USER'S Manual FOR Oxygen Concentrator



Important: Make sure you read and understandall of the information contained in this manual before operating your oxygen concentrator!

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1. Foreword

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

This operation manual contains function, operation steps, basic trouble solution and so on.

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

2. Symbols

The following table is a list of symbols and definitions that used with the Oxy-pure Oxygen Concentrator.

Symbol	Description	Symbol	Description
WARNING	Warning – Describes a hazard or unsafe practice that can result in severe bodily injury or death	C € 0197	Indicating its conformity with the Medical Devices Directive 93/42/EEC.The 0197 is the number of the Notified Body.
CAUTION	Caution – Describes a hazard or unsafe practice that can result in property damage		"ON" (power)
	Follow User's Manual		"OFF" (power)
	CLASS II equipment	SN	Serial number
EC REP	Authorised Representative in the European Community		Separate collection for electrical and electronic equipment

À	Type BF Applied Part, F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS		Variability, rotational adjustment. To identify the control by means of which a quantity is controlled. The controlled quantity increases/decreases by rotation with the figure width.
\sim	Date of manufacture	~	Alternating current
***	Manufacturer	F6.3AL/ 250V	Type and rating of fuse
1	Fragile, handle with care		Keep dry
<u> </u>	This way up	X[=]	Stacking limit by number
	No open flame; Fire, open ignition source and smoking prohibited	4	No smoking

3. Safety notice

Can be hazardous, 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 oxygen concentrator.

warring: In the event of an alarm, you observe your oxygen concentrator not working properly, or if you feel discomfort, consult your Equipment Provider and /or your physician immediately.



ARNING: Use only voltage specified on rating label.

WARNING: This device manufactures high concentration oxygen, which promotes rapid burning.

Keep oxygen concentrator far away from open flames and no smoking around the patient.

is turned on without use, the oxygen will help the flammable material get fire.

WARNING: Use no lubricants, grease, or petroleum-based products on or near your oxygen concentrator.

Electrical shock hazard. Do not remove covers while the unit is plugged in. Only your Equipment Provider or a qualified service technician should remove the covers or service the unit.

Care should be taken to prevent the unit from getting wet or allowing water to enter the unit.

(I) :The oxygen concentrator should be set to use in an environment without dust, corruption or toxicological harm gas.

<u>1</u> :Do not place the oxygen concentrator in surroundings where its airflow is obstructed.

I) CAUTION: Do not place items on top of the concentrator.

(Always place the concentrator on a hard surface. Never place the concentrator on a surface such as bed or couch, where the concentrator may tip or fall.

[NEVER leave the concentrator unattended when plugged in.

(! \ CAUTION :Ensure the bottom smooth exhaustion during operating, or else the oxyger

concentrator will be over-heated.

(I) Solution 5 minutes are needed from oxygen concentrator from warming up to reach regular function and nominal performance.

NOTE: If oxygen does not seem to flow, first verify that the flowmeter ball is registering a flow. Then, place the tip of the cannula into a glass of water; if bubbles come out of the cannula, oxygen is flowing. If bubbles do not appear, turn off the oxygen concentrator immediately and refer to Troubleshooting.

NOTE: There is never a danger of depleting the oxygen in a room when you use your oxygen concentrator.

Radio Frequency Interference

Most electronic equipment is influenced by Radio Frequency Interference (RFI). When there is strong electromagnetic interference, maybe the LCD will be slightly affected, but the oxygen concentrator is still running. ALWAYS exercise CAUTION with regard to the use of portable communications equipment in the area around such equipment.

Requirement of environment protection

The materials used in the system won't create environment hazard. The packing materials of the system are recyclable, and they must be collected and disposed according to the related regulation in the country or region where the package of the system or its accessories is opened. The nasal oxygen tube is made of medical PVC, and if it is thrown away, it could not be bio-degradable, so it will cause the pollution. Any material of the system, that may cause pollution in the environment, must be collected disposed strictly complied with the local rules and requirements.

Contraindication

None.

4. Product introduction

Medical oxygen concentrator is a device that extracts oxygen from atmospheric air. It will typically be an electrically-powered molecular sieve (artificial zeolite) used to separate nitrogen from ambient air. It could be applied widely in the hospitals at all different level, clinics, health centers and family nursing, health care for the old person, mental workers and students, etc.. Whether the user is professional or not, the users could operate the oxygen concentrator by themselves after reading this user's manual. The oxygen concentrator can supply 1 patient, with steady oxygen flowing out, safe and reliable, low cost, adjustable flow. The key parts of the concentrator adopt anti-tiring and anti-aging design.

5. Operation conditions and Environment

Ambient temperature: 10°C-40°C

Relative humidity: 30%-85%

Air pressure: 700 hPa-1060 hPa

Altitude: Up to 2286m without degradation; Consult your equipment provider for further information regarding to 2286m to 4000m No corrosive gas and strong magnetic field around.

6. Scope of application:

For Medical Use:

Medical oxygen supplied by the concentrator is beneficial to cure the disease or heart and blood vessel system, chronic pulmonary system, the brain and blood vessel system, chronic pulmonary tuberculosis, and other oxygen lacking symptoms, etc.

For Health care:

Medical oxygen can be used for athletics and intellectuals and brainworkers, etc. to eliminate fatigue and also suit for the departments of health care, sanatorium, healthy, plateau military camps and hotels and other places where need oxygen.

7. Technical Parameters

Rated power (VA)	300
Operation voltage (V/Hz)	AC230/50
Oxygen flow (L/min)	0.5-5
Oxygen concentration (%)	93%±3%
Outlet pressure (Mpa)	0.04—0.07
Alarm	Power failure; low&high pressure; low purity; temperature(optional)
Noise (dB(A))	≤43
Large LCD display	Pressure digital(accuracy:0.001MPa); accumulating timing(range:0- 99999 hours); present timing(accuracy:1 minute); presetting timing(accuracy:1 minute) Optional: temperature digital(accuracy:0.1);
Electrical category:	Class II, Type B
Net Weight (kg)	16
Dimension (mm)	280 (deep)*348 (width)*51 0(height)
Low purity alarm (OCSI)	When oxygen purity is \square 85%, the blue lamp is on, when oxygen purity is <85%, red lamp is on, indicating low purity Accuracy: $\pm 3\%$
Mains Fuse	F6.3AL/250V

8. Structures and Functions





Figure 1 Figure 2

8.1 Indicating Lamp

Total 6 indicating lamps and their indication for each model are as follows:

- a. P.O.: power switch (green lamp)
- b. P.F.: power failure(red lamp)
- c. L.P.: low pressure(yellow lamp)
- d. H.P. /H.T: high pressure/over heated temperature (red lamp)
- e. H.O₂: oxygen purity is □ 85%, (blue lamp)(Accuracy:±3%)
- f. L.O₂.:oxygen purity is < 85%,(red lamp)(Accuracy:±3%)
 - 8.2 Power switch

8.3 Oxygen flow meter

The location of float in the oxygen flow meter shows the outlet oxygen flow (L/min.).

8.4 Knob of oxygen flow meter switch

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.

- **8.5 Outlet for Atomization** (optional)
- 8.6 Intake air filter

Once need to replace, refer to **11.2** on page15

8.7 LCD display(Liquid crystal display)

- a.. It can display some status of during operation of the oxygen concentrator, refer to **7.** on page 9
- b. When starting the oxygen concentrator, the LCD screen is lighted, and it will return to screen saver mode in 15 minutes. But if you press the right key during working, the screen will be lighted again.

8.8 Timing buttons

The two buttons are used for timing adjustment, and each press of the left button(Δ) will increase timing by 10min, the max timing is 40 hours. And each press of the right button(∇) will decrease timing by 10min. When the right button(∇) is pressed to reduce timing till "0", the oxygen concentrator will turn off automatically.

8.9 **Humidifier**

Humidifier which is used for humidifying oxygen and preventing throat and nasal mucosa stimulated by dry oxygen and dry hard sputum difficult to spit out.

- 8.10 **Knob of Atomizer switch** (optional)
- 8.11 Rating label
- 8.12 **Appliance inlet**
- 8.13 Holder

9. Operation instructions

The plug is the disconnection device of the oxygen concentrator, when the plug is pulled, there is no power supply. In order to pull the plug easily, be certain to place the unit where all sides are at least 30 cm away from walls, draperies, furniture, or other obstructions. Do not place the unit in a confined area.

:Do not turn on or off frequently. To restart the oxygen concentrator after turning off, no less than 5 minutes are necessary (namely, exhaust internal gas of the oxygen concentrator completely, for if air compressor turns on with pressure, its life will be shortened)

9.1 If used with a humidifier, unscrew the flask from the humidifier in clockwise direction, pour in proper distilled water or cold boiled water within the scale between the max line and

the min line (see 11.4), then re-connect the top cover to the humidifier bottle, as shown in Figure 3 and Figure 4. The humidifier used with Oxy-pure must comply with the general

requirement of the 93/42/EEC European Directive as appropriate.





Figure 3 Figure 4

9.2. connect the nasal oxygen canula to the humidifier outlet nozzle or to the concentrator outlet if a humidifier has not been prescribed. Then set the nasal oxygen cannula over patient's ears, insert the nasal oxygen cannula into patient's nostrils to absorb oxygen; The nasal oxygen canula should be limited to 20 meters long, in order to ensure that the oxygen flow rate remains within specification values. The best absorbing time for health care keeps 40-50 minutes per time, absorbing time for medical treatment shall be followed doctor's advice, as shown in Figure 5.

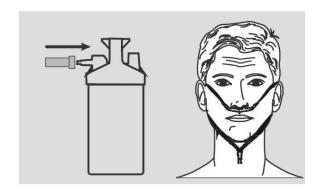


Figure 5

9.3. Insert the power plug plug into the electrical outlet of the correct voltage and frequency as defined in **7**(Technical Parameters)on page 8, and the power connector connected with

the appliance inlet of the oxygen concentrator, then set the I/O power switch to the "I" position to turn the unit on, at the same time the O.P. lamp will light(**8.1a**).



Figure 6

9.4. To set the flow of supplemental oxygen, turn the knob of oxygen flow meter switch left or right until the ball inside the flowmeter centers on the flow line number recommended oxygen absorbing flow.(counterclockwise—on, clockwise—off).

Figure 7

Flow value:

10position flow value from $0.5 \sim 5$ L/min on flowmeter as shown in Figure 7. The maximum recommended flow: 5L/min.

In compliance with the EN ISO 80601-2-69 standard, the flow supplied is equal to the flow set on the flowmeter, accurate to within \square 10% or 200ml/min, whichever is the larger of the two.

The variation of the maximum recommended flow does not exceed $\ \square$ 10% of the indicated value when a back pressure of 7kPa is applied to the output of the device. The maximum outlet pressure is 70kPa

Oxygen Concentration:

-at 2L/min: >90%

-at 5L/min: 93%(□ 3%)

List is very important to select only the prescribed level of oxygen. Change the flow selection only under the guidance of your physician.

9.5. When finished the absorbing, set the I/O power switch to the "O" position to turn off the unit, if there is discontinuous use, please unplug the power plug, as shown in Figure 8.

Unplug the power plug

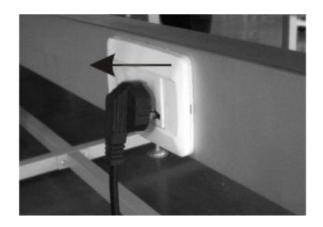


Figure 8

9.6. If the patient needs timing oxygen absorbing, please refer to 8.9 on page 10

Atomization operation methods (for optional)

The atomization function of the concentrator is applicable to help to cure the sufferers of chronic pulmonary tuberculosis and respiratory system, etc.

/!\
caution: Atomization treatment must be under advice and suggestion of your physician.

If atomizing cannot work then open the cover of the bottle and add clean water in small amount. Rotate the white ball which lies in the bottle with the gas resource connected and select the proper angle to gain a better atomization.

a. Open the cover of medical cup, and add atomization remedy that needed, then close the cover.

- b. Connect the joint of atomization nozzle (or mask) with the cover of medical cup, and then connect the other end of atomizer connection tube with the atomization outlet and turn on atomizer.
- c. Turn on the power of oxygen concentrator, and shut up flow meter, then it is ready for atomization treatment.
- d. Do clean the atomization devices followed by the instructions of the atomization devices.

10. Alarms-Safety devices

10.1 Alarms

- a. **Power failure alarm**: In case of a loss of mains power or when the power cord is not plugged into the wall outlet, an audible alarm is activated with red indicator on (8.1b on page 10). The troubleshooting is referred to 12 on page 17.
- b. low&high pressure alarm: There is a pressure sensor on the main board to check the system pressure, when the pressure is lower than 0.1Mpa,there is an audible alarm with yellow indicator on (8.1d on page 10) and the oxygen concentrator is still working; When the pressure is higher than 0.23Mpa,there is an audible alarm with red indicator on (8.1c on page 10) and the oxygen concentrator is stopped. The troubleshooting is referred to 12 on page 17.
- c. Low oxygen concentration alarm(OCSI): The oxygen concentration will rise to the normal level in five minutes of operation. When oxygen purity is □ 85%, the green lamp (8.1f on page 10) is on, when oxygen purity is <85%, red lamp is on for audible alarm, indicating low purity(8.1h on page 10). Refer to the troubleshooting on page 17. Or call your supplier to service the device
- d. Temperature alarm: There is a temperature sensor on the main board to check the internal temperature, when the temperature is higher than 50°C in the oxygen concentrator, there is an audible alarm with red indicator on (see H.T. on the lamp) and the oxygen concentrator will be stopped. The troubleshooting is referred to 12 on page 17.

10.2 Safety devices

a. Compressor motor:

Thermal safety is ensured by a thermal switch situated in the motor winding(145±5°C).

b. Safety valve:

This is fitted on the compressor outlet and is calibrated to 2.5 bar(250kPa).

11. Maintenance

ZARNING: Disconnect the power cord from the electrical outlet before you clean the cabinet.

These actions could permanently damage the concentrator.

NOTE: If legally binding regulations govern the installation, service and/or the operation of the product, it is the responsibility for the operator to observe and follow these regulations.

NOTE: Modifying the product is not permitted.

11.1. Clean the whole body: In the condition of power off, make a clean for the outside body by soft towel with little mild household cleaner, and then wipe it up with dry towel, once or twice per month.





Figure 9

11.2. Clean air filter: It is a critical step for daily maintenance to clean intake air filter an interval about 300 hours.

Detail steps: remove the two intake air filters on both sides of the body, clean them with mild household cleaner and clean it with clean water completely, get ride of extra water and dry up naturally, finally set back after dry up, as shown in Figure 10.





11.3. Clean secondary filter

Clean secondary filter an interval about 800 hours. First, remove the silicone tube connected with oxygen output, take down the humidification bottle, Rotate the air filter with counterclockwise direction as Figure 11, take down the filter cloth, clean with detergent, wash by clean water, wipe off the water. and make it to be dry in air naturally ,then install back to the Air filter.



Figure 11

Figure

11.4. Clean the humidifier (if the humidifier is prescribed by a physician)

- Empty the water from the humidifier.

Daily:

- Rinse the humidifier flask under running water.
- Fill humidifier up to the mask with distilled water. Regularly:
- Disinfect the humidifier parts by immersing them in a disinfectant solution (in general, we recommend using water containing a small amount of chlorine bleach).

- Rinse and dry.
- Check that the humidifier lid seal is in good condition.

11.5. Clean Oxygen tubing and nasal cannula Follow

the manufacturer's instructions

11.6. Replacement of fuse tube

Remove the cover of fuse, which is in the appliance inlet, dismantle the fuse tube off by small screwdriver. Close the cover of fuse after fuse tube is replaced.

The other fuse tube is located at the intake of internal power line; the method of replacement is the same with that above.

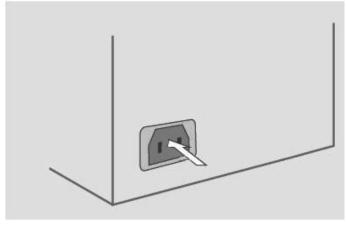


Figure 12

12. Troubleshooting

If your concentrator fails to operate properly, please refer to the troubleshooting chart on the following pages for probable causes and solutions. If problems with the equipment continue, please contact your Equipment Provider.

NOTE: If the unit has not been used for an extended time period, it needs to operate for several minutes before power failure alarm can become activated.

No.	Trouble	Causes	Solution
	No operation after power connected and the P.F. lamp is light with audible alarm.	concentrator and power 2. Circuit of fuse	 Check out whether plug, power line connection. Replace the fuse and find the
		protector broken.	cause switch, in good

	3.	There is no power supply.		protector
outtake flow		no smooth outtake Filter clogged, no	2. 3.	Connect the oxygen tube again Clean the filter Take off the cover, screw well the cover, block the outtake by thumb after turning on, and there will some sound from the humidifier after 5 second around (the safety valve of humidifier turns on)

	1	I	T
3	No exhaust sound	 Air controller cannot work Electrical control board cannot work 	1.Have air control valve replaced 2.Have electric control board replaced
4	Too noisy exhaustion	 The joint of exhaustion muffler fallen off Exhaustion muffler broken 	1.Connect the joint well 2.Have the muffler replaced
5	The oxygen concentrator is working but the L.P. lamp is light with audible alarm.	The system pressure is too low.	Check every gas circuit connectors with soapy water whether there are air leakage.
6	The oxygen concentrator is stopped and the H.T. lamp is light with audible alarm.	The temperature in the oxygen concentrator is too high.	1.Check the fan's connector on the main board whether it is bad contact. 2.turn off the oxygen concentrator and consult your Equipment Provider.
7	The oxygen concentrator is stopped and the H.P. lamp is light with audible alarm.	The system pressure is too high.	Turn off the oxygen concentrator and consult your Equipment Provider.
8	The oxygen concentrator is working but the L.O2 lamp is light.	Oxygen concentration is too low.	1. Check every gas circuit connectors with soapy water whether there are air leakage. 2. Turn off the oxygen concentrator and consult your Equipment Provider.

13.Information on Electromagnetic compatibility

The Oxy-pure needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents; Portable and mobile RF communications equipment can affect the Oxy-pure.

All cables and maximum length of cables, Transducers and other accessories with which the manufacturer of the Oxy-pure claims compliance with the requirements, Accessories that do not affect compliance with the requirements of these sub clauses need not be listed. Accessories, transducers and cables may be specified either generically or specifically.

NOTE:

Transducers and cables sold by the manufacturer of the Oxy-pure as replacement parts for internal components need not be listed.

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of The Oxy-pure as replacement parts for internal components, may result in increased emissions or decreased immunity of The Oxy-pure.

14. Accessories

Your concentrator includes the following components:

- Intake air filter (one piece, part number:GL-04)
- Secondary filter (one piece, part number:GL-05)

The concentrator comes with two air filters and one secondary filter already installed.

WARNING: Please use the parts mentioned in this chapter, if the use of other parts can degrade minimum safety and performance.



- be oxygen compatible,d
 - be biocompatible,
 - include a means to prevent the propagation of fire and accord with requirements of EN ISO 80601-2-69:2014

15. Condition for transportation and storage

Environment temperature scale: -40~55°C

Comparative humidity scale: ≤95%

Air pressure scale: 700 -1060 hpa

16. Quality Warranty

Warranty for whole unit:15 months

Warranty for magnetic valve:24 months