Uncertified Version－Not for Commercial Distribution

Oxygen Concentrator
Instruction Manual

Model: KF08-5YW

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Before using this product, read this manual carefully and save for further reference.

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I. Intended Use /Special Notes

- **Intended use / Indications for use**

The molecular sieve oxygen concentrator is intended to provide supplemental oxygen to persons suffering from various discomforts caused by lack of oxygen or for oxygen therapy. It is not intended to sustain or support life.

✧ The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

- **Intended patient population：** Adult patients(＞18 years old).
- **Intended users:** Professional medical staff, or lay users.
- **Contraindications**

✧ The molecular sieve oxygen concentrator is not intended for use in surgical procedures or emergency treatment, or for patients who are critically ill.

✧ Use of the molecular sieve oxygen concentrator is contraindicated in patients suffering from oxygen poisoning or oxygen allergy.

Note:

✧ The oxygen concentrator is intended for use with a humidifier bottle and a nasal cannula. The nasal cannula, humidifier bottle, and connecting tube are single-use products. When replacing them, please refer to the specifications in the Instructions for Use when purchasing, or contact your distributor to purchase. To prevent cross-contamination, please do not reuse single-use components or accessories.

✧ This product is for single-patient use only. Avoid multiple-patient use to prevent the risk of cross-contamination.

- **Work principle**: Pressure swing adsorption principle, filtering by molecular sieve.
- **Special Notes**

✧ Warnings and cautions in this manual apply to all hazardous operations that may result in bodily injury or property damage.

✧ For definitions of warnings/dangers, please refer to the table below:

Mark	Indication
DANGER	Indicates a high degree of danger that, if not avoided, will result in death or severe bodily injury.
WARNING	Indicates a potential danger that, if not avoided, may result in death or severe bodily injury.
CAUTION	Indicates a potential danger that, if not avoided, may result in property damage.

Note: A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

⚠ **WARNING**

- ✧ Do not operate this product without reading and fully understanding this manual!
- ✧ If you have any problems in understanding the warnings and operating instructions, please contact our technical service personnel, and do not operate the machine before you get guidance. Failure to do so may result in severe bodily injury or property damage.
- ✧ Please seek the advice of a physician before use.
- ✧ Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- ✧ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ✧ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
- ✧ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- ✧ MR Unsafe：Under no circumstances should this device or its accessories be brought into an MR environment (i.e., a magnetic resonance imaging (MRI) scanning room) to avoid serious physical injuryor equipment failure.

■ Product Disposal

Warning: Improper disposal may result in infection or environmental hazards. Please strictly follow the instructions below.

✧ Disposal of Consumables (Infection Hazard):

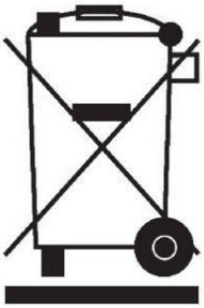
Single-use consumables (including nasal cannulas, humidifier bottles, and connecting tubes) may be contaminated with patient secretions or potentially infectious substances after use. These items must be disposed of as medical infectious waste in accordance with local regulations; do not discard them with regular household trash.

✧ Equipment Disposal (Physical and Environmental Hazards):

This device contains electronic components and a power cord. The device is marked with the following symbol, indicating that it must not be disposed of as unsorted municipal waste. To comply with the Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU), please take this device to a designated electronic waste collection facility for proper recycling at the end of its life.

✧ General Compliance Requirements:

Always dispose of this device and its accessories in accordance with applicable local, regional, and national environmental and medical waste regulations.



II. Safety Precautions

CAUTION!

- It is recommended to have an alternate source of oxygen supply in case of accidental power outage, alarm condition, or mechanical failure. Consult your physician or device provider about the type of backup system required.
- It is recommended that the molecular sieve oxygen concentrator should be on for more than 30 min for each time of use to achieve the optimal performance. Frequent start-up of the machine over a short period of time will reduce the service life. If the power cord or plug of the molecular sieve oxygen concentrator is damaged, or the machine works abnormally, falls or is exposed to water, please contact authorized service personnel for overhaul.
- Most electric appliances are susceptible to radio frequency interference. The use of portable communication devices in the vicinity of the molecular sieve oxygen concentrator will cause interference with the machine. Avoid using the molecular sieve oxygen concentrator in a strong magnetic field environment.
- It is recommended to adjust oxygen flow under the guidance of a healthcare provider. Patients with severe pulmonary diseases should consult a medical professional for decision of oxygen flow rate.
- The molecular sieve oxygen concentrator is intended for supplemental oxygen supply rather than for emergency treatment or life sustaining, so patients are recommended to have an alternate source of oxygen available, such as cylinder oxygen, in addition to the oxygen concentrator.
- Avoid direct sunlight while using the molecular sieve oxygen concentrator, as excessive sunlight may accelerate the aging of the equipment, and guard against dust, cotton fiber and other debris from blocking the air inlet of the oxygen concentrator.

WARNING

- During oxygen therapy, there is a risk of fire due to the increased oxygen concentration. Do not use the oxygen concentrator or accessories in the presence of sparks or an open flame".
- To ensure that the required oxygen amount is obtained for oxygen therapy according to the patient's medical condition, Cofoe KF08-5YW Oxygen Concentrator must be used:
  -only under the individually prescribed flow setting(s) based on the patient's specific activity level.
  -in combination with components designated by the manufacturer of the molecular sieve

oxygen concentrator under the prescribed flow setting.

- Use only oxygen-compatible water-based lotions or salves before or during oxygen therapy. Use no oil or petroleum-based lotions or salves so as to avoid the risk of fire and burning.
- Do not lubricate the fittings, tubing, or other accessories of the oxygen concentrator so as to avoid the risk of fire."
- Use only spare parts recommended by the manufacturer to ensure proper device functionality and avoid the risk of fire."
- At altitudes greater than 1828 m above sea level or temperatures outside the 5°C–40°C range or relative humidity > 80%, the oxygen flow and concentration will be compromised, and thus the treatment effect will be impaired."
- Oxygen makes ignition and flame propagation easier. Do not leave the device and accessies on bed or chair cushions. If the oxygen concentrator is turned on but not in use, the oxygen will make the material flammable. The oxygen concentrator should be turned off when not in use to avoid oxygen accumulation."
- If you feel uncomfortable or have a medical emergency during oxygen therapy, seek medical help immediately to avoid injury."
- When the elderly or other patients are unable to express discomfort, additional monitoring measures or distributed alarm systems should be available to indicate the discomfort and medical emergencies to the responsible caregiver to avoid injury."
- Smoking during oxygen therapy is dangerous and may cause facial burns and possibly death. Do not allow smoking within the same room of the oxygen concentrator or any other oxygen-carrying accessory. If you want to smoke, turn off the oxygen concentrator, take off the nasal cannula, and leave the room where the nasal cannula, the face mask, or the oxygen concentrator is located. If you can't leave the room, you must wait until the oxygen concentrator is turned off for 10 min before starting to smoke."
- Open flames during oxygen therapy are dangerous and may result in fire or possibly death. Do not allow open flames within 2 m of the oxygen concentrator or any oxygen-carrying accessory."
- To avoid the danger of strangulation from cables or tubing, the guardian should pay particular attention when the oxygen concentrator is used on an infant or child. In case of emergency, turn off the power supply as soon as possible, loosen the cable or tubing, or where necessary, directly cut off the cable or tubing, and seek medical treatment immediately.
- If a child accidentally swallows a small component that has fallen from the oxygen concentrator, the guardian should perform the Heimlich maneuver for first aid and seek immediate medical treatment. If information regarding the swallowed component is required during medical treatment, please contact the manufacturer without delay.
- Long-term wearing of the nasal cannula may cause skin irritation and itching, as the gasket and securing strap of the nasal cannula may rub the skin. Therefore, you should follow the medical advice and check the physical condition regularly when wearing the nasal cannula for a long period of time.

DANGER

Electrical shock danger! Never disassemble the device yourself! Contact the authorized service

personnel at the service center for technical assistance. Please read the following instructions before operating the molecular sieve oxygen concentrator.

- Before using this product, please perform an integrity check on the product and its accessories. If any damage is found, please contact after-sales service first; do not start using the product.
- Do not move the molecular sieve oxygen concentrator by pulling the power cord! It is recommended to use the device within 5 m of the patient.
- Do not drop or insert any objects into any openings on the device!
- Keep the power cord away from heat sources or hot surfaces!
- Unplug the machine when not in use!
- Do not connect this product with other molecular sieve oxygen concentrators or oxygen therapy equipment in parallel or in series!
- To reduce the risk of burns, electrical shock, fire, and bodily injury, please note the following:
  - Do not use the device during a shower. If continuous use of the molecular sieve oxygen concentrator is required for the patient, the device must be placed in a room at least 2 m away from the bathroom.
  - Do not place the portable multiple socket-outlet on the ground to prevent fluid ingress and avoid mechanical damage. The portable multiple socket-outlet has a maximum permissible load of 10 A and can only be used to supply power to the molecular sieve oxygen concentrator system and for no other purposes.
  - Do not use the oxygen concentrator in locations where oil, grease, or oily substances are present or near flammable materials.

DISCLAIMER

DISCLAIMER: For effectiveness of the therapy, it is advisable that the oxygen output setting of the oxygen concentrator be reassessed periodically.

DISCLAIMER: Oxygen output settings should be made individually for each patient, depending on the configuration of the device and accessories.

DISCLAIMER: The oxygen concentrator and its components and accessories are specified for use at the prescribed flow.

DISCLAIMER: Incompatible components and accessories may result in performance reduction.

DISCLAIMER: It is the responsibility of the responsible party to ensure that all components and accessories connected to the patient are compatible with the oxygen concentrator before use.

DISCLAIMER: Proper placement and orientation of the patient interface is the key to treatment.

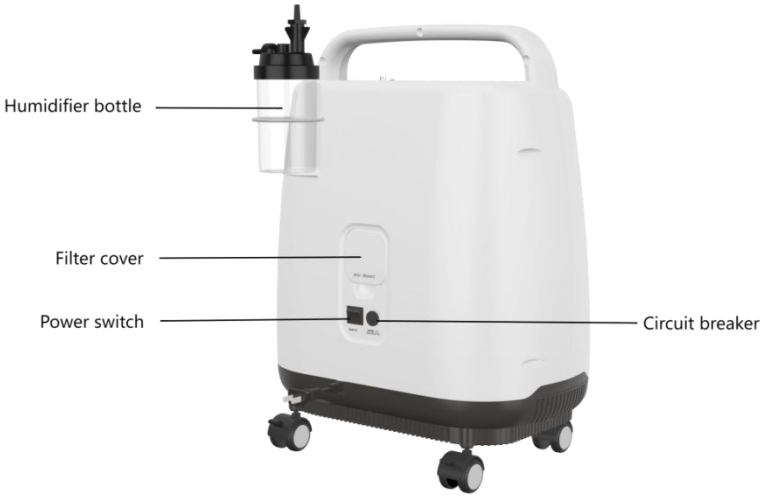
DISCLAIMER: Do not use grease that is not recommended by the manufacturer.

DISCLAIMER: Incompatible components and accessories may result in performance reduction.

DISCLAIMER: Before using the oxygen concentrator, please connect the humidifier bottle correctly, otherwise it may lead to water getting into the oxygen outlet line of the oxygen concentrator.

III. Product Features





IV. Product Specifications

Product name	Oxygen Concentrator
Model	KF08-5YW
Rated voltage and frequency	AC220-240V, 50Hz
Mode of operation	Continuous duty
Rated input power	450VA
Noise level (average)	≤ 60 dB (A) at 5 L/min;
Alarm sound volume	≥ 62 dB（A）

Altitude	It can be used normally in environments below 1828 m above sea level. It is not recommended for use at altitudes higher than 1828 m. Oxygen flow and concentration will be significantly compromised at altitudes above 1828 m.
Physical and chemical parameters of output oxygen	*The claimed oxygen concentration level (93% ± 3%) (V/V) can be obtained after a certain period of warm-up (approximately 30 min after power-on). Carbon dioxide content: ≤ 0.01% (V/V) Carbon monoxide content: ≤ 0.0005% (V/V) Particle size of solid substance: ≤ 10 μm Solid substance content: ≤ 0.5 mg/m³
Maximum output pressure	≤ 70 kPa
Flow range	0.6-5 L/min
Flow accuracy	The flow should be ± 10% of the indicated value or ± 200 mL/min at the back pressure of 0 kPa and 7 kPa, whichever is greater.
Low flow alert	There is an alert in sharp beeps when the flow is below 0.6 L/min (when no accessories are connected to the device).
Maximum system allowable pressure (Pressure protection)	241 ± 24.1 kPa
Flow fluctuation (at the back pressure of 7 kPa)	< 0.6 L/min
Circuit breaker	F6.3AH250V
Filters	Oxygen outlet filter and compressor inlet filter
Safety system	Oxygen concentration/flow display　Compressor error alarm Compressor high temperature　Circulation pressure fault alarm

	protection Low oxygen concentration alarm — System communication fault alarm Low supply voltage alarm — Temperature error alarm Power outage alarm — No-breathing alarm Low flow alert — Low oxygen concentration alert
IP rating	IP21: solid object ingress protection level 2, water ingress protection level 1
Size	42 (L) *28(W) *55(H)CM
Weight	16.35kg
Operating environment	Temperature: 5℃ ～ 40℃ Relative humidity: ≤80% Atmospheric pressure: 81kPa-106kPa
Exhaust air temperature	No higher than 75°C
Output oxygen temperature	No higher than 45°C Note: Under the specified environmental and operational conditions, the temperature in question is considered safe for prolonged oxygen administration to patients via a nasal cannula, posing no risk of burns or thermal damage. Oxygen undergoes rapid cooling as it flows through the catheter and mixes with ambient air. The actual temperature of oxygen perceived within the patient's nasal cavity will not be significantly higher than the ambient temperature.
Electricity	No extended power cord
Main components and structure	The product consists of a filtration system, a compressor, left and right sieve canister assemblies, a circuit control system, a noise reduction system, pulse oxygen delivery system, electronic flow regulation system, intelligent voice system, embedded software (release version No.: ZY004), a humidifier bottle, and connecting tubing.
Placement	No less than 7.5 cm away from a wall, furniture, tapestry or similar object.
Continuous operation time per day	24h

Storage and transportation environment	Temperature: -20℃ ～ 55℃ Relative humidity: ≤93% Atmospheric pressure: 81kPa-106kPa		
Manufacturing date	See the outer packaging		
Service life/ Shelf life	5 years		
Type BF applied part	Nasal cannula		
Indicator Light			
State	Indicator LED (diode)		
Alert	Red LED		
Alarm	Yellow LED		
Normal operation	Green LED		
Circuit Breaker			
686Series 125/250VAC/50VDC F6.3AH250V	When the input current of the oxygen concentrator exceeds the rated current of the circuit breaker, the circuit breaker will be automatically deactivated for protection in case of electric shock, and the oxygen concentrator will stop working. When the user excludes abnormal power supply, just press the button on the top of the circuit breaker, and the circuit breaker can resume working		
Accessories	**Name**	**Quantity**	**Remarks**
	Instruction manual	1	Standard
	Remote controller	1	Optional
	Nasal cannula	1	Standard

V. Explanation of Symbols

Symbol	Explanation	Symbol	Explanation
LOT	Batch number	⚠	Warning/Caution: consult accompanying documents

	Manufacturer		European Authorised Representative
	MR Unsafe		Date of manufacture
	Keep away from sunlight		Type BF applied part
	Keep dry		Use-by date
	WEEE Marking. Dispose of this equipment in accordance with local regulations.		Class II equipment
	Alternating current		On (mains supply)
	Off (mains supply)		No smoking
	Do not expose to open flames		Medical Device
	Unique Device Identifier		Refer to instruction manual or booklet
	Serial Number	IP21	Degree of Protection Against. Ingress of Water and Particulates.

VI. Handling of Product

Keep the machine up during transportation to prevent damage to the enclosure of the molecular sieve oxygen concentrator, and the container used for transportation should be able to effectively protect the molecular sieve oxygen concentrator.

1. Unpacking

(1) Inspect the outer packaging and all contents for visible damage. If there is visible

damage, notify the shipping company or local dealer.

(2) Remove all fillers from the packaging carton.

(3) Carefully take the device and accessories (nasal cannula, nebulizer kit, humidifier bottle (the accessories are all externally purchased products that have been certified with a CE mark), warranty card, and the instruction manual).

NOTE: Unless used immediately, retain the carton and all packaging materials to store the machine until the next use.

2. Inspection

Inspect the appearance of the molecular sieve oxygen concentrator for defects, dents, scratches or other damage.

3. Storage

(1) Store the repackaged molecular sieve oxygen concentrators in a dry place.

(2) Do not place any articles on the repackaged molecular sieve oxygen concentrator.

VII. Product Description

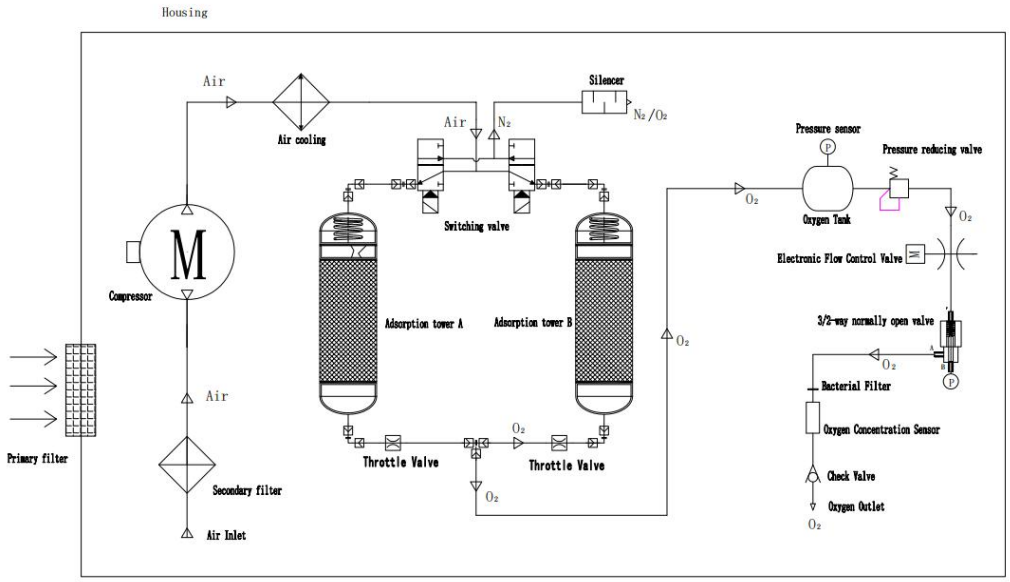
The molecular sieve oxygen concentrator, intended for supplemental oxygen supply for people who cannot get enough oxygen from the air, can produce oxygen with a concentration of 93% ± 3% (V/V) that meets medical requirements, and it can also be used for oxygen therapy. For other people, oxygen inhalation can alleviate various kinds of discomforts caused by hypoxia. The oxygen concentrator can be used in conjunction with a humidifier bottle and a nasal cannula .

Molecular sieve oxygen concentrators are not recommended for use in surgery, emergency, and critically ill patients. If the oxygen concentrator is used in these cases, oxygen therapy may not achieve the desired results and result in patient injury.

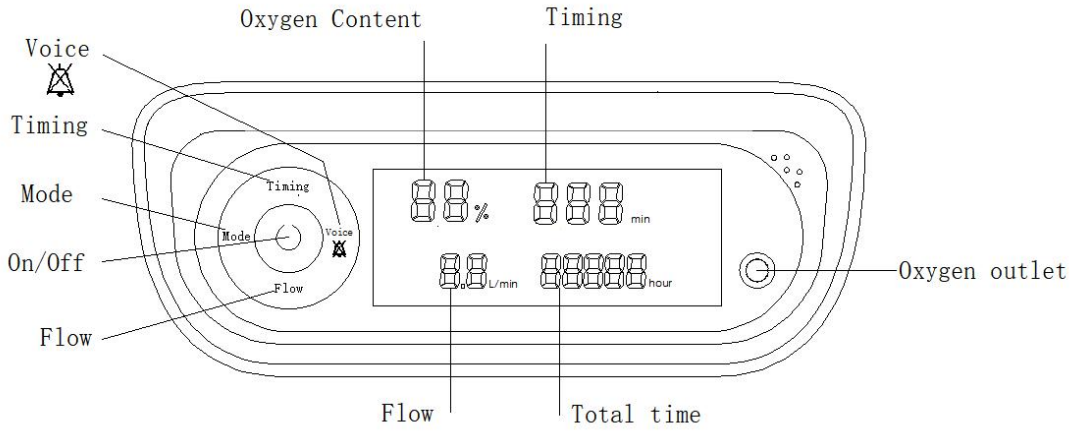
The molecular sieve oxygen concentrator is not intended for use in health care settings.

The molecular sieve oxygen concentrator is for use in single patient only. It is an appliance that separates oxygen from air. The molecular sieve oxygen concentrator outputs oxygen at a concentration of 93% ± 3% (V/V). It provides a high concentration of oxygen directly through the nasal cannula. Clinical studies have demonstrated the equivalence of direct oxygen supply from the molecular sieve oxygen concentrator to other oxygen supply methods.

The seller will demonstrate how to operate and use the molecular sieve oxygen concentrator. Please contact the distributor for any questions or problems. The description of the molecular sieve oxygen concentrator in the user's manual can be used as a reference for use.



KF08-5YW Air circuits Diagram



（Schematic diagram of operation panel information）

VIII. Operating Instructions and Precautions

1. Selection of the right place

Choose a place indoors where it is most convenient to use the molecular sieve oxygen concentrator. Casters at the bottom of the machine allow for very easy movement of the machine. Ensure that the air inlet and the gas outlet of the oxygen concentrator are in well-ventilated locations and are free from intake of pollutants an smoke.

2. Optimal use environment recommended to the end user

Temperature: +5°C–+40°C

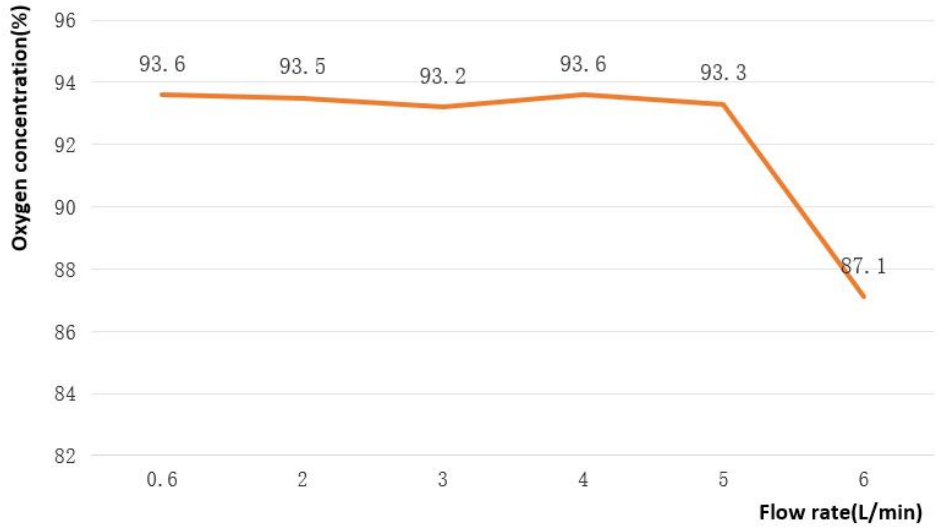
Relative humidity: ≤ 80%

Environment: Use in well-ventilated places, and avoid use in smoke, dust environments or narrow spaces.

Power cord: No extension cord.

Flow: Under dry conditions at standard temperature and atmospheric pressure,

0.6 L/min to 5 L/min; the flow lower than 1 L/min is not recommended; the maximum recommended flow is 5 L/min, at which the output oxygen concentration is 93% ± 3% (V/V); when the flow is over 5 L/min, the oxygen concentration will be gradually reduced along with the increase in the flow (see the figure below).



*The molecular sieve oxygen concentrator can reach the flow of 5 L/min and the oxygen concentration of more than 90% within 120 s after the device is turned on, but the device needs to run for a certain period of time before it reaches the optimal working condition. Therefore, the recommended minimum use time is 30 min.

*At altitudes greater than 1828 m above sea level or temperatures outside the range of 5°C–40°C or relative humidity greater than 80%, the oxygen flow and concentration will be compromised, and thus the treatment effect will be impaired.

*The oxygen content output to the patient's respiratory system is determined by the position of nasal cannula in the nostril and the direction of gas outlet.

Note: The molecular sieve oxygen concentrator should be located not less than 7.5 cm away from walls, furniture, tapestries or similar surfaces to ensure adequate air supply. Keep the device away from thick carpets, heaters, radiators, and warmer.

*At an ambient temperature of 20°C, the time required for the oxygen concentrator to be ready for its intended use from the lowest storage temperature after use is 1 h.

*At an ambient temperature of 20°C, the time required for the oxygen concentrator to be ready for its intended use from the maximum storage temperature after use is 1 h.

3. Power cord connection

Plug the power cord into an outlet.

4. Humidifier bottle connection (not exceeding the maximum water line)

(1) Fill the humidifier bottle with distilled water to the proper position. (Not exceeding the maximum water line)

WARNING: Do not overfill the humidifier bottle. Close the cap of the humidifier bottle and screw

tightly. Do not install reversed oxygen input and output connections on the humidifier bottle, otherwise water in the humidifier bottle will be delivered directly to the user through the nasal cannula. (As shown in Figure 1)

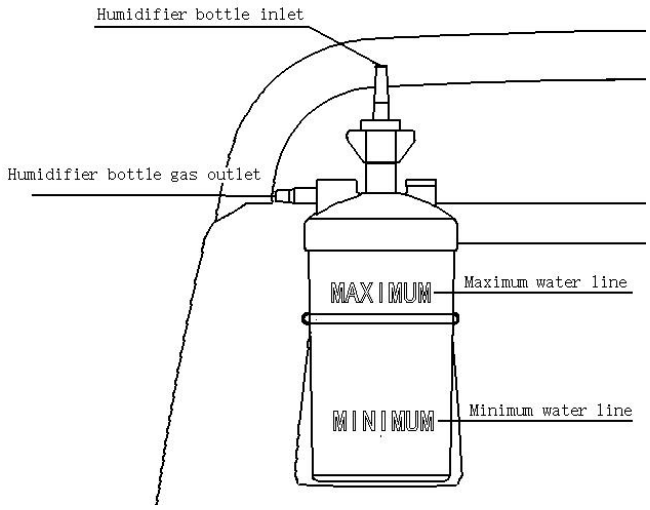


Figure 1.

(2) Place the humidifier bottle in the recess at the back of the machine enclosure, and connect the inlet port of the humidifier bottle to the oxygen outlet of the molecular sieve oxygen concentrator through the oxygen tubing.

The humidifier bottle is a gas flow direction-sensitive component, so when connecting its tubing, pay special attention to the directions of the gas inlet and outlet of the humidifier bottle. (As shown in Figure 2)

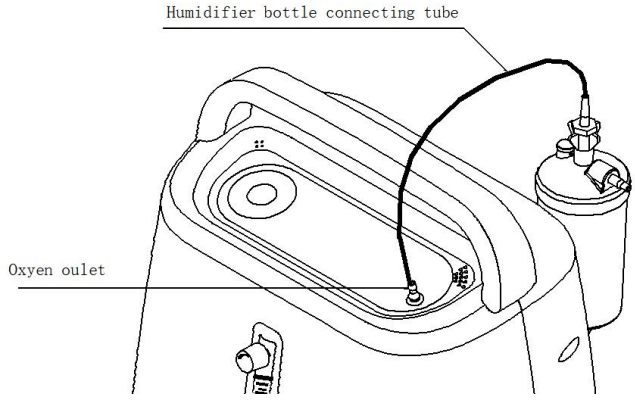


Figure 2

(3) Install the nasal cannula to the humidifier bottle oxygen outlet.

(4) Check after installation to ensure that oxygen is passing through the nasal cannula.

WARNING: For optimal performance, it is recommended to use the device for at least 30 min each time; frequent start-up of the device over a short period can reduce the service life of the device.

5. Power switch

Turn on the power switch. All control panel lights will be activated within one second, indicating that the machine is functioning properly, immediately after that only green power light stays on (when the system is normal).

6. Flow

(1) Adjust the oxygen flow to the value on the flow meter recommended by the healthcare provider.

(2) The adjustment of the oxygen flow is realized by the "Flow" button on the panel. When the "flow" button is pressed long, the oxygen flow jumps at the step distance of 1L/min, and when the "flow" button is pressed short, the oxygen flow jumps at the step distance of 0.1L/min. (As shown in Figure 3) KF08-5YW oxygen concentrator flow regulation can circulate between 0.6-5.0L/min.

WARNING: Do not change the oxygen flow. Keep the oxygen flow constant unless advised by the healthcare provider. Children should be prevented from playing with the adjustment knob on the flow meter, as which will result in changes in oxygen flow. The oxygen flow regulation below 1L/min is not recommended.

NOTE: If a humidifier bottle is used, the nasal cannula should be connected to the gas outlet of the humidifier bottle. Turn on the oxygen concentrator and set it to the desired oxygen flow. The gas should flow smoothly to the nasal cannula, and you should hear or feel the gas flow at the outlet of the nasal cannula. Put your hand in front of the gas outlet of the nasal cannula. If you cannot feel airflow, check the nasal cannula connection for leaks.

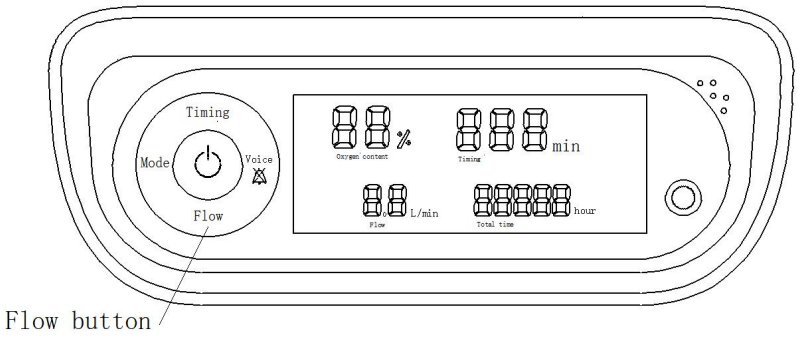


Figure 3

(3) If the flow shown on the flow meter is less than 0.6 L/min, the low flow alert will be activated. There are sharp beeps at this point. Check the tubing and accessories for blockage, the tubes for kinks, and the humidifier bottle for fault.

7. Voice

The oxygen concentrator contains voice prompt function and voice wake-up function, which can be turned on and off by voice button.

Voice prompts: When the oxygen concentrator performs related procedures and functional feedback, it will give voice prompts, such as start-up prompts, button function prompts, alarm prompts, maintenance prompts, etc.

Voice wake-up: the oxygen concentrator has voice wake-up function, which can perform relevant operations according to the user's voice commands. The voice commands and corresponding functions are shown in the table below.

Wake-up word	**Function explain**
Hello,Cofoe	The wake-up command can enable the voice wake-up function, which is the basic command, and all functions

	need to execute the basic command first.
Turn on	Turn on/off the oxygen concentrator
Turn off	
Cancel Timing	
Switch mode	
Pulse flow Mode	
Continuous flow mode	
Set timer for X hour	Example 1: Set timer for 1 hour Example 2: Set timer for 60 minutes Note: Timing time is 30 minutes and 60 minutes or multiples of 1 hour, Timing 5 hours to start timing is multiples of 1 hour.
Change the flow rate to X liters	Change the flow rate to three liters. Change the flow rate to two point five liters. Note: Flow rate adjusted to multiples of 0.1 liters.
Increase / Decrease flow rate	Note: Each increase or decrease in flow step was 0.5L/min

When the environment is noisy, it may affect the recognition sensitivity of the oxygen concentrator to the wake-up command. At the same time, the distance between the user and the oxygen concentrator and the sound intensity of the user's wake-up command will also affect the recognition sensitivity of the wake-up command. It is recommended that the distance between the user and the oxygen concentrator should not exceed 1m when using the voice wake-up.

8. Model

KF08 oxygen concentrator is divided into continuous flow mode and pulse flow mode.

Continuous flow mode: Continuous flow mode means that the oxygen supply mode of the oxygen concentrator is continuous.

Pulse flow mode: Pulse flow mode refers to the oxygen concentrator oxygen supply mode is pulse oxygen supply mode, in the pulse flow mode, the oxygen generator will detect the user's breathing state, when the user is detected in the inspiratory state, the oxygen generator will spray a stream of oxygen for the user in a short time, when the user is detected in the inspiratory state, the oxygen concentrator will not release oxygen.

Pulse flow mode and continuous flow mode can be switched by the mode button. In pulse flow mode, the oxygen concentrator will automatically detect the user's respiratory rate and match the respiratory rate with the preset oxygen supply.

When in pulse flow mode, the original flow display position will be displayed as the current user breathing rate.

When in pulse flow mode, users are not advised to use a humidifier bottle.

Note: KF08 series oxygen concentrator has maintenance reminder function. When the oxygen concentrator maintenance reminder is triggered and the user confirms that the maintenance has been carried out, after the restart, long press the mode button to remove the maintenance reminder.

When using the pulse flow mode, the nasal oxygen tube connected to the oxygen outlet of the oxygen concentrator should be removed first, and then press the mode button. After entering the

pulse flow mode, wait about 3 seconds, and then insert the nasal oxygen tube, otherwise it may lead to inaccurate respiratory rate detection.

Table of respiratory rate and single-pulse oxygen supply

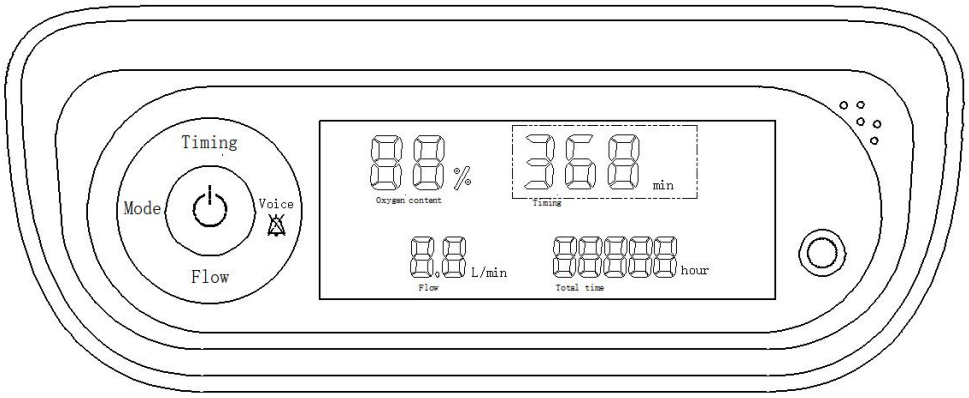
respiratory rate（RR）	single-pulse oxygen supply
0＜RR≤15	35ml±15%
15＜RR≤20	25ml±15%
20＜RR≤25	20ml±15%
25＜RR≤30	16ml±15%
30＜RR≤35	17ml±15%
35＜RR≤40	11ml±15%

Respiratory sensitivity triggers pressure: ＜0.5cmH_2O/s

9. Timing

KF08 oxygen concentrator has timing function, the longest timing time can be 900min, timing button can be long press and short press. Short time, each jump step is 15 minutes, long time, will be 15 minutes as the rapid jump.

At the end of the timing, the oxygen concentrator will automatically stop. The timing time display area is shown in the dashed box in the figure below.



10. Screen off

KF08 Oxygen concentrator has the function of resting screen automatically, when the oxygen concentrator detects that there is no function operation for 3 minutes, the oxygen concentrator will rest the screen automatically, after resting the screen, you can lift it by pressing any button.

11. Oxygen concentration indicator light

The oxygen concentration sensor monitors the concentration of oxygen produced by the molecular sieve oxygen concentrator. If the oxygen concentration falls below the level claimed by the manufacturer, the indicator light on the control panel will be on accordingly.

12. Initial startup of molecular sieve oxygen concentrator

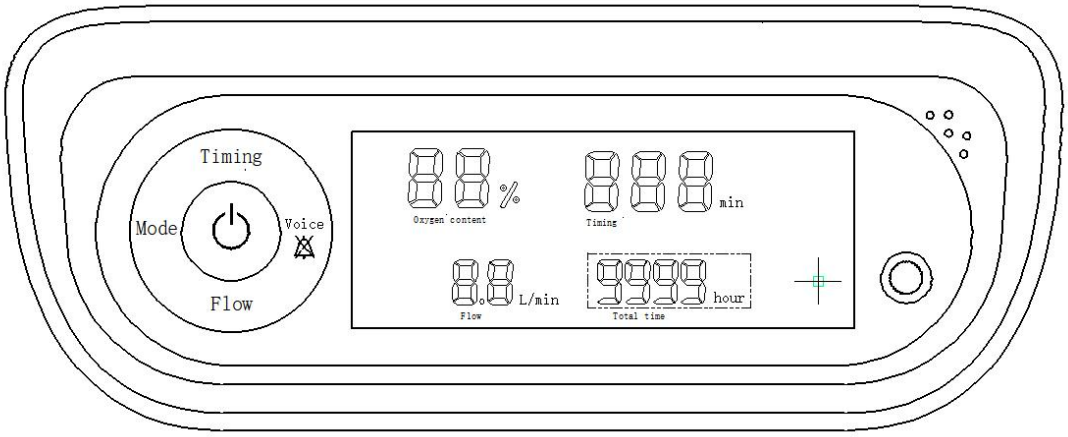
Note: The device can also be used during warm-up, before the oxygen concentration reaches its maximum value.

After the device is powered on, the illumination of the green LED indicates that the system is normal and that the oxygen concentration is greater than 82%. After 2 min, the oxygen

concentration sensor works normally and controls the indicator LEDs according to the oxygen concentration.

13. Hour meter

The hour meter shows the cumulative hours of operation of the oxygen generator. The cumulative hour of operation is shown in the dashed box below.



14. Use of remote control

The oxygen concentrator can use the remote control to perform the relevant button operation function.

15. Moving and handling

When moving and handling the oxygen concentrator, please hold the handle of the oxygen concentrator tightly to prevent the oxygen concentrator from falling or dumping during transportation.

IX. Maintenance and Cleaning

1. Maintenance of Oxygen Concentrator

Note: Routine maintenance shall be implemented by the user or the guardian. The routine maintenance procedures are as follows.

Note: The molecular sieve oxygen concentrator is designed in a configuration that requires minimal times of routine maintenance, which is preferably once a year. More maintenance is required if it is used in dusty or smoky areas. Preventive maintenance shall be performed at least once a year to ensure a longer service life. Maintenance can only be carried out by personnel authorized or trained by the manufacturer. Unplug the power supply before maintenance.

2. Replacement of filter felt and dust filter wool

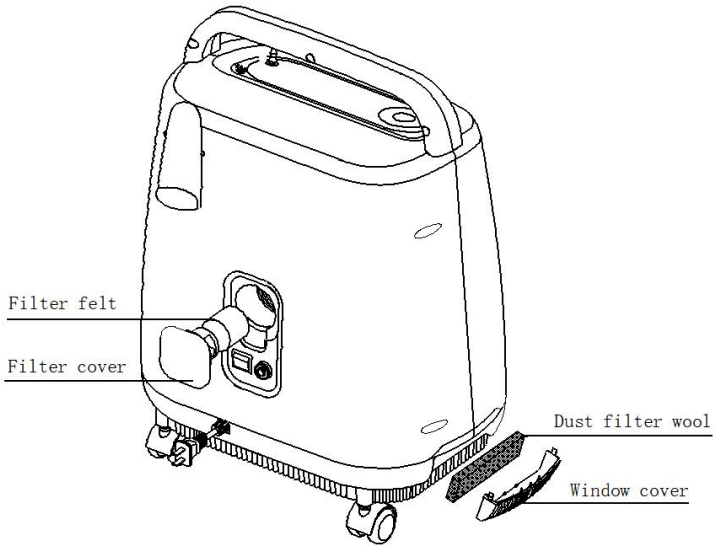
It is very important to replace filter felt and dust filter wool in time to protect the compressor and molecular sieves and prolong the lifetime of the oxygen concentrator.

WARNING:

- Do not operate the oxygen concentrator when the filter felt and dust filter wool are not

installed or are wet, as such operation will result in lasting damage to the machine.

- Filter felt and dust filter wool are normally replaced every 200 hours of machine operation.
- Do not operate the machine without the filter felt installed. Do not operate the oxygen concentrator when the felt is wet.



Disassembly:

- The filter felt is located in the center of the back of the machine and can be replaced when removed from the inside of the filter cover.
- The dust filter wool is located on the left and right sides of the machine base and can be taken out for replacement after opening the window cover.

3. Cleaning of the enclosure and buttons

Wipe the device casing and buttons with 75% alcohol for 3 minutes until no visible residue remains, then allow to air dry or wipe with a clean, soft cloth. Never spray any liquid directly onto the device and avoid allowing liquid to seep inside the device.

WARNING:

- Turn off the power when cleaning and disinfecting the device. Do not disassemble the enclosure without authorization to avoid electric shock;
- During the cleaning process, avoid excessive wetting of the enclosure seams and avoid liquid water from penetrating deep into the interior of the unit, especially vents and power cord plugs;
- It is necessary to wait until the moisture on the surface of the equipment has dried before using the equipment.

X. Fault Alarms, Alerts and Handling

1. Alarms and Alerts

The equipment can give visual alarms and alerts, and audible alarms and alerts to indicate that the equipment is in an abnormal alarm condition or abnormal status, prompting the user to handle it in

a timely manner to prevent damage to the equipment and the patient and ensure the safe use of the equipment.

Visual alarm: When it is activated, the yellow indicator light is steady on and the corresponding alarm code is shown on the display.

Audible alarm: The oxygen concentrator emits 1 beep, which repeats every 18 s or so. The alarm sound shall exceed 62 dB(A) at 1 m away from the equipment.

Visual alert: When it is activated, the red indicator light is steady on, the corresponding alarm code is shown on the display, and the equipment stops working.

Audible alert: The oxygen concentrator emits a set of beeps, which repeats every 6 s or so. The alert sound shall exceed 62 dB(A) at 1 m away from the equipment.

Note: Misoperation of the equipment by non-professionals or delayed handling of alarms or alerts can result in serious harm. Therefore, when an alarm or alert is activated, it is important to exercise caution, have back-up oxygen available, and contact the equipment service personnel. In the case that power outage lasts for no more than 30 s, the alarm settings prior to the power outage shall be automatically restored.

Description of operator position: Intended to be 1 m from the equipment's display.

The alarms given by this equipment are all low-priority alarms in technical alarm conditions with non-latched alarm signals. When multiple low-priority alarms are triggered, the equipment will process them according to the default alarm program.

When the low oxygen concentration alarm or the too low supply voltage alarm is triggered, there will be a delay in the alarm condition, and the alarm signal generation will be delayed for 30 s.

When the power outage alarm is triggered, there will be no delay in the alarm condition and alarm signal generation.

2. Responses to alarms and alerts

Type	Signs and Indication	Solution
Low oxygen concentration alarm (low priority)	Oxygen concentration: 50%–82%; the display shows E7, the yellow indicator light is on, and the equipment emits an audible alarm	Check whether the oxygen flow rate is within the machine's rated range
Low supply voltage alarm (low priority)	The supply voltage is lower than 187 V; the display shows E4, the yellow LED is on, and the equipment emits an audible alarm	Replace the power strip, check whether the power supply is normal, and then restart the equipment after ensuring that the power supply is normal
Power outage alarm (low priority)	The system power supply is abnormally interrupted; the yellow LED is on, and the equipment emits an audible alarm	Replace the power strip, check whether the power supply is normal, and then restart the equipment after ensuring that the circuit breaker is reset normally
Compressor error	The compressor voltage is too high or too low; the display shows E2, the	Stop using the equipment and contact the equipment service

alarm(low priority)	yellow LED is on, and the equipment emits an audible alarm and stops working	personnel
Circulation pressure fault alarm(low priority)	The system circulating pressure is too high or too low; the display shows E3, the yellow LED is on, and the equipment emits an audible alarm and stops working	Stop using the equipment and contact the equipment service personnel
System communication fault alarm(low priority)	The sensor communication is abnormal; the display shows E5, the yellow LED is on, and the equipment emits an audible alarm and stops working	Stop using the equipment and contact the equipment service personnel
Temperature error alarm(low priority)	The internal temperature of the equipment is too high; the display shows E6, the yellow LED is on, and the equipment emits an audible alarm and stops working	Check whether the location of the machine is well-ventilated for heat dissipation. If there is no abnormality, stop using the equipment and contact the equipment service personnel
No-breathing alarm (low priority)	In pulse flow mode, if the user's breathing is not detected, the display shows E8, the yellow LED is on, and the equipment beeps and enters continuous oxygen supply mode.	Check whether the nasal cannula is properly worn.
Low flow alert	The oxygen flow rate is lower than 0.6 L/min; the display shows E1, the red LED is on, and the equipment beeps and stops working	Check whether the flow adjustment is normal Check whether the tubing is blocked or kinked
Low oxygen concentration alert	The oxygen concentration is < 50%; the display shows LO, the red LED is on, and the equipment beeps and stops working	Stop using the equipment and contact the equipment service personnel

3. Alarm inspection

Where necessary, test the machine's alarm system according to the following test method of typical alarm functions to ensure that the alarm system is working properly.

Self-inspection of Power Outage Alarm: After the oxygen concentrator has been turned on and running for 3 minutes, unplug the power cord plug of the oxygen concentrator. The yellow indicator light of the device should turn on and an alarm sound should be emitted.

4. Non-activated condition of alarm signal

When the equipment is in an alarm condition, press the "Voice" button on the panel, the audible alarm will be suspended, the indicator light will still be on, and the content on the display will

remain unchanged. Press the "Voice" button on the panel again, and the audible alarm will be restored.

WARNING: Pressing the "Voice" button only mutes the audible alarm; it does not indicate that the cause of the alarm has been resolved. If the indicator light remains on, it indicates that the alarm condition still exists. Immediately check the device status in accordance with Section X of the IFU and take appropriate measures.

XI. Electromagnetic Compatibility

This product in the working mode meets the requirements of IEC60601-1-2. The EMC standard is developed for the safe use of medical electrical equipment, which specifies that interference from electromagnetic waves generated by the equipment to other equipment, as well as electromagnetic waves emitted by other equipment (cell phones, etc.), shall be controlled within certain limits. IEC60601-1-2 stipulates that users need to be provided with detailed information on the EMC environment for the safe operation of equipment. The following is a description of EMC-related technical statement. (Please refer to IEC60601-1-2 for details).

When this product is operated in an electromagnetic environment specified in this EMC technical data, the essential performance described in its scope of application is not affected.

- Definition of EMC (electromagnetic compatibility);
  - ✧ EMC refers to the ability to meet the following two requirements:
  - ✧ Does not emit intolerable electromagnetic interference noise to other nearby electronic equipment. (Radiation)
  - ✧ The equipment functions normally in an electromagnetic environment where other electronic equipment emits noise or introduces other interference. (Immunity)
- EMC-related technical statements;
  - ✧ Warning: Portable and mobile radio frequency (RF) communication equipment may affect the normal operation of this equipment.
  - ✧ Warning: The user is responsible for ensuring the electromagnetic environment of the equipment so that it can work properly.
  - ✧ Warning: It is prohibited to use this equipment next to a strong radiation source, otherwise it may interfere with the normal operation of this equipment.
  - ✧ Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of KF08-5YW Molecular Sieve Oxygen Concentrator as spare parts for internal components could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment or its system.
  - ✧ Warning: KF08-5YW Molecular Sieve Oxygen Concentrator shall not be used in the proximity of or stacked with other equipment, if it is necessary to use it in the proximity of or tacked with other equipment, whether it works properly under its configurations shall be observed and verified.
  - ✧ Warning: The user shall install and use the equipment as per the EMC information provided in the accompanying documents.

  The EMC information on the equipment is detailed in Tables 1, 2, 3, and 4.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance level**
Electrostatic discharge (ESD) 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
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle

Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**IEC 60601-1-2 Test Level** (V/m)	**Compliance level** (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA	Pulse modulation 18 Hz	28	28
	870					
	930					

			850, LTE Band 5			
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test Frequency**	**Modulation**	**IEC 60601-1-2 Test Level** (A/m)	**Compliance level** (A/m)
	30 kHz	CW	8	8
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	Pulse modulation 50 kHz	7.5	7.5

XII. Quality Assurance

This warranty applies only to the original purchaser/user of our products.

This product is warranted for the original purchaser to be free from defects in material and workmanship within one year. If any such product proves to be defective during this warranty period, we will repair or replace such product in a manner to be determined by the company. This warranty does not cover any labor or transportation costs incurred in the installation, replacement of parts, or repair of any such product. Our sole liability and your exclusive remedy under this warranty are limited to such repair and/or replacement.

Please contact the distributor who sold you the product for after-sales service. If satisfactory warranty service is not available, please write directly to us at the address on the back cover, giving the distributor's name and address, product model, and date of purchase, and stating the nature of the product's defect and the serial number (if any).

The company will issue a letter of authorization for repair. If applicable, the serial number must be used as an identification of the nonconforming component or part to be returned for inspection within thirty (30) days from the date of repair authorization. Products shall not be returned to our factory without our prior consent. Freight charges shall be prepaid as we do not accept a cash-on-delivery shipping method.

Limitations and exclusions: This warranty does not apply to problems caused by normal wear and tear or failure to follow the instructions in the accompanying documents. In addition, the foregoing warranty does not apply to the sequentially numbered products whose serial numbers have been removed or damaged; products affected by negligent, accidental, and improper handling, maintenance, or storage; products that have been refitted without the express written permission of the company, including (but not limited to) refitting using unauthorized parts or accessories; products damaged due to repairs to any component without the express consent of the company; products damaged due to circumstances beyond the control of the company; and products that have been repaired by anyone other than the company's distributors. The assessment of such circumstances shall be determined by the company at its sole discretion.

The foregoing warranty is exclusive and in lieu of any other express warranties (if any), including the implied warranties of merchantability or fitness for a particular purpose.

The duration of these warranties shall not exceed that of the expressly warranted contents set forth in this warranty, and the remedy for breach of the implied warranties shall be limited to the repair or replacement of the defective product in accordance with the terms of this warranty. The company is not liable for any consequential or incidental damage.

XIII. Warranty Card

After-sales Service Card

Customer name		Tel.	
Product model		Purchase date	
Serial Number		Seal by distributor	
Notes: 1. The purchaser is entitled to one year of repair and maintenance for the molecular sieve oxygen concentrator free of charge starting from the date of purchase, provided that the purchase invoice and warranty card are presented, except for the consumable parts (filter wool, filters, and components from other providers). 2. Free warranty services are not available for faults caused by the following reasons: ◆ Faults caused by unauthorized disassembly and refitting of the product;			

◆ Faults caused by lack of reasonable maintenance; ◆ Faults caused by failure to operate correctly according to the Instruction Manual; ◆ Faults caused by improper repairs at the unauthorized repair shops and so on. 3. Reasonable fees will be charged for out-of-warranty repair services. 4. Please contact the distributor when requesting warranty service. 5. When carrying out warranty service, product circuit diagrams and repairable component information may be provided to the qualified technicians recognized by us if necessary.

Service Records	Time	Content

Receipt Card (kept by distributor for review)

Product model	
Sequence No.	
Purchase date	
Customer Information seal by distributor	
Customer name	
Tel.	

【After-sales service】: Cofoe Medical Technology Co., Ltd.

【Address 】: No. 87, Section 1 of Huanbao East Road, Yuhua District, 410000 Changsha, Hunan, PEOPLE’S REPUBLIC OF CHINA

【E-mail】: cofoemedical@cofoe.com