

## Faciox Oxygen Concentrator

### Model:

OC505-BL 、 OC505-BW 、 OC505-SR 、

OC505-TG 、 OC505-GY

OC505-PB 、 OC505-PO 、 OC505-PC 、

OC505-PY 、 OC505-PG 、 OC505-PR

OC505-QW 、 OC505-QB 、 OC505-QO 、

OC505-QC 、 OC505-QY 、 OC505-QG 、

OC505-QR

Faciox Oxygen Concentrator USER MANUAL



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## PREFACE

Dear user:

The Faciox Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is a MIT (Made in Taiwan) product: developing the product, designing the appearance, and manufacturing are entirely completed by FACIOX INC. in Taiwan.

This user manual contains precautions about the product, operating procedures, basic functions, specifications, troubleshooting information, repair instructions, etc. To operate this machine effectively, please read and understand the instructions in this manual carefully before using it.

Please note that some illustrations in this manual may not apply to the exact machine you have.

The accessories for this device, including humidifier bottles and nasal cannula, should meet the basic criteria for this specific product, and have the approval of the local country's health authority.

If you have any questions or concerns about this Oxygen Concentrator, please contact the supplier or manufacturer for service.

## WARNINGS AND PRECAUTIONS



**DANGER** (Violation of the following items may cause serious injury or death.)

- ◆ Measures to reduce the risk of burn, electric shock, fire, or injury:
  - Avoid using the Oxygen Concentrator while taking a bath. If it is necessary, please follow your doctor's or home care's instructions. The Oxygen Concentrator must be placed in another room away from the bathroom. The recommended length of the oxygen tube is less than 11 meters; the nasal cannula should not be bent.
  - DO NOT place or store the Oxygen Concentrator where water or other liquid can spill into the enclosure.
  - Oxygen is highly flammable. Do not use this device while smoking or near an open flame.
  
- ◆ Improper use of the cord and plug may cause fire or electric shocks and burns.
  
- ◆ Please DO NOT use the machine with a damaged AC power cord.
  
- ◆ Before cleaning dust off the Oxygen Concentrator's shell, please unplug the power to prevent electric shock.
  
- ◆ When the machine is working, to avoid damage from touching the operating parts, please do not open the machine shell or internal box.



**WARNING** (The following items must be strictly implemented, or serious consequences may result.)

- ◆ In order to continue receiving oxygen in the event the Oxygen Concentrator malfunctions or experiences AC power source failure, users who need a constant oxygen supply must be equipped with an alternative oxygen supply

device (such as an oxygen cylinder, etc.). In the case of a malfunction or power failure, please remove the nasal cannula immediately.

- ◆ This product is not intended for life support. Patients in need of respiratory therapy should follow their doctor's guidance when selecting the oxygen flow and time on the device.
- ◆ If any discomfort or abnormal reactions arise, please immediately stop using this product, and contact the manufacturer or your doctor.
- ◆ Severe patients would need additional indications to operate the products or additional associated medicine. Please consult a doctor before use. If you have any adverse reactions, please inform your doctor immediately.
- ◆ If the device is used at an altitude of over 1828 meters, the output oxygen purity will be less than 90% even when the device is set to its maximum flow capacity.
- ◆ To avoid cross infection caused by viruses or bacteria, do not share the same set of nasal cannula between users.
- ◆ Please use a humidifier bottle approved by the local country's health authority. Do not replace the humidifier bottle without consulting the supplier or your doctor; otherwise, you may experience discomfort or difficulties with inhaling oxygen.
- ◆ The nasal cannula should not be placed under a coverlet or cushion, and should not be sat upon. Avoiding these situations can help you to use your device successfully and efficiently.
- ◆ When no one is using the Oxygen Concentrator, it is recommended to turn off the power, and unplug the device to avoid catching fire.
- ◆ Be aware of potential tripping hazards resulting from an AC power cord that is too long when using the Oxygen Concentrator. We suggest that patients operate the device near a power outlet.
- ◆ For safety, the use of the Oxygen Concentrator is prohibited on airplanes.
- ◆ Do not perform maintenance or repair while the machine is running.
- ◆ User modifications to the machine are not allowed.



**PRECAUTIONS** (Pay attention to the following content to avoid damaging the machine.)

- ◆ Do not open the machine's casing or remove the mainboard for maintenance. If the user finds any issues or abnormalities in the device such as emergency alarms, please do not disassemble or repair them without permission from the supplier or manufacture. Contact the supplier or manufacture immediately for maintenance.
- ◆ The Oxygen Concentrator should be used in a clean, dust-free, noncorrosive and nonpoisonous environment. Do not use this product under in an environment with a strong magnetic field.
- ◆ The air entrance of the machine should be located in a well-ventilated spot and should be placed where the least amount of pollutants are present (pollutants refers to: burning gases, exhaust systems, air vents, other anesthesia vacuum exhaust ports, etc.).
- ◆ Please avoid placing the machine in locations where the temperature and humidity may change rapidly. Keep the machine away from direct sunlight, strong light, high temperatures, and chemicals.
- ◆ Please connect the separate AC power outlet in order to use this product, do not connect the device's AC power cord with an extension cord. Do not use other electrical appliances simultaneously on the same plug when you are operating the Oxygen Concentrator. Do not use damaged or worn power cords. If damaged, please contact the supplier or manufacturer for repairs.
- ◆ The machine must not have any contact with oil or grease. If oil or grease are needed for the connection between pipelines, valves, or connectors, the connection parts should be cleaned and patients should ensure the device is well cleaned, and that no oil or grease is left on the device before installation. During the connection process, be careful to keep all parts clean. No connections on the machine should touch any

combustible oily liquid.

- ◆ Ensure the bottom of the device is able to exhaust efficiently while using the machine. The back of the device should not lean on the wall. To avoid damage due to overheating, the machine should be placed at least 30cm from the wall.
- ◆ This device should not be operated if the room temperature is above 35°C (95°F). The oxygen output of this device might be higher than the room temperature by at most 6°C (11°F). If the room is 35°C (95°F), the released oxygen may be above 41°C (106°F), which may result in damage to the respiratory tract..
- ◆ This machine is not designed to switch on and off frequently. The time interval in between switching it on and off should not be less than five minutes, to reduce the risk of shortening the compressor's lifespan. The manufacturers recommend spacing each operation out by 30 minutes.
- ◆ The machine can only be used for medical oxygen supply. When the output of the gas in is set at the rated flow, the purity of the output oxygen can go up to 93%±3% .
- ◆ Twisting the rotary flow control knob too hard risks damaging the spool. If the flow control knob is turned to the highest setting and the flow indicator is zero, please turn off the power immediately and check for a fault.



NOTICE (You must pay special attention to this information.)

- ◆ The purity of output oxygen will be up to 93%±3% after the device is turned on for 10 minutes.
- ◆ The nasal cannula used by patients needs to be cleaned and sterilized before each use.
- ◆ The humidifier bottle should be cleaned every two to three days. The air filter foam should be cleaned every 100 hours. The air filter should be replaced after 3000 hours of use. If the device is used and stored in an

environment with excessive dust or soot, the above parts should be replaced in a shorter time interval. To ensure efficient operation of the device, parts should be replaced within the suggested time interval.

- ◆ The humidifier bottle must be filled with only distilled water or cold water; please do not fill it with unfiltered tap water. The humidifier bottle should be cleaned every two to three days, and rinsed daily during the summer. If the device is idle for more than one day, please remove water from the humidifier bottle and dry it for future use.
- ◆ DO NOT use cleaning products that contain bleach, chlorine, alcohol, or any kind of fragrance. DO NOT use moisturizing soap, antibacterial soap, or essential oil to clean the Oxygen Concentrator or nasal cannula. The aforementioned products might cause hardening in the parts of the Oxygen Concentrator and can shorten its service life.
- ◆ Do not throw away the humidifier bottle or nasal cannula. They should be disposed of at a nearby medical waste disposal facility.
- ◆ Please select the suitable humidifier bottle for your device and fix it on the machine as required. Do not operate under a revolving situation. (Refer to the humidifier bottle connection indicator diagram).
- ◆ When using the humidifier bottle, take note of the maximum and minimum water levels while filling up the bottle as required.
- ◆ When this machine is scrapped, please contact your local supplier or manufacturer.
- ◇ Please refer to the “SYMBOL KEY” for the Faciox symbol printed on the device, package, and in the manual.
- ◇ Please refer to the “DEVICE AND ACCESSORIES DESCRIPTION” to test the equipped components when receiving the device and before use, and then operate it as per the “PRODUCT OPERATING PROCEDURE”.

## SYMBOL KEY

	Off(Total power supply)		On(Total power supply)
	Follow the instructions		No open flames
	No Smoking		Date of manufacture
	Warnings		Serial Number
	Cautions		Up Put
	Double insulated		Keep dry
	Type BF applied part		Fragile, handle with care.
220V~	AC 220V		Do not sit on
	Non-ionizing electromagnetic radiation		
	Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive) after the valid term within three years, the machine should be treated per local law or regulation requirements to avoid injury to users and polluting the environment.		

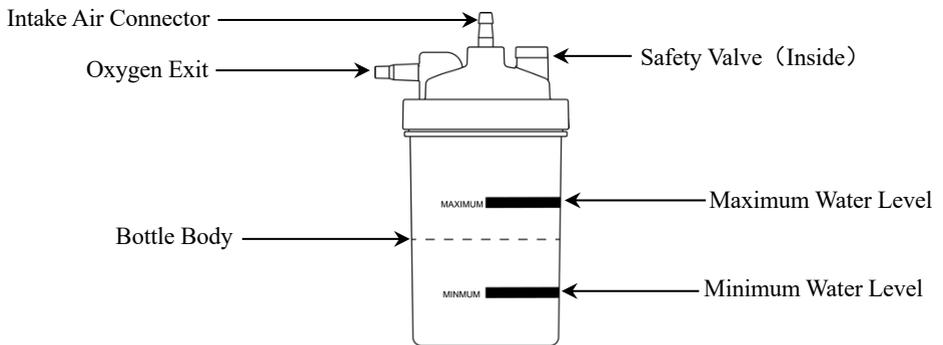
## DEVICE AND ACCESSORIES DESCRIPTION

When you receive the product, please open and check the package carefully. This product is equipped with upper and lower foam protection covers. If the protective cover is damaged, please immediately check whether the product is damaged or not. Then, check whether there are any missing parts or accessories according to the packing list below.

Packing List			
Number	Product /Component Name	Quantity	Unit
1	Oxygen Concentrator	1	Unit
2	Air filter foam	1	Piece
3	User Manual	1	Piece

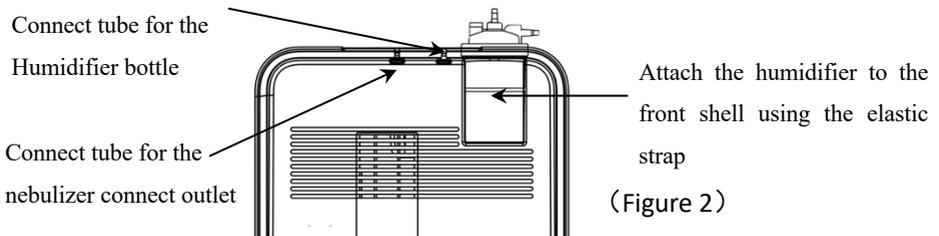
## OPERATING INSTRUCTIONS

- 1、 This product must be placed at least 30cm away from the wall while in use, and any protective foam or other items at the bottom must be removed. The bottom should be kept free of clutter to ensure proper airflow and normal heat dissipation.
- 2、 Connect the humidifier bottle and operate it per the following instructions:



(Figure1)

- a. Fill the humidifier bottle with distilled water as instructed. DO NOT fill above or below the water levels marked on the bottle. Put the cap back on the humidifier bottle (Figure 1):



(Figure 2)

- b. Attach the humidifier bottle to the front shell with the elastic strap and connect to the air intake connector through humidifier bottle tubes with the oxygen output spot. (Figure2).



Notice: The recommended place to install the humidifier bottle is shown in figure 2.

3. Remove the AC power cord from the retaining strap and confirm that the switch is in the off position. Plug in the Oxygen Concentrator.
4. After turning on the power, the indicator on the display will stay on. This means the machine is working perfectly.
5. Adjust the output flow of oxygen according to the needs of the patient. Turn the flow adjustment knob counterclockwise to increase the flow, and turn it clockwise to decrease the flow.
6. Insert the nasal cannula in the output spot of the humidifier bottle, hang the nasal cannula on the user's ears, then insert the nasal plug and breathe. See Figure 3.



(Figure 3)

7. When the machine is running, if the alarm goes off, please check whether the plug is loose, or if the external power supply has been interrupted.
8. When done using the device, please turn off the power. Clean the nasal cannula according to the instructions. If the machine is not used in a fixed location, please unplug the device, strap the AC power cord, and move the machine to where it is stored.

## INTRODUCTION

The Oxygen Concentrator provides low-flow oxygen therapy to patients at home. Our oxygen generator product produces concentrated oxygen from room air for delivery to a patient requiring low-flow oxygen therapy. Oxygen in the air is concentrated using a molecular sieve and a pressure swing adsorption process. When the device is operating at room temperature, the oxygen in the air can be separated and concentrated to meet medical standards.

## STRUCTURE

This product contains the body of the Oxygen Concentrator, and a flowmeter.

## SCOPE OF APPLICATION

The equipment is mainly suitable for medical use with oxygen.

## CONTRAINDICATIONS

None

## ENVIRONMENT REQUIREMENTS

1. Environmental Temperature:  $5^{\circ}\text{C}\sim 35^{\circ}\text{C}$ ;
2. Relative Humidity:  $\leq 80\%$ ;
3. Atmospheric Pressure:  $86\text{ kPa}\sim 106\text{ kPa}$  ;  
No corrosive gas or strong magnetic fields in the surrounding environment.

## TRANSPORTATION AND STORAGE CONDITIONS

1. Storage and Transport Temperature: - 20°C~ +55°C;
2. Storage and Transport Humidity:  $\leq 93\%$ ; with no condensation phenomenon;
3. Storage and Transport Atmospheric Pressure: 50 kPa to 106 kPa.



**Notice: When the storage temperature is under 5°C , the machine should be placed in a room temperature environment for at least four hours before use.**

## ADDITIONAL REMARKS

Classification of protection against electric shock: Class II

Classification according to the degree of protection against electric shock:

Class BF

Classification according to the degree of protection of the liquid into the machine: IPX0 Device;

According to the degree of safety classification used in flammable anesthetic mixture with air or oxygen or Nitrous Oxide anesthetic mixture case: when do not use of flammable gas and air mixed with oxygen or Nitrous Oxide or anesthetic mixture under the condition of the equipment ;

classification according to the operation mode: Continuous operation;

No signal output and signal input part;

Usage Voltage: 220V~, 50 or 60Hz, 350VA;

Working: Continuous working;

\* Altitude:

0 meters to 1828 meters, oxygen purity:  $93\% \pm 3\%$ ,

1829 meters to 4000 meters,  $\leq 90\%$

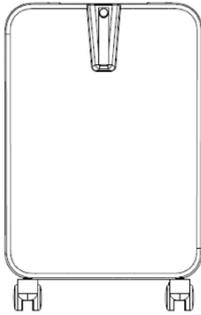
## SPECIFICATIONS

Model	OC505
Working Voltage	220V~, 50/60 Hz
Rated Power (VA)	350
Output Pressure=0 and 7kPa, the flow range (L/min)	0.5~5
Output Pressure=0, the purity value (within 10min, up to the standard)	Oxygen flow=0.5~5 L/min, purity $\geq 93\% \pm 3\%$ , Output pressure >6.0 psig
Highest Flow	5 L/min
Highest Flow with 7kPa pressure, change of flow	$\leq 0.5$ L/min
Highest Flow, purity (within 10min, up to the standard)	Oxygen purity $\geq 93\% \pm 3\%$ , output pressure >6.0 psig
Range of adjusting flow	0~5L/min adjusted continuously
Net Weight (Kg)	14.3
Noise dB(A)	$\leq 47$
Dimension (mm)	L380 × W249 × H593
Oxygen output pressure	60kPa $\pm$ 6kPa
Alarm indicator light	Refer to 15.b and c. Fault code description

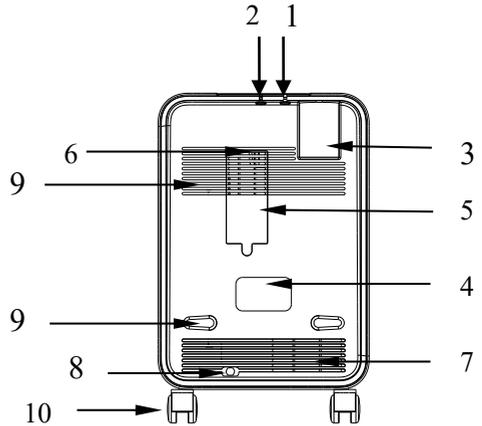
Compressor safety valve release pressure: 250kPa  $\pm$  30kPa

Oxygen output temperature:  $\leq 41^{\circ}\text{C}$

## SYSTEM OVERVIEW



(Figure 4)



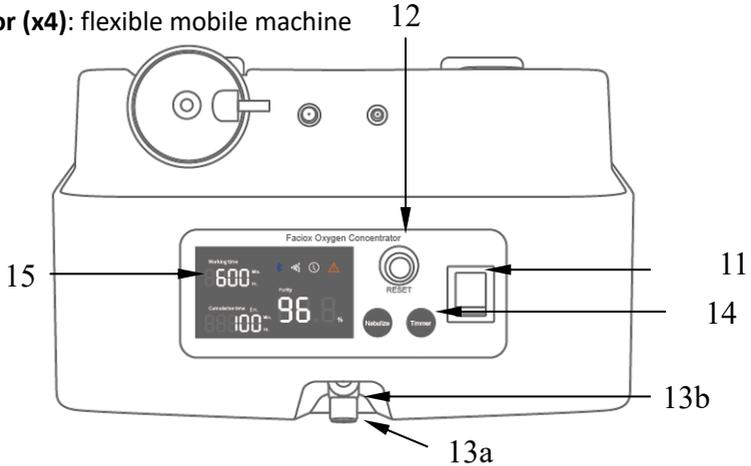
(Figure 5)

\* The following component description refers to figure 4 and figure 5 \*

1. **Oxygen outlet:** Connect to the humidifier bottle or nasal cannula using the connecting tube
2. **Nebulizer connection outlet**
3. **Position to place humidifier bottle**
4. **Product label:** product performance, product serial number
5. **Air filter cover:** contains air filtering device and air filter foam.
6. **Air filter foam:** To prevent dirt, dust, and fibers from entering the machine.
7. **Heat vent:** Located on the bottom of the machine to release heat from the device. The vent should not be blocked while the machine is operating.
8. **Straight out of the AC power cord** (with plug).

**9. AC power core bracket.**

**10. Castor (x4):** flexible mobile machine



(Figure 6)

**11. Power switch:** **O**: Off / **I**: On

**12. Reset:** Reset AC power when overloaded.

**13. Oxygen flow meter**

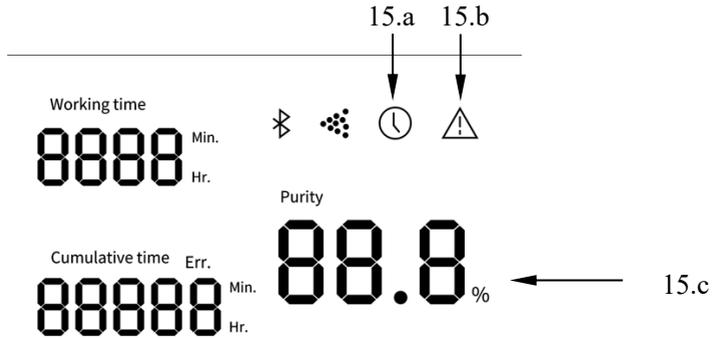
- a. The ball inside the flow meter shows the oxygen flow. A higher position is a faster flow, and a lower position is a slower flow (L/min).
- b. **Flow meter knob:** Adjust the flow by turning clockwise (slower flow) or counter clockwise (faster flow) to control the oxygen flow volume.



**Note:** Pay attention to the position of the ball on the flow meter and set the oxygen flow according to the doctor's instructions. (The OC505 series supports a flow up to 5L/min. DO NOT set the flow over 5L/min.)

**14. Timer button:** The timer illuminates when it is turned on. There is the option for 30 to 480 (30/60/90/120/180/240/300/360/420/480 minutes in ten intervals) minutes with the timer sign light up on the LED display. Every click of the button will increase the operating time by one interval.

Pressing once more after setting it to 480 minutes will cancel the timer function.



(Figure 7)

## 15. LED Display (Reference figure 7)

- a. Timer Indicator - Timer set and start
- b. Alarm indicator - Contact the manufacturer
- c. Digital display slot:
  - Oxygen purity
  - Working time (time count in minutes and hours; it will show hours after 600 minutes): Calculate the operating time for each use.
  - Cumulative time (time count in minutes and hours; it will show hours after 600 minutes) : Digital show for six digits.
    - Total operating hours after the machine leaves the factory.
    - When the machine is turned on or the timer function is cancelled, the total running hours of the machine will be displayed briefly, as shown in Figure 7.
  - Fault code description:
    - E01 - Cycle fault alarm or oxygen purity < 82%
    - E02 - Low pressure alarm
    - E03 - Cycle fault and low-pressure alarm
    - E04 - High pressure alarm

- E05 - Cycle fault and high-pressure alarm
- E06 - High temperature alarm
- E07 - Low flow alarm
- E08 - Oxygen port clogging alarm
- E09 - Electronic parts failure

When the oxygen concentrator is working, it will automatically monitor the machine status.

If the oxygen purity is below 82% the machine will illuminate the Yellow Low Purity Indicator, issue an alarm and display "E01" on the LED display. Please turn off the power and contact your local service center or the manufacture.

If low pressure occurs, the machine will light up the Red Alarm Indicator, issue an alarm and display "E02" on the LED display. The Oxygen Concentrator will stop working within one minute. Please turn off the power and contact your local service center or the manufacturer.

If both a cycle error and low pressure occur at same time, the machine will light up the Red Alarm Indicator, issue an alarm and display "E03" on the LED display. The Oxygen Concentrator will stop working within one minute. Please turn off the power and contact your local service center or manufacturer.

If high pressure occurs, the machine will light up the Red Alarm Indicator, issue an alarm and display "E04" on the LED display. The Oxygen Concentrator will stop working within one minute. Please turn off the power and contact your local service center or the manufacturer.

If both a cycle error and high pressure occur at same time then the machine will light up the Red Alarm Indicator, issue an alarm and display "E05" on the LED display. The Oxygen Concentrator will stop working within one minute. Please turn off the power and contact your local service center or manufacturer.

If the air temperature of the oxygen outlet is over 41 °C, the machine will light up the Red Alarm Indicator, issue an alarm and the display "E06" on the LED display. The machine will stop working within one minute. Please turn off the power and contact your local service center or manufacturer.

If the oxygen outlet or pipeline is blocked, the machine will light up the Red Alarm Indicator, issue an alarm and display "E07" or "E08" on the LED display. Please turn off the power; check whether the humidifier bottle or tube are blocked. If either one are blocked, please check if it is possible to clean it. If not, please contact your local service center or manufacturer.

In the case of an electronic parts failure, the machine will light up the Red Alarm Indicator, issue an alarm and display "E09" on the LED display. Please turn off the power and contact your local service center or manufacturer.

 **Note: All alarms of this Oxygen Concentrator are considered low priority. The alarm system of the Oxygen Concentrator is set before leaving the factory, and users CANNOT change the settings of the alarm system.**

## CLEANING AND MAINTENANCE INSTRUCTIONS

- 1、 Clean the outside shell: 1~2 times per month. Turn off the power and disconnect from the power source before cleaning. Clean the device exterior using a wet towel with a mild household cleaner and wipe it dry.
- 2、 Clean the humidifier bottle: Use detergent and hot water to clean the humidifier bottle separately. Soak the humidifier bottle in the solution for 30 minutes and wipe it dry.
- 3、 Clean the air filter foam: Take off the filter foam from the back side of the device exterior, clean it with detergent and rinse thoroughly with clean water. Air dry the filter foam. Please do not use the air filter foam if it is not completely dried. This is an important step to protect the machine. The air filter foam should be cleaned twice per month.

## WARRANTY

The warranty period is one year from the date of purchase; consumables are not covered under this warranty. If the product fails to operate normally due to non-human causes, the manufacturer will provide free repair or replacement of parts.

- 1、 This warranty covers defects in materials and workmanship under normal and proper use and when correctly maintained in accordance with applicable instructions, for a period of one year from the date of purchase.
- 2、 Machines that fail due to unauthorized modifications or additional functions will not be accepted for repair.
- 3、 If the product fails to perform in accordance with the product specifications, repair or replacement are provided – at its option – of the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

**The following conditions are not free of maintenance:**

- 1、 Products over the warranty period;
- 2、 Failure to operate the device following the manual requirements;
- 3、 Failure, scratches or damage due to transportation;
- 4、 Undergoing repair, decomposition, or assembly without allowance from professional service personnel.
- 5、 Normal damage of the wearing parts;
- 6、 Failure and damage due to nature causes (e.g. fire, flood, earthquake, etc.).

## TROUBLESHOOTING



In order to avoid electric shock, please do not open the device. The covers should only be removed by Faciox service personnel.

The table below lists common problems and actions you can take. If you are unable to resolve a problem, please contact your home care provider.

Symptom	Possible Cause	Remedy
<b>A.</b> Unit does not operate. Panel light is off when the power switch is “on”. Audible alarm is pulsing and Service Required light is flashing.	1. Power cord not properly inserted into wall outlet.	Check power connection at the wall outlet. On 220 voltage units, check the back of the unit.
	2. No power at wall outlet.	Check your home circuit breaker and reset if necessary. Use a different wall outlet if the situation occurs again.
	3. Oxygen Concentrator circuit breaker activated	Press the concentrator circuit breaker button (if equipped) located below the power switch. Use a different wall outlet if the situation occurs again.
<b>B.</b> Unit operates within 1 min; the Panel light is on when the Power switch is “On”. Alarm indicator light is illuminated. Audible alarm may be sounding.	1. Air filter foam is blocked.	Check the air filter foam. If the air filter foam is dirty, wash it by following the cleaning instructions on page 22.
	2. Exhaust is blocked.	Check the exhaust area; make sure there is nothing restricting the unit exhaust.
	3. Blocked or defective nasal cannula.	Detach nasal cannula from the device. If proper flow is restored, clean or replace nasal cannula if necessary.
<b>C.</b> Alarm indicator light is on and the audible signal is sounding.	A fault code is shown.	Please following the “Fault code description” on pages 19 - 21.
If the machine is still not working properly, please contact the product supplier or service point.		

\* If there is no special description, please follow the instructions above.

## Electromagnetic Compatibility



### Notice:

- ◆ The OC505 Oxygen Concentrator complies with the electromagnetic compatibility requirements of the IEC 60601-1-2 standard.
- ◆ Users should follow the electromagnetic compatibility information provided in this manual for installation and operation.
- ◆ The use of accessories or products from other manufacturers may impact EMC (electromagnetic compatibility). Using unauthorized accessories or products may void the product warranty and could potentially cause harm to you, others, and/or the Oxygen Concentrator.
- ◆ Portable and mobile radio frequency communication devices may affect the performance of the OC505 Oxygen Concentrator. To avoid strong electromagnetic interference, refrain from using it near devices such as mobile phones and microwave ovens.



### Cautions:

- ◆ The OC505 Oxygen Concentrator should not be placed close to or stacked with other devices. If it is necessary to position it near or stack it with other devices, make sure that it can operate normally in the configured setup.
- ◆ Except for cables sold by the manufacturer of the OC505 Oxygen Concentrator as spare parts for internal components, the use of accessories and cables not specified in the guidelines may result in increased emissions or reduced immunity to interference by the OC505 Oxygen Concentrator.

## EMC INFORMATION

### Guidance and manufacturer's declaration-electromagnetic emissions

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

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>ME</u> uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>ME</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

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

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

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment -</b>
Electrostatic discharge (ESD) IEC 61000-4-2	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV line(s) to line(s) + 2kV line(s) to earth	+ 1kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <u>ME</u> requires continued operation during power mains interruptions, it is recommended that the <u>ME</u> be powered from an uninterruptible power

			supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	The <u>ME</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the A.C. mains voltage prior to application of the test level.			

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

The ME is intended for use in the electromagnetic environment specified below. The customer or the user of the ME should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the <u>ME</u> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b> $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a, should be less than the

			<p>compliance level in each frequency range, b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			<p>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 <u>ME</u> is used exceeds the applicable RF compliance level above, the <u>ME</u> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the <u>ME</u>.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>

## ENVIRONMENT PROTECTION

Dispose of the device in accordance with local regulations. When the product is at the end of its life and the user intends to discard the product, it must be disposed of separately from other waste. Please contact your local agency or waste disposal service center for instruction and local disposal laws.



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