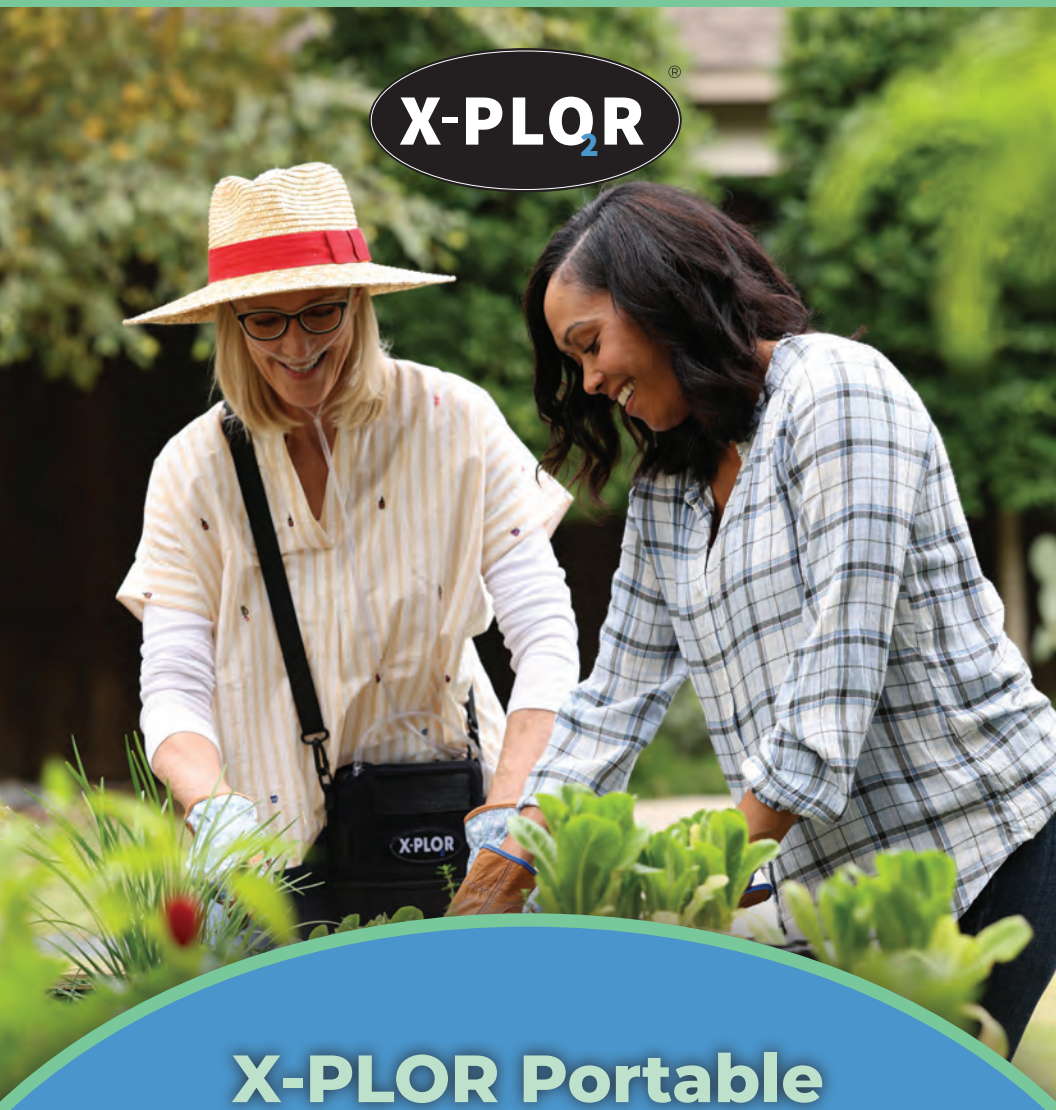

X-PLOR Portable Oxygen Concentrator

USER-MANUAL

Live Life. Breathe Easy. Go X-PLO$_2$R®

belluscura®

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X-PLOR Quick Start Guide Checklist

Ensure the following X-PLOR components have arrived in your package:

X-PLOR Unit

8-Cell Battery

Cartridge*

Air filter

AC Power Supply

DC Power Supply

Carry Bag

Carry Bag Handle

Carry Bag Shoulder Strap

WARNING: Do not use the X-PLOR 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 X-PLOR or any accessory shows any sign of damage, contact your equipment provider.

*Cartridge will be installed in unit. Additional cartirdges will be found in Mylar bag.

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. VERIFY CARTRIDGE IS INSERTED

- Ensure the cartridge is inserted all the way into the unit so the handle lays flat.

2. INSERT INTO BAG & ATTACH 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 close.

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 6 hours for an 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.

5. NASAL CANNULA

- Nasal cannula MAY be included.
- 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 device and enjoy your new found mobility!

1. Introduction

This user manual serves as a reference for users of the X-PLOR and should be read in its entirety before operating the X-PLOR. The term “POC” (Portable Oxygen Concentrator) may be used to refer to the X-PLOR. “Patient” and “User” are used interchangeably. X-PLOR enables patients who need a POC to be treated at home according to a clinician’s prescription.

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

Please refer to the X-PLOR 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.

INDICATION FOR USE

The X-PLOR is a small, portable, software-monitored oxygen delivery system for patients with acute or chronic respiratory disorders and whose physicians have prescribed concentrated oxygen (typically above 82%) in order to enhance their blood oxygen saturation (as measured by pulse oximetry). It may be used as needed or continuously in home, institutional, travel, or mobile environments.

INTENDED USE

X-PLOR delivers concentrated oxygen in pulse mode by responding to the patient’s inhalations. It is a portable, prescription-only device, and is designed for indoor and outdoor use. The prescribed oxygen delivery setting should be reassessed periodically by a healthcare provider.

INTENDED LIFE

The expected service life for the X-PLOR is 5 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 500 full charge/discharge cycles.

2. Safety Information

This section describes the warnings and cautions for the use of the X-PLOR. 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 used in life-supporting or life-sustaining situations, by patients who have had a tracheotomy, in an operating or surgical environment, or by newborns, infants or pediatrics.

WARNING: Under certain circumstances, the use of non-prescribed oxygen 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-PLOR is not designed or specified to be used in conjunction with a humidifier, 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-PLOR. 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 likely to result in facial burns or death. **DO NOT ALLOW SMOKING OR OPEN FLAMES WITHIN THE SAME ROOM OF THE X-PLOR 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-PLOR or any of the accessories in liquid. Do not expose to water, 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-PLOR to avoid the risk of fire or burns. Use products that are oxygen compatible when using or setting up near the X-PLOR.

WARNINGS

- The operator should read and understand this entire manual before using the X-PLOR.
- The POC is not intended for life support. Where the prescribing healthcare 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-PLOR 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-PLOR batteries, AC and DC power supplies and cords.
- Use of unauthorized parts and accessories could cause injury, invalidate the warranty, or result in costly damage.
- Use of accessories other than those approved by Belluscura could result in increased electromagnetic emissions or decreased electromagnetic immunity of X-PLOR. Either of these results could affect operation of your unit.
- Only use a standard single lumen nasal cannual. 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.
- Repairs and adjustments must be performed by authorized X-PLOR 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.

WARNINGS CONTINUED

- 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 104°F/40°C) or altitude (10,000 /3048 m) is expected to have an adverse effect on oxygen delivery.
- Leaving POC in a motor vehicle unattended for an extended period can have adverse effects.
- The settings of X-PLOR may not correspond with continuous flow oxygen.
- The settings of other models or brands of oxygen equipment do not correspond with the settings of the X-PLOR.
- Wind or strong drafts can adversely affect accurate delivery of oxygen.
- This device produces enriched oxygen gas which accelerates combustion. **DO NOT ALLOW SMOKING, VAPING, OR OPEN FLAMES** within 10 feet of this device while in use.
- **DO NOT USE** in conjunction with other medical equipment or medical systems.
- The lower respiration rate during sleep may result in a decrease in the X-PLOR oxygen delivery rate.
- The elevated respiration rate during exercise may result in an insufficient oxygen delivery rate from the X-PLOR.

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 outlet while starting the vehicle. 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-PLOR 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.

CAUTIONS CONTINUED

- Use X-PLOR 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.

NOTES TO PRESCRIBER

A prescriber of concentrated oxygen should:

- Periodically re-evaluate the patient's condition and, if necessary, adjust the prescribed X-PLOR setting accordingly.
- Anticipate the possibility that, at low flow rates, the patient may experience retention of carbon dioxide for some conditions.
- Re-evaluate the initially prescribed X-PLOR setting prior to discharge from acute care and periodically at appropriate intervals after discharge.

3. Operating the X-PLOR

The X-PLOR is a pulse mode POC.

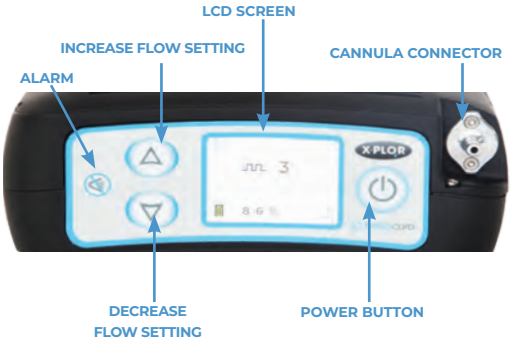
Pulse Dose Mode:

Pulse dose is designed to work with a patient's inhaling and exhaling patterns. It senses a change in air pressure and releases a pulse of air, also known as a bolus, through a nasal cannula. Once a breath is detected, a breath icon will appear in the upper left corner of the LCD screen. This icon will appear each time a breath is detected and a pulse of oxygen is delivered. Use the UP/DOWN buttons to set the oxygen flow level (1-4).

No Breath Detected Mode:

If the X-PLOR does not detect a breath from the user for 45 seconds, a No Breath Detect alarm icon will display and an alarm (beep) will sound. After another 45 seconds if a new breath is not detected, the X-PLOR will go into No Breath Detected Mode [Auto pulse 15 breaths per minute (BPM) at current setting] for 2 hours or until unit detects another breath.

OVERVIEW OF THE X-PLOR



POWER BUTTON

TURNING ON THE X-PLOR

- PRESS and HOLD the POWER button for two seconds.
- While the X-PLOR is warming-up (total warm-up time is less than two minutes) the X-PLOR logo 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 "Please wait" icon which will remain until warm-up is complete.
- X-PLOR should be operated in an upright position.
- After warm-up, proper operation of the X-PLOR is indicated by the delivery of oxygen pulses in response to inhalation and the absence alarms.

TURNING OFF THE X-PLOR

- To turn off the X-PLOR, PRESS and HOLD the POWER button for two seconds.
- After holding the POWER button, the shutdown process will approximately take up to 30 seconds.

IMPORTANT: If turned off at a specific flow setting, the X-PLOR will restart at pulse setting 2 at next start-up.

AUDIBLE ALARM BUTTON

- Pressing this button during an active alarm will acknowledge and mute the audible alarm. This will not remove the visual icon on the POC display.

For more information on the Alarms see Chapter 8.

FLOW SETTING CONTROL BUTTONS

The X-PLOR provides both Pulse Dose and No Breath Detected Mode to provide oxygen when the user needs it most.

Pulse Dose Mode:

To navigate through Settings 1-4 for Pulse Dose Mode, PRESS the UP/DOWN button to reach the appropriate setting. The X-PLOR will provide a pulse of oxygen once the unit is warmed up.

No Breath Detected Mode:

If the X-PLOR does not detect a breath from the user for 45 seconds, a No Breath Detect alarm icon will display and an alarm (beep) will sound. After another 45 seconds if a new breath is not detected, the X-PLOR will go into No Breath Detected Mode [Auto pulse 15 breaths per minute (BPM) at current setting] for 2 hours or until unit detects another breath.

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

The air filter **SHOULD 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 **mild liquid detergent and water at room temperature**; **rinse** in **water at room temperature** and allow to **completely dry** before reuse.

CARRYING BAG

The carrying bag provides protection and convenience. Always use your X-PLOR in the supplied carrying bag, with the supplied handle and/or shoulder strap. When the X-PLOR 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-PLOR comes with an 8-cell lithium ion battery that powers the X-PLOR with or without an external power supply connected. Fully charge the battery before using the X-PLOR.

Charge the X-PLOR battery only with the power supplies provided with the X-PLOR. 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-PLOR 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-PLOR to be powered and the battery to be charged from a vehicle's standard 12 VDC outlet.

BATTERY LIFE

- Up to 4.5 hours of battery life with the 8-cell battery.

WARNING: Use only with Belluscura X-PLOR. 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.

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

BATTERY INDICATOR ON LCD SCREEN

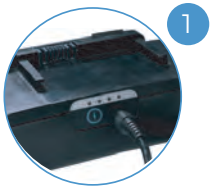
- When POC is turned on, the battery indicator will show the level of the battery charge.
- Each of the five horizontal yellow bars represents approximately 20% of the total battery charge.
- When the X-PLOR is using an external AC or DC power supply, the icon will appear on the LCD screen. If there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

MESSAGE DISPLAY & TEXT	ICONS	CONDITION/ACTION/EXPLANATION
Battery low Attach power source		The battery has less than 20% charge. Attach external power or swap out with 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-PLOR. Without the battery connected, the X-PLOR 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 cartridge and battery pack. Cool system off before changing parts.
WARNING:	When operating X-PLOR 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-PLOR.
CAUTION:	Only remove the battery when X-PLOR is turned off. Do not remove the battery while the X-PLOR 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

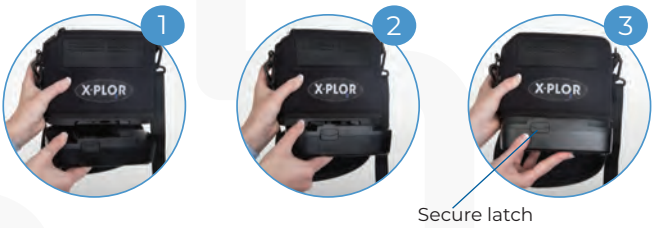
1. Connect the power supply to the X-PLOR power receptacle on the front of the battery. (Image 1)
2. Plug the other end of the AC power supply (Image 2) into a power outlet, or start the car and plug in the DC (Image 3) power supply into the car's DC outlet.
3. If the battery is connected to the X-PLOR, 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 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.



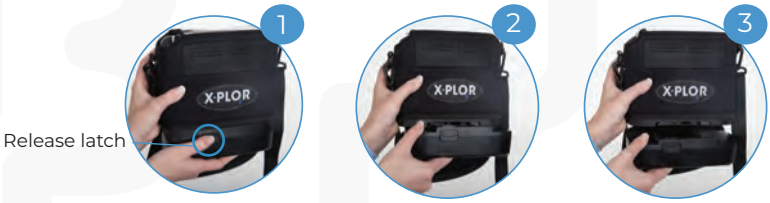
STEPS TO CONNECT & DISCONNECT THE BATTERY

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 Cartridge

Your X-PLOR will have a cartridge inserted into your unit. Any additional catridges will be found in a Mylar bag. Do not remove the dust cap until it is time to install the cartridge. Only replace cartridge when directed to by your unit.

To insert the cartridge, first ensure the POC is powered off and then disconnect the battery (See Chapter 4). Remove cartridge from mylar bag and then remove dust cap from the top of the cartridge (See page 13). Push the cartridge top first into the unit until it is fully inside and the handle lays flat (See page 13). 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, such as high elevation or very dry climate.

CAUTION: Cartridge replacement instructions are only to be used when replacement is required. Keep the cartridge in its sealed Mylar bag until it is time to install it in the X-PLOR unit. Leave the cartridge in the X-PLOR until it needs to be repalced and do not remove it between uses of the X-PLOR.

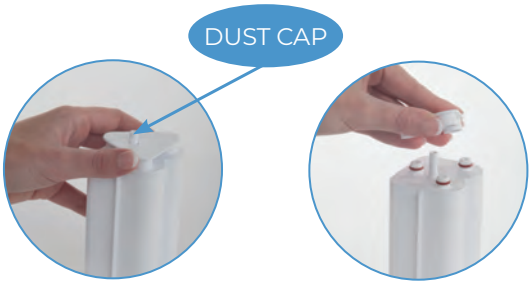
The following cartridge alarm messages are accompanied by a sound and a yellow ⚠

MESSAGE DISPLAY & TEXT	ICONS	CONDITION/ACTION/EXPLANATION
Replace cartridge		Replace the cartridge as soon as possible. Contact your equipment provider to arrange for replacement. If replacing the cartridge does not clear the alarm, then switch to a backup source of oxygen and contact your equipment provider.

NOTE: Replacement cartridge may vary in appearance to original cartridge.

CARTRIDGE REPLACEMENT

1. Turn off the X-PLOR by pressing the power button to shut down the POC.
2. Remove the X-PLOR from the carrying bag, if applicable.
3. Remove the battery from the X-PLOR. (See chapter 4)
4. Place the X-PLOR on its side to access the underside of the POC. (See image 1)
5. Remove the cartridge by pulling on the handle. (See image 2)
6. Remove the cartridge completely from the X-PLOR 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-PLOR. Do not leave the cartridge ends exposed; the cartridge should be inserted into the X-PLOR as soon the old cartridge is removed. (See image 4)
9. Push the cartridge into the X-PLOR such that the cartridge is fully seated into the X-PLOR. (See image 5)
10. The cartridge pull handle should lay flat once cartridge is secured. (See image 6)
11. Connect a charged battery to the X-PLOR.
12. Turn on the X-PLOR 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

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

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-PLOR.
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-PLOR will detect a breath and deliver the oxygen during inhalation.

7. Troubleshooting

The table below lists common problems and corrective 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-PLOR 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.
Alarm occurs	Device malfunction	Contact your equipment provider.
	The device needs your attention	Review the Alarm Indicators and Screen Symbols section for information about specific alarms.

NOTIFICATIONS

The X-PLOR has only one type of alarm (an icon on the display combined with an audible tone): that arises when monitored equipment functions indicate that the user's attention is required. Alarm notifications are audible at levels ranging from 65 dB(A) to 85 dB(A), depending on the equipment condition and the user's position. The maximum distance that the user can move away from the POC is determined by the surrounding noise level.

ALARMS

X-PLOR 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.

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

MESSAGE DISPLAY & TEXT	ICONS	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		The battery has less than 20% charge. Attach external power or swap out with 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 swap out with a charged battery, then restart.
Replace battery		Battery error has occurred. Stop using the battery and swap out with a charged 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 filter 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.
Replace cartridge		Replace the cartridge as soon as possible. Contact your equipment provider to arrange for replacement. If replacing the 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 is running on battery power and is not charging. Switch external power supply or exchange battery. If the problem persists contact your equipment provider.

MESSAGE DISPLAY & TEXT	ICONS	CONDITION/ACTION/EXPLANATION
No breath detected Check cannula		When the X-PLOR has not detected a breath for 45 seconds, this alarm will alert the user. If the X-PLOR is left idle, the alarm will continue for another 45 seconds before transitioning into No Breath Detected Mode (Auto pulse 15 BPM at current setting). The unit will remain in No Breath Detected Mode for 2 hours or until a breath is detected. To dismiss the alarm, check that the cannula is connected to the X-PLOR, positioned properly in your nose, and that there are no kinks in the tubing.

These alarms can result in the shutdown of the POC.

MESSAGE DISPLAY & TEXT	ICONS	CONDITION/ACTION/EXPLANATION
Sensor fail		The POC oxygen sensor has malfunctioned. The POC will automatically shut down. Switch to a backup source of oxygen and contact your equipment provider.
Oxygen delivery error		The POC 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 at the same time, the corresponding icons will cycle for 5 seconds on the display. If one of the alarm conditions requires the POC's shutdown, the icon for that condition will be displayed for 10 seconds before the POC shuts 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 be used to mute and acknowledge additional alarms without removing the visual alarm on the device.

INFORMATIONAL MESSAGES

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

ICONS	MEANING
X-PLOR	X-PLOR logo is displayed at startup.
X X X X %	**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 and Repleacement Parts

X-PLOR accessories available to order:

PICTURE #	ACCESSORY NAME	MODEL #
1	8-Cell Battery	50188
2	Cartridge	50073
3	Air filter	50351
4	Carry Bag	52191
5	AC Power Supply	53011
6	DC Power Supply	53021
7	Backpack	52291

1

8-Cell Battery

2

Cartridge

3

Air filter

4

Carry Bag

5

AC Power Supply

6

DC Power Supply

7

Backpack

TO REORDER CALL 877-GO-XPLOR OR VISIT XPLOROXYGEN.COM

10. Maintenance & Cleaning

DO NOT ATTEMPT TO REPAIR THE DEVICE. Contact your equipment provider or distributor for assistance. The cartridge, air filter and battery may be replaced by the patient. 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 POC's service life 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. As long as it is charged or powered the X-PLOR will operate 24 hours/7 days per week, daytime/nighttime. However, 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 in conjunction with terms and conditions for their country.

CLEANING

WARNING: To avoid electrical shock, do not disassemble the X-PLOR. The plastic outer shell should be removed 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 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-PLOR & RECHARCHEABLE BATTERY

The X-PLOR exterior shell and rechargeable battery should be cleaned as needed.

X-PLOR

To clean the exterior: wipe the outside surface of the case with a cloth dampened in 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 in 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

You may clean the carrying bag with a damp cloth and mild liquid detergent and water at room temperature.

1. Remove the X-PLOR from the carrying bag.
2. Dampen a cloth in a mild liquid detergent and water solution at room temperature. Then wipe the outside surface of the bag.
3. Allow time for the bag to completely dry before placing the X-PLOR 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 completely dry before using them again.

AIR FILTER

The air filter **SHOULD 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 **mild liquid detergent and water at room temperature**; **rinse** in **water at room temperature** and allow to **completely dry** before reuse.

WARNING: Unauthorized personnel are prohibited from disassembling the access cover.

11. Labeling symbols

SYMBOLS	MEANING
	Refer to instruction manual/ booklet.
WARNING	A warning indicates that the personal safety of the patient may be involved. Disregarding a warning could result in significant injury.
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.
Rx only	Caution: Federal (USA) law restricts this device to sale by order of a physician.
	AC Power
	DC Power
	No Smoking while device is in use.
	No Open Flames
	Manufacturer
	Keep Dry
	This Side Up
	Use No Oil or Grease.
CARTRIDGE	Replaceable cartridge
MODEL #	Model number of device

SYMBOLS	MEANING
	Do Not Disassemble (Contact your equipment provider for servicing by authorized personnel).
	Do Not Dispose of In Unsorted Municipal Waste.
	Class II Electrical Device
	Use by date
	Type BF Applied Part, complies with IEC 60601-1.
0% 95%	Non-condensing humidity lower limit 0%; upper limit 95%
140°F (60°C) 32°F (0°C)	Lower temperature limit: 0 ° C (32 ° F); Upper temperature limit: 60 ° C (140 ° F)
IP22	Ingress Protection Level 22
	Do not reuse
MR	MR Unsafe
	The manufacturer of this POC has determined this device conforms to all applicable FAA requirements for POC carriage and use on board aircraft.
RECHARGEABLE LITHIUM BATTERY Li-ion	Rechargeable Lithium-ion battery
	Fragile

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.
	Please Wait

SYMBOLS	MEANING
	User Attention Required
	Bluetooth is on
	Pulse Dose Flow

12. Specifications

CONCENTRATOR

Dimensions: With 8-cell battery	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: 3.25 lbs; with 8-cell battery: 3.75 lbs
Warm-Up Time:	Less than 2 minutes
Flow Settings:	1-4 Pulse Settings
Breath Rate:	15-40 breaths per minute
Inhalation Trigger Pressure:	<-0.2 cmH2O
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 4.5 hours for an 8-cell battery
Battery Charging Time:	Up to 6 hours for an 8-cell battery
Environmental Ranges Intended for Use:	Temperature: 41 to 104°F (5 to 40°C) Humidity: 5% to 85%, non-condensing Altitude: 0 to 10,000 feet (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% and above 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
Tested by Independent Laboratory:	Safety: IEC 60601-1 Electromagnetic Compatibility: IEC 60601-1-2

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. (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 ≤ t < 1 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	28	42	50
20	11	21	32	38
25	9	17	25	30
30	7	14	21	25
35	6	12	18	21
40	5	11	16	19
Total Volume Per Minute (ml/min)	215	425	635	750
No Breath Detected Mode	14	28	42	50

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 above 82% 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	
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.

TEST/STANDARD	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
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-PLOR system requires continued operation during power mains interruptions, it is recommended that the X-PLOR 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-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. 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-PLOR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X-PLOR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the X-PLOR 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

FCC Regulatory Compliance (FCC ID: 2BFXJ50051)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Regulatory Compliance (cont.)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

RF Exposure Compliance

This device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction. This device and its antena(s) must not be co=located or operated in conjunction with any other antenna or transmitter.

14. TRAVELING WITH X-PLOR

When you travel with your X-PLOR, 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-PLOR on board all U.S. aircrafts. The X-PLOR 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 may be required.

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. You will need to notify them in advance and find out if there is any paperwork that may be required. Carriers outside the United States may have additional requirements for POCs. Be sure you contact them in advance for any requirements or specifications.

TRAVELING IN A CAR OR MOTORIZED VEHICLE

You can charge your X-PLOR battery using your vehicle's cigarette lighter/auxiliary DC power supply. You can continue using your X-PLOR 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.

X-PLOR
X-PLOR

To contact customer service, reorder accessories, or more:

Please visit XPLOROxygen.com or call (877)-GO-XPLOR.

Belluscura Company Address:
15 Fetter Lane - London, United Kingdom EC4A 1BW
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