

SIMO₂

by drive

Portable Oxygen Concentrator Model SIMO2DS



R_x ONLY

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.



No Smoking



MR Unsafe



Not manufactured with natural rubber latex.

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 the device retailer for assistance or further information.

CONTENTS

1.0 SYMBOLS GLOSSARY	3
2.0 INTRODUCTION	3
2.1 Indication For Use	3
2.1.1 Operator Notes	3
2.2 How Your Device Works	3
2.3 Contraindications	3
2.4 Risk Of Minor Injury Or Discomfort	3
2.5 Essential Performance	4
2.6 Specifications	5
2.7 Standard Pulse Dose Output	6
2.8 Safety Instructions	6
3.0 POC OVERVIEW	11
3.1 Setup Instructions	11
Important Parts Of Your Concentrator	11
3.2 Operating Instructions	15
3.3 Care / Cleaning	18
3.4 Maintenance	19
3.5 Storage	20
3.6 Expected Service Life	21
3.7 Poc Return And Disposal Of Lithium-Ion Batteries	21
3.8 Instructions On Accessories	21
3.9 External Battery Charger (Optional Accessory)	22
3.10 Dc Power Cable	23
4.0 TROUBLESHOOTING & ALARM SYSTEM	24
4.1 Troubleshooting	24
4.2 Overview Of Alarms	24
5.0 ADDITIONAL INFORMATION	27
5.1 Warranty	27
Warranty Claims Submissions	28
6.0 PROVIDER INFORMATION	28
6.1 Provider's Checklist	28
7.0 ELECTROMAGNETIC COMPATIBILITY INFORMATION	29

1.0 SYMBOLS GLOSSARY

For a Glossary of Symbols visit:

www.drivemedical.com/symbols-glossary.com

Or scan the QR code below.



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

2.0 INTRODUCTION

2.1 INDICATION FOR USE

The SIMO2 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 professional healthcare facilities.

2.1.1 OPERATOR NOTES

The operator of the POC shall have the ability to read and understand this manual in order to operate the equipment properly. A patient who meets the above requirements and is conscious can be the operator of the device. Intended environment: home and institution (refer to professional healthcare facilities).



WARNING: The device is intended only for adult patients requiring respiratory therapy on a prescriptive basis.

2.2 HOW YOUR DEVICE WORKS

A concentrator separates oxygen from room air which allows high-purity supplemental oxygen to be delivered to you through the oxygen outlet.

Although the concentrator filters the oxygen, it does not affect the normal amount of oxygen in your 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 “No breath detected” alarm until breathing is detected again or battery is depleted.

It is the responsibility of the patient to plan for a back-up oxygen supply when traveling; Drive 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 your 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 tracheotomised patient.

2.4 RISK OF MINOR INJURY OR DISCOMFORT

The device, parts and accessories are specified for use at flow rates between setting 1 and setting 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 the device retailer.

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 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 could lead to electrical shock and/or damage. For optimal sieve beds life, the product should be used frequently.
- 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 interrupting 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 to cool down before handling to avoid injury.
- 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.

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:1260ml +/-15%. 2. Oxygen concentration is 90%(-3%,+6%).
Power supply failure technical alarm condition	When power supply failure,ME equipment generate an alarm.
No breath detected alarm condition	When no breath detected,ME equipment generate an alarm.
Low-oxygen concentration technical alarm condition	When the oxygen concentration<82% after powering on, the ME equipment should generate an alarm.

Note: the ME equipment means the SIMO2 Portable Oxygen Concentrator

2.6 SPECIFICATIONS

Dimensions (H xWx L)	Host (exclude battery): 187 X 88 X 184 mm (7.36 in. x 3.46 in x 7.24 in.) Host Include battery: 187 X 88 X 217 mm (8-Core battery) (7.36 in. x 3.46 in. x 8.54 in.)		
Weight	2.13 kg (4.7 lbs.) with 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*	70kPa 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		
Maximum outlet pressure	<199kpa(28.9psi)		
Maximum Breathing Rate	40 BPM		
Warm up time	2 minutes		
Output oxygen concentration**	90% + 6% and - 3% at all settings		
Inspiratory trigger sensitivity	<0.12 cm H ₂ O		
Sound Level	43 dBA typical at setting 2 Maximum system sound pressure of 61 dBA Maximum system sound power of 66 dBA		
AC/DC adapter powered	Input: 100-240VA.C., 50-60 Hz, 2.0-1.0A Output: 24V D.C., 5A, 120W		
Battery powered	14.8V D.C., 6.4A, 94.72Wh		
OSD Set Points	82% - Normal Oxygen Symbol (Green) < 82% - Low Oxygen Symbol (Yellow) and Audible Alert		
Type of Protection Against Electrical Shock	Class II		
Ingress of water or particulate matter into ME EQUIPMENT	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 or 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.		
Uncertainty of parameter measurement	Test parameter	Device Accuracy	Measurement uncertainty
	Pulse volumes	± 15% of rated volume	±2.3%
	Oxygen concentration	+ 6% and - 3% at all setting	1.3%
	Pressure	±1.5%	±0.66%
	Note: The tolerances declared in the documents include the uncertainty of the measurement.		

***Operating outside of these operational specifications can limit the concentrator's ability to meeting Oxygen Concentration specification**



WARNING

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

AUDIBLE ALERTS:

LOW PRIORITY ALARM. (The following Low-Priority Alarms are accompanied by two beeps repeated every 25 seconds and a solid yellow frame)

• 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 triple beeps repeated every 25 seconds and a flash yellow frame)

- 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 adult indicated by the physician. It is a body-worn device, and is not intended to be used with other medical devices.
- If an extension cord is necessary, use a UL list 15 amp or higher cord. **Do not** connect any other devices on the same extension cord. **Do not** use a multi-socketed extension cord.
- 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 (not included) 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 in the case that the accessory cannula (not included) becomes ignited. The Fire Stop Check Valve should be located as close to the user as 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 near the oxygen concentrator or any of its accessories. Smoking is strictly prohibited while the machine is operating or when you are near someone receiving oxygen therapy. **Do not** use in 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 (not included) on bed coverings or chair cushions if the oxygen concentrator is turned on but not in use; the oxygen will 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 (not included) unattended while POC is delivering oxygen.

High concentrations of oxygen can cause rapid burning.

WARNING: To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition, SIMO2 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 conserver or accessory manufacturer.

WARNING: The settings of SIMO2 might not correspond with continuous flow oxygen device.

WARNING: The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of SIMO2.

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 into 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 the device retailer for instructions on obtaining service. 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 (15.24 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 to make it difficult to operate the disconnection device. (Plug, appliance coupler or adapter considered as disconnection device 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 draughts 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 a burn, fire, or other electric shock hazards. **Do not** use the POC if the power cord is damaged.
- Locate oxygen tubing and power supply cords to prevent tripping hazards and reduce the possibility of entanglement or strangulation.
- Equipment 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 this area.



WARNING

- If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.
- Geriatric or any other patient unable to communicate discomfort can 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 (3048M) 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 has to 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 be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels. It is to 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 (not included) 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 draughts can adversely affect accurate delivery of oxygen therapy.
- This device is not intended for use with a tracheotomised 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** exposure or use the device or accessories into 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** exposure 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, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact the device retailer.
- 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 working. To prevent voltage fluctuations from affecting the oxygen generator, please use a stable power supply.
- When the oxygen generator suddenly unexpected 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 leaking, do not allow the liquid to come in contact with the 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. Exposure of 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 to water, 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 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.
- Use only the battery in the application for which it was intended.
- Periodically inspect connection cords, connector tips and the 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), low humidity, no dust and no corrosive gas atmosphere. 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 equipment and will void your warranty.
- Never leave the device in an environment which can reach high temperatures, such as an unoccupied car in high temperature environments. 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 (not included) is properly connected to the nozzle fitting and that the tubing is not kinked or pinched in any way.
- Replace the nasal cannula (not included) on a regular basis. Check with the device retailer or physician to determine how often the cannula (not included) 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.

The User Manual for this device has been written to account for training and knowledge of the patient population in order to operate the device appropriately.

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 the device retailer for assistance or further information.

3.0 POC OVERVIEW

3.1 SETUP INSTRUCTIONS

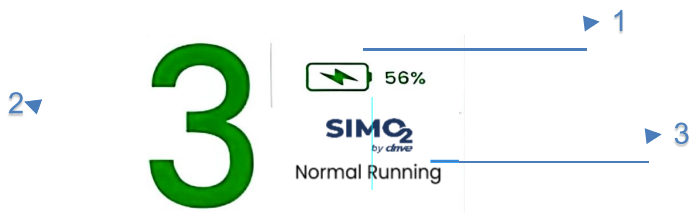
IMPORTANT PARTS OF YOUR CONCENTRATOR

DISPLAY SCREEN

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



The display screen in battery power

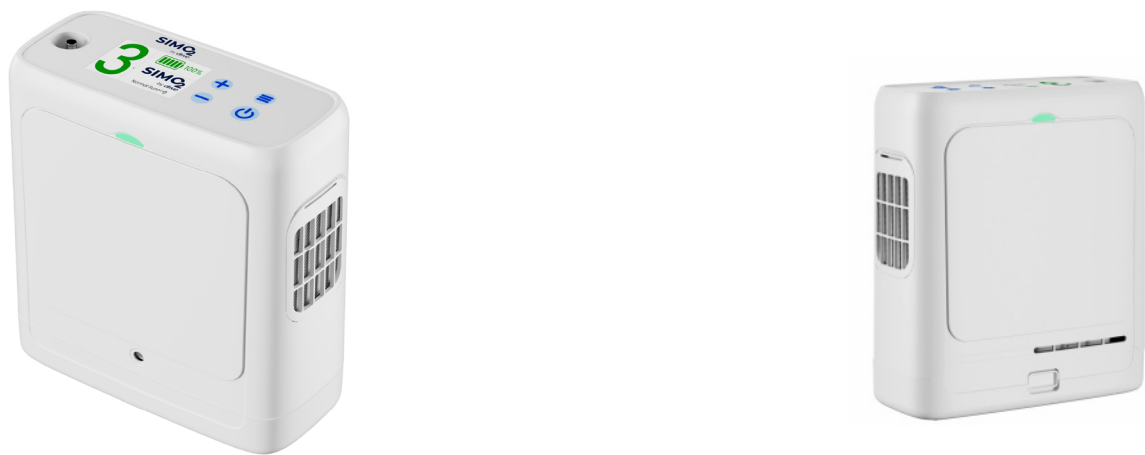


The display screen in AC power supply

No.	Icon Name	Description
1	Power status icons	It locates in the upper right. Displays ICONS when the battery works alone. When AC power supply is plugged in, the battery graph turns to lightning and shows the battery is charged.
2	Flow setting	It locates in left side. It displays the current flow setting. It could change through the flow control (+) button or flow control (-) button.
3	Working status	The device works normally with company logo (Drive) and “Normal running”. If device works in abnormal conditions, it will show alarm icons and message with yellow frame on LCD screen.

- i NOTE**—A backlight will illuminate the screen within 60 seconds no matter which button is briefly pressed.
- i NOTE**— A backlight will illuminate the screen under the alarm conditions.
- i NOTE**— When the machine is in normal operation and no one is operating, the backlight is off.

Fig. 1 Overview



i NOTE: 

Both sides Oxygen inhalation indicator will turn green with each inhalation of oxygen.

⚠ WARNING

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

⚠ NOTE – Oxygen Inhalation indicator does not provide a visual alarm signal indication.

Fig. 2 User Interface



Item	Description	Function button
1	Display screen	The display shows information about the status of the device such as flow setting, power status, battery volume and alarms.
2	Flow setting plus button	Increase flow setting
3	Flow setting minus button	Decrease flow setting
4	On/Off button	Pressing and holding the button turns the device on and off.
5	Function Button	Press this button to show the information of this device.

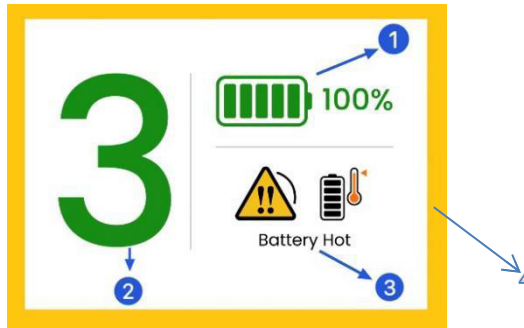


Fig. 3 LCD display when alarm condition is triggered

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 refer to chapter 4.2
4	Yellow graphical simulation of an indicator light	When the alarm condition is triggered, the simulation light will turn on in yellow.

FUNCTION BUTTON ()

Press 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 show below 3 information screens.

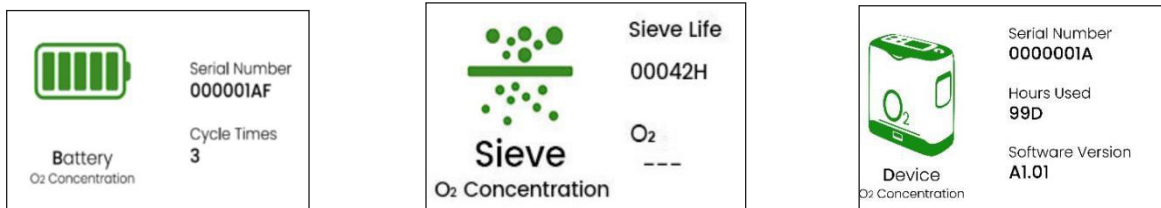


Fig. 5

Press flow control (-) 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. Locate 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 device. (Fig.6)
4. Insert the battery by sliding battery into place until the latch returns to the upper position and heard “clicking” sound. (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)

i NOTE—The POC battery can be used for backup power in the event of a planned or unexpected loss of the AC power supply. When operating the SIMO2 POC from AC power supply, a properly inserted battery should be maintained in the POC. This procedure will ensure uninterrupted operation and will operate all alerts and alerts in the event of a loss of external power supply.



Fig. 6



Fig. 7



Fig. 8

STARTUP

Turn on your device by pressing and holding the  Button. A single short beep will sound before the DRIVE 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 up to 2 minutes will initiate. During this period the oxygen concentration is building to but may not have reached specification. Additional warm-up time may be needed if your device has been stored in extremely cold temperatures.

The device starts working in the previous flow setting.

INITIAL BATTERY USE AND ACTIVATION

Before using the device on battery power for the first time, the battery must be fully charged. Any optional spare batteries should also be fully charged prior to initial use.

Step 1: Install the battery pack correctly into the host device

Step 2: Connect the external power adapter; the battery pack will be automatically activated and charged

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). Too high or too low flow rate may eventually lead to harm.

Pulse mode: In pulse mode, the device will deliver a bolus of oxygen at the beginning of each of your inhalation. Pulse mode of operation can be adjusted from setting 1 to setting 6 in 1 increment with the “+” button on the control panel. If press “-” button to adjust the oxygen setting lower.

Table 2 Flow rates

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

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

- i NOTE**– Ensure the power cord is fully inserted into the device connector and the power plug is completely inserted into a fully functioning AC wall outlet. Failure to do so may cause an electrical safety hazard.
- i 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.
- Connect cannula tubing to oxygen outlet.(Fig.10)



Fig. 9



Fig. 10

- Press and hold the  Button to turn on device.
 - Check the Prescription Setting. Press “+” Increase or “-” Decrease setting buttons to adjust the flow to your prescription
- i NOTE**– For your safety, the POC must be used according to the prescription determined by your physician.
- Attach the nasal cannula (not included) to your nose and face. Breathe normally through the cannula. (Fig.11)

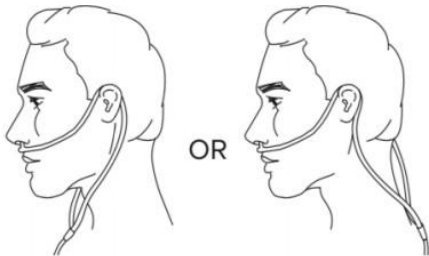


Fig. 11

INFORMATION OF DISPOSABLE NASAL CANNULA

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

Specification:	
Item	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	3mm
Bio-compatibility	Meets ISO-10993



WARNING: One single lumen nasal cannula (not included) should not be used by two or more persons.

WARNING: Do not re-use the disposable nasal cannula (not included) to protect infection.

WARNING: Only use Nasal Cannulas (not included) that meet the above specifications with this device. Using cannulas (not included) 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 (not included).



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



NOTE– The Drive 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.

6. 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.

7. 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.

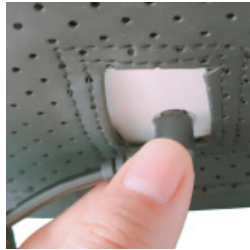
WEARING THE DEVICE

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

Choose the matching case and simply place the POC in the case and adjust the shoulder strap to the desired length.

Focus on 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  button and  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 SIMO2 can be used on 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)	Extended Battery
1	Up to 5 hours	Up to 10 hours
2	Up to 4 hours	Up to 8 hours
3	Up to 3 hours	Up to 6 hours
4	Up to 2 hours 15 min	Up to 4 hr 30 min
5	Up to 1 hour 45 min	Up to 3 hr 30 min
6	Up to 1 hour 30 min	Up to 3 hours

i NOTE - Battery time varies with environmental conditions; times shown are typical maximum durations on a fully charged single battery.

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)

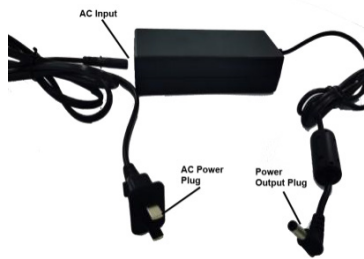


Fig. 12

- Charge only with the adapter specified in this manual to avoid unacceptable risks (like Thermal injury, electric shock injury, equipment damage, etc.)
- When using the adapter for power supply, please also 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 as part of the equipment.

DC POWER ADAPTER (FOR USE IN A VEHICLE)

The DC Power Adapter is now packaged with the SIMO2 and allows the device to be operated or charged from a vehicle's 12 V DC accessory outlet (cigarette-lighter / auxiliary socket).

- 1) Plug the DC adapter connector into the SIMO2 device DC input port.
- 2) Plug the other end into the vehicle's 12 V DC accessory outlet.
- 3) Ensure the vehicle engine is running before connecting to avoid draining the vehicle battery. Rated 11-16 V DC

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 SIMO2 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.

i NOTE–Before using the device on battery power for the first time, the battery needs to be fully charges. Fully charging the device with a standard battery will take approximately 3 hours; however, it can take up to 5 hours to reach a full charge when operating the device while charging.

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 bars steady green	20 ~ 39%
1 bar steady Red	10 ~ 20%
1 bar steady Red along with beeping audible alarm	5 ~ 10%
1 bar steady Red, "Low Battery Shutdown" notification along with beeping audible alarm	0~5%

- Only use the batteries specified in this manual to power the device, incorrect replacement of batteries may result in unacceptable risks (like Thermal injury, electric shock injury, equipment damage, etc.).

3.3 CARE / CLEANING

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. 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.
- 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.

EXTERIOR COVER & BATTERY

Clean the concentrator exterior cover and battery as needed:

- Ensure battery is installed while cleaning the cover. Wipe it with a Dry Cloth as needed.
- 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 environment. To purchase additional particle filters, contact the device retailer.



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:

- Remove the device from the carrying case before cleaning.
- As needed, clean the case by using a damp cloth with a mild household cleaner and wipe dry.

POWER SUPPLY, AC POWER CORD

- Disconnect cords from the device and power source before cleaning.
- 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 (not included) and tubing according to the Manufacturer's instructions.

CLEANING

	Suggested Cleaning Interval	Number of Cleaning Cycles	Compatible Cleaning Method
Exterior Cover	7 days	260	Mild dish soap (2 tbsp) and warm water
Battery Bay	As needed	As needed	Wipe with dry cloth
Particle Filters	7 days (more often in dusty environments)	As needed	Mild dish soap (2 tbsp) and warm water
Cannula and Tubing	Follow the cannula manufacturer's instruction	Follow the cannula manufacturer's instruction	Follow the cannula manufacturer's instruction
Power Supply and Cords	7 days	260	Mild dish soap (2 tbsp) and warm water
Carrying Case	7 days	260	Mild dish soap (2 tbsp) and warm water

*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 your “REPLACEMENT ITEMS or SPARE PARTS (which are listed in section 3.8 of User manual)” is out of the date, please contact the retailer, the following is the contact information of the retailer:

Inspyre Health Systems, LLC Add: 1004 Commerce Drive Grafton, OH 44044

Contact Person: John Heithaus Tel: 1(513) 314-6021

E-mail: heithaus@inspyrehealth.com

The retailer will tell you how to purchase the “REPLACEMENT ITEMS and SPARE PARTS”, and after you receive the delivery of REPLACEMENT ITEMS or SPARE PARTS, please contact the retailer again (with above contact information), the retailer will come and replace the “REPLACEMENT ITEMS and SPARE PARTS” for you.

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

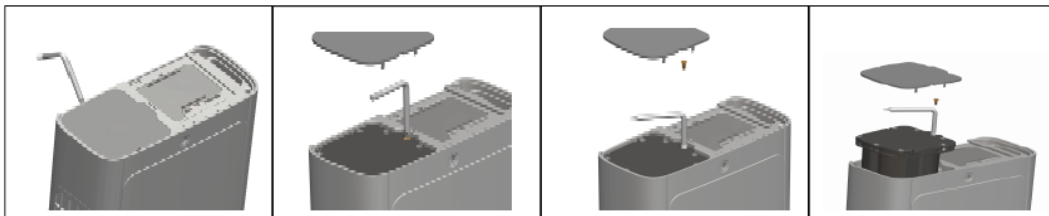
DISCONNECT SUPPLY BEFORE SERVICING

Visual inspection of the device periodic 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 your device retailer. If you experience an issue that Troubleshooting refers to sieve bed replacement, please contact the device retailer (retailer information listed in section 3.4 page 19).The sieve beds are only replaceable by a trained person of the device retailer.



This replacement procedure is only to be used when maintenance is required and is not intended for practice purpose.

1. Turn off the POC.
2. Take out the POC from carry bag, if necessary.
3. Remove battery from the device. Place the device on its side so that the underside is visible.
4. Remove the sieve beds door with the flat-blade screwdriver end of the L 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 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 dust caps of 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 POC as soon as the dust caps have been removed.
10. Push the column assembly into the device that the column is fully seated into the POC. Fasten the screw with the L tool.
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 void your warranty.

INLET FILTER CHANGE

The inlet filter is designed to ensure the clean air into the compressor

1. Removed the battery from the host. The inlet filter cotton is in the bottom cover of the host.
2. Take out the bottom cover with a slotted type screwdriver.
3. Put a new inlet filter on 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 filter can be purchased from the device retailer (retailer information listed in section 3.4 page 19).

CANNULA REPLACEMENT

Your nasal cannula (not included) should be replaced on a regular basis. Consult with your physician and/or equipment provider and/or cannula manufacturer's instructions for replacement information. Only use the specification single lumen cannula (page 26) 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 recharge.
- 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 below 77°F (25°C), low humidity, no dust and no corrosive gas atmosphere. Store fully charged if possible. Avoid storage in direct sunlight. High temperature storage (above 104°F / 40°C), such as in a hot car, 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 131°F (55°C), the device will not charge the battery.

- Charging will be resumed when the battery temperature drops to 122°F (50°C) or below.

LONG TERM STORAGE

- Do not** store batteries longer than 1 year without recharge.

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 to recover sieve beds to their full potential.

3.6 EXPECTED SERVICE LIFE

- Oxygen Concentrator - 5 years
Sieve Beds 3500 Hours

The expected service life of the POC, and in particular 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 OF LITHIUM-ION BATTERIES

This device may not be disposed of with household waste. After use of the device, please return the device to the device retailer (retailer information listed in section 3.4 page 26) for disposal. This device contains electrical and /or electronic components that are to be recycled per EU Directive 2012/19/EU-Waste Electrical and Electronic Equipment (WEEE.) Non-infectious used accessories (e. g. nasal cannula) can be disposed of as residential waste.

The disposal of infectious accessories (e. g. nasal cannula from an infected user) must be made via an approved waste disposal company. Names and addresses can be obtained from the local municipality.

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 case of not fully discharged batteries, provide for a risk against short circuits. Short circuits can be prevented by isolating the terminals with tape.

3.8 INSTRUCTIONS ON ACCESSORIES

UNPACKING & LISTING

First, unpack your device and identify all items.

- SIMO2 Portable Oxygen Concentrator
- Single Battery Pack
- Power Supply (AC Adapter)
- AC Power Cord
- Instructions for Use (this document)
- DC Power Adapter (packaged with device)



Do not use the device or any accessory that shows any sign of damage, contact the device retailer (retailer information listed in section 3.4 page 19).

REPLACEMENT ITEMS AND SPARE PARTS

The following items can be purchased separately as replacement items or spare parts for your SIMO2 POC.

Module	Item
SIMO2-0229013	AC Adapter
SIMO2-0229014	AC Power Cord
SIMO2-0229015	DC Adapter
SIMO2-0229008	8 CELL Single Battery
SIMO2-0229008-16	16 CELL Single Battery
SIMO2-0229090	Sieve Bed
SIMO2-0229022	External Battery Charger
SIMO2-0238009	Carry Bag
SIMO2-0229010	Particle Filter
SIMO2-0229010	Particle Filter

To purchase replacement items and spare parts, please contact your equipment retailer.

3.9 EXTERNAL BATTERY CHARGER (OPTIONAL ACCESSORY)

The External Battery Charger is an optional accessory designed for use with the SIMO2 POC lithium-ion battery pack. It is not included as a standard accessory with the system but can be purchased separately. The battery may also be charged through the SIMO2 POC when the device is plugged into an AC power supply.

Charge only with the charger and AC adapter specified in this manual to avoid unacceptable risks (such as thermal injury, electric shock injury, or equipment damage).



Fig. 14 Charger – Front (LED Side)



Fig. 15 Charger – Back (Battery Interface)

TO CHARGE THE BATTERY USING THE EXTERNAL BATTERY CHARGER CHARGING PROCEDURE

Follow the steps below to charge a SIMO2 battery pack using the External Battery Charger:

1. Connect the AC power plug into an electrical outlet.
2. Connect the AC input plug into the AC power supply (adapter model EM11012M).
3. Connect the power output plug from the AC adapter into the External Battery Charger.
4. Attach the External Battery Charger by sliding it onto the battery pack until it audibly clicks and locks onto the battery.
5. Once the devices are properly connected, a solid red light will illuminate, indicating the battery is charging.
6. When the green light illuminates, the battery is fully charged.
7. Press the battery latch down and slide the charger off the battery.

NOTE — Initial battery use must include a full charge before first operation. Charging time from fully drained to fully charged is approximately 3 hours when using the External Battery Charger.

LED INDICATOR STATUS

LED Indicator	Charger / Battery Status
Solid Red	Battery is charging.
Solid Green	Battery is fully charged.
Flashing Red	Fault — unplug the charger and repeat steps 1 – 4. If the fault persists, contact your equipment provider.

NOTE — If the red light continues to flash after re-connection, stop using the charger and contact your equipment provider.

WARNING

1. Use only the AC adapter and battery specified in this manual. Incorrect replacement of these components may result in unacceptable risks (such as thermal injury, electric shock injury, or equipment damage).
2. Do not touch the recessed electrical contacts of the External Battery Charger; damage to contacts may affect charger operation.
3. Keep the charger dry at all times. Exposure to water could lead to electrical shock and/or damage.
4. Do not use the charger or any accessory that shows any sign of damage.

CAUTION

Do not place the charger near heat sources or in direct sunlight while charging.

3.10 DC POWER CABLE

The DC power cable (model ED1010E(32), manufactured by EDAC POWER ELECTRONICS CO., LTD.) consists of a single cable with one end that plugs directly into the device and another end that goes into the DC outlet of a vehicle (such as a car or RV cigarette lighter / auxiliary socket).

TO USE THE DC POWER CABLE

- Plug one end of the DC power cable into the DC auxiliary port.
- Plug the other end of the DC power cable into the device.
- Make sure the device is secure before operating.

WARNING

Do not touch the tip of the DC power cable after use because it will be hot. Touching the tip of the DC power cable immediately after removal from the DC auxiliary port may cause injury.

VEHICLE OPERATION WARNINGS

WARNING

- Do not use the DC power cord with a plug splitter. This may cause overheating of the DC power cord.
- Do not jump start the automobile with the DC power cord connected. This may lead to voltage spikes which could shut down and/or damage the device.
- Do not leave the device in an environment which can reach high temperatures, such as an unoccupied car in high temperature environments.
- Do not wrap cords around the power supply for storage. Do not drive, drag or place objects over the cord. Doing so may lead to damaged cords and a failure to provide power to the concentrator.
- Ensure the automobile power socket is clean and the adapter plug fits properly, otherwise overheating may occur.
- Ensure that the automobile power socket is adequately fused for the device power requirement (minimum 15 Amp). If the power socket cannot support a 15 Amp load, the fuse may blow, or the socket may be damaged.
- When powering the device in an automobile, ensure the vehicle's engine is running first before connecting the DC power cord into the DC auxiliary outlet. Operating the device without the engine running may drain the vehicle's battery.
- The device should be kept dry at all times. Exposure to water could lead to electrical shock and/or damage.

NOTE — 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.

4.0 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 avoid electric shock hazard, 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 the device retailer for replacement
	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 the device retailer (retailer information listed in section 3.4 page 19)
	6.Faulty AC accessory power port outlet	6.Check the power port
	7.Device malfunction	7.Contact the device retailer (retailer information listed in section 3.4 page 19).
Cannot adjust/change the Oxygen Prescription setting	Device malfunction	Contact the device retailer (retailer information listed in section 3.4 page 19).
Device not triggering properly	Sensor needs re-calibrated	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
Any about LCD screen display, indicator light and/or alerts.	Please refer to chapter 4.2	Please 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 the device retailer immediately.		

4.2 OVERVIEW OF ALARMS

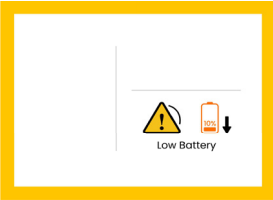
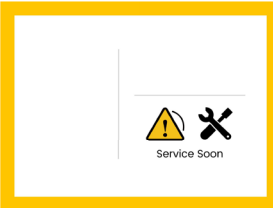
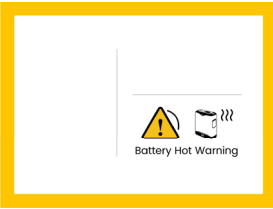
NOTIFICATION

A notification is a non-urgent signal provided by the POC to inform the user of important information or upcoming maintenance requirements. It serves as a proactive reminder rather than an emergency warning, allowing the user to continue normal operation of the device while planning appropriate follow-up actions.

Your portable oxygen concentrator is equipped with a notification feature designed to support timely maintenance of your sieve beds. Upon powering on the device, you may hear a double beep accompanied by a symbol in the display. This is the notification signal. It indicates that the sieve beds, the specialized internal components responsible for concentrating oxygen from room air, are gradually approaching the end of their effective service life. The device will continue to function safely and deliver your prescribed oxygen therapy as intended during this period. The notification serves as an advance reminder that the sieve beds will likely require professional replacement within approximately the next month. Please continue using your concentrator normally, and contact your equipment provider or healthcare service team at your earliest convenience to schedule the necessary replacement of the sieve beds.

LOW PRIORITY ALARMS

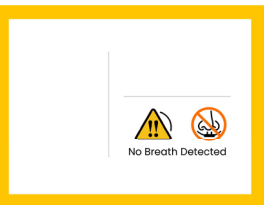
The following low priority alert messages are accompanied by a double beep and a solid yellow frame on the display. Repeat every 25 seconds.

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 beds replacement is proposed within 30 day s.	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 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 Hot Battery has exceeded temperature limit while concentrator is running on battery power.	Move the oxygen concentrator to a cool 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	System Hot The system temperature exceeds the limits temperature, and the device automatically shut 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 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	High Pressure The pressure exceeds the Max. limit value, the device will automatically shut down after 10 seconds.	Contact your equipment supplier and switch to a backup source of oxygen.
 Low Battery Shutdown	Low Battery Shutdown Battery remaining is less than 5%. 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	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	Sensor Fail The concentrator's oxygen sensor has malfunctioned. The concentrator will shut down and stop producing Oxygen.	Contact your equipment supplier and switch to a backup source of oxygen.

Alarm Message	Description	Action
	Oxygen Delivery Error A breath has been recognized, but proper oxygen delivery has not been detected. The concentrator will shut down and stop producing Oxygen.	Contact your equipment supplier and switch to a backup source of oxygen.
	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. The concentrator will shut down and stop producing oxygen.	Contact your equipment supplier and switch to a backup source of oxygen.

5.0 ADDITIONAL INFORMATION

5.1 WARRANTY

Description	Period
Portable Oxygen Concentrator	5 years
Other accessories (adapter, power cord)	3 years
Battery	1 year
Sieve beds	2 years
Disposables (particle filter, inlet filter)	No Warranty

Drive Medical warrants our Portable Oxygen Concentrator under the conditions and limitations stated below. Drive Medical warrants this equipment to be free from defects in workmanship and materials for five (5) years from date of factory shipment to the original purchaser (typically the healthcare provider) with the exceptions of the Sieve Beds (warranted for 2 years), and Battery (warranted for 1 year). These warranties are limited to the Buyer of new equipment purchased directly from Drive Medical, or one of its Retailer, Distributors, or Agents. Drive Medical's obligation under this warranty is limited to product repair (parts and labor) at its factory or at an Authorized Service Center. Routine maintenance items, such as filters, are not covered under this warranty, nor does it cover normal wear and tear.

Drive Medical properly provides circuit diagrams, component part lists, descriptions, and calibration instructions to designated service personnel for component repair.

WARRANTY CLAIMS SUBMISSIONS

The original purchaser must submit any warranty claim to Inspyre Health Systems or to an Authorized Service Center. Upon verification of the warranty status, instructions will be issued. For all returns, the original purchaser must (1) properly package the unit or parts in a Drive approved shipping container, (2) properly identify the claim with the Return Authorization Number, and (3) send the shipment freight prepaid. Service under this warranty must be performed by Drive and/or an Authorized Service Center.

i NOTE— This warranty does not obligate Drive to provide a loaner unit during the time that an oxygen concentrator is undergoing repair.

i NOTE— Replacement components are warranted for the unexpired portion of the original Limited Warranty.

This warranty shall be voided, and the manufacturer shall be relieved of any obligation or liability if:

- The device has been misused, abused, tampered with, or used improperly during this period.
- Malfunction results from inadequate cleaning or failure to follow the instructions.
- The equipment is operated or maintained outside the parameters indicated in the Drive operating and service instructions.
- Unqualified service personnel conduct routine maintenance, servicing, or repairs.
- Unauthorized parts or components (i.e., regenerated sieve material) are used to repair or alter the equipment.
- Unapproved filters are used with the unit.

i NOTE— International warranties may vary.

6.0 PROVIDER INFORMATION

6.1 PROVIDER'S CHECKLIST

i NOTE— If the device fails to operate properly, oxygen concentration is not within specification, or external/internal damage is found, contact Drive for instructions. Service instructions will be available to qualified Drive retailer; please request through customer service. Run the device for 20 minutes every 6 weeks while in storage for optimal performance.

1. Upon arrival, check the Drive POC for damage that may have occurred during shipping and notify Drive of any damage. (Obvious shipping damage should be reported to Drive within 10 calendar days after 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.

i NOTE— Drive recommends leaving a reserve oxygen supply with the patient when setting up the Drive POC, and instructing the patient to always keep reserve oxygen on hand.

7.0 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 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, 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 result in improper operation.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

The SIMO2 by Drive Portable Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The user of the SIMO2 by Drive Portable Oxygen Concentrator should make sure it is used in such an environment.

Immunity Test	IEC60601 Test level	Compliance level	Electromagnetic environment - Guide
Electrostatic discharge (ESD) IEC 61000-4-2	±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 0,15MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Applicable	
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 - IMMUNITY TO PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATIONS EQUIPMENT

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: 1kHzsine	28V/m	28V/m
	710 MHz	LTE Band 13, 17	**Pulse Modulation: 217Hz	9V/m	9V/m
	745 MHz				
	780 MHz				
	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	GSM1800; 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 because while it does not represent actual modulation, it would be worst case Note** -The carrier shall be modulated using a 50 % duty cycle square wave signal					

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS:

The SIMO2 by Drive Portable Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The user of the SIMO2 by Drive Portable Oxygen Concentrator should make sure 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	

MANUFACTURER

Distributed by: Drive Medical
99 Seaview Blvd
Port Washington, NY 11050
www.drivemedical.com
Customer service phone number:
877-224-094

Rev. B.5.26