# OXYGEN CONCENTRATOR

(Models: CP502)

FOSHAN MIC MEDICAL TECHNOLOGY CO., LTD

User Manual

(Version: V1. 0)

## Contents

**Foreword**

Dear user:

Thank you for your support！Hope you can be our satisfied user.

This manual introduces the notices, operation steps, basic functions, technical parameters, basic troubleshooting, return repair instructions and other content, so that you will be more familiar with the product and operate it much clear and correctly.

In order to take the most effective use of this machine, please read the instructions of this manual carefully. Before operating the machine, please make sure that you have read and understood the basic operation of this product. Please pay special attention to “SAFETY GUIDE”.

The humidification bottle, oxygen tubes, oxygen masks, filters and other random components mentioned in this manual should be selected in accordance with the requirements of product specifications.

If you have any problems for the usage, please do not hesitate to contact the after-sale service of the manufacturer.

## 1. SAFETY GUIDE

Please read the entire instruction manual before using OXYGEN CONCENTRATOR. It will give you a better understanding of how the product works. If you are unsure whether a medical condition should preclude you from using the device, consult your medical practitioner.

### 1.1 Warnings

 There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.

 Do not modify the machine in any way or the warranty will be compromised.

 To ensure that the therapeutic amount of oxygen deliver to the user according to the user's medical condition, [FOSHAN MIC MEDICAL TECHNOLOGY CO., LTD] must

- be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.

- be used with the specific combination of parts and accessories that are in line with the specification of the manufacturer as well as being used while your settings were completed.

 Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns.

 Do not lubricate fittings, connections, tubing or other accessories of the oxygen concentrator to avoid the risk of fire and burns.

 Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.

 Use of this device at an altitude above over 2000 meters or outside a temperature of 5~40℃ or a relative humidity above 80% is expected to adversely affect the flowrate and the percentage of oxygen and consequently the quality of the therapy.

 Oxygen makes it easier for fire to start and spread.

 Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the oxygen concentrator is turned on but not in use; the oxygen will make these materials flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.

 If you feel discomfort or are experiencing a medical emergency while undergoing oxygentherapy, seek medical assistance immediately to avoid harm.

 Geriatric, paediatric or any other patient who are unable to express discomfort require an additional monitoring or a distributed alarm system to convey the information about discomfort or medical urgency to the responsible care giver to avoid harm.

 Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the oxygen concentrator or any oxygen-carrying accessories are located.

 If you intend to smoke, you must always turn the oxygen concentrator off, remove the cannula and mask, then leave the room where the oxygen concentrator is located. If unable to leave the room, you should smoke at least 10 minutes later after you have turned the oxygen concentrator off.

 Open flame is dangerous to the oxygen therapy and is likely to result in fire or death. Do not allow open flame close within 2 m of the oxygen concentrator or any oxygen-carrying accessories.

 The inappropriate use of power line and a plug may cause fire or other dangerous electric shock, burn. Do not use the machine with broken power line.

 The power plug must be pull out before cleaning the machine dust in the shell to prevent electric shock.

 When the machine is working, please do not open the machine shell and internal box to prevent the damage caused by mechanical touch operation.

 In order to prevent power outage or fail to deliver oxygen, please always prepare oxygen supply device (such as oxygen bottles, oxygen bag etc.) for emergent situation (such as the urgent need for oxygen and severe patients).

 Do not let people use the same set of nasal oxygen tube or oxygen mask to avoid cross infection between users due to viruses or bacteria.

### 1.2 Precautions

 This product cannot be used for life-support, the patients with aerobic treatment are suggested to follow up your doctor's guidance to choose the oxygen flow and time when using this machine.

 If any discomfort or abnormal reaction arise, please immediately stop using this product, and contact the manufacturer or doctor.

 The seriously ill patients need to collocate with an additional indication equipment or additional medical coordination when they use this product. Please consult a doctor before use. If you have any adverse reactions, please inform your doctor immediately.

 We should use the humidification bottle meets the specification. Do not replace it arbitrarily, otherwise it may cause consequence of discomfort or failure of oxygen inhalation.

 The nasal oxygen tube should not be placed under the coverlet or cushion when use the machine, and other pressure should not be added to the tube in order to make sure the machine operates successfully and effectively.

 When the machine is out of using condition, it is recommended to turn off the power switch and unplug to avoid burning.

 Power switch is provided as a mean of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles. In the use of this product, pay attention to whether the power line is too long for obstruct other walking so advice to use the closest power socket.

 This product cannot be equipped with the non-specified humidification bottle or dosing accessories, so as not to affect the performance of the product.

 Do not open the machine shell and the internal box for maintenance. If users find any problems or abnormal alarm, do not disassemble or repair by yourselves, you should contact the dealer or manufacturer immediately.

 It should be placed on a clean, free of dust, non-corrosive and non-poisonous environment. Do not use this product in environments with strong magnetic fields.

 The air entrance of the machine should be well ventilated, the air source inlet including exhaust system, air vents and other anesthesia vacuum exhaust port should not be placed any pollutants like burning gas.

 To ensure good exhaust performance at the bottom of the machine during use, the back of the machine does not stick to the wall but leaves at least 30 cm away from it, otherwise it will cause damage to the machine because of overheating.

 This machine should not be frequently started and shut down, the time interval of start and shut down should not less than 5 minutes, so as not to affect the service life of the compressor. The manufacturers recommend each operation interval should be over 30 minutes.

 The machine is only used as a medical oxygen supply, the output of the gas in the rated flow, the purity can up to 90%.

 Rotary flow control knob cannot be forced too hard, or it may damage the spool. When the flow control knob is turned on to the highest mode, but the flow indicator shows zero, please turn off the power and then check the fault.

 When receive the products to operate and test, cut off the tie on the bottom of the machine otherwise it will cause damage to the machine.

 Be aware that the power cord and/or tubing could present a tripping or strangulation hazard. Always place the power cord and/or tubing in a manner that prevents crushing by casters or others.

 Please pay attention to prevent chocking resulting from swallowing of the small parts. Close supervision is necessary when the oxygen concentrator is used near children or physically challenged individuals.

 Be aware that degraded sensors might degrade performance of the machine.

### 1.3 Notice

 If the performance of the concentrator is changed, contact technical support to qualified service personnel.

 The purity of oxygen will be up to 90% after boot for 2 mins.

 The Air intake filtering foam need to be cleaned every 100 hours. The Air filter is recommended to replace after 1000 hours of machine use. If there is large dust or soot in the use environment, please increase the time interval of cleaning or replacement of the parts mentioned above. In order to ensure the use effect, it is recommended to replace the parts as soon as possible.

 The water added to the humidified bottle must be distilled water or cold water, the untreated tap water should not be added to the bottle directly. The water bottle should be cleaned every 2~3 days on summer, it is recommended daily replacement, if you plan to not use this product for the next few days after using it, please drain the humidification bottle and dry it completely.

 Select the nasal oxygen tube and oxygen mask meet the specification. If change different one, ask the professional or the manufacturer first.

 Do not throw the humidification bottle, nasal oxygen tube and mask at any place. The nearby waste disposal mechanism is the best choice.

 Please select the suitable humidification bottle, rotate and fix in the machine as required. Do not use under the revolving situation. (Refer to the humidified bottle connection indicator diagram).

 When use the humidification bottle, pay attention to add water but not above the highest and not below the lowest water level marked on the bottle body.

 When this machine is scrapped, please contact your local supplier or manufacturer.

 When using in home environment, users should contact the manufacturer if need assistance in setting up, using or maintaining the machine, or report unexpected operations or events.

 The patient is an intended operator.

### 1.4 Contraindications

 Oxygen poisoning and oxygen allergy sufferers are prohibited.

### 1.5 Adverse Reactions

 N/A

### 1.6 Special Population

 Oxygen poisoning and oxygen allergy sufferers.

### 1.7 Intended Use/Indications for Use

 The OXYGEN CONCENTRATOR is intended to provide supplemental oxygen in a home, institutional, or travel environment.

## 2. DEVICE DESCRIPTION

### 2.1 General Description

The OXYGEN CONCENTRATOR is a mobile oxygen concentrator. It is adopted the pressure swing adsorption principle, air pressure and pressure, after the molecular sieve nitrogen and oxygen molecules in the air separation, oxygen retention, nitrogen discharge. The oxygen concentration level of the output gas ranges from 93%±3%. The OXYGEN CONCENTRATOR can be used in Travel, home or institution. The device is not intended to be life supporting or life sustaining.

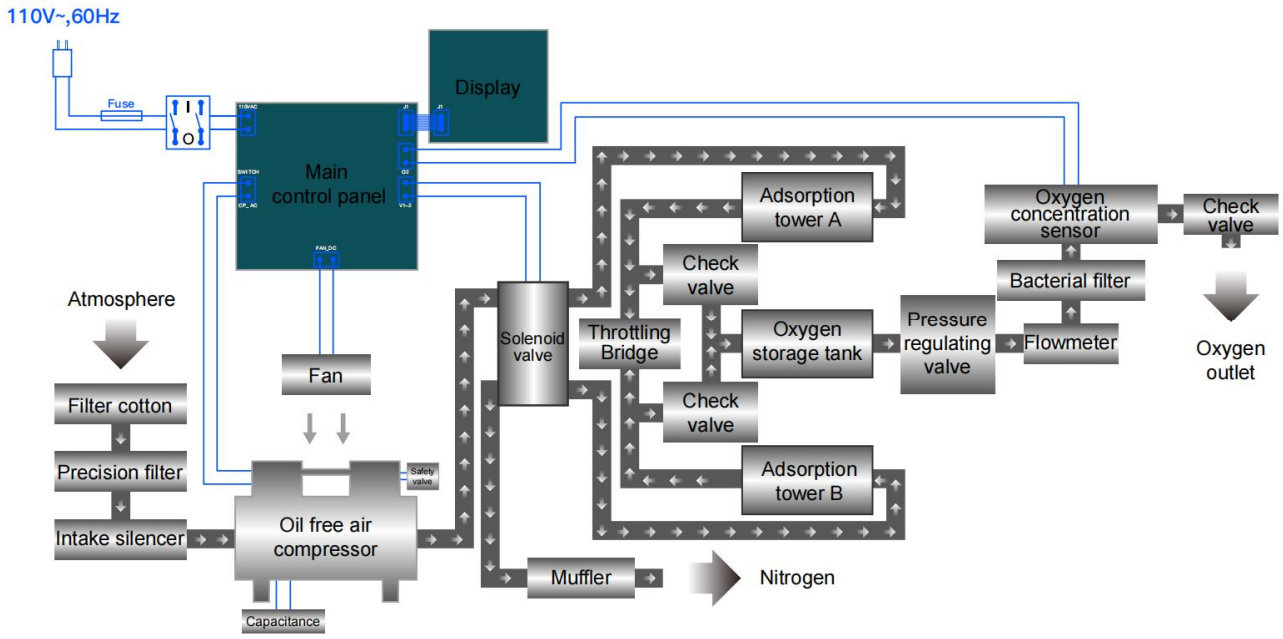
This device is composed of the machine body, flowmeter (in the host), humidification bottle, nasal oxygen tube or oxygen mask. humidification bottle, nasal oxygen tube or oxygen mask are not sold with the host, users need to purchase the accessories by themselves that are legally marketed.

The device is a molecular sieve oxygen generator, and its working principle is compressed air is injected into an airtight adsorption tower equipped with molecular sieves to increase the pressure in the adsorption tower. The molecular sieves absorb a large amount of the Nitrogen in the compressed air as the pressure increases, while the oxygen in compressed air still exists in the form of a gas and is collected through certain pipes. This process is usually called as the “adsorption”.

When the molecular sieve which absorbing the nitrogen in the container reaches the critical state of adsorption saturation, blow and depressurize the adsorption tower. As the ambient pressure decreases, the molecular sieve's ability to adsorb nitrogen decreases, and the nitrogen is released from the molecular sieve to the gas phase and discharged as exhaust gas. This process is often called as “desorption”.

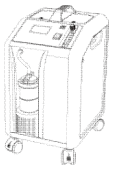
In order to ensure the continuous and stable output of oxygen, the equipment adopts two adsorption towers equipped with molecular sieves. Controlled by the solenoid valves, while one adsorption tower is in the adsorption process and the other is in the desorption process, and these two towers work alternately to complete the oxygen production process continuously. The concentration range of the output oxygen is 90%～96% (V/V)

The figure below is a schematic diagram of the gas path, the arrow in the figure represents the gas flow direction.




## 2.2 Device Drawing

Drawing of model's main units is as below.

| | |
|---|---|
| **Model Name** | CP502 |
| **Appearance Picture** |  |
| **Size and Weight** | 407.5mm x 300 mm x 540mm<br>About 14.5 kg |
| **Power supply** | 110 VAC, 60 Hz |
| **Oxygen Concent ration** | 90%~96% |
| **Equival Ent Flow Rates** | 0.5-5 LPM |
| **Compres Sor model** | YQC280D2-67/1.5-C |
| **Working principle** | Using zeolite molecular sieve as adsorbent, physical pressure swing adsorption (PSA) is used to separate the oxygen and nitrogen in the air to obtain oxygen that meets the standard requirements. |

## 2.3 Check the packaging and packing list

After receiving the product, please open the package carefully. This product is equipped with upper and lower foam protective covers. If the protective cover is damaged, please immediately check whether the product is damaged. Then, when checking the product packing list, check for any missing parts or accessories.

| Packing List | | | |
|---|---|---|---|
| Number | Product /Component Name | Quantity | Unit |
| 1 | Oxygen Concentrator | 1 | Unit |
| 2 | Air intake filtering foam | 1 | Piece |
| 3 | User Manual | 1 | Piece |
| 4 | Fire safety valve | 1 | Piece |

**Table 2-2 Packing List**

**Accessories (not sold with the device)**

1. Humidification bottle

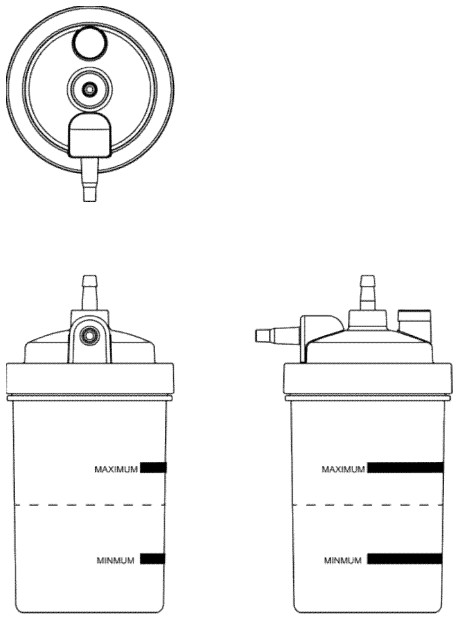



Figure 2.3.1 Dimension of humidification bottle

Note: Humidifier are not sold with the device, consumers need to buy legally sold accessories of the same size by themselves.

2. Nasal oxygen tube and oxygen mask

Nasal oxygen tube or oxygen mask are not sold with the device, consumers need to buy legally sold accessories by themselves.

## 2.4 Component name and function description

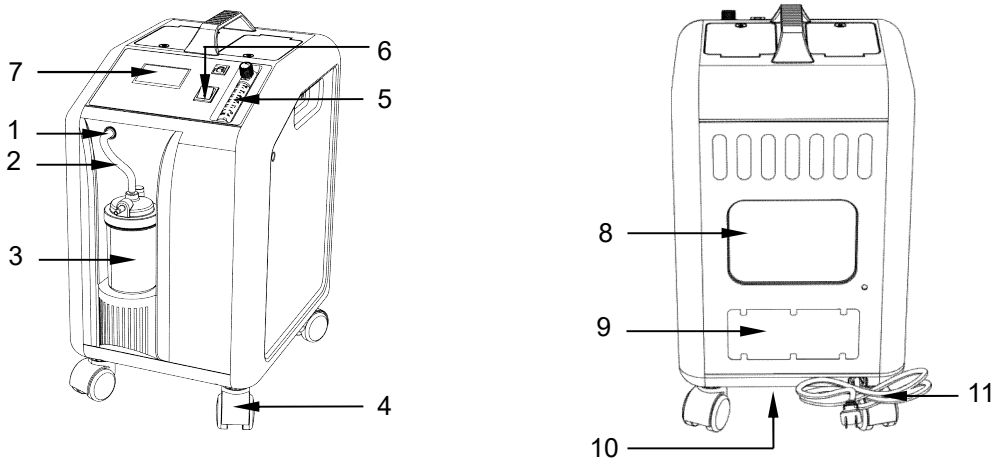



**Figure 2-1 Host introduction**

1. Oxygen outlet: Connect to the humidified bottle or nasal oxygen tube by connecting tube
2. Humidified bottle connecting tube
3. Humidification bottle
4. Castor (*4): flexible mobile machine
5. Oxygen flow meter

a. The position of the flow knot in the oxygen flow meter indicates the size of the flow (L/min).
b. Flow adjusted valve: on/off button on the flow meter, adjust and control the flow of output oxygen.

Note:

 Test the oxygen flow meter and make sure the knot in the regular tick mark (CP502 Max flow 5 L/min, do not let the knot over 5 liter).

 The oxygen flow is so important so do not add or down the flow, just refer to the flow the doctor required.

 Flow will be reduced if the flow meter is rotated clockwise. (Will eventually shut down the flow of oxygen), If the counter clockwise rotation, the flow will increase.

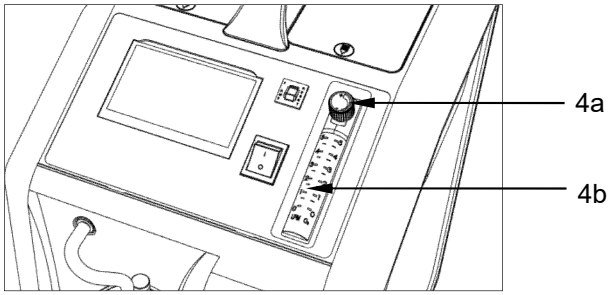



**Figure 2-2 Introduction to the upper plane**

6. Power switch: On / OFF

7. LCD display: The specific functions are introduced as shown in Figure 2-3.

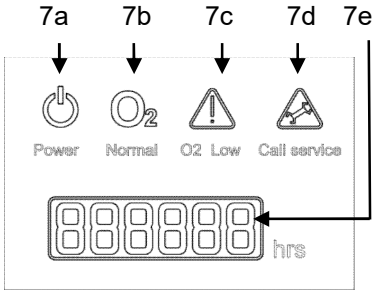



**Figure 2-3 LCD Display**

a. Green power indicator light: Start operating
b. Green indicator light: Oxygen output normally
c. Indicator light: Low Purity
d. Indicator light: Contact the manufacturer
e. Digital display slot: Cumulative timing: Digital show, This is also for alarm condition display

8. Air intake flitering foam: To prevent dirt, dust, fibers into the machine

9. Product nameplate/serial number label: Product performance, product serial number

10. Heat sink: On the bottom of the machine, the equipment can not be blocked at work

11. Power cable: Straight out of the AC power cord (with plug)

### 2.5 Alarm description

1. $O_2$ concentration is greater than 82%. - Green light illuminates (Figure2-3: 7b). Normal Operation.

2. $O_2$ concentration is less than 82%. - Yellow light illuminate (Figure2-3: 7c) and alarm sounds. Call Supplier Immediately. You may continue to use the concentrator unless instructed otherwise by your supplier. Be certain that BACKUP OXYGEN is nearby.

3. Pressure failure alarm - alarm sounds and panel shows word “Lo-P” or “Hi-P”. Total unit shutdown. Switch immediately to backup oxygen supply. Call supplier immediately.

4. Compressor failure alarm - alarm sounds and panel shows word “Lo- Po2”. Total unit shutdown. Switch immediately to backup oxygen supply. Call supplier immediately.

5. Over temperature alarm - alarm sounds and panel shows word “HI-t”. Total unit shutdown. Switch immediately to backup oxygen supply. Call supplier immediately.

6. Low flowrate alarm - alarm sounds and panel shows word “E08”. Total unit shutdown. Switch immediately to backup oxygen supply. Call supplier immediately.

Low flowrate alarm signal will be generated after the alarm condition has occurred approximately 30 seconds.

7. Power loss alarm - alarm sound , no display , no machine working. Please check the power input.

Note:

All the alarm state of the oxygen making machine belongs to the low priority. The alarm system has been set up in the factory, the user cannot change the alarm system settings.

## 2.6 Specifications

| | |
|---|---|
| Product Name | OXYGEN CONCENTRATOR |
| Models | CP502 |
| Dimensions | 407.5mm x 300 mm x 540mm |
| Weight | About 14.5 kg |
| Electrical | 110 VAC, 60 Hz |
| Oxygen Concentration | 93%±3% |
| Equivalent Flow Rates | 0.5-5 LPM, increments of 0.5 LPM |
| Acoustic Noise | ≤50 dBA |
| Type of Protection against electric shock | Type BF |
| Oxygen output pressure | 40kPa-60kPa |
| Highest Flow with 7kPa pressure, change of flow | ≤0.5 L/min |
| Output Pressure=0,the purity value（within 2 mins, up to the standard） | ≥90% |
| IPXX | IP21 |
| Operation mode | Continuous operation |
| Altitude limit | ≤2000m |
| Maximum duration of continuous use | 8 hours |
| Expected service life | 5 years |
| Operating Environment | Temperature: 5~40℃<br>Humidity: ≤ 80%<br>Atmospheric Pressure: 86 kPa～106 kPa |
| Shipping / Storage Conditions | Temperature: -20~+55℃<br>Humidity: ≤ 93%<br>Atmospheric Pressure: 50 kPa～106 kPa |
| Standards Met | AAMI ANSI ES60601-1<br>IEC 60601-1-2 IEC 60601-1-8<br>IEC 60601-1-11 ISO 80601-2-69 |

Oxygen concentration vs. oxygen flow: tested at standard temperature and pressure dry location. (STPD: 101.3kPa, 20℃)

| Flow (L/min) | 0.5 | 1 | 1.5 | 2 | 2.5 | 3 | 3.5 | 4 | 4.5 | 5 |
|---|---|---|---|---|---|---|---|---|---|---|
| Oxygen concentration (%) | 93%±3% | | | | | | | | | |

## 3. USING INSTRUCTIONS

1．The cable tie at the bottom of the machine need to be cut off before starting. The back of the machine needs to be away from the wall at least 30 cm. The bubble plate at the bottom of the machine must be opened to ensure the air circulation and the normal operation of the cooling system.

2．Connect the humidification bottle and operate it as following instruction:

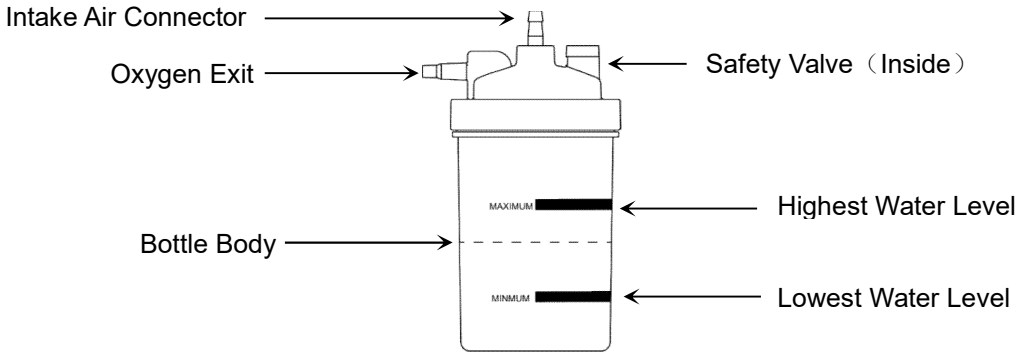



**Figure 3-1 Components of humidification bottle**

a. Put distilled water into the humidification bottle as the water level instructions. Fix the cover to the body (as Figure 3-1).

b. Fix the humidification bottle on the front shell with elastic and the connect the air intake connector by the connecting tube of the bottle while another part to connect the oxygen exit. (as Figure 3-2).

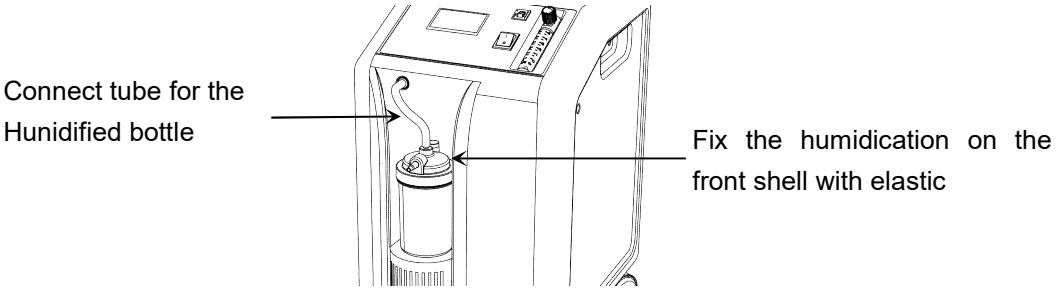



**Figure 3-2 Humidification bottle installation position**

**3.** Connect the Fire safety valve (accessories) and the nasal oxygen cannula to the oxygen outlet. (See Figure 3-3)

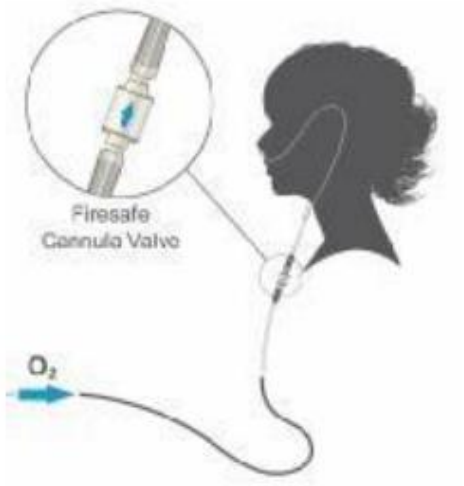



**Figure 3-3 Fire safety valve installation position**

4．Remove the AC power line from the retaining strip, confirm the switch in the off position. Insert the plug into the indoor power outlet at this time.

5．Turn on the device, the instruction light will shin for three time. Several minutes later.

6．According to the output flow, turn the flow control knob counterclockwise to increase the flow, and turn it clockwise to decrease the flow.

7．Put the nasal oxygen tube (or nasal mask) intake air connector to the air exit of the bottle, and then put the nasal tube at the back of the user' ears, insert the nasal plug in the oxygen inhalation tube and to the nostrils of the oxygen inhalation person to make the oxygen inhalation (as Figure 3-4), or put the nasal mask in the correct position of the nasal cavity.

**Figure 3-4 Schematic diagram of inhalation tube placement**

8．When the machine is running, if the alarm is sounded, please check whether the power supply connection is loose or not or whether the external power supply has been interrupted.

9． When the oxygen therapy is finished, please turn off the power switch. Clean the oxygen inhalation tube and oxygen mask according to the prompt. If do not use frequently, please unplug power supply, tie the AC power line with the fuselage drawstring, and put the machine in an adaptable place.

Note:

 The air intake as well as the exhaust of the OXYGEN CONCENTRATOR should be located in a well-ventilated area.

 OPERATOR shall take actions per TROUBLE SHOOTING section in this manual when the OXYGEN CONCENTRATOR indicates an abnormal condition.

 The OXYGEN CONCENTRATOR should be located in an adaptable environment so as to avoid pollutants or fumes.

 Oxygen delivery settings of the OXYGEN CONCENTRATOR should be periodically reassessed for the effectiveness of the therapy.

 Oxygen delivery setting shall be determined for each patient individually with the configuration of the equipment to be used, including accessories.

 The proper placement of the prongs of the nasal cannula in the nose is critical to the amount of oxygen delivered to the respiratory system of the patient.

 The qualitative investigation method of the gas leakage and gas flow of the accessories of the oxygen generator: place the end of the nasal oxygen suction tube in a cup filled with half a glass of water and observe whether there are bubbles.

 When the oxygen concentrator is stored outside the temperature range specified under normal operating condition, please put the device in normal operating condition more than 4 hours before operating.

 If power cable is found broken, do not use the machine and contact the supplier for immediate assistance.

## 4. CLEANING AND MAINTENANCE

1．Clean the outside shell: once or twice each month. Please unplug the power supply firstly, use a wet soft towel with a little detergent to wipe the exterior, then use a dry towel to wipe it again.

2．Clean the humidification bottle: You can use detergent and hot water to clean the humidification bottle separately, or put a kind of mixture which mixed by vinegar and water at the ratio of 1:3 in the humidification bottle about 30 minutes, when the mixture solution has stratified, drain the liquid and then dry the bottle.

3．Clean the Air intake filtering foam: take off the cotton on the back side of the box, clean it with detergent and rinse thoroughly with clear water. Dry in the air. If do not dry thoroughly, please don't use it. This is the important step for protect the machine.

Note:

Lubricants must not be used for equipment maintenance.

The instrument shall not be maintained while in use with the patient.

## 5. STORAGE

1．Range of Environmental Temperature: - 20℃~+55℃;

2．Range of Relative Humidity: ≤ 93%, without no condensation phenomenon;

3．Range of atmospheric Pressure: 50 kPa~106 kPa.

Note:

When the storage temperature is under 5℃, it should be put the machine under the normal temperature environment for over four hours before use it.

## 6. TROUBLE SHOOTING

Attached below the fault and repairing comparison table will help you analyze the fault and repair oxygen machine. If the proposed steps do not help, please use the spare oxygen machine, and notify the oxygen machine supplier. Please don't try any other repairs.

| Symptom | Possible Cause | Remedy |
|---|---|---|
| **A.**Unit does not operate. Power light is off when the power | 1. Power cord not properly inserted into wall outlet. | Check power connection at the wall outlet. On 110 voltage units, check the back of the unit. |

| | | |
|---|---|---|
| switch is “on”. Audible alarm is pulsing and Service Required light is flashing. | 2. No power at wall outlet. | Check your home circuit breaker and reset if necessary. Use a different wall outlet if the situation occurs again. |
| | 3.Oxygen concentrator circuit breaker activated (selected units). | Press the concentrator circuit breaker button （if equipped） located below the power switch. Use a different wall outlet if the situation occurs again. |
| **B.**Unit operates within 1min; the Power light is on when the Power switch is “On”. Red Service Required light is illuminated. Audible alarm may be sounding. | 1. Air intake flitering foam is blocked. | Check the Air intake flitering foam. If the flitering foam is dirty, wash it following the cleaning instructions section 4. |
| | 2. Exhaust is blocked. | Check the exhaust area; make sure there is nothing restricting the unit exhaust. |
| | 3. Blocked or defective nasal cannula, catheter, face mask or oxygen tubing. | Detach nasal cannula, catheter, or face mask. If proper flow is restored, clean or replace if necessary. Disconnect the oxygen tubing at the oxygen outlet. If proper flow is restored, check oxygen tubing for obstructions or kinked. Replace if necessary. |
| **C.**Unit operates the power light is on when power switch is “on “, audible low-frequency vibration sound is detected. | The tie on the bottom of the machine do not be cut off | Turn off the machine and put off the power plug，then put the machine side，cut off the tie and put out. |
| **D.**Both the green Normal Oxygen and the yellow Low Oxygen lights are either on or off. | O.C.I malfunction | Contact your supplier |
| **E.**Yellow Low Oxygen light is on or the yellow low Oxygen light is on and the intermittent audible Signal is sounding. | 1. Flow meter is not properly yet. | Ensure the flow meter is properly set to the prescribed. |
| | 2. Air intake flitering foam is blocked. | Check the Air intake flitering foam. If the flitering foam is dirty, wash it following the cleaning instructions on page 6. |
| | 3. Exhaust is blocked. | Check the exhaust area: make sure there is nothing restricting the unit exhaust. |
| **F.**Service Required light is on and an intermittent audible signal is sounding. | 1. Flow meter is not properly yet. | Ensure the flow meter is properly set to the prescribed. |
| | 2. Air filter is blocked. | To check if the Air filter have blocked, jam, please clean up the clutter.<br>Check whether the Air filter is dirty, if dirty, please timely replace as required section 3. |
| | 3. Exhaust is blocked. | Check the exhaust area: make sure there is nothing restricting the unit exhaust. If the above remedies do not work, contact your Medical provider. |
| If the machine is still not working properly, please contact the product supplier or service point. MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair. | | |

## 7. DISPOSAL

1. The device and accessories out of shelf life or use life should not be thrown randomly and should be recycled by the manufacturer.

2. To dispose of packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.

## 8. WARRANTY CARD

1. From the date of purchase 2 years or 8000 hours (to the expiration of the time cut-off point) considered as the quality assurance period, such as the product is not for human operation fault, manufacturing plants should provide with free service for the user to repair or replace parts.

2. Do not accept the failure machine which with unauthorized modification or installation of other features.

The following conditions are not free of maintenance:

Products over the warranty period;

Do not follow the manual requirement leads failure of operation.;

Failure, scratch or damage caused by movement;

Do the repair, decomposition, assembly without allowance from professional personnel;

Normal damage of wearing parts and parts;

Failure and damage caused by force majeure (e.g. fire, flood, earthquake, etc.).

Any question, please contact us:

*FOSHAN MIC MEDICAL TECHNOLOGY CO., LTD,*

*Address:* # 501-1, 503, Bldg-A7, Hantian Industrial Park, Nanhai, Foshan, 528200 Guangdong, China

E-*mail:* lucuixia@micmedtech.com

## 9. LABEL SYMBOLS

Label symbols are shown in the following table:

| | | |
|---|---|---|
| 1 |  | Keep away from rain |
| 2 |  | Refer to instruction manual/booklet. |

| | | |
|---|---|---|
| 3 |  | No discard it at will is allowed. |
| 4 |  | This way up |
| 5 |   | Serial number |
| 6 |   | Batch code |
| 7 |  | Fragile, handle with care |
| 8 |  | Non-ionizing electromagnetic radiation |
| 9 |  | Type BF Applied Part |
| 10 |  | DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture. |
| 11 |  | Symbol for "MANUFACTURER". This symbol shall be accompanied by the name and the address of the manufacturer. |
| 12 |  | Stacking limit by number |
| 13 |  | No sitting |
| 14 |  | No smoking |

| | | |
|---|---|---|
| 15 |  | No open flame; Fire, open ignition source and smoking prohibited |
| 16 |  | Keep away from sunlight |
| 17 | $R_x$ Only | Prescription use |
| 18 | IP21 | The first characteristic number “2”: protected against access to hazardous parts with a finger.<br>The second characteristic number “1”: protected against vertically falling water drops. |
| 19 |  | MR Unsafe |

## 10. ELECTROMAGNETIC COMPATIBILITY

The essential performance description of subject device:

The subject device in both normal condition and single fault condition of oxygen concentration should be 93%±3% and highest flow with 7 kPa pressure and lowest flow with 0 kPa pressure, change of flow should be ≤0.5 L/min.

Otherwise When a failure occurs, the generation of an alarm condition:

power supply failure: alarm sound, no display, no machine working;

O2 concentration is less than 82%: Yellow light illuminate ( 

) and alarm sounds. Call supplier immediately ( 

 )

Compressor failure alarm: alarm sounds and panel shows word “Lo- Po2”. Total unit shutdown. Switch immediately to backup oxygen supply ( 

 ).

Pressure failure alarm: alarm sounds and panel shows word “Lo-P” or “Hi-P”. Total unit shutdown. Switch immediately to backup oxygen supply. Call supplier immediately ( 

 )

Over temperature alarm: alarm sounds and panel shows word “HI-t”. Total unit shutdown. Switch immediately to backup oxygen supply. Call supplier immediately ( 

 ).

Low flowrate alarm: alarm sounds and panel shows word “E08”. Total unit shutdown. Switch immediately to backup oxygen supply. Call supplier immediately ( 

 ). Low flowrate alarm signal will be generated after the alarm condition has occurred approximately 30 seconds.

This device complies with Medical EMC Standard IEC 60601-1-2:2014.

| **Guidance and manufacturer’s declaration – electromagnetic emissions** | | |
|---|---|---|
| This equipment is intended for use in the electromagnetic environments specified below, and the purchasers or users shall ensure that it is used in these electromagnetic environments. | | |
| **Emissions** | **Compliance** | **Electromagnetic environment-- guidance** |
| RF emissions CISPR 11 | Group 1 | The device uses RF energy only for its internal function.<br>Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The device is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer’s declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that It is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment--guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air | Floors should be wood,concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst<br>IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV for input/output lines | ±2kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1 kV line to line<br>±2 kV line to earth | ±1 kV line to line | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, Short interruptions and voltage variations on power supply | <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 % | <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 | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires Continued operation during power mains interruptions, it is recommended |

| | | | |
|---|---|---|---|
| input lines IEC 61000-4-11 | dip in UT) for 5s | *UT)* for 5 sec | that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic fieldI EC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level | | | |

**Guidance and manufacturer's declaration – electromagnetic immunity**

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

| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment-guidance** |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz<br><br>6 Vrms in ISM bands | 3 Vrms 150 kHz to 80 MHz<br><br>6 Vrms in ISM bands | Portable and mobile RF communications equipment should be used no closer to any part of OXYGEN CONCENTRATOR, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommend ed separation distance**<br>$d=[3,5/V1]\times P^{1/2}$<br>$d=1.2\times P^{1/2}$ 80 MHz to 800 MHz<br>$d=2.3\times P^{1/2}$ 800 MHz to 2.7 GHz<br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation Distance in meters (m).<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]<br>Interference may occur in the vicinity of Equipment marked with the following symbol:<br>  |
| Conducted RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz<br><br>385MHz-5785MHz Test specifications for ENCLOSUR E PORT IMMUNITY to RF wireless Communicati on equipment (Refer to table 9 of IEC 60601-1- 2:2014) | 3 V/m 80 MHz to 2.7 GHz<br><br>385MHz-5785MHz Test specifications for ENCLOSUR E PORT IMMUNITY to RF wireless Communicati on equipment (Refer to table 9 of IEC 60601-1- 2:2014) | |
| 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 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 OXYGEN CONCENTRATOR is used exceeds the applicable RF compliance level above, the OXYGEN CONCENTRATOR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating OXYGEN CONCENTRATOR.

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

**Recommended separation distances between portable and mobile**

**RF communications equipment and the EQUIPMENT or SYSTEM – For EQUIPMENT and SYSTMES that are not LIFE – SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and the Automatic Wrist Blood Pressure Monitor

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

| Rated maximum output of transmitter (W) | Separation distance according to frequency of transmitter(m) | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d=1.2\times P^{1/2}$ | 80 MHz to 800 MHz $d=1.2\times P^{1/2}$ | 800 MHz to 2.7 GHz $=2.3\times P^{1/2}$ |
| 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 transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (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.

**Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment**

| Test frequency (MHz) | Band [a] (MHz) | Service [a] | Modulation [b] | Maximu m power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380-390 | TETRA 400 | Pulse modulation [b] 18Hz | 1.8 | 0.3 | 27 |
| 450 | 430-470 | GMRS 460, FRS 460 | FM [c] ±5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704-787 | LTE Band 13,17 | Pulse modulation [b] 217Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800-960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation [b] 18Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700-1900 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation [b] 217Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400-2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation [b] 217Hz | 2 | 0.3 | 28 |
| 5240 | 5100-5800 | WLAN 802.11a/n | Pulse modulation [b] 217Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.

b. The carrier shall be modulated using a 50% pulse duty cycle square wave signal.

c. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

FOSHAN MIC MEDICAL TECHNOLOGY CO., LTD

Address: # 501-1, 503, Bldg-A7, Hantian Industrial Park, Nanhai, Foshan, 528200 Guangdong, China

Tel: +86 757 86678238

Fax: +86 757 86678231

E-mail: lucuixia@micmedtech.com