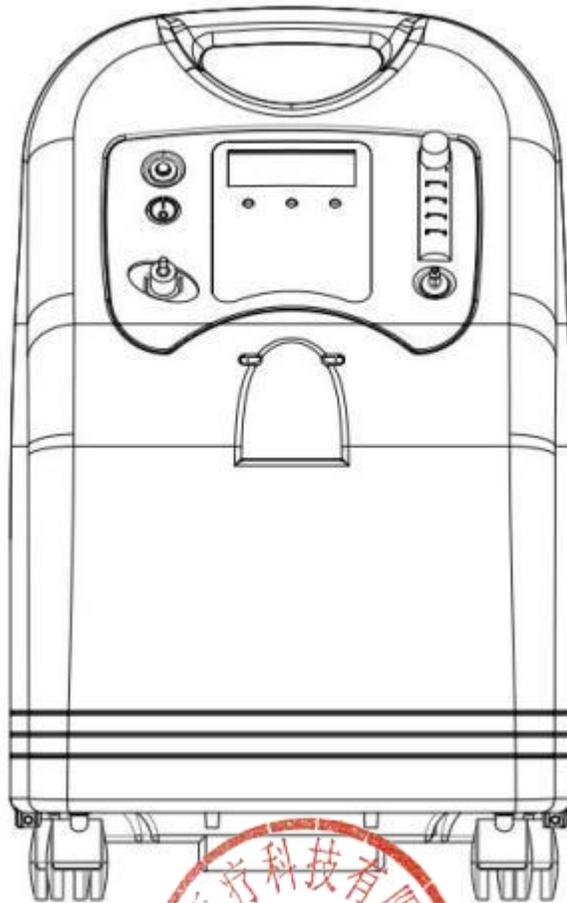




User Manual of V10-W-NS Oxygen Concentrator For Medical Use



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Foreword

Thank you for purchasing our products, hope you will be satisfied with our products.

This manual contains functions, operation steps, attention, technical specifications, trouble shooting and so on.

To ensure your efficient use of the machine, please have a close read of this operation manual before operating it.

Maybe there are some pictures which are different from what you have seen in the actual model.

Warning

- This product cannot be used for life maintaining, it is suggested that if any patient who needs oxygen treatment, please follow doctor's advice to choose the right flow and period for oxygen before using the machine.
- If any adverse reaction appeared or revealed during taking oxygen, please contact with equipment supplier or doctor as soon as possible.
- For serious patients who set an indicating device additional, any adverse reaction appeared, please contact with equipment supplier or doctor as soon as possible.
- Do not put disposable nasal oxygen cannula under bed cover or cushion, the oxygen that caused by machine turning on without breathing may be combustion-supporting.
- Turn off the switch if no body takes oxygen.
- For oxygen can be combustion-supporting, keep oxygen concentrator far away from naked light or fire resource, no smoking or naked light around the patient.
- Oxygen machine, or any attachments containing oxygen within the scope of the 2 m are not allowed to exist flames.
- Before cleaning the dust on the net of oxygen concentrator, the plug must be pulled out in case of electric attack.
- When using the machine, do not open the front and back cover at all. In case there are quality problems, do not dismantle it secretly. Any alarm or other abnormal phenomenon has been found, contact with equipment supplier or manufacturer.
- Do not modify this equipment without authorization of the manufacturer.
- The breathing system hoses may cause strangulation due to excessive length.
- Keep the equipment away from the child and pet.
- Be careful of the small parts of accessories. Don't swallow.
- Contact with the doctor if you got allergic reactions.
- Please use accessories and detachable parts specified/authorized by manufacturer.
- Otherwise, it may cause damage to the unit or danger to the user/patient.
- Oxygen concentrator cannot be mixed with flammable gas, oxygen or mixture of nitrous oxide.
- Do not do lubrication to the spare parts of oxygen concentrator such as connector, tubes and other attachments in order to avoid risk of fire.
- The machine is strictly prohibited contact with oils and greases.
- The machine did not use lubricant, please consult the manufacturer or service provider if needed.

- Only for manufacturer recommended spare parts according to the requirements specifications of the accessories, to ensure normal function and avoid the risk of fire.
- In the altitude of more than [maximum rated at an altitude of 3000 m] or over temperature(-5°C~+40°C] or relative humidity above [15%~90 %] will affect the flow and the oxygen purity, even further affect the quality of treatment.
- Smoking during oxygen therapy is dangerous and could lead to facial burns or death. When oxygen machine or any other entity of oxygen attachments stored in the same room, smoking is not allowed. If you are going to smoke, must be closed oxygen machine, remove the Nasal oxygen cannula, leave the oxygen mask or Nasal oxygen cannula machine room. If you can't leave the room, must wait for 10 min oxygen machine closing for smoking.
- The oxygen machine users (including patients) should have good cognitive ability, can describe the symptoms. The elderly and other communication disorders of patients can't express discomfort or cognitive understanding of oxygen machine icon and instruction for use, or when using this product can't hear or see alarm prompt patients need special care, to ensure the normal use of this product. The operation and use of oxygen machine do not need user special skills.
- If you can't understand this instruction manual, please contact the manufacturer or after-sales service, the company provides consulting and training services, to ensure that users understand this manual when using this product.
- Patients can be used as intended users.
- The equipment cannot be used in a complex environment with electromagnetic interference.
- Spare parts needn't to be replaced during oxygen absorption.
- The maintenance of the equipment is limited to the replacement of air filters and simple appearance cleaning, and disassembly is prohibited. Please contact professional maintenance staff if the equipment fails. Please contact the manufacturer or local distributor if need schematic diagrams and information on key components.

Notice

- The oxygen concentrator should be set to use in an environment without dust, corruption, oxidizer, and toxicological harm gas.
- Air intake of the oxygen concentrator should be located in well-ventilated space, in case there are polluted air or smog in the oxygen.
- Ensure the bottom exhaustion smooth during operating, or else the machine will be over-heated.
- There is intermitted exhaustion sound during operating (8 seconds in intermission).
- 5 minutes are needed for oxygen concentrator from warming up to reach regular function. In the startup process, when oxygen purity doesn't reach the rated purity, oxygen purity drop icon appears on the LCD without sound and light alarm. Don't need to take any measures at this time, such as oxygen concentrator running stable, Alarm automatically eliminate. Users are requested to take oxygen after the alarm is removed.
- The machine is only for medical oxygen supply, and the oxygen concentration will be up to 90% when air outlet reaches its rated flow.
- Humidifier shall adopt distilled water or cold boiled water, added shall be kept under the scale line.

- Use the humidifier bottle with the machine, do not replace it at will, or else may cause patient uncomfortable or other harms.
- In case state indicator shows abnormal oxygen operator should declare to dealer or factory in favor of maintain.
- The humidifier, filter paper and filter are the items needed to clean, among which humidifier should be cleared every 3 days, and external filter paper should be cleared every 100 hours, and filter paper should be cleared every 1500 hours.
- Once open the adjust knob for flow in full, but oxygen outlet feel no gas, turn off the machine immediately and have a check for trouble.
- Do not turn on and off frequently: To restart the machine after turning off should have an interval no less than 5 minutes (exhaust internal gas of the machine completely, avoid air compressor turns on with pressure will shorten its life)
- Do not turn on the power with flow switch adjusting shut up.
- Refresh the water in the humidifier bottle every 2-3 days, especially in summer. If do not use it in several days, please pour out the water completely, and wipe dry the bottle
- Use the Nasal oxygen cannula and humidifier bottle with the machine or those of the same model, if change to use other model devices, please ensure close connection with the oxygen concentrator. The Nasal oxygen cannula is only for the patient, and do not throw it at will.
- The Nasal oxygen cannula, oxygen mask and aerosol mask that have touched with the patient should keep clean, disinfected and sterilized.
- The Nasal oxygen cannula that have touched with the patient after each operation should be disinfected by wiping it with 75% medical use alcohol or other disinfecting methods. To prevent cross infection, do not share Nasal oxygen cannula.
- 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 remove the cover by unauthorized persons.
- Medical equipment waste treatment, according to the local medical waste treatment related regulations, or returned to the manufacturer centralized treatment, the use of waste materials should be destroyed, disinfection, waste.
- In order to the effectiveness of the treatment, the output of oxygen concentrator should be set intervals of one year. Assessment may contact after-sales service department.
- The alarm system should be verified by professionals; you may contact maintenance personnel validation needed.
- The machine pressure relief devices (valve) is located in the compressor outlet, pressure is $300 \pm 10\%$ kPa.
- The oxygen concentrator use power plug as isolation measures of net power disconnected, so please do not fixing the oxygen concentrator, to prevent an emergency oxygen machine is disconnected from power net connection.
- The Nasal oxygen cannula and aerosol mask are single-use, please don't reuse.

- The device should be set to use in an environment without dust, direct sunshine. Because of the small parts of accessories, in order to prevent children from accidentally swallowing, it should be placed away from children.
- To ensure the normal use of the device, please use accessories and detachable parts specified/authorized by manufacturer.
- Please use the nasal oxygen tube that meets the requirements of accessories list. Do not use too longer oxygen tube to prevent any breathing discomfort or death due to neck twining during sleep.
- When the storage temperature is close -25℃ and 70℃, please place the oxygen concentrator in the environment of ambient temperature for two hours to recover, then electrify to use, to protect the oxygen concentrator from damage.
- Position of nasal cannula in the nostrils and the direction of the oxygen outlet determine oxygen output to patient's respiratory system. The user should wear nasal cannula properly. So that can get good therapy.
- The user and/or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- This product is not intended for use in MR environment.

Product introduction

The oxygen concentrator adopts pressure swing adsorption principle, which can separate oxygen, nitrogen and other gas from the air. At normal temperature, as soon as power is connected, the oxygen can be separated from air constantly. Oxygen is generated by pure physical method. There is no influence on indoor oxygen percent during the concentrator operating.

It is not suitable for patients who are in urgent need of oxygen, severe patients and those who have no spontaneous breathing function during surgery.

Intended purpose: The Oxygen Concentrator for Medical Use is mainly used for generating oxygen with purity above 90%, and is used to provide high purity oxygen to adults who are diagnosed as needing supplemental oxygen. It can be used in hospitals, homes and offices, not as life support equipment.

Contraindications: This device is not intended to be life-sustaining or life-supporting; This device is not intended for pediatric use; Smoking cigarettes while undergoing treatment, especially during treatment, is prohibited.

Intended patient population: The Oxygen Concentrator for Medical Use is used for adults.

Intended user: The Oxygen Concentrator for Medical Use is intended for use by medical staff and lay persons.

Shell material: ABS

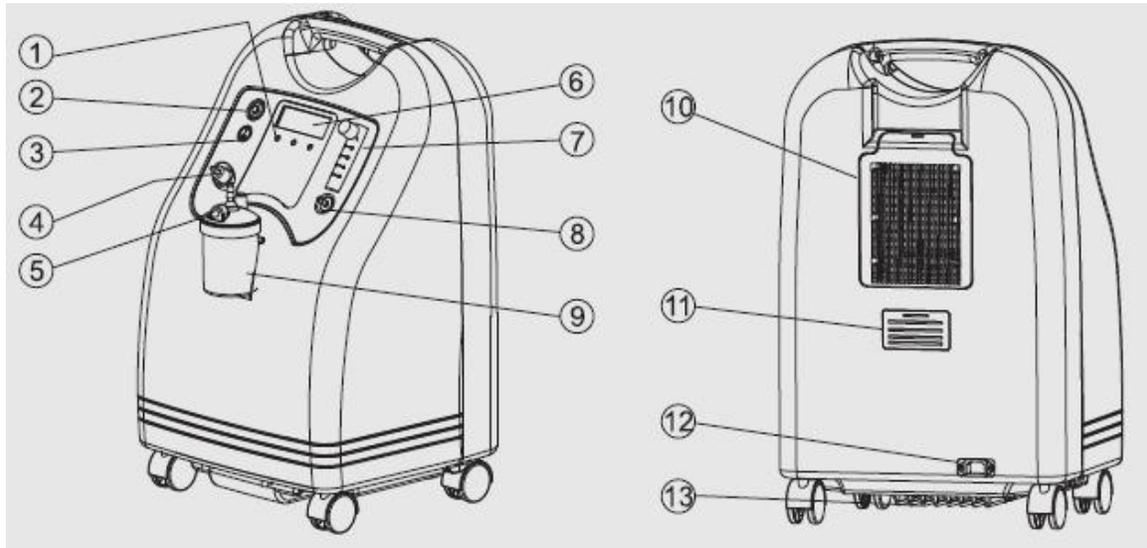
Applied parts: Nasal oxygen cannula, Aerosol mask (Aerosol mask with CE-mark and within the validity period; Connection tube with inner diameter of ϕ 6mm).

Net Weight (kg)	25
Dimension (mm)	W390×D337×H620
IP Classification	IP 21
Atomization Particle	$\leq 5\mu$ reaches 90% only for atomization type

Symbols

Symbol	Description
	This way up
	Fragile handle with care
	Keep dry
	Stacking limit number
	OFF(power)
	ON(power)
	Manufacturer
	Authorized Representative in the European Community
	Refer to instruction manual/booklet
	No open flame; Fire, open ignition source and smoking prohibited P0003
	Alternating current
	Batch code
	Use-by date
	Sterilized using ethylene oxide
	Do not re-use
	Do not use if package is damaged
	Consult instructions for use
	Type BF Applied Part
	Class II
	Date of manufacture
	Caution
IP21	2 Protected against solid objects of 12.5mm and greater 1: Protection against vertically falling water drops
	Serial number
	Be careful of your feet while moving the machine
	CE mark
	Medical device

Operation introduction



1) Indicator light

Total 3 indicator lights, and the code of them are 1,2,3 from left to right, and their indication for each model are as follows:

1. Power indicator (green), Power-off alarm (red)
2. Trouble indicator, proper functioning(off), defective happened(Red)
3. Oxygen percent (green-normal, yellow alarm the oxygen percent is lower than 82%)

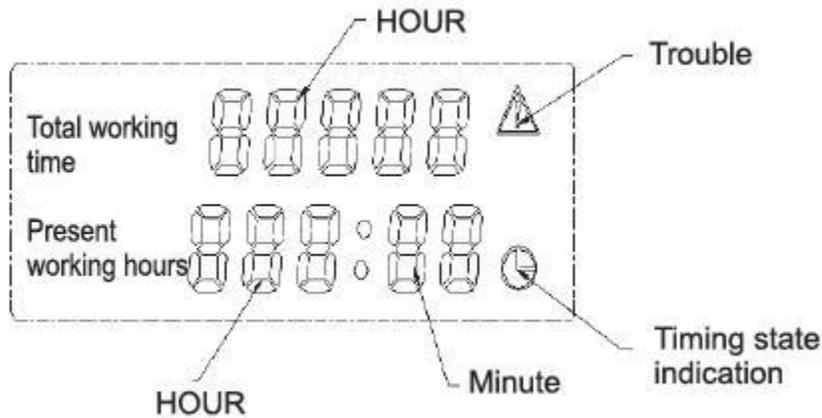
2) Resettable short circuit protection switch

3) Power switch

4) Function switch for setting timing of oxygen supply

5) Liquid crystal display. It can display cumulative operation time and start time of this time, which may guide the user to operator concentrator in a more scientific and safe way.

6) Knob of oxygen flow meter Switch is flow control valve(L/min). It adjusts and controls the outlet oxygen flow. Do not Switch it over-forced, or else it is easy to damage the valve core. Switch it counterclockwise to turn on, clockwise to turn off.



7) Oxygen outlet mouth

8) Humidifier

Dampen bottle also called oxygen humidifier which used for humidifying oxygen and preventing throat and nasal mucosa stimulated by dry oxygen and dry sputum difficult to spit out.

9) Intake air filter

Once need to replace, replace it by special assembly for the machine.

10) Data plate

11) Power socket

12) Exhaust Port

Operation steps for first time using

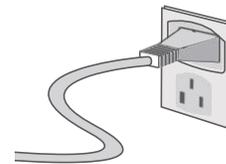
1. Take off the Humidifier Bottle. Fill in proper distilled water or cold boiled water within the scale between the top scale line and the lowest one.



2. Position of Humidifier Bottle. Please place the Humidifier

Bottle on the back casing and fixed. Then connect the disposable nasal oxygen cannula to the oxygen outlet.

3. Connect the power, put the plug of power line connected with the power socket of the oxygen concentrator, and the other end of the plug connects with indoor power socket, turn on the power switch.



4. Adjust well oxygen output flow according to the request, the green part at the bottom of the flow meter is recommended oxygen flowrate (counterclockwise-On, clockwise-Off, for common single treatment, the flow may be adjusted to 1.5-2L/mln, for double use, the flow may be adjusted to $\geq 3L/min$).

5. Nasal oxygen cannula by ethylene oxide sterilization, before use to ensure that the packaging in good condition, packing damage do not use. Put the Nasal oxygen cannula inlet end of wetting bottle on the export of appropriate unobstructed flow of gas to the Nasal oxygen cannula, can hear or feel the Nasal oxygen cannula of the outlet of the air. Their hands into the Nasal oxygen cannula in front of the air outlet, if you can't feel the air flow, check leakage Nasal oxygen cannula connection. After confirming the Nasal oxygen cannula was not leaking, the Nasal oxygen cannula set in the ears of oxygen, insert the disposable nasal oxygen cannula blocked nose the nostrils of the oxygen in oxygen.

6. When finished the absorbing, turn off the power, if there is discontinuity use, please unplug the power plug. The oxygen concentrator net electrical connection power cord plugs unplug from the net electrical outlet.

7. If the patient need timing oxygen absorbing, first, press the M switch of continue / timing, then the timing clock flickers, and adjust the timing time by ▲ ▼ keys, and finally, press ← confirm the timing state. Under the timing state, it is able to switch to continue state by pressing the M switch which can covert between continue / timing.

8. Oxygen purity alarm is a new function after turning on the oxygen percent indicator, which is on the oxygen Concentrator, shows the oxygen percent that measured before last turning off, judging by the color of the indicator, green indicate normal operation, yellow indicate that the machine needed maintenance or servicing. After 5 minutes (the time for pre-hot of internal oxygen percent sensor) it indicates the scale of oxygen purity that produced after this turning on. Oxygen purity measurement is timing simple mode. When the machine is in the condition of oxygen generation, it measures oxygen purity continuously.

9. In case oxygen concentrator is connect with power but the whole machine is still in the state of power off with alarm sound, please check out the connection part of power whether it is in good connection, or whether there is a power off in external power supply.

Self-diagnoses Function

Alarm status	Technical alarm				
Name of alarm	Low oxygen concentration alarm	High temperature alarm	High pressure alarm	Low pressure alarm	Power failure alarm
Alarm level	Medium	High	High	High	Medium
Alarm mode	Sound-light alarm				
Sound alarm	Beep- Beep- Beep	Beep- Beep- Beep- Beep-	Beep- Beep- Beep- Beep-	Beep- Beep- Beep- Beep-	Continuous sound for more

		Beep- Beep- Beep- Beep- Beep- Beep	Beep- Beep- Beep- Beep- Beep- Beep	Beep- Beep- Beep- Beep- Beep- Beep	than 1 minute
Alarm volume dB(A)	55	60	60	60	55
Visual alarm	Indicator flash	Indicator flash	Indicator flash	Indicator flash	Indicator always bright
Alarm light color	Yellow	Red	Red	Red	Red
Alarm delay	10s	5s	5s	5s	No
Alarm preset value	<82%	>46°C	>300kPa	<1atm	

The alarm pre-value cannot be adjusted.

The alarm system needs to be verified by professionals, if you need verification, you can contact the maintenance personnel.

If the equipment is used in a separate area with the same or similar equipment at the same time, please do not confuse it with the alarm preset value of other equipment. The operator needs to operate the oxygen machine in front of the operation panel of the oxygen concentrator.

Alarming code list: In alarming mode, the alarming indicator will be on as well as the sound indication, and the number was displayed on the screen will notify the end user for what happened.

Code “10000” - Overheat warning

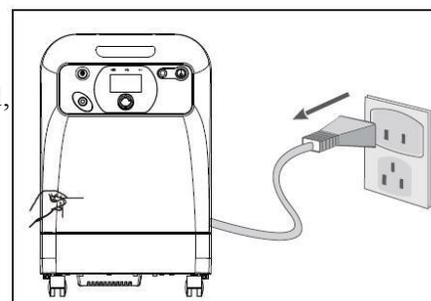
Code “00300” - Over pressure warning

Code “00040” - Low pressure warning

Note: Please contact the local after sales service people when the machine is in alarming.

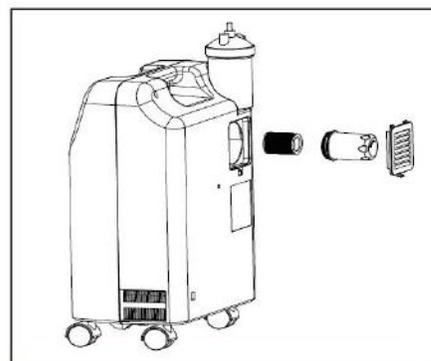
Maintenance description

1. In the condition of power off, make a clean for the outside body by soft towel with little detergent, and then wipe it up with dry towel, once or twice per month.



2. It is a critical step for daily maintenance to clean filter net for gas intake, at least twice a month.

Detail steps: Please clean the filter window by liquid detergent,



then rinse the filter window by clean water, please wait the filter window dry in air.

3.Clean air intake filter

Clean air intake filter an interval about 1000 hours, open the filter window on the back casing, then unplug and replace the filter bottle inside.

4. If the oxygen machine is not likely to be used for a while, open the intake window at the back of the machine and remove the battery.

5. The internal battery replacement (Operation by manufacturer). Remove the inlet filter window on the back of the machine, remove the batteries in the lower right corner. Installing a new battery must pay attention to the battery terminals are negative and is negative. Battery terminals and card prison after the battery back on the lower right corner, the inlet filter window card back to the original position.

Condition for transportation and storage

Environment temperature scale: -25°C - 70°C

Comparative humidity scale: $<95\%$, No condensation

Air pressure scale: 700 hpa - 1060 hpa

Note: Please do place the machine at a good ventilation area, please make sure that the exhaust port underneath the machine not be covered.

Packing list(with replaceable parts)

Oxygen concentrator 1 unit

User manual 1 piece

Disposable nasal oxygen cannula 2 pieces

Quality certification 1 piece

Power line 1piece

Air intake filter net 1piece(replaceable part)

Plastic T-connector 1set

Paper Filter 1piece(replaceable part)

Warranty Card 1 piece

Humidifying bottles 1piece

Quality Warrant

Scale for the whole machine repair: one year guarantee.

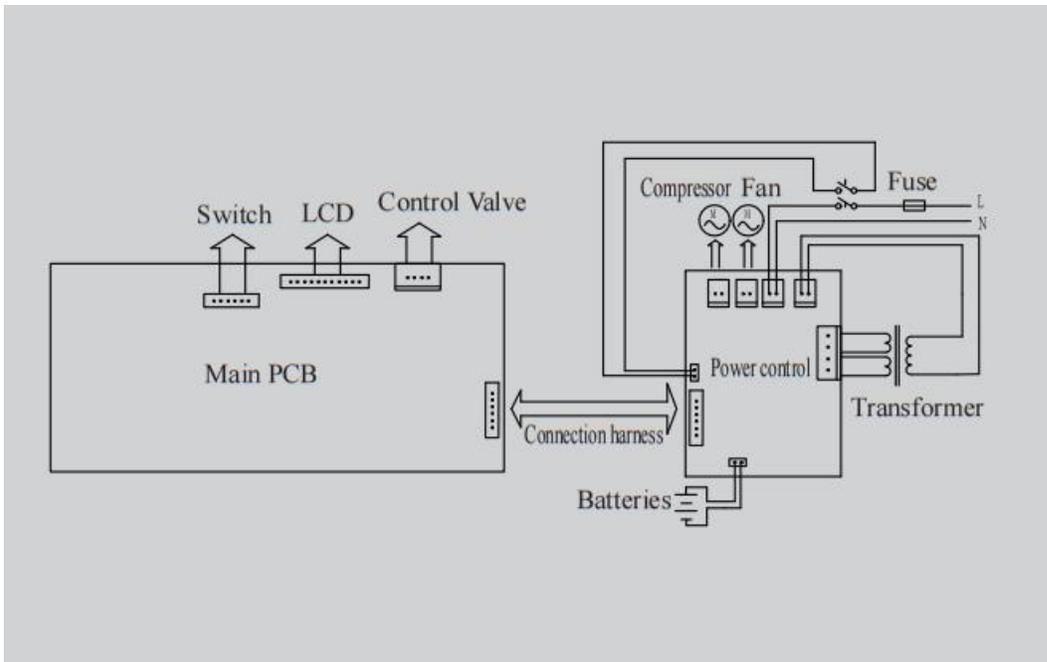
The expected service life of the equipment is 20000 hours or 5 years whichever comes first.

Troubles and solution

When necessary, the manufacturer may provide to the designated maintainer information such as circuit diagram, component list, legend or calibration method.

No.	Trouble	Causes	Solution
1	No operation after power connected	<ol style="list-style-type: none"> 1. No connection between circuit of oxygen generator and power. 2. Circuit of fuse protector broken. 3. Capacitor of compressor broken. 4. Compressor broken. 	<ol style="list-style-type: none"> 1. Check out whether switch plug, power line in good connection. 2. Replace the fuse protector and find the cause. 3. Replace start capacitor. 4. Have the compressor replace
2	No oxygen out or tiny outtake flow	<ol style="list-style-type: none"> 1. Folded inside oxygen tube, no smooth outtake. 2. Filter clogged, no smooth intake. 3. The cover of dampen bottle leaking. 	<ol style="list-style-type: none"> 1. Connect the oxygen tube again. 2. Clean the filter. 3. Take off the cover screw well the cover. block the outtake by thumb after turning on. and there will some sound from the dampen bottle after 5 second around(the safety valve of dampen bottle turns on.
3	No exhaust sound	<ol style="list-style-type: none"> 1. Air controller cannot work. 2. Electrical control board cannot work. 	Have air control valve replaced Have electric control board replaced
4	Too noisy exhaustion	<ol style="list-style-type: none"> 1. The joint of exhaustion muffler fallen off. 2. Exhaustion muffler broken. 	Connect the joint well Have the muffler replaced

Connection diagram



EMC Information

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded	Number	Cable classification
AC Power Line	1.5m Unshielded	1 Set	AC Power

Important information regarding Electro Magnetic Compatibility (EMC)

The Oxygen Concentrator for medical use needs special precautions regarding EMC and put into service according to the EMC information. provided in the user manual; The Oxygen Concentrator for medical use conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- 1.The Oxygen Concentrator for medical use with no ESSENTIAL PERFORMANCE/Following ESSENTIAL.
- 2.The Oxygen Concentrator for medical use is intended used in a HOME HEALTHCARE ENVIRONMENT.

ESSENTIAL PERFORMANCE:

- 1.Oxygen flow rate and accuracy: V10-W-NS: 10L/min, $\pm 10\%$
- 2.Oxygen outlet concentration level: $\geq 90\%$ (reach stated oxygen concentration level after turning on the machine for five minutes)
- 3.Oxygen outlet pressure: 40Kpa $\pm 10\%$
- 4.Power failure alarm: Sound and light alarm. When the oxygen concentrator is turned off.
- 5.Oxygen concentration alarm: When oxygen purity of the oxygen concentrator is lower than 82%($\pm 3\%$),will send out visual and sound alarm.

6. Temperature alarm: When gas temperature up to $46^{\circ}\text{C}\pm 2$ in the ultrasonic tube, will send out visual and sound alarm.

7. Start-up period ALARM: The time from turn on to the desired oxygen purity of the device is 5 min, during this time, the low purity prompt will appear on the screen. It will disappear once it reaches the desired purity. there will be sound and light alarm if the desired purity is not achieved after 5min.

WARNING:

1. 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 Oxygen Concentrator for medical use, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

The use of accessories, and cables other than those specified by Shenyang Canta Medical Tech. Co., Ltd., with the exception of accessories and cables sold by Shenyang Canta Medical Tech. Co., Ltd. of The Oxygen Concentrator for medical use as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Oxygen Concentrator for medical use.

When the AC input voltage is interrupted, the Oxygen Concentrator for medical use will shut down and if the power supply restored, it should be recovered by operator manually, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

Guidance and Manufacturer's declaration-electromagnetic emissions is intended for use in the electromagnetic environment specified below. The customer or the user of the Turtle series should assure that it is used in such an environment.

EMI Compliance Table

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment-guidance
RF emissions	CISPR 11 Group 1, Class B	The device uses RF energy only for it's internal function. Therefore, it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic distortion	IEC 61000-3-2 Class A	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network.
Voltage fluctuations and flicker	Compliance	

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz

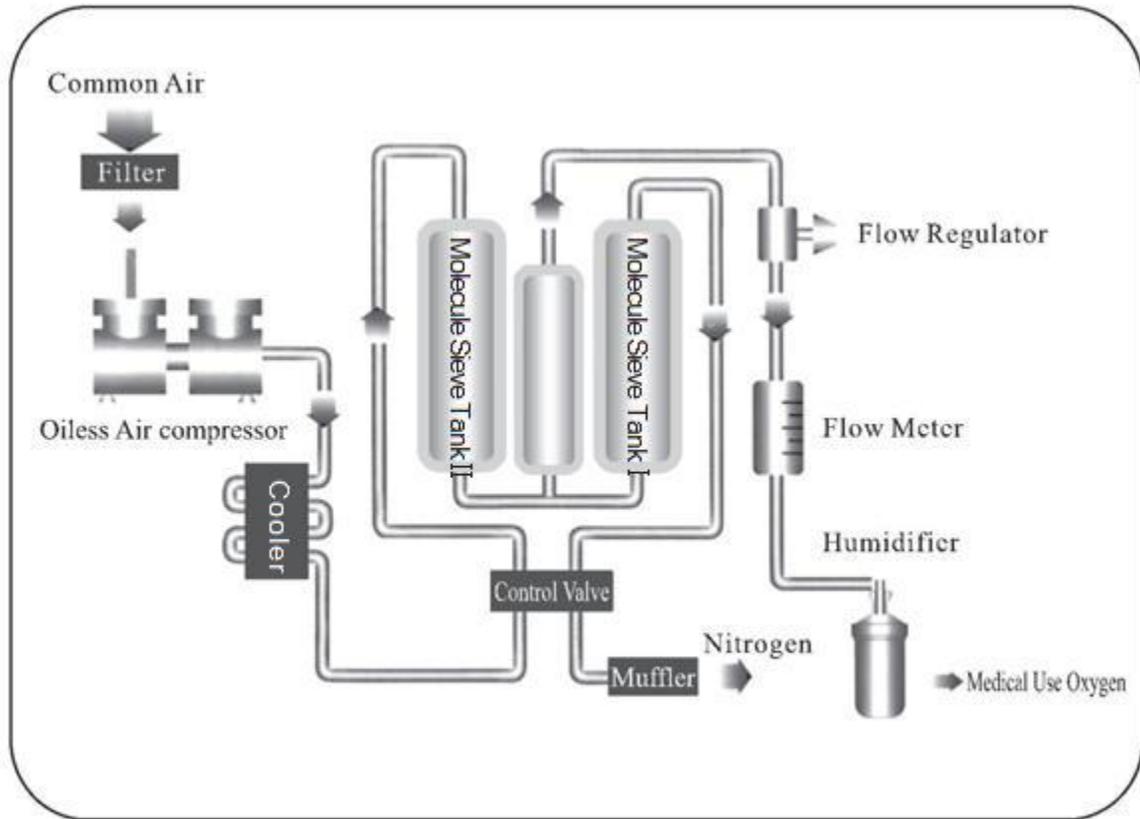
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency(MHz)	Band(MHz)	Immunity test levels
385	380-390	Pulse modulation 18Hz,27V/m
450	380-390	FM,±5kHz deviation,1kHz sine,28V/m
710	704-787	Pulse modulation 217Hz,9V/m
745		
780		
810	800-960	Pulse modulation 18Hz,28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz,28V/m
1845		
1970		
2450	2450-2570	Pulse modulation 217Hz,28V/m
5240	5100-5800	Pulse modulation 217Hz,9V/m
5500		
5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV,±1 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V,0.15MHz-80MHz 6V in ISM bands and amateur radio bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U _T ; 0.5 cycle At 0°,45°,90°,135°,180°,225°,270° and 315°
		0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U _T ; 250/300 cycles



Classify

Classify by type of Anti-shock: class II of External power supply device.

Classify by degree of resistance to electric shock: BF application part;

Classify by degree of Anti-entry liquid: Non-anti-entry liquid device;

Classify by safety level when use it with flammable anesthetic gas mixed with air and air, flammable anesthetic gas mixed with nitrous oxide: can't use with flammable anesthetic gas mixed with air and air, flammable anesthetic gas mixed with nitrous oxide.

Classify by operation mode: Continuous operation device.

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