 250 KPa. | Medium-l evel | Pause after the "Drip-Drip-Drip Drip-Drip" sound. It will sound 10 seconds later. | Yellow light | Technical alarm status | |
| E4 | The system pressure is lower than 40 KPa. | Medium-l evel | Pause after the "Drip-Drip-Drip Drip-Drip" sound. It will sound 10 seconds later. | Yellow light | Technical alarm status | |
| E5 | Oxygen sensor and control board communication failure | High-leve | Pause after the "Drip-Drip-Drip- Drip-Drip" sound. It will sound 5 seconds later. | Red light | Technical alarm status | |
| E6 | The oxygen flow rate is lower than 0.5L/min during oxygen generation | Medium-l evel | Pause after the "Drip-Drip-Drip- Drip-Drip" sound. It will sound 10 seconds later. | Yellow light | Technical alarm status | |
| | When the machine is running, the power is off | High-leve 1 | Pause after the "Drip-Drip-Drip- Drip-Drip" sound. It will sound 5 seconds later. | Red light | Technical alarm status | |

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WARNING: Please do not change the alarm preset of the oxygen concentrator; do not change the memory contents of the oxygen concentrator MCU.

Repairing and Maintenance of Oxygen Concentrator

MARNING: Please cut off the power of oxygen concentrator before cleaning.

I. Cleaning of oxygen humidification bottle

Please clean the humidification bottle every day.

Cleaning steps: Clean it with cold boiled water and then dry with a towel.

II. Catheters, masks and nasal tubes:

Catheters, masks, and nasal tubes are disposable. Please replace them regularly. The cleaning, disinfection and sterilization methods are shown on the packaging or User's Manual.

III. Air filter cotton:

Clean the air filter cotton once per every week. Clean following the steps below:

- 1. Remove the air filter cotton (Fig. 16)
- 2. Rinse thoroughly with cold boiled water and dry naturally. Filter cotton must be fully dried before the next use.

A

Caution: To prevent damage to the oxygen concentrator, do not attempt to operate the oxygen concentrator when there is no air filter or when the filter is dry.

IV. Air intake filter:

The air intake filter needs to be replaced every 1000 hours of operation. If the environment is harsh and there are many hazes, it is recommended to shorten the replacement time appropriately. If you need to replace the new air intake filter, please purchase from a dealer authorized. Please follow the steps below:

- 1. Remove the used air intake filter (Fig. 16).
- 2. Install the new air intake filter and cover up the air filter cotton.

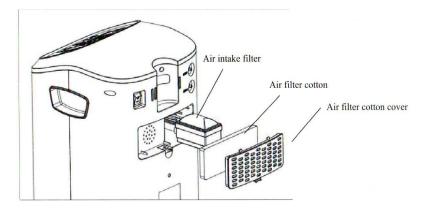


Fig. 16

Remarks: After the filter usage time expires, the filter indicator will be on. After replacing the filter, press and hold the voice and nebulizing buttons for about 3 seconds simultaneously. The filter indicator will be off, and the filter usage time is restored to 1000 hours.

V. Housing:

The housing is to be cleaned at least once a month. Please cut off the power before cleaning. Wipe with a clean, soft, damp cotton cloth or sponge. Do not allow liquid to penetrate the gaps in the case.



WARNING: To avoid electric shock, do not open the housing. The housing can only be opened by a service engineer authorized .

VI. Accessories:

The accessories of the oxygen concentrator are as follows:

- 1. Humidification bottle
- 2. Mask and catheter (Mask and catheter are not included. It is recommended to use masks and catheters with a medical device registration certificate).
- 3. Nasal oxygen tube (Nasal oxygen tube is not included. It is recommended to use a nasal oxygen tube with a medical device registration certificate).

The oxygen concentrator is equipped with an oxygen output alarm device. When the oxygen concentrator is turned on, the four indicators (power, normal, low concentration and maintenance) on the panel will temporarily light up. After a few seconds, only the power indicator and normal indicator will continue to work.

VII. Description of panel light is as follows:

- 1. Power indicator (green)-When it is on, it indicates that the equipment starts running;
- 2. Normal operation indicator (green)-When it is on, it indicates that the equipment is running normally:
- 3. Low concentration indicator (yellow)-When it is on, it indicates that the oxygen output concentration of your equipment is low, or the oxygen system pressure is abnormal;
- 4. Service indicator (red)-When it is on, it indicates that your equipment needs maintenance. Please contact a dealer authorized.

If the oxygen concentration is lower than the acceptable level, the green normal operation indicator will turn off and the yellow abnormal indicator will turn on. At this time, please switch to your backup oxygen source. Please refer to "Identifying and Removing Failures" on Page 13 of this Manual. If necessary, please contact a dealer authorized .



Note: The oxygen generator does not need lubrication. Please do not apply any lubricant on the product.

• Identifying and Removing Failures

The following "Checklist of Identifying and Removing Failures" will help you to conduct analysis. If the suggested steps do not help troubleshooting, please switch to the backup oxygen source and contact a dealer authorized.

Checklist of Identifying and Removing Failures

| Checkist of Identifying and Removing Fandres | | | | | |
|--|---|--|--|--|--|
| Failure performance | Possible cause | Troubleshooting | | | |
| A. When the "power switch" is turned on and the "ON / | 1. The power cord is not plugged into a power socket properly. | Check the connection between the power cord and power socket. The power system should be consistent with the specification indicated on the nameplate. | | | |
| OFF" button is pressed, the oxygen concentrator does not run, the power indicator light is not on, | 2. The power socket is not powered. | Check the circuit breaker at home and restart if necessary. If the same problem reoccurs, use another socket. If it still does not work after the above steps, please contact your dealer. | | | |
| the alarm sounds and the maintenance light flashes. | 3. The "overload protector" of the oxygen concentrator is disconnected. | 3. Press the "overload protector" of the oxygen concentrator. The "overload protector" is next to the power cord. If the same problem reoccurs, use another socket. If it still does not work after the above steps, please contact your dealer. | | | |
| | The air filter cotton is blocked. | Check the air filter cotton. If it is dirty, clean it according to the instructions on Page 13. | | | |
| B. When the switch is turned on, the oxygen concentrator will run, the power indicator will be | 2. The exhausting device is blocked. | Check the exhaust port and make sure that nothing is blocked at the exhaust port of the oxygen concentrator. | | | |
| on, the red maintenance indicator will be on and the alarm sound may be | 3. The air intake filter is blocked. | Check the air inlet filter. If it is dirty, replace it according to the instructions on Page 13. | | | |
| heard. | 4. The nasal oxygen tube or mask is blocked. | Disconnect the nasal oxygen tube from the oxygen outlet If the flow increases, check whether the nasal oxygen tube is blocked. Please replace the nasal oxygen tube or mask i necessary. | | | |
| C. When the switch is turned on, the oxygen concentrator will run, the power indicator light will be on and the low-frequency vibration sounds can be heard. | The solenoid valve does not work normally. | Immediately switch off the oxygen concentrator, switch to the backup oxygen source, and contact your dealer. | | | |

If it still does not work after the above steps, please contact a dealer authorized

If the fuse is damaged, please contact a professional technician to disassemble the case back cover and replace the fuse.

Our company will provide the circuit diagram, component list, diagram notes, etc. to the qualified technical personnel of the user as requested.

If the alarm system does not work, please contact an dealer authorized.

Specifications and Parameters

I. Basic parameters

| Model | Oxygen produced (L/min) | Oxygen concentrati on (V/V) | Nebulizing rate (ml/min) | Maximum outlet pressure (kpa) | Nebulizi ng function | Input power (VA) |
|--------|-------------------------------|-----------------------------------|--------------------------------|--|----------------------------|------------------------|
| CR-P3W | 3 | 93%±3% | ≥0.15 | 20 | Available | 300 |
| CR-P5W | 5 | 93%±3% | ≥0.15 | 20 | Available | 450 |

- II. Under the nominal recommended flow, the oxygen concentration in the product gas is 93%±3% (V/V); when a back pressure of 7kPa is applied, the maximum recommended flow rate should change within ±10%.
- III. There is a pressure release device in the humidification bottle. The pressure release value is 20±2kpa.
- IV. Normal operating conditions:
 - 1. Ambient temperature: 5°C~40°C
 - 2. Relative humidity: ≤80%
 - 3. Air pressure range: 86 kPa~106 kPa
 - 4. Power: AC220V/50Hz
- V. Oxygen concentration: 93%±3% (V/V)
- VI. The noise of oxygen concentrator should be ≤60dB (A) during normal operation.
- VII. Alarm for abnormal oxygen concentration: The oxygen concentration is lower than 82% five minutes after the oxygen concentrator is turned on, with an error of $\pm 3\%$.
- VIII. Alarm sound:> 60dB (A)
- IX. Temperature rise of oxygen concentrator: Under normal working conditions, the maximum temperature of the plastic housing is \leq 60°C, and the gas temperature at the oxygen outlet of the oxygen concentrator is \leq 46°C.
- X. Nebulizing characteristics: The working pressure should be within the range of 30 kPa \sim 180 kPa, the gas flow should be \geq 5L/min, the residual liquid volume should be \leq 1mL, and the nebulizing rate should be \geq 0.15 mL/min.

After-sales Services

I. Scope of warranty:

The following consumables: The air intake filter, air filter cotton, humidification bottle, accompanying materials and other consumables are not covered by the warranty.

- II. Non-warranty coverage:
 - 1. Damage to the product caused by incorrect use;
 - 2. Damage caused by unauthorized removal or modification of any part of this product;

- 3. Fail to use the product in accordance with the precautions in the Manual;
- Damage to the product caused by abnormal voltage or accidents (such as fire, flood, etc.) caused by any other force majeure factors;
- 5. No warranty certificate or altered warranty certificate;
- 6. The product has expired the warranty period.
- III. Warranty time: The warranty period of the whole machine is one year from the purchasing date. The service is to be charged if the damage is caused by failure of following the normal operation or exceeding the warranty period. If any maintenance or repair is required, please contact the dealer of the purchased product. Please present the warranty certificate when repairing. If a charge is required, the service staff will explain the composition of the charge and carry out charged repair upon your consent.
- IV. In order to avoid accidental loss, please repair the oxygen concentrator at the dealer or service point authorized.

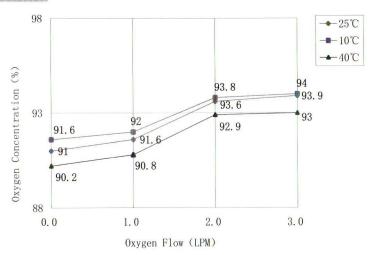
• Environmental Protection

The disposal of wastes and residues shall comply with the relevant national laws and regulations.

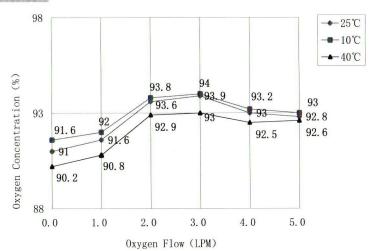
• Graph of Oxygen Concentration Value and Fow Function

Graph of Oxygen Concentration Value and Fow Function when the nominal pressure at the outlet is zero

Model: CR-P3W



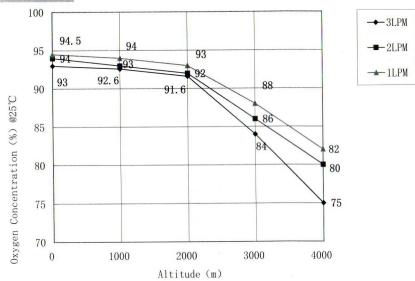
Model: CR-P5W



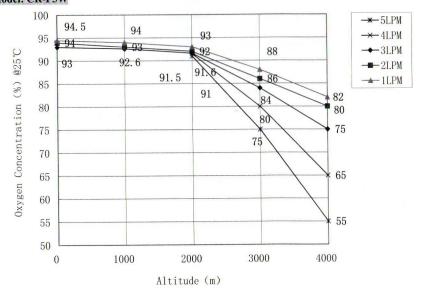
• Change of Oxygen Concentration with Flow under Different Pressure

Conditions in the Altitude Range of 0-4000m

Model: CR-P3W



Model: CR-P5W



• Electromagnetic Compatibility (EMC)

Notes:

- ➤ The oxygen concentrator complies with relevant requirements of YY0505 standard Electromagnetic Compatibility.
- Users should install and use the equipment according to the EMC information in the accompanying document.
- Portable and mobile RF communication devices may affect the performance of oxygen concentrator. Avoid strong electromagnetic interference during operation, such as getting close to mobile phones, microwave ovens, etc.;
- > See the detailed information of guidelines and manufacturer's statement in the appendix.

WARNING:

- ➤ The oxygen concentrator should not be placed close or stacked up to other equipment. If it is inevitable to do so, it should be observed and verified that it can operate normally under the existing configuration.
- In addition to the cables sold by the manufacturer of oxygen concentrator as spare parts of internal components, the use of accessories and cables other than those specified may lead to an increase in emission or a decrease in immunity of oxygen concentrator;

Appendix:

Guidelines and Manufacturer's Statement-Electromagnetic Emission

The oxygen concentrator is expected to be used in the following specified electromagnetic environments. The purchaser or user shall ensure that it is used in such an electromagnetic environment:

| Emission test | Compliance | Electromagnetic Environment - Guidelines |
|--|------------|---|
| RF emission GB4824 | 1 group | The oxygen concentrator only consumes RF energy to enable its internal functions. Therefore, it only generates slight amount of radio frequency emission, and has little chance to cause interference to nearby electronic equipment. |
| RF emission GB4824 | Class B | |
| Harmonic emission GB 17625.1 | Class A | The oxygen concentrator are suitable for use in all installations, including domestic installations and public low-voltage power supply networks directly connected |
| Voltage fluctuation/scintillation emission | Conforming | to domestic dwellings |

| 0 | D | 7 | 62 | 5 | | |
|-----|----------|-----|-----|----|-----|--|
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Guidelines and Manufacturer's Statement-Electromagnetic Immunity

The oxygen concentrator is expected to be used in the following specified electromagnetic environments. The purchaser or user shall ensure that it is used in such an electromagnetic environment:

| Immunity test | IEC 60601 Test Level | Coincidence level | Electromagnetic Environment - Guidelines |
|---|--|--|--|
| ESD GB/T 17626.2 | ±6 kV Contact discharge ±8 kV Air discharge | ±6 kV Contact discharge ±8 kV Air discharge | The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%. |
| EFT GB/T 17626.4 | ±2kV For power cord ±1kV For input/output cable | ±2kV For power cord NA | Network power supply should be of high quality for using in typical commercial or hospital environments |
| Surge GB/T 17626.5 | ±1 kV line to line ±2 kV line to ground | ±1 kV line to line NA | Network power supply should be of high quality for using in typical commercial or hospital environments |
| Voltage sags, short-term interruptions and voltage variations on power input lines GB/T 17626.11 | <5 % $U_{\rm T}$, last for 0.5 cycle (Above UT, >95% voltage sag) 40 % $U_{\rm T}$, last for 5 cycles (Above $U_{\rm T}$, 60% voltage sag) 70% $U_{\rm T}$, last for 25 cycles (Above $U_{\rm T}$, 30% voltage sag) 5% $U_{\rm T}$, last for 5s (Above UT, >95% voltage sag) | <5 % $U_{\rm T}$, last for 0.5 cycle (Above UT, >95% voltage sag) 40 % $U_{\rm T}$, last for 5 cycles (Above $U_{\rm T}$, 60% voltage sag) 70% $U_{\rm T}$, last for 25 cycles (Above $U_{\rm T}$, 30% voltage sag) 5% $U_{\rm T}$, last for 5s (Above UT, >95% voltage sag) | Network power supply should be of high quality for using in typical commercial or hospital environments It continuous operation of oxygen concentrator during power interruption is requested by the user uninterrupted power supply of battery is recommended. |
| Power frequency magnetic field (50/60Hz) GB/T 17626.8 | 3A/m | 3A/m, 50Hz | The power frequency magnetic field should have horizontal characteristics of power frequency magnetic field in typical commercial of hospital environments. |

Guidelines and Manufacturer's Statement-Electromagnetic Immunity

The oxygen concentrator is expected to be used in the following specified electromagnetic environments.

The purchaser or user shall ensure that it is used in such an electromagnetic environment.

| Immunity test | IEC 60601 Test Level | Coincidence level | Electromagnetic Environment - Guidelines |
|---|---|----------------------------|---|
| Radiofrequency conduction GB/T 17626.6 Radiofrequency radiation GB/T 17626.3 | 3V (effective value) 150 kHz~80 MHz 3V/m 80 MHz~ 2.5 GHz | 3V (effective value) | Portable and mobile RF communication devices should not be used closer to any part of the oxygen concentrator, including cables, than the recommended isolation distance. The distance should be calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance d = 1.2√P d = 1.2√P 80 MHz~800 MHz d = 2.3√P 800 MHz~2.5 GHz Where: P—According to the maximum rated output power of the transmitter provided by the transmitter manufacturer (unit: Watt (W)); d—Recommended isolation distance (unit: m). The field strength of fixed RF transmitter is determined by survey of electromagnetic field a. In each frequency range b should be lower than coincidence level. Disturbance may occur near the equipment marked with the following symbols. (((**))) |

Note 1: The formula of higher frequency band is used on 80 MHz and 800MHz frequency.

Note 2: These guidelines may not apply to all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human body.

a The field strength of fixed transmitter, such as base station of wireless (cellular/cordless) telephone and ground mobile radio, amateur radio, AM and FM radio and TV broadcasting, cannot be accurately predicted in theory. To evaluate the electromagnetic environment of fixed radio frequency transmitter, the survey of electromagnetic field should be considered. If the measured field strength of oxygen concentrator is higher than the above radio frequency coincidence level, oxygen concentrator should be observed to verify whether it can run normally. If any abnormal performance is observed, supplement measures may be necessary, such as readjusting the direction or position of oxygen concentrator.

b In the whole frequency range from 150 kHz to 80 MHz, the field strength should be less than 3V/m.

Recommended isolation distance between portable and mobile RF communication equipment and oxygen concentrator

Oxygen concentrator is expected to be used in electromagnetic environment with radio frequency radiation disturbance. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) as recommended below.

| Rated maximum | Isolation distance/m corresponding to different transmitter frequencies | | | | | |
|-------------------------------------|---|---|---|--|--|--|
| output power of transmitter W | $150 \text{ kHz} \sim 80 \text{ MHz}$ $d = 1.2 \sqrt{P}$ | 80 MHz \sim 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz \sim 2.5 GHz $d = 2.3\sqrt{P}$ | | | |
| 0.01 | 0.12 | 0.12 | 0.23 | | | |
| 0.1 | 0.38 | 0.38 | 0.73 | | | |
| 1 | 1.2 | 1.2 | 2.3 | | | |
| 10 | 3.8 | 3.8 | 7.3 | | | |
| 100 | 12 | 12 | 23 | | | |

For the rated maximum output power of the transmitter not listed in the table above, isolation distance d is recommended (unit: meter (m)) which can be determined by the formula in the corresponding transmitter frequency bar. Where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer (unit: watts (W)).

NOTE 1: The formula of higher frequency band is used on 80 MHz and 800MHz frequency.

NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human body. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human body.

• Supplementary Instruction

- 1. Classified by anti-shock type: Class II
- 2. Classified by anti-shock type: Class BF application
- 3. Classified by protection degree to liquid inlet: conventional device
- 4. Classified by the safety degree when using the instrument with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: non-AP/APG
- 5. Classified by operating mode: Continuous operation
- 6. No signal output and signal input part
- 7. Power supply: AC220V/50Hz
- 8. Working system: continuous operation
- 9. The oxygen concentrator has no application part that protects against defibrillation discharge effects.
- 10. The oxygen concentrator is a permanent installation device.

• Storage and Transportation Conditions

Ambient temperature range for storage: -20°C \sim +50°C;

Relative humidity range: <93%RH (no condensation)

Air pressure range: 50 kPa~106 kPa;

This equipment should be placed in a cool, dry and well ventilated place without humidity corrosion

and corrosive gas. Do not expose it to open weather.

Service Life

Production date: See the label.

Service life: 5 years (under the use, repair and maintenance conditions recommended by the

manufacturer)

Packing List

| No. | Description | Qty |
|-----|--|-------|
| 1 | Oxygen concentrator | 1 set |
| 2 | Nasal oxygen tube (commissioning gift) | 1 pc |
| 3 | Nebulizing cup (commissioning gift) | 1 set |
| 4 | Air filter cotton | 1 pc |
| 5 | User's Manual | 1 |
| 6 | IR remote control | 1 |