



DISCOV-RTM
BY belluscura



DISCOV-R Portable Oxygen Concentrator

USER-MANUAL

Live Life. Breathe Easy. Go X-PL₂O₂RTM

 belluscura[®]

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DISCOV-R Quick Start Guide Checklist

Ensure the following DISCOV-R™ components have arrived in your package:



DISCOV-R Unit



8-Cell Battery



Cartridges
found in
Mylar bag

Cartridges



Air Filter



AC Power Supply



DC Power Supply



Carry Bag



Carry Bag Handle



Carry Bag
Shoulder Strap

WARNING:

Do not use the DISCOV-R 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 DISCOV-R or any accessory shows any sign of damage, contact your equipment provider.

NOTE: Product appearance may vary.

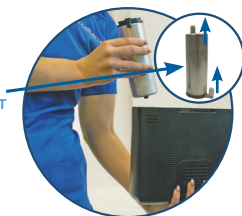
Quick Start Guide

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

1. REMOVE DUST CAPS & INSERT CARTRIDGES

- Check to see if the cartridges are already inserted into your device.
- Remove cartridges from mylar bag.
- Remove the dust caps from the cartridges.
- Then insert the cartridges all the way into the unit.

REMOVE DUST CAPS



2. ATTACH THE BATTERY & INSERT INTO BAG

- To attach the battery, slide it on until the latch is in the locked position.
- Insert your DISCOV-R into the carry bag. When the DISCOV-R is correctly inserted into the bag, the cannula connector should be lined up with the top cut-out and the air intake and exhaust are aligned with mesh panels.

RELEASE LATCH



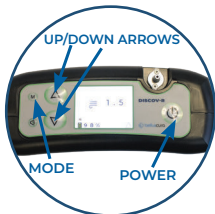
3. CHARGE THE BATTERY

- Place in a well-ventilated area to fully charge the battery before using your DISCOV-R, 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 DISCOV-R.
- Use the UP/DOWN ARROWS to set the oxygen flow level, as specified in your oxygen prescription. Use the MODE button to switch between pulse flow and continuous flow settings.



5. NASAL CANNULA

- Nasal cannula MAY be included.
- Connect the nasal cannula to the oxygen output nozzle located on top of the DISCOV-R.
- 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 DISCOV-R

- Attach the shoulder strap and handle to your DISCOV-R device and enjoy your new found mobility!



1. Introduction

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

Before using the DISCOV-R 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 DISCOV-R in order to operate the POC.

Please refer to the DISCOV-R 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 DISCOV-R 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% by volume) 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

DISCOV-R delivers concentrated oxygen in pulse mode by responding to the patient’s inhalations and continuous flow. 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 DISCOV-R is 5 years. The service life of the replaceable cartridges will depend on operating conditions. Replace the cartridges as needed, when indicated by the alarm message (For more information on the Replaceable Cartridges 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 DISCOV-R. 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 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:** Any modification to the equipment may impair performance or damage equipment and will void your warranty.

GENERAL PRECAUTIONS

- WARNING:** Smoking while using oxygen is dangerous and likely to result in facial burns or death. **DO NOT ALLOW SMOKING OR OPEN FLAMES WITHIN THE SAME ROOM OF THE DISCOV-R 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 DISCOV-R 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 DISCOV-R to avoid the risk of fire or burns. Use products that are oxygen compatible when using or setting up near the DISCOV-R.

WARNINGS

- The operator should read and understand this entire manual before using the DISCOV-R.
- 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 DISCOV-R 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 DISCOV-R 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 DISCOV-R. Either of these results could affect operation of your unit.
- Only use a standard single lumen nasal cannula. Nasal cannula should be rated for 10 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 DISCOV-R 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 pulse settings of DISCOV-R 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 DISCOV-R.
- Wind or strong drafts can adversely affect accurate delivery of oxygen.
- 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.


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 DISCOV-R 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 DISCOV-R 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 DISCOV-R

The DISCOV-R offers pulse dose and continuous flow.

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 (1-8).

Continuous Flow:

Continuous flow will deliver a continuous flow of oxygen. Please note that the higher power draw will shorten battery run time. Use the MODE (M) button or UP/DOWN button to set the oxygen flow level 0.5 LPM to 2.0 LPM.


No Breath Detected Mode:

If the DISCOV-R 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 DISCOV-R 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. Only detecting breath in Pulse Dose Mode.

OVERVIEW OF THE DISCOV-R



TURNING ON THE DISCOV-R

- PRESS and HOLD the POWER button for two seconds.
- While the DISCOV-R is warming-up (total warm-up time is less than two minutes) the DISCOV-R 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.
- DISCOV-R should be operated in an upright position.
- After warm-up, proper operation of the DISCOV-R is indicated by the delivery of oxygen pulses in response to inhalation and the absence alarms.

TURNING OFF THE DISCOV-R

- To turn off the DISCOV-R, 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 DISCOV-R will remain at that flow-setting upon 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 DISCOV-R provides both Pulse Dose and Continuous Flow to provide oxygen when the user needs it most.



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 (1-8).

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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 DISCOV-R 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 DISCOV-R 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 DISCOV-R without the air filter in place. Particles drawn into POC may damage the DISCOV-R. 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 DISCOV-R in the supplied carrying bag, with the supplied handle and/or shoulder strap. The DISCOV-R is correctly inserted in the bag when the cannula connector is aligned with the cut out and the air intake and exhaust are aligned with mesh panels.



4. Battery

DISCOV-R comes with an 8-cell lithium ion battery that powers the DISCOV-R with or without an external power supply connected. Fully charge the battery before using the DISCOV-R.

Charge the DISCOV-R battery only with the power supplies provided with the DISCOV-R. 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

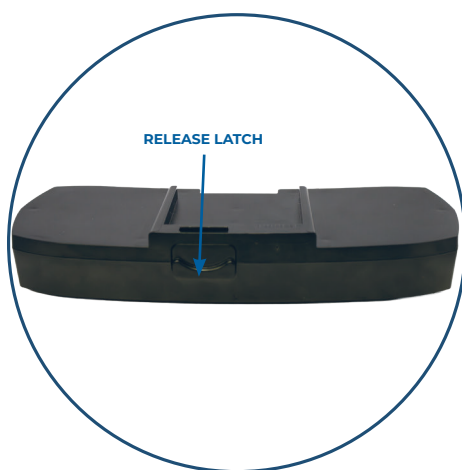
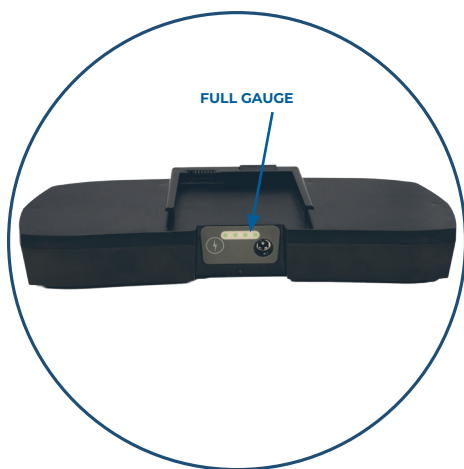
The AC power supply allows the DISCOV-R to be powered on and the battery to be charged from a standard 100-240 VAC, 50/60 Hz electrical outlet.

The DC power supply allows the DISCOV-R 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 DISCOV-R provided batteries. 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 DISCOV-R 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 DISCOV-R. Without the battery connected, the DISCOV-R 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 cartridges and battery pack. Cool system off before changing parts.
- WARNING:**


When operating DISCOV-R 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:**

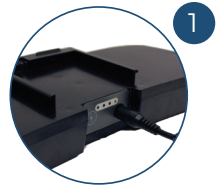
The battery should be fully charged before the first time you use that battery with the DISCOV-R.
- CAUTION:**

Only remove the battery when DISCOV-R is turned off. Do not remove the battery while the DISCOV-R 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 DISCOV-R 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 DISCOV-R, 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 DISCOV-R, 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 DISCOV-R or while the battery is disconnected from the DISCOV-R.
 - 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 DISCOV-R 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



Secure latch

STEPS TO DISCONNECT



Release latch

5. User-Replaceable Cartridges


Your DISCOV-R may have cartridges inserted into your unit. Cartridges not inserted will arrive in a Mylar bag in the box with your DISCOV-R. You have to insert the cartridges into the unit before using the DISCOV-R. Do not remove the dust caps until it is time to install the cartridges.


To insert the cartridges, first ensure the POC is powered off and then disconnect the battery (See Chapter 4). Remove cartridges from mylar bag and then remove dust caps from the top of the cartridges (See page 13). Push the cartridges top first into the unit until they are fully inside and the latches lock into place. (See page 13). Once the cartridges are in place, reconnect the battery.

Over time cartridges, like a filter, can lose their effectiveness and need be to replaced. The service life of the cartridges depend 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.



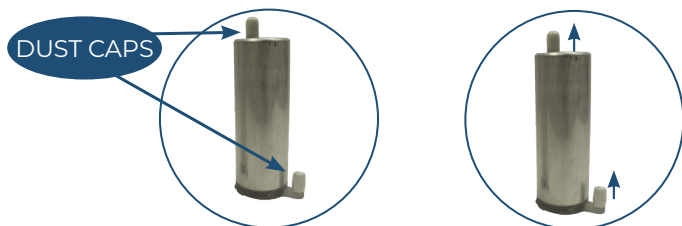
CAUTION: Cartridge replacement instructions are only to be used when maintenance is required and are not intended for practice purpose.

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

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

CARTRIDGES REPLACEMENT

1. Turn off the DISCOV-R by pressing the power button to shut down the POC.
2. Remove the DISCOV-R from the carrying bag, if applicable.
3. Remove the battery from the DISCOV-R. (See chapter 4)
4. Place the DISCOV-R on its side to access the underside of the POC. (See image 1)
5. Remove cartridges by pulling on the handle. (See image 2)
6. Remove cartridges completely from the DISCOV-R and throw it away. (See image 3)
7. Remove cartridges from Mylar bag. The new cartridges have 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 cartridges top first into the DISCOV-R. Do not leave the cartridges ends exposed; the cartridges should be inserted into the DISCOV-R as soon the old cartridges is removed. (See image 4)
9. Push the cartridges into the DISCOV-R such that the cartridges are fully seated into the DISCOV-R. (See image 5)
10. The cartridge should engage and the pull handle should lay flat once cartridges are secured. (See image 6)
11. Connect a charged battery to the DISCOV-R.
12. Turn on the DISCOV-R by pressing the power button for 2 seconds. Set the Flow Setting to your prescribed setting and use normally.



STEPS FOR CARTRIDGES REPLACEMENT

REMOVING CARTRIDGES



INSTALLING CARTRIDGES




6. Nasal Cannula

One nasal cannula may be included with the DISCOV-R kit.

The proper placement and positioning of the nasal cannula in the nose is critical to the consistent operation of the DISCOV-R. 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 DISCOV-R.
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 in pulse mode, 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. DISCOV-R will detect a breath and deliver the oxygen during inhalation during pulse mode. Continuous flow setting oxygen will be delivered at the set volume.



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 | DISCOV-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. |
| 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. |


8. Alarms








NOTIFICATIONS


The DISCOV-R 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



DISCOV-R 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 cartridges |  | Replace the cartridges as soon as possible. Contact your equipment provider to arrange for replacement. If replacing the cartridges does not clear the alarm, then switch to a backup source of oxygen and contact your equipment provider. |

| MESSAGE DISPLAY & TEXT | ICONS | CONDITION/ACTION/EXPLANATION |
|-------------------------------------|---|--|
| No breath detected Check cannula |  | When the DISCOV-R has not detected a breath for 45 seconds, this alarm will alert the user. If the DISCOV-R 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 until a breath is detected. To dismiss the alarm, check that the cannula is connected to the DISCOV-R, positioned properly in your nose, and that there are no kinks in the tubing. |



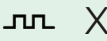
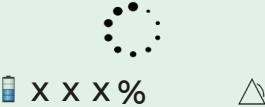

These alarms can result in the shutdown of the POC.

| 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 |
|---|---|
|  | DISCOV-R logo is displayed at startup. |
|  | XXX ml/min is the IFU stated flow |
|  | 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 Replacement Parts

DISCOV-R accessories available to order:

| PICTURE # | ACCESSORY NAME | MODEL # |
|-----------|-----------------|---------|
| 1 | 8-Cell Battery | 70188 |
| 2 | Cartridges | 70073 |
| 3 | Air filter | 70351 |
| 4 | Carry Bag | 72191 |
| 5 | AC Power Supply | 73011 |
| 6 | DC Power Supply | 73021 |
| 7 | Backpack | 72291 |
| 8 | Cart | 72391 |

1



8-Cell Battery

2



Cartridges

3



Air filter

4



Carry Bag

5



AC Power Supply

6



DC Power Supply

7



Backpack

8



Cart

**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 cartridges, 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 DISCOV-R 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 DISCOV-R. 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.

DISCOV-R & RECHARGEABLE BATTERY

The DISCOV-R exterior shell and rechargeable battery should be cleaned as needed.

DISCOV-R

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 DISCOV-R 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 DISCOV-R 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 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 | 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 | SYMBOLS | MEANING |
|---|-------------------------------------|---|-------------------------|
|  | The Audible Alarm has been enabled. |  | User Attention Required |
|  | The Audible Alarm is disabled. |  | Continuous Flow |
|  | Please Wait |  | Pulse Dose Flow |

12. Specifications

CONCENTRATOR

| | |
|--|--|
| Dimensions: With 8-cell battery | L / W / H : 9.3 in. (23.6 cm.) / 4.1 in. (10.4 cm.) / 9.9 in. (25.2 cm.) |
| Weight of unit with: | Without battery: 6.5 lbs; with 8-cell battery: 7.1 lbs |
| Warm-Up Time: | Less than 2 minutes |
| Flow & Continuous Control Settings: | 1-8 pulse; 0.5 to 2 LPM continuous |
| Breath Rate: | 15-40 breaths per minute |
| Inhalation Trigger Pressure: | <-0.24 cmH2O |
| Maximum Outlet Pressure: | 21 psig (144.79 kPa) |
| Sound: | <54 dB(A) at 2 lpm continuous flow |
| 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 (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: | Above 82% 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: | $10s \leq t < 1 \text{ min}$ 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 | Setting 5 | Setting 6 | Setting 7 | Setting 8 |
|----------------------------------|--|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Breaths Per Minute | Pulse volumes (ml) +/- 15%, per ISO 80601-2-67 | | | | | | | |
| 15 | 16.7 | 33.3 | 50.0 | 66.7 | 83.3 | 93.3 | 103.3 | 113.3 |
| 20 | 12.5 | 25.0 | 37.5 | 50.0 | 62.5 | 70.0 | 77.5 | 85.0 |
| 25 | 10.0 | 20.0 | 30.0 | 40.0 | 50.0 | 56.0 | 62.0 | 68.0 |
| 30 | 8.3 | 16.7 | 25.0 | 33.3 | 41.7 | 46.7 | 51.7 | 56.7 |
| 35 | 7.1 | 14.3 | 21.4 | 28.6 | 35.7 | 40.0 | 44.3 | 48.6 |
| 40 | 6.3 | 12.5 | 18.8 | 25.0 | 31.3 | 35.0 | 38.8 | 42.5 |
| Total Volume Per Minute (ml/min) | 250 | 500 | 750 | 1000 | 1250 | 1400 | 1550 | 1700 |

| Continuous Flow | | | |
|-----------------|-----|-------|-----|
| 0.5 L | 1 L | 1.5 L | 2 L |

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


DISCOV-R 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 DISCOV-R are related only to its internal function, and it is unlikely to interfere with other equipment.

- WARNING:** Do not stack the DISCOV-R 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 DISCOV-R while it is in operation. RF equipment may degrade the performance of the POC. If DISCOV-R is exposed to a radio frequency of 450 MHz, it may shut down without providing an alarm. This shutdown will not harm DISCOV-R and it can be restarted after it is relocated away from the source of the emission.

GUIDANCE & MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The DISCOV-R 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 DISCOV-R system requires continued operation during power mains interruptions, it is recommended that the DISCOV-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 DISCOV-R is exposed to a radio frequency of 450 MHz, it may shut down without providing an alarm. This shutdown will not harm DISCOV-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 DISCOV-R is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DISCOV-R can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the DISCOV-R 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 DISCOV-R

When you travel with your DISCOV-R, 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 DISCOV-R on board all U.S. aircrafts. The DISCOV-R 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 DISCOV-R battery using your vehicle's cigarette lighter/auxiliary DC power supply. You can continue using your DISCOV-R 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.





To contact customer service, reorder accessories, or more:

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

Belluscura Company Address:

15 Fetter Lane - London, United Kingdom EC4A 1BW
5504 Democracy Drive, Suite 200, Plano, TX 75024



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