Regalia

Oxygen Concentrator

REGALIA
INSTRUCTION MANUAL

P/N 5167 Rev B
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Warnings and Cautions

Warning and Caution notices used in this manual apply to hazards or unsafe practices that could result in personal injury or property damage.

Not for medical purposes.

"Read Instruction Manual" ***Do Not*** operate this oxygen concentrator without first reading and understanding this manual. If you are unable to understand the warnings and instructions, contact your local AIRSEP dealer or authorized service representative before attempting to use this oxygen concentrator.

"Caution or Attention" In certain circumstances, oxygen therapy can be hazardous, therefore, it is advisable to seek medical advice before using the oxygen concentrator.

Warning: "No Smoking or Naked Flames" The use of oxygen requires that special care be taken to reduce the risk of fire. Material that burns in air and even some material that will not burn in air are easily ignited and burn rapidly in high concentrations of oxygen. For safety concerns, all possible sources of ignition must be kept away from the oxygen concentrator and preferably out of the room in which it is being used. Smoking in the proximity of an operating oxygen concentrator is dangerous, and can permanently damage the device and void the warranty.

"Use No Oil or Grease" A spontaneous and violent ignition may occur if oil, grease or other petroleum substances come into contact with oxygen under pressure. Keep these substances away from the oxygen concentrator, tubing and connections and any other oxygen source. ***Do Not*** use any petroleum based or other lubricants unless recommended byAIRSEP.

- Keep oxygen concentrator and cord away from hot surfaces. ***Do Not*** use the oxygen concentrator if it has a damaged cord or plug; contact qualified service personnel for examination and repair.
- Air intake of the oxygen concentrator should be located in a well-ventilated area.
- Oxygen concentrator should be located so as to avoid pollutants and fumes.
- If oxygen concentrator has been dropped, damaged or exposed to water, contact qualified service personnel for examination or repair.
- ***Do Not*** drop or insert any object into any opening.
- ***Do Not*** block the air opening of the oxygen concentrator or place it on a soft surface, such as a bed or couch, where the bottom air opening may become blocked.
- ***Do Not*** cover unit with a blanket, towel, quilt, etc.
- ***Do Not*** place objects (pillow, blanket) under unit. Maintain at least ½ inch clearance under unit.
- **Warning:** ***Do Not*** remove the cover. Cover should only be removed by qualified service personnel.
- **Warning:** An alternate source of supplemental oxygen is recommended in the event of a power outage, alarm condition, or mechanical failure.

Indications for Use

The Regalia Oxygen Concentrator is intended to provide only non-medical oxygen. It is not for medical purposes.

This oxygen concentrator is not intended for life supporting or life sustaining applications.

Introduction

The Regalia Oxygen Concentrator is an electronically operated oxygen concentrator that separates oxygen from room air. It does not remove oxygen from a room any more than by simply breathing the same room air. You utilize the oxygen by attaching tubing to the oxygen outlet fitting.

As with any electrically powered device, the user may experience periods of non-operation as the result of electrical power interruption, or the need to have the oxygen concentrator serviced by a technician. This instruction manual will inform you about the use and care of the Regalia Oxygen Concentrator and will serve as a reference as you use your oxygen concentrator.

Important Safety Instructions are shown under the following headings:

Warning: Important safety information for hazards that might cause serious injury.

Caution: Information for preventing damage to the oxygen concentrator.

Do Not: Information to which you should pay special attention.

Important: Clarifying information, specific instructions, commentary, sidelights, or interesting points.

Symbols Used in Instruction Manual and on Oxygen Concentrator

Refer to this section for an explanation of the symbols and the warnings that accompany them.

"Read Instructions" This symbol, when used alone or in conjunction with any of the following symbols, indicates the need to consult the operating instructions provided with the product. A potential risk exists if the operating instructions are not followed.

"Attention or Caution" Consult accompanying documents. This symbol indicates important information that requires the user to take special precautions when certain conditions are present.

"No Smoking or Naked Flames" The use of oxygen requires that special care be taken to reduce the risk of fire. Materials that burn in air and even some material that will not burn in air are easily ignited and burn rapidly in high concentrations of oxygen. For safety concerns, all possible sources of ignition must be kept away from the oxygen concentrator and preferably out of the room in which it is being used. Smoking in the proximity of an operating oxygen concentrator is dangerous, and can permanently damage the device and void the warranty.

"Use No Oil or Grease" Indicates important information about the possibility of spontaneous and violent ignition that may occur if oil, grease or other petroleum based substances come into contact with oxygen under pressure.

"Electrical Shock" Indicates the presence of an electric shock hazard. **Warning:** *To reduce the risk of electric shock,* ***do not remove cover.*** ***There are no user serviceable parts inside****.*

"Audible Alarm" An audible indicator is provided to announce, in a tone distinctly different from the sounds generated by the oxygen concentrator during normal operation, a reduction in oxygen concentration, or when the mains power has been interrupted.

"Normal Operation" Green light is on indicating the concentrator is running under normal operating conditions.

"ON/OFF" (condition) Push button starts concentrator running.

"Flow Rate Adjustment" The controlled quantity of oxygen increases or decreases in increments of 0.5 LPM with each press of the "+" and "-" flow rate adjustment buttons, respectively.

"Type BF Equipment" F type applied part complying with the specified requirements of IEC 60601-1 to provide a higher degree of protection against electrical shock than provided by type B applied part.

"Class II Equipment" Equipment in which protection against electrical shock does not rely on basic insulation only, but in which additional safety precautions are provided.

A

"Amperes"

"Alternating Current"

Oxygen Concentrator Information

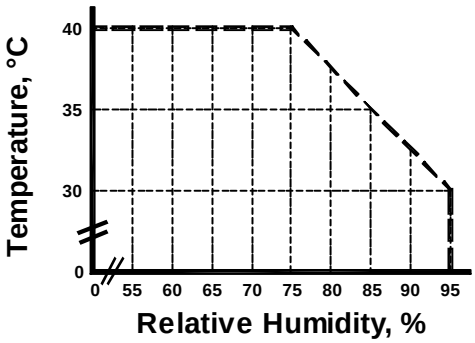
The Regalia Oxygen Concentrators are quiet, reliable and low maintenance sources of oxygen. The Regalia is designed and constructed to consistently provide high concentrations of oxygen in a lightweight, compact cabinet that is easy to maneuver.

Using Oxygen Concentrators

"No Smoking or Naked Flames" The use of oxygen requires that special care be taken to reduce the risk of fire. Materials that burn in air and even some material that will not burn in air are easily ignited and burn rapidly in high concentrations of oxygen. For safety concerns, all possible sources of ignition must be kept away from the oxygen concentrator and preferably out of the room in which it is being used. Smoking in the proximity of an operating oxygen concentrator is dangerous, and can permanently damage the device and void the warranty.

Recommended Operating Environment Guidelines

Temperature	50° F to 104° F (10° C to 40° C)
Electrical	Use no extension cords or electrical outlets controlled by a switch.
Placement	No closer than 3 inches (7.6 cm) from the wall, draperies and furniture.
Environment	Smoke, pollutant, and fume free. Relative Humidity: 10% - 95%
Operating Time	Up to 24 hours per day.
Flow Rate	From 0.5 LPM to 10.0 LPM (for the 10 LPM version)
	From 0.5 LPM to 7.0 LPM (for the 7 LPM version)



Important: For rated performance at 10 LPM (or 7 LPM for the 7 LPM version) do not operate the Oxygen concentrator above the indicated boundaries. Operating at flow rates less than 10 (or 7 LPM for the 7 LPM version) LPM will tolerate higher temperature/humidity conditions.

The Proper Location

Usage in environments other than those described on the previous page may result in the need for increased oxygen concentrator maintenance. Select a location in a well ventilated space that avoids fumes and pollutants and allows the oxygen concentrator to draw in room air through the intake filter on the top of the cabinet without being restricted. Make sure the oxygen concentrator is at least three to six (3 - 6) inches (7.6 – 15.2 cm) away from walls, furniture and especially curtains or draperies that can impede or block adequate airflow to the oxygen concentrator. ***Do Not*** cover unit with a blanket, towel, quilt, etc. ***Do Not*** place objects under unit. Maintain at least ½ inch clearance under unit. Keep the oxygen concentrator at least five (5) feet (1.5 m) away from hot, sparking objects or open sources of flame. ***Do Not*** locate the unit near any heat source or heat register.

Before Operating Your Oxygen Concentrator

There are many different types of oxygen tubing that can be used with this oxygen concentrator.

- **Oxygen Tubing - C**onnect the oxygen tubing directly to the oxygen outlet port. Connect the other end of the tube to the application, if not already attached. **Important:** The tube fitting may be tight - ***Do Not*** use oil or grease to lubricate. To ensure there is enough pressure to deliver oxygen, the length of the tubing should not exceed 50 feet (15.2m). Maximum extension tubing length is dependent upon environmental conditions, tubing type, liter flow and any accessories used between DISS fitting and application. Shorter tubing lengths will be required in some cases. The internal diameter of the tubing should be no less than 3/16-inch (0.48 cm).

- **Alarm System** - The oxygen concentrator has an alarm system with a red visual alarm indicator light and buzzer. The alarm system will activate in the event of an internal fault or power outage. The red and/or yellow light may stay on for up to ten (10) minutes after start-up, OM models only. This is a normal condition during the initial warm-up period.

- If the oxygen concentrator is equipped with an oxygen concentration monitor (OM model), this monitor indicates if the oxygen concentrator is performing to the correct specifications. At normal oxygen concentration levels, the green light is activated. At lower than normal oxygen levels, the yellow light is activated. The red light activates and the unit alarms if the system malfunctions or when service is needed. The oxygen concentrator will continue to run at lower levels of oxygen but may shut down under other system malfunctions. If the red light turns on, you should discontinue use of the oxygen concentrator and refer to the troubleshooting section of this manual.

Operating Your Oxygen Concentrator

This manual serves as a supplemental reference to help you operate and maintain the unit. If you have any further questions or problems call your AIRSEP dealer or authorized service representative.

General Precautions – Retain the product's safety and operating instructions for future reference. Follow all operating and usage instructions. Observe all warnings on the product and in the operating instructions. To reduce the risk of fire, bodily injuries, and damage to the oxygen concentrator, observe all safety precautions.

Do Not connect to an extension cord or electrical outlet controlled by a switch. No other appliance should be plugged into the wall outlet. Voltage requirements are marked on the label on back of unit.

Important: Read "Important Safety Guidelines" section of this manual before plugging-in the power cord. ***Do Not*** use the unit if the power cord is damaged.

Warning: Improper use of the power cord and plug may result in a fire or electrical shock hazard.

- Check to see if the power cord is plugged in and there is power to the outlet.

- Check that the oxygen concentrator is not placed near a heat register.

Important: AIRSEP products operate safely when used according to their marked electrical ratings and product usage instructions. The power cord used with the Regalia Oxygen Concentrator must meet the requirements of the country where the product is used.

Installation Instructions

1. **Select a Location**

Caution: Locate oxygen concentrator in a well-ventilated space that provides adequate airflow and check if air is being prevented from entering the oxygen concentrator by furniture, draperies or clothing.

2. **Inspect Inlet Air Filter**

Air filter cleaning instructions are located in the maintenance section of this manual.

Caution: *Always check to see if the inlet air filter is clean.*

3. **ON/OFF Button**

Insert the plug into the electrical wall outlet. Push the On/Off button; the green light will illuminate to indicate the unit is running.

4. **Warm-up Period**

After initially turning on the unit, allow three (3) to ten (10) minutes for the unit to reach its specified performance. If the unit is equipped with an oxygen concentration monitor (OM models only), the red, yellow and green light will intermittently illuminate while the unit is warming up. For details on warm-up refer to the Display of Operating Conditions table on Page 9.

Note: After an initial startup or after a power interruption the unit may automatically reduce the flow rate briefly before returning to the set flow rate.

5. **Flow Rate Adjustment**

Adjust the flow rate to desired setting. Press the Plus "+" button to increase or the Minus "–" button to decrease the flow rate until the proper level is displayed.

Power Management Feature

In the event of a Power Interruption:

Warning: *Because the duration of a power interruption is unknown, seek an alternate supply of oxygen during the power interruption. Resume use of the Regalia when power is restored.*

If a power outage occurs, the Regalia will activate both an audible and a visual red light alarm to inform you that the Regalia is not operating. The Regalia should be located where the alarms can be seen and heard.

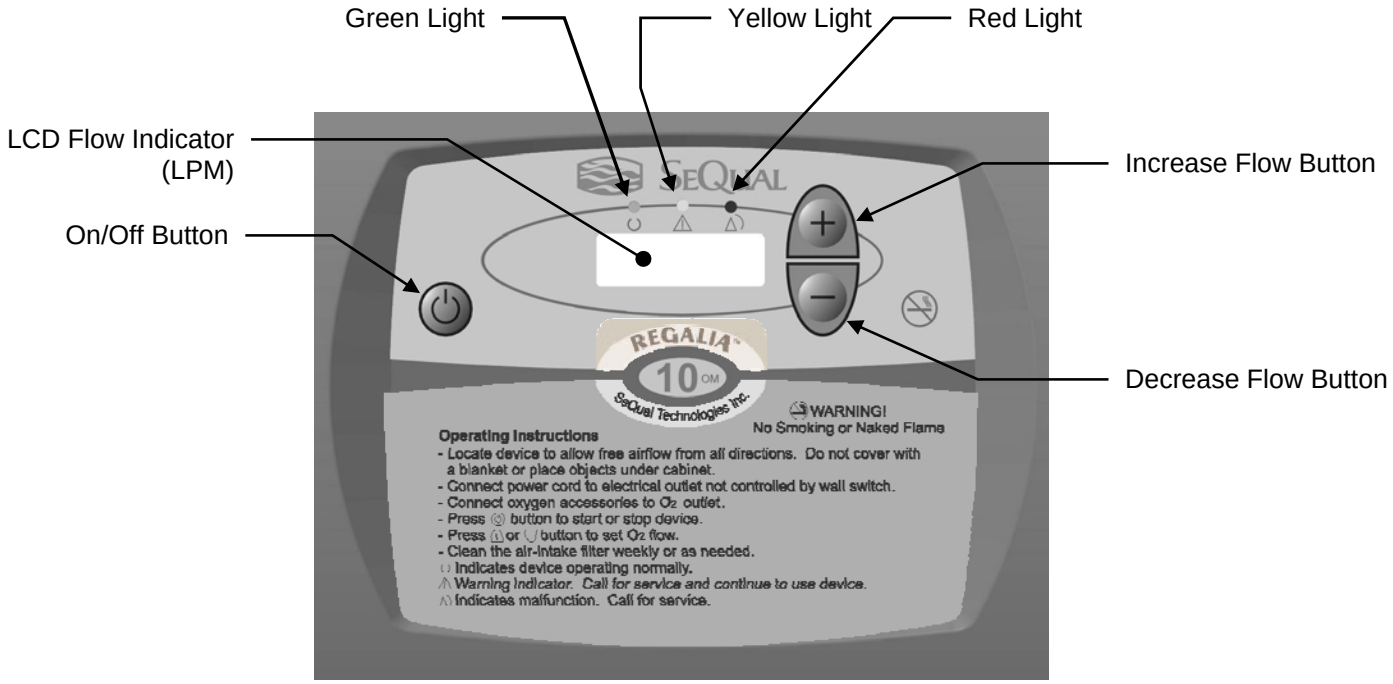
If the duration of the interruption is shorter than twenty seconds and the unit has not been turned off, the Regalia will resume operation twenty seconds after the initial interruption.

Important:
During the power interruption:

- The user can press the ON/OFF button to silence the alarms and turn the unit off.
- If the unit **was not** turned off the Regalia will automatically resume operation once power is restored.
- If the unit **was** turned off during the power interruption, the user must press the ON/OFF button again, after the power is restored, to turn the unit on.

Operating Conditions

1. **Control Panel Display –** If the concentrator is an OM Model (equipped with an oxygen monitor), the oxygen concentration is being continuously monitored while the Regalia is running and oxygen is being produced. If the concentration level falls below preset levels, an indicator light will activate. Operating conditions are described in the table on the following page.



2. Display of Operating Conditions

Flow Rate Shown?	Green Light	Yellow Light	Red Light	Audible Alarm	Unit State	Operating Condition
No	Off	Off	Off	Off	Not Energized	Unit not running / Flow Indicator Display Not Lit
No	Off	Off	Off	Off	Energized	Unit not running / Flow Indicator Display Lit
Yes	On	On	On	On for 3 seconds	Started Running	Unit is Starting
Yes	On	On	On	Periodic Beep	Running	Unit is warming up*
Yes	On	On	Off	Periodic Beep	Running	
Yes	On	Off	Off	Off	Running	Normal Operating Condition
Yes	Off	On	Off	Periodic Beep	Not Running	Unit turned On/Off/On Quickly
Yes	Off	Flashing	Off	Off	Running	Oxygen Concentration Below Normal Level *
Yes	Off	Off	Flashing	On	Running	Oxygen Concentration Abnormal Level *[1]
Yes	Off	On	Off	Off	Running	Button Stuck
Yes	On	On	Off	Off	Running	9V Battery Low Voltage (if enabled)
No	Off	Off	Flashing	On	Not Running	Unit is overheating
						Compressor Malfunction
						Power Interruption
						Internal Fuse Blown
No	On or Off	On or Off	On	On	Running	System Malfunction[2]

*** These conditions are displayed only on units equipped with oxygen monitor.**

[1] If abnormal conditions are detected and cannot be remedied, refer to Troubleshoot section of this manual.

[2] During System Malfunction condition the Green and Yellow lights may be On or Off.

3. Non-Usage - When not using the oxygen concentrator, press the On/Off button to turn it off.

Maintenance

Routine Maintenance: Routine maintenance consists of cleaning the air inlet filter at regular intervals to keep the unit functioning for years. The user can easily achieve this maintenance.

Warning: Unplug the oxygen concentrator from the power outlet before cleaning or routine maintenance. Use a damp cloth for cleaning. ***Do Not*** directly apply liquid spray cleaners or aerosol cleaners.

- **Cabinet and Power Cord**
  The cabinet and power cord can be cleaned with a mild detergent solution applied with a damp cloth and towel dried.

- **Air Inlet Filter**
  Room air is drawn into the oxygen concentrator through the air inlet filter located on the top backside of the cabinet. Cleaning the air inlet filter is the most important activity you will perform to keep your oxygen concentrator performing properly. Check this air filter daily and clean it at least once per week.

  1. Remove the filter from the cabinet.
  2. Wash the filter in warm water using a mild detergent solution.
  3. Rinse the filter thoroughly and squeeze out the excess water.
  4. Allow the filter to air dry.

Caution: The filter should be free of liquid water and dry to the touch before reinstallation, as excess moisture may impair the proper operation of the oxygen concentrator.

  5. Reinsert the filter in the cabinet.

Caution: The air inlet filter should be replaced as needed. If the oxygen concentrator is used in a dusty environment, the filter may need to be replaced more often. ***Do Not*** operate the oxygen concentrator for more than 30 minutes without a filter installed.

- **Oxygen Delivery Accessories -** Follow the instructions supplied by the manufacturer.

Trouble Shooting Guide

Table 1: Concentrator is not Running

Symptom	Probable Cause	Remedy
Cannot Start Unit Flow Indicator Blank Back Light Off	Power cord not plugged into wall outlet.	Plug in power cord.
	Internal Fuse Blown	Service required.
Audible Alarm Blinking Red Light Flow Indicator Blank Back Light Off	Power cord pulled from wall outlet.	Plug in power cord.
	Power outage.	Push On/Off Button to turn off unit. Push On/Off Button to restart unit when power comes back on.
	No power at wall outlet.	Ensure the unit is not plugged into a wall switched outlet. Check house circuit breaker or fuse - reset or replace as needed.
Audible Alarm Blinking Red Light Flow Indicator Blank Back Light On	Unit overheating	Remove any obstruction(s) from air openings and refer to page 6 “The Proper Location”.
	Compressor malfunction	Service required.

Table 2: Concentrator Running

Symptom	Probable Cause	Remedy
No oxygen / flow (see Alarm Indications in Table on Page 11)	Tubing blocked or kinked	Clean or replace tubing. Remove tube kink.
	Air Inlet Filter blocked	Clean air inlet filter.
	Internal component malfunction	Service required.
Low oxygen / flow (see Alarm Indications in Table on Page 11)	Restriction in tubing.	Repair or replace as required.
	Air Inlet Filter restricted	Clean air inlet filter.
	Internal component worn or malfunctioning	Service required.
Yellow Light On	Button is stuck	Service required.
Flow Rate not visible on Flow Indicator Display	LCD malfunction	Service required.
Audible Alarm Red Light On Flow Indicator Blank Back Light On	System malfunction	Remove power cord from wall outlet. Service required.

Technical Data

Flow Rate	0.5 to 10.0 LPM (for the 10 LPM version)
	0.5 to 7 LPM (for the 7 LPM version)
Oxygen Concentration	1.0 to 10.0 LPM 91 ± 3% at sea level (for the 10 LPM version)
	1.0 to 7.0 LPM 91 ± 3% at sea level (for the 7 LPM version)
Oxygen Concentration Indicator	Green Light = Normal Operation Yellow Light Flashing = Below Normal Operation (85%*) Red Light Flashing = Abnormal Operation (70%**)
Oxygen Outlet Pressure	Nominal 6.0 psi (41.4 kPa) [1] - Maximum 11.0 psi (75.8 kPa)
Electrical Power	115V~, 60Hz, 5.0A Nominal, 220-240V~, 50Hz, 2.2A Nominal
Operating Temperature	50° F to 104° F (10° C to 40° C)
Dimensions (H x W x D)	26.5 in. (66 cm) H × 14.7in. (37 cm) W × 19.5 in. (50 cm) D
Audible Alarm Indicators	Power Interruption Power Surge (simulated circuit breaker) Compressor Malfunction Excessive Internal Temperature Outlet Pressure [35-36 psig (241.2-248.1 kPa) relief valve] Low Oxygen Output** <70% oxygen
Back-up Alarm Power	9V Battery
Filters	Cabinet Air Inlet, Compressor Inlet and HEPA
Device Classification	IEC Class II, Type BF Applied Part, Continuous Operation
Transport/Storage Requirements	Temperature: -4° F (-20° C) to +140° F (+60° C) Humidity: Up to 95% Non-Condensing
Back pressure Effect on Flow Indicator	0 psig (0 kPa): 10.0 LPM 1 psig (7 kPa): 10.0 LPM Nominal
	0 psig (0 kPa): 7.0 LPM 1 psig (7 kPa): 7.0 LPM Nominal
OSCI Operation*	Temperature: 50° F to 104° F (10° C to 40° C) Independent of Atmospheric Pressure.
	85±3% and 70±5% oxygen concentration measurement accuracy

*Where equipped. Subject to ±3% system concentration accuracy, and for backpressures up to 7kPa.

**Where equipped. Subject to ±5% system concentration accuracy, and for backpressures up to 7kPa.

[1]Outlet pressure may decline to 5.0 psig (34.5 kPa) nominal at 10,000 ft altitude.

The system performance may decline above 10,000 ft (3048m).

Electromagnetic Compatibility

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2: 1994 Electromagnetic Compatibility standard. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed according with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation distance between the equipment.
- Connect the equipment into an outlet on a circuit different from that which the other device(s) are connected.
- Consult the manufacturer or service technician for help.

Disposal of Equipment and Accessories

Follow local governing ordinances and recycling plans regarding disposal of device components.

Manufacturer:

Airsep Corp
260 Creekside Drive
Buffalo, NY 14228-2075 USA

By telephone:

+1.770.721.7759 or toll-free in the United States at 1.800.482.2473

By facsimile:

+1.770.721.7758 or toll-free in the United States at 1.888.932.2473

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