



X-PLO₂™ PORTABLE OXYGEN CONCENTRATOR

USER MANUAL



LIVE LIFE. BREATHE EASY. GO X-PLO₂™.

TABLE OF CONTENTS

| | | |
|-------------|---|----|
| | X-PLO ₂ R Checklist | 1 |
| | Quick Start Guide | 2 |
| SECTION 1. | Introduction | 3 |
| SECTION 2. | Safety Information | 4 |
| | Contraindications | 4 |
| | General Precautions | 4 |
| | Warnings | 5 |
| | Cautions | 7 |
| SECTION 3. | Operating the X-PLO ₂ R | 8 |
| | Turning the X-PLO ₂ R ON & OFF | 8 |
| | Audible Alarm | 9 |
| | Flow Setting | 9 |
| | LCD Screen | 9 |
| | Air Intake & Exhaust | 9 |
| | Carrying Bag | 9 |
| SECTION 4. | Battery | 10 |
| | Battery Life | 10 |
| | Charging the Battery | 12 |
| | Steps to Connect & Disconnect the Battery | 12 |
| SECTION 5. | User-Replaceable Cartridges | 13 |
| SECTION 6. | Nasal Cannula | 16 |
| SECTION 7. | Troubleshooting | 18 |
| SECTION 8. | Alarms | 18 |
| SECTION 9. | Accessories & Replacement Parts | 20 |
| SECTION 10. | Maintenance & Cleaning | 21 |
| SECTION 11. | Labeling Symbols | 23 |
| SECTION 12. | Specifications | 25 |
| | Flow Settings & Pulse Volume | 26 |
| SECTION 13. | Electromagnetic Interference | 27 |
| SECTION 14. | Traveling with the X-PLO ₂ R | 29 |
| SECTION 15. | Trademarks & Disclaimer | 31 |

X-PLO₂R INCLUDES THE FOLLOWING



X-PLO₂R



ONE 4-CELL OR
8-CELL BATTERY



CARTRIDGE



AIR INTAKE FILTER



AC POWER SUPPLY



DC POWER SUPPLY



CARRYING BAG



CARRYING BAG
HANDLE



CARRYING BAG
SHOULDER STRAP



QUICK START GUIDE



USER MANUAL

WARNING: Do not use the X-PLO₂R or any accessory if they show any sign of damage. Call your equipment provider for replacement.

IMPORTANT: While the box or packaging may look to have damage, such as tears or dents, the device may still be in a usable condition. If the POC or any accessory shows any sign of damage, contact your equipment provider.

QUICK START GUIDE

It is quick and easy to get your X-PLOR started, but please read the entire User Manual before using your X-PLOR. **DO NOT TURN ON X-PLOR UNTIL STEP 4.**

1. REMOVE DUST CAP & INSERT CARTRIDGE

- Remove the dust cap from the cartridge.
- Then insert the cartridge all the way into the unit so the handle lays flat.



2. LOCATE THE BATTERY

- Insert your X-PLOR into the carry bag. When the X-PLOR is correctly inserted into the bag, the LCD screen is seen through the plastic window and the air intake and exhaust are aligned with mesh panels.
- To attach the battery, slide it on until the latch is in the locked position and zip the bag.
- To disconnect the battery, simply push the release latch down and slide the battery towards you.

REMOVE DUST CAP



RELEASE LATCH

3. CHARGE THE BATTERY

- Place in a well-ventilated area to fully charge the battery before using your X-PLOR, which can take up to 5 hours for the 4-cell battery and up to 6 hours for the 8-cell battery.
- To charge, insert the AC power connector into the battery's power receptacle and the other end into an electrical outlet.



4. TURN ON & SET OXYGEN FLOW

- When powered on, position the unit upright to warm-up (warm-up time is less than 2 minutes.)
- Press the POWER button for 2 seconds to turn on your X-PLOR.
- Use the UP/DOWN ARROWS to set the oxygen flow level, as specified in your oxygen prescription.

UP/DOWN ARROWS



POWER

5. NASAL CANNULA

- NOTE: Cannula must be purchased separately.
- Connect the nasal cannula to the oxygen output nozzle located on top of the X-PLOR.
- Place the other end in your nostrils. Oxygen will be delivered through the nasal cannula with each breath.
- Remember to breathe through your nose as normal.



6. GO X-PLOR!

Attach the shoulder strap and handle to your X-PLOR carrying bag, and you are ready to go!



1. INTRODUCTION

This user manual serves as a reference for users of the X-PLO₂R and should be read in its entirety before operating the X-PLO₂R. The term “POC” (Portable Oxygen Concentrator) will be used to refer to the X-PLO₂R. “Patient” and “User” are used interchangeably. The term “sieve cartridge” and “cartridge” will be used interchangeably throughout the document.

X-PLO₂R enables patients who need a POC to be treated at home according to a clinician’s prescription.

Before using the X-PLO₂R for the first time, make sure the battery is fully charged. This can take up to 5 hours for the 4-cell battery and up to 6 hours for the 8-cell battery. The battery must be charged and connected to the X-PLO₂R in order to operate the POC.

Please refer to the X-PLO₂R manual for detailed information regarding any warnings, cautions, specifications, and additional information. We hope the manual answers all of your questions, but if you still have questions, please call your equipment provider.

INTENDED USE

The X-PLO₂R is a transportable, software-monitored device designed to be used by patients as a portable oxygen delivery system requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in home, institutional, and travel or mobile environments.

X-PLO₂R provides supplemental oxygen to patients with chronic pulmonary diseases, such as COPD, and any patient requiring supplemental oxygen. X-PLO₂R is a pulse only mode POC. X-PLO₂R is not intended for use in life supporting or life sustaining situations or by patients who have had a tracheotomy. It is a prescription only device and designed for indoor and outdoor use. The prescribed oxygen delivery setting should be periodically reassessed by healthcare provider.

X-PLO₂R Portable Oxygen Concentrator is not intended to be used:

- in life-supporting or life-sustaining situations
- in an operating or surgical environment
- in conjunction with flammable anesthetic or flammable materials
- with newborns, infants or pediatrics

INTENDED LIFE

The expected service life for the X-PLO₂R is 3 years. The service life of the replaceable cartridge will depend on operating conditions. Replace the cartridge as needed, when indicated by the alarm message (for more information on the Replaceable Cartridge see Chapter 5). The battery has an expected life of 200 full charge / discharge cycles.

2. SAFETY INFORMATION

This section describes the warnings and cautions for the use of the X-PLO₂R. The following guidelines apply to this document:

WARNING: Indicates possibility of serious adverse reactions & potential safety hazards.

CAUTION: Indicates possibility of damage to the equipment.

IMPORTANT: Statements calling attention to additional significant information about the device.

WARNING: USA Federal law restricts the sale of this POC to the order of a physician. May also be applicable in other countries.

WARNING: Availability of an alternate source of oxygen is recommended in case of power outage or mechanical failure. Consult your equipment provider for type of back-up system recommended.

WARNING: It is the responsibility of the patient to make back-up arrangements for alternative oxygen supply when traveling. Belluscura® assumes no liability for persons choosing not to adhere to manufacturer recommendations.

CONTRAINDICATIONS

WARNING: This POC is **NOT INTENDED** to be life sustaining or life supporting.

WARNING: Under certain circumstances, the use of non-prescribed oxygen therapy can be hazardous. This POC and specific settings should be used only when prescribed by a physician.

WARNING: Additional monitoring or attention may be required for geriatric or any other patients using this device who are unable to hear or see alarms or communicate discomfort. If the patient shows any signs of discomfort, consult a physician immediately.

CAUTION: The X-PLO₂R is not designed or specified to be used in conjunction with a humidifier or nebulizer, or to be connected to any other equipment. Do not use this POC with a humidifier or nebulizer or connect it to any other equipment. Doing so may impair the performance and could damage the equipment. Do not modify the X-PLO₂R. Any modification to the equipment may impair performance or damage equipment and will void your warranty.

GENERAL PRECAUTIONS

WARNING: Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. **DO NOT ALLOW SMOKING OR OPEN FLAMES WITHIN THE SAME ROOM OF THE X-PLO₂R OR ANY OXYGEN CARRYING ACCESSORIES.**

If you smoke, you must always turn the oxygen concentrator off, remove the cannula and leave the room where either the cannula or oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after the flow of oxygen has been stopped.

WARNING: Do not submerge the X-PLO₂R or any of the accessories in liquid. Do not expose to water or precipitation or allow any liquid to enter the enclosure. Do not operate the POC while exposed to rain.

WARNING: Do not use oil, grease, or petroleum-based products on or near the X-PLO₂R to avoid the risk of fire or burns. Use only water-based lotions or salves that are oxygen compatible when using or setting up near the X-PLO₂R.

WARNINGS

- The operator should read and understand this entire manual before using X-PLO₂R.
- The POC is not intended for life support. Where the prescribing health care professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternate source of oxygen should be available for immediate use.
- Do not use the POC in the presence of a flammable anesthetic mixture in combination with oxygen or air, in the presence of nitrous oxide, cleaning agents or other chemical vapors.
- Do not use the POC in the presence of pollutants, smoke or fumes.
- Do not use oil or grease on the POC or its components as these substances, when combined with oxygen, can greatly increase the potential for a fire hazard and personal injury.
- Use only approved X-PLO₂R parts and accessories to avoid the risk of fire.
- Turn the POC off when not in use as concentrated oxygen makes furnishings flammable.
- If you notice any of the following, discontinue use and contact your equipment provider:
 1. unexplained changes in the performance of this device
 2. unusual or harsh sounds
 3. dropped or mishandled device or power supply
 4. water spilled into the enclosure
 5. broken enclosure
- Use only with the X-PLO₂R batteries and AC and DC power supplies and cords.
- Use only approved X-PLO₂R parts and accessories to maintain the efficacy of oxygen therapy for prescribed settings.
- Use of accessories other than those approved by Belluscura could result in increased electromagnetic emissions or decreased electromagnetic immunity of X-PLO₂R. Either of these results could affect operation of your unit.
- Only use a standard single lumen nasal cannula. Nasal cannula should be rated for 4 liters per minute, for example the Salter 16SOFT, to ensure proper patient usage and oxygen output.
- Replace the cannula on a regular basis. Check with your POC distributor or clinician to determine how often the cannula should be replaced. Always follow the cannula manufacturer's instructions for proper use.

WARNINGS CONTINUED

- Repairs and adjustments must be performed by authorized X-PLO₂R service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Periodically inspect electrical cords, cables, and the power supplies for damage or signs of wear. Discontinue use and replace if damaged.
- Be aware that the electrical cord or tubing could present a tripping or strangulation hazard.
- To avoid electric shock, unplug the POC and remove the battery before servicing or cleaning the POC. DO NOT immerse the POC in any fluids.
- Never drop or insert any object into any opening of the POC.
- For proper operation, the POC requires unobstructed ventilation. Always make sure any openings in the case are not obstructed by items which may impede ventilation. Do not place the POC in a small closed space (such as a closet). The POC should not be used adjacent to or stacked with other equipment. For more information, contact your equipment provider.
- Do not obstruct air intake or exhaust when operating the POC. Blockage of air circulation or proximity to a heat source may lead to internal heat buildup and shutdown or damage to the POC.
- Do not use an extension cord with the POC.
- Operation of the POC outside of the specified limits for temperature (41°F/5°C to 95°F/35°C) or altitude (10,000 /3048 m) is expected to have an adverse effect on therapy
- The settings of Belluscura X-PLO₂R may not correspond with continuous flow oxygen.
- The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of the Belluscura X-PLO₂R.
- Wind or strong drafts can adversely affect accurate delivery of oxygen therapy.
- This device produces enriched oxygen gas which accelerates combustion. **DO NOT ALLOW SMOKING OR OPEN FLAMES** within 10 feet of this device while in use.
- **DO NOT USE** in conjunction with other medical equipment or medical systems.


CAUTIONS

- When the POC is used in an automobile, disconnect it from the DC auto adapter outlet when the automobile is turned off.
- Do not operate the POC in a non-running vehicle for an extended period of time, as this may deplete the vehicle's battery and prevent the vehicle from starting.
- Do not allow the POC to be connected to the auto adapter outlet while starting the vehicle normally or while you are starting the vehicle with battery recharging cables. Wait until the vehicle starts before connecting the POC to the DC power outlet.
- All vehicles' auxiliary power varies significantly; therefore rate of charging may vary.
- Do not connect the X-PLO₂R to a backup generator.
- Secure the POC when used in any moving vehicle.
- Turn off the POC before removing the battery. The POC cannot be operated without the battery installed.
- Only use the supplied handle and shoulder strap to carry your device. With every use, verify that the case, shoulder strap and handle are in good condition.
- Use X-PLO₂R within its carry bag for ease of use. The insulation in the carry bag will keep the maximum surface temperature of the device for patient contact to less than 48 °C.

NOTE: Additional warnings, cautions and notes are located throughout the manual.

3. OPERATING THE X-PL₂R

The X-PL₂R is a Pulse Mode POC. Each time you inhale through your nose, you will feel a pulse of oxygen that the POC provides, determined by your breath rate and the setting number.

As soon as you begin breathing through the cannula, the X-PL₂R will sense you are breathing from it and begin delivering pulses of oxygen based on your breathing. When a breath is detected, a breath icon  will appear in the upper left corner of the LCD screen and a pulse of oxygen will be delivered.

If the POC does not sense a breath after 15 seconds, a “No Breath Detected” message will appear on the screen and the alarm (beep) will sound.

OVERVIEW OF THE X-PL₂R



POWER BUTTON

TURNING ON THE X-PL₂R

- Hold down the POWER button for TWO SECONDS.
- While the X-PL₂R is warming-up (total warm-up time is less than two minutes), the X-PL₂R name will appear on the LCD screen. Ten seconds after power on, the Pulse Setting, Battery, and Audible Alarm icons will appear on the LCD screen with the message "Please wait" which will remain until warm-up is complete. X-PL₂R should be operated in an upright position.
- After warm-up, proper operation of the X-PL₂R is indicated by the delivery of oxygen pulses in response to inhalation, and the absence of alarms.

TURNING OFF THE X-PL₂R

- Hold down the POWER button for TWO SECONDS.
- The shutdown period will last up to 30 seconds.

IMPORTANT: The X-PL₂R will automatically start the oxygen level at the flow setting used when the X-PL₂R was last turned off.



AUDIBLE ALARM BUTTON

- Pressing this button will toggle the X-PLO₂R breath detection audible alarm on and off. The corresponding icon will be displayed on the screen.
- Pressing this button during an active alarm will acknowledge and mute the audible alarm. This will not remove the visual message on the POC display.

For more information on the Alarms see Chapter 8.



FLOW SETTING CONTROL BUTTONS



- The X-PLO₂R provides a PULSE of oxygen in response to each inhalation.
- The X-PLO₂R will provide a pulse of oxygen once the unit is warmed up.
- Flow setting can be changed by pushing the up or down arrows. To change the flow setting when the screen is dimmed, activate the screen first by pressing the POWER button for less than two seconds.

LCD SCREEN

The LCD screen displays information regarding flow setting, battery life, power status and alarms. The LCD screen has a backlight that turns on and off automatically. The backlight will automatically shut off after 10 seconds as a power-saving feature.



The backlight turns on:

- When the X-PLO₂R is turned on or shuts down.
- Automatically for any alarm indications. An audible signal (beep) will also indicate either a change in operating status or a condition that may need a response.
- Any time when the POWER button is pressed briefly (less than 2 seconds).

AIR INTAKE & EXHAUST

Place the X-PLO₂R in a well-ventilated location. Air intake and exhaust must not be obstructed. Exhaust is located on the front and back of the POC. Do not use the X-PLO₂R without the air intake filter in place. Particles drawn into POC may damage the X-PLO₂R.



AIR INTAKE



EXHAUST

CARRYING BAG

The carrying bag provides protection and convenience. Always use your X-PLO₂R in the supplied carrying bag, with the supplied handle and/or shoulder strap. When the X-PLO₂R is correctly inserted in the bag, the LCD screen is seen through the plastic window and the air intake and exhaust are aligned with mesh panels.



4. BATTERY

X-PLQ₂R comes with a 4-cell lithium-ion battery (optional 8-cell lithium-ion battery also available) that powers the X-PLQ₂R with or without an external power supply connected. The X-PLQ₂R ships to you with the battery. Fully charge the battery before using the X-PLQ₂R.

Charge the X-PLQ₂R battery only with the power supplies provided with the X-PLQ₂R. To maximize battery life and run time, avoid letting the battery drain to empty. Always check the battery level prior to use to ensure adequate charge level.

AC & DC POWER SUPPLIES

The AC power supply allows the X-PLQ₂R to be powered on and the battery to be charged from a standard 100-240 VAC, 50/60 Hz electrical outlet.


The DC power supply allows the X-PLQ₂R to be powered and the battery to be charged from a vehicle's standard 12 VDC outlet.

BATTERY LIFE

- Up to 2.5 hours of battery life with the 4-cell battery
- Up to 5 hours of battery life with the 8-cell battery

WARNING: Use only with Belluscura X-PLQ₂R. Use only the power supply listed in the manual. There is a risk of fire, burns, explosion, and release of toxic material if the battery and the power supply are not used properly. Do not crush or heat above 176° F (80° C). Do not short circuit or reverse polarity.

BATTERY INDICATOR ON LCD SCREEN

- When POC is turned on, the battery indicator will show the level of the battery charge.
- Each of the five horizontal yellow bars represents approximately 20% of the total battery charge.
- When the X-PLO₂R is using an external AC or DC power supply, the  icon will appear on the LCD screen. If there is no icon, the battery is working without external power.

The following alarm messages are accompanied by a sound and a yellow .

| MESSAGE DISPLAY & TEXT | CONDITION/ACTION/EXPLANATION |
|--------------------------------------|--|
| Battery low Attach power source | Battery power is low, with less than 20% of charge remaining. Attach external power or turn off and then use a charged battery. |
| Battery empty Attach power source | POC has insufficient battery power to produce oxygen. Attach external power supply or, if necessary, power off the POC and exchange the battery, then restart. |
| Replace battery | Battery error has occurred. Stop using the battery and switch to a new battery, connected to an external power supply, if needed. |

WARNING: Always have the battery connected to the X-PLO₂R. Without the battery connected, the X-PLO₂R will not turn on.

WARNING: If loss of battery charge is imminent, ensure you have access to an external AC or DC power source. Use of AC supply may cause surface temperature to be hot to the touch. Use care in replacing sieve cartridge and battery pack. Cool system off before changing parts.


WARNING: When operating X-PLO₂R while it is connected to an external power source, ensure that it is positioned so that it is not difficult to disconnect the power source if the necessity arises.

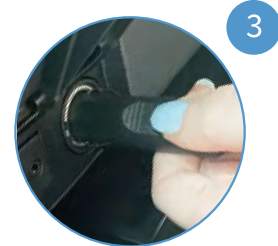
CAUTION: The battery should be fully charged before the first time you use that battery with the X-PLO₂R.

CAUTION: Only remove the battery when X-PLO₂R is turned off. Do not remove the battery while the X-PLO₂R is operating.

IMPORTANT: The battery run time may vary based on the breathing rate, age of battery, and environmental conditions. If the battery is near the end of its life, you may experience shorter battery run times.

STEPS TO CHARGING THE BATTERY

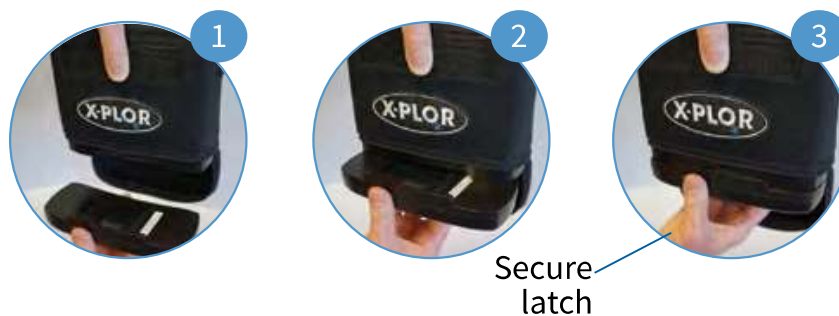
1. Connect the power supply to the X-PLOR power receptacle on the front of the battery. (image 1)
 2. Plug the other end of the AC power supply (image 2) into a power outlet, or start the car and plug in the DC (image 3) power supply into the car's DC outlet.
 3. If the battery is connected to the X-PLOR, turn the POC on. If POC is charging, this icon  will be displayed on the LCD screen.
 4. If the battery is not connected to the X-PLOR, check the indicator lights on the battery to ensure the battery is being charged.
 5. It could take the 4-cell battery up to 5 hours and the 8-cell up to 6 hours to attain full charge.
 6. To check the battery charge, press the charge indicator button on the battery. (image 4) The battery charge level is indicated by 4 green lights on the battery, each light representing approximately 25% charge.
- The battery can be charged while connected to the X-PLOR or while the battery is disconnected from the X-PLOR.
 - The battery can be charged by using either the AC or DC power supply source provided.



STEPS TO CONNECT & DISCONNECT THE BATTERY

Connect the battery to the bottom of the X-PLOR by sliding the battery into place until the latch returns to the locked position. To disconnect, push the release latch down and slide the battery toward you.

STEPS TO CONNECT



STEPS TO DISCONNECT



5. USER-REPLACEABLE CARTRIDGES

A cartridge will arrive in a Mylar bag in the box with your X-PLOR. You have to insert the cartridge into the unit before using the X-PLOR. Do not remove the dust cap until it is time to install the cartridge.

To insert the cartridge, first ensure the POC is powered off and then disconnect the battery (see Chapter 4). Remove the dust cap from the top of the cartridge (see page 14). Push the cartridge top first into the unit until it is fully inside and the handle lays flat (see page 15). Once the cartridge is in place, reconnect the battery.

Over time cartridges, like a filter, can lose their effectiveness and need be to replaced. The service life of a cartridge depends on the operating conditions, including oxygen setting levels, the amount of time the POC is used, and environmental conditions, like high elevation or very dry climate.



CAUTION: Cartridge replacement instructions are only to be used when maintenance is required and are not intended for practice purpose.

The following alarm messages are accompanied by a sound and a yellow 

| MESSAGE DISPLAY & TEXT | CONDITION/ACTION/EXPLANATION |
|-------------------------|---|
| Oxygen Low | The sieve cartridge is nearing the end of its service life. Contact your equipment provider to arrange for replacement. |
| Replace sieve cartridge | Replace the sieve cartridge as soon as possible. Contact your equipment provider to arrange for replacement. If replacing the sieve cartridge does not clear the alarm, then switch to a backup source of oxygen and contact your equipment provider. |

CARTRIDGE REPLACEMENT

1. Turn off the X-PLO₂R by pressing the power button to shut down the POC.
2. Remove the X-PLO₂R from the carrying bag, if applicable.
3. Remove the battery from the X-PLO₂R.
4. Place the X-PLO₂R on its side to access the underside of the POC. (see image 1)
5. Pull the cartridge assembly out of the POC by pulling on the cartridge pull handle. (see image 2)
6. Remove the cartridge completely from the X-PLO₂R and throw it away. (see image 3)
7. Remove cartridge from Mylar bag. The new cartridge has a dust cap on top. Remove the dust cap. Make sure there is no dust or debris where the dust cap was located.
8. Insert new cartridge top first into the X-PLO₂R. Do not leave the cartridge ends exposed; the cartridge should be inserted into the X-PLO₂R as soon the old cartridge is removed. (see image 4)
9. Push the cartridge into the X-PLO₂R such that the cartridge is fully seated into the X-PLO₂R. (see image 5)
10. The cartridge pull handle should lay flat once the cartridge is secured. (see image 6)
11. Connect a charged battery to the X-PLO₂R.
12. Turn on the X-PLO₂R by pressing the power button for 2 seconds. Set the Flow Setting to your prescribed setting and use normally.



STEPS FOR CARTRIDGE REPLACEMENT

REMOVING CARTRIDGE



INSTALLING CARTRIDGE




6. NASAL CANNULA

Nasal cannula is not included with the X-PLO₂R and must be purchased separately.

The proper placement and positioning of the nasal cannula in the nose is critical to the consistent operation of the X-PLO₂R. The length of the cannula should not exceed 25 feet in length. Tubing lengths greater than 25 feet may impede proper flow.

Take care that any hose lying on the floor is not trapped under heavy items or allowed to kink. Ensure the tubing is not laid across the floor where it can be a tripping hazard.

Attaching the cannula:

1. Ensure the cannula is not being pinched or kinked to avoid a disruption of oxygen flow.
2. Align the patient cannula to the oxygen output nozzle on the X-PLO₂R.
3. Install the cannula by pressing onto the nozzle. Press down to fully seal the connection and test with a light pull.
4. While the system is running, squeeze the distal end of the nasal cannula and then you will see  displayed on the screen. Then release the cannula, allowing the bolus of oxygen to release. Repeat the process several times to verify the flow of oxygen.

Positioning the nasal cannula on your face:

1. Position the nasal cannula with the nasal prongs facing upward and curved toward the face.
2. Insert the two nasal prongs into the nostrils.
3. Wrap the headset loop up and over both ears or for alternative placement: Secure headset loop behind your head.
4. Glide the bolo up under your chin.
5. Leave enough space to fit at least two fingers between the bolo and chin.
6. Once the cannula is secured, breathe normally through your nose. X-PLO₂R will detect a breath and deliver the oxygen during inhalation.



7. TROUBLESHOOTING

The table below lists common problems and actions you can take. If you are unable to resolve a problem, please contact your equipment provider.

| PROBLEM | POSSIBLE CAUSE | WHAT YOU SHOULD DO |
|---|--------------------------------------|---|
| Device won't turn on | Battery charge is depleted | Use the AC or DC power cord to operate the device (with the battery inserted) to recharge the battery. If this does not resolve the problem, contact your equipment provider. |
| | Power button not pressed long enough | Press the power button for two seconds. |
| | Switch is defective | Remove AC power cord if installed. Detach battery. Discontinue use and contact your equipment provider. |
| Device won't turn off | Power button not pressed long enough | Press the power button for two seconds. |
| | Switch is defective | Remove AC power cord if installed. Detach battery. Discontinue use and contact your equipment provider. |
| Device will not trigger a pulse of oxygen | X-PLO _R is not turned on | Press the power for two seconds. |
| | Cannula tubing is kinked or twisted | Make sure the tubing is connected properly to the oxygen outlet port and that it is free of any obstruction. |
| | Device malfunction | Contact your equipment provider. |
| Alarm occurs | The device needs your attention | See the Alarm Indicators and Screen Symbols section for information about specific alarms and what you should do. |

8. ALARMS




NOTIFICATIONS

X-PLO₂R incorporates alarms (a message on the display combined with an audible tone) of only one type: those that arise from monitored equipment functions, which indicate that the user's attention to the alarm condition is required. Audible notifications, ranging from 65 dB(A) to 85 dB(A), depending on equipment conditions and the user's position, are to alarm the user of problems. To ensure that audible notifications may be heard, the maximum distance that the user can move away from it must be determined to suit the surrounding noise level.

X-PLO₂R monitors various parameters during operation and utilizes an intelligent alarm system to indicate a malfunction of the POC. Mathematical algorithms and time delays are used to reduce the probability of false alarms while still ensuring proper notification of an alarm condition. All alarms are classified as Low Priority technical alarm condition.

ALARMS

The following alarm messages are accompanied by a sound and a yellow . If the suggested procedures do not clear the alarm condition, switch to a backup source of oxygen and contact your equipment provider.

| MESSAGE DISPLAY & TEXT | CONDITION/ACTION/EXPLANATION |
|--------------------------------------|---|
| Shutting down | On/Off button has been pressed for two seconds. POC is performing system shut down. |
| Battery low Attach power source | Battery power is low, with less than 20% of charge remaining. Attach external power or turn off and then use a charged battery |
| Battery empty Attach power source | POC has insufficient battery power to produce oxygen. Attache external power supply, or, if necessary, power off the POC and exchange the battery, then restart. |
| Replace battery | Battery error has occurred. Stop using the battery and switch to a new battery, connected to an external power supply, if needed. |
| System hot | POC temperature is too high. Ensure air intake and outlet vents have clear access and particle filters are clean. If the vents are not obstructed, the filter is clean and this alarm condition does not clear, try moving to a cooler environment. |
| System cold | POC temperature is too cold. Try moving to a warmer environment. |
| Oxygen low | The sieve cartridge is nearing the end of its service life. Contact your equipment provider to arrange for replacement. |
| Replace sieve cartridge | Replace the sieve cartridge as soon as possible. Contact your equipment provider to arrange for replacement. If replacing the sieve cartridge does not clear the alarm, then switch to a backup source of oxygen and contact your equipment provider. |
| External Power Failure | The POC is plugged in, but the POC is running on battery power and is not charging. Switch external power supply or exchange battery. If the problem persists please contact your equipment provider. |

These alarms can result in the shutdown of the POC.


| MESSAGE DISPLAY & TEXT | CONDITION/ACTION/EXPLANATION |
|-------------------------------------|--|
| No breath detected Check cannula | POC has not detected a breath for 15 seconds. Check that cannula is connected to POC, there are no kinks in the tubing and cannula is positioned properly in your nose. The alarm will sound again 30 seconds after the first alarm if the condition is not corrected. If the condition is not corrected within 60 seconds of the first alarm, the POC will shut itself down automatically. If the condition appears to be corrected and the POC still shuts down, then switch to a backup source of oxygen and contact your equipment provider. |
| Sensor fail | The POC oxygen sensor has malfunctioned. The POC will shut itself down automatically. Switch to a backup source of oxygen and contact your equipment provider. |
| Oxygen delivery error | The POC's has detected a mechanical or electrical problem that prevents normal operation. The POC will shut itself down automatically. Switch to a backup source of oxygen and contact your equipment provider. |

NOTE: When two alarm conditions occur simultaneously, each of the corresponding messages will cycle on the display for 5 seconds. If one of the alarm conditions requires the POC to shut down, then the message for that condition will display for 10 seconds and the POC will shut itself down.

NOTE: When the audible alarm button is pressed to acknowledge and mute an alarm, new alarm conditions will cancel the mute feature. The audible alarm button can mute and acknowledge the new alarm without removing the visual alarm on the display.

INFORMATIONAL MESSAGES

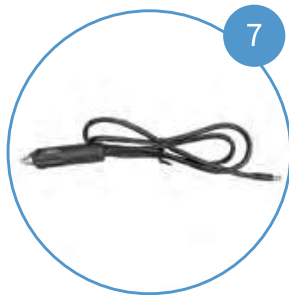
The following information displays are not accompanied by any audible feedback or any visual change in the indicator lights.

| MESSAGE DISPLAY & TEXT | MEANING |
|---|---|
| X-PLO _R | X-PLO _R logo is displayed at startup. |
| Setting X Please wait | Displayed during warm up. "X" represents the selected flow setting (e.g., Setting 2). |
| Setting X Battery xx% | Default display when operating on battery power. "X" represents the selected flow setting (e.g., Setting 2). "xx%" represents the approximate battery charge remaining. 99% is fully charged. |
|  | This icon appears when the POC detects inhalation. |

9. ACCESSORIES & REPLACEMENT PARTS

Some of the accessories are included with your X-PLOR. All are also available to order:

| PICTURE # | ACCESSORY NAME | MODEL # |
|-----------|--------------------------|---------|
| 1 | 4-Cell Battery | 50084 |
| 2 | 8-Cell Battery | 50188 |
| 3 | Cartridge | 50073-1 |
| 4 | Air Intake Filter | 50351-1 |
| 5 | Carry Bag | 52191-1 |
| 6 | AC Power Supply | 53011-1 |
| 7 | DC Power Supply | 53021-1 |
| 8 | Carry Bag Hand Strap | 52192-1 |
| 9 | Carry Bag Shoulder Strap | 52193-1 |
| 10 | Backpack | 52291-1 |



See MyX-PLOR.com
for backpack instructions.

10. MAINTENANCE & CLEANING

DO NOT ATTEMPT TO REPAIR THE DEVICE. Contact your equipment provider or distributor for assistance. The cartridge, air intake filter and the battery may be replaced by the patient as determined by the equipment provider or distributor. All other maintenance or repair must be performed by trained service personnel.

Store the POC in a place where it will remain clean and dry. Do not store the POC in extreme temperatures, below 32° F (0° C) or above 140° F (60° C).

SERVICE LIFE

The service lives of this POC and its major components are dependent on operating and environmental conditions. Should your POC indicate an alarm that requires you to contact your equipment provider, the provider may determine that the POC needs to be returned.

The manufacturer recommends that you have an alternative source of supplemental oxygen in the event of power outage, alarm condition or mechanical failure. Although the X-PLO₂R will operate 24 hours/7 days per week, daytime/nighttime (as long as it is charged or powered), in order to preserve the life of the POC this type of use should be limited to situations when you are traveling, on vacation, or other short term situations where your primary oxygen source is not immediately available.

DISPOSAL

Belluscura expects end users to dispose of the POC 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 POC contains lithium ion batteries, and end users should contact their local distributor for disposal, collection and recycling options and terms and conditions for their country.

CLEANING

WARNING: To avoid electrical shock, do not disassemble the X-PLO₂R. The plastic outer shell should be removed only by authorized service personnel. Do not use alcohol, solvents, polishes or any oily substances on the device, as they are flammable.

CAUTION: Do not use cleaning agents other than those specified in this manual. Allow the cleaning solution to dry from the cleaned surface before use. Do not use water at temperatures higher than room temperature.

CAUTION: Always disconnect power and turn off this POC before cleaning. Clean the exterior with a soft cloth slightly dampened with soapy water..

CAUTION: Do not operate the POC without air intake filter in place. If a second filter is provided, insert the replacement filter before you clean the dirty filter. Clean the dirty filter in a warm soap and water solution then dry thoroughly prior to use.

CAUTION: Do not allow liquids into any of the controls, the interior of the case, or the oxygen tubing connector. **DO NOT ATTEMPT TO TAKE THE DEVICE APART YOURSELF.** Contact your equipment provider for assistance.

X-PLQ₂R & RECHARGEABLE BATTERY

The exterior shell of the X-PLQ₂R and the rechargeable battery should be cleaned as needed.

X-PLQ₂R

To clean the exterior: wipe the outside surface of the case with a cloth dampened with a mild liquid detergent and water solution at room temperature.

BATTERY

To clean the exterior: wipe the outside surface of the case with a cloth dampened with a mild liquid detergent and water solution at room temperature.

NASAL CANNULA

Replace your supply tubing and cannula on a regular basis as recommended by your equipment provider. Your physician or equipment provider should provide you with cleaning, disinfection and replacement information.

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

CARRYING BAG, HANDLE & STRAP

If necessary, you may clean the carrying bag with a damp cloth and a mild liquid detergent and water at room temperature.

1. Remove the X-PLQ₂R from the carrying bag, if applicable.
2. Dampen a cloth in a mild liquid detergent and water solution at room temperature and wipe the outside surface of the bag.
3. Allow time for the bag to dry before placing the X-PLQ₂R back inside.

AC & DC POWER SUPPLY CORDS

The AC and DC power supplies should be cleaned as needed.





















1. Disconnect cords from the POC before cleaning.
2. Disconnect the power supply from the AC or DC power source.
3. Clean the cords using a mild liquid detergent and water solution at room temperature and wipe the outside surface.
4. Allow cords to dry thoroughly before using them again.

AIR INTAKE FILTER





The air intake filter **MUST BE CLEANED WEEKLY** to ensure the ease of air flow.

1. Remove the filter from the side of the POC.
2. Clean the filter with a mild liquid detergent and water at room temperature; rinse in water at room temperature and dry before reuse.







11. LABELING SYMBOLS

| SYMBOLS | MEANING | SYMBOLS | MEANING |
|---|--|---|---|
|  | Refer to instruction manual/ booklet. |  | Do Not Disassemble (contact your equipment provider for servicing by authorized personnel) |
| WARNING | A warning indicates that the personal safety of the patient may be involved. Disregarding a warning could result in significant injury. |  | Do Not Dispose of In Unsorted Municipal Waste |
| CAUTION | A caution indicates that a precaution or service procedure must be followed. Disregarding a caution could lead to a minor injury or damage to equipment. |  | Class II Electrical Device |
| Rx only | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |  | Intertek ETL listed mark, ETL# 5020429 |
|  | AC Power |  | Type BF Applied Part, complies with IEC 60601-1 |
|  | DC Power |  | Non-condensing humidity lower limit 0%; upper limit 95% |
|  | No Smoking while device is in use. |  | Lower temperature limit: 0° C (32° F); Upper temperature limit: 60° C (140° F) |
|  | No Open Flames | IP22 | Ingress Protection Level 22 |
|  | Manufacturer |  | Do not reuse |
|  | Keep Dry |  | MR Unsafe |
|  | Indoor or Dry Location Use Only, Do Not Get Wet |  | The manufacturer of this POC has determined this device conforms to all applicable FAA requirements for POC carriage and use on board aircraft. |
|  | Use No Oil or Grease |  | Use by date |

USER INTERFACE LABEL



| SYMBOLS | MEANING |
|---|---------------------------------------|
|  | ON / OFF Button |
|  | Increase Flow Setting |
|  | Decrease Flow Setting |
|  | Audible Alarm Enable / Disable Button |

POWER STATUS ICONS

| SYMBOLS | MEANING |
|--|---|
|  X% | Battery charge level is 0-19%. The actual percentage will be displayed next to the icon. |
|  X% | Battery charge level is 20-39%. The actual percentage will be displayed next to the icon. |
|  X% | Battery charge level is 40-59%. The actual percentage will be displayed next to the icon. |
|  X% | Battery charge level is 60-79%. The actual percentage will be displayed next to the icon. |
|  X% | Battery charge level is 80-99%. The actual percentage will be displayed next to the icon. |
|  | Battery is charging. |

MODE ICONS

These are the mode icons shown in the displays window.

| SYMBOLS | MEANING |
|---|-------------------------------------|
|  | The audible alarm has been enabled. |
|  | The audible alarm is disabled. |

12. SPECIFICATIONS

CONCENTRATOR

| | |
|---|---|
| Dimensions: With 4-cell battery With 8-cell battery | L / W / H : 7.3 in. (18.5 cm.) / 2.9 in. (7.4 cm.) / 6.5 in. (16.5 cm.) L / W / H : 7.3 in. (18.5 cm.) / 2.9 in. (7.4 cm.) / 7 in. (17.8 cm.) L / W / H : 7.3 in. (18.5 cm.) / 2.9 in. (7.4 cm.) / 7.6 in. (19.3 cm.) |
| Weight of unit with: | Without battery: 2.5 lbs; with 4-cell battery: 3.25 lbs; with 8-cell battery: 3.75 lbs |
| Warm-Up Time: | Less than 2 minutes |
| Flow Control Settings: | 1-4 Pulse Settings |
| Breath Rate: | 15-40 breaths per minute |
| Inhalation Trigger Pressure: | <-0.2 cmH ₂ O |
| Maximum Outlet Pressure: | 10 psig (41.37 kPa) |
| Sound: | <39 dB(A) at Level 2 |
| Power: AC Power Supply DC Power Supply | AC Input: 100 to 240 VAC; 50 to 60 Hz Auto-Sensing 1.0A DC Input: 15 V |
| Battery Duration: | Up to 2.5 hours for a 4-cell battery Up to 5 hours for an 8-cell battery |
| Battery Charging Time: | Up to 5 hours for a 4-cell battery Up to 6 hours for an 8-cell battery |
| Environmental Ranges Intended for Use: | Temperature: 41 to 95°F (5 to 35°C) Humidity: 5% to 85%, non-condensing Altitude: 0 to 10,000 (0 to 3048 meters) Atmospheric pressure: 700 to 1060 mbar |
| Environmental Ranges Intended for Shipping and Storage: | Temperature: 32 to 140°F (0 to 60°C) Humidity: 0% to 95%, non-condensing Store in a dry environment |
| Oxygen purity: | 82% to 92% at all flow settings and over the rated ranges for ambient temperature, humidity, and atmospheric pressure, after initial warm-up period (less than two minutes after power on) |
| Transportation: | Keep dry, handle with care |

WARNING: Only use the POC within the environmental limits to avoid adverse effects on oxygen concentration and flow rate.

CLASSIFICATIONS

| MODE OF OPERATION: | CONTINUOUS DUTY: |
|---|---|
| Type of Protection Against Electrical Shock: | Class II |
| Degree of Protection to Concentrator Components Against Electrical Shock: | Type BF |
| Degree of Protection to Concentrator Components Against Ingress of Water: | IP22 - Vertically falling drops of water shall have no harmful effects when enclosure is tilted at any angle up to 15° on either side of the vertical. The enclosure is designed to prevent access by (1) a finger that is 12 mm in diameter and 80 mm long, and (2) a solid foreign object that is greater than 12.5 mm in diameter. |
| Degree of Safety for Application in Presence of Anesthetic Gases: | Not suitable for such application |
| Applied Part Having Contact with the Patient for a Time: | $10s \leq t < 1 \text{ min}$ is 60 °C (140 °F) |

Refer to Technical Manual for more information.

FLOW SETTINGS & OXYGEN PULSE VOLUME

| | Setting 1 | Setting 2 | Setting 3 | Setting 4 |
|----------------------------------|--|-----------|-----------|-----------|
| Breaths Per Minute | Pulse volumes (ml) +/- 15%, per ISO 80601-2-67 | | | |
| 15 | 14 | 27 | 40 | 53 |
| 20 | 10 | 20 | 30 | 40 |
| 25 | 8 | 16 | 24 | 32 |
| 30 | 7 | 14 | 20 | 27 |
| 35 | 6 | 12 | 17 | 23 |
| 40 | 5 | 10 | 15 | 20 |
| Total Volume Per Minute (ml/min) | 200 | 400 | 600 | 800 |

The nominal pulsed volume in the table below is in (ml) at STPD (standard temperature and pressure dry) 101.3kPa at an operating temperature of 20 °C dry. Ranges apply over the rated ranges for ambient temperatures, humidity, and atmospheric pressure. Oxygen purity is 82% to 92% at all flow settings.

13. ELECTROMAGNETIC INTERFERENCE

X-PLOR provides supplemental oxygen and it will display an alarm message if there is a condition that interferes with its function. It is designed for use in environments that are within a public low-voltage power supply network used for homes and businesses, in which radio frequency (RF) disturbances are controlled. It has been tested according to the requirements of IEC 60601-1-2 and it complies with the electromagnetic compatibility limits contained in that standard. These limits are specified to provide reasonable protection against typical RF interference. Conversely, the electromagnetic emissions of the X-PLOR are related only to its internal function and it is unlikely to interfere with other equipment.


WARNING: Do not stack the X-PLOR on or place it adjacent to other electrical equipment while it is in operation. If it is suspected that your POC is experiencing interference caused by electromagnetic emissions from another device, then you can try increasing the distance between that device and your POC. Because electromagnetic emissions are affected by reflection from and absorption by surrounding objects, finding the right position and distance with respect to a potentially interfering device may require several trials.

WARNING: Do not use radio frequency (RF) communications equipment within 12 inches (30 centimeters) of the X-PLOR while it is operation. RF equipment may degrade the performance of the POC. If X-PLOR is exposed to a radio frequency of 450 MHz, it may shut down without providing an alarm. This shutdown will not harm X-PLOR and it can be restarted after it is relocated away from the source of the emission.

GUIDANCE & MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The X-PLOR software is intended for use in the electromagnetic environment specified below. The user of the product should make sure it is used in such an environment.

| TEST/STANDARD | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT-GUIDANCE |
|---|----------------------|------------------|---|
| AC Mains Conducted Emissions CISPR 11 | Class B Group 1 | Class B Group 1 | This system 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. |
| Radiated Emissions CISPR 11 | Class B Group 1 | Class B Group 1 | The system is suitable for use in all establishments, including domestic or residential, and directly connected to the public low-voltage power supply network that supplies buildings Harmonic emissions used for domestic purposes. |
| Harmonics IEC 61000-3-2 | Class A | Class A | |
| Voltage fluctuations and flicker IEC 61000-3-3 | All parameters | Complies | |

| TEST/ STANDARD | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT- GUIDANCE |
|---|--|--|---|
| Electro-Static Discharge Immunity IEC 61000-4-2 | 8kV contact/ 15kV Air discharge | 8kV contact/ 15kV Air discharge | 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 Immunity Test IEC 61000-4-4 | AC Mains ±2 kV, 100 kHz | AC Mains ±2 kV, 100 kHz | Mains power quality should be that of a typical residential, commercial or hospital environment. |
| Immunity to Surges IEC 61000-4-5 | AC Mains Line to Line ±0.5kV, ±1kV | AC Mains Line to Line ±0.5kV, ±1kV | Mains power quality should be that of a typical residential, commercial or hospital environment. |
| Power Frequency Magnetic Field Immunity IEC 61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment. |
| Voltage Dips/ Interruptions Immunity Test IEC 61000-4-11 | 0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° | 0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° | Mains power quality should be that of a typical residential commercial or hospital environment. If the user of the X-PLO ₂ R system requires continued operation during power mains interruptions, it is recommended that the X-PLO ₂ R system be powered from an uninterrupted power supply or a fully charged battery. |
| Conducted RF IEC 61000-4-6 | AC Mains 3V 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz 6V ISM Home: 6V Amateur radio 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz | AC Mains 3V 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz 6V ISM Home: 6V Amateur radio 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended 30 cm separation distance. If X-PLO ₂ R is exposed to a radio frequency of 450 MHz, it may shut down without providing an alarm. This shutdown will not harm X-PLO ₂ R and it can be restarted after it is relocated away from the source of the emission. Using this equipment outside of its operating range may increase interference or susceptibility and negatively impact system performance. Interference may occur in the vicinity of equipment marked with symbol:  |
| Radiated RF IEC 61000-4-3 | 10V/m 80% AM at 1 kHz 80-2700MHz | 10V/m 80% AM at 1 kHz 80-2700MHz | |

The X-PLO₂R is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X-PLO₂R can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the X-PLO₂R as recommended below, according to the maximum output power of the communications equipment.

| RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (WATTS) | SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (d, METERS; P, WATTS) | | |
|--|--|---|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 0.35\sqrt{P}$ | 800 MHz to 2,5 GHz $d = 0.7\sqrt{P}$ |
| .01 | .12 | .04 | .07 |
| .1 | .38 | .11 | .22 |
| 1 | 1.17 | 1.35 | .70 |
| 10 | 3.69 | 1.11 | 2.21 |
| 100 | 11.67 | 3.50 | 7.00 |

14. TRAVELING WITH X-PLO₂R

When you travel with your X-PLO₂R, make sure you pack the following:

- Fully charged battery
- Enough fully charged batteries to last at least 150% of the length of your flight or the period of time when you will not be able to charge your battery
- AC and DC power supply
- Shoulder and hand strap
- Extra cannula

Depending on your travel destination, domestic or international, be sure you have the proper power supply outlet adapter for the country or countries where you are traveling.

Bring contact information for your equipment provider and physician in case of an emergency.

TRAVELING BY AIR

The U.S. Federal Aviation Administration (FAA) allows X-PLO₂R on board all U.S. aircraft. The X-PLO₂R is labeled on the back confirming that it is FAA compliant. Prior to flying, contact your airline to let them know you are bringing a POC on board and find out if there is any paperwork, such as a statement from your doctor, that might be needed.

CAUTION: A change in altitude, like from sea level to the mountains, may affect total oxygen available to the patient. Consult your physician before traveling to higher or lower altitudes to determine if your flow setting should be changed.

IMPORTANT: Lithium ion batteries are prohibited from being placed in checked baggage on an aircraft. Take all your spare batteries with you in your carry-on luggage.

TRAVELING BY TRAIN, BUS OR BOAT

Most carriers and cruise lines allow POCs on board, but you will need to notify them in advance and find out if there is any paperwork that may be needed. Carriers outside the United States may have additional requirements for POCs so be sure you contact them in advance for any requirements or specifications.

TRAVELING IN A CAR OR MOTORIZED VEHICLE

You can charge your X-PLO₂R battery using your vehicle's cigarette lighter/auxiliary DC power supply. You can continue using your X-PLO₂R while it is running from a DC power source.

CAUTION: Make sure the vehicle has been started before plugging in your DC power supply to help avoid draining the battery.

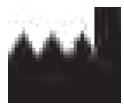


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How to Contact Belluscura: customerservice@belluscura.com / 1-888-469-7567

To return a POC, contact your equipment provider.
If you need to contact Belluscura directly, email the customer service team at customerservice@belluscura.com.

You can also use the following address:



Belluscura
5504 Democracy Drive, Suite 200
Plano, TX 75024

15 Fetter Lane
London, United Kingdom
EC4A 1BW

Please visit belluscura.com for a complete listing of trademarks.