ITEM # ZY-5AC

RHYTHM HEALTHCARE

OXY BV

5L Stationary Oxygen Concentrator

NL

EN

Do not use this device without first reading and understanding this manual. If you do not understand the warnings and instructions, contact your device supplier before attempting to use this device; otherwise, injury or damage may result.

There is a fire hazard associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames. Smoking while using oxygen is the leading cause of burns and related deaths. Please follow these safety warnings:

- Do not allow smoking, burning candles, or open flames in the same room as the device or within 2 meters of the oxygen-delivery accessories.
- Smoking while wearing a nasal cannula can cause facial burns and possibly death.
- Placing the cannula on bedding, sofas, or other soft or fabric surfaces can cause a fire if it comes into contact with a cigarette, heat source, or open flame.
- If you plan to smoke, you must first turn off the oxygen concentrator, remove the cannula, and move to a location where no oxygen equipment is present. If you cannot leave the room, you must wait 10 minutes after turning off the oxygen concentrator before smoking.

TABLE OF CONTENTS

Indications for Use: The oxygen concentrator delivers supplemental oxygen at a low flow rate for oxygen therapy in adult, geriatric, and pediatric patients in home settings, nursing homes, patient care facilities, etc. Pediatric patients must be treated under adult supervision. The device is not intended as a life-support device and does not provide patient monitoring capabilities.

WARNING: Under certain circumstances, oxygen therapy can be dangerous. It is advisable to seek medical advice before using an oxygen concentrator.

NOTE: Any serious incident that has occurred in connection with the device must be reported to the manufacturer and to the competent authority of the countries/regions where the user and/or patient is located.

INTENDED USE

The oxygen concentrator is intended to provide supplemental oxygen to patients with hypoxemia who require oxygen therapy. The device is not intended for life support or life-saving purposes.

INDICATIONS

Patients with hypoxemia caused by chronic obstructive pulmonary disease (COPD), pulmonary hypertension, or obstructive sleep apnea (OSA).

CONTRA INDICATIONS

The ZY-5AC 5L stationary oxygen concentrator is not intended for use in the following situations:

- Life-support or life-saving situations
- In operating rooms or surgical environments
- For newborns or infants
- In the presence of flammable anesthetics or flammable materials

INTENDED TARGET PATIENT POPULATIONS

Adults

CIRCUMSTANCES IN WHICH THE USER A HEALTHCARE PROFESSIONAL SHOULD CONSULT

a. Patients with a rapid respiratory rate (more than 20 breaths per minute) who require a higher oxygen setting may need more oxygen than this device can provide. In such cases, consult your supplier for an alternative treatment.

b. An alternative oxygen source is recommended in the event of a power outage or mechanical failure. Consult your supplier for a suitable backup oxygen system.

c. If you cannot hear or see alarms, do not have normal tactile sensitivity, or are unable to communicate discomfort, consult your supplier before using this device.

d. New or persistent symptoms. Supplemental oxygen is not addictive. Your provider has prescribed a specific oxygen flow rate to address symptoms such as headache, drowsiness, confusion, fatigue, or irritability. If these symptoms persist after you begin oxygen therapy, consult your provider.

e. If you experience discomfort or have a medical emergency during oxygen therapy, seek medical help immediately.

WARNING: Modification of this device is not permitted. The housing may only must be removed by authorized personnel. Modifying this device will void the warranty.

WARNING: For your safety, the oxygen concentrator must be used in accordance with the instructions provided by your supplier. If you feel unwell or experience a medical emergency during oxygen therapy, seek immediate medical attention to prevent injury.

WARNING: The supplier providing the ZY-5AC 5L stationary oxygen concentrator is responsible for ensuring the safe and effective use of the device in accordance with the supplier's guidelines for supplemental oxygen. Although this user manual is intended to support safe operation, the ultimate responsibility for patient safety rests with the prescribing healthcare professional.

WARNING: An alternative oxygen source must be available in the event of a power outage or mechanical failure. Backup oxygen, such as oxygen cylinders, must be accessible.

WARNING: Do not use the oxygen concentrator in the presence of flammable gases. Exposure to flammable gases can lead to rapid combustion, resulting in property damage, personal injury, or death. Do not use oil, grease, petroleum products, or other flammable substances in combination with oxygen delivery accessories. Use only water-based, oxygen-compatible lotions or ointments on the skin. Oxygen accelerates the combustion of flammable materials.

WARNING: Clean the housing, control panel, and power cord with a mild detergent applied with a damp (not wet) cloth or sponge. Dry all surfaces thoroughly. Do not allow any liquid to enter the device. Ensure that the oxygen outlet of the cannula connector remains free of dust, dirt, and particles.

WARNING: Do not use the device in a confined or enclosed space (e.g., small suitcases or handbags) where ventilation may be limited. Failure to comply may result in overheating and reduced performance of the oxygen concentrator.

WARNING: Place the oxygen concentrator in a location free from smoke, contaminants, or vapors.

WARNING: Using oxygen delivery accessories not specified for this oxygen concentrator may reduce performance. Refer to this user manual for recommended accessories. The use of unspecified or non-recommended accessories will void the warranty.

NOTE: The Rhythm Healthcare ZY-5AC is equipped with a flame-retardant outlet coupling that prevents the spread of fire within the device.

WARNING: If the oxygen concentrator has been dropped, damaged, or exposed to water, contact your supplier. Do not use the oxygen concentrator if the power cord or plug is damaged.

WARNING: Ensure that neither the air intake nor the air outlet openings are blocked. Do not drop or insert any objects into the unit's openings. Failure to do so may cause the oxygen concentrator to overheat and reduce its performance.

WARNING: Do not overfill the optional humidifier bottle. Fill it only with water up to the level indicated by the humidifier bottle manufacturer.

WARNING: If you experience discomfort or a medical emergency, seek medical attention immediately.

WARNING: Using this device at altitudes above 2,000 meters, outside the temperature range of 5°C to 40°C, or in environments with relative humidity above 80% may adversely affect the oxygen flow rate and oxygen concentration, thereby reducing the effectiveness of the therapy.

WARNING: Do not place the oxygen concentrator directly next to or stacked on top of other equipment. If this is unavoidable, discuss the placement with your supplier before using the oxygen concentrator.

If an alarm sounds or the oxygen concentrator is not functioning properly, refer to the troubleshooting section in this user manual or contact your supplier for assistance. Failure to follow all manufacturer instructions may void the warranty.

WARNING: Do not perform any maintenance other than the troubleshooting steps listed in this user manual. Do not attempt to remove the casings of this device. Only your supplier or a qualified service technician is authorized to open or service the device.

WARNING: Do not leave a nasal cannula on or under clothing, bedding, or chair or sofa cushions. If the device is left running while not in use, oxygen may accumulate and increase the risk of fire. Always turn off the oxygen concentrator when it is not in use.

WARNING: Do not use this device while sleeping, unless directed to do so by your supplier.

To prevent overtreatment, the patient's SpO_2 levels must be continuously monitored with a CE-marked pulse oximeter during oxygen therapy via the concentrator.

Always position the oxygen supply tubing and power cords in such a way as to prevent tripping hazards.

WARNING: DO NOT use the device in the presence of flammable anesthetics.

WARNING: The device is not suitable for patients for whom a temporary interruption of oxygen therapy would have adverse medical consequences.

IMPORTANT PARTS OF YOUR CONCENTRATOR

Familiarize yourself with your oxygen concentrator before using it. Unpacking Checklist

Before using this product, check that you have the following items:

- 1 × User Manual
- 1 × Oxygen concentrator (set)
- 1 × Power cord
- 1 × Humidifier bottle (optional)
- 1 × Humidifier bottle adapter (optional)
- 1 × Nasal cannula
- 1 × Detachable power cord (included separately in the box)

HUMIDIFIER BOTTLE

If used, clean the humidifier bottle daily to reduce the risk of contamination. Follow the cleaning recommendations on page 14 or as recommended by the humidifier bottle manufacturer or your supplier (do not overfill the humidifier bottle).

WARNING

WARNING: Rhythm Healthcare has not tested accessories from other manufacturers and does not recommend their use with Rhythm Healthcare products.

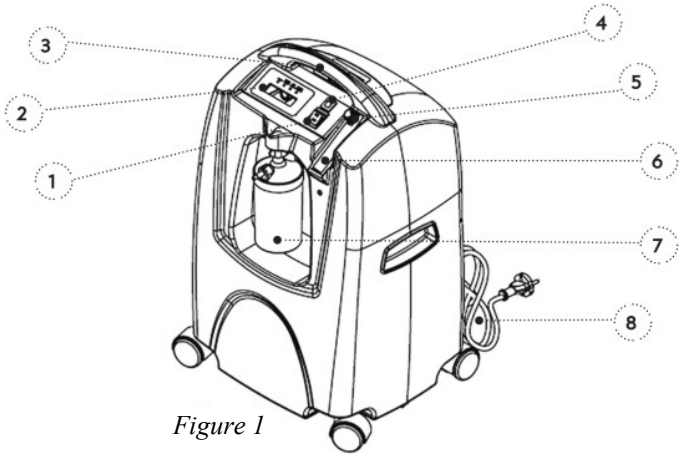
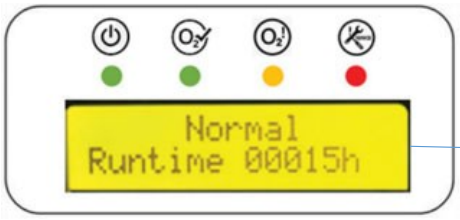


Figure 1

1. Power **Switch**— I = ON O = OFF

2. **Monitor**—Indicates the system pressure status (Figure 2). Displays the device's current operating time.



Normal
Operating Time
00015 h

Figure 2

Indicator lights:

Power: (Green)

Normal oxygen level: (Green - O_2 > 82%)

Low oxygen level: (Yellow indicator lights - O_2 < 82%)

Service Required: (Red—turn off the device and contact your supplier. Switch to your backup oxygen system)

3. Warning Label (Figure 3a)
4. Circuit Breaker - (on select models) resets the device after it has been shut down due to an electrical overload.
5. Flow Meter Knob (Figure 3b)
6. Flow Meter

NOTE: Turn the flow control knob to the setting specified by your supplier.
The recommended flow rate is between 1 L/min and 5 L/min.

NOTE: Read the flow meter using the indicator lines on the tube, which show the oxygen flow rate in liters per minute (L/min). Turn the flow control knob until the float ball rises to the prescribed flow rate, and make sure the center of the ball is aligned with the corresponding line.

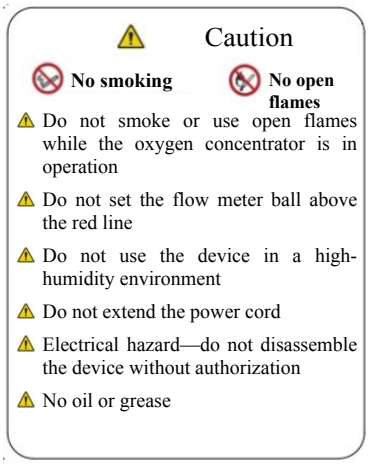


Figure 3a

NOTE Do not set the flow rate higher than 5 L/min.

7. Humidifier bottle (optional)
8. Detachable power cord (included separately in the box)

Figure 3b

Rear view (Figure 4)

9. Cover
10. Air filter
11. Nameplate
12. Exhaust port

WARNING **WARNING:** The user must read and understand this entire user manual before using the device.

WARNING **WARNING:** This device is not intended for life-support use. If the supplier determines that any interruption in the oxygen supply could pose a serious risk to the patient's health, an alternative oxygen source must be available immediately.

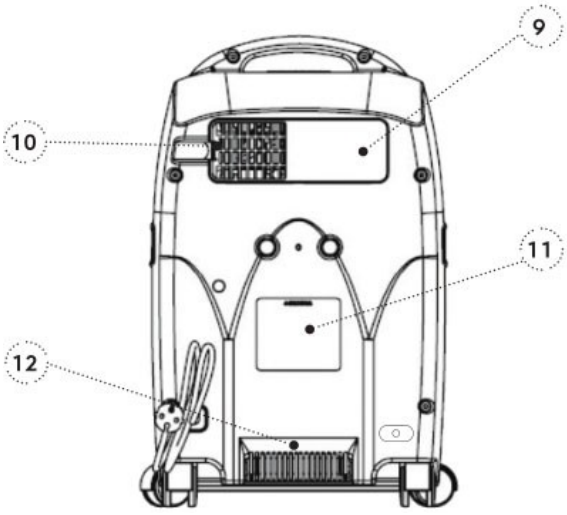


Figure 4

SETTING UP YOUR OXYGEN CONCENTRATOR

1. Place your device near an electrical outlet in the room where you spend most of your time.

WARNING: Keep the oxygen concentrator at least 2 meters away from heat sources, sparks, or open flames.

NOTE: Do not plug the device into an outlet controlled by a wall switch. The outlet used must be dedicated exclusively to the oxygen concentrator; no other devices should be plugged into the same outlet. Do not plug the device into a power strip or surge protector. Be sure to use a grounded outlet.

2. Place your device at least 16 cm away from walls, curtains, or other objects that could obstruct proper airflow into and out of the oxygen concentrator. Place the oxygen concentrator in a location free from contaminants, vapors, or airborne pollutants.

WARNING: Using the device above or outside the specified limits for voltage, temperature, relative humidity, and/or altitude may result in lower oxygen concentration.

1. Before each use, check that the sponge intake filters (on the back of the device) are clean. See the section on Care and Periodic Maintenance of Your Device on pages 14 and 15.
2. Connect the appropriate oxygen accessories to the oxygen outlet.

USING THE OXYGEN CONCENTRATOR WITHOUT A HUMIDIFIER BOTTLE

a. Connect the oxygen outlet connector to the oxygen outlet.

b. Attach the oxygen tubing directly to the connector (Figure 5).

Figure 5

USING THE OXYGEN CONCENTRATOR WITH THE HUMIDIFIER BOTTLE

NOTE: Connect the humidifier bottle only if prescribed.

ATTACHING THE HUMIDIFIER BOTTLE

a. Fill the bottle with distilled water. Do not overfill.

b. Screw the wing nut on the top of the bottle onto the oxygen outlet so that the bottle is suspended (Figure 6). Make sure it is tightly secured.

c. Attach the oxygen tubing directly to the bottle's outlet connector (Figure 7).

Your supplier has prescribed a nasal cannula, catheter, or face mask; in most cases, these are already attached to the oxygen tubing. If this is not the case, follow the manufacturer's instructions for attachment. Instructions continue on the next page.

Figure 6

Figure 7

CONNECTING THE POWER CORD TO YOUR CONCENTRATOR

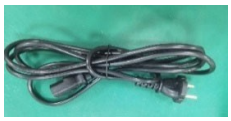
If your ZY-5AC oxygen concentrator is equipped with a detachable power cord, remove the cord from the packaging, verify that it is the correct type for your setup, and securely connect it to the power jack on the bottom of the unit (see Figure 8 and Figure 9).

If your ZY-5AC oxygen concentrator is already equipped with a fixed power cord, unroll the cord completely from the cord holder, make sure the on/off switch is in the "OFF" position, and plug the cord into an outlet.

Figure 8

Figure 9

NOTE: The following three types of detachable power cords have been tested by Rhythm Healthcare with the Rhythm ZY-5AC to ensure electrical safety:

Description / Part Number #	Manufacturer	Type/Model	Technical Specifications	Conformity marks[1]
 Power cord with standard European plug / 3.02.J5A030	Jingyi Electronics	Cable: H05VV-F	2×0.27 mm²	VDE 40025196
		Connector: JYT2	10 A, 250 V~	TÜV Rheinland ENEC 18
		Plug: JY-02	16A, 250 V~	VDE 40005422
 Power cord with UK plug / 3.02.J5A033	Jingyi Electronics	Cable: H05VV-F	2×0.27 mm²	VDE 40025196
		Connector: JYT2	10 A, 250 V~	TÜV Rheinland ENEC 18
		Plug: JY13A (GEM insert M87053)	250 V, heavy-duty	SGS KM 72974
 Power cord with Swiss plug / 3.02.J5A034	Jingyi Electronics	Cable: H05VV-F	2×0.27 mm²	VDE 40025196
		Connector: JYT2	10 A, 250 V~	TÜV Rheinland ENEC 18
		Plug: JY-32	10A, 250 V~	Swiss 24.0071

CONNECTING THE NASAL CANNULA

Always follow the nasal cannula manufacturer's instructions for proper use.

a. Using the Oxygen Concentrator Without a Humidifier Bottle

Connect the cannula tubing to the oxygen outlet connector as shown in Figure 5.

b. To attach the cannula to the user:

Connect the cannula tubing to the humidifier bottle or the oxygen outlet and place the nasal cannula on your face as shown below; breathe normally through your nose.

Replace the cannula and the oxygen supply tubing regularly, as recommended by your supplier. Clean and replace the cannula according to your supplier's instructions.

NOTE: Make sure the cannula is fully inserted and securely in place. As you inhale, you should be able to hear or feel the flow of oxygen through the prongs of the nasal cannula.

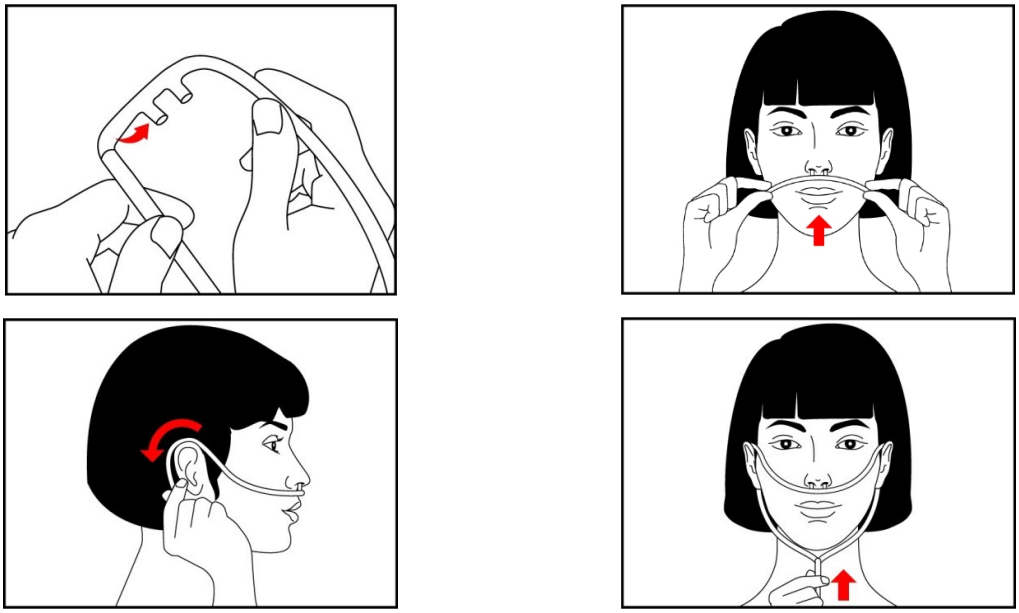


Figure 10

c. Disconnect the power cord from the cord holder. Make sure the on/off switch is in the "OFF" position before plugging the power cord into an outlet. The device is double-insulated to protect against electric shock. Do not connect the device to an outlet controlled by a wall switch. Make sure the outlet is grounded.

NOTE: When the humidifier bottle and tubing are properly installed and the flow rate is set above 1 L/min, you should feel oxygen flowing through the cannula and see air bubbles rising to the water's surface.

NOTE: The oxygen delivery accessory (patient tubing) must be equipped with a fire safety device that automatically stops the flow of oxygen to the patient in the event of a fire. This safety device must be placed as close to the patient as possible. Contact your supplier for additional information.

CAUTION

Replace the cannula regularly.

Consult your supplier to determine how often the cannula should be replaced.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC), as it can cause interference with other electronic devices. If possible, keep a safe distance from other electronic equipment to minimize interference.

Oxygen supports rapid combustion. Do not smoke while the oxygen concentrator is in operation or in the vicinity of people receiving oxygen therapy. Keep the oxygen concentrator at least 2 meters away from heat sources, sparks, or open flames.

Improper use of the power cord and plugs can cause burns, fire, or other hazards due to electric shock. Do not use the device if the power cord is damaged.

Service or maintenance must not be performed while the device is in use by the patient.

This device is intended for prescription use only. Oxygen concentration, flow rate, and duration of use must be set according to the prescription established by your supplier.

1. PRESS THE ON/OFF SWITCH TO THE "ON" POSITION.

When the device is turned on, the Power and Normal Oxygen Concentration indicator lights will illuminate. The device will start the oxygen flow and reach the set flow rate and normal oxygen concentration within 2 minutes.

2. CHECK THAT THE ALARM SYSTEM IS FUNCTIONING PROPERLY AS FOLLOWS:

Let the oxygen concentrator run for 2 minutes, then turn the flow meter knob clockwise to completely shut off the oxygen flow. The flow meter ball should be aligned with the 0 L/min mark. Within 30 seconds, the low-flow alarm should activate and the red SERVICE REQUIRED indicator light should come on. Then reset the flow rate to approximately 1 L/min; the alarm should stop within 60 seconds.

NOTE: If an audible low-frequency humming sound is heard, the device is not functioning properly. Refer to the Simple Troubleshooting chart on page 18 and contact your supplier if necessary.

NOTE: If, after 2 minutes, the LOW OXYGEN LEVEL or SERVICE REQUIRED light is on and the alarm is sounding, the device is not functioning properly. Refer to the Simple Troubleshooting chart and contact your supplier if necessary.

NOTE: If the alarm sounds and the device is not operating, there is no power to the device. Refer to the Simple Troubleshooting chart on page 18 and contact your supplier if necessary.

3. Make sure the flow meter ball is aligned with the specified flow rate. Adjust it as needed by turning the flow meter knob.

Instructions continue on the next page

4. Flow Rate Adjustment:

- Turning the knob clockwise (to the right) reduces the flow rate and eventually shuts off the oxygen flow.
- Turning the knob counterclockwise (to the left) increases the flow rate.
- Make sure the ball is centered on the line corresponding to the number of liters. The flow meter ball must not touch or cross the red line (Figure 11). Setting the flow rate higher than 5 L/min can lower the oxygen concentration and trigger the E2 alarm (low oxygen concentration alarm).

Figure 11

CAUTION

It is crucial to follow your oxygen prescription. Do not increase or decrease the oxygen flow rate without first consulting your supplier.

NOTE: The low-flow alarm may be triggered if the flow meter is set below 1 L/min or if there is a gas leak in the system. The device will continue to operate; however, the SERVICE REQUIRED indicator light will illuminate, accompanied by an audible alarm. Set the flow meter to the prescribed flow rate.

Ensure that all delivery accessories are securely connected and that there are no gas leaks. To check, completely block the cannula; if there is no leak, the flow meter ball should drop to the zero mark (0).

5. The oxygen concentrator is now ready for use.

Position the cannula correctly (page 12) and wait 2 minutes until the oxygen concentrator has reached the specified performance level.

NOTE: The Rhythm Healthcare ZY-5AC 5L stationary oxygen concentrator is equipped with an oxygen sensor to monitor the oxygen concentration level. When the concentration is within the acceptable range, the NORMAL OXYGEN LEVEL indicator light will illuminate. If the concentration falls below the acceptable range, the green NORMAL OXYGEN LEVEL indicator light turns off and the yellow LOW OXYGEN LEVEL indicator light turns on. Switch to your backup oxygen system. Refer to the “Simple Troubleshooting” section (page 18) and contact your supplier if necessary.

NOTE: As an additional safety feature, if the oxygen purity continues to drop, the SERVICE REQUIRED light and the audible alarm will be activated. Contact your supplier immediately. If necessary, switch to your backup oxygen. Do not perform any other maintenance. See the ALARM AND WARNING SYSTEM section for more information.

WARNING: Turn off the device before performing any cleaning procedures.

OXYGEN HUMIDIFIER (REUSABLE BOTTLES)

If your healthcare provider has prescribed humidification, clean the humidifier bottle daily. Follow the instructions provided by the manufacturer. **If no cleaning instructions are included, follow these steps:**

1. Wash the humidifier bottle in a solution of hot water and mild dish soap.
2. Soak the humidifier bottle for 30 minutes in a solution of one part white vinegar and three parts hot water. This solution acts as a germicide.
3. Rinse thoroughly with warm tap water and refill with distilled water before use. Do not overfill.

CANULA

Connect the cannula to the humidifier bottle or the oxygen outlet and position the nasal cannula on your face; see page 12 for detailed instructions.

Replace the cannula and the oxygen delivery tubing regularly, as recommended by your supplier. Clean and replace the cannula according to your supplier's instructions.

NOTE: Make sure the cannula is fully inserted and securely in place. This ensures that the oxygen concentrator can correctly detect your breathing to deliver oxygen. As you breathe in, you should be able to hear or feel the oxygen flow toward the prongs of the nasal cannula.

SPONGE INLET FILTER AND OXYGEN OUTLET CONNECTOR

The sponge intake filter and the connector must be cleaned at least once a week. To clean them, follow these steps:

1. Remove the sponge inlet filter (located on the back of the device). Remove the oxygen outlet connector (if used).
2. Wash them in a solution of warm water and mild dish soap.
3. Rinse thoroughly with warm tap water and dry with a towel. The filter must be COMPLETELY dry before being reinserted.

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

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

WARNING: To prevent damage to the product, do not use the device without the sponge intake filter or while the filter is still damp.

WARNING: To prevent electric shock, do not remove the concentrator's housing. The housing may only be removed by a qualified medical technician. Do not apply liquid directly to the housing, and do not use petroleum-based solvents or cleaning agents.

Clean the outer housing of the concentrator with a damp cloth or sponge and a mild household cleaner, then dry it thoroughly. Sterilization is not necessary.

PERIODIC MAINTENANCE OF YOUR DEVICE

1. Clean the sponge intake filter (LM5BA-ITF) once a week or as needed. Replace the filter if it is damaged or torn. The steps for cleaning the sponge intake filter are as follows:
   a. Remove the sponge inlet filter (LM5BA-ITF) and clean the cabinet door (LM5BA-VD) with a vacuum cleaner or cleaner, or wash it in warm soapy water and rinse thoroughly.
   b. Dry the sponge inlet filter completely before reinserting it.

WARNING: Do the oxygen concentrator without the sponge inlet filter in place. If a second sponge inlet filter is available, first install the replacement sponge inlet filter before cleaning the sponge inlet filter. Clean the dirty sponge inlet filter in a warm solution of water and soap and dry it completely before use.

2. Inspect the HEPA inlet filter (LM5BA-ILF) between patients and replace it as needed. Replace this filter if it is torn or damaged, as needed, or every three years.
   Follow these steps:
   a. Open the cabinet door (LM5BA-VD).
   b. Pull the old HEPA inlet filter out of the concentrator.
   c. Then insert the new HEPA inlet filter.
   d. Insert the sponge inlet filter and close the cabinet door.

ACCESSORIES

The following accessories have been tested by Rhythm Healthcare with oxygen concentrators:

Accessory	Part Number	Material Code
Nasal cannula	LM5BA-CAN	
Humidifier bottle	LM5BA-HUMI	
Humidifier adapter	LM5BA-HUMIADP	
Humidification Bottle	LM209058	3.07.0225
Sponge Inlet Filter	LM5BA-ITF	3.07.0012

There are many different types of humidifiers, oxygen tubing, cannulas, and masks that can be used with this device. Contact your supplier for recommendations on which of these accessories are most suitable for you. They can also guide you on proper use, maintenance, and cleaning.

NOTE: The use of certain humidifiers and accessories (not specified above) may reduce the performance of the oxygen concentrator.

NOTE: If the device is not operating, the SERVICE REQUIRED light is on, and the alarm is beeping, power is not being supplied to the device. Refer to the Simple Troubleshooting chart on page 18 and contact your supplier.

NOTE: All waste from the Rhythm ZY-5AC Oxygen Concentrator must be disposed of in accordance with the appropriate methods established by local authorities.

NOTE: To protect the environment, the concentrator must be disposed of in accordance with the methods prescribed by local authorities.

The EU certificates for the Nasal Cannula and Humidifier Bottle are listed in the table below. These accessories can be purchased directly from the listed manufacturers.

Item	Manufacturer	Model	Specifications	Conformity Marking1
Humidifier Bottle	SALTER LABS	REF7100	Capacity: 200 ml for flow rates up to 10 L/min	CE 2797
Nasal cannula	Ningbo MFLAB Medical Instruments Co., Ltd.	Adults/L	Length: 3 m, Ø (5.3 mm)	CE 0197

To ensure optimal performance of your oxygen concentrator, you should use only humidifier bottles and nasal cannulas that meet the specifications listed above. It is recommended that you purchase these components directly from the manufacturers and strictly follow the manufacturer's guidelines for use, cleaning, and maintenance.

NOTE: The wetting bottle must be equipped with a non-removable fire-stop device. If a humidifier bottle without a permanent fire-stop device must be used, a secondary fire-stop device must be installed and placed as close as possible to the humidifier bottle. Failure to comply with this requirement may increase the risk of fire. Contact your supplier for further information.

NOTE: The oxygen delivery accessory (patient tubing) must be equipped with a device that shuts off the oxygen supply to the patient in the event of a fire. This safety device must be placed as close to the patient as possible. Contact your supplier for further information.

NOTE: If the SERVICE REQUIRED light is on, the alarm is sounding, and the unit is not operating, there is no power to the unit. Refer to the Simple Troubleshooting chart on page 18 and contact your supplier if necessary.

NOTE: To protect the environment, the concentrator must be disposed of in accordance with the methods prescribed by local authorities.

1. The ZY-5AC is equipped with a low-priority technical alarm system featuring visual LED indicators, an audible alarm, and error codes displayed on the screen. The system monitors the device's status and alerts users in the event of abnormal operation, loss of essential performance, or system failures.
2. LED indicators: When the LEDs light up, an audible alarm sounds.

Light Color	Flash rate	Alarm Interval	May only be performed by authorized service personnel*
Red	Fast	Five beeps at 3- to 5-second intervals	Turn the flow meter knob clockwise to reset the flow to zero.
Yellow	Average	Three beeps at 3- to 5-second intervals	Turn the flow meter knob counterclockwise to increase the flow rate to the maximum line.
Yellow	Continuously lit	One beep at 23–25-second intervals	Disconnect the air hose connected to the PCB pressure sensor.

This procedure may only be performed by trained and qualified service technicians authorized to repair or maintain the device.

3. ALARM SYSTEM

Error code	Light Color	Warning Meaning	Audible signal
Oxygen Too Low	Flashing red	After 2 minutes of operation, the oxygen concentration is ≤73±3%	Five beeps in a repeating pattern every 5 seconds.
Oxygen Low	Yellow flashing	After 2 minutes of operation, the oxygen concentration is 82±3%	Five beeps in a repeating pattern every 16 seconds.
High Pressure	Solid yellow	After 2 minutes of operation, the system pressure is too high	One beep repeated every 24 seconds.
Low Pressure	Solid yellow	After 2 minutes of operation, the system pressure is too low	A single beep repeated every 24 seconds.
No Oxygen Sensor	Flashing red	No signal from the oxygen sensor circuit board after 2 minutes of operation	Five beeps in a repeating pattern every 5 seconds.
Low Flow	Flashing red	After 2 minutes of operation, the flow rate is less than 0.4 L/min (+10%)	Five beeps in a repeating pattern every 5 seconds.
/	Flashing red	A sudden power outage occurs during operation	Five beeps in a repeating pattern every 5 seconds. The alarm continues to sound for more than 30 seconds. Lasts longer than 30 seconds.

4. Actions to Take After a Warning

If the oxygen concentration drops below the acceptable level, the green NORMAL OXYGEN LEVEL LED turns off. The yellow LOW OXYGEN LEVEL LED or the red LED lights up, and an error code is displayed. Switch immediately to your backup oxygen system. Refer to the Troubleshooting section in this manual and contact your supplier.

If "FLOW LOW" is displayed after startup, the red LED lights up, and the audible alarm sounds: adjust the flow control knob so that the float ball indicates a flow rate between 1 and 5 L/min. If the alarm does not stop, contact your supplier for assistance.

If the power interruption lasts less than 30 seconds, the alarm system will reset automatically.

WARNING: Geriatric, pediatric, or other users who may experience discomfort require additional monitoring or observation during oxygen therapy.

SIMPLE TROUBLESHOOTING

Problem	Possible Cause	Solution
A. The device is not working; the The Power indicator light is NOT on when the on/off switch is set to "ON." The audible alarm sounds and the Service Required light flashes.	1. The power cord is not properly plugged into the outlet.	Check the power connection at the outlet. For 115 V/220 V devices: check the back of the device.
	2. No power at the outlet.	Check your home's circuit breaker and reset it if necessary. Use a different outlet if this happens again.
	3. The oxygen concentrator's circuit breaker has tripped (on select models).	Press the concentrator's circuit breaker (if present) located below the on/off switch. Use a different outlet if this happens again.
B. The device is operating; the Power indicator light is on when the on/off switch is set to "ON." The red "Service Required" light is on. The audible alarm may sound.	1. Air filter is clogged.	Check the air filter. If the filter is dirty, wash it according to the cleaning instructions on page 14.
	2. Exhaust blocked.	Check the exhaust; make sure nothing is obstructing the device's exhaust.
	3. Blocked or defective cannula, catheter, face mask or oxygen tubing.	Disconnect the cannula, catheter, or face mask. If the correct flow rate is restored, clean or replace as needed. Disconnect the oxygen tubing from the oxygen outlet. If the correct flow rate is restored, check the oxygen tubing for blockages or kinks. Replace if necessary.
	4. Blocked or defective Humidifier Bottle.	Disconnect the Humidifier Bottle from the Oxygen Outlet. If the correct flow rate is achieved, clean or replace the Humidifier Bottle.
	5. Gas leak	Check the connection between the device outlet and the hose, and between the hose and the humidifier bottle, for leaks. Replace if necessary.
	6. Compressor malfunction	Contact your supplier
	7. Filter beds may be defective or expired	Contact your supplier
	8. Flow meter set too low.	Set the flow meter to the specified flow rate. If the above does not resolve the issue, contact your supplier
	9. Other	Contact your supplier
C. The device is working; the Power indicator light is on when the on/off switch is set to "ON"; a audible low-frequency humming sound is heard.		Turn the device OFF, switch to your backup oxygen system, and contact your supplier immediately.
D. If you experience any other problems with your oxygen concentrator:		Turn the device OFF. Switch to your backup oxygen system and contact your supplier immediately.

Problem	Possible Cause	Solution
E. The red "Service Required" light is on and an intermittent audible alarm is sounding.	1. Flow meter not set correctly.	Make sure the flow meter is set correctly to the specified flow rate.
	2. Air filter is clogged.	Check the sponge intake filter. If dirty, clean it according to the instructions on page 14. The HEPA intake filter must be clean according to the instructions on page 15.
	3. Outlet is blocked.	Check the exhaust; make sure nothing is obstructing it. If the solutions above do not work, contact your supplier.
F. The yellow light is on and an intermittent audible alarm sounds.	1. Flow meter not set correctly.	Make sure the flow meter is set correctly to the specified flow rate.
	2. Air filter is blocked.	Check the sponge intake filter. If dirty, clean it according to the instructions on page 14. The HEPA intake filter must be clean according to the instructions on page 15.
	3. Outlet is blocked.	Check the outlet area: Make sure nothing is obstructing the device's outlet. If the solutions above do not work, contact your OXTM supplier.
	4. Blocked or defective cannula, catheter, face mask or oxygen tubing.	Disconnect the cannula, catheter, or face mask. If the correct flow rate is restored, clean or replace as needed. Disconnect the oxygen tubing from the oxygen outlet. If the correct flow rate is restored, check the oxygen tubing for blockages or kinks. Replace if necessary.
	5. Blocked or defective Humidifier Bottle.	Disconnect the Humidifier Bottle from the Oxygen Outlet. If the correct flow rate is achieved, clean or replace the Humidifier Bottle.
	6. Gas leak	Check the connection between the device outlet and the tubing, and between the tubing and the humidifier bottle, for leaks. Replace if necessary.

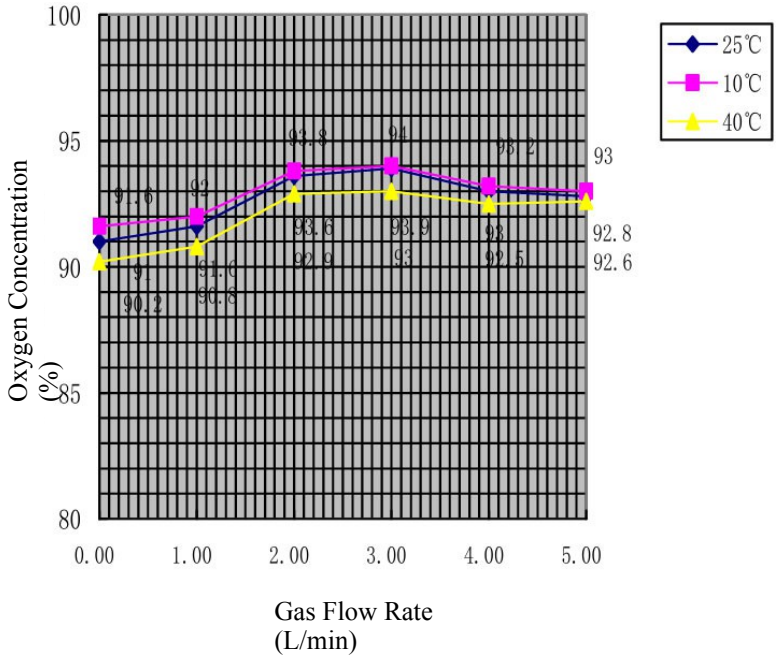
SPECIFICATIONS

Item	Nominal Values
Delivery Rate (Flow Rate)	1 to 5 L/min
Maximum Recommended Flow Rate (at nominal outlet pressures of 0 and 7 kPa)	5±10% L/min
Outlet pressure under normal conditions	40 to 80 kPa, 5.8 to 11.6 PSI
Electrical ratings	230 VAC, 50 Hz, 365 VA
Oxygen percentage	93% ± 3% at 1 L/min – 5 L/min
Operating environment	Temperature: 5°C to 40°C Relative humidity: ≤ 80% Atmospheric pressure: 86 to 106 kPa (10.3 to 15.4 PSI)
Operating altitude: 0–2,000 meters (tested only at 21°C)	Regarding the voltage range: No reduction in performance
"LOW OXYGEN" Indicator	Less than 82% (±3%) activates the yellow "Low Oxygen Level" indicator light
Maximum limited pressure under a single fault condition	150 kPa ± 20 kPa (21.75 psi ± 2.9 psi)
Back pressure	7 kPa with the humidifier bottle connected; 0 kPa if the humidifier bottle is not connected
Product weight	15.2 kg
Noise level	33.92 dB(A) at 3 LPM (MDS-Hi)
Dimensions	36 × 29 × 58 cm
Operating Principle	Time cycle / Pressure cycle
Storage Conditions	Temperature: -30°C to 70°C Relative humidity: 10% to 95% Atmospheric pressure: 50 to 106 kPa (7.3 to 15.4 PSI)
Device Class and Type	Type of protection against electric shock: Class II Degree of protection against electric shock: TYPE BF applied component
Expected service life	5 years
Warranty	5 years
Expected service life of the molecular sieve system	2 years
Molecular sieve bed	Dimensions: 230 (L) × 80 (W) × 328 (H) mm Weight: 2.84 kg Outlet pressure: 40 to 60 kPa (5.8 to 8.7 PSI) Outlet size: 7.3 Molecular sieve specification/type: SXS, 0.6 mm Manufacturer: ARKEMA

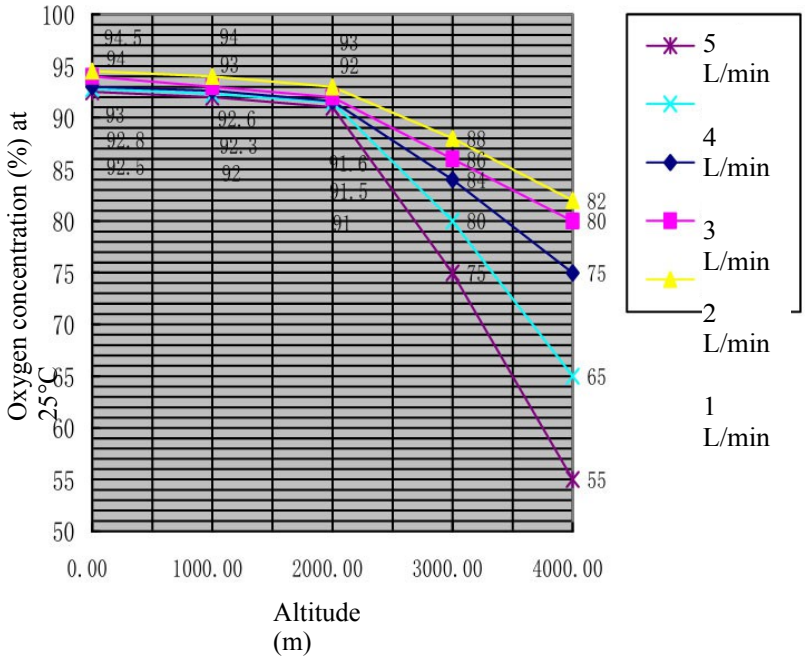
★ *The expected service life applies provided that the unit is used in accordance with all instructions in this User Manual regarding safe use, maintenance, storage, handling, and general use. The expected service life of the device—and in particular of the sieve beds and the compressor—may vary depending on the operating environment, storage, handling, and the frequency and intensity of use.*

The following two graphs showing temperature, flow rate, and oxygen concentration for the ZY-5AC are for reference only.

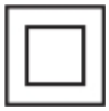
Temperature, Flow Rate, and Oxygen Concentration Chart



Altitude, Flow Rate, and Oxygen Concentration Graph



SYMBOLS

	Warning - Describes a hazard or unsafe practice that, if not avoided, could result in serious bodily injury, death, or property damage.
	Caution - Describes a hazard or unsafe practice that, if not avoided, could result in minor physical injury or property damage.
NOTE	Emphasizes important information.
	TYPE BF APPLICABLE COMPONENT
	Class II equipment, double-insulated
	Do not expose to open flames
	Do not smoke near the device
	Do not disassemble
	Operating Instructions
	Follow the instructions for use
SN	Manufacturer’s serial number
	Manufacturer

	This device contains electrical and/or electronic components that must be recycled in accordance with EU Directive 2012/19/EU—Waste Electrical and Electronic Equipment (WEEE)—or other local regulations.
	European CE marking with Notified Body No. 2460
	FRAGILE - The contents of the shipping package are fragile and must therefore be handled with care.
	THIS SIDE UP - Indicates the correct upright position of the shipping container.
IP21	Degree of protection against ingress - Protected against finger access to hazardous parts; protected against vertically falling water droplets.
	Protect the shipping container from rain.
	Non-ionizing electromagnetic radiation
EU REP	Indicates the EU representative
UDI	Unique identification of the medical device
MD	Medical device
LOT	Indicates the batch code so that the batch or lot can be identified

	Identifies an item that may pose unacceptable risks to the patient, healthcare personnel, or other individuals within the medical device environment. When color printing is not practical, the symbol may be printed in black and white. Use of the colored version is strongly recommended due to the added visibility and information that color provides.
	Date of Manufacture
	Net Weight
	Model Number
	Made in China
	Importer
	Temperature Limits
	Relative humidity
	Atmospheric pressure

ELECTROMAGNETIC INFORMATION

Medical electrical equipment requires special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and used in accordance with the EMC information in this User Manual.

WARNING: Do not use the device in the vicinity of active high-frequency (HF) surgical equipment or within the RF-shielded area of an MRI system, where electromagnetic interference may be high.

WARNING: Avoid using this device immediately adjacent to or stacked with other equipment, as this may result in malfunction. If such use is necessary, both this device and the other equipment must be monitored to verify normal operation.

WARNING: The use of accessories, transducers, and cables other than those specified or supplied by the Manufacturer may increase electromagnetic emissions or reduce electromagnetic immunity, which may result in malfunction. The use of accessories, transducers, and cables other than those specified or supplied by the Manufacturer will void the Warranty.

WARNING: Portable RF communication equipment (including peripherals such as antenna cables and external antennas) must be kept at least 30 cm (12 inches) away from any part of this device, including cables specified by the manufacturer. Failure to maintain this distance may reduce the performance of the equipment.

NOTE: The EMC tables and guidelines in this User Manual contain essential information for the customer or user to determine the suitability of the equipment or system for the intended electromagnetic environment. These guidelines help ensure that the equipment can perform its intended function without causing interference with other equipment, systems, or non-medical electrical devices.

The Rhythm Healthcare ZY-5AC 5L Stationary Oxygen Concentrator is intended for use in the electromagnetic environment specified in this manual. The customer or user must ensure that the concentrator is used in accordance with these specifications.

Table 1: Guidelines and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidelines
RF Emissions CISPR 11	Group 1	The device uses RF energy solely for its internal operation. Therefore, RF emissions are very low and are unlikely to cause interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all environments, including residential environments and environments directly connected to the public low-voltage power grid that supplies buildings for provides electricity for household use.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Table 2: Guidelines and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidelines**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Compliant	Floors must be made of wood, concrete, or ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Fast electrical transients /bursts IEC 61000-4-4	±2 kV for power lines; ±1 kV for signal inputs/outputs; repetition frequency 100 kHz	Complies	The quality of the mains power supply must be equivalent to that of a typical commercial or hospital environment.
Surge voltage IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common-mode	Compliant	
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles; single-phase: at 0°. 0% UT; 250/300 cycles	Meets requirements	The quality of the mains power supply must be equivalent to that of a typical commercial or hospital environment. If the user of the concentrator requires continuous operation during power outages, it is recommended that the concentrator be powered by an uninterruptible power supply (UPS) or battery.
Power-frequency magnetic field IEC 61000-4-8	30 A/m, 50 Hz	Compliant	Power-frequency magnetic fields should be at levels typical of a typical location in a commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V, 0.15 MHz – 80 MHz; 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz; 80% AM at 1 kHz	Complies	
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz – 2.7 GHz; 80% AM at 1 kHz	Complies	Field strengths outside the shielded area of fixed RF transmitters, as determined by an electromagnetic site survey, must be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE: UT is the AC voltage before applying the test level.			

Table 3: Guidelines and Manufacturer's Declaration – Electromagnetic Immunity						
	Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance Level**
Radiated RF IEC 61000-4-3 (Test Specifications for immunity of the ENCLOSURE PORT RF-shielded communication equipment)	385	380–390	TETRA 400	Pulse modulatio	27	27
	450	430–470	GMRS 460, FRS 460	FM ±5 kHz deviation, 1 kHz sine	28	28
	700	704–787	LTE Band 13, 17	Pulse modulation	9	9
	745					
	780					
	810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulatio n 18 Hz	28	28
	870					
	930					
	1,720	1,700 - 1,990	GSM 1800; CDMA 1,900; GSM 1,900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation	28	28
	1,845					
	1,970					
	2,450	2,400 - 2,570	Bluetooth, Wi-Fi, 802.11 b/g/n, RFID 2,450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5,240	5,100 - 5,800	Wi-Fi 802.11 a/n	Pulse modulation 217 Hz	9	9
	5,500					
	5,785					

Table 4: Guidelines and Manufacturer's Declaration – Electromagnetic Immunity				
	Test frequency	**Modulation**	**IEC 60601-1-2 Test Level (A/m)**	**Compliance level (A/m)**
Radiated RF IEC 61000-4-39 (Test specifications for immunity of the ENCLOSURE PORT against proximity magnetic fields)	30 kHz	CW	8	8
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 kHz	Pulse modulation 50 kHz	7.5	7.5

Rhythm Healthcare, LLC warrants the Rhythm Healthcare ZY-5AC 5L Stationary Oxygen Concentrator subject to the terms and limitations set forth below. Rhythm Healthcare, LLC warrants that this device is free from defects in workmanship and materials for five (5) years from the date of shipment from the factory to the original purchaser (typically the healthcare provider), unless otherwise agreed upon in a contract. This warranty is limited to the purchaser of new equipment purchased directly from Rhythm Healthcare, LLC, or from one of its suppliers, distributors, or agents. Rhythm Healthcare, LLC's obligations under this warranty are 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 by this warranty; nor does this warranty cover normal wear and tear.

WARRANTY CLAIMS

The original purchaser must submit any warranty claim to Rhythm Healthcare, LLC or to an Authorized Service Center. Further instructions will be provided after verification of warranty status. For all returns, the original purchaser must: (1) properly package the device in shipping packaging approved by Rhythm Healthcare, LLC, (2) properly identify the claim with the return authorization number, and (3) ship the package 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 to provide a replacement device while an oxygen concentrator is being repaired.

NOTE: Replacement components are warranted for the remaining, unexpired portion of the original Limited Warranty. This warranty is void, and Rhythm Healthcare, LLC is released from any obligation or liability if:

- the device is misused, abused, tampered with, or operated improperly during this period;
- a malfunction results from insufficient cleaning or failure to follow the instructions;
- the equipment is used or maintained outside the parameters specified in the operating and service instructions;
- routine maintenance or service is performed by unqualified service personnel;
- unauthorized parts or components (e.g., remanufactured filter media) are used to repair or modify the equipment;
- unapproved filters are used with the device.

MANUFACTURER

Manufacturer
Foshan Care Medical Technology CO., LTD

Address
#2 Haitang Road
National Ecological Industry Park, Danzao Town, Nanhai District, Foshan, Guangdong, China

Product Name:
Oxygen Concentrator

CE 2460

Catalog Number
ZY-5AC

Phone
+86-757 85409876

Email
info@caremedical.com.cn

Regulatory contacts by market

Market	Importer	Authorized Representative/ Responsible Person (UK)
EU	Rhythm Healthcare SAS 3 Rue de Genève 69006 Lyon, France	EU REP EverBiz GmbH Landsberger Str., 155 80687 Munich, Germany Phone: +49 89 5455 8164, Fax: +49 89 5455 8333 Email: info@everbiz.de
UK	**UKRP** MedEnvoy UK Limited 167–169 Great Portland Street, 5th Floor, London, W1W 5PF United Kingdom	
CH	CH REP MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland	

This device must not be disposed of with household waste.

This device contains electrical and/or electronic components that must be recycled in accordance with EU Directive 2012/19/EU—Waste Electrical and Electronic Equipment (WEEE)—and other local regulations.

Non-infectious used accessories (e.g., nasal cannula) may be disposed of as household waste. Infectious accessories (e.g., a nasal cannula from an infected user) must be disposed of through an authorized waste disposal facility or company. Names and addresses are available from your local municipality.

REPORTING SYSTEM FOR SERIOUS INCIDENTS

Contact the Manufacturer and the local Competent Authority as listed in the table below as soon as a Serious Incident involving the oxygen concentrator occurs.

Country	Contact Information	Website
Belgium	**MDD AIMDD - IVDMD** Head of the Vigilance Department: Th. Roisin **MDD AIMDD Vigilance: C. Driesmans** Phone: +32 2 528 4418 IVDMD Vigilance: J. Poels Tel: +32 2 528 4449 Email: vigilance.meddev@fagg-afmps.be **FAMHP - Federal Agency for Medicines and Health Products** Place Victor Horta 40, Box 40, B-1060 Brussels, Fax: +32 2 528 4120	https://www.afmps.be/fr
Bulgaria	**Executive Director of the BDA: Bogdan Kirilov, M.Pharm.; Head of the "Medical Devices" Department: Todor Darakchiev, Bulgarian Medicines Agency** 8 Damyan Gruev St., BG - 1303 Sofia, tel: +359 2 890 34 83, fax: +359 2 890 34 34 Email:todor.darakchiev@bda.bg , bda@bda.bg	https://www.bda.bg/bg/
Czech Republic	**Ivana Justová, State Institute for Drug Control** Šrobárova 48, 100 41 Prague 10, Czech Republic, tel: +420 272 185 794, fax: +420 272 185 764 Email:urgent@sukl.cz , ivana.justova@sukl.cz	/
Croatia	**Krunoslav Kranjcec, Agency for Medicines and Medical Devices** Ksaverska cesta 4, 10 000 Zagreb, tel: +385 1 4884 327, fax: +381 1 4884 110 Email:medpro@halmed.hr , Krunoslav.kranjcec@halmed.hr	https://www.halmed.hr/?ln=en
Denmark	**Danish Medicines Agency** Axel Heides Gade 1, DK - 2300 - Copenhagen, tel: +45 44 88 9595, fax: +45 44 88 9599 Email:med-udstyr@dkma.dk , Websites: www.medicinskudstyr.dk	https://laegemiddelstyrelsen.dk/en/devices/
Germany	**AIMDD, MDD - Dr. Ekkehard Stößlein** Phone: +49 228 207 5384 **IVDMD - Prof. Dr. Rüdiger Siekmeier** Tel: +49 228 207 5360 **Federal Institute for Drugs and Medical Devices** Kurt Georg Kiesinger Allee 3, D - 53175 Bonn, fax: +49 228 207 5300 Email: medizinprodukte@bfarm.de **IVDMD - Dr. Markus Funk** Phone: +49 6103 77 3115 **Jochen Halbauer** Tel.: +49 6103 77 3114 **Paul Ehrlich Institute** Pharmacovigilance Section 2, Paul-Ehrlich-Strasse 51-59, D - 63225 Lange, Fax: +49 6103 77 1268 Email: pharmacovigilance2@pei.de	https://www.bfarm.de/DE/Home/_node.html https://www.pei.de/DE/home/home-node.html
Estonia	**Sofia Ratusnaja** Tel: +372 744 7425 **Health Council, Medical Devices Division** 1a Põllu St., EE - Tartu 50303 Email: mso@terviseamet.ee	https://www.terviseamet.ee/en/medical-devices

Country	Contact Information	Website
Ireland	**Health Products Regulatory Authority** Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IE - Dublin 2 Email: devicesafety@hpra.ie	https://www.hpra.ie/
Greece	**Eleni Papaioannou, MD -** Phone: +30 213 20 40542, Fax: +30 210 65 49585 Email: vigilancematerial@eof.gr **National Organization for Medicines** 284 Mesogion Ave, GR-15562 Holargos, Athens	/
Spain	**Carmen Abad,** **Carmen Valls** Tel: +34 91 822 5255, Fax: +34 91 822 5289 **Spanish Agency for Medicines and Health Products** C/ Campezo 1, Building 8, ES - 28022 Madrid Email: psvigilancia@aemps.es	https://www.aemps.gob.es/
France	**Emilie Alliez** Tel: +33 1 55 87 33 46, Fax: +33 1 55 87 37 02 **National Agency for the Safety of Medicines and Health Products (ANSM)** 143–147 Boulevard Anatole France, FR – 93285 Saint-Denis Cedex Emails: **For correspondence between authorities only:** medicaldevicesvigilance@ansm.sante.fr For other purposes: materiovigilance@ansm.sante.fr	http://www.afssaps.fr/
Italy	**Medical Device Vigilance** Head of Unit 5 - Dr. Lucia Lispi, tel: +39 06 5994 2055 Email:dgfdm@postacert.sanita.it ,vigilance@sanita.it , l.lispi@sanita.it **MDD AIMDD Vigilance - Dr. Antonella Campanale –** **Dr. Daniela Minella** Tel: +39 06 5994 3038, +39 06 5994 3069 Email:dgfdm@postacert.sanita.it ,vigilance@sanita.it ,a.campanale@sanita.it ; d.minella@sanita.it **Head of Unit 4 – Dr. Antonella Colliardo** Tel: +39 06 59943968. IVDMD Vigilance **Dr. Maria Gabriella Cividino, Dr.** **Maria Elena Russotel** +39 06 59943785, +39 06 59942516 Email:dgfdm@postacert.sanita.it ,mg.cividino@sanita.it ;me.russo@sanita.it ; a.colliardo@sanita.it **Ministry of Health, Directorate-General for Medical Devices and** **Pharmaceutical Services** Via Giorgio Ribotta 5, IT - 00144 Rome	/
Cyprus ######	**Ioannis Argyropoulos** tel: +357 22 605785 **Cyprus Medical Devices Competent Authority** Prodromou 1 & Chilonos 17 Corner, CY - 1449 Nicosia Fax: +357 22 468427 Email: cymda@mphs.moh.gov.cy	/

Country	Contact Information	Website
Latvia	**Medical Device Evaluation Department** Tel: +371 67 078 466, Tel: +371 67078466 **State Medicines Agency,** 15 Jersikas Street, LV - 1003 Riga Email: info@zva.gov.lv	/
Lithuania	**Director: Nora Ribokiene** Phone: +370 5 261 51 77, Fax: +370 5 212 73 10 **State Accreditation Agency for Healthcare, under the Ministry of Health of the Republic of Lithuania**, 21 Jeruzales St., LT-08420 Vilnius Email: vaspvt@vaspvt.gov.lt	https://vaspvt.gov.lt/
Luxembourg	**Ministry of Health, Directorate of Public Health** Tel: +352 247 85612 Villa Louvigny - allée Marconi, L-2120 Luxembourg Email: meddevices.vigilance@ms.etat.lu	https://sante.public.lu/fr/health-policy/ministry-of-health/index.html
Malta	**Maltese Medicines Authority - Medical Devices Division** Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta Tel: +356 2343 9000, Email: devices.medicinesauthority@gov.mt	https://medicinesauthority.gov.mt/medicaldevices
Hungary	**Dr. Kornel Szerdi** Tel: +36 1 886 9329, Fax: +36 1 269 1255 **Center for Health Registration and Training, Department of Medical Devices** 1051, Budapest, Zrínyi Street 3, Hungary Email: amd.vig@ogyei.gov.hu	/
Netherlands	**Sietske Eerens, Esther Klinckenberg** Tel: +31 88 120 5000, Fax: +31 88 120 5001 **Dutch Health and Youth Care Inspectorate (IGJ) Information Center (Reporting Center)** Visiting address: Stadsplateau 1 | 3521 AZ | Utrecht, mailing address: P.O. Box 2518 | 6401 DA | Heerlen Email: meldpunt@igj.nl	https://www.igj.nl/
Austria	**Federal Office for Safety in Healthcare (BASG) - Federal Office for Safety in Healthcare, Institute for Supervision, Medical Devices Supervision Division**, Traisengasse 5, A-1200 Vienna, fax: +43 50555 36409 Email: medizinprodukte@basg.gv.at	https://www.urpl.gov.pl/pl
Poland	**Competent Authority: Andrzej Karczewicz** Tel: +48 22 492 11 90, **Beata Koziozemska** Tel: +48 22 492 11 68 **Office for the Registration of Medicines, Medical Devices, and Biocidal Products** Al. Jerozolimskie 181C, 02-222 Warsaw Fax: +48 22 492 11 99 Email: incydenty@urpl.gov.pl	https://www.urpl.gov.pl/pl

Country	Contact Information	Website
Portugal	**Raquel Alves** Phone: +351 21 798 7297, Phone: +351 21 798 7145, Fax: +351 211 117 559 **Infarmed - National Authority for Medicines and Health Products, Health Products Surveillance Unit of the Health Products Directorate** Lisbon Health Park, Av. do Brasil, No. 53, PT - 1749-004 Lisbon Email: dvps@infarmed.pt	https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/vigilancia-de-dispositivos-medicos
Romania	**Oana Arsenescu, Georgeta Herta** Tel: +40 21.222.86.52, +40 21 260.01.58, +40 21 260.01.59 Fax: +40 21.222.86.83 **Romanian National Agency for Medicines and Medical Devices** 58, Nicolae Titulescu Street, Sector 1, Bucharest Email:mdevice@anm.ro , georgeta.herta@anm.ro	https://www.anm.ro/
Slovenia	**JAZMP - Agency for Medicines and Medical Devices of the Republic of Slovenia** Slovenčeva ulica 22, SI - 1000 Ljubljana - - Tel: +386 8 2000 500 Email:info@jazmp.si , meddev.vigilance@jazmp.si	https://www.jazmp.si/en/medical-devices/vigilance-of-medical-devices/
Slovak Republic / Slovakia	**Darina Kaminská** Tel: +421 2 50701215 **State Institute for Drug Control, Medical Devices Section** Kvetna 11, SK - 825 08 Bratislava Email: darina.kaminska@sukl.sk	https://www.sukl.sk/hlavna-stranka/english-version?page_id=256
Finland	**Finnish Medicines Agency Fimea, Medical Devices Department** Mannerheimintie 166, P.O. Box 55, FI-00034 FIMEA, FINLAND, tel: +358 29 522 3602 Email:meddev.vigilance@fimea.fi , registry@fimea.fi	https://www.valvira.fi/
Sweden	**Swedish Medical Products Agency, Medical Devices Division** P.O. Box 26, SE-751 03 Uppsala Tel: +46 18 174600 Email: meddev.central@lakemedelsverket.se	https://www.lakemedelsverket.se/sv
Norway	**AIMDD, MDD IVDMD - Raymond Ludvigsen / Bjørn Kristian Berge** **Norwegian Medicines Agency** P.O. Box 6167 Etterstad, N-0602 Oslo Tel: +47 22 89 77 00 Email: meddev-no@legemiddelverket.no	https://legemiddelverket.no/English
Island	**Haukur Eggertsson** Phone: +354 520 2100, Fax: +354 561 2170 **Icelandic Medicines Agency** Vínlandsleið 14, IS-113 Reykjavík Email: Haukur.Eggertsson@lyfjastofnun.is	https://www.lyfjastofnun.is/
Liechtenstein	**Martin Stricker,** Phone: +423 236 73 36 **Office of Public Health** Äulestrasse 51, P.O. Box 684, FL - 9490 Vaduz Email: medical.devices@llv.li	https://www.llv.li/inhalt/1908/amtsstellen/amt-fur-gesundheit
Turkey	**Ministry of Health, Turkish Medicines and Medical Devices Agency, Vice Presidency of Inspection, Medical Devices Vigilance Unit** Söğütözü Mahallesi 2176. Street No. 5, P.O. Box 06520 Çankaya, Ankara, TURKEY Email: meddev.vigilance@titck.gov.tr	/

RHYTHM HEALTHCARE

OXY BV

Foshan Care Medical Technology CO., LTD #2 Haitang Rd, National Ecological Industrial Park, Danzao Town, Nanhai District, Foshan, CN 528000

Email:contactus@rhythmhc.com
Website:
www.rhythmhc.com

V8: 10/07/26