

LM5A STATIONARY OXYGEN CONCENTRATOR



Table of Contents

1.	Safety Notes	3
1.1	Important Information	4
1.2	Before Installation	4
1.3	Placement.....	5
1.4	Fire Warning and Explosion.....	5
1.5	Maintenance	6
1.6	Radio Frequency Interference	6
1.7	Reduce the Risk of Burns, Electrocution, Fire or Injury to Persons	6
2.	Features.....	8
2.1	Summary	8
2.2	Characteristics	8
2.3	Specifications.....	9
3.	Handling	11
3.1	Unpacking.....	11
3.2	Inspection.....	11
3.3	Storage	11
4.	Installation and Operation	12
4.1	Features	12
4.2	Prepare for Use	14
4.3	Turning the Concentrator On	14
4.4	Status Indicator Display.....	15
4.5	Turning the Concentrator Off	15
5.	Maintenance	17
5.1	Cleaning the Cabinet	17
5.2	Cleaning or Replacing the Filters.....	17
5.3	Cleaning the Optional Humidifier Bottle.....	18
5.4	Oxygen Nasal Cannula	18
5.5	Tube Maintenance	18
5.6	Note: For Each New Patient	19
6	Troubleshooting Guide.....	20
7	Additional Important Items.....	22
7.1	Warranty	22
7.2	Treatment of Waste and Disposables	23
7.3	Accessories and Replacement Parts.....	23
7.4	EMC REPORT	24

2. SAFETY NOTES

WARNING: Users who require continuous oxygenation must plan for alternate sources of power and oxygen in the event of a failure or loss of power. This device is to be used as an oxygen supplement and is NOT considered life-supporting or life-sustaining!

WARNING: 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.

WARNING: To ensure you are receiving the therapeutic amount of oxygen delivery according to your medical condition this device must

- Be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
- 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.

WARNING: 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.

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

WARNING: Use only replacement parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.

WARNING: Use of this device outside of the ranges for altitude, temperature or relative humidity listed in the Specifications Section of this manual are expected to adversely affect the flowrate, the percentage of oxygen and consequently the quality of the therapy.




WARNING: 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.

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

WARNING: 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.

2. SAFETY NOTES

WARNING: Open flames during oxygen therapy are dangerous and likely to result in fire or death. Do not allow open flames within 6.5 feet of the oxygen concentrator or any oxygen carrying accessories.

Symbol	Meaning
	Indicates imminent RISK if warnings are not followed (e.g. "Causes burns", "Risk of explosion", etc.).
	Indicates steps that should be avoided to prevent damage (e.g. "Do not open", "Do not drop", etc.).
	Indicates required actions (e.g. "Wear protective gloves", "Scrub before entering", etc.).

1. Safety Notes

1.1 Important Information



Risk of electric shock.



DO NOT disassemble. Refer service to a qualified service personnel.



DO NOT modify this equipment without authorization of the manufacturer.



Read the following information before operating this product.

1.2 Before Installation



The concentrator should always be kept in the upright position to prevent damage during transport.



If the electrical power source becomes unstable, discontinue use and find an alternate source.



Only use stable and safe electrical power sources.





The oxygen concentrator cabinet should ONLY be opened by an authorized equipment provider.


2. SAFETY NOTES


1.3 Placement


- Select a room in your home where using your oxygen concentrator would be most convenient. Your concentrator can easily roll from room to room on its casters.


 Do not place the oxygen concentrator in an area where its airflow may be obstructed.


 Be sure to place the oxygen concentrator so that all sides are at least 10 cm (4") away from walls, draperies, furniture, or similar surfaces. Avoid placing on deep pile carpets. Avoid placing near heaters, radiators, and hot air registers.


 Do not place the unit in a confined area.

 The oxygen concentrator **MUST** be kept away from heat, fire, and water sources.

 The oxygen concentrator should be placed in an area that is clear of pollutants and fumes.


 Do not place items on top of the concentrator.


 **NEVER** block the air intake or air exhaust of the device, and keep them free from lint, hair, and dust.

 Do not place the unit on a soft surface, such as a bed or couch, where the concentrator may tip or fall.

1.4 Fire Warning and Explosion


 Keep the concentrator away from flammable and explosive areas.

 Users **MUST NOT SMOKE** while using this device. Keep all matches, lighted cigarettes or other sources of ignition out of the room in which this product is being used. **NO SMOKING** signs should be prominently displayed. Textiles and other materials, even those that may not normally burn easily, will quickly ignite and burn with high intensity when exposed to oxygen-enriched air. Failure to observe this warning can result in severe fire, property damage, physical injury, or **DEATH**.

 Use of oxygen therapy requires that special care be taken to reduce the risk of fire. Many materials, even those that may not be flammable under normal conditions, are easily ignited and will burn rapidly when exposed to high


2. SAFETY NOTES


concentrations of oxygen. For safety concerns, it is necessary that all sources of ignition be kept away from the product and out of the room in which it is being used.

 A spontaneous and violent ignition may occur if oil, grease or greasy substances come into contact with oxygen that is under pressure. These substances **MUST** be kept away from the oxygen concentrator, its tubing and connections, and all other oxygen equipment.

 **DO NOT** use any lubricants unless recommended by manufacturer.


1.5 Maintenance


 The Oxygen Concentrator should be serviced at least once a year by a trained service professional approved by the manufacturer.

 **DO NOT** service this device while it is in use.


● For optimum performance, the manufacturer recommends that the concentrator be run for a minimum of 30 minutes at a time. Shorter periods of operation may reduce maximum product life.


1.6 Radio Frequency Interference

 Most electronic equipment is influenced by Radio Frequency Interference (RFI). Always exercise **CAUTION** when using portable communications devices around such equipment.

 This device uses Radio Frequency energy solely for its operation, so the radio frequency output is very low and will not affect the running of other electronic equipment in the area.


1.7 Reduce the Risk of Burns, Electrocution, Fire or Injury to Persons


 Avoid using while bathing. If continuous usage is required according to the physician's prescription, then the concentrator must be located in another room at least 2.5 meters (8.2 feet) from the bathing area.


 **DO NOT** come into contact with the concentrator while wet.


 **DO NOT** place or store the device where it can drop into water or other liquids.

2. SAFETY NOTES


 DO NOT reach for the device if it has fallen into water or other liquids. UNPLUG IMMEDIATELY and call a qualified service personnel for examination and repair.


 The device should NEVER be left unattended when plugged in.


 This device is to be used only in accordance with a physician's prescription and this User's Manual. If at any time the patient or attendant concludes that the patient is receiving an insufficient amount of oxygen, contact the provider and/or physician immediately. No adjustments should be made to the flow rate unless prescribed by a physician.


 Close supervision is necessary when this product is used near children or physically challenged individuals.


 Use this product only for its intended use and as described in this manual.


 DO NOT use parts, accessories, or adapters other than those authorized by manufacturer. Use of certain humidifiers and accessories not specified for use with this oxygen concentrator may impair its performance.

 If replacement parts are used in this device that do not comply with the manufacturer's specifications, then the manufacturer is not responsible in the event of an accident.


 DO NOT connect the concentrator, neither in parallel nor in series, with other oxygen concentrators or oxygen therapy devices.


 In certain circumstances oxygen therapy can be hazardous. Seek medical advice before using this product.

 Avoid creation of sparks near medical oxygen equipment. This includes sparks from static electricity created by any type of friction.

 Consult a qualified service professional for examination and repair if the concentrator has a damaged cord or plug, if it is not working properly, or if it has been dropped or damaged.

 Keep the cord away from HEATED and HOT surfaces.

 Do not move or relocate the concentrator by pulling on its cord.

 NEVER drop or insert any object into any opening.

2. FEATURES

2. Features

2.1 Summary

The *Oxygen Concentrator* is intended for individual use as an oxygen supplement device in a home or care facility. The patient is the intended operator. The concentrator is an electronically-operated device that separates oxygen from the ambient air. It provides a high concentration of oxygen directly to you through a nasal cannula or other methods. Clinical studies have documented that oxygen concentrators are therapeutically equivalent to other types of oxygen delivery systems.

This equipment takes 120V ~ power source as power source, air as raw material, adopts high quality and high efficiency molecular sieve, and through PSA method at room temperature, produces high purity oxygen conforming to medical standards, thus achieving sustainable and uninterrupted oxygen supply.

This user manual contains important information about the use of your concentrator and will serve as a reference for you as you use your concentrator.

2.2 Characteristics

- The oxygen concentrator is comprised of the main unit, a humidifier, and a flow meter.
- Reliable, safe, completely plastic outer shell, with circuit breaker.
- Display screen shows total runtime of the device.
- Pressure safety valve helps ensure correct operating pressure.
- Power loss alarm function.
- High and low pressure alarm function.
- Low oxygen concentration alarm function.
- Heat protection to ensure safety of the compressor and concentrator.

2. FEATURES

2.3 Specifications

1. **Power supply:** AC120V, 60Hz; Current:3.5A; Power: 450VA
2. **Sound level:** ≤ 50dB (A) Acoustic power level: 58.5dB (A)
3. **Maximum recommended flow:** 5L/min
4. **Flow Range at Outlet Pressure of 0 kPa:** 0.5~5L/min
Flow Range at Outlet Pressure of 7 kPa: 0.5~5L/min
Change in maximum recommended flow when back pressure of 7 kPa is applied: < 0.5 L/min
5. **Oxygen Concentration:** When 0.5~5L/min ,93%±3% (after turning on 30 minutes)
6. **Output Pressure:** 38kPa±5kPa
7. **Release Pressure during machine operation:** 250kPa±50kPa
8. **Weight:** 35.5lbs
9. **Dimension:** 13"×10.3"×21.3" (330×260×540mm)
10. **Altitude:** The oxygen concentration will not reduce at altitudes up to 6,000ft / 1828 meters. At altitudes between 6,000ft / 1828 meters and 13,100ft / 4,000 meters, the efficiency will decrease to less than 90%.
11. **Safety System:**
 - ① Current overload or line surge auto-shutdown.
 - ② High temperature compressor auto-shutdown.
 - ③ High pressure alarm and auto-shutdown.
 - ④ Low pressure alarm and auto-shutdown.
 - ⑤ Low oxygen concentration alarm.
12. **Minimum Operating Time:** 30 minutes
13. **Electric Classification:** Class II equipment, Type BF applied part (Nasal oxygen cannula)
14. **Mode of Operation:** Continuous duty

2. FEATURES

15. Normal Operating Environment:

Overvoltage Category: II, pollution degree:2, altitude: ≤6,562 feet / 2,000m

1. Temperature range: 41°F to 104°F (5°C to 40°C)
2. Relative humidity: ≤80%
3. Atmospheric pressure: 86kPa to 106kPa (12.47psi to 15.37psi)

NOTE: When the storage temperature of the device has been below 41°F (5°C), place the device in a location within normal operating temperatures for at least 4 hours before use.

Operating the equipment outside normal recommended conditions will reduce its efficiency and lifespan.

16. Electrical category: II IP21

17. Oxygen Output Temperature: No higher than +43°F (+6°C) above ambient temperature.

18. Tube: Avoid bending the nasal oxygen tube. Tube extensions should not exceed 49 feet (15.2 meters).

19. Storage and Transport Environment:

1. Temperature Range: 32°F to 131°F (0°C to +55°C)
2. Relative Humidity Range: 10% to 90%
3. Atmospheric pressure: 70kPa to 106kPa (10.2psi to 15.37psi)

NOTE: The oxygen concentrator should be stored in an area free from gas and fumes. During transport, it should always be secured to prevent vibrations and remain upright at all times.

20. This device is expected to work for a period of 6 years. For a longer use, please consult your Equipment Provider and physician.

21. Software Version: A1.0

22. Contraindication: Do not use for patients with oxygen allergy or oxygen poisoning.

3. HANDLING

3. Handling

3.1 Unpacking

NOTE: Unless the oxygen concentrator is to be used immediately, retain shipping box and all packing materials for storage until concentrator use is required.

- Check for any obvious damage to the shipping box and its contents. If damage is evident, please notify the carrier or local dealer.
- Remove all loose packing materials from the box.
- Carefully remove all the components from the box.

3.2 Inspection

- Examine exterior of the oxygen concentrator for nicks, dents, scratches or other damage.
- Inspect all components.

3.3 Storage

- Repackage the oxygen concentrator when not in use, and store it in a dry area.
- ⊘ DO NOT place anything on top of the repackaged concentrator.

4. INSTALLATION AND OPERATION

4. Installation and Operation



Figure 1: Oxygen Concentrator Features

4.1 Features

1. Flow meter - Set oxygen flow rate by adjusting the knob.
2. Status indicator light (Alarm/Normal/Low)
3. Oxygen tube
4. Outlet connector
5. Circuit breaker - To protect the machine and user, the circuit breaker will disconnect power automatically when current $\geq 5A$. After cooling, the machine can be turned back on after pushing up the breaker.
6. Connection for humidifier bottle.
7. Humidifier bottle - For some users, dry oxygen inhalation may cause respiratory discomfort. This accessory is recommended to humidify the oxygen.
8. Power switch
9. Elapsed Time Meter - Records the total operation time since powered on.
10. Power cord
11. Transom filter

4. INSTALLATION AND OPERATION



Figure 2: Humidifier Features

⊘ DO NOT add water over the maximum water level. Add purified water to the humidifier bottle between maximum and minimum water level indicated.

- Power switch: | indicates the power is on, O indicates the power is off. If the switch is set to “ON” when a power outage occurs, the oxygen concentrator will not run, and an audible alarm will sound.
- The oxygen will pass through the humidifier. Purified water should be added to the humidifier between maximum and minimum water level as indicated. If the oxygen tube exiting the humidifier is dislodged or jammed, the pressure in the humidifier will increase to $25\pm 5\text{kPa}$ and the safety valve of humidifier will open to release the pressure.

To verify that this safety feature of the humidifier is working:

1. Use the soft PVC tube to connect the humidifier bottle to the oxygen outlet of the device.
2. Turn on the oxygen concentrator and adjust the flow rate to about 5L/min.
3. Block the exit point of the humidifier.
4. After about 5 seconds, the safety valve will open, the gas will release, and the valve will close. This indicates that the safety valve of the humidifier is working as expected.

4. INSTALLATION AND OPERATION

4.2 Prepare for Use

- Unscrew the cover of the humidifier. Add purified or distilled water into the humidifier bottle between the maximum and minimum water level lines. (If needed, add medicine into the water per doctor's recommendations.) Then screw the humidifier bottle onto the device.
- Screw the humidifier bottle connector onto the cover of the humidifier. Then insert the humidifier into the holder on the front of the unit. Finally, connect the other end of the cannula to the oxygen outlet.
- Plug in power supply: Ensure that the power switch is off. Then plug the concentrator's AC plug into power outlet.

4.3 Turning the Concentrator On

- Press power switch to the | position. The display will read "HELLO". At that time, the green, yellow, and red lights will turn on simultaneously indicating the machine is functioning as expected. After about 1 second, only the green light will remain on. After 4 seconds, the display will show the runtime.
- To properly read the flow meter, locate the prescribed flow rate line on the flow meter. Next, turn the flow knob until the ball rises to the line. Now, center the ball on the L/min line as prescribed (Figure 3).

NOTE: Oxygenation times and the flow rate ranges are established and prescribed by your physician.

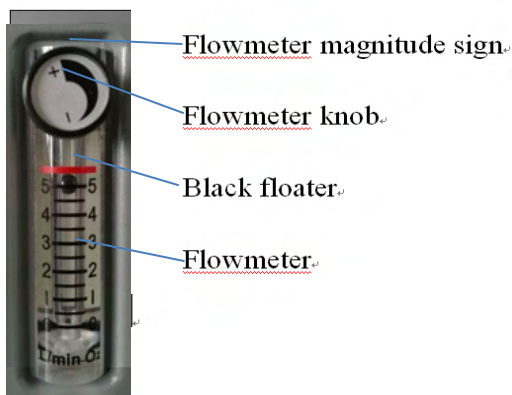


Figure 3

CAUTION: If the flow rate on the flow meter ever falls below 0.5L/min, check the tubing for blockage or kinks and check for a defective humidifier bottle.

4. INSTALLATION AND OPERATION

4.4 Status Indicator Display

NOTE: The concentrator may be used during the initial warm-up time (approximately 30 minutes) while the O₂ concentration is reaching its maximum level.

When the unit is turned on, the green light will turn on (indicating the O₂ concentration is greater than 82%±3%). After 5 minutes, the oxygen sensor will be operating normally and the indicator lights will adjust if the oxygen concentration values change. The explanations of the indicator light functions are as follows:



















1. **Green Light** - O₂ concentration is greater than 85%±2%. Normal Operation.
2. **Yellow Light** - O₂ concentration is greater than 73%± 2% and less than 85%±2%.
3. **Red Light** - O₂ concentration is less than 73%±2%. An intermittent audible alarm will sound.

4.5 Turning the Concentrator Off

Press power switch to the O position and unplug the concentrator from the power outlet.

4. INSTALLATION AND OPERATION

4.6 Symbols and Descriptions

Symbol	Meaning	Symbol	Meaning
~	Alternating current		Refer to instruction manual
	Class II Equipment		Type BF applied part
O	OFF (power)		ON (power)
	Circuit Breaker		No open flame. Fire, open ignition source and smoking are prohibited
	Height		Avoid sun exposure
	Serial number		Date of manufacture
	Keep upright		Manufacturer
	Keep dry		Temperature limitation
	Fragile, handle with care		No smoking
	Batch code		Usage reference
IP21	IP classification		Atmospheric pressure limitation

5. MAINTENANCE

⚠ WARNING: Power should be disconnected before beginning preventive maintenance on the concentrator.

⊘ DO NOT service or maintain while in use.

The concentrator regularly performs a self-check to verify pressure and oxygen purity. In addition, yearly maintenance by a qualified service professional is recommended for optimal performance. In environments that collect dust easily, it may need to be serviced more often.

5. Maintenance

5.1 Cleaning the Cabinet

Check the cabinet once a month and clean if visibly dirty.

- Turn off the power switch and unplug the concentrator from the wall outlet.
- Only the outside of the concentrator needs to be cleaned. Use a soft dry cloth, a damp sponge, or wipes with an alcohol-based cleaning solution. Do not use acetone, solvents or any other flammable products. Do not spill liquids inside the cabinet.

5.2 Cleaning or Replacing the Filters

Clean and replace the filters as often as specified below in order to protect the compressor and extend the concentrator's life:

- ⊘ DO NOT operate the concentrator without the filters installed, or if the filters are wet. This can permanently damage the concentrator.

1. **Transom filter** - Clean as needed. Check the filter every 2 weeks and clean if visibly dirty. Use a small screwdriver to unscrew the block of transom filter holder, then take the transom filter holder out from the access door. Separate the holder pieces and take the filter out.



5. MAINTENANCE

2. **Intake filter** - Clean as needed (usually annually or until it turns black.) If necessary, replace the filter.
- The intake filter door is on the left side of the concentrator. The intake filter is behind the Transom Filter. Using a small screwdriver, open the access door. Unscrew the filter core. Remove the intake filter.
 - The maintenance frequency of the filter is based on actual time used and the environment. Replace the filtration core when it turns black. Check more frequently if in an environment that collects dusty easily and clean when visibly dirty.



5.3 Cleaning the Optional Humidifier Bottle


- Change the water in the humidifier bottle every day.
- To Clean: Wash the humidifier bottle weekly using household detergent. Then rinse it completely under running water and dry.
- To Disinfect: Disinfect the humidifier parts by immersing them in a disinfecting solution, or a solution of 1-part vinegar diluted with 10 parts water. Then rinse it completely under running water and dry.
- To remove and disassemble the humidifier bottle:
 - (1) Disconnect the tubing from the humidifier bottle and the device
 - (2) Remove the humidifier bottle from the holder on the device and remove the cover from the humidifier bottle to clean and disinfect.

5.4 Oxygen Nasal Cannula

Refer to the nasal cannula manufacturer's instructions for cleaning.

5. MAINTENANCE

5.6 Note: For Each New Patient

 **WARNING: To prevent injury from infection or damage to this device, only qualified personnel should perform the cleaning and disinfection of this device between patients.**

Follow the manufacturer's instructions when using this device for a new patient, including:

1. Wash or replace the cabinet air filters.
2. Dispose of and replace all accessories not suitable for multiple patient use, including but not limited to:
 - Nasal Cannula and Tubing
 - Mask
 - Humidifier Bottle
3. Perform maintenance procedures described in this manual and ensure all device functions and alarms are in working order.
4. Include user manual when distributing device to a new patient.

6. TROUBLESHOOTING

6 Troubleshooting Guide

Symptom	Possible causes	Solution	Remark
Elapsed time meter displays, the green and yellow lights are on, but the oxygen concentrator stops running immediately and has a continuous audible alarm.	1) The valve's plug has not been inserted completely	1) Check and connect the circuit board to the valve's plug.	Repairs must be performed by qualified service personnel.
	2) Exhaust sound buffer box jammed.	2) Replace it.	
	3) Valve is unable to open.	3) Replace it.	
	4) Failure of the main electronic control circuit board.	4) Replace it.	
The nasal cannula has more fogging or droplets.	1) The unit is not properly ventilated, so operating temperature is too high.	1) Make sure the machine is at least 10 cm away from walls, heaters and other obstructions..	Repairs must be performed by a qualified service personnel.
	2) Fan inside the machine is unable to run or running speed is slow making the operating temperature too high.	2a) Remove any obstructions blocking the fan.	
		2b). Replace it.	
	3) Temperature of the water in humidifier bottle is too high.	3) Add cold water to the humidifier bottle.	
4) Too much water was added to the humidifier.	4) Water added should be between the maximum and minimum level.		

6. TROUBLESHOOTING

Symptom	Possible Causes	Solution
Concentrator works, but yellow light is on.	1) Concentrator's oxygen concentration is safe but is decreasing.	1) Clean or replace filters.
	2) Unit is overheating due to blocked air intake.	2) Move concentrator at least 10 cm (4 inches) away from walls, draperies, furniture, or similar surfaces.
	3) Concentrator is safe to use, but if condition persists, contact equipment provider immediately.	
Concentrator doesn't work, red light illuminates, continuous audible alarm sounds.	1) Low pressure	1) Clean or replace filters. If condition persists, discontinue use and contact equipment provider immediately.
	2) High pressure	2) Contact equipment provider immediately.
	3) If condition persists, contact equipment provider immediately.	
Concentrator doesn't work, continuous audible alarm sounds.	1) Compressor open circuit alarm. 2) Compressor short circuit alarm.	Contact equipment provider immediately.

NOTE: If you experience a problem with your concentrator and are unable to resolve it using the troubleshooting steps above, contact the equipment provider from whom you purchased the concentrator.

6. ADDITIONAL IMPORTANT ITEMS

7 Additional Important Items

7.1 Warranty

Rhythm Healthcare, LLC warrants the LM5A Oxygen Concentrator under the conditions and limitations stated below. Rhythm Healthcare, LLC warrants this equipment to be free from defects in workmanship and materials for three (3) years from date of factory shipment to the original purchaser, (typically the healthcare provider) unless contractually specified otherwise. This warranty is limited to the Buyer of new equipment purchased directly from Rhythm Healthcare, LLC, or one of its Providers, Distributors, or Agents. Rhythm Healthcare, LLC's obligation under this warranty is limited to product repair (parts and labor) at its factory or at an Authorized Service Center. Routine maintenance items, such as filters, are not covered under this warranty, nor does it cover normal wear and tear.

Warranty Claims Submissions

The original purchaser must submit any warranty claim to Rhythm Healthcare, LLC or to an Authorized Service Center. Upon verification of the warranty status, instructions will be issued. For all returns, the original purchaser must (1) properly package the unit in a Rhythm Healthcare, LLC's approved shipping container, (2) properly identify the claim with the Return Authorization Number, and (3) send the shipment freight prepaid. Service under this warranty must be performed by Rhythm Healthcare, LLC and/or an Authorized Service Center.

NOTE – This warranty does not obligate Rhythm Healthcare, LLC's to provide a loaner unit during the time that an oxygen concentrator is undergoing repair.

NOTE – Replacement components are warranted for the unexpired portion of the original Limited Warranty.

This warranty shall be voided, and Rhythm Healthcare, LLC shall be relieved of any obligation or liability if:

- The device has been misused, abused, tampered with, or used improperly during this period.
- Malfunction results from inadequate cleaning or failure to follow the instructions.
- The equipment is operated or maintained outside the parameters indicated in the operating and service instructions.
- Unqualified service personnel conduct routine maintenance or servicing.
- Unauthorized parts or components (i.e., regenerated sieve material) are used to repair or alter the equipment.
- Unapproved filters are used with the unit.

6. ADDITIONAL IMPORTANT ITEMS

THERE IS NO OTHER EXPRESS WARRANTY. IMPLIED WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY AND TO THE EXTENT PERMITTED BY LAW ANY AND ALL IMPLIED WARRANTIES ARE EXCLUDED. THIS IS THE EXCLUSIVE REMEDY AND LIABILITY FOR CONSEQUENTIAL AND INCIDENTAL DAMAGES UNDER ANY AND ALL WARRANTIES ARE EXCLUDED TO THE EXTENT EXCLUSION IS PERMITTED BY LAW. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, OR THE LIMITATION OR EXCLUSION OF CONSEQUENTIAL OR INCIDENTAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

7.2 Treatment of Waste and Disposables

The handling of waste and disposable components shall conform to all local laws and regulations.

7.3 Accessories and Replacement Parts

The accessories used must be oxygen compatible and biocompatible.

Note: The connectors, tubes, nasal cannula or masks must be designed for oxygen therapy use. The set of accessories that have been supplied with the device comply with these requirements. Contact your equipment supplier to obtain replacements.

6. ADDITIONAL IMPORTANT ITEMS


7.4 EMC REPORT

Guidance and declaration of manufacturer - Electromagnetic Emission - For all Equipment and Systems		
The <i>Oxygen Concentrator</i> is intended for use in an environment specified below. The customer or the user of <i>Oxygen Concentrator</i> should assure that the unit is used in such an environment.		
Emission test	Compliance	Electromagnetic environment- regulations
RF emissions CISPR 11	Group 1	The <i>Oxygen Concentrator</i> uses RF energy solely for its internal functions. Therefore, its RF emission are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The <i>Oxygen Concentrator</i> is suitable for use in all establishments, including domestic establishments, and those directly connected to public low voltage power supply networks that supply power to buildings used for domestic purposes.
Emission of harmonics IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

6. ADDITIONAL IMPORTANT ITEMS

Guidance and declaration of manufacturer - Electromagnetic Immunity For all Equipment and Systems			
The <i>Oxygen Concentrator</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Oxygen Concentrator</i> should ensure that the unit is used in such an environment.			
Immunity	IEC 61000-4-2 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood or concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode II	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 cycles	< 5% UT (>95% dip in UT) for 0.5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Oxygen Concentrator requires continued operation during power mains interruptions, it is recommended that the Oxygen Concentrator be powered from an interruptible power supply or a battery.
	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30 % dip in UT) for 25 cycles	
	<5% UT (95% dip in UT) for 5 seconds	<5% UT (95 % dip in UT) for 5 seconds	
Power frequency (50/60Hz) magnetic IEC 61000-4-8	3 A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

6. ADDITIONAL IMPORTANT ITEMS

Guidance and declaration of manufacturer - Electromagnetic Immunity For all Equipment and Systems that are not LIFE SUPPORTING			
The <i>Oxygen Concentrator</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Oxygen Concentrator</i> should ensure that the unit is used in such an 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the OXYGEN CONCENTRATOR, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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.			
<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 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 reorienting or relocating the OXYGEN CONCENTRATOR.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

6. ADDITIONAL IMPORTANT ITEMS

Recommended separation distances between portable and mobile RF communications equipment and the Equipment and Systems that are NOT LIFE SUPPORTING

The *OXYGEN CONCENTRATOR* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *OXYGEN CONCENTRATOR* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *OXYGEN CONCENTRATOR* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.



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