Item **33955**

Resp-O2™

Portable Oxygen Concentrator

User's Manual

DEHP

MR

IP22

1060 hPa
700 hPa

90%
10%

140˚F
60˚C
-4˚F
-20˚C

The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.

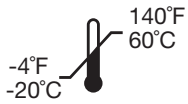
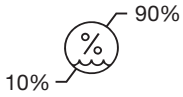
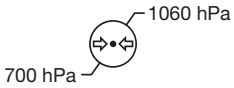
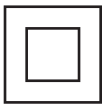
℞ Only

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Not made with natural rubber latex.

Contents

1. Symbol Definitions

Symbol	Description
	Does not contain Phthalates (DEHP)
	Keep dry
	Keep away from sunlight Note: This symbol can also mean "Keep away from heat," as referenced in ISO 7000:1989.
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Consult instructions for use
	Warnings/Caution/Attention
	Type BF applied part
	Class II equipment
	Prescription use only
	Serial number
	Fragile, handle with care
	Top
	The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.

Symbol	Description
	WEEE; waste electrical and electronic equipment
IP22	Ingress protection
	Not to be serviced by users
	No oil or grease
	MR unsafe
	No Smoking
	No Open Flame, no open ignition source, and smoking is prohibited
	Not made with natural rubber latex.
	Power switch
	Increase prescription setting button
	Decrease prescription setting button

2. Introduction

Note: In this manual, the Resp-O_2™ Portable Oxygen Concentrator may be referred to as the "Resp-O_2 POC," "POC," "Unit," or "Device".

2.1 Indication for Use

The Resp-O_2™ Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to adult patients requiring respiratory therapy on a prescriptive basis. It may be used in the home and in professional healthcare facilities.

2.1.1 Operator Notes

The operator of the POC should have the ability to read and understand this manual in order to operate the equipment properly.

A conscious patient who meets the above requirements may operate the device. Intended environment: home and professional healthcare facilities.

⚠ **WARNING**: This device is not intended for adolescent, pediatric, newborn, or infant use. The device is intended only for adult patients requiring respiratory therapy on a prescriptive basis only.

2.2 How the Device Works

A concentrator separates oxygen from room air, which allows high-purity supplemental oxygen to be delivered to the patient through the oxygen outlet. Although the concentrator filters the oxygen, it does not affect the normal amount of oxygen in the room. This pulse concentrator delivers the full dose (bolus) of oxygen on each breath, right at the start of inhalation.

If the device is on and no breathing is detected after 60 seconds, the device will trigger the "No Breath Detected" alarm until breathing is detected again or battery is depleted.

It is the responsibility of the patient to plan for a backup oxygen supply when traveling; Dynarex assumes no liability for any disruptions in oxygen supply if a backup source is not secured.

If you feel ill or uncomfortable, or if the concentrator does not signal an oxygen pulse and you are unable to hear and/or feel the oxygen pulse, consult a physician **IMMEDIATELY**.

2.3 Contraindications

The device is not intended to be life-supporting or life-sustaining, nor does it provide any patient monitoring capabilities.

Only use this product if the patient is capable of spontaneous breathing (able to inhale and exhale without the use of a machine).

Some respiratory efforts of the patient might not trigger the conserving equipment.

Do not use on patients whose breathing during normal resting is unable to trigger the device.

This device is not intended to be used with other medical devices. Do not use in parallel with other oxygen concentrators or oxygen therapy devices.

The device is not intended for use with a tracheotomized patient.

2.4 Risk of Minor Injury or Discomfort

The device, parts, and accessories are specified for use at flow rates between settings 1 and 6. Incompatible parts and accessories can result in degraded performance or damage and may void your warranty.

The device is designed to provide a flow of high-purity oxygen. An advisory alert, "Oxygen Low", will inform you if oxygen concentration drops. If alarm persists, contact your point of purchase, the manufacturer, or an authorized service center for assistance.

The oxygen flow setting must be determined and recorded for each patient individually by the prescriber, including the configuration of the device, its parts, and the accessories. It is the responsibility of the patient to periodically reassess the setting(s) of the therapy for effectiveness.

Do not modify the device. Any modifications performed on the equipment may impair performance or damage equipment and will void your warranty unless indicated or instructed to do so.

Do not obstruct air intake or exhaust when operating the device. Blocking air circulation or placing the device close to a heat source may lead to internal heat buildup and shutdown or damage to the concentrator. In the event of changes to the performance of the device, please refer to the troubleshooting section of this document.

Do not operate the device without the particle filters in place. Particles drawn into the system may damage the equipment.

Do not wrap cords around power supply for storage. Do not drive, drag, or place objects over cord. Doing so may lead to damaged cords and a failure to provide power to the concentrator.

Do not disassemble the power supply. This may lead to component failure and/or safety risk.

The device will perform as specified only when used within the altitude, temperature, and humidity ranges as specified in these instructions for use.

The device should be kept dry at all times. Exposure to water may lead to electrical shock and/or damage.

For optimal sieve bed life, the product is intended for frequent use.

The device's battery acts as a secondary power supply in the event of a planned or unexpected loss of the external power supply. Even when operating the device from an external power supply, a properly inserted battery should be maintained in the unit. Doing so will minimize the risk of interrupted operation and will keep alarms functioning.

The power supply should be placed in a well-ventilated location, as it relies on air circulation for heat dissipation. The power supply may become hot during operation. If this happens, allow it to cool down before handling to avoid injury.

A change in altitude (for example, from sea level to mountains) may affect the 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.

2.5 ESSENTIAL PERFORMANCE

The device maintains the following as essential performance requirements:

Item	Description
Delivery of oxygen, in both normal condition and single fault condition, within the performance levels as indicated in the instructions for use or generation of an alarm condition	1. Maximum recommended flow: 1260 mL +/- 15%. 2. Oxygen concentration: 90% (-3%, +6%).
Power supply failure technical alarm condition	When a power supply failure occurs, the ME equipment generates an alarm.
No breath detected alarm condition	When no breath is detected, the ME equipment generates an alarm.
Low oxygen concentration technical alarm condition	When the oxygen concentration is <87% after powering on, the ME equipment generates an alarm.
Component failures	The ME equipment shall have no component failures.
Changes in programmable parameters or settings	The ME equipment shall not change programmable parameters or settings
Reset to default settings	The ME equipment shall not reset to default settings.
Change of operating mode	The ME equipment shall not change operating modes
Initiation of an unintended operation	The ME equipment shall not initiate an unintended operation.

Note: the ME equipment means the Resp-O2 Portable Oxygen Concentrator.

2.6 ESSENTIAL SPECIFICATIONS

Dimensions (H x W x L)	(excluding battery): 187 x 88 x 184 mm (including battery): 187 x 88 x 217 mm (8-Core battery)
Weight	1.64 kg without battery 2.16 kg with 8-core battery
Oxygen Prescription Settings	1-6 Flow settings
Operating Temperature Range*	5°C - 40°C (41°F -104°F)
Operating Humidity Range	15% to 90%, non-condensing
Operating Atmospheric Pressure Range*	70 kPa to 106 kPa (0 - 10,000 ft (0 - 3048 m)
Transport & Storage Temperature Range	- 20°C +60°C (-4°F to +140°F)
Transport & Storage Humidity Range	10% to 90% non-condensing. Store in a dry environment.
Initiation of an unintended operation	The ME equipment shall not initiate an unintended operation.
Maximum Outlet Pressure	<199 kPa (28.9 psi)
Maximum Breathing Rate	40 BPM
Warm up time	2 minutes
Output Oxygen Concentration*	90% + 6% and - 3% at all settings

<table>
<tr><td>Inspiratory Trigger Sensitivity</td><td colspan="3"><0.12 cm H_2O</td></tr>
<tr><td>Sound Level</td><td colspan="3">43 dBA typical at setting 2
Maximum system sound pressure of 61 dBA
Maximum system sound power of 66 dBA</td></tr>
<tr><td>AC/DC Adaptor Powered</td><td colspan="3">Input: 100-240VA.C., 50-60 Hz, 2.0-1.0A
Output: 24V D.C., 5A, 120W</td></tr>
<tr><td>Battery Powered</td><td colspan="3">14.8V D.C., 6.4A, 94.72 Wh</td></tr>
<tr><td>OSD Set Points</td><td colspan="3">≥ 82% - Normal Oxygen Symbol (Green)
< 82% - Low Oxygen Symbol (Yellow) and Audible Alert</td></tr>
<tr><td>Type of Protection Against Electrical Shock</td><td colspan="3">Class II</td></tr>
<tr><td>Ingress of Water or Particulate Matter into ME Equipment</td><td colspan="3">IP22
The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm Φ, 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mm Φ and greater.
The second number 2: Protected against vertically falling water drops when enclosure is tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.</td></tr>
<tr><td rowspan="5">Uncertainty of Parameter Measurement</td><td>Test Parameter</td><td>Device Accuracy</td><td>Measurement Uncertainty</td></tr>
<tr><td>Pulse Volumes</td><td>± 15% of rated volume</td><td>±2.3%</td></tr>
<tr><td>Oxygen Concentration</td><td>+ 6% and - 3% at all setting</td><td>1.3%</td></tr>
<tr><td>Pressure</td><td>±1.5%</td><td>±0.66%</td></tr>
<tr><td colspan="3">Note: The tolerances declared in this document include the uncertainty of the measurement.</td></tr>
</table>

*Operating outside these operational specifications may prevent the concentrator from meeting the oxygen concentration and flow delivery values listed in the technical specifications section of this manual.

WARNING

When moving the POC from an extreme environment, allow time for the device to acclimate to the recommended operating environment. Operating the concentrator outside the recommended operating environment may impact performance, cause damage, and will void the warranty.

AUDIBLE ALERTS:

Low Priority Alarms (The following low-priority alarms are accompanied by two beeps and a solid yellow frame) repeated every 25 seconds:

- Low Battery • Oxygen Low • Service Soon • Replace Sieve beds• Warming Up
- System Hot Warning • Battery Hot Warning

Medium Priority Alarms (The following low-medium priority alarms are accompanied by three beeps and a yellow frame flash) repeated every 25 seconds:

- System Malfunction • Fan Failure • High Pressure
- No Breath Detected
- Oxygen Error and Oxygen Delivery Error
- Battery Hot, System Hot, and System Cold
- Sensor Fail
- Low Battery, Shutdown

2.7 STANDARD PULSE DOSE OUTPUT

Pulse Volumes per Flow Setting (Deliverable accuracy: mL/breath±15% Per ISO 80601-2-67 at STPD*)							
Breath Per Minute		Setting 1	Setting 2	Setting 3	Setting 4	Setting 5	Setting 6
		Pulse Volumes (mL)					
10		21.0	42.0	63.0	84.0	105.0	126.0
15		14.0	28.0	42.0	56.0	70.0	84.0
20		10.5	21.0	31.5	42.0	52.5	63.0
25		8.4	16.8	25.2	33.6	42.0	50.4
30		7.0	14.0	21.0	28.0	35.0	42.0
35		6.0	12.0	18.0	24.0	30.0	36.0
40		5.25	10.5	15.75	21.0	26.3	31.5
Flow Rate	Total volume per minute (mL/min)	210	420	630	840	1050	1260
	Total volume per minute (L/min)	0.21	0.42	0.63	0.84	1.05	1.26

*STPD is 101.3 kPa at an operating temperature of 20°C, dry

2.8 SAFETY INSTRUCTIONS

READ ALL INSTRUCTIONS BEFORE USING.

IMPORTANT

- The device is to be used only on the instruction of a licensed physician. It is intended for the administration of supplemental oxygen to adults as indicated by the physician. It is a body-worn device, and is not intended to be used with other medical devices.
- Do not use an extension cord or power strip with the concentrator. Plug directly into a grounded wall outlet.
- Inhale through the nose for the concentrator to work most effectively. Inhaling through the mouth may result in less effective oxygen therapy.

⚠ WARNING

- **DANGER-NO SMOKING**
- Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking or open flames within the same room as the oxygen concentrator 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 mask or the oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after you have turned the oxygen concentrator off.
- ISO 80601-2-69 (Standard for Oxygen Concentrators) highly recommends that the accessory cannula that delivers gas to the user from the oxygen concentrator should include a Fire Stop Check Valve to stop the flow of oxygen towards the user if the accessory cannula ignites. The Fire Stop Check Valve should be located as close to the user as is reasonably practicable. The organization that supplies this equipment to the patient is responsible for ensuring the compatibility of the accessories used to connect the patient to the oxygen concentrator to meet the requirements of ISO 80601-2-69.
- Do not smoke where the oxygen concentrator or any oxygen carrying accessories are located. Do not smoke while your oxygen concentrator is operating, or when you are near a person utilizing oxygen therapy.
- Do not use in an oxygen-rich environment.
- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.
- Open flames during oxygen therapy are dangerous and are likely to result in fire or death. Do not allow open flames or hot, sparking objects within 2 m (6.5 feet) of the oxygen concentrator, cannula, or any oxygen carrying accessories.

Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula on bed coverings or chair cushions when the oxygen concentrator is turned on but not in use, as this may make the materials flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.

- Do not leave device running when not in use. Do not leave cannula unattended while POC is delivering oxygen. High concentrations of oxygen can cause rapid burning.

WARNING: To ensure the therapeutic amount of oxygen delivery is received according to your medical condition, the Portable Oxygen Concentrator must:

- Be used with settings that have been individually determined or prescribed for you at your activity levels with your accessories.
- Be used with a specific combination of parts and accessories that are in line with the specifications of the oxygen concentrator or accessory manufacturer.

WARNING: The settings of the POC might not correspond with continuous flow oxygen devices.

WARNING: The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of the POC.

WARNING: Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.

WARNING: Do not lubricate fittings, connections, tubing, or other accessories of the oxygen concentrator to avoid the risk of fire and burns.

⚠ WARNING

WARNING - ELECTRIC SHOCK HAZARD

- Do not use while bathing.
- Do not immerse this device in water or any other liquid.
- The equipment must be connected to an appropriate power source when loss of power source would result in an unacceptable risk.
- Do not use power supplies, power cables, or accessories other than those specified in this User Manual. The use of non-specified power supplies, power cables, or accessories may create a safety hazard and/or impair equipment performance.
- Do not attempt to open or remove the cover. There are no user-serviceable internal components. If service is required, contact your point of purchase, the manufacturer, or an authorized service center for assistance. Opening or attempting to service your device will void the warranty.

⚠ WARNING - POSITION AND USAGE

- Position your POC near an electrical outlet at least 6 inches (16 cm) from walls, draperies, or any other objects that might prevent the proper flow of air in and out of your device. The POC should be located so as to avoid pollutants or fumes, and placed in a well-ventilated place so that the air inlet and exhaust are not blocked. Do not cover POC with a blanket, towel, quilt, or other covering, as the POC may overheat.
- Do not position equipment in a way that makes it difficult to operate the disconnection device. (Plug, appliance coupler, or adaptor are considered disconnection devices from mains supply.)
- Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns.

WARNING: Wind or strong drafts can adversely affect accurate delivery of oxygen therapy.

- The responsible organization is accountable for ensuring the compatibility of the oxygen conserving equipment and all of the parts or accessories used to connect to the patient before use.
- Improper use of the power cord and plugs can cause burns, fires, or other electric shock hazards. Do not use the POC if the power cord is damaged.
- Position oxygen tubing and power supply cords to prevent tripping hazards and reduce the possibility of entanglement or strangulation.
- Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

- When device is used under extreme operating conditions, the temperature near the exhaust vents on the bottom of the POC may reach 57˚C (134.6˚F). Keep bare skin away from this area.
- The following surface temperatures may exceed 41˚C (105.8˚F) under extreme conditions:
- External surface of POC..... 52˚C (125.6˚F)
- External power supply..... 43˚C (109.4˚F)
- Exhaust gas at discharge port..... 53˚C (127.4˚F)
- Battery Pack..... 60˚C (140.0˚F)

Keep bare skin away from these areas.

⚠ WARNING

- If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.
- Geriatric patients or any other patients unable to communicate discomfort may require additional monitoring and/or a distributed alarm system to convey the information about the discomfort and/or the medical urgency to the responsible caregiver to avoid harm.
- Use of this device at an altitude above 10,000 feet (3048 m) or above a temperature of 40˚C (101˚F) or greater than 90% relative humidity (non-condensing) is expected to adversely affect the flow volume and the percentage of oxygen, and consequently the quality of the therapy.
- Smoking during oxygen therapy is dangerous. Refer to specifications for details regarding parameters tested.
- The oxygen delivery setting must be determined for each patient individually with the configuration of the equipment to be used, including accessories. It is very important to follow the prescription determined by your physician.
- Your delivery settings of the oxygen concentrator should be periodically reassessed for the effectiveness of therapy.
- To ensure you receive the therapeutic amount of oxygen delivery according to your medical condition, this device must:
  - o be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
  - o be used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer and that were used while your settings were determined.
- The setting of other models or brands of oxygen therapy equipment do not correspond with the settings of this device.

⚠ WARNING

- The proper placement and positioning of the prongs of the nasal cannula in the nose is critical to the amount of oxygen delivered to the respiratory system of the patient.
- Some respiratory efforts of the patient might not trigger the conserving equipment.
- Wind or strong drafts can adversely affect accurate delivery of oxygen therapy.
- This device is not intended for use with a tracheotomized patient.

⚠ WARNING

- To avoid electric shock, do not remove the concentrator cover. The cover should only be removed by a qualified technician. Do not apply liquid directly to the cover or utilize any petroleum-based solvents or cleaning agents.
- Before attempting any cleaning procedures, turn the device "Off" and disconnect from AC power.
- Do not service or clean this device while in use with a patient.
- Use no lubricants, oils, or grease.
- Use of harsh chemicals (including alcohol) is not recommended. If bactericidal cleaning is required, a non-alcohol-based product should be used to avoid inadvertent damage.

WARNING

- This device contains electrical and/or electronic equipment. Follow local governing ordinances and recycling plans regarding disposal of device components.
- Do not expose or use the device or accessories in a Magnetic Resonance (MR) environment, as it may cause unacceptable risk to the patient or damage to the POC or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
- Do not expose or use the device or accessories in an environment with electromagnetic equipment such as diathermy, lithotripsy, CT scanners, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems like anti-theft/electronic article surveillance systems, metal detectors, as well as wireless power transfer (WPT) to prevent unacceptable risk to the patient or damage to the POC. Some electromagnetic sources may not be apparent. If you notice any unexplained changes in the performance of this device or if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your point of purchase, the manufacturer, or an authorized service center for assistance.
- This device is suitable for use in home and healthcare environments except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of Electromagnetic Disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- When voltage variations or dips in the power supply occur, the compressor of the oxygen generator will stop for approximately 0.5 seconds and then return to normal operation. To prevent voltage fluctuations from affecting the oxygen generator, please use a stable power supply.
- When the oxygen generator suddenly and unexpectedly loses external power supply, it will stop working and generate an alarm. Even when operating the device from an external power supply, a properly inserted battery should be maintained in the oxygen generator. Doing so will minimize the risk of interrupting operation and will keep alarms functioning.

WARNING

THE FOLLOWING BATTERY SAFETY WARNINGS MUST BE OBSERVED AT ALL TIMES:

- Do not drop, hit, crush, or otherwise abuse the battery as this may result in the exposure of the cell contents, which are corrosive.
- Do not subject battery to mechanical shock.
- In the event of a battery leak, do not allow the liquid to come in contact with skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- Do not expose the battery to fire or extreme heat. Do not incinerate. Exposing the battery to extreme heat may result in an explosion. Avoid storage in direct sunlight.
- Do not expose the battery to water, rain, or moisture of any type.
- Do not expose the battery to fire, or excessive heat.
- Do not crush, disassemble, puncture, or short-circuit the connector terminals.
- Do not open, disassemble, or attempt to repair the battery. There are no user-serviceable parts inside.
- Do not short-circuit the battery.
- Do not store batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.
- Keep batteries out of the reach of children.

- Keep batteries clean and dry.
- Only use the battery in the application for which it was intended.
- Periodically inspect connection cords, connector tips, and power supply for damage or signs of wear. Discontinue use if damaged.
- Charge the battery before initial use.
- Recommended maximum time between charges = 1 year.
- Recommendation: Store the battery below 25°C (77°F), in a low-humidity, dust-free environment, away from corrosive gases. Store fully charged if possible.
- This device contains electrical and/or electronic equipment. Follow local governing ordinances and recycling plans regarding disposal of device components.
- The battery must be recycled or disposed of properly.

⚠ CAUTION

- Additional monitoring or attention may be required for patients using this device who are unable to hear or see alerts or communicate discomfort. If the patient shows any signs of discomfort, a physician should be consulted immediately.
- The device is not designed or specified to be used in conjunction with a humidifier, nebulizer, or connected with any other equipment. Use of this device with a humidifier, nebulizer, or connected with any other equipment may impair performance and/or damage the equipment. Do not modify the device. Any modifications performed on the equipment may impair performance or damage the equipment and will void your warranty.
- Never leave the device in an environment that may reach high temperatures, such as an unoccupied vehicle in hot weather. This could damage the device.
- Do not operate the device without the particle filters in place. Particles drawn into the system may damage the equipment.
- To ensure oxygen flow, ensure that the nasal cannula is properly connected to the nozzle fitting and that the tubing is not kinked or pinched in any way.
- Replace the nasal cannula on a regular basis. Check with the manufacturer or physician to determine how often the cannula should be replaced.
- Ensure the power supply is powered from only one power source at any given time.
- A change in altitude (for example, from sea level to 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.

This User Manual is intended for the specified patient population and reflects the expected training and knowledge required for appropriate device operation.

WARNING: Do not use the product without first reading the User Manual. Do not operate this device if unsure of its operation or function. Contact your point of purchase, the manufacturer, or an authorized service center for assistance.

3. POC OVERVIEW

3.1 Setup Instructions

- **IMPORTANT PARTS OF YOUR CONCENTRATOR**

DISPLAY SCREEN

The POC display contains power status icons, flow setting icons, text within informational messages, and error notifications.

The display screen in battery mode

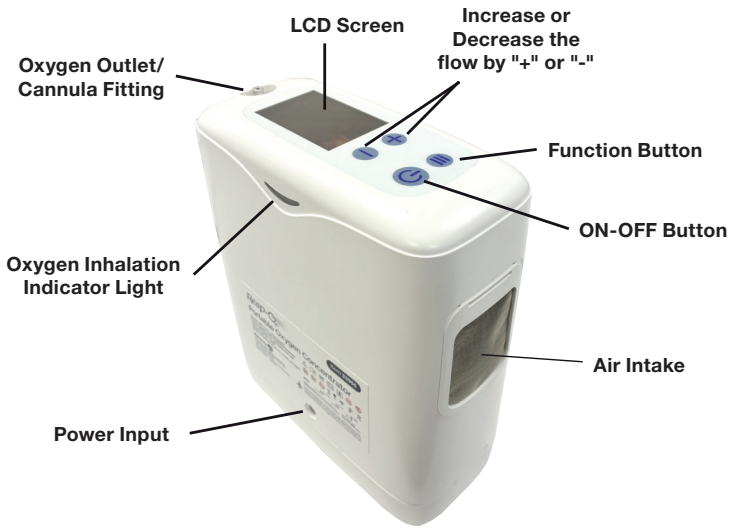
The display screen in AC mode

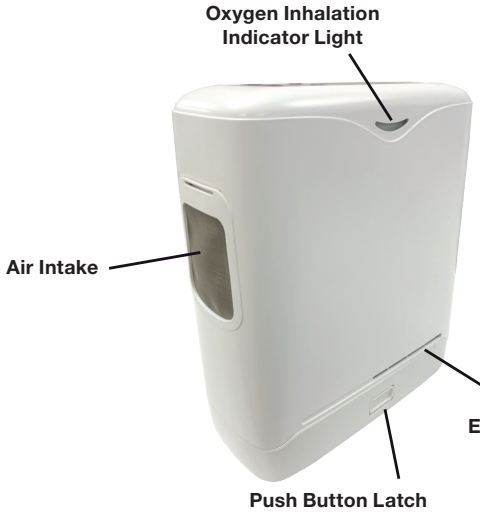
No.	Icon Name	Description
1	Power Status Icons	Located on the upper right. Displays ICONS when the battery works alone. When AC power supply is plugged in, the battery graph displays a lightning icon to indicate that the battery is charged.
2	Flow Setting	Located on the left side. It displays the current flow setting. It can be changed through the flow control (+) button or flow control (-) button.
3	Working Status	When the device is operating normally, the Resp-O_2™ logo and "Normal Running" are displayed on the LCD screen. If the device is operating under abnormal conditions, alarm icons and messages will appear in a yellow frame on the LCD screen.

NOTE–A backlight will illuminate the screen within 60 seconds, no matter which button is briefly pressed.

NOTE–A backlight will illuminate the screen under alarm conditions.

NOTE–During normal operation, the backlight turns off when the device is not being operated.





NOTE: Both sides light up when inspiration is sensed.

WARNING
This area can emit hot exhaust gas. Do not place near bare skin.

Fig. 1

NOTE– The Oxygen Inhalation Indicator does not provide a visual alarm signal.

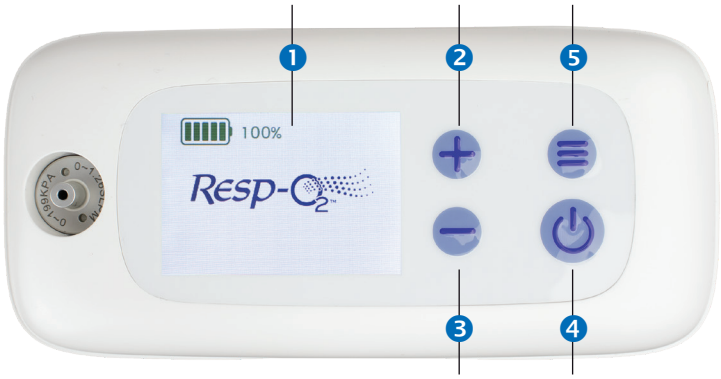


Fig. 2 User Interface

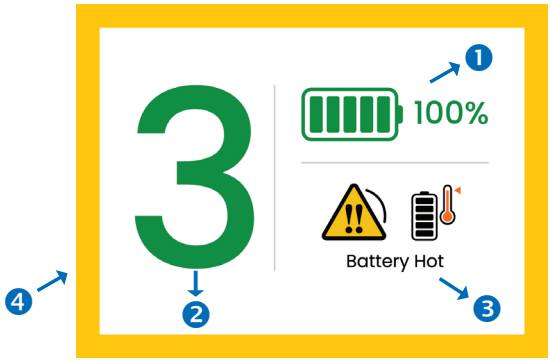


Fig. 3 LCD Display When Alarm Condition is Triggered

Item	Description	Function Button
1	Battery Status	"" shows the status of the battery and battery volume. - "NN%" shows: percent of battery remaining. - "" means: Charging
2	Current Setting	There are six settings, from 1 to 6.
3	Alarm Symbol and Information	Details are included in Section 4.2.
4	Yellow Graphical Simulation of an Indicator Light	When the alarm condition is triggered, the simulation light will turn yellow.

FUNCTION BUTTON

Press the function button once to enter the following interface to view the information or check the parameters of each function module.

It includes battery, sieve, and device selection (fig. 4).

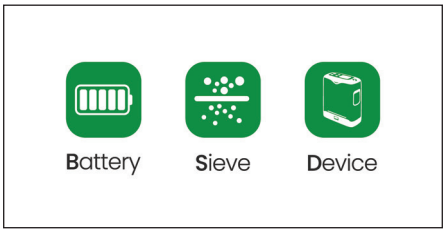


Fig. 4

Use flow control (+) to locate and press function button to select. It will display the 3 information screens below.

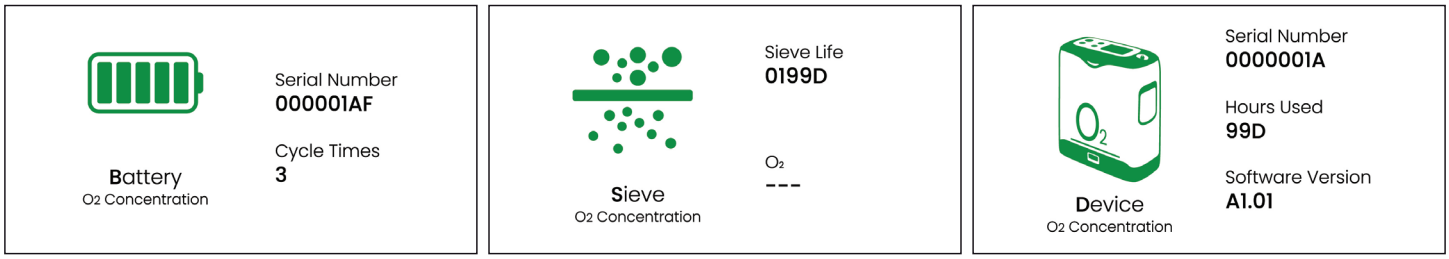


Fig. 5

Press flow control (-) to return to normal running screen. (fig. 5)

- **SYSTEM ASSEMBLY**

1) Place the device in a well-ventilated location. (fig. 6)
2) Air intake and exhaust must have clear access. Position the device in such a way that any auditory alerts may be heard. Always operate the device in an upright position. (fig. 6)
3) Ensure both particle filters are in place at both ends of the device. (fig. 6)
4) Insert the battery by sliding the battery into place until the latch returns to the upper position and a "clicking" sound is heard. (fig. 7)
5) Connect the AC power plug to the power source and connect the power output plug to the device. The green LED on the power supply will be illuminated, and a beep will sound from the concentrator. (fig. 8)

NOTE–The POC battery can be used for backup power in the event of a planned or unexpected loss of AC power. When operating the POC from AC power, keep a properly inserted battery in the POC. This helps maintain uninterrupted operation and enables all alerts in the event of external power loss.

Fig. 6

Fig. 7

Fig. 8

- **START UP**

Turn on your device by pressing and holding the ⏻ Button. A single short beep will sound before the Resp-O_2™ logo is displayed. The settings will appear while the device starts up. The display will indicate the selected flow setting and power condition. Following a brief start-up sequence, a warm-up period of up to 2 minutes will initiate. During this period, the oxygen concentration is building and may not have reached the declared specification. Additional warm-up time may be needed if your device has been stored in extremely cold temperatures.

The device starts working at the previously selected flow setting.

- **OXYGEN PRESCRIPTION FLOW SETTING**

The oxygen prescription setting is displayed on the main device screen. The flow rate is prescribed by your physician. It is a "dose" of oxygen. Always set the flow rates in units of liters-per-minute according to Table 2 (Flow rates). Flow rates that are too high or too low may pose a risk of patient harm.

Pulse Mode: In Pulse Mode, the device delivers a bolus of oxygen at the beginning of each inhalation. Pulse Mode can be adjusted from setting 1 to setting 6 in increments of one using the "+" button on the control panel. Press the "–" button to decrease the oxygen setting.

Settings	Flow Rates	
	Milliliters Per Minute	Liters Per Minute
1	210	0.21
2	420	0.42
3	630	0.63
4	840	0.84
5	1050	1.05
6	1260	1.26

3.2 Operating Instructions

- **DAILY OPERATION**

Fig. 9

- Align the battery with the bottom housing of the device. (fig. 9)
- Slide the battery into place until you hear an audible click, indicating that the latch has returned to the upper position. (fig. 9)

NOTE–Ensure the power cord is fully inserted into the device connector and the power cord plug is completely inserted into a fully functioning AC wall outlet. Failure to do so may cause an electrical safety hazard.

NOTE–Before using the device on battery power for the first time, the battery needs to be fully charged. Refer to Battery – Initial Battery Charge for details.

Ensure battery is charged, or attach concentrator to AC power to check battery charge level.

1) Connect cannula tubing to oxygen outlet. (fig. 10)

Fig. 10

2) Press and hold the ⏻ Button to turn on device.

3) Check the Prescription Setting. Press "+" Increase or "-" Decrease setting buttons to adjust the flow to your prescription setting.

NOTE–For your safety, the POC must be used according to the prescription determined by your physician.

4) Attach the nasal cannula to your nose and face. Breathe normally through the cannula. (fig. 11)

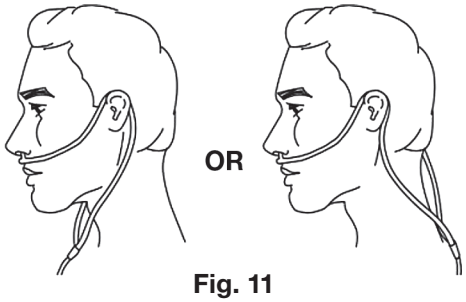


Fig. 11

- **Disposable Nasal Cannula Information**

NOTE–Only use a nasal cannula with the following specifications:

Specification:	
Material	PVC, PP
	High Flow, Crush-Resistant
Prong Size	Adult
Oxygen Tube	Hexagonal inner diameter
	Length: 2.1m
	Flow rate up to 6 LPM at max pressure of 3.6 psi
Oxygen Connector	Standard
Adjusting Loop	3 mm
Biocompatibility	Meets ISO-10993

WARNING: One single-lumen flared-tip nasal cannula should not be used by two or more persons.

WARNING: Do not reuse the disposable nasal cannula to prevent infection.

WARNING: Only use nasal cannulas that meet the above specifications with this device. Using cannulas that do not meet the above specifications may impair the performance of this device, including flow rate or oxygen purity.

NOTE–To check that your device is functioning properly during use, simply watch for the green normal oxygen symbol to blink upon inhalation. You can also pinch the tubing for 3-4 seconds then release it, and feel a dose delivered at the cannula.

NOTE–Upon startup, it will take up to 2 minutes for the oxygen output content to be 90% (-3%, +6%).

NOTE–The POC has an oxygen sensing device to monitor oxygen purity once the oxygen stabilization process is complete (after approximately 2 minutes of operation). Once stabilized, the OSD monitors the oxygen purity and will alert if the concentration falls below an acceptable level.

5) To change the battery during operation: Turn off the device. Grasp the battery cap and pull it straight up. Then insert a charged battery and press until it clicks into place.

6) Press and hold the Power Button for 2 seconds to turn off the concentrator when finished using the device.

NOTE–The device should not be used on battery power when sleeping. The battery will not provide a long enough run time for a full night's sleep. Attach concentrator to power for overnight use.

- **WEARING THE DEVICE**

The carrying case allows you to easily take the POC with you while on the go.

Place the POC inside the matching case and adjust the shoulder strap to the desired length.

Ensure the following:

1) The case must have a cannula opening & power input opening.

2) The top of the case is transparent and easy to open for immediate viewing or operation of the machine.

3) Air intake vents and exhaust vents should not be wrapped or blocked.

- **SILENCING ALARM CONDITION**

To silence an audible alert during operation, simply press the and buttons simultaneously to turn off alarm sound.

NOTE–If the device is shut off during an alarm condition, the audible alert will sound when device is turned on again.

- **POWER OPTIONS**

Your battery can be used with the 2 following power sources:

Battery Power – The POC will use battery power if no other power source is present. However, if power is connected, the device will run on that power source, thus conserving battery charge level. If the other power source is disconnected, the device will automatically switch to battery power.

This table shows the typical durations for a new battery pack:

Device Setting	Single Battery Duration HH:MM (battery model: 320120)
1	Min to 4:20
2	Min to 3:30
3	Min to 2:30
4	Min to 1:50
5	Min to 1:30
6	Min to 1:10

NOTE–Battery time varies with environmental conditions and time shown above table is the minimum time.

AC Power Adapter (for use at home or where standard AC power is available) – Attach the universal AC Power Supply to the concentrator and an AC power outlet using the AC Power Cord. (fig. 12)

Fig. 12

- Charge only with the adapter specified in this manual. Using other adapters may result in thermal injury, electric shock, or equipment damage.
- When using the adapter for power supply, please ensure that the battery compartment is properly installed to avoid the risk of electric shock from exposed live parts.
- The power adapter model is: EM11012M produced by EDACPOWER ELEC. Input: 100- 240V~, 2.0-1.0A, 50-60Hz; Output: 24.0Vd.c., 5.0A. The adapter is considered part of the equipment.

- **BATTERY**

INITIAL BATTERY CHARGE

Before using the device on battery power for the first time, the battery needs to be fully charged. Optional spare batteries purchased should also be fully charged before first use.

TO CHARGE #33955 BATTERY

Using AC Power - attach the power supply to the device and an AC power source using the appropriate power cord.

BATTERY RECHARGE TIME

The time to recharge the battery from fully drained to fully charged is not more than 5 hours when your POC is operating and plugged into AC power.

NOTE–When your POC is OFF and plugged into AC power, it will take no more than 3 hours to fully charge the battery from a drained state.

DISCHARGING BATTERY BAR TABLE (UNPLUGGED)

Battery Bar Display # of Bars Lit	Remaining Charge
5 bars steady green	90-100%
4 bars steady green	80-89%
3 bars steady green	60-79%
2 bars steady green	40-59%
1 bar steady green	20-39%
1 bar steady red	10-20%
1 bar steady Red along with beep audible alarm	5-10%
1 bar steady Red, "Low Battery Shutdown" notification along with beep audible alarm	0-5%

- Only use the batteries specified in this manual to power the device. Using other batteries may result in thermal injury, electric shock, or equipment damage.

3.3 Care/Cleaning

WARNING

1) To avoid electric shock, do not remove the concentrator cover. The cover should only be removed by a qualified technician. Do not apply liquid directly to the cover or utilize any petroleum-based solvents or cleaning agents. Use of harsh chemicals (including alcohol) is not recommended. If bactericidal cleaning is required, a non-alcohol-based product should be used to avoid inadvertent damage.

2) Before attempting any cleaning procedures, turn the device "Off" and disconnect from AC power.

3) Do not service or clean this device while in use with a patient.

EXTERIOR COVER & BATTERY

Clean the concentrator exterior cover and battery as needed:

1) Ensure battery is installed while cleaning the cover. Wipe it with a dry cloth as needed.

2) Use a damp cloth or sponge with a mild household cleaner on the exterior cover and wipe it dry. If the battery is removed, wipe the battery bay with a dry cloth only.

CAUTION
Do not apply liquid directly to the cover.

Particle Filters

Remove particle filters from the device (fig. 13). Clean the particle filters with a mild liquid detergent and water, rinse in water and dry before reuse. It may be necessary to clean the particle filters more often in dusty environments. To purchase additional particle filters, contact your point of purchase, the manufacturer, or an authorized service center for assistance.

Fig. 13

The particle filters must be cleaned weekly to ensure the ease of air flow.

CARRYING CASE (IF USED)

The carrying case should be cleaned as needed. To clean, follow these steps:

1) Remove the device from the carrying case before cleaning.

2) As needed, clean the case by using a damp cloth with a mild household cleaner and wipe dry.

POWER SUPPLY, AC POWER CORD

1) Disconnect cords from the device and power source before cleaning.

2) Clean the cords as needed by using a damp cloth with a mild household cleaner and wipe dry.

CANNULA AND TUBING

Clean and replace the cannula and tubing according to the manufacturer's instructions.

CLEANING

	Suggested cleaning interval	Number of cleaning cycles*	Compatible cleaning method
Outer Cabinet and Battery	7 days	260	Mild dish soap (2 tbsp) and warm water (2 cups)
Power Supply and Cords	7 days	260	Mild dish soap (2 tbsp) and warm water (2 cups)
Carrying Case	7 days	260	Mild dish soap (2 tbsp) and warm water (2 cups)

*number of cleaning cycles determined by suggested cleaning interval and expected service life.

3.4 MAINTENANCE

Operator should perform periodic visual inspection of the device. ISO 80601-2-67 Clause 201.79.2.12

If the replacement items or spare parts listed in Section 3.8 of the User Manual are out of date, contact your point of purchase, the manufacturer, or an authorized service center for assistance. Contact Dynarex Corporation, 155 Chestnut Ridge Rd., Suite 2202, Montvale, NJ, 888-396-2739, info@dynarex.com.

The manufacturer will provide information on how to purchase replacement items and spare parts listed in Section 3.8. After receiving the replacement items or spare parts, contact your point of purchase, the manufacturer, or an authorized service center for assistance.

NOTE: Before completing the replacement of your replacement items or spare parts, if you are no longer receiving functional oxygen support from the Portable Oxygen Concentrator, please contact your doctor for an alternative oxygen supplement.

WARNING

- Disconnect power supply before servicing.

Visual inspection of the device periodically is required to ensure no damage to the exposed components is apparent. A typical visual inspection includes:

- Battery connectors- these should not be bent.

- Cannula nozzle- this should be straight and fully seated against the housing.
- Plastic Housing- the housing should be fully seated and secure with no cracking or other visible damage.
- Particle filters - these should be in place and clear of debris, dust, or other obstructions.

SIEVE BED CHANGE

Sieve beds are replaceable items that can be changed by the manufacturer. If you experience an issue that requires sieve bed replacement, please contact your point of purchase, the manufacturer, or an authorized service center for assistance (manufacturer information listed in section 3.4 page 22). The sieve beds are only replaceable by qualified personnel of the manufacturer.

This replacement procedure shall be performed only when maintenance is required and not for training or demonstration purposes.

1) Turn off the POC.
2) Take the POC out of the carry bag, if necessary.
3) Remove the battery from the device. Place the device on its side so that the underside is visible.
4) Remove the sieve bed door with the flat-blade screwdriver end of the L-shaped tool.
5) The metal column assembly can be seen on one side of the device.
6) Remove the middle screw at the column bottom by using the flat-blade screwdriver end of the L-shaped tool.
7) Screw the threaded end of the L-shaped tool into the screw hole to push the sieve bed out of the device. Then pull the sieve bed column straight upward to remove it.
8) Remove the dust caps from the new column assembly. Make sure there is no dust or debris where the dust caps were located.
9) Insert column assembly into the POC. Column assembly should be inserted into the POC as soon as the dust caps have been removed.
10) Push the column assembly into the device so that the column is fully seated into the POC. Fasten the screw with a Phillips screwdriver.
11) Connect the AC power supply cord to the POC and plug the power supply AC cord into an electrical outlet. Then turn on the device.
12) Press the Function button to enter the main menu. Press the "+" button to select the Sieve screen, then press the Function button to enter the sieve settings screen.
13) On this screen, press and hold both the "+" and "–" buttons for 5 seconds until the Sieve Life value changes to 00000H.
14) Press the "–" button to exit back to the main operating screen.
15) Do not use any sieve beds other than those specified in this User Manual. The use of non- specified sieve beds may create a safety hazard and/or impair equipment performance and will void your warranty.

INLET FILTER CHANGE

The inlet filter is designed to ensure that clean air enters the compressor.

1) Remove the battery from the device. The inlet filter is located inside the bottom cover of the device.
2) Take out the bottom cover with a flat-blade screwdriver.
3) Place a new inlet filter in the bottom cover.
4) Install the bottom cover.

The inlet filter must be replaced every 3500 hours to ensure the ease of air flow. Inlet filters can be purchased from the manufacturer or authorized service center (manufacturer information listed in section 3.4 on page 22).

CANNULA REPLACEMENT

Your nasal cannula should be replaced on a regular basis. Consult your physician and/or equipment provider and/or the cannula manufacturer's instructions for replacement information. Only use the specified single-lumen cannula (page 19) to ensure proper breath detection and oxygen delivery.

3.5 STORAGE

When not in use, your device and batteries should be stored in a cool, dry location within the specified storage parameters (refer to Specifications).

- Do not store batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.
- Do not store batteries longer than 1 year without recharging.
- Lithium-ion batteries can be stored from -4°F to 140°F (-20°C to 60°C) at up to 90% relative humidity.
- Recommendation: Store the battery at temperatures below 77°F (25°C), in a low-humidity, dust-free, and non-corrosive environment. Store fully charged if possible. Avoid storage in direct sunlight. High temperature storage (above 104°F / 40°C), such as in a hot vehicle, may degrade battery performance and reduce battery life. Low temperature storage may affect battery performance.

The best battery charge conditions are within a temperature range of 32°F to 113°F (0°C to 45°C) at up to 90% relative humidity. If the battery temperature exceeds 113°F (45°C), the device will not charge the battery.

Charging will resume when the battery temperature drops to 111°F (44°C) or below.

LONG TERM STORAGE

Do not store batteries longer than 1 year without recharging.

NOTE–Using the POC more frequently will prolong sieve bed life. If the POC has been stored for an extended period of time, it may take up to 30 minutes of operation for sieve beds to recover full performance.

3.6 EXPECTED SERVICE LIFE

- Oxygen Concentrator - 5 years
- Sieve Beds - 3500 hours
- Battery - 500 charge-discharge cycles
- Inlet filter - 3500 hours

The expected service life of the POC, particularly the sieve beds and battery, may vary based on the operating environment, storage, handling, and the frequency and intensity of use.

3.7 POC RETURN AND DISPOSAL

This device may not be disposed of with household waste. At the end of the device's service life, please return the device to the manufacturer (manufacturer information listed in section 3.4 page 22) for disposal. At end of use, dispose of concentrator and battery through approved electronic waste or medical equipment recycling facility.

This device contains electrical and/or electronic components that must be recycled according to local or national regulations. Non-infectious used accessories (e.g., nasal cannulas) may be disposed of as residential waste. The disposal of infectious accessories (e.g., a cannula from an infected user) must be made via an approved waste disposal company. Names and addresses can be obtained from the local municipality.

DISPOSAL OF LITHIUM-ION BATTERIES

Lithium-ion batteries should be recycled. Recycle batteries according to national and local regulations. Contact your local

representative for assistance. The batteries must be disposed only in a discharged state at the collection center. In the case of batteries that are not fully discharged, there is a risk of short circuit. To reduce the risk of short circuits, insulate the battery terminals with tape.

3.8 Instructions for Accessories

- **UNPACKING & LI STING**

First, unpack your device and identify all items.

1. Resp-O_2™ Portable Oxygen Concentrator
2. 8-Cell Battery
3. Power Supply (AC Adapter)
4. AC Power Cord
5. DC Adapter
6. Carry Bag
7. Shoulder Strap
8. Nasal Cannula
9. Filter Kit
10. Instructions for Use (this document)

⚠ Do not use the device or any accessory that shows any sign of damage. Contact your point of purchase, the manufacturer, or an authorized service center for assistance. (Manufacturer information listed in section 3.4 page 22).

- **REPLACEMENT ITEMS AND SPARE PARTS**

The following items can be purchased separately as replacement items or spare parts for your Resp-O_2™ POC.

Part	Item Number
Battery 8 Cell	RPPO-01B
Double Battery 16 Cell	RPPO-01DB
External Battery Charger	RPPO-01BC
Sieve Bed (Pair)	RPPO-02SB
Filter Kit	RPPO-06F
AC Adapter	RPPO-07AC
DC Adapter	RPPO-07DC
Power Cord	RPPO-08PC
Carry Bag	RPPO-09CB

To purchase replacement items and spare parts, please contact your point of purchase, the manufacturer, or an authorized service center for assistance.

4. TROUBLESHOOTING & ALARM SYSTEM

4.1 Troubleshooting

The following troubleshooting chart will help you analyze and correct minor malfunctions. If the suggested procedures do not help, switch to your reserve oxygen system and call your home care provider. Do not attempt any other maintenance.

WARNING

To reduce the risk of electric shock, do not remove the covers. There are no user serviceable internal components. The covers should only be removed by a qualified home care technician.

Symptom	Possible Cause	Remedy
After pressing the power button, the machine does not respond.	1. Power button was not held.	1. Press Power button and hold for 2 seconds.
	2. No battery installed.	2. Battery must be installed for device to operate regardless of power source.
	3. Battery depleted or defective battery.	3. Install charged battery or contact your point of purchase, the manufacturer, or an authorized service center for assistance.
	4. External power not attached and battery is depleted.	4. Check cord connections to device, power supply, and power source.
	5. Faulty Power Supply, AC Power Cord.	5. Contact your point of purchase, the manufacturer, or an authorized service center for assistance.
	6. Faulty AC accessory power port outlet.	6. Check the power port.
	7. Device malfunction	7. Contact your point of purchase, the manufacturer, or an authorized service center for assistance. (Manufacturer information listed in section 3.4 page 22).
Cannot adjust/ change the Oxygen Prescription setting.	Device malfunction	Contact your point of purchase, the manufacturer, or an authorized service center for assistance. (Manufacturer information listed in section 3.4 page 22).
Device not triggering properly	Sensor needs recalibration	Turn device ON, but do not use it for 5 minutes to auto-calibrate the sensor.
No oxygen	Concentrator is not powered on.	Press ⏻ button to power concentrator.
	Nasal cannula is not connected properly or is kinked or obstructed.	Check nasal cannula and its connection to concentrator nozzle.
LCD display, indicator light, or alert issue	Refer to chapter 4.2	Refer to chapter 4.2
If any other problems occur with your POC, turn your device off and switch to your reserve oxygen system. Contact your point of purchase, the manufacturer, or an authorized service center for assistance.		

4.2 Overview of Alarms

NOTIFICATION

Audible notifications (from 65dba to 70 dba in 1 meter range) are used to warn users of problems. When the POC works normally, the user can correctly and clearly perceive the visual alarm signal within 4-meter range and take relevant measures in time. To ensure that sound notifications can be heard, the maximum distance between the user and the POC must be determined to accommodate surrounding noise level. The alarm system of the POC has been set up before leaving factory, and users cannot change the setting of the alarm system.

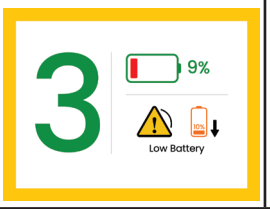
The POC monitors various parameters during operation and uses intelligent alarm systems to indicate equipment failure. Mathematical algorithms and time delays are used to reduce the probability of false alarms, while still ensuring correct notification of alert conditions.

If more than one alert condition is detected, the alert with the higher priority is displayed, and if more than one alarm with the same priority is detected, the alarms will vary every 5 seconds to display.

Note that for low and medium priority alerts, failure to respond to the alert status may result in only discomfort or reversible minor damage that develops in sufficient time to switch to a backup oxygen source.

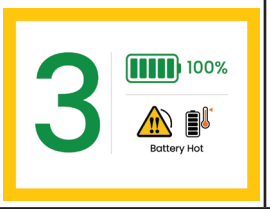
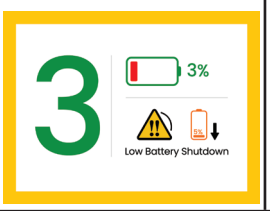
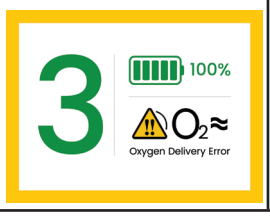
LOW PRIORITY ALARMS

The following low priority alert messages are accompanied by a double beep and a solid yellow frame on the display. The alert repeats every 25 seconds.

Alarm Message	Description	Action
	**Low Battery** Battery power is low with less than 10% battery volume.	Connect to external power or turn off the power and replace with a fully charged battery.
	**Oxygen Low** The oxygen concentrator has been producing oxygen at a slightly low level (<82%) for more than 10 minutes.	If the condition persists, please contact your equipment supplier.
	**Service Soon** The oxygen concentrator requires servicing at the earliest convenience. The concentrator is operating to specification and may continue to be used.	Contact your equipment supplier to arrange for service.
	**Replace Sieve Beds** Sieve bed replacement is recommended within 30 days.	Contact your equipment supplier to arrange for service or order new sieve beds from the manufacturer.
	**Battery Hot Warning** The battery temperature is nearing the temperature limit while the concentrator is running on battery power.	If possible, move the oxygen concentrator to a cooler location or power unit with an external power supply and remove battery. If condition persists, contact your equipment supplier.
	**System Hot Warning** The oxygen concentrator temperature is nearing the temperature limit.	If possible, move the oxygen concentrator to a cooler location. Ensure air intake and outlet vents have clear access and particle filters are clean. If the condition persists, contact your equipment supplier.
	**Warming Up** Oxygen concentration is <87% two minutes after the device's start up and at least 10 breaths have been detected within the last minute.	Wait a few minutes to see if the oxygen concentrator improves (alarm will clear). If condition persists, a secondary alarm will sound. Follow the instructions for that alarm or contact your equipment supplier.

MEDIUM PRIORITY ALARMS

The following medium priority alert messages are accompanied by a triple beep, repeated every 25 seconds, and a flashing yellow frame.

Alarm Message	Description	Action
	**Battery Hot** Battery has exceeded the temperature limit while the concentrator is running on battery power.	Move the oxygen concentrator to a cooler location OR power device with an external power supply and remove battery. If condition persists, contact your equipment supplier and switch to a backup source of oxygen.
	**System Hot** The system temperature exceeds the temperature limit, and the device automatically shuts down.	Cool down the device and then try again. If the condition persists, contact your equipment supplier and switch to a backup source of oxygen.
	**Fan Failure** Fan rotation is not detected. The machine will automatically shut down after 10 seconds.	Contact your equipment supplier and switch to a backup source of oxygen.
	**High Pressure** The pressure exceeds the maximum limit. The device automatically shuts down after 10 seconds.	Contact your equipment supplier and switch to a backup source of oxygen.
	**Low Battery Shutdown** Battery level is less than 5%. The device will automatically shut down soon.	Attach external power supply or power down and insert a fully charged battery, or switch to a backup source of oxygen.
	**System Cold** The system is cold (<2˚C). The concentrator will shut down and stop producing oxygen.	Move to a warmer environment to allow the device to warm up before starting it. If condition persists, switch to a backup source of oxygen and contact your equipment supplier.
	**Sensor Fail** The concentrator's oxygen sensor has malfunctioned.	Contact your equipment supplier and switch to a backup source of oxygen.
	**Oxygen Delivery Error** A breath has been recognized, but proper oxygen delivery has not been detected.	Contact your equipment supplier and switch to a backup source of oxygen.

Alarm Message	Description	Action
	**Oxygen Error** Oxygen output concentration has been below 50% for 10 minutes.	Contact your equipment supplier and switch to a backup source of oxygen.
	**No Breath Detected** The concentrator has not detected a breath for 60 seconds.	The oxygen concentrator has not monitored breathing for 60 seconds. Check that the nasal oxygen tubing is attached to the oxygen concentrator, is not kinked, and is properly placed in the nose.
	**System Malfunction** The concentrator has stopped producing oxygen.	Contact your equipment supplier and switch to a backup source of oxygen.

5. ADDITIONAL INFORMATION

5.1 Limited Warranty

Your Dynarex Product is warrantied to be free of defects in materials and workmanship for Fifteen (15) years on structural Steel, Three (3) years on electrical and mechanical, and One (1) year on all other parts and components from the original date of purchase. This item was built to exacting standards and carefully inspected prior to shipment. This warranty is an expression of our confidence in the materials and workmanship of our products and our assurance to the consumer of years of dependable service.

The Warranty shall not apply under the following conditions:

- Problems arising from normal wear
- Problems arising from failure to adhere to the product instructions
- Problems arising from misuse, negligence, accident or improper operation, maintenance or storage
- Problems arising from modifications or unauthorized repairs, parts or attachments
- Products where the serial number has been removed or defaced
- Problems with non-durable components, such as rubber accessories, casters, and grips, which are subject to normal wear and need periodic replacement

Dynarex shall not be liable for any consequential or incidental damages whatsoever. Dynarex shall repair or replace defective products at its option. The foregoing warranty is exclusive and in lieu of other express warranties, if any, including the implied warranties of merchantability and fitness of a particular purpose. The remedy for any violation of the implied warranty shall be limited to repair or replacement of the defective product pursuant to the terms contained herein.

If you have a question about your Dynarex device or this warranty, please contact an authorized Dynarex dealer.

6. PROVIDER INFORMATION

6.1 Provider's Checklist

NOTE–If the device fails to operate properly, oxygen concentration is not within specification, or external/internal damage is found, contact Dynarex for instructions. Service instructions will be available to authorized Dynarex service centers. Please request through customer service. Run the device for 20 minutes every 6 weeks while in storage for optimal performance.

1) Upon delivery, check the Resp-O2 POC for damage that may have occurred during shipping and notify Dynarex of any damage. (Obvious shipping damage should be reported to Dynarex within 2 days of arrival.) Do not use damaged equipment. Save the carton, noting the position of the device and placement of the packing material for possible future return.
2) Instruct the user on the safe operation of the portable oxygen concentrator. Review the Important Safeguards, and observe all Warnings and Cautions on the product and in the instruction guide.
3) Leave a copy of this instruction guide with the user.

NOTE–Dynarex recommends leaving a reserve oxygen supply with the patient when setting up the Resp-O_2™ POC, and instructing the patient to always keep reserve oxygen on hand.

7. ELECTROMAGNETIC COMPATIBILITY INFORMATION

WARNING

- Don't use the device near high-frequency surgical equipment, near magnetic resonance imaging equipment, or where the intensity of electromagnetic disturbances may be high.
- Use of this device near other equipment should be avoided, as it may result in improper operation. If such use is necessary, observe this device and the other equipment to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, and may result in improper operation.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

The Resp-O_2™ Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The user of the POC should ensure it is used in such an environment.

Immunity Test	IEC60601 Test level	Compliance Level	Electromagnetic Environment - Guide
Electrostatic Discharge (ESD)IEC610 00-4-2	±8 kV contact ±2KV, ±4KV, ±8KV, ±15kV air	±8 kV contact ±2KV, ±4KV, ±8KV, ±15kV air	The floor should be wood, concrete, or tile, and if the floor is covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields IEC 61000-4-3	3V/m (Professional healthcare facility environment); 10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	10V/m (Home healthcare environment) 3V/m (Professional healthcare facility environment); 80MHz – 2.7GHz 80% AM at 1kHz	Mains power quality should be that of a home healthcare environment or professional healthcare facility environment.
Electrical fast transients / bursts (IEC 61000-4-4)	±2kV AC power supply lines; ±2kV DC power ±1kV Signal input/ output parts PORT 100 kHz repetition frequency	±2kV AC mains power input	Mains power quality should be that of a home healthcare environment or professional healthcare facility environment.
Surges (IEC 61000-4-5)	±0.5kV, ±1kV lines to lines. ±0.5kV, ±1kV, ±2kV lines to ground	±0.5kV, ±1kV lines to neutral	Mains power quality should be that of a home healthcare environment or professional healthcare facility environment.
Conducted disturbances induced by RF fields (IEC 61000-4-6)	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	Applicable	

Immunity Test	IEC60601 Test level	Compliance Level	Electromagnetic Environment - Guide
The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			
RATED power frequency magnetic fields (IEC 61000-4-8)	30A/m 50Hz or 60Hz	30A/m 50Hz and 60Hz	Power frequency magnetic fields should be at levels characteristic of a home healthcare environment or a professional healthcare facility environment.
Voltage dips (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°	Applicable	Mains power quality should be that of a home healthcare environment or a professional healthcare facility environment.
Voltage interruptions (IEC 61000-4-11)	0% UT; 250/300 cycle	Applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

Immunity test	IEC60601 test level				Compliance level
	Test frequency	Service	Modulation	Immunity level	
Radiated RF IEC61000-4-3	385 MHz	TETRA 400	*Pulse Modulation: 18Hz	27V/m	27V/m
	450 MHz	GMRS 460, FRS 460	FM+5Hz Deviation: 1 kHz sine	28V/m	28V/m
	710 MHz 745 MHz 780 MHZ	LTE Band 13, 17	**Pulse Modulation: 217Hz	9V/m	9V/m
	810MHz 870MHz 930 MHz	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	**Pulse Modulation: 18Hz	28V/m	28V/m
	1720 MHz 1845 MHz 1970 MHZ	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	**Pulse Modulation: 217Hz	28V/m	28V/m
	2450 MHz	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	**Pulse Modulation: 217Hz	28V/m	28V/m
	5240 MHz 5500 MHz 5785 MHz	WLAN 802.11 a/n	**Pulse Modulation: 217Hz	9V/m	9V/m
Note*-As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used. Although this does not represent actual modulation, it represents a worst-case condition. Note**-The carrier shall be modulated using a 50% duty cycle square-wave signal.					

Guidance and Manufacturer's Declaration –Electromagnetic Emissions:

The Resp-O_2™ Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The user of the POC should ensure it is used in such an environment.

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

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