PROFESSIONAL MEDICAL PRODUCTS

OXYGEN CONCENTRATOR 5 L

REF **CONTEC21 (GIMA 34582)**

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CE 0123

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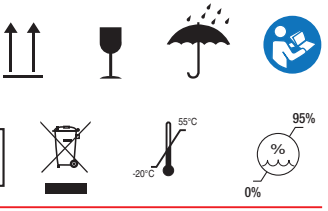

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USER NOTICE

Dear users, thanks for purchasing the Oxygen Concentrator (hereinafter referred to as machine).

This Manual is written and compiled in accordance with the council directive IEC 60601-1:2020 and ISO 80601-2-69:2020. The information contained in this document is subject to change without notice.

The Manual describes, in accordance with the machine's features and requirements, main structure, performance, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage,etc. As well as the safety procedures to protect both the user and machine. Refer to the respective chapters for details.

Please read the Manual carefully before using this machine. These instructions describe the operating procedures to be followed strictly. This Manual will tell you the operating procedures, possible abnormal operation, possible damage to this machine and danger to personal injury which must be noticed during using this machine. Our company is not responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the machine you received may not be totally in accordance with the description of this Manual. We would sincerely regret for that.

This machine is a medical device, which can be used repeatedly.

Warning:

- This Manual only provides technical instruction, please follow doctor's advice for oxygen healthcare.
- The machine doesn't suit for surgery or the salvage of no spontaneous respiratory.
- Keep the machine away from strong magnetic field or electromagnetic interference source.
- Open flames during oxygen therapy are dangerous and is likely to result in fire or death. Do not allow open flames within 2 m of the machine or any oxygen carrying accessories.
- Avoid placing the machine in environment with contaminants or fumes.
- Please refer to the correlative medical literature about the clinical restrictions and contraindications.
- The machine is only used for supplying oxygen, don't use it for first-aid treatment or sustaining life.
- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.
- To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition: the machine must be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.And the machine must be used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer and that were used while your settings were determined.

Our company reserves the final elucidative right.

Contents

Important information

Please read the Manual carefully before using the machine.Do not use this product or any available optional equipment without first completely reading and understanding these instructions. If you are unable to understand the warnings, cautions or instructions, contact a healthcare personnel before attempting to use this equipment-otherwise,injury or damage may occur.

The safety prompt symbols(such as warning, attention, etc.) described in the Manual apply to all dangerous operations which may result in the loss of personal property, as defined below:

Symbol	Meanings
⚠	Warning: high hazard, improper operation may cause injury and death to person or loss to property.
🔔	Attention: potential hazard, improper operation may cause injury to person or loss to property.

Warning:

⚠No modification of this equipment is allowed.

⚠Do not modify this equipment without authorization of the manufacturer.

⚠If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

⚠Additional monitoring or attention may be required for patients using this device who are unable to hear or see alarms or communicate discomfort.

⚠The machine is only applicable for use following the applied range described in the Manual, it can't be used for first-aid treatment or sustaining life.

⚠Oxygen therapy in certain circumstances can be hazardous, seeking medical advice before using the machine is advisable.

⚠The concentrator should always be kept in the upright position to prevent cabinet damage while being transported .

⚠Avoid severe vibration and lying upside down during transportation.

⚠To avoid electroshock hazard, maintenance to the machine only can be performed by the personnel appointed or authorized by manufacturer. Users are not permitted to maintain it by themselves.

⚠Such as power supply voltage instability, beyond AC220 V±22 V range, please install the regulator before use.

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

⚠The oil, grease or such substances contacted with oxygen at a certain pressure may

produce strong self-ignition. So they should be placed far away from the machine, pipeline, connector and other equipment related to the oxygen. No lubricant can be used in the machine without prior written consent of the manufacturer.

⚠Oxygen is a kind of combustion-supporting material, so don't use the machine in environment with inflammable and explosive goods. And smoking or naked flames (including the electrostatic spark caused by friction) is prohibited during using.

⚠Don't place the machine in wet environment, and avoid dripping water or other liquid into the machine.

- Don't immerse the machine into any liquid. If the machine is splashed or coagulated by water, please stop operating.
- Avoid using it during bathing. If the patient needs to be provided oxygen continuously, please use it in the other room which is far away from the bathroom at least 2.5 m.
- If the machine drops into water or other liquid carelessly, please don't touch, shut off the power immediately and contact the authorized dealer or manufacturer.

⚠The machine should be used in a well-ventilated room, and it should be placed far away from the wall, furniture or similar goods for more than 10 cm.

⚠NEVER block the air opening of the product or place it on a soft surface,such as a bed or couch, where the air opening may be blocked.Keep the opening free from lint,hair and the like.

⚠Keep the machine clean, and don't drip or insert any substance into the outlet.

⚠To reduce the accidental risk, please obey the following operations:

- Don't move the machine under the state of working.
- After connecting to the power, the machine needs to be looked after always.
- Keep the power cord away from the objects generated heat or heating objects.
- When the machine is not used, please cut off power. Don’t use the device in a place where it is difficult to disconnect the power supply.
- In order to cut off from the network power supply, the plug must be unplugged when the device is not used.
- Don't drag the power cord to avoid electric shock hazard.

⚠It may influence the machine performance when using it near the portable communication equipment.

⚠Do not use the machine near the device with the frequency of 430 MHz~470 MHz, such as wireless intercom equipment, or it may cause an unexpected interference to the machine and once occurred, the machine need a restart.

⚠There is a risk of inaccurate results or unexpected interference to use the machine during specific investigations or treatments.

⚠Please operate the machine following doctor's advice or operation steps described in the Manual, if lack of oxygen or insufficient oxygen concentration, please contact the doctor or dealer immediately, don't adjust it by yourselves.

⚠Check the machine periodically to make sure that there is no visible damage that may affect patient's safety or monitoring performance. It is recommended that the machine should be inspected weekly at least. When there is obvious damage, or any one of the following situations appears: (1)the power cord or the plug is broken, (2)the machine can't work normally, (3)the machine is broken, please contact the engineer for maintaining.

⚠Please don't connect the machine with other concentrator or oxygen therapeutic equipment in series or parallel.

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

⚠It is recommended by the manufacturer that keep the machine working for thirty minutes at least after switching on it, and avoid switching on/off the machine frequently, otherwise it will shorten the life of the machine.

⚠The oxygen delivery settings of the oxygen concentrator should periodically reassessed for the effectiveness of the therapy.

⚠Medical disposable nasal cannula is sterilized by ethylene oxide gas. Please don't use it if the package is damaged.

⚠DO NOT use the machine while examining by MRI and CT, as the induced current may cause burn.

⚠The device cannot be used in the MRI environment.

⚠The disposal of scrap machine and its accessories, packings, wastes and residue should comply with the corresponding national laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.

⚠Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the oxygen concentrator or any oxygen carrying accessories are located. If you intend to smoke, you must always turn the oxygen concentrator off, remove the cannula and leave the room where either the cannula or mask or the oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after you have turned the oxygen concentrator off before smoking.

⚠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.

⚠Oxygen makes it easier for a fire to start and spread.Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the oxygen concentrator is turned on, but not in use; the oxygen will make the materials flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.

⚠Geriatric, paediatric or any other patient unable to communicate discomfort can require additional monitoring and or a distributed alarm system to convey the information about the discomfort and or the medical urgency to the responsible care giver to avoid harm.

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

⚠The oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories.

⚠The proper placement and positioning of the PATIENT interface is critical to the effectiveness of the therapy.

⚠ It is dangerous for children to play with the accessories, ensure the accessories are placed where the children are out of reaching.

Attention:

- Keep the machine away from dust, vibration, corrosive or flammable substances, and higher or lower temperature and humidity.
- The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this machine.
- Accessories must be routed and secured properly. Don't position the tubes or cords around the neck. Ensure the patient can move freely while wearing the cannula. Ensure the tiny parts be placed away from children to avoid accident swallow.
- Keep children and pets away from nasal cannula and tubing to avoid choking or strangulation or in case they may cause an unexpected change on the controller.
- Please check the packing before use to make sure the machine and accessories are totally in accordance with the packing list, or else the machine may have the possibility of working abnormally.
- Please use the accessories properly, for example, use of a paediatric cannula on an adult patient may cause adverse effect on the therapy.
- Ensure the oxygen concentrator, its parts and accessories are specified for use at rated flowrate.
- Incompatible parts or accessories can result in degraded performance.
- The responsible organization can be accountable for ensuring the compatibility of the oxygen concentrator and all of the parts or accessories used to connect to the patient before use.
- When the machine is carried from cold environment to warm or humid environment, please do not use it immediately, wait four hours at least is recommended.

- Never try to sterilize the machine by high temperature or high pressure or steam sterilizing process, please refer to relative chapters in the Manual for cleaning and disinfection.
- The machine doesn't suit all users, if you can't get satisfactory result, please stop using it.
- Date of manufacture: see the label.
- During the test normal operation of the OXYGEN CONCENTRATOR will deplete the ambient oxygen inside the environmental chamber if the gas output leaves the environmental chamber. An external air source is required to compensate and monitoring of the oxygen concentration inside the chamber is recommended.
- 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.
- If necessary, our company can provide some information(such as circuit diagrams, component lists, illustrations, calibration methods, etc.), so that the qualified technical personnel of the user can repair the machine components designated by our company.

Chapter 1 Overview

The machine is a small and mobile Oxygen Concentrator which is consisted of main unit, humidifier bottle, flowrate controller, etc. It takes the molecular sieve as the adsorbent, adopts pressure swing absorbers(PSA) directly concentrate the medical oxygen from the air.

The machine takes the advantages of small in volume, light in weight, convenient in moving(as it has the turning truckle), stable in performance, high in safety, easy in operating, low in noise, safe in working, which complies with requirements of medical device.

1.1 Features

a. Easy and convenient to operate.

b. Small in volume, light in weight and low in power consumption.

c. Concentrate the oxygen with high concentration from the air directly, easy to operate.

1.2 Applied range

1.2.1 Intended use / intended purpose

The device can be used in medical institutions for supplying oxygen for hypoxia patients.

1.2.2 Patient Population

Adult and child.

1.2.3 Intended users

Professional medical staff.

1.2.4 Medical indications

The device can be used for adjuvant therapy of diseases (including cardiovascular disease, respiratory system disease, hypoxic disease).

1.2.5 Contraindications

Patients with oxygen poisoning or oxygen allergy.

1.3 Environment

a. Temperature: 10 ℃~40 ℃

b. Relative humidity: ≤80 %

c. Atmospheric pressure: 860 hPa~1060 hPa

d. Power supply: AC220 V, 50 Hz

e. Input power: 450 VA

Attention:

① If stored or used the machine outside the temperature and humidity specified by the manufacturer, the system may not achieve the performance standards declared.

② The temperature and atmospheric pressure range of oxygen concentration status indicator(OCSI) is consistent with the machine.

③ Use of this device at an altitude above 1900m is expected to adversely affect the flowrate and the percentage of oxygen and consequently the quality of the therapy.

Chapter 2 Principle

2.1 Basic principles

The device takes air as the material, adopts pressure swing adsorption (PSA) to generate the oxygen (concentration 90 % ~ 96 %, oxygen 93 percent for short).

2.2 Oxygen swing absorbers(PSA)

Pressure swing adsorption, atmospheric pressure desorption. The compressed air passed the air filter respectively enters the separated electromagnetic valve, then the nitrogen, carbon dioxide, vapour in air is selectively adsorbed by the molecular sieve, and oxygen enrichment passed the separation unit of nitrogen and oxygen to form product gas. When the molecular sieve in the separation unit of nitrogen and oxygen adsorbs near the status of saturation, the compressed air enters the other molecular sieve regenerated to continue adsorbing oxygen. The saturated tower makes the molecular sieve desorb and regenerate by decompressing to atmospheric pressure and introducing some oxygen for cleaning the beds of molecular sieve, to prepare for next adsorption. The separation unit of nitrogen and oxygen consisted in series or parallel achieves the purpose of getting continuous production of oxygen through the PLC system controlling.

Sieve is a porous filtering material and is considered a wear item. Some factors that could affect sieve material life include humidity, temperature, particulates, air contaminates, air intake, vibration and other environmental conditions. The frequency or intensity of use may also affect the effective service life.

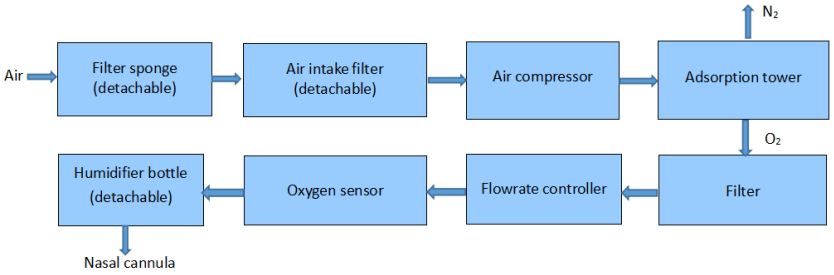


Figure 1

2.3 Uncertainty of parameter measurement

Serial number	test parameter	value	Device error	measurement uncertainty
1	Maximum recommended flowrate	5 L/min	±10%	±2%
2	concentration	93%	±3 %	±0.4%

Note: The tolerances declared in the documents include the uncertainty of the measurement.

Chapter 3 Technical characteristic

3.1 Main performance

1) With turning truckle, easy to move.
2) Remove the impurity by built-in filter.
3) OCSI function.
4) Function of accumulating time.
5) Function of timing shutdown.
6) Alarm for power failure.
7) Alarm for low power supply.
8) Alarm for high/low pressure protection.
9) Alarm for low flowrate.
10) Alarm for high temperature.
11) With working indicator.

3.2 Main parameters

1) Maximum recommended flowrate: 5 L/min
2) Flowrate range: 0.5 L/min~5 L/min
3) Oxygen concentration(reach the stated oxygen concentration after turning on the machine for about 30 minutes): 93 %±3 % (percentage of volume) when the flowrate at the range of 0.5 L/min~5 L/min.
4) Flowrate range when the outlet nominal pressure is 0 and 7 kPa: 0.5 L/min ~ 5 L/min
5) Flowrate change in maximum recommended flowrate when back pressure of 7 kPa is applied: <0.5 L/min.
6) Outlet pressure: 20 kPa~50 kPa
7) Input power: 450 VA
8) Working voltage: AC220 V±10 %, 50 Hz±1 Hz
9) Operating noise: ≤55 dB(A), at the flowrate of 5 L/min
10) When the outlet nominal pressure is 0, the function diagram for oxygen concentration and flowrate is shown as Figure 2:

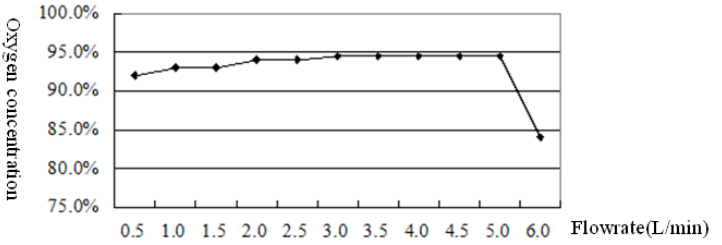


Figure 2

11) The relationship between oxygen concentration and altitude

In the plateau environment, with the increase of altitude, the atmospheric pressure gradually decreases, the oxygen intake rate also decreases. At the same flowrate, the

output oxygen concentration in the plateau environment is lower than that in the plain environment.

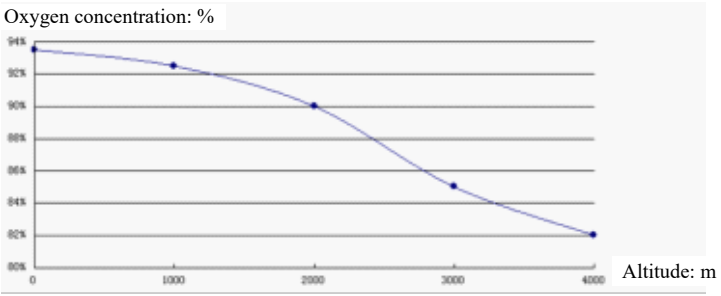


Figure 3

12) Dimension: 508 mm×260 mm×530 mm

13) Weight: 21 kg

3.3 Safety categories

a. Device class: class II equipment

b. The degree of protection against electroshock: type BF applied part(medical disposable nasal cannula)

c. The degree of protection against ingress of water: IP21

d. Operation mode: continuous operation

e. Applied part for protecting defibrillator discharge effect: no

f. Signal input/output parts: no

Chapter 4 Introduction for parts and functions

4.1 Parts name

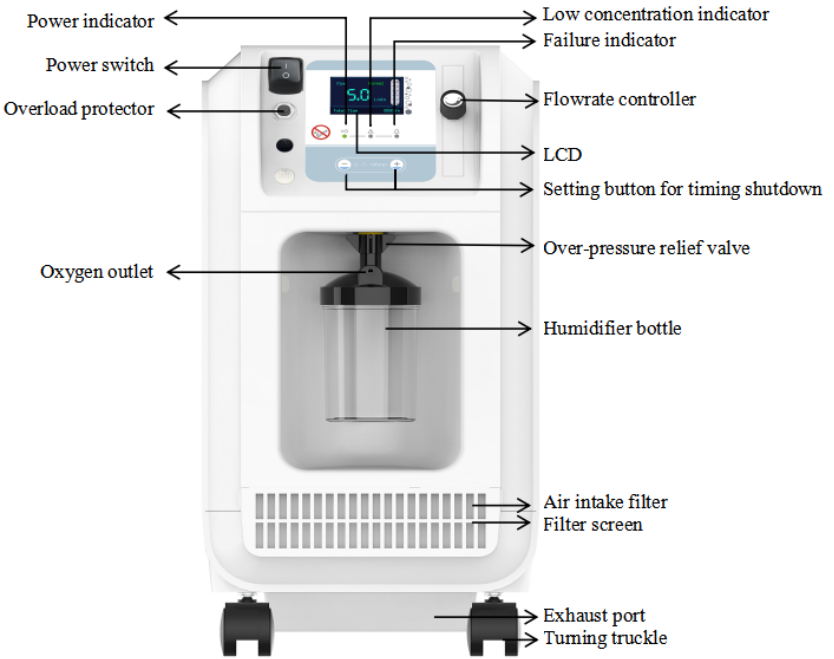


Figure 4 Front panel view

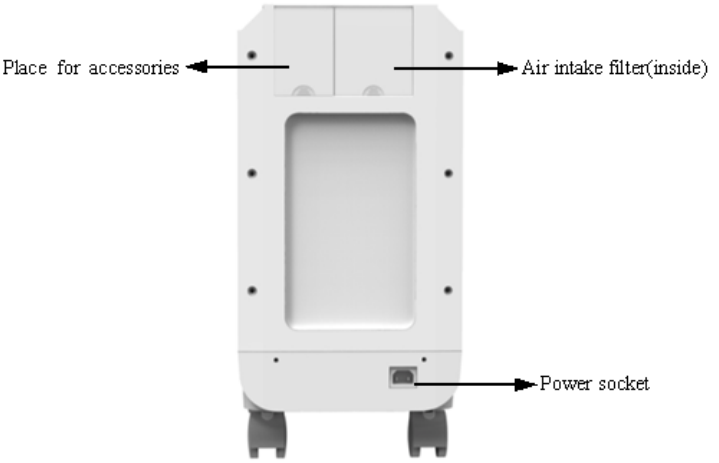


Figure 5 Rear panel view

- Flowrate controller: anti-clockwise rotate the knob to increase the oxygen flowrate(the maximum recommended is 5 L/min); clockwise rotate it to decrease the oxygen flowrate(the minimum recommended is 0.5 L/min). And the LCD displays the flowrate value.

  Note:There will be a delay in the flow of electronic display. Please adjust the flow after the display is stable.
- Power switch: switch on the power to open the machine, then it can work normally, switch off the power, then it stops working. The concentrator is isolated from the SUPPLY MAIN by the Power switch.
- Overload protector: when the operating current exceeds the current value limited by the overload protector, the overload protector disconnects and the machine turns off, then turn off the power switch and cut off the power immediately, after excluding the over-current reasons, press it, the machine will return to normal.
- Power indicator: it is green when the power is turned on; in power failure state, switch on the power switch, the indicator is not light.
- Low concentration indicator: the yellow indicator is light when the oxygen concentration is below 82 %(+3 %), and the red indicator is light when the oxygen concentration is below 60 %(±5 %).
- Setting button for timing shutdown: press “+”, “-” to adjust the time for timing shutdown, range: 0~120 minutes, step: 5 minutes.
- Oxygen outlet: when the machine starts working, it exports high-concentration oxygen with constant speed from this outlet.
- Over-pressure relief valve: when the pressure in the humidifier bottle is too high which is arisen from occlusion or bending of nasal oxygen cannula, the over-pressure relief valve will reduce the pressure in the bottle by releasing the oxygen in the humidifier bottle, to ensure that the machine can work normally.
- Humidifier bottle: connect the top screw cap with the oxygen outlet of the machine. The oxygen entered into the humidifier bottle is humidified, then output the oxygen from the oxygen outlet.
- Air intake filter: be used to purify the air inhaled by the machine, and it is placed in air intake filter box.
- Power socket: the power cord connects with the machine by this socket, to provide stable AC for the machine. Plug power cord to an electrical outlet otherwise you can not use the concentrator.
- Exhaust port: be used for ventilation, heat radiation and waste gas output. It should be kept smooth.

⚠ **Use the accessories not specified by the manufacturer may affect the machine performance.**

4.2 Alarm

A. Alarm for power interruption

When the machine works normally, cut off the mains power, the machine gives an auditory

alarm, which will stop after continuing for a moment.

When the alarm occurs, turn off the machine at first. Then make sure the power plug is connected well and there is no power failure. Turn on the machine again, if alarm still exists, please turn off and contact the dealer.

This alarm can be triggered by unplugging the power cord during normal operation.

B.Alarm for low power supply

When the power supply falls below the value necessary to maintain normal operation of the concentrator, it will give a visual (the red indicator flashing (frequency:2 Hz) for alarm) and auditory alarm.

When alarm occurs, better to use a voltage regulator as power supply to the concentrator.

C. Alarm for high/low pressure protection

When the abnormalities(the pressure in the oxygen tank is too low or high) appear, the machine will give a visual (the red indicator flashing (frequency:2 Hz) for alarm) and auditory alarm.

When the alarm occurs, make sure the flowrate is adjusted within normal range. Rolling the knob clockwise to decrease it or anti-clockwise to increase it. Once corrected, turn it off for 60 seconds and then turn power back on.

D. Alarm for low flowrate

When the machine works normally, if the flowrate is lower than 0.5 L/min, the machine will give a visual (the red indicator flashing (frequency:2 Hz) for alarm) and auditory alarm.

When the alarm occurs, rolling the knob anti-clockwise to increase it, and wait with a few minutes.

This alarm can be triggered by setting the flowrate below 0.5 L/min.

E. Alarm for high temperature

When the machine works abnormally, and the air temperature is higher than default setting, the machine will give a visual (the red indicator flashing (frequency:2 Hz) for alarm) and auditory alarm.

When the alarm occurs, check if the cabinet filters requires replacement. Make sure the oxygen concentrator is at least three inches away from walls,draperies or furniture. And don’t use it within a short time to make sure the machine cools down adequately.

F. Alarm for low oxygen concentration

When the machine works normally, if the oxygen concentration is less than 82 %(+3 %), the yellow indicator is light, then please contact the suppliers, users can continue to use it, but make sure that there is spare oxygen nearby. When the oxygen concentration is less than 60 %(±5 %), the red indicator flashes, please turn it off immediately, use the spare oxygen and contact the suppliers in time.

This alarm can be triggered by setting the flowrate to maximum, the yellow indicator light illuminates first, and then the red .

4.3 Functions for accumulating time

When the machine works normally, the LCD displays the accumulated time, unit is hour, when it arrives 99999, the machine stops accumulating.

When using the function of timing shutdown, the LCD can't display the accumulated time.

Turn it on again, the LCD will accumulate the time automatically.

4.4 Filter

A filter is placed between the oxygen tank and oxygen outlet, it can filter such particles whose diameter is more than 1 μm, which ensures the oxygen quality.

4.5 Function of timing shutdown

The machine has the function of timing shutdown, user can set the working time (range: 0~120 minutes) according to requirements.

4.6 Accessories

a. A humidifier bottle(M14×1.5)
b. A User Manual
c. A power cord (HSC-401+HSC-406)
d. A medical disposable nasal oxygen tube(gift for test machine)

4.7 Software information

Software name:

CONTEC21

Software model: no

Version: V1

Naming rule for version: <Major enhancive software upgrade>.<Minor enhancive software upgrade>

The software version can be found in the machine.

Chapter 5 Operation

A. Check the filter sponge

Before turning on the machine, please check the intake filter sponge to make sure that it is clear and dry. Refer to section 6.1 for its maintenance.

B. Connect with humidifier bottle

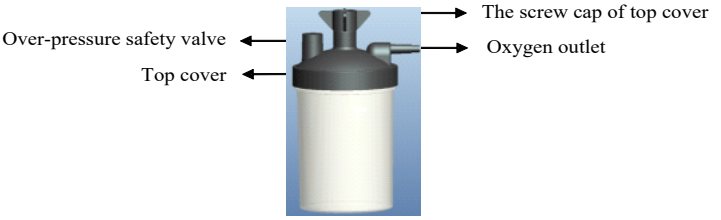


Figure 6 Humidifier bottle

1) Clockwise screw the knob on the top cover of the humidifier bottle, to take out the humidifier bottle.
2) Remove the top cover of the humidifier bottle. Inject distilled water or cold water to the humidifier bottle to the position between "MINIMUM" and "MAXIMUM", then tighten the top cover of humidifier bottle.
3) Connect the humidifier bottle to the oxygen outlet of the machine in counter clockwise direction.
4) Connect the oxygen tube to the oxygen outlet of the machine.

⚠ Please inject water to the humidifier bottle following the Manual, the water volume should not exceed the maximum scale marked on the humidifier bottle, otherwise it may spilled over from the cannula which can cause the user choked.

C. Connect the power cord

Turn off the power switch, connect the machine to the power socket by the power cord.

D. Startup for the machine

Turn on the power switch, the power indicator is light, then the machine can work normally. After the the start-up interface showed as figure 7, it enters the main interface, as figure 8. It displays the status “Normal” and the accumulation time(as “00004h”) normally.

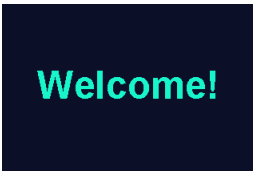


Figure 7 start-up interface

Figure 8 main interface

Adjust the flow controller clockwise to decrease it or anti-clockwise to increase it, to make it in the location recommended by the medical personnel, then the machine will export

continuous and stable oxygen.

When it is abnormal, the status displayed in the screen would change, like “EL” “EH” “ELL” “ET”“EP”. And other visual and auditory alarm could occur in the meantime.

E. Start absorbing oxygen after connecting the oxygen tube

Place the cannula over your ears and position the prongs in your nose as instructed.

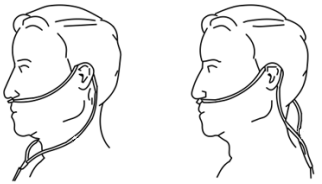


Figure 9

Gas flow at the outlet of the cannula can be checked while the concentrator is warming up. Wave your hand in front of the nasal prongs. You should be able to hear and feel the flow of gas. If you do not feel the gas flow, check the cannula connection for leaks. Or place the end of the nasal cannula under the surface of half-full cup of water and look for the bubbles.

F. Setting for timing shutdown

After turning on the machine, the accumulated time displays on the LCD, press “+” or “-” to enter timing interface, the original value is 30 minutes, it increases five minutes each pressing “+” once, the maximum is 120 minutes. The timing time decreases five minutes each pressing “-” once, 0 minutes at least. Set a value as medical personnel recommend, when the machine runs to the set time, it will turn off automatically.

Figure 10 original timing time

Figure 11 after pressing button“-”

G. Finish absorbing oxygen

After stopping absorbing oxygen, turn off the power switch, pull out the power plug to cut off the power.

Chapter 6 Maintenance, transportation and storage

⚠ Don't maintain the machine when operating.

6.1 Cleaning and disinfection

⚠ Please cut off the power before cleaning or disinfection.

A. Cleaning for the humidifier bottle

1) Take off the humidifier bottle.

2) Unscrew the bottle cap, Remove the small cap at the end of the air duct on the bottle cap, immerse the removed cap, cup body and cap in 3 L of 1:270 (detergent to water ratio) Ruhof cleaning solution for 10 minutes.

3) Soak the cleaning cloth with cleaning solution until it drips water.

4) Scrub the cup body and bottle cap part with a cleaning cloth, especially the rotating thread of the cup cap, the cavity and the hose connected with the cup cap, and scrub each part for 2 minutes.

5) Use a small brush to soak the cleaning solution in the above steps to brush the cap, inner wall of the air duct, threads and small holes on the bottle cap, and each part shall be brushed for 1 minute.

6) Rinse the cup and cap with running water for 1 minute per section.

7) Dry the cup and cap with a clean soft cloth or air dry.

8)Please carry out visual inspection for the bottle and cover after above operations.Repeat the operation 2-8) if there is still visible impurity remained.

B. Cleaning/replacement for the intake filter sponge

Figure 12

Figure 13

1) Remove the grid, take out the sponge.

2) Soak the sponge in 1:270 Ruhof cleaning solution (the ratio of detergent to water) for 5 minutes.

3) Rub the sponge in the cleaning solution for 2 minutes.

4) Rinse the foam on the sponge with running water for 2 minutes until there is no foam.

5) Dry it for future use.

6) Please carry out visual inspection for the sponge after above operations. Repeat the operation 2-5) if there is still visible impurity remained.

Note: it is recommended that the filter sponge should be cleaned once per 100 hours, clean it with water, reinstall it to the machine after fully drying. Please replace another new filter

sponge if the one cleaned is not completely dry if the device need to be used immediately.

⚠It may cause harm to the machine if the intake filter sponge is not installed to the machine or turning on the machine when the intake filter sponge is not fully dried.

C. Replacement for the intake filter

Figure 14

Figure 15

Check the internal filter material by the plastic shell of the intake filter, it is recommended to replace it when the black area reaches 80% or more. Press the filter cover by hand, open the cover after unlocking, then unplug the intake filter to replace it.

It is recommended that the intake filter should be replaced once per 1000 hours at most. Or the lifetime of the machine could be influenced to a certain degree, even the oxygen concentration could be reduced when the filter is clogged severely.

⚠ The intake filter is a dissipative part which is not applicable for long-term use.

D. Replacement of nasal oxygen tube

The nasal oxygen tube is a sterile and disposable product, do not use it repeatedly or crosswise, or it will be insanitary and may be harmful to your health. User can purchase the nasal oxygen tube certificated by self.

⚠To avoid cross-infection, it is recommended that each person uses the oxygen tube solely. The oxygen tube is disposable, repeated use have a risk of infection.

The nasal oxygen tube is the only parts or accessories of the oxygen concentrator intend for single use.

Cannula requirements: length of 4-25 ft including all oxygen tubing, with crush-proof and single lumen tubing. For example, adult standard flow (rated for up to 6L/min continuous flow) for lengths up to 7 ft.

Note: The nasal oxygen tube may become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

Note: Patients should use disposable nasal oxygen tubes of appropriate specificaations. The following action is prohibited: Use of a paediatric cannula on an adult patient.

6.2 Maintenance

1) Please cleaning and disinfection refer to relative chapters (6.1) in the Manual.
2) The machine has 3-year service life, and sieve beds for a period of one year. It is recommended to replace the molecular sieve when it reaches up to the expected hours or the low oxygen concentration alarm appears. Keep the machine working for 30

minutes at least after switching it on, and avoid switching on/off the machine frequently, otherwise it will shorten the life of the machine.

Note: No lubricants other than those recommended by the manufacturer are to be used.

6.3 Transportation and storage

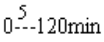
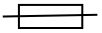
1) The packed machine can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and splashing with rain or snow, and to avoid damage, please keep upright, no turning over.
2) The packed machine should be stored in room with no corrosive gases and good ventilation. Temperature:-20 °C ~ +55 °C; Relative Humidity: ≤95 %.
3) Unpackaged machine should be stored in a dry area, humidity of 40 % or below is recommended. High humidity may influence the life of the sieve beds.

Chapter 7 Troubleshooting

Trouble	Possible Reason	Solution
Turn on the power switch, the machine doesn't work or the indicator isn't light.	1) The power plug is not inserted well. 2) No live with the power socket. 3) The control board of the machine is broken.	1) Check the power plug. 2) Check the power. 3) Please contact the dealer.
The machine stops after working for a period of time, or the oxygen concentration descends.	1) Occlusion for the air intake or exhaust port 2) The intake filter sponge is dirty. 3) The air intake filter is dirty. 4) Too high temperature. 5) Too low voltage of the machine. 6) The fan doesn't work. 7) The molecular sieve failure.	1) Place the machine to the clear location in room, or check the air intake or exhaust port. 2) Install the intake filter sponge via cleaning and drying. 3) Replace the filter. 4) Place the machine to the ventilated location. 5) Collocate the manostat to ensure the voltage is in the range of 220 V±10 %. 6) Replace the fan. 7) Contact the suppliers to replace the molecular sieve.
The machine can't export oxygen, and there is no bubble in the humidifier bottle.	1) The knob of flow controller is close. 2) The oxygen tube is kinked or damaged. 3) The top cover of humidifier bottle is not screwed. 4) The machine failure.	1) Open the flow controller and check. 2) Unwrap the knot or replace the oxygen tube. 3) Screw down the top cover of the humidifier tube. 4) Please contact the dealer.
Big noise with abnormal sound.	The machine failure.	Please contact the dealer.
LCD display "ELL"	low flow alarm: kinked or blocked tubing, cannula or humidifier.	1) Inspect for kinks or blockages.Correct,clean or replace item.Inspect the flowrate controller and LCD,if it is lower than 0.5 L/min, rolling the knob anti-clockwise to increase it. 2) Please contact the dealer.

LCD display "EL"	System low pressure	1) Inspect the flowrate controller and LCD,if it is higher than 5 L/min,rolling the knob clockwise to decrease it. 2) Please contact the dealer.
LCD display "EH"	System high pressure	1) Inspect for kinks or blockages.Inspect the flowrate controller,if it is lower than 0.5 L/min,rolling the knob anti-clockwise to increase it. 2) Please contact the dealer.
LCD display "ET"	Overheat alarm: unit overheating due to blocked air intake.	1) Remove and clean cabinet filters. 2) Ensure oxygen concentrator at least three inches away from walls, draperies or furniture. 3) Wait at least an hour with the machine off, then turn on again. 4) Please contact the dealer.
LCD display "EP"	Power supply falls below the value necessary to maintain normal operation.	A voltage regulator is suggested when the power supply is not stable.

Chapter 8 Symbol Meanings

Symbol	Meanings
	Follow instructions for use
	O_2 between 60 % to 82 %
	Alarm
	Do not smoke
	No open flame: Fire, open ignition source and smoking prohibited
	Power indicator
	Power ON Switch
	Power OFF Switch
	Decrease the time for timing shutdown
	Increase the time for timing shutdown
	Timing range: 0 ~ 120 minutes, step: 5 minutes
+	Increase the flowrate
-	Decrease the flowrate
	Overload protection（250V, 3A）
	Type BF applied part
	Class II applied
IP21	Covering Protection rate
	Manufacturer
SN	Serial Number

	Ethylene oxide sterilization
	Disposable device, do not re-use
	Lot number
	This way up
	Fragile, handle with care
	Keep in a cool, dry place
	Stacking layers limit
	Atmospheric pressure limit
	Temperature limit
	Humidity limit
	WEEE disposal
	Expiration date
	Date of manufacture
	Authorized representative in the European community
	Product code
	Date of manufacture
	Medical Device complies with Directive 93/42/EEC

Appendix 1 Alarm information

	State	Screen display	Grouping of alarm conditions	Delay time	Priority
1	Power failure	——	Technical alarm	No delay	Low
2	Low power supply	EP	Technical alarm	2 s	High
3	High temperature	ET	Technical alarm	1 s	High
4	High pressure	EH	Technical alarm	8 s	High
5	Low oxygen concentration	Normal	Technical alarm	10 s	High
		Normal	Technical alarm	10 s	Low
6	Low flowrate	ELL	Technical alarm	10 s	High
7	Low pressure	EL	Technical alarm	8 s	High

Audio characteristic for alarm:

High-level alarm: pulse burst composed of 10 pulses, interval: 3 s, fundamental frequency: 750 Hz.

Low-level alarm: single pulse, non-repetitive, fundamental frequency: 750 Hz.

Response frequency for buzzer in power interruption: about 0.32 Hz.

Verification of the functionality of the Alarm system:

Operator can verify the functionality of the Alarm system until oxygen concentrator stabilizes(2 minutes or more after machine starts).

For example, to trigger the alarm for low flowrate, operator can adjust the flowrate of the oxygen concentrator below 0.5 L/min, and this will cause a high-level alarm with “ELL” display, as indicated above or in chapter 4.2. Another example, alarm for low oxygen concentration can be triggered by setting the flowrate to maximum, the yellow indicator light will illuminates after several seconds(low-level alarm), and it may become a high-level one if the oxygen concentrate is low enough, that’s depend on the actual situation of the machine.

Appendix 2 EMC guidance and manufacturer's declaration

⚠ **Warnings** ⚠

- The machine is subject to special EMC precautions and it must be installed and used in accordance with these guidelines.
- The electromagnetic field can affect the machine performance, so other equipment used near the machine must meet the corresponding EMC requirements. Mobile phones, X-rays or MRI devices are possible interference source, as they can emit high-intensity electromagnetic radiation.
- The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

The following cable types must be used to ensure that they comply with interference radiation and immunity standards:

Name	Cable length(m)
Power cord	1.8 m

Cable introduction

- The machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used.
- Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.
- Portable and mobile RF equipment may affect the use of medical electrical equipment.
- Operation of the machine or system below the minimum amplitude or minimum value may result in inaccurate results.
- Devices or systems may still be interfered by other equipment, even if other equipment meets the requirements of the corresponding national standard.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
The Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Concentrator should assure that it is used in such an environment.	
Emissions test	**Compliance**

RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
The Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Concentrator should assure that it is used in such an environment		
Immunity Test	**IEC 60601 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output	±2 kV for power supply lines Not Applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode Not Applicable
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 (50Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz	30 A/m 50Hz
NOTE UT is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity		
The Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Concentrator should assure that it is used in such an environment		
Immunity Test	**IEC 60601 Test level**	**Compliance level**
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz	3 V/m 80 MHz – 2,7 GHz
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Oxygen Concentrator is used exceeds the applicable RF compliance level above, the Oxygen Concentrator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Oxygen Concentrator. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity							
The Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Concentrator should assure that it is used in such an environment							
Radiated RF IEC61000-4-3 (Test specificat	**Test Frequency (MHz)**	**Band a) (MHz)**	**Service a)**	**Modulation b)**	**Modulation b) (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**

ions for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 –390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5500						
	5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							

a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Table 5

Guidance and manufacturer's declaration - electromagnetic Immunity			
The Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxygen Concentrator should assure that it is used in such an environment			
Radiated fields in close proximity IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IMMUNITY Test Level (A/m)
	134.2 kHz	Pulse modulation 2.1 kHz	65
	13.56 MHz	Pulse modulation 50 kHz	7.5

⚠ **Warning** ⚠

- 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 Oxygen Concentrator, including cables specified by the manufacturer.Otherwise, degradation of the performance of this equipment could result.

Note:

- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies