LifeChoice

Activox™

breaking boundaries

PORTABLE OXYGEN CONCENTRATOR

Operator's Manual

FOR USE WITH MODEL:
XYC100B-P4L

Manufactured & Distributed by **Inova**Labs

www.InovaLabs.com

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TABLE OF CONTENTS

INTRODUCTION

This Operator's Manual will provide familiarity with the LifeChoice Activox Portable Oxygen Concentrator (POC) model XYC100B-P4L and its accessories. Be sure to read all of the enclosed information in its entirety before using the device.

The device is an internally powered, Type BF device when powered by the Internal Battery and a Class II, Type BF device when connected to the external AC Power Supply, DC Power Supply or rechargeable External Battery. The essential performance of the device is to provide oxygen at a volume that remains within tolerance (the tolerance was defined based on technical judgment from within the manufacturer's expertise in this specific medical application). In addition, the device's ability to detect certain error conditions (such as low purity or no breath) and create an alarm is also considered a part of essential performance.

APPLICATION/INDICATIONS FOR USE

This manual applies to the LifeChoice Activox POC REF XYC100B-P4L.

INDICATIONS FOR USE: The LifeChoice Activox Oxygen Concentrator is used on a prescriptive basis by adult patients who are diagnosed as requiring supplemental oxygen. This oxygen concentrator will provide supplemental, high concentration oxygen to these patients. It is not life-supporting nor life-sustaining. It may be used continuously in a home, institution or travel environment. The LifeChoice Activox is also portable.

This device should be used only when prescribed by a physician.

SYMBOL DESCRIPTIONS

Symbol	Description	Symbol	Description	Symbol	Description
	Caution		Consult instructions for use		No smoking
	No open flame		No oil or grease		Do not disassemble
	Temperature limit		Humidity limitation		Keep dry
	This side up		Fragile, handle with care		Compliant with WEEE
	Manufacturer		Date of manufacture		Class II equipment
	Type BF applied part Device that has conductive contact with patient	REF	Catalogue number	CE	CE Marking of Conformity Representative
O_2	Gas flow	Rx ONLY	Prescription only		Radio frequency
	Rechargeable battery	POC	Portable Oxygen Concentrator Connection	EC REP	Authorized representative in the European Community
SN	Serial number				

WARNINGS

1. U.S. Federal law restricts this device to sale by or on the order of a physician.
2. It is the responsibility of the patient and/or provider to make back-up arrangements for an alternative oxygen supply.
3. Availability of an alternate source of oxygen is required in case of power outage or mechanical failure.
4. The device is to be operated in the approved carry case provided.
5. The device should be located as to avoid pollutants or flames.
6. Portable and mobile RF communications equipment can affect medical electrical equipment.
7. The device should not be used adjacent to or stacked with other equipment.
8. When traveling by air, the device and External Battery must be transported as carry-on (not checked) baggage.
9. The device and External Battery contain lithium-ion batteries that are subject to special shipping regulations. If shipping either the device or External Battery, notify the shipper that the shipment will contain lithium-ion batteries.
10. In the event of a battery's cell leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

CONTRAINDICATIONS

1. The device is not intended to be life-sustaining or life-supporting.
2. In certain circumstances, oxygen therapy can be hazardous. Please seek medical advice before using this device.
3. The device is designed to provide a flow of high purity oxygen up to 4 LPMeq pulse. The device should only be used by patients prescribed oxygen therapy within this range.
4. As the device will alarm through audio and visual indicators, patients who are unable to communicate discomfort, hear, see and/or understand the alarms may require additional monitoring.

ADVERSE EVENTS/HAZARDS

Inova Labs Inc. assumes no liability for persons choosing not to adhere to manufacturer's recommendations. Failure to adhere to the statements below may impair performance of the device and will void all warranties.

1. DO NOT use oil, grease or petroleum-based products on or near the device as the use of such products may damage the electronic components of the device.
2. DO NOT use power supplies or accessories other than those that came with the device as the use of non-specified accessories may impair performance.

3. DO NOT allow smoking or open flames within 10 ft. (3 m) of the device as the device produces enriched oxygen gas which accelerates combustion.
4. DO NOT operate the device in the accessory bag or any other enclosed bag as improper ventilation will impair performance.

5. DO NOT submerge or expose the device to liquids as it may damage the electronic components of the device.

6. DO NOT operate or expose the device to temperatures and humidity levels outside of the specified operational environment conditions listed in the Specifications section on page 19. Extreme temperatures and humidity levels may damage the device.
7. DO NOT press the Control Panel buttons or screen with any hard, sharp and/or small object as it may damage the surface.
8. DO NOT dismantle, open or shred secondary cells or batteries.
9. DO NOT expose cells or batteries to heat or fire and avoid storage in direct sunglight.

STANDARD PACKAGE CONTENTS

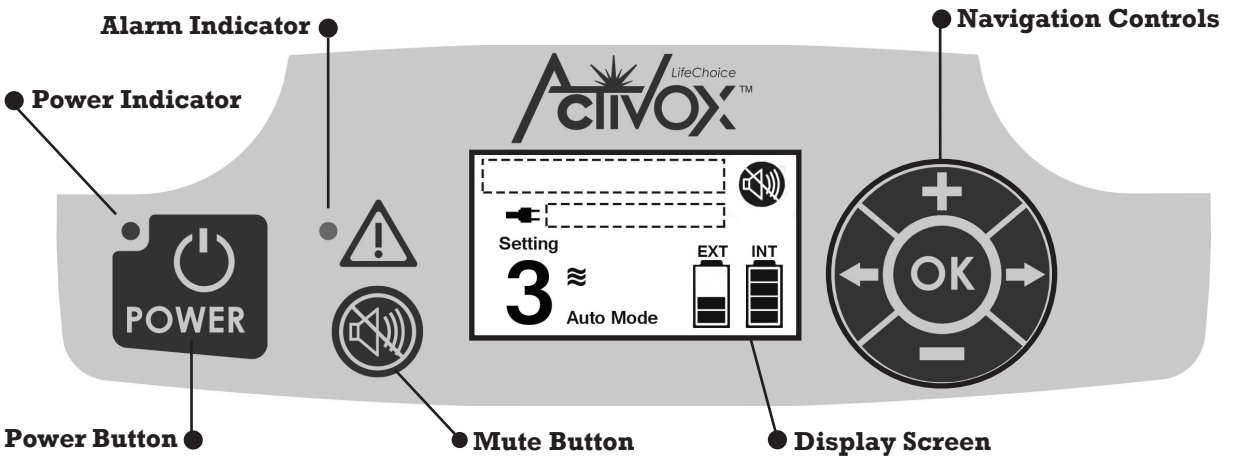
1. **LifeChoice Activox 4L POC**
   Model identified on device and packaging labels. See REF.
2. **4-Way Carry Case**
   Use as a backpack, shoulder bag, waist pack or briefcase
3. **Adjustable Straps**
   For use with 4-Way Carry Case
4. **DC Power Supply**
5. **AC Power Supply**
6. **Standard 7-Foot (2-meter) Single Lumen Nasal Cannula***
7. **Accessory Bag**

An optional External Battery (not included in the Standard Package) is available for purchase which provides up to 4.75 hours of additional battery time.

*Nasal cannula may not be included. Based on international requirements.See your doctor for compatibility of other accessories (CPAP, BiPAP, etc.).

USER CONTROLS

Control Panel



Alarm Indicator: A red LED will illuminate and an audible signal (tone) will sound if there is a change in operating status or a condition occurs that may need response (alarm).

Display Screen: Displays operational indicators. (Reference Display Screen diagram on page 7.)

Mute Button: Disables audible alarm signals during operation. If an alarm has been muted, the Mute symbol will appear on the Display Screen. (Reference Display Screen diagram on page 7.)

CAUTION: Please use the Mute function appropriately as it silences important audio signals regarding the status of the device.

Navigation Controls: The Plus, Minus, Right Arrow, Left Arrow and OK buttons enable navigation within operating menus.

Plus/Minus Buttons: Adjust the Pulse Setting (1, 2, 3 or 4 LPMeq).

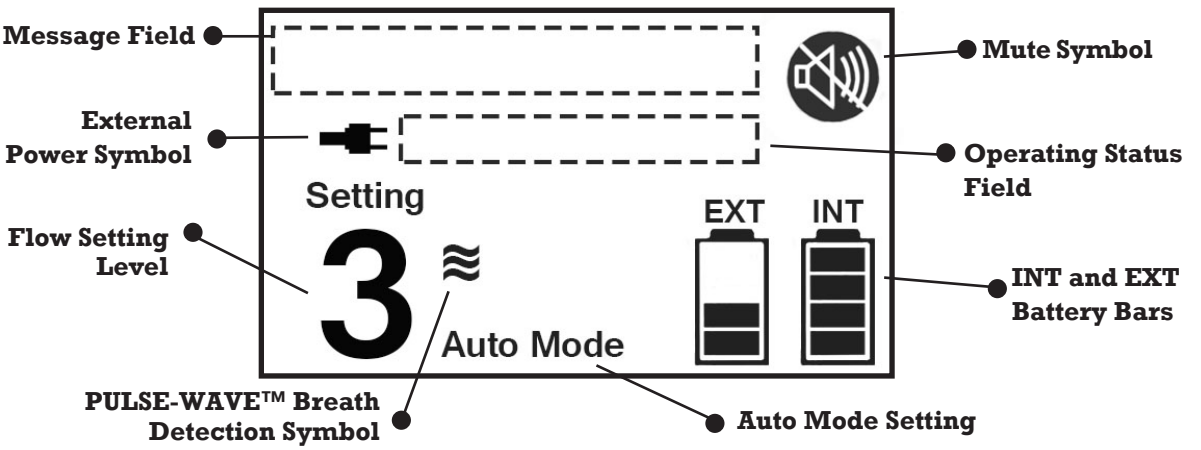
OK Button: Press once to illuminate the screen. Press and hold down to display the serial number and hours of operation.

Right/Left Arrow Buttons: Press once to illuminate the screen. Service personnel will also use these buttons to access maintenance menus for troubleshooting.

Power Button: To turn on, briefly press the Power Button. To turn off, press and hold down the Power Button until you hear a tone.

Power Indicator: A green LED will illuminate when the POC is turned on and in use.

Display Screen

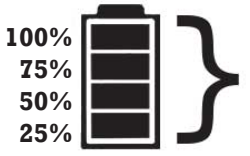


Auto Mode Setting: There are two inhalation sensitivity modes on the device: Active and Rest, which automatically adjust based on your breathing patterns. The activated Auto Mode setting will appear on the display.

External Power Symbol: This symbol is displayed only when the unit is connected to an external power supply (AC or DC).

Flow Setting Level: Represents the selected Pulse Setting (1, 2, 3 or 4 LPMeq). Use the Plus and Minus Buttons to adjust the Pulse Setting up or down.

INT and EXT Battery Bars: Represent the charging level of the Internal (INT) and External (EXT) Batteries.



Each Battery Bar is divided into 4 segments that represent 25% charge levels. As the charge level of the device increases, more segments will appear until full.

Message Field: Displays the title of an alarm if activated. (Reference Alarm Indicators section on page 15.)

Mute Symbol: Appears only when the Mute Button has been pressed.

Operating Status Field: This field will indicate if the device is "Running" or "Charging" the INT or EXT Battery. When the battery is fully charged, "Charging INT" or "Charging EXT" will disappear from the display.

PULSE-WAVE™ Breath Detection Symbol: Appears when a breath is detected and the device delivers a pulse of oxygen.

PART NAMES

Cannula Nozzle Fitting: Connect the nasal cannula to this fitting at the top of the device.

Charger Port: Connect the AC or DC Power Supply to this port on the device.

Control Panel: All user controls are located on this panel. (Reference User Controls section on page 6 for details.)

External Battery Port: Connect the External Battery, if purchased, to this port. The flat end of the External Battery plug should be facing upwards when plugging into the port on the device.

Fan Inlet Vent: Cooling air is drawn in through this opening.

Fan Outlet Vent: Processed air is exhausted through this opening.

Nasal Cannula: A standard single lumen nasal cannula or equivalent must be used with the device to provide oxygen from the concentrator.† The maximum length recommended for use is 7-feet (2-meter). For a replacement cannula, please contact your local medical equipment provider. Follow cleaning and care instructions provided with the nasal cannula.

CAUTION: Use of some accessories and/or service equipment not specified for use with this oxygen concentrator may impair the performance.

† Nasal cannula may not be included. Based on international requirements. See your doctor for compatibility of other accessories (CPAP, BiPAP, etc.).

OPERATING INSTRUCTIONS

The LifeChoice Activox POC must be operated and stored in its carry case at all times.

BEFORE FIRST USE:

1. Fully charge the device. It can take up to 4 hours to reach a full charge on the Internal Battery. Begin charging by connecting the AC Power Supply to the Charger Port on the device and an electrical outlet.
2. Verify that the INT Battery Bar, the External Power Symbol and the message "Charging INT" appear on the display. This indicates that the system recognizes the external power source and is charging the Internal Battery.

   If an External Battery was purchased, connect it to the External Battery Port. By design, the External Battery will begin charging after the Internal Battery has reached a full charge. When connected, the External Battery Bar, the External Power Symbol and the message "Charging EXT" appear on the display. It can take up to 2 hours to fully charge the External Battery.

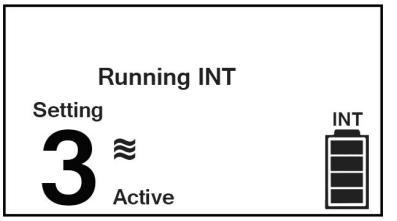
⚠ **CAUTION:** Never use an external battery that is not authorized by Inova Labs Inc.

POWERING YOUR POC

The device can be powered from four different sources: (1) Internal Battery, (2) AC Power Supply, (3) DC Power Supply and (4) External Battery (optional, sold separately from the Standard Package).

1. **Internal Battery:** A rechargeable internal battery is located within each device. When the device is being powered from the Internal Battery, the display will read "Running INT" and the INT Battery Bar will appear.

   A fully charged Internal Battery can provide up to 10.25 hours of runtime depending on breath rate. (Reference Battery Life Timetable on page 12.)



   If not connected to the AC or DC Power Supply, the Internal Battery will slowly discharge over time even when not in use.

   Always check the battery level prior to use to ensure adequate charge level.

   The Internal Battery is maintenance-free and can only be replaced at the factory or by an authorized repair facility.

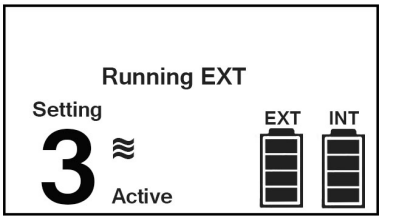
2. **AC Power Supply:** This power supply allows the device to be powered and charged from a standard 100-240 VAC, 50/60 Hz electrical outlet. When using this option, power from the AC outlet powers the unit and recharges the Internal and/or External Battery. The External Power symbol will also appear on the display screen when connected to this power supply.

NOTE: Using an AC Power Supply that is not specified by Inova Labs may damage the device and will void all warranties.

3. **DC Power Supply:** This power supply can be connected from the device to a vehicle's (car, boat, motor home, etc.) standard 12 VDC outlet. When the system is connected to this option, power from the vehicle battery powers the device and recharges the Internal and/or External Battery. The External Power symbol will also appear on the display screen when connected to this power supply.

NOTE: The 12 VDC outlets in some vehicles will not provide sufficient current to operate the device and charge the battery at the same time. Verify that a DC outlet can provide at least 10 amps at 12 VDC. Car auxiliary power varies significantly; therefore, the rate of charging will vary. It is recommended that the vehicle be turned on before plugging the DC Power Supply into the device.

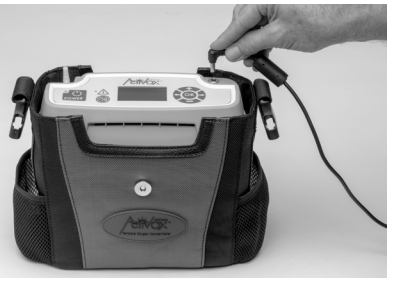
4. **External Battery:** This power supply connects directly into the device's External Battery Port. When the system is connected to this option, the display will read "Running EXT" and the EXT Battery Bar will appear. A fully charged External Battery can provide up to 4.75 additional hours of power to the device depending on breath rate.



The External Battery is maintenance-free and replacements can be purchased from your equipment provider.

CHARGING YOUR POC

INTERNAL BATTERY CHARGING



1. Connect the device to either an AC or DC Power Supply and corresponding charger to a suitable outlet.
2. Verify that the INT Battery Bar, the External Power Symbol and the message "Charging INT" appear on the screen.
3. It can take a fully discharged Internal Battery up to 4 hours to reach a full charge. Refer to the INT Battery Bar on the display screen to check the charging progress. Each segment in the Battery Bar represents 25%. When the Internal Battery is fully charged, the message "Charging INT" will disappear from the display screen.

   NOTE: It is recommended to recharge the Internal Battery, even if only partially depleted as often as possible. The Internal Battery cannot be overcharged, so it is okay to leave the device plugged into an external power supply continuously.

EXTERNAL BATTERY CHARGING

1. Connect the External Battery to the External Battery Port. The flat end of the External Battery plug should be facing upwards when plugging into the port on the device. Then connect the device to either an AC or DC Power Supply and corresponding charger to a suitable outlet. **To prolong battery life and maintain communication with the POC, it is recommended to charge the External Battery when you charge the Internal Battery.**
2. Verify that the EXT Battery Bar, the External Power Symbol and the message "Charging EXT" appear on the display.

   NOTE: By design, the Internal Battery will charge first. The External Battery will not start charging until the Internal Battery reaches a full charge.
3. It can take up to 2 hours for a fully discharged External Battery to reach a full charge. Refer to the EXT Battery Bar on the display screen to check the charging progress. Each segment in the Battery Bar represents 25%. When the External Battery is fully charged, the message "Charging EXT" will disappear from the display screen.

NOTE: By design, the External Battery will power the device when plugged in. Once the External Battery depletes, the device will switch to Internal Battery power. If both the Internal and External batteries are fully discharged, it can take up to 6 hours to achieve a full charge in both batteries.

In the event the power supply is interrupted to the device when the AC or DC Power Supply is connected, a two-second audible alarm will sound and the compressors will transition from external to internal power.

NOTE: If the POC is powered off and either the AC or DC Power Supply is connected, the internal fans will continue to operate until the temperature inside the unit is sufficiently cooled.

BATTERY LIFE TIMETABLE

Battery Type	Pulse Setting			
	1 LPMeq	2 LPMeq	3 LPMeq	4 LPMeq
Internal Battery*	10.25 Hours	8.25 Hours	5 Hours	4 Hours
External Battery*	4.75 Hours	3.75 Hours	2.75 Hours	2.25 Hours

BATTERY RECHARGE TIMETABLE

Battery Type	Hours
Internal Battery*	4
External Battery*	2

* Hours are approximate and based on breaths per minute. As batteries age, charge times and runtimes may change.

REPRESSURIZATION TECHNOLOGY

If the unit has not been used for a period of one or more days, it will automatically re-pressurize itself. During this time, you may hear the compressors running for a few seconds. There is no action required on your part, this feature is intended to prolong the life of the device.

OPERATING PROCEDURE

1. Position the device so that the Fan Inlet Vent and Fan Outlet Vent are not obstructed and in a well-ventilated space.

2. Briefly press the Power Button to turn the device on. The Display Screen and green Power Indicator will illuminate. This indicates that the device is powered on, ready for use, and the settings may now be changed.

NOTE: After powering on the device, allow 3 minutes for the system to reach stated performance. If used routinely, the Pulse Setting last used will appear on the display after powering on.

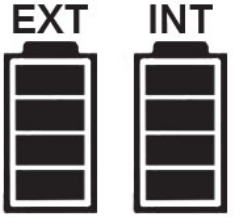
3. Use the Plus/Minus Buttons to select the Pulse Setting prescribed by your doctor (1, 2, 3 or 4). To change a setting at any time, use the Plus and Minus buttons.

4. Place the nasal cannula onto the Cannula Nozzle Fitting on the device and the cannula prongs into your nasal passages and breathe normally. When the device senses inhalation, oxygen is supplied through the cannula. The duration and size of the pulse is dependent upon the Pulse Setting selected.

NOTE: The device utilizes PULSE-WAVE™ Delivery which delivers oxygen congruent with your inhalation rate. **Because this type of delivery is very gentle, you may not feel the pulse of oxygen**. To verify that oxygen is being delivered, reference the ≋ symbol next to your selected Pulse Setting on the display. This symbol will flash every time a breath is detected and a bolus of oxygen is delivered.

5. Check to make sure the batteries are fully charged before venturing out with the device.

6. To turn the device off, press and hold the Power Button until you hear an audible tone.



NORMAL OPERATION INDICATORS

During normal operation, the Control Panel and Display Screen should appear as described below:

OPERATION	DESCRIPTION
Active or Rest Mode Activitated	The word "Active Mode" or "Rest Mode" will appear next to your selected pulse setting. If "Active Mode" is displayed it means your breath rate is typical for an active user. If "Rest Mode" is displayed it means your breath rate is slower than your normal active breath rate.
Alarm Muted	The audible alarm signal will be muted and the Mute symbol will display on screen. The red alarm LED will remain illuminated on the Control Panel and the alarm title will remain on the display.
Breath Detected	The PULSE-WAVE™ Breath Detection Symbol will flash as you breathe. This is confirmation the device is delivering a dose of oxygen with each inhaled breath.
Charging Status	The following messages will appear on the display depending on the battery being used or charged. "Charging INT" means the Internal Battery is charging. "Charging EXT" means the External Battery is charging. "Running INT" means the Internal Battery is in use. "Running EXT" means the External Battery is in use. **NOTE:** By design, the device will preserve the Internal Battery charge as long as possible. This means that the External Battery will deplete before the Internal Battery and the Internal Battery will charge before the External Battery when connected.
Power Interruption	The device will emit a two second audible tone if the AC or DC Power is interrupted or intentionally unplugged. The unit will automatically switch to battery operation. If the power was not intentionally removed, check all connections between the unit and the power source to ensure all are secure and firmly plugged in. If the power indicator icon does not show on the display, switch to another power source (AC or DC) or source of oxygen and contact your equipment provider.
Powered On	The Power Indicator is illuminated green and the Display Screen is on.
Setting Selected	"1", "2", "3" or "4" will appear under "Setting" on the Display Screen.

ALARM INDICATORS

The device will alarm to inform you of conditions that may require your attention or action. Each alarm will trigger:

- A repeating audible tone (1 second ON, 2 seconds OFF) sounds
- Illuminated red Alarm Indicator on the Control Panel
- Alarm title displayed in the Message Field *(unless noted differently below)*

ALARM TITLE	DESCRIPTION & CORRECTIVE ACTION
Low Battery	This alarm is triggered when the Internal Battery has approximately less than 15% charge remaining. Connect the device to the AC or DC Power Supply. Ensure all your charger connections are secure and the message "Charging INT" and the External Power symbol appear on the display. The device will begin charging and the alarm should stop. If the alarm persists, switch to another source of oxygen and call your equipment provider.
Low Oxygen Purity	This alarm can be triggered when the oxygen purity falls below 85%. This can occur if you are breathing at a high breath rate that exceeds the oxygen production capacity of the device or if the device requires sieve bed replacement. Take slow deep breaths until your breath rate recovers.This allows the device time to recover purity levels. If the alarm stops, the device is safe to use. If the alarm persists for an extended period of time after you have recovered your breath rate, change to another source of oxygen and contact your equipment provider.
No Breath Detected	This alarm can be triggered by a kinked cannula or shallow and/or mouth breathing. Check the cannula connection and hose for kinks and fix if found. If the cannula was not impaired, the alarm could be caused by shallow and/or mouth breathing. Breathe deeply through your nose until the alarm stops. If the alarm persists, switch to another source of oxygen and contact your equipment provider.
High Temperature	This alarm is triggered when the internal temperature of the device exceeds 140°F (63°C). When this alarm is activated, the device will stop producing oxygen. Move the device away from any potential heat source and change to another source of oxygen. The alarm will continue until the device sufficiently cools or you turn it off. After allowing sufficient time to cool, turn on the device. If the alarm has disappeared, the device is safe to use. If the alarm persists, continue to use another source of oxygen and contact your equipment provider.
Reset Required	This alarm can be triggered when the device experiences a sudden spike in current from an external power supply. The Display Screen will be blank when this alarm is activated. Follow the Electronic Reset directions on page 17 to reset the device to default factory settings. If the alarm continues immediately after the reset, switch to another source of oxygen and contact your equipment provider.

CARRY CASE CONFIGURATION INSTRUCTIONS

The Carry Case can be configured as a shoulder bag, backpack, waist pack or briefcase using the adjustable straps and/or briefcase handle. Below are instructions for configuring the backpack.

BACKPACK

1. Adjust each strap to make sure they are the same length.
2. Unfold the snaps that are tucked into the mesh pocket on the backside of the Carry Case.
3. Attach one strap to the top left and bottom right snaps on the Carry Case making sure the shoulder pad is near the top clip.
4. Attach the second strap to the top right and bottom left snaps on the Carry Case making sure the shoulder strap is near the top clip.
5. Form an "X" with the straps at the top and slide arms into the configuration as if putting on a backpack. Assistance may be required with this step.
6. Adjust straps as needed. Assistance may be required with this step.

FLYING WITH YOUR POC

The LifeChoice Activox POC is approved by the FAA for use on commercial aircraft. The FAA-approved POC list shows "*Inova Labs LifeChoice Activox*." This approval is listed as a part of the labeling on the bottom panel of the device. As every airline has specific information required for traveling with oxygen you should review your airline's specific requirements in addition to following the instructions below.

1. Two weeks prior to your trip, verify that the Internal and, if purchased, External Battery runtimes will provide you with enough battery life for the trip. Typically, airlines require you to have enough battery life for 1.5 times the flying duration.
2. Fully charge the Internal and, if purchased, External Battery within 24 hours of a trip. Keep the device connected to a power supply until you leave.
3. Pack all required accessories (AC and DC Power Supplies, Operator's Manual, small extension cord, etc.)
4. Download and complete the "Physician Statement" from www.InovaLabs.com. Bring the signed and completed Physician Statement to the airport and be ready to provide it to the airline if requested.

Authorized by FAA for use onboard aircraft 14CFR Part 121, SFAR 106

ROUTINE CLEANING AND MAINTENANCE

The device was designed to minimize the amount of routine maintenance that is required. There are no end-user repairable parts. Aside from the preventative maintenance outlined below, all other maintenance must be performed by qualified service personnel.

Fan Inlet Vent Cleaning: There is one inlet vent located on the right side (facing the unit) of the device. The carrying case for the unit has mesh material corresponding to the location of the Fan Inlet Vent. You should visually check to ensure that there is no buildup of lint, hair or other materials that could obstruct the flow of air into the unit's fan inlet vent. At least once a month inspect the grille of the intake vent and if it appears dirty, use a dry cotton swab (Q-Tip or similar) to clean it.

Device and Carrying Case Cleaning: If it is necessary to clean the device and/or carrying case, use only warm water and a mild liquid dish detergent. Dampen a cloth in the solution and carefully wipe the outside surfaces of the device and/or carrying case. Allow sufficient time to dry before placing the device back in the case.

⚠ **CAUTION:** DO NOT use alcohol, solvents, polishes or any oily substances as they may be flammable.

Nasal Cannula Inspection: At least once a week, visually inspect the nasal cannula. Make sure there are no kinks or obstructions. Replace as needed with a standard 7-foot. (2-meter) single lumen nasal cannula from your equipment provider.

Reserve Oxygen Supply: Your local equipment provider should provide or suggest an alternative source of supplemental oxygen therapy in case there is a mechanical failure or power outage.

Electronic Reset: If the Display Screen does not appear as described on page 7 or the Reset Required alarm is activated, follow the steps below to reset the device to default factory settings:

1. Turn the device off.
2. After the device has turned off, press and hold the Power button until the Greeting Screen stops flashing and the display turns blank. Once the display is blank, release the Power button.
3. Allow approximately 15 seconds for the device to cycle through a short sequence. During this time the device will power on and off.
4. Power the device back on. Verify that the Display Screen is appearing as described on page 7. If this reset does not resolve the issue, contact your equipment provider.

SERVICE LIFE

The service life of this device and it's major components is dependent on operating and environmental conditions. Daily use of the device may actually extend the replacement time for some of these items (i.e., sieve bed). It is recommended that the device be powered on and run for a few hours, if it is has not been used on a daily basis.

Should your device indicate an alarm that requires you to contact your equipment provider, the provider may determine the device must be sent in for service.

TECHNICAL SUPPORT

Please contact the local medical equipment company that provided or sold you the device for any technical or emergency support.

If any additional information is needed, Inova Labs' Customer Care Team can be reached Monday-Friday, 7:00AM-7:00PM CST at 1.512.617.1744 or toll-free at 1.800.220.0977.

DISPOSAL

Inova Labs expects end users to dispose of the device in an environmentally friendly way and in accordance with local laws and regulations. Electrical and electronic equipment is labeled with the crossed-out wheeled bin symbol indicating that the equipment should be disposed of by the end user separate from other types of waste. The device contains lithium-ion batteries, and end users should contact Inova Labs or their local distributor for disposal, collection and recycling options and terms and conditions for their country. In 2002, the European Union introduced the Directive on Waste Electrical and Electronic Equipment (WEEE). The main aim of the Directive is to ensure that WEEE is collected and treated separately. WEEE items may contain hazardous substances that should not end up in the human environment and can have adverse effects on it if they do.

SPECIFICATIONS

Device Electrical Classification: Class II, Type BF*

Weight: 4.8 lbs. (2 kg)

Dimensions: 9.05" w x 7.875" h x 4.38" d (22.98 cm w x 20.00 cm h x 11.12 cm d)

Mode of Operation: Stationary/Portable

Flow Control Pulse Settings: 1, 2, 3 & 4 LPMeq

Oxygen Concentration: 90% (+/- 3%)

Oxygen Concentration Sensor Alarm: 85% or less

Maximum Outlet Pressure: 17.9 psi (123 kPa) (+/- 10%)

Average Sound Level At 2 LPMeq: 44 dB at 3 ft. (1 m)

Approximate Battery Duration: See Battery Life Timetable on page 12

Approximate Battery Recharge Time: See Battery Recharge Timetable on page 12

AC Power Supply: Input: 100-240VAC, 50 - 60 Hz; Output: 19VAC, 6.3A

DC Power Supply: Input: 11-16VDC, 10A; Output: 19VAC, 6.3A

External Battery Power Supply: Battery 12 to16.8 VDC

LifeChoice Activox POC Input: 19VDC, 6A

Nasal Cannula: 7 ft. (2 m) maximum

Environmental Conditions for Use, Storage and Transport

Operational Temperature Range: 41°F to 104°F (5°C to 40°C)

Operational Humidity Range: Up to 93%, Non-condensing

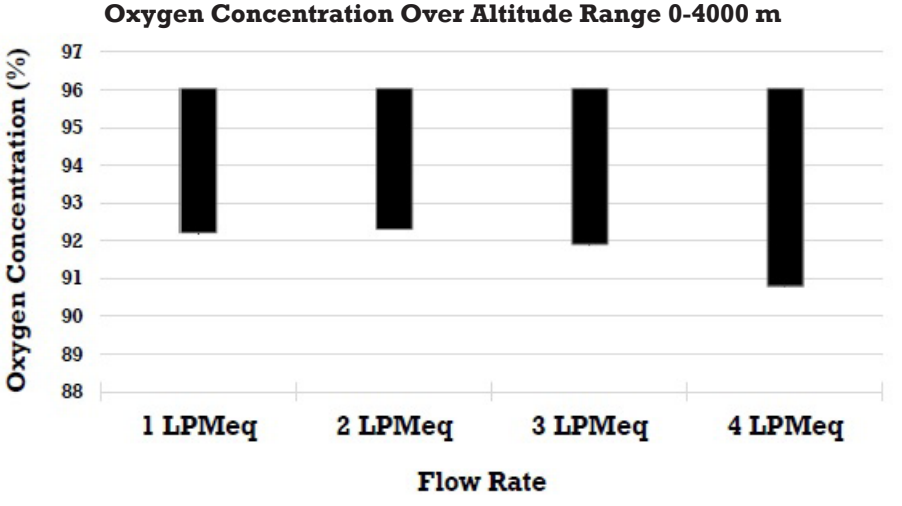
Storage Temperature Range: 32°F to 140°F (0°C to 60°C)

Storage Humidity Range: Up to 93%, Non-condensing

Operational Altitude Max: 13,000 ft. (4,000 m)†

* When powered by the external AC or DC Power Supply, or External or Internal Battery.
† Performance degradation may occur at high altitude.

OXYGEN CONCENTRATION OVER ALTITUDE AND FLOW RATE



ACCESSORIES (ADDITIONAL/REPLACEMENT/SPARE)

4-Way Carry Case
Includes adjustable strap system that allows case to be used as a backpack, shoulder strap, waist strap or carried as a briefcase. Included with purchase of the Standard Package.
Product Number: XYC105B

AC Power Supply*
Used to charge and run the device simultaneously. 10 ft. (3 m).Included with purchase of the Standard Package.
Product Number: XYC103

DC Power Supply*
Used to charge and run the device simultaneously. 6 ft. (1.8 m). For use at home or in the car, RV, motor boat, etc. Included with purchase of the Standard Package.
Product Number: XYC104

Accessory Bag
Used to store accessories when not in use. Included with purchase of the Standard Package.
Product Number: XYC340

External Battery
Used to power the device. Not included with purchase of the Standard Package.
Product Number: 200122

*Accessories, adapters, and cables other than those specified, with the exception of adapters and cables sold by the manufacturer of the medical electrical equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the Model XYC100B-P4L.

LIMITED WARRANTY AND DISCLAIMER
("Limited Warranty")

NOTE: This Limited Warranty provides specific legal rights. The Purchaser may also have other rights which vary from state to state or country to country and in some cases, due to applicable laws, certain limitations or exclusions of this Limited Warranty may not apply.

Inova Labs, Inc. ("Inova Labs") warrants solely to the first purchaser from Inova Labs ("Purchaser") that each new portable unit (or any combination thereof) excluding the Sieve Bed, Accessories, and Batteries (such new units excluding the Sieve Bed, Accessories, and Batteries hereinafter referred to as "Product") shall be free from defects of design, materials, and workmanship under normal use, operation and service for three (3) years from the date of purchase (meaning the date of purchase as evidenced by the sales receipt from Inova Labs, hereafter referred to as the "Date of Purchase"). The Sieve Bed is warranted to Purchaser be free of defects of design, materials, and workmanship under normal use, operation and service, for one (1) year from the Date of Purchase for Sieve Beds on portable oxygen concentrators ("POC"). Accessories and Batteries are warranted to Purchaser solely to be free of defects, for one (1) year from the Date of Purchase for Accessories and Batteries. Refer to the table below for a detailed description of the relevant timeframes under this Limited Warranty. Product components (which include the Outer Shell, Control Panel, Compressors, Computer Controller & Power Boards, and PSA Lung Assembly), Sieve Beds, Accessories, and Batteries are collectively referred to as "Items."

ITEM	LENGTH OF COVERAGE
Outer Shell (POC Housing)	3 Years
Control Panel (POC Keypad)	3 Years
Compressors	3 Years
Computer Controller & Power Boards	3 Years
PSA Lung Assembly	3 Years
Sieve Bed	1 Year
Battery – Internal	1 Year
Battery – External/Supplemental	1 Year
Accessories	1 Year

The Limited Warranty extends only to the Purchaser and is not transferable unless otherwise expressly agreed to in writing by Inova Labs.

Inova Labs' oxygen concentrators produce enriched oxygen gas which accelerates combustion. DO NOT ALLOW SMOKING OR OPEN FLAMES within ten (10) feet (three (3) meters) of these devices while in use. A user's SMOKING of any kind (including cigarette, cigar, and pipe) while using Product, and evidence that a user has smoked while using the Product, will void all warranties with respect to that Product and related Items.

An extended warranty on the Product is available at a maximum of two (2) additional years and must be purchased at the time of the original Date of Purchase. An extended warranty on the Product covers components included in the Standard Package (POC, Sieve Bed, Accessories and Internal Battery). Extended warranties are offered to the original Purchaser only and are non-transferrable unless otherwise expressly agreed to in writing by Inova Labs.

The Limited Warranty excludes from coverage any damage, failure, or malfunction caused by or related to:

a. Abuse, misuse, negligence or accident;
b. Failure to comply with instructions contained in the Operator's Manual;
c. Alteration, tampering, or modification by someone other than an authorized Inova Labs representative;
d. Unauthorized repairs or alterations;
e. Environmental conditions (including but not limited to water, flame, chemicals, fumes in the Atmosphere, extreme heat or cold, food or liquid, sand, dirt or the like);
f. Lack of regular, preventive maintenance and cleaning;
g. Damage in shipment to Inova Labs;
h. Other acts beyond the reasonable control of Inova Labs; and
i. Any damage caused by improper packaging when returning Items to Inova Labs.

Warranty Service and Coverage

PURCHASER'S EXCLUSIVE REMEDY AND INOVA LABS' SOLE OBLIGATION HEREUNDER SHALL BE LIMITED TO REPAIR OR REPLACEMENT OF THE DEFECTIVE ITEM OR REFUND OF THE APPLICABLE PURCHASE PRICE, AT INOVA LABS' OPTION.

Inova Lab's warranty obligations hereunder are conditioned upon Purchaser's compliance with the warranty procedures set forth herein. If an Item fails to conform to the Limited Warranty set forth herein, Purchaser must give prompt written notice to Inova Labs (with such notice in no event beyond the applicable warranty period), at which time Inova Labs or its authorized distributor will issue a Return Material Authorization ("RMA") number.

All Items claimed to be defective within the warranty period shall be properly packaged and shipped on a prepaid basis to Inova Labs (USA sales) or its authorized distributor at Purchaser's expense.

The exterior of the shipping container must clearly display the RMA number which properly identifies returned Items and the Item must be packaged together with proof of Date of Purchase. Items returned without a proper RMA number and proof of the Date of Purchase shall be refused and returned to Purchaser at Purchaser's expense. All returned Items are subject to warranty confirmation by Inova Labs. Inova Labs shall pay for standard shipment back to Purchaser for repair or replacement of Items properly covered under this Limited Warranty.

When repairing or replacing the Item, Inova Labs may use functionally equivalent products or parts that are new, equivalent to new or refurbished. All parts removed in the replacement of any Item shall become the property of Inova Labs.

To the full extent permitted under applicable law, the warranty coverage will not be extended or renewed or otherwise affected due to Inova Labs' authorized repair or replacement. However, part(s) repaired or replacement Items will be warranted for the unexpired portion of the original Limited Warranty.

Disclaimer of Warranties.

NO REPRESENTATIVE OF INOVA LABS HAS AUTHORITY TO MAKE ANY REPRESENTATIONS OR PROMISES EXCEPT AS EXPRESSLY STATED HEREIN. NO AGREEMENT VARYING OR EXTENDING THIS LIMITED WARRANTY SHALL BE BINDING UPON INOVA LABS UNLESS IN WRITING, SIGNED BY A DULY AUTHORIZED REPRESENTATIVE OF INOVA LABS. THIS LIMITED WARRANTY IS EXCLUSIVE AND GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER WARRANTIES, AND TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW INOVA LABS EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

Limitation of Liability.

TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW, IN NO EVENT SHALL INOVA LABS HAVE ANY LIABILITY FOR ANY CONSEQUENTIAL, SPECIAL, INCIDENTAL, INDIRECT, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS, LOSS OF USE AND LOST REVENUE, REGARDLESS OF THE FORM OF THE CLAIM, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF OR RELATING TO INOVA LABS' ITEMS, MATERIALS AND/OR SERVICES, AND EVEN IF INOVA LABS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, INOVA LABS' LIABILITY HEREUNDER OR RELATING HERETO

SHALL NOT EXCEED THE PURCHASE PRICE PAID FOR THE ITEMS, REGARDLESS OF THE FORUM AND REGARDLESS OF WHETHER ANY ACTION OR CLAIM IS BASED ON CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE. PURCHASER AGREES AND ACKNOWLEDGES THAT THE ITEMS ARE OF A SIZE, DESIGN AND CAPACITY SELECTED BY ITS MEDICAL PROVIDER.

Basis of Bargain

PURCHASER ACCEPTS THESE DISCLAIMERS OF WARRANTIES AND LIMITATIONS OF LIABILITY CONTAINED HEREIN AS PART OF A BARGAIN WITH RESPECT TO THE PRICING OF THE ITEMS AND UNDERSTANDS THAT THE PRICING WOULD LIKELY BE HIGHER IF INOVA LABS WERE REQUIRED TO BEAR LIABILITY IN EXCESS OF THAT STATED HEREIN. ALL OF THE LIMITATIONS AND DISCLAIMERS SET FORTH HEREIN SHALL APPLY NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

Governing Law and Jurisdiction

The rights and obligations of the parties pursuant to this Limited Warranty and any dispute arising hereunder shall be governed by and interpreted in accordance with the internal (but not the conflicts) laws of the State of Texas, USA. The 1980 U.N. Convention on Contracts for the International Sale of Goods shall not apply. If any provision of this Limited Warranty is inconsistent with applicable laws relating to Purchaser, Purchaser agrees to waive any and all rights and remedies it may have under such laws to the extent it may waive such rights and remedies. This Limited Warranty is offered as an additional benefit to Purchaser's statutory rights and it does not affect such statutory rights in any way. The parties agree and consent that the state or federal courts in Texas shall have exclusive jurisdiction with respect to any dispute arising out of or relating to this Limited Warranty. If any provision of this Limited Warranty is held to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that this Limited Warranty will otherwise remain in full force and effect and enforceable. EACH PARTY EXPRESSLY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

Technical Support

Inova Labs' Customer Care Team can be reached Monday-Friday, 7:00AM-7:00PM CST at 1.512.617.1744.

EMC INFORMATION

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying tables.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The LifeChoice® Activox Portable Oxygen Concentrator Model XYC100B-P4L is intended for use in the electromagnetic environment specified below. The customer or the user of the Model XYC100B-P4L should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/-6 kV contact +/-8 kV air	+/-6 kV contact +/-8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	+/-2 kV for power supply lines +/-1kV for input/ output lines	+/-2 kV for power supply lines Not applicable	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line-to-line +/-2 kV line-to-earth	+/-1 kV line-to-line +/-2 kV line-to-earth	Main 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% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	Main power quality should be that of a typical commercial or hospital environment. If the user of the Model XYC100B-P4L requires continued operation during power mains interruptions, it is recommended that the Model XYC100B-P4L be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The LifeChoice® Activox Portable Oxygen Concentrator Model XYC100B-P4L is intended for use in the electromagnetic environment specified below. The customer or the user of the Model XYC100B-P4L should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and Mobile RF communications equipment should be used no closer to any part of the Model XYC100B-P4L, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150kHz-80MHz	3 V	$d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$, 80MHz to 800MHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz-2.5GHz	3 V/m	$d = 2.33 \sqrt{P}$, 800MHz to 2.5GHz

Where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 'd' is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80MHz and 800MHz, 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.

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 Model XYC100B-P4L is to be used exceeds the applicable RF compliance level above, the Model XYC100B-P4L should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model XYC100B-P4L.

b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and The LifeChoice® Activox Portable Oxygen Concentrator Model XYC100B-P4L

The LifeChoice® Activox Portable Oxygen Concentrator Model XYC100B-P4L is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model XYC100B-P4L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model XYC100B-P4L as recommended below, according to the maximum output power of the communications equipment.

Separation Distance According to the Frequency of Transmitter (m)

Rated Maximum Output Power of Transmitter (W)	150kHz to 80MHz $d=1.17\sqrt{P}$	80MHz to 800MHz $d=1.17\sqrt{P}$	800MHz to 2.5GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance 'd' in meters 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 80MHz and 800MHz, 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.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The LifeChoice® Activox Portable Oxygen Concentrator Model XYC100B-P4L is intended for use in the electromagnetic environment specified below. The customer or the user of the Model XYC100B-P4L should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions, CISPR 11	Group 1	The Model XYC100B-P4L uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The Model XYC100B-P4L is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	Complies	

OWNER'S NOTES

OWNER'S NOTES

LifeChoice

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breaking boundaries

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