Operator's Manual

DirectHome MEDICAL

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LifeChoice®

Portable Oxygen Concentrator

On the go with O_2!

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INTRODUCTION

This patient manual will familiarize you with the LifeChoice Portable Oxygen Concentrator (POC) and its accessories. Be sure to thoroughly read all of the information in this manual in its entirety before using the LifeChoice POC. The LifeChoice POC 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 battery. The essential performance of the LifeChoice POC is to provide oxygen at a volume that remains within tolerance (the tolerance was defined based on technical judgement 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 concentration or no breath) and create an alarm is also considered a part of essential performance.

APPLICATION

This manual applies to the LifeChoice POC REF XYC100.

INDICATIONS FOR USE: The LifeChoice Oxygen Concentrator is used on a prescriptive basis by 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 is also portable.

The LifeChoice POC is FAA approved for air travel. The required FAA sticker is located on the bottom of the LifeChoice POC. FAA approval is listed as Inova Labs LifeChoice. Every airline has specific information required for traveling with oxygen. Before traveling, review your airline's specific requirements.

Authorized by US FAA for use onboard aircraft 14CFR Part 121
(Docket No. FAA-2004-185963 SFAR 106) Rin 2120-A181

SYMBOL DESCRIPTIONS

Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer		Temperature Limitation		Radio Frequency
	Humidity Limitation	GAS FLOW	Gas Flow		Type BF Applied Part
			DC Power		Device that has conductive contact with patient
	Waste Disposal		Class II Equipment		
REF	Catalogue Number		General Warning, Caution, Risk of Danger	CE	CE Marking of Conformity
	Keep Dry		Danger, No Smoking or Open Flame	EC REP	EU Authorized Representative

WARNINGS

1. This device is NOT INTENDED to be life-sustaining or life-supporting.
2. This device should be used only when prescribed by a physician.
3. In certain circumstances, oxygen therapy can be hazardous. Please seek medical advice before using the LifeChoice POC.
4. U.S. Federal law restricts this device to sale by or on the order of a physician.
5. The LifeChoice POC is designed to provide a flow of high purity oxygen. Patients with a fast breathing rate or requiring high oxygen flow may require more oxygen than the LifeChoice POC can produce and, therefore, may not be a suitable candidate.
6. This device is not suitable for patients who are unable to hear or see alarms or communicate discomfort. If the patient shows any signs of discomfort, a physician should be consulted immediately.
7. It is the responsibility of the patient and/or provider to make back-up arrangements for an alternative oxygen supply when traveling; Inova Labs Inc. assumes no liability for persons choosing not to adhere to manufacturer recommendations.
8. Availability of an alternate source of oxygen is required in case of power outage or mechanical failure. Consult your physician or medical equipment supplier for the type of back-up system required.
9. The LifeChoice POC is designed to be used in the provided/approved carry case.
10. The LifeChoice should be located so as to avoid pollutants or fumes.
11. Do not use oil, grease or petroleum-based products on or near the LifeChoice POC. Do not use power supplies/adapters, carry bags or accessories other than those which come with the LifeChoice POC. The use of non-specified accessories may impair equipment performance and will void all warranties.
12. The LifeChoice POC produces enriched oxygen gas which accelerates combustion. **DO NOT ALLOW SMOKING OR OPEN FLAMES** within 10 feet *(3 meters)* of this device while in use. Cigarette/cigar/pipe SMOKING while using the LifeChoice POC will VOID all warranties.
13. Never operate the LifeChoice POC in the accessory bag.
14. Do not submerge the LifeChoice POC or any of the accessories in liquid. Do not expose to water or precipitation. Do not operate in rain. This could lead to damage.
15. Portable and mobile RF communications equipment can effect medical electrical equipment.
16. The LifeChoice POC should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the POC should be observed to verify normal operation in the configuration in which it will be used.


Carry Case


Accessory Bag

USER CONTROLS

The user controls on the LifeChoice POC are specifically designed to be pressed by a finger. Never press any of the buttons with a pen, screwdriver, stylus or any other object. Pressing the buttons with any hard, sharp and/or small object can damage the user controls and void all warranties.

Indicator Lights: Colored lights indicate either a change in operating status or a condition that may need response *(alarm)*.

Audible Signals: An audible signal *(beep)* indicates either a change in operating status or a condition that may need response *(alarm)*.

Gross Particle Filter: A filter mesh is in place inside the intake vents on the front and back of the concentrator during operation to keep large particles and debris out of the intake air. See Section **Air Intake Filter Cleaning** for cleaning instructions.

Nasal Cannula: A standard single lumen nasal cannula or equivalent must be used with the LifeChoice POC to provide oxygen from the concentrator. A standard single lumen type cannula, 7-foot *(2-meter)*, is recommended for use. An Adult Nasal Cannula like # 1107 by Ventlab Corporation is supplied with each LifeChoice POC purchase. For replacement cannulas, please contact your local medical equipment supplier.

Cannula Nozzle Fitting: The nasal cannula connects to the oxygen output nozzle at the top of the LifeChoice POC. Do not place cannula into nasal passages until the LifeChoice POC is fully powered on. Breathing through the cannula during start-up will prevent the system from powering on.

Breath Auto Mode LED: There are two inhalation sensitivity modes on the control panel: Active-High and Sleep-Low, which automatically adjust based on oxygen requirements.

Pulse Setting Controls: There are three individual pulse flow controls on the panel: 1, 2 and 3 which are equivalent to 1, 2 or 3 liters per minute settings on a continuous flow device.

LIFECHOICE POC MOBILITY PACKAGE (REF XYC100)

The LifeChoice POC can be operated using AC power, DC power or battery power during transport while inside the approved carry case.

1. **4-Way Carry Case** *Use as a convertible backpack, over-the-shoulder strap, briefcase or waist pack*
2. **(1) Three-hour external battery with carry case**
3. **(1) Standard single lumen 7-foot** *(2-meter)* **long nasal cannula**
4. **LifeChoice Accessory Bag**
5. **LifeChoice Portable Oxygen Concentrator with 2-hour internal battery**
6. **AC power adapter** *(universal 100v – 240v; 50hz – 60hz)*
7. **DC power adapter** *(12v) with standard "car" adapter plug*

LIFECHOICE POC PART NAMES

1. **Cannula Nozzle Fitting**
2. **Power**
3. **Alarm Indicator Light**
4. **Breath Auto Mode Active-High**
5. **Breath Auto Mode Sleep-Low**
6. **Exhaust/Fan Vents**
7. **Battery Charge Level Gauge**
8. **Battery Check**
9. **Pulse Settings 1, 2, 3**
10. **Intake Vents** *Vents located on front and back*
11. **FAA Approval Sticker** *(located on bottom)*

OPERATING INSTRUCTIONS

BEFORE USING THE LIFECHOICE POC FOR THE FIRST TIME

The LifeChoice POC and external battery should be charged for a minimum of 6 hours before initial use. Connect the external battery to the LifeChoice POC, connect the AC adapter to the external battery and plug the AC adapter into an electrical outlet.

Make sure to verify the green LED light above the **Battery Check** is solid green. This indicates the system recognizes the external power source. If the external battery is plugged into the LifeChoice POC and the green LED light above the **Battery Check** does not turn solid, the source is not recognized. If charging the unit through the external battery when this occurs, the charge will not reach the internal battery. This may be an indication the external battery needs to be reset. Instructions for resetting the battery are provided in the **Powering the LifeChoice POC section.**

When more than two hours battery operation is needed, the LifeChoice POC should be powered using the external battery first and then the internal battery. The LifeChoice POC will automatically switch to the internal battery once the external battery has been depleted.

Carry Case

The LifeChoice POC is recommended and designed to be operated and stored in its carry case at all times.

Verify that the intake vents are clean and free from obstruction.

Connect the nasal cannula securely to the LifeChoice POC cannula nozzle fitting.

POWERING THE LIFECHOICE

The LifeChoice POC can be powered in four different ways – the internal battery, an AC power supply, DC power supply or the external battery. The rechargeable batteries are maintenance-free and can only be exchanged at the factory.

1. **Internal Battery:** A rechargeable internal battery is located within each LifeChoice POC unit. When it is fully charged, it supplies power to the Life Choice POC for up to 2+ hours. When using internal battery power, the green LED light above the **Battery Check** will illuminate and flash slowly.

When the AC, DC or external battery is plugged into the LifeChoice POC, whether powered on or off, the green LED light above the **Battery Check** will illuminate solid green. This is verification that the external source has been recognized. When using an external source to power the LifeChoice POC, verify that the green LED light above the **Battery Check** is solid green indicating the system is being powered by the external source. If not connected to an AC or DC adapter, 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.

2. **AC Power Supply:** An AC power supply allows the LifeChoice POC to be connected to a 100-240 volt, 50/60 Hz outlet. The power supply converts 100-240 volt AC to a DC voltage for the LifeChoice POC unit. When the unit is operated with the AC power supply, power from the AC outlet powers the unit and recharges the internal and/or the external battery simultaneously.

When using an external source to power the LifeChoice POC, verify that the green LED light above the **Battery Check** is solid green indicating the system is being powered by the external source.

3. **DC Power Supply:** A DC power supply can be connected from the LifeChoice POC unit to an automobile's *(boat, motor home, etc.)* 12-volt DC outlet. When the system is connected to the automobile's/vehicle's DC outlet, power from the automobile/vehicle battery powers the LifeChoice POC unit and recharges the internal and/or external battery simultaneously.

When using an external source to power the LifeChoice POC, verify that the green LED light above the **Battery Check** is solid

green indicating the system is being powered by the external source. The AC, DC and external battery are each connected to the receptacle on the top of the LifeChoice POC. *(External battery shown as example.)* If the external battery is connected to the LifeChoice POC, the AC or DC adapter can be connected to the external battery and will charge both batteries and operate the LifeChoice POC simultaneously.

4. **External Battery:** A rechargeable external battery is included with every LifeChoice POC XYC100 unit. When fully charged, it supplies power to the Life Choice POC for up to 3+ hours.

   When using external battery power, the green LED light above the **Battery Check** will illuminate solid green. When using the external battery to power the LifeChoice POC, the system will automatically switch to internal battery power when the external battery has been depleted - approximately 3 hours. When this occurs, the green LED light above the **Battery Check** will turn from solid green to flashing green. When the external battery is required for extended time away from an AC or DC power source, it is recommended to power the LifeChoice POC with the external battery first and then the internal battery for maximum combined battery time.

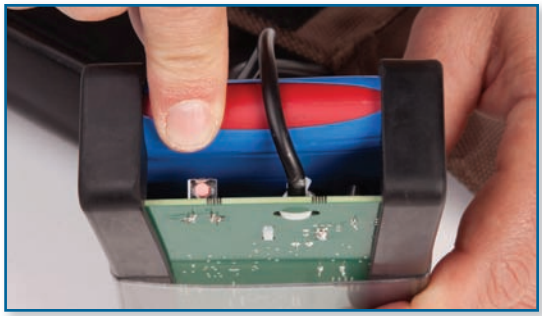
   Charge time for a depleted external battery is a minimum of 6 hours with either the AC or DC adapter. To check charge level on the external battery, disconnect from AC or DC adapters, press and hold yellow button on the top of the external battery. LED lights will illuminate indicating charge level.

   When the LifeChoice POC is in use and the external battery is plugged into the unit, verify that the green LED light above the **Battery Check** turns solid green. If the LED light does not illuminate solid green when the external battery is connected to the LifeChoice POC, this indicates that the LifeChoice POC is not being powered by the external battery, and the external battery may have "tripped" due to a power surge.

To prolong the level of charge when not in use, it is **highly** recommended that the external battery be plugged into itself. This is done by inserting the male end of the plug into the female receptacle on the battery pack.

Reset the external battery as indicated in the following steps.

RESETTING THE EXTERNAL BATTERY



1. Unplug the external battery from the charger and the LifeChoice POC.
2. Remove the battery from the case.
3. Look at the end of the battery with the cable for a lit red LED light. If lit, press and hold the "pink" button until the red LED light turns off to reset.
4. Put the battery back in the case.

BATTERY CHARGING

To charge the internal battery, connect LifeChoice POC to either an AC power supply and a 100-240 volt, 50/60 Hz AC power outlet, or connect it to a DC power outlet in an automobile *(boat, motor home, etc.)*. It takes a minimum of 4 hours for a discharged internal battery to fully charge. It is recommended to recharge the battery, even if only partially depleted, as often as possible. To check the battery charge level, disconnect the LifeChoice POC from all external power sources and power the LifeChoice POC on. Once fully powered on, press the **Battery Check** to verify internal battery charge level.

If not charged for the correct amount of time, a 100% battery charge indicator green LED light may be illuminated, but the actual charge could be between 85-100%.

The internal battery cannot be overcharged, and it is recommended to leave the LifeChoice POC plugged in via the AC or DC adapter as often as possible.

When charging the LifeChoice POC from the supplied AC or DC adapter, confirm that the green LED light above the **Battery Check** is solid green. This indicates the LifeChoice has recognized an external power/charging source. The green LED light will be solid green if the system is on or off.

If charging the internal and external battery at the same time, powered on or off, first connect the external battery to the LifeChoice POC, and verify that the green LED light above the **Battery Check** illuminates solid green. If the green LED light is not solid green, **follow steps in battery charging section** to determine if the external battery has tripped. If the green LED light is solid green, connect the AC or DC adapter to the external battery, and charge for 6 hours. The LifeChoice POC can be used while charging with AC /DC power.

OPERATING PROCEDURE

1. Locate and position the LifeChoice POC so that the intake vents and exhaust fan vents are not obstructed. The unit, particularly the air intake vents and the exhaust fan vents, should be located in a well-ventilated space.
2. The unit may be powered by the internal battery, external battery, DC power supply or AC power supply using the DC or AC adapters.

If you are in an automobile (*boat, motor home, etc.*), connect one end of the DC adapter into the LifeChoice POC power inlet and the other end into the DC outlet; or

If you are near an AC outlet, connect one end of the AC adapter into the LifeChoice POC power inlet and the other end into the AC outlet; or

Connect one end of the external battery into the LifeChoice POC power inlet.

Plugging the AC or DC adapter directly into the Lifechoice POC will charge the internal battery and operate the system at the same time.

The external battery pack can be connected to the LifeChoice POC, and the AC or DC adapter can then be plugged into the external battery. This configuration will charge the internal and external batteries and operate the system at the same time.

If the LifeChoice POC is powered off and the external battery, AC or DC adapters are connected to the system, the internal fans will operate for approximately 4 hours to help keep the internal battery cool during charging.

3. Press **Power** once to turn on. An audible beep will occur, and the green LED light above the **Power**, **Active-High Mode** and **Pulse Setting** of **1** will illuminate. This indicates that LifeChoice POC is powered on, is ready for use, and settings may now be changed. Pressing **Power** for extended time after the audible beep will cause the system to cycle back to the off position.

CAUTION

Do not place cannula into nasal passages until the LifeChoice POC is fully powered on. Breathing through the cannula during start-up will prevent the system from powering on.

4. There are two inhalation sensitivity modes on the control panel: **Active-High** and **Sleep-Low**, which automatically adjust based on oxygen requirements. No action is required to start this feature.

5. Select the flow setting 1, 2 or 3 as prescribed by your doctor. These settings are equivalent to 1, 2 or 3 LPM settings on a continuous flow device. Place the nasal cannula in the nasal passages and breathe normally. When the LifeChoice POC senses inhalation, oxygen is supplied through the cannula. The duration of this pulse flow and size of the pulse is dependent upon the pulse flow setting (1, 2, or 3) selected. The green LED light above the selected number (1, 2, or 3) illuminates and will flash each time inhalation is detected indicating that a pulse of oxygen has been delivered.

6. Check to make sure your unit's battery is fully charged *(minimum of 4 hours charge time for fully depleted battery)* before venturing out with LifeChoice POC for the first time or upon subsequent use. **To accurately measure the internal battery charge the unit must be powered "on" and disconnected from the AC/DC power supply or external battery.** The battery gauge/indicator LED lights next to the **Battery Check** will illuminate to indicate the level of battery charge *(25% to 100%)*. The battery charge indicator LED lights are a reference only. If a fully depleted internal battery is not charged for a minimum of 4 hours, it will not supply 2+ hours of use. If not charged for the correct amount of time, a 100% battery charge indicator LED light may be illuminated, but the actual charge could be less than 100%.

7. To turn the LifeChoice POC off, press **Power** and hold for 2 seconds until the green LED light above **Power** goes out and the unit shuts off. When the LifeChoice POC is powered off, the internal fans will continue to operate for approximately 30-45 seconds for additional cooling.

ALARMS/LIGHT INDICATORS

Start-Up: A brief audible beep sounds at start-up when **Power** is pushed. Release **Power** as soon as the tone sounds. Pressing **Power** for extended time after the audible beep will cause the system to cycle back to the off position. The LifeChoice POC will not power on if the cannula is being moved or inserted in the nasal passages during start-up.

Low Battery Alarm: As the internal battery power approaches a low level (less than10 minutes of battery power remaining), the green LED light next to the **Battery Check** turns red and flashes slowly. There is also an audible long, loud beep that will sound once every 65 seconds. When this occurs, connect the LifeChoice POC to a DC power outlet, an AC power outlet, a fully charged external battery, or change to another source of oxygen immediately.

When there is approximately 10 seconds of battery power remaining, the red LED light above the **Battery Check** that was slowly flashing will begin flashing quickly, and a fast audible beep will sound, after which the unit will shut off. When this occurs, connect the LifeChoice POC to a DC power outlet, an AC power outlet, a fully charged external battery, or change to another source of oxygen immediately.

When the LifeChoice POC is connected to a DC power outlet or to an AC power outlet, the unit operates while recharging the internal battery simultaneously. The level of battery charge is indicated by disconnecting the LifeChoice POC from the AC or DC adapters while powered on and pressing **Battery Check**. The battery charge indicator LED lights are for reference only. If a fully depleted internal battery is not charged for a minimum of 4 hours, it will not supply 2+ hours of use.

No Inhalation/No Breath Alarm: When the LifeChoice POC is powered on but does not sense breathing within a predetermined time period, approximately 75 seconds, an audible alarm beeps and the red LED light next to **Alarm** flashes. If this occurs, check the connection from the cannula to the LifeChoice POC, make sure that the nasal cannula is positioned properly on your face and ensure that you are breathing through your nose. Once the system detects a breath, the alarm will automatically turn off. If the alarm continues to sound, change to an alternate source of oxygen, and contact your equipment provider.

General Malfunction Alarm: If the LifeChoice POC has a general malfunction, a continuous audible alarm sounds, and the red LED light next to **Alarm** will continuously illuminate. When this occurs, the concentration of oxygen that LifeChoice POC is supplying is outside of specifications. You should change to another source of oxygen and contact your equipment provider.

NORMAL OPERATION INDICATORS

Normal Operation	Audible Alarm	LED Light Alarm	Action
LifeChoice POC turned on	Brief Audible Tone	 Green LED lights of **Power**, **Active-High Mode** and **Pulse Setting** of **1** are illuminated	You may begin to use your LifeChoice POC unit
LifeChoice POC has detected an inhalation/ breath and is delivering a pulse of oxygen	No	 Green LED light of selected pulse setting flashes with each breath	LifeChoice POC is functioning normally
LifeChoice POC powered by internal battery	No	 Green LED light above **Battery Check** slowly flashes	LifeChoice POC is functioning normally
LifeChoice POC plugged into or powered by external source *(AC, DC or external battery)*	No	 Green LED light above **Battery Check** is solid green	LifeChoice POC is functioning normally

ALARM TABLE

Problem	Audible Alarm	LED Light Alarm	Action
No breath detected by the unit for approximately 75 seconds	Intermittent: Beep	 Red LED light next to **Alarm** flashes	Check the cannula connection. Ensure that you are breathing through your nose. Once the system detects a breath, the alarm will shut off. *If the alarm persists, contact your equipment provider.*
Low Battery Alarm *(Approximately 10 minutes of battery power)*	Single, loud, long, beep every 65 seconds	 Red LED light above **Battery Check** slowly flashes	Connect the LifeChoice POC unit to a DC adapter, an AC adapter, or change to another source of oxygen.
Critical Low Battery Alarm *(Approximately 10 seconds of battery power)*	Fast audible beep *(Unit shuts down)*	 Red LED light above **Battery Check** begins flashing quickly	Connect the LifeChoice POC unit to a DC adapter, an AC adapter, or change to another source of oxygen.
General malfunction of the LifeChoice POC	Continuous audible alarm	 Red LED light next to **Alarm** continuously illuminates	Turn off the unit. Change to another source of oxygen, and contact your equipment provider.

ROUTINE MAINTENANCE

The LifeChoice has no end user repairable parts.

Intake Vent Cleaning: One vent located on each side of the LifeChoice POC. At least once a week or anytime the gross mesh air filter intakes appear dirty, use a cotton swab *(Q-Tip® or similar)* to clean the mesh filter media in the intake vents on the front and back of the unit. Follow these steps to properly clean the air intake filter:

Gently rub the cotton swab along the intake vents *(front and back of unit)* to clean and remove any debris from the intake filter mesh. Do not poke or gouge the mesh filter; just gently rub the cotton swab cleaner along the intake vent areas. The LifeChoice POC does not need to be removed from the carry case to clean the air intake filter as described above.

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 type cannula from your local medical equipment supplier.

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

LIFECHOICE SPECIFICATIONS

Maximum outlet pressure: 19 psi (131 kPa)

Device Electrical Classification: Class II

Oxygen Concentration: 90% (+/- 3%) [1]

Oxygen Concentration Sensor Alarm: 85% or Less

Flow Control Pulse Settings: 1, 2 & 3 LPM (Equivalent to Continuous Flow) ±20%

Mode of Operation: Continuous equipment and mobility: portable

Weight: 4.9 Pounds (2.2kg)

Dimensions: Height - 9.5" (24cm), Width - 7.5" (19cm) at widest point, Depth - 3.125" (7.9cm)

Power Supply: AC 100 to 240 VAC, 50 to 60 Hz cycles, DC 12 to 19 VDC

LifeChoice Oxygen Concentrator, XYC100-Input: 19Vdc, 6A

External AC Power Adapter, XYC103AC-Input: 100-240V, 2.5A Output: 19V, 6.3A

External DC Power Adapter, XYC104DC-Input: 11.5-16VDC, 5.6A Output: 19V, 6.3A

External Rechargeable Battery, XYC102-Input: 14.2-23.7V, Output: 14.2-23.7V

Approximate Internal Battery Duration: 2+ Hours

Minimum Internal Battery Recharge Time: 4 Hours

Approximate External Battery Duration: 3+ Hours

Minimum External Battery Recharge Time: 6 Hours

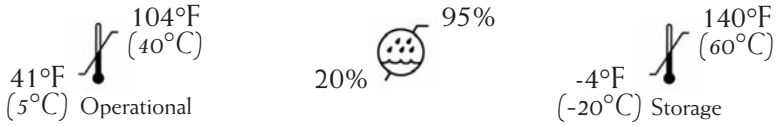
Warm-up Time: 2 Minutes with an LED Signal

Sound: Less than 50 Decibels at 10 ft (3.05m), 54.4 Decibals at 3.3ft (1m)

Operational Humidity Range: 20% to 95%, Non-condensing

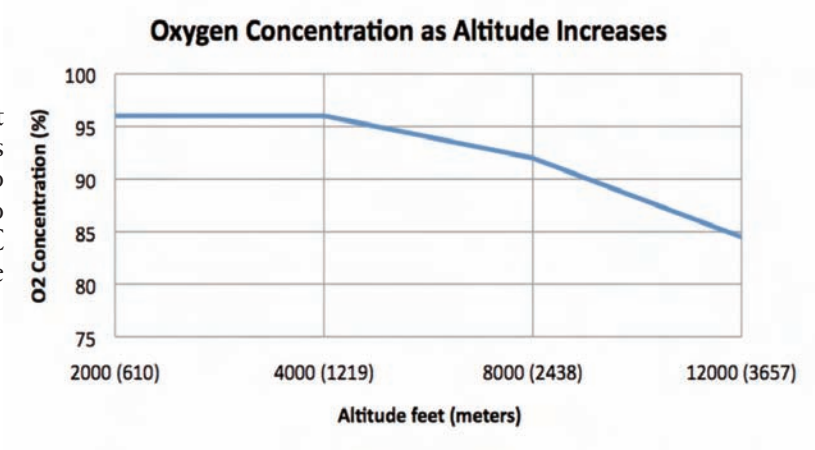
Operational Altitude Max: 10,000 Feet (3km)

Environmental Conditions for Use, Storage and Transport:



1 When powered by the external AC adapter, external DC adapter, or external or internal battery.

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 documents.



Immunity Requirements

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Model XYC100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model XYC100 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 for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line-to-line +/-2kV line-to-earth	+/-1 kV line-to-line +/-2kV line-to-earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model XYC100 requires continued operation during power mains interruptions, it is recommended that the Model XYC100 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 location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Immunity Requirements

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Model XYC100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model XYC100 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 XYC100, 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 150 kHz – 80 MHz outside ISM bands[a]	3 V	d = 1.17 x sqrt(P)
	10 Vrms 150 kHz – 80 MHz in ISM bands[a]	10 V	d = 1.20 x sqrt(P)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.5 GHz	3 V/m	d = 1.17 x sqrt(P), 80MHz to 800MHz d = 2.33 x 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).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.			
b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.			
c) 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 XYC100 is to used exceeds the applicable RF compliance level above, the Model XYC100 should be observed to verify normal operation. If the abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model XYC100.			
d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Separation Distance/ Portable & Mobile RF Communications Equipment

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MODEL XYC100

The Model XYC100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model XYC100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model XYC100 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)			
	150kHz to 80MHz outside ISM bands d=1.17 x sqrt (P)	**150kHz to 80MHz in ISM bands d=1.20 x sqrt (P)**	**80MHz to 800Mhz d=1.17 x sqrt (P)**	**800Mhz to 2.5GHz d=2.33 x sqrt (P)**
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.37	0.74
1	1.2	1.2	1.2	2.3
10	3.7	3.8	3.7	7.4
100	12	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: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Emissions Requirements

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Model XYC100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model XYC100 should assure that it is used in such an environment.

Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions, CISPR 11	Group 1	The Model XYC100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class A	The Model XYC100 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	

WARRANTY

INOVA LABS, INC.
LIMITED WARRANTY AND DISCLAIMER
("Limited Warranty")

NOTE: This Limited Warranty does not affect Purchaser's statutory rights under applicable national laws.

Inova Labs, Inc. *("Inova Labs")* warrants that each new LifeChoice® Portable Oxygen Concentrator *("POC")* shall be free from defects under normal use, operation and service for three (3) years. Any LifeChoice POC Accessories, the Sieve Bed and all Batteries are warranted for one (1) year. See the table below for detailed coverage under this Limited Warranty.

The Limited Warranty extends only to the first Purchaser (it is not transferable) and begins on the date of purchase as evidenced by the sales receipt directly from Inova Labs or through one of its authorized distributors. This Limited Warranty is only offered in connection with sales through Inova Labs' authorized distribution channels.

ITEM	LENGTH OF COVERAGE	ITEM	LENGTH OF COVERAGE
Outer Shell	3 years	Sieve Bed	1 year
Compressors	3 years	Battery – Internal	1 year
Computer Controller & Power Boards	3 years	Battery – External / Supplemental	1 year
PSA Lung Assembly	3 years	Accessories	1 year

The Limited Warranty Excludes From Coverage

1. Defects caused by or related to:
    a. Abuse, misuse, negligence or accident;
    b. Failure to comply with instructions contained in the Operating Manual;
    c. Alteration or modification by Purchaser;
    d. Unauthorized repairs or alterations;
    e. Environmental conditions (including but not limited to water, chemicals, fumes in the atmosphere, extreme heat, spillage of food or liquid, sand, dirt or the like);
    f. Lack of regular, preventive maintenance and cleaning;
    g. Damage in shipment;
    h. Other acts beyond the reasonable control of Inova Labs.
2. Deterioration due to normal wear and tear.
3. Regular maintenance and service items.

Warranty Service and Coverage

Purchaser's exclusive remedy and Inova Labs' sole obligation hereunder shall be limited to repair, replacement or refund of the purchase price, at Inova Lab's option. However, this Limited Warranty shall not exclude or limit (1) Purchaser's statutory rights under the applicable national laws, or (2) Purchaser's rights against the authorized distributor or vendor.

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. A prior obtained Return Authorization Number issued by Inova Labs (USA) or its authorized distributor must properly identify returned items together with proof of purchase date. Items returned without a Return Authorization Number shall be refused and returned to Purchaser at Purchaser's expense. Inova Labs shall pay for regular shipment back to Purchaser for repair or replacement of items under this Limited Warranty.

WARRANTY

Purchaser shall notify Inova Labs or its authorized distributor of the alleged defect within a reasonable time of discovery of the issue and in any event no later than prior to the expiry of the Limited Warranty coverage.

When repairing or replacing the item Inova Labs may use functionally equivalent products or parts that are new, equivalent to new or re-conditioned.

As far as national laws permit, 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 product will be warranted for the unexpired portion of the original Limited Warranty or for sixty (60) days from the date of repair or replacement, whichever is longer.

NO REPRESENTATIVE OF INOVA LABS HAS AUTHORITY TO MAKE ANY REPRESENTATIONS OR PROMISES EXCEPT AS STATED HEREIN. THIS LIMITED WARRANTY IS EXCLUSIVE AND GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. INOVA LABS SHALL HAVE NO FURTHER LIBALITY FOR ANY DAMAGE, LOSS, COST OR FEE OF WHATEVER KIND OR NATURE, WHETHER FORSEEABLE OR NOT, INCLUDING BUT NOT LIMITED TO ATTORNEYS' FEES, CONSEQUENTIAL, GENERAL, SPECIAL, INCIDENTAL, INDIRECT, EXEMPLARY OR PUNITIVE DAMAGES, REGARDLESS OF THE FORM OF THE CLAIM, WHETHER IN CONTRACT, TORT OR OTHERWISE, ARISING OUT OF OR RELATING TO INOVA LABS' PRODUCTS, AND EVEN IF INOVA LABS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, LOSSES, COSTS OR FEES. TO THE EXTENT PERMITTED BY APPLICABLE LAW, INOVA LABS' LIABILITY HEREUNDER OR RELATING HERETO SHALL NOT EXCEED THE PURCHASE PRICE PAID FOR THE PRODUCT, REGARDLESS OF THE FORUM AND REGARDLESS OF WHETHER ANY ACTION OR CLAIM IS BASED ON CONTRACT, TORT OR OTHERWISE. PURCHASER AGREES AND ACKNOWLEDGES THAT THE PRODUCT IS OF A SIZE, DESIGN AND CAPACITY SELECTED BY ITS MEDICAL PROVIDER. 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.

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. EACH PARTY EXPRESSLY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

Technical Support

Please contact the local medical equipment company that provided or sold the LifeChoice® POC to you for any technical or emergency support.

ACCESSORIES-ADDITIONAL/REPLACEMENT/SPARE

Product	Product Number	Description
	XYC055	**Standard carry case** for LifeChoice POC comes complete with strap system that allows case to be used as a back pack, shoulder strap, waist strap or carried as a briefcase *(Included with purchase of LifeChoice POC.)*
	XYC102	**3-hour external battery.** Extended time battery for more mobility. Comes with battery belt carry case. *(Included with purchase of LifeChoice POC.)**
	XYC283S	**Extra small waist belt** strap for external battery pack. *(Included with purchase of LifeChoice POC.)*
	XYC103AC 10′ (3m)	**AC and DC power adapters.** Used to charge and run the LifeChoice POC simultaneously. Used at home or in the car, RV, motor boat, etc. *(Included with purchase of LifeChoice POC.)**
	XYC104DC 6′ (1.8m)	
	XYC262	**7′(2.1m) standard single lumen cannula.** *(Included with purchase of LifeChoice POC.)*
	XYC340	**Accessory Bag**

** 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 XYC100.*

LIFECHOICE POC — MOBILITY PACKAGE

Model Number XYC100: Includes unit *(7.5"w x 3.125"d x 9.5"h, 4.9 pounds)*; 4-way carry case which can be used as a convertible backpack, over-the-shoulder strap, briefcase or waist pack; 5+ hours of battery time; AC and DC adapters/chargers for home and car, RV, motor boat use, etc.; and nasal cannula. Each LifeChoice POC comes with a limited three (3) year warranty.

LIFECHOICE POC — STANDARD PACKAGE

Model Number XYC200: Includes unit *(7.5"w x 3.125"d x 9.5"h, 4.9 pounds)*; 4-way carry case which can be used as a convertible backpack, over-the-shoulder strap, briefcase or waist pack; 2+ hours of battery time; and nasal cannula. Each LifeChoice POC comes with a limited three (3) year warranty.

DISPOSAL

Inova Labs expects end users to dispose of LifeChoice POC in an environmentally friendly way. Electrical and electronic equipment is label 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 LifeChoice POC device contains lithium-ion batteries, and the 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.

OWNER'S NOTES

LifeChoice® $_2$

Portable Oxygen Concentrator

On the go with O_2!

www.LifeChoiceOxygen.com

1.800.220.0977

Manufactured and Distributed by
Inova Labs Inc. | 3500 Comsouth Drive, Suite 100
Austin, Texas 78744 | Corporate Office 512.617.1700

XYC276 REV F Nov 2011