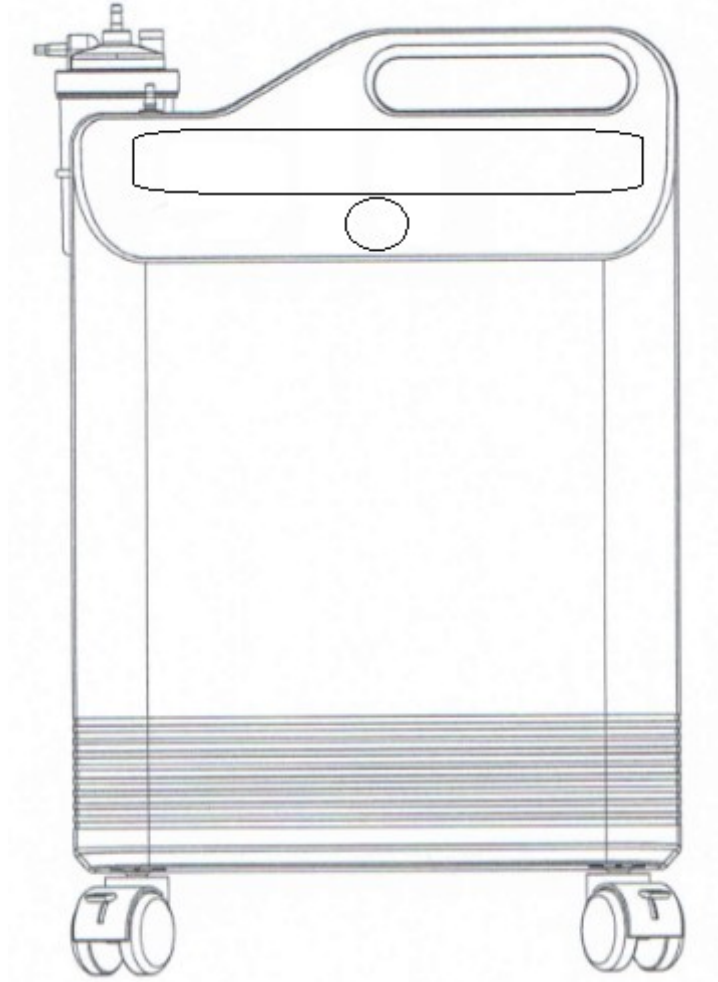


# FORAS OXYGEN CONCENTRATOR



## USER MANUAL MODEL : OXY300 – OXY500




CAUTION: Please read this manual before using.

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## INTRODUCTION

This manual will introduce OXY300 and OXY500 Oxygen Concentrators. Read this manual and understand the user manual before operating the device. Important safety precautions are described in this manual. Please pay attention to all information. Consult your doctor in any adverse situation.

 **CAUTION** : For your safety, use in accordance with the advice of specialist physician.

 **WARNING** : Do not smoke near the person who receives oxygen therapy while the oxygen concentrator is operating. Oxygen causes rapid combustion. Keep the oxygen concentrator at least 2 meters away from sparkable objects and bare sources of flame.

## **CAUTIONS AND GENERAL PRECAUTIONS**

- It does not require special training and skills to use the device. Professional or first-time users will have met the minimum terms of usage conditions when reading the user manual.
- In the event of a power cut, failure of the Oxygen Concentrator or insufficient oxygen supply to the patient, it is obligatory to carry a spare oxygen provider or oxygen cylinder with you. This is your responsibility. Foras Medical does not accept any responsibility for customers who do not comply with the manufacturer's instructions.
- Foras Medical does not accept any problems that may arise from materials used other than the recommended accessories. Do not modify the device and do not allow any company except Foras Medical to intervene device during the warranty period. In such cases, the device will be excluded from warranty.
- Do not carry the device when there is water in water tank or take precautions to avoid overturning. If water leaks into the device, the device is out of warranty.
- Do not smoke in the room/environment where the device operates.
- Since the oxygen is a flammable gas, care should be taken against risk of ignition. Keep far away.
- Keep the device away from humid (more than 95% humidity) environment. Do not expose to water and sediment. Do not operate in the rain, it may cause electric shock.
- Do not use the device in an excessive dusty and smoky environment. Check the filter frequently. When the device is operating in a dusty environment, it will cause the oxygen level to decrease due to the blockage of the air inlet filter.
- The device may show low performance at high temperatures (over 40 ° C). Do not expose the device to direct sunlight. Use the device in a shade and airy place.
- Do not keep petroleum-based products (oil, petrol grease, etc.), flammable and sparkler materials (thinner, alcohol, cologne etc.) near the device. Care should be taken against the risk of burning the device
- It is not used on these patients as there is no clinical trial for its use in the treatment of pregnant, lactating women and young children.
- Device has wheels underneath for easy movement. Open the brakes on the wheel while moving on the ground. Otherwise, it may cause the device to overturn.
- Carrying handle should be used for easy transportation of the device.
- Do not place the device on tables, coffee tables, etc. It should be noted that the device can be toppled because it emits vibration while operating.

- If you feel sick or uncomfortable while using the device, consult your physician.
- The doctor or caregiver should take protective measures against the risk of cross-infection if the patient has an infection. At the same time, no one at the risk of infection should have contact with the patient.
- Operate the device in an upright position. The device should not be operated horizontally.
- When the device has completed its life, it should not be disposed with household waste, it should be disposed with medical waste.
- **The device does not operate at full performance for 24 hours. Therefore, it should be closed at least 2 hours in a day. For such cases, an oxygen cylinder and a backup oxygen provider should be available.**
- **Keep the right, left and back of the device at least 50 cm away from the wall. Keep away from heating devices such as stove and heater.**
- **It is not suitable to use with MR devices.**

## WHY IS OXYGEN THERAPY RECOMMENDED ?

Many people suffer from heart, lung and other respiratory diseases. Most of these people benefit from additional oxygen therapy. Our body needs constant oxygen to function properly. Your doctor prescribes for supplemental oxygen because you can not get enough oxygen in the ambient air. This additional oxygen will meet your body's oxygen needs.

Supplemental oxygen is not addictive. Your doctor has prescribed a specific oxygen flow to enhance symptoms such as headache, drowsiness, fatigue or increased irritability. Contact your doctor if these symptoms persist after starting treatment.

Today, oxygen concentrators are reliable, efficient and convenient source of oxygen. Oxygen concentrator separates the oxygen from the air in the environment, thus the concentrator filters the oxygen in a tank and provides high purity supplemental oxygen to the patient from the oxygen output.

## INDICATIONS AND INTENDED USE

It is used for chronic lung disease (Chronic Obstructive Pulmonary Disease - COPD), on the treatment of patients who need supplemental oxygen and in cases where the patients need pure oxygen due to heart disease.

## CONTRAINDICATIONS AND ADVERSE EFFECTS

Side effects and contraindications that may occur in use of the device contrary to the user manual;

- Other than the recommended use by physician, oxygen therapy of the device may be harmful.
- In the use of patients with vision/hearing loss, problems may occur if the instruction is not followed.
- The oxygen concentrator should not be used with other respiratory apparatus other than the recommended devices. Low performance can be observed use with other devices. As a result of this, the patient and the device may be damaged.
- If the device is not used for its intended use, it may harm the patient.
- If it is not used as recommended in the instruction, it may take risk because it contains oxygen.
- Device can be damaged as a result of water leak in case of using humidifier.

- Smoking in the environment where the device is located and to keep flammable materials near the device may be dangerous.
- If the device is used above the moisture specified in the instructions, oxygen treatment will not be possible because the columns will be damaged.
- If the device is used above the temperature which specified in the instruction, it should be noted that there will be low performance on the device.
- It is objectionable to approach the device with flammable and explosive materials.

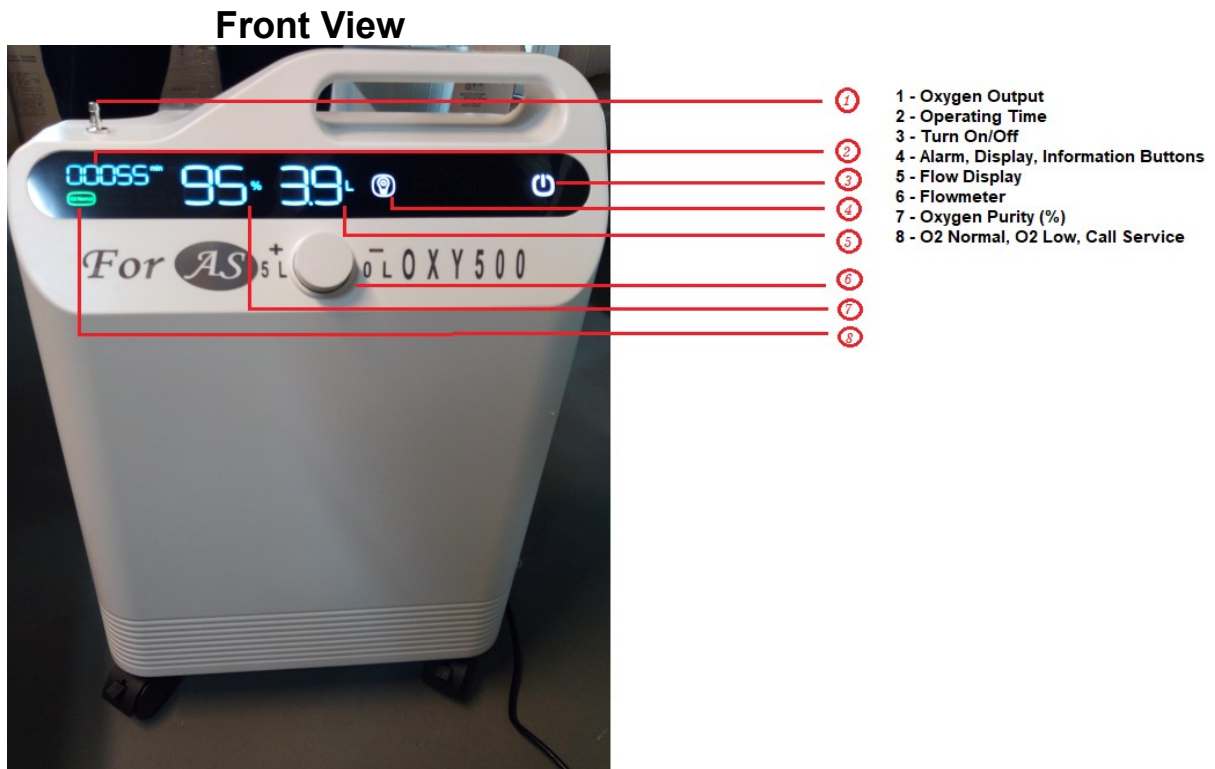
### PATIENT POPULATION

It is used in chronic lung system disease, other diseases due to lack of oxygen and for patients that need supplemental oxygen who are prescribed by doctor. It is not used in following patients as there is no clinical study has been conducted on the use of pregnant and breastfeeding women, kid.

### ACCESSORIES OF OXYGEN CONCENTRATOR

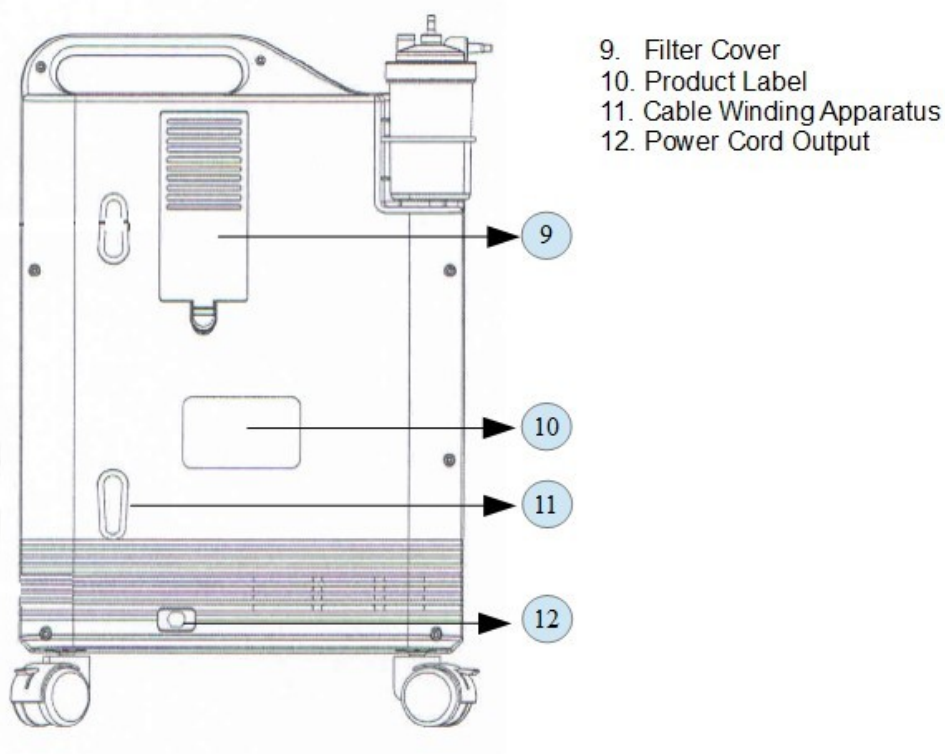
The following parts are included in standard package content of Oxygen Concentrator.

- Oxygen concentrator main unit
- Humidifier bottle
- Humidifier bottle connection tube
- Nasal cannula
- User manual



(Figure 1)

### Back View



(Figure 2)

**Display View**

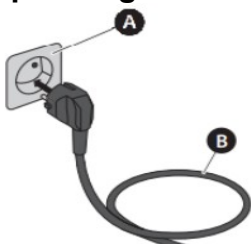


(Figure 3)

Note: When there is electricity, the icon on the power indicator is green colored. It is red colored when O2 Low and Call Service icons appeared.

**BEFORE OPERATE THE OXYGEN CONCENTRATOR**

After removing the device from its box, the instructions for use must be read before operating device.



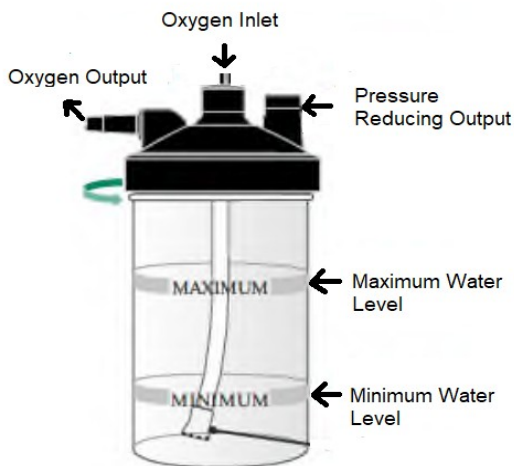
1. After the device is removed from box, it is checked whether there is physical damage. Then the electrical cord of the device is plugged into the electrical outlet in the room.  
 A. Mains Electricity (Outlet)  
 B. Concentrator Power Cord

(Figure 4)

**Note:** Do not attach any other device to the outlet where the oxygen concentrator is connected.

2. Before operating the device always make sure that the air filter is installed and clean.
3. Attach the recommended Oxygen Concentrator accessories (Humidifier Bottle and Cannula) to the device.

### Humidifier Bottle Usage



(Figure 5)

- a.) Remove the humidifier bottle cover by turning it in the direction of narrow.
- b.) Put water to humidifier bottle until Maximum level. Do not exceed maximum level (As manufacturer, we recommend you to put water between maximum-minimum levels and to replenish the water every day.) Put boiled and chilled or bottled water to the humidifier bottle. (Do not use tap water)
- c.) Close the lid and replace the humidifier bottle on oncentrator. When installing the cover, make sure it is properly installed. Otherwise it could leak oxygen through the hatch.
- d.) Connect the oxygen hose that comes from oxygen concentrator to the oxygen inlet.
- e.) Connect the cannula to the oxygen outlet.
- f.) Make sure there is no calcification or sediment in the humidifier bottle.

### Humidifier Bottle Tube Connection



(Figure 6)

1. Interconnecting tube is connects from oxygen outlet of device to the place on the humidifier bottle that shown in Figure 6.
2. Nasal cannula connects to oxygen outlet.


**NOTE:** Care should be taken to avoid calcification and blockage of the hose tip in the humidifier bottle. If the humidifier bottle will not be used, the cannula must be connected directly to oxygen outlet.

If the humidifier bottel is not to used, the cannula should be connected directly to the oxygen outlet. The image of the humidifier bottle is its representation, it can differs from the original. Humidifier bottle should be changed once in a month.

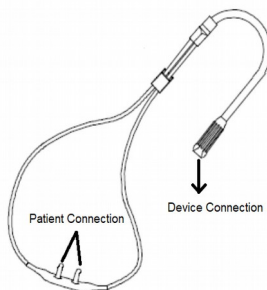
## Nasal Cannula Usage

It is a tubing system made of from plastic-derived biocompatible material that placed in the nostrils of the patient who use the device and it provides oxygen delivery to the patient. This tubing system, does not prevent to patient's deating/drinking activities. Patient can continue his/her daily life with nasal cannula. In case of any tear, break and wear out, do not use the cannula and replace it with new one.

Cannula should be connected to the oxygen outlet of the humidifier bottle of the Oxygen Concentrator. The recommended cannula length is 2 meters.

 If there is a risk of infection on the patient, protective equipment should be used when applying nasal cannula to the patient. Precautions should be taken against the risk of cross-infection from the patient or the risk of infection to the patient. Cannula removed from the patient must be disposed of in accordance with medical waste procedure.

**CAUTION !:** In case of obstruction of cannula, keep the tube away from children and animals.



(Figure 7)



(Figure 8)


*Figure 7 shows the general view of the cannula and Figure 8 shows the patient connection form of the cannula.*

*Make sure that the cannula used is not fold, broken and torsion. Otherwise, patient might have a problem due to oxygen therapy can not be applied.*

Note: Use the cannula or mask recommended by your doctor. It is recommended to replace once in a month.

## TURN ON / OFF FOR OXYGEN CONCENTRATOR

Do not operate the device without taking the necessary controls and precautions before operating the device.

 **CAUTION :** Do not smoke near the device, do not let smokers close to device.



(Figure 9)

After plugging the power cord of the device into the outlet, start the device by pressing "I" shaped position as showed in Figure 9. The display lights turn on when the button is pressed. Then, working time of the device appears and it starts operating.

Contact the manufacturer if the device does not work or any abnormalities are detected. Starting of device takes 1 second when the power button is pressed.



### Flowmeter



After operating the device, desired setting should be made by adjustment knob shown in Figure 10. When the button is turned to the "+" side, the flow increases. When the button is turned to the "-" side the flow decreases. If there is no change in the flow of the display when the button is turned, contact technical service.

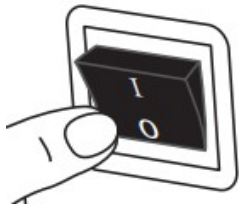
(Figure 10)

Flow increases when the adjustment knob is turned to the "+" side. Flow decreases when the adjustment knob is turned to the other side.

When the flowmeter is turned clockwise, it decreases and stops at the last point. It rises when reversed.

**CAUTION ! :** Use the flowmeter to adjust the oxygen recommended by your doctor. Otherwise, do not change the oxygen flowmeter setting by yourself.

**Not:** You may want to set the oxygen flowmeter for you where you bought the device.



Device can be turned off by pressing "0" as shown in Figure 11. When the button is presses, it turns on immediately.

(Figure 11)

## MAINTENANCE AND CONTROLS



Grease oil, machine oil and any kind of oil like this should not be used in the device in any way.

**CAUTION !:** Keep the device off while performing general controls and maintenance.



Make sure that the cabinet of device is not opened by yourself or unauthorized persons. Do not use it in any way in case there is an opening in cabinet. The cabin must be opened only by an authorized personnel. Avoid liquid contact with the device.

**It is recommended that the device serviced once in every 12 months. The performance of the device depends on its proper operating.**

## **Oxygen Humidifier Bottle Checkings**

If your doctor recommends using the device with humidifier;

- Check the humidifier bottle periodically, as sediment and lime will form in the water tank during extended use.
- It is recommended to change the humidifier bottle once a month.
- Add drinking water (bottled water) or boiled water daily. Do not use tap water.
- Do not put more / less water than the indicated level.
- Make sure the lid is properly closed after adding water.

## **Cannula Checking**

Make sure that the cannula used is not broken and not torsion. We recommend that you change the cannula at the latest in 1 month depending on the intensity of use.

## **Filter Checking**

Under the normal use conditions, it is recommended that the bacteria filter of device to be changed once in a month. However, this time gets shorter using in very dusty environment. The filter should be checked and changed frequently. This responsibility belongs to patient. The device and the patient may be damaged by the blockage of the filter. If the device is damaged due to failure to filter not being replaced on time, the device will be out of warranty even it is under warranty term.

Changing the filter;

- Open the filter cover on the back of the device.
- Remove the filter and replace it. (Never try to clean the filter)

The sponge filter on the device (if any) should be checked frequently and removed when it is contaminated. After washing with warm water, it should be dried and used again. Worn filters should not be used.

The proper operation of the device is not only depends on device. Accessories are very important. Checkings should be carried out as described above. Otherwise, performance will decrease.

## **CALIBRATION**

Operation of the device at the desired performance can be achieved by following the instructions. In normal use, it is sufficient to calibrate the device once in 12 months. If it is suspected that there is a decrease in the oxygen rate of the device, it should be verified by measuring it with a calibrated oxygen analyzer.

## **CLEANING**

Do not use petroleum based and solvent based products when cleaning the cabinet of device. Clean the outer cabinet of device with alcohol through cloth. Thanks by this, there will be no residue. Unplug the power cord from outlet while cleaning.

## ALARMS

**O<sup>2</sup> Low :** When that audible and visual alarm emerges on device, it indicates that the oxygen level decreases below %82..

**Call Service :** The device gives an audible and visual alarm in the event of a power failure and when the flowmeter is 0 (zero).

## TECHNICAL SPECIFICATIONS

OXY300		OXY500	
Oxygen Level	1-3 LPM	Oxygen Level	1-5 LPM
Pressure	8,5 psi (58.6 kpa)	Pressure	8,5 psi (58.6 kpa)
Watt	300W	Watt	300W
Electrical Spec.	230V, 50Hz, 1.8A <sub>(max)</sub>	Electrical Spec.	230V, 50Hz, 1.8A <sub>(max)</sub>
Oxygen Percentage	1~3 LPM 94%±3%	Oxygen Percentage	1~5 LPM 94%±3%
Fuse	15A	Fuse	15A
Av. O <sup>2</sup> Purity	1 lt/min. : %94±3% 2 lt/min. : %94±3% 3 lt/min. : %94±3%	Av. O <sup>2</sup> Purity	2 lt/min. : %94±3% 4 lt/min. : %93±3% 5 lt/min. : %92±3%
Operating Conditions	Temp. :10°C / 40°C Humidity : %30 / %70 Pressure : 50/106kpa	Operating Conditions	Temp. :10°C / 40°C Humidity : %30 / %70 Pressure : 50/106kpa
Weight	14kg	Weight	15kg
Sound Level	<48dbA	Sound Level	<48dbA
Dimensions	400*300*510mm	Dimensions	400*300*510mm
Storage Conditions	Temp. :-20°C/ 50°C Humidity : %0 / %95 Pressure : 50/106kpa	Storage Conditions	Temp. :-20°C / 50°C Humidity : %0 / %95 Pressure : 50/106kpa
O <sup>2</sup> Capacity	3 Liter	O <sup>2</sup> Capacity	5 Liter
Model Diff.	Continuously 3 lt	Model Diff.	Continuously 5 lt
Working System	Producing electric withO <sup>2</sup>	Working System	Producing electric withO <sup>2</sup>
Class/Protection type	II / BF	Class/Protection type	II / BF
Expected Operating Life	10 years	Expected Operating Life	10 years
Warranty	2 years	Warranty	2 years
IP Value	IP21	IP Value	IP21
Alarm	Available	Alarm	Available

















## ENVIRONMENTAL CONDITIONS

- Do not use oxygen concentrator devices in any toxic environment.
- Do not use oxygen concentrator devices in environmental conditions where explosive and chemical gases or other flammable anaesthetic agents are present. Keep fire away.
- Do not use under rain, direct sunlight, in extremely humid-dusty environment or in smoking areas.
- Storage Conditions: Temperature -20°C / 50 °C, Humidity %0 - %95, Pressure 50kPa/106kPa
- Operating Conditions: Temperature 10°C / 40 °C, Humidity %30 - %70, Pressure 50kPa/106kPa
- The device performance will decrease in case of storing out of abovementioned temperature, humidity and pressure limits.

## TROUBLESHOOTING TABLES

Trouble	Solution
Device does not deliver oxygen	<ul style="list-style-type: none"> <li>* Make sure that the power cord of device is plugged to outlet.</li> <li>* Make sure that device is operating.</li> <li>* Make sure the flowmeter is set as required.</li> <li>* Check the connections of nasal cannula.</li> <li>* Make sure the lid of humidifier bottle is closed properly.</li> <li>* Make sure the tube inside humidifier bottle is not blocked.</li> <li>* Contact technical service</li> </ul>
Device gets overheat	<ul style="list-style-type: none"> <li>* Make sure that device is not close to wall.</li> <li>* Make sure the filters are not dirty.</li> <li>* Pay attention that the environment is not too hot where the device is used.</li> <li>* Pay attention to the ventilation of the environment where the device is used.</li> <li>* Contact technical service.</li> </ul>
Device emerges O <sup>2</sup> Low alarm	<ul style="list-style-type: none"> <li>* Ventilate the environment where device is located.</li> <li>* Contact technical service.</li> </ul>
Device shows Call Service alarm	<ul style="list-style-type: none"> <li>* Make sure that electrical power is supplied to the device.</li> <li>* Make sure flowmeter setting is not at 0 (zero) or over 5.</li> <li>* Contact technical service.</li> </ul>
Device operates noisily	<ul style="list-style-type: none"> <li>* Operate the device on flat surface.</li> <li>* Contact technical service.</li> </ul>
No air flow on device	<ul style="list-style-type: none"> <li>* Put your finger to the oxygen outlet of the device.</li> <li>* Check the flow showed on display.</li> <li>* Contact technical service.</li> </ul>

**SYMBOLS EXPLANATION**

<b>Symbols</b>	<b>Explanation</b>
WARNING	“WARNING”, indicates the situations that safety of patient may be in danger.
CAUTION	“CAUTION”, indicates that precautions should be taken and maintenance instructions should be followed
	Check the user manual for instructions
	Do not smoke while using device
	Keep fire away
	Check the user manual for instructions
	Manufacturer
	Keep dry
	It is not suitable for use with MR device.
	Do not dispose in street garbage
	BF type
	Clas II Equipment
	CE Mark and Notified Body Identification Number
	Do not expose to sunlight
	Humidity Limits
	Temperature Limits
	Pressure Limits
	Production Date
IP21	IP Rate

**RESIDUAL RISKS**Potential Risk

Application of Line Voltage  
 Voltage Leakage To User  
 Electric Shock  
 Magnetic Field/Radiation  
 Ionized Radiation Energy  
 Non-Ionising Radiation  
 Heat Given By Device  
 Falling  
 High Sound Emission  
 Titration  
 Stored Energy  
 Acoustic Energy  
 Not given O2 due to cannula  
 Gases formed by chemical wastes  
 Medical Gases  
 Additives  
 Residue on the device  
 Bacteria, virus and other agents  
 Again or Cross Infection  
 Biocompatibility  
 Contaminants  
 Function error  
 Model Difference  
 Error due to lack of attention  
 Causing memory weakness

Damage due to misuse  
 Lack of knowledge  
 Frequent violations  
 Improper use of device acc.  
 Error before device operation  
 Long-term use errors  
 Lack of side eff. and warnings  
 Deflagration

Usage in extremely humid envr.  
 Usage in a dusty environment  
 Using on pregnant and children  
 Water leakage into device  
 Problems due to critical material  
 Assemble Error  
 Plastic manufacturing failure  
 Adverse events  
 Recalls  
 Untraceability  
 Usage out of intended purpose

Residual Risk

Usage without reading user manual  
 Failure to perform leakage tests and final checks  
 Failure to perform leakage tests and final checks  
 EMC test values are not declared in the manual  
 Usage outside declared values  
 Usage outside declared values  
 Intervention to the device out of service  
 Inappropriate carrying of device  
 Improper assemble and production  
 Improper assemble and production  
 Sensor failure or manual adjustment  
 Usage outside declared values  
 Failure to comply with intended use  
 Non-compliance with given trainings  
 Non-compliance with given trainings  
 Failure to comply with critical raw material instruction  
 Failure to read user manual  
 Non-compliance with trainings and instructions  
 Usage of non-informed persons  
 Product use without CE certificate  
 Not paying attention to manual  
 Failure of final checkings and malfunction of sensors  
 Patient's failure to use appropriate device  
 Not paying attention to manual  
 Failure to use appropriate device for report and prescription  
 No training and not reading of manual  
 Failure to read the manual and rejection of training  
 Not reading the manual and wrong habits  
 No training and not reading of manual  
 Failure to read the manual and not receive training  
 Failure to read the manual and not receive training  
 Not paying attention to product labels and symbols  
 Not reading the manual and not paying attention to labels  
 Not paying attention to product labels  
 Use of untrained persons  
 Usage of untrained persons and not reading manual  
 Usage of untrained persons and not reading manual  
 Failure to follow instructions  
 Staff Carelessness  
 Failure to act in accordance with the list  
 Lack of knowing responsibilities and authorities  
 Lack of knowing responsibilities and authorities  
 Hazırlanan form ve kayıtların tutulmaması  
 Failure to fill the inspection and test forms

Continuation of identified problems	Failure to perform corrective actions
Packaging Mistake	Failure to comply with procedure
Labelling Mistake	Failure to comply with instructions
Lack of operational instructions	Failure to read user manual
Disposal of the device to trash	Usage of untrained persons and not reading manual
Lack of warnings	Not reading the manual, not paying attention to the label
Software Failure	Failure to perform final control tests
Processor Failure	Failure of performing input checkings
Failure of the device	Failure to act in accordance with user manual
Sensor Errors	Failure to perform final checks
Device error after service	Failure to act in accordance with the instruction
Failure of the device	Failure to comply with instructions
Not enough oxygen for patient	Usage of untrained persons and not reading manual
Encountered Problems	Lack of risk assessment
Storage Concitions	Failure to comply with requirements on product labels

## RELATED DIRECTIVES





Medical Devices Directive 93/42 / EEC is taken as reference.

## ELECTROMAGNETIC COMPATIBILITY

Foras OXY Oxygen Concentrator complies with the electromagnetic compatibility limitations of the medical device directive 93/42/EEC. (En 55011 BF class and EN 60601-1-2) IEC 60601-1-2 requirements for EMC have been completed.

## Description of Manual and Manufacturer Electromagnetic Immunity:

The oxygen concentrator is suitable for use in the electro-magnetic environment which described below. The user should pay attention to the environment when using the concentrator and use it as in the declared environment.

Immunity Test	IEC 60601 Test Level	Compatibility Level	Electromagnetic Env.-Guide
Electrostatic Discharge 61000-4-2	 ± 8 kV Contact  ± 15 kV Air	 ± 8 kV Contact  ± 15 kV Air	The floor should be wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the humidity should be at least 30%.
Radiated RF 61000-4-3	3V/m 80 - 2700 Mhz	1 kHz	Portable and mobile RF communications equipment should not be used closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Advised separation distance equation; $d = 1.2\sqrt{P}$ 150 kHz to 80 Mhz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz 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). The field intensity determined by electromagnetic field research of RF transmitters must be less than the level of conformity in each frequency range. Confusion may occur with devices bearing the following symbols on them.
Conducted 61000-4-6	3V 150 kHz - 80 Mhz	3 V	
Electrical rapid transient regime / immunity against sudden impact 61000-4-4	± 2 kV for power supply lines ± 1kV for Input Output Lines	± 2 kV for power supply lines ± 1kV for Input Output Lines	The power quality of the network should be similar to that of a typical workplace or hospital.
Pulse Immunity 61000-4-5	Lines/Line, lines / lines ±0.5 kV, ±1kV, ±2kV, Line/lines to ground ±0.5 kV, ±1kV, ±2kV	Lines/Line, lines / lines ±0.5 kV, ±1kV, ±2kV, line/lines to ground ±0.5 kV, ±1kV, ±2kV	The power quality of the network should be similar to that of a typical workplace or hospital.
Mains frequency magnetic field immunity (50-60Hz) 61000-4-8	30 A/m	30 A/m	The level of power frequency magnetic fields should be as in typical places, such as a normal hospital or home environment.
Voltage dips, short interruptions and voltage variations immunity tests 61000-4-11	10 s(min) 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° Cycle 3	0=0,5 0=1 70=25 0=250	The power quality of the network should be similar to that of a typical workplace or hospital. If the user (Me device and Me system) needs to continue operating despite power grid outages (Me device and me system), they must operate with a power supply or battery that is not interrupted.

**Note:** Higher frequency range applies at 80MHz and 800MHz.

**Note:** This information may not be available in all situations. Absorption caused by structures, objects and people affects electromagnetic propagation.



Broadcast Test	Compatibility	Electromagnetic Environment- Guidance
RF Broadcast CISPR 11	1. Group	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Broadcast CISPR 11	Group B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic Emissions 61000-3-2	Group A	
Voltage Change/Vibrating Emissions 61000-3-3	Compliance	

## COMPLIANCE WITH STANDARTS

IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, ISO 80601-2-67, ISO 80601-2-69 standarts are referenced in the production of oxygen concentrators.

## IEC 60601-1 CLASSIFICATION

Protection type against electric shock : Class II  
 Protection degree against electric shock : Type BF  
 Degree of protection against impact and waterproof : IP 21

## SOFTWARE INFORMATION

Firmware is included in class A software security class. Class A: Does not cause injury or damage to health. The version definition is used for traceability of software updates. Updates are performed on all models. The current version of oxygen concentrators is 1.0.

**Software Difference:** OXY300 model oxygen concentrator has the same visuality, same hardware and the same physical characteristics as the OXY500 model as it goes through the same manufacturing processes. The difference between them is software and the OXY300 model has the capacity to give 3 liters of oxygen per minute, while the OXY500 model has the ability to give 5 liters of oxygen per minute.

**Software Operation:** : In both models, when the power cable of the device is plugged in and the turn on button is pressed, the device starts in 1 second. Then it starts operating and continues to supply oxygen to the patient at the adjusted flow.



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