GCE HEALTHCARE

Zen-O™

Portable Oxygen Concentrator
Models: RS-00500 & RS-00500C

User Manual

GCE® Healthcare

EN

English

User manual: Zen-O™ Portable Oxygen Concentrator (Models: RS-00500 & RS-00500C)

CONTENT

1. FOREWORD

Please refer to this manual for detailed instructions on warnings, cautions, specifications, and additional information.

Important: Users should read this entire manual before operating the Zen-O™ Portable Oxygen Concentrator. Failure to do so could result in personal injury and/or death. If you have questions about the information in this user manual or about the safe operation of this system, contact your distributor.

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1.1. GENERAL INFORMATION

This user manual provides information for users of the Zen-O™ Portable Oxygen Concentrator. For the sake of brevity, the terms “concentrator,” "POC", “unit,” or “device” are sometimes used in this document to refer to the Zen-O™ Portable Oxygen Concentrator. "Patient" and "User" are used interchangeably.

1.2. CLASSIFICATION

This device is listed with an internationally recognised testing laboratory and classified with respect to electric shock, fire, and mechanical hazards in accordance with the following standards:

- IEC/EN 60601-1:2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC/EN 60601-1-2:2014, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC/EN 60601-1-6:2010+A1:2013 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
- IEC/60601-1-8:2006 Medical Electrical Equipment – Part 1-8: General Requirements for Safety – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
- IEC/60601-1-11:2011 Medical Electrical Equipment - Part 1-11: General Requirements for Safety - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
- ISO 80601-2-67:2014, Medical Electrical Equipment - Part 2-67: Particular Requirements for Basic Safety and Essential Performance of Oxygen Conserving Equipment.
- ISO 80601-2-69:2014, Medical Electrical Equipment - Part 2-69: Particular Requirements for Basic Safety and Essential Performance of Oxygen Concentrator Equipment.
- CAN/CSA C22.2 No. 60601-1:14, Canadian Standard, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
- RTCA DO-160G:12/8/2010 Environmental Conditions and Test Procedures for Airborne Equipment.

- ISO 7637-2:2011 Road Vehicles - Electrical disturbances from conduction and coupling- Part 2: Electrical transient conduction along supply lines only.
- Medical Device Directive 93/42/EEC.

This equipment is classified as:

- Class II FDA classifification
- Class IIa according to the MDD 93/42/EEC
- Type BF in accordance with IEC 60601
- IP22 in accordance with IEC 60509

1.3. TYPOGRAPHICAL CONVENTIONS

This user manual contains warnings, cautions, and notes to help call attention to the most important safety and operational aspects of the device. To help identify these items when they occur in the text, they are shown using the following typographical conventions:

⚠ **WARNING: Statements that describe serious adverse reactions and potential safety hazards.**

⚠ **CAUTION**: Statements that call attention to information regarding any special care to be exercised by the practitioner and/ or patient for the safe and effective use of the device.

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

2. INTENDED USE

Zen-O™ portable oxygen concentrator is intended to provide supplemental oxygen to patients with chronic pulmonary diseases and any patient requiring supplemental oxygen.

The device is portable, enabling patients who need an oxygen device to be treated at home according to a clinician's prescription or direction.

Zen-O™ is not intended for use in life supporting or life sustaining situations, and is provided non-sterile. It is a prescription only device, and designed for indoor and outdoor use. For correct operational conditions see Chapter 15 - Technical Description.

Zen-O™ Portable Oxygen Concentrator is not intended to be used:

- in life-supporting or life-sustaining situations
- in an operating or surgical environment
- with a non-adult population
- in conjunction with flammable anaesthetic or flammable materials

3. SAFETY INSTRUCTIONS

⚠ 3.1. WARNINGS OVERVIEW

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1. The device must be used in the carry bag to provide protection from liquid intrusion from rain and/or spills.
2. There is a risk of fire associated with oxygen equipment and therapy. Do not use near sparks or open flames.
3. The pulse settings of Zen-O™ Portable Oxygen Concentrator RS-00500/RS-00500C might not correspond with continuous flow oxygen.
4. The settings of other models or brands of portable oxygen concentrators do not correspond with the settings of Zen-O™ Portable Oxygen Concentrator RS-00500/RS-00500C.
5. Wind or strong drafts can adversely affect accurate delivery of oxygen therapy.
6. Geriatrics or any other patient unable to communicate discomfort can require additional monitoring to avoid harm.
7. Smoking (including e-cigarettes) during oxygen therapy is dangerous and is likely to result in facial burns, serious injury or death of the patient and others from fire. Do not allow smoking or open flames within the same room as the portable 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 the concentrator is located. If unable to leave the room, you must wait 10 minutes after the flow of oxygen has been stopped.
8. Use only water based lotions that are oxygen compatible, before and during oxygen therapy. Never use petroleum or oil based lotions or salves when operating the device to avoid the risk of fire and burns.
9. Open flames during oxygen therapy are dangerous and are likely to result in fire or death. Do not allow open flames within 3 metres (10 feet) of the oxygen concentrator or any oxygen carrying accessory.
10. Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula on bed coverings or chair cushions with the concentrator on, but not in use; the oxygen will make the materials flammable. Turn the concentrator off when not in use to prevent oxygen enrichment.
11. Explosion hazard. Do not use in the presence of flammable anaesthetics!
12. Do not use this device in the presence of pollutants or fumes.
13. Do not submerge this device in liquid. Do not expose to water or precipitation. Do not expose to dusty conditions.
14. Do not use a device or any accessory that shows any sign of damage.

15. Do not use lubricants on this device or any of its accessories to avoid the risk of fire and burns.
16. Use of this device at an altitude above 4,000 m (13,000 feet), or outside the temperature range of 5°C (41°F) to 40°C (104°F), or outside the humidity range of 5% to 93% may adversely affect the flowrate and percentage of oxygen and consequently the quality of therapy. When not in use, the device should be stored in a clean, dry environment between -20°C and 60°C (-4°F and 140°F). Use and/or storage outside of the valid conditions may damage the product. For more technical details see Chapter 15 - Technical Description. Allow this device up to 20 minutes to warm/cool from storage temperatures to operating temperature before use.
17. Always ensure at least one battery is inserted before using this device.
18. If feeling ill or experiencing discomfort while using this device, contact your clinician or seek medical assistance immediately to avoid harm.
19. Your home oxygen provider must verify the compatibility of the device and all accessories used prior to use. To ensure you are receiving the therapeutic amount of oxygen for your medical condition, the device and accessories must only be used after one of more settings have been determined or prescribed for you at your specific activity levels by a healthcare professional.
20. The electrical cord and tubing could present a tripping or strangulation hazard. Keep away from children and pets.
21. Do not disassemble or modify this device or any of its accessories. Do not attempt any maintenance other than tasks described in Chapter 10 - Troubleshooting. Disassembly can create an electric shock hazard and will void the warranty. Contact your distributor for servicing by authorised personnel.
22. Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
23. Do not repair or perform service work while the device is in use by the patient.
24. Do not position your device and its power supply such that it is, difficult to unplug from the power source in the event of an emergency or it is difficult to isolate the device in the event of a fire, electrical hazard or any other incident.

⚠ 3.2. CAUTIONS OVERVIEW

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1. Keep away from heat sources (fireplaces, radiant heaters, etc.) that could cause the operating temperature at or near the device to exceed 40°C (104°F).
2. The display may be difficult to read under bright lighting conditions (sunlight, interior lights, etc.), move away from direct light for viewing the display.
3. Keep away from lint or other loose material that could block the intake vents.
4. Some countries restrict this device to be sold by or on an order of a prescribing clinician. Please ensure you comply with relevant local laws.
5. Non-prescribed oxygen therapy can be hazardous under certain circumstances. Use this device only when prescribed by a clinician.
6. Patients with a fast breathing rate requiring a higher oxygen setting may require more oxygen than this device can produce - see Chapter 15 - Technical Description. This device may not be appropriate in that case. Consult your clinician for alternative treatment.
7. Always operate the device at the setting prescribed by a clinician. Do not alter the setting unless prescribed by a clinician. Periodic reassessment of the flow settings should be done by a clinician.
8. Do not use this device while sleeping unless prescribed by your clinician.
9. It is recommended for an alternate source of oxygen to be made available in the event of power outage or mechanical failure. Consult your home oxygen provider or clinician for an appropriate backup system.
10. This device may not reach specified oxygen concentration purity until it has been in use for up to 2 minutes at set flowrate. Additional warm up time of up to 30 minutes may be required to reach an optimum oxygen purity level, if the device has been stored/unused for an extended period or kept in cold temperatures.
11. This device is designed for use by one patient at a time.
12. If you are unable to hear or see alarms, do not have normal tactile sensitivity, or cannot communicate discomfort, consult a clinician before using this device.
13. If oxygen concentration drops below the specified level, an alarm will indicate this condition. If alarm persists, stop using this device, switch to an alternate source of oxygen, and contact your home oxygen provider.
14. Only use approved accessories with this device. See approved accessories list in section 6.1. and cannula approved for use with this device. Using unapproved accessories or cannula may impair the performance of this device.
15. This device is not designed for use with a nebuliser. If a nebuliser is used with this device, performance may be diminished and the device may be damaged.
16. A humidifier should only be used with this device when in continuous flow mode mode. Follow the humidifier manufacturer's user instructions.

17. Always follow cannula manufacturer's instructions for proper use.
18. Replace the cannula on a regular basis. Check with your home oxygen provider or clinician to determine how often the cannula should be replaced.
19. Check that this device operates on battery after disconnecting from the power source.
20. Only charge battery in this device or in an approved charger. (See approved accessories list.)
21. Remove battery if this device is not going to be used for more than seven days. Store battery in a cool, dry place.
22. Do not use cleaning agents other than those specified in this manual. Allow the cleaning solution to dry from the cleaned surface before use.
23. Always turn off this device when not in use.
24. Always disconnect power and turn off this device before cleaning. See Chapter 11 - Maintenance and Cleaning.
25. Do not obstruct air intake or exhaust vents when operating this device. Blockage can cause buildup of internal heat and shut down or damage this device.
26. Do not place objects on top of this device.
27. Keep away from children and pets to prevent damage to the device and accessories and/or inadvertent setting changes.
28. Keep the device away from pets and pests.
29. This device is rated IP22 while used in the carry bag. Do not use in dusty or wet conditions.
30. Always use in a well ventilated location.
31. Always follow the maintenance schedule as specified in Section 11.1. Routine Maintenance.
32. If this device indicates an abnormal condition, see Chapter 10 - Troubleshooting.
33. Use caution when touching this device in high ambient temperatures.
34. The device can be re-used by a new patient. The device should be cleaned as indicated in section 11.2 of this user manual and, according to local laws and prescriptions prior to delivering to a new patient.
35. The device can be isolated from power by disconnecting the power supply from the input connector, see fig. 1, position the device for easy access to the power supply input connector.

3.3. IMPORTANT INFORMATION

1. *If an extension cord is necessary, use a UL listed 15 amp or higher cord. Do not connect any other devices on the same extension cord. Do not use a multisocketed extension cord.*
2. *Inhale through the nose for the concentrator to work most effectively. Inhaling through the mouth may result in less effective oxygen therapy.*
3. *This oxygen concentrator can operate in either continuous flow mode or pulse delivery mode. Your clinician will provide you with specific instructions for both modes if applicable. See Chapter 15 - Technical Description.*
4. *Your device is designed for everyday use, for optimum performance use your device for a minimum of 4 hours a day.*

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4. INSTRUCTIONS AND TRAINING

The Medical Devices Directive 93/42/EEC states that the product provider must ensure that all users of the device are provided with the User Manual. 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 your home oxygen provider for assistance or further information.**

5. PRODUCT DESCRIPTION

5.1. SCHEMATIC DESCRIPTION

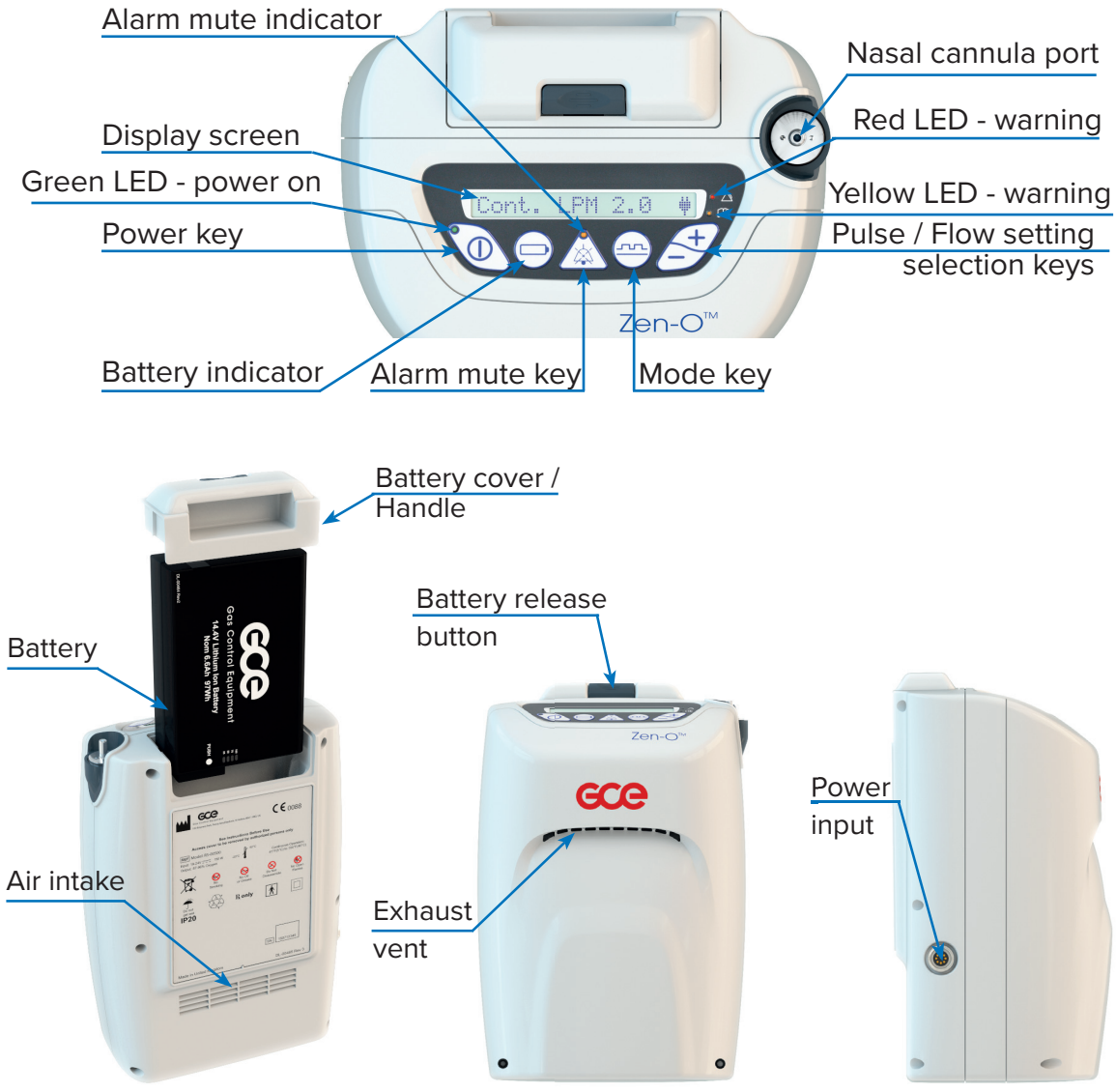

Fig. 1

- The device uses a process called pressure swing adsorption to produce high concentration of oxygen from the atmosphere, a nasal cannula is used to deliver the oxygen to the patient.

6. GENERAL INSTRUCTIONS BEFORE USE

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A variety of accessories can enhance the portability and use of the Zen-O™ Portable Oxygen Concentrator. In addition to the device, the package contains accessories to get started and a user manual. Contact your home oxygen provider for a complete list of available accessories.

Always inspect the device and its accessories for any sign of damage before use.

Important: While the box or packaging may exhibit some damage, e.g., tears or dents, the device may still be in a usable condition. If the device or any accessory shows any sign of damage, contact your home oxygen provider.

Before you get started, check to make sure you have the following:

- Concentrator
- Battery
- Carry bag
- Accessory bag
- AC power supply
- DC power supply
- Pull Cart

Fig. 2

Fig. 3

6.1. ACCESSORIES LIST

Only use power supplies/adapters or accessories specified in this manual. Using accessories that are not specified may create a hazard and/or negatively affect the performance of the device.

- Rechargeable battery (RS-00501)
- AC power supply – European cord (RS-00520)
- AC power supply – United Kingdom cord (RS-00521)
- AC power supply – North America cord (RS-00522)
- AC power supply without cord (RS-00510)
- DC power supply (RS-00508)
- Carry bag (RS-00509)
- Pull cart (RS-00507)
- European power cord (RS-00504)

- United Kingdom cord (RS- 00506)
- North America cord (RS-00503)
- External battery charger - European (RS-00516)
- External battery charger - North America (RS-00515)
- External battery charger - United Kingdom (RS-00517)
- Humidifier kit (RS-00534)
- Nasal cannula MM6012

Note: Contact your provider or retailer if your specific power supply connection is not listed.

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⚠ **WARNING: Do not use the device or any accessory that shows any sign of damage.**

6.2. BATTERY

Zen-O™ Portable Oxygen Concentrator can always be used when directly connected to a power source. However, to enhance its portability, the concentrator is equipped with a rechargeable lithium-ion internal battery. Two batteries can be placed in the concentrator battery slots or one battery can be placed in either slot.

⚠ **WARNING: Always ensure that at least one battery is inserted before using this device.**

IMPORTANT: Optional power cords are available for various global use and travel (see Section 6.1. Accessories List).

6.2.1. Charging the Battery / Batteries

⚠ **CAUTION**: Only charge the battery in this device or in an approved charger. (See Section 6.1. Accessories List.)

- Prior to using the device for the first time, install one or two batteries as shown in Fig. 2. each battery will latch when fully seated.
- Connect the AC/DC power supply by plugging the round connector into the power input on the side of the concentrator Fig. 3.
- Plug the other end of the AC/DC power supply into a power outlet. Always use caution when inserting the power supply to a wall outlet.
- The display shows **Charging NN%** .

The charger is universal and supports a wide variety of international markets, so it can be plugged into an outlet with 100-240V AC, 50-60 Hz.

Allow the battery/batteries to fully charge before first time use. Once completely charged, the device can run for up to 4 hours with one battery or 8 hours with two batteries at setting 2 in pulse mode, at 18 breaths per minute. In continuous mode at setting 2 the device can run for up to 0.75 hours on one battery and 1.5 hours on two batteries.

IMPORTANT: Battery run time may vary based on breathing rate, age of battery, and environmental conditions. See displayed text on device for battery charge status.

IMPORTANT: Ensure power status icon (see Fig. 7) indicates power is connected. If not, check that cord is plugged in completely. (See Chapter 10 - Troubleshooting for more information.)

IMPORTANT: While the concentrator is powered from the DC power supply and operating in continuous mode at setting 2, the battery will not charge.

IMPORTANT: The DC power supply should be utilised on vehicles with the proper power output rating.

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IMPORTANT: The vehicle should be running while utilising the DC adapter to power the Zen-O Portable Oxygen Concentrator.

To maximise battery life and run time, avoid letting the battery deplete and use while connected to a power source whenever possible. The battery will automatically charge whenever the concentrator is connected to a power source. You can use the device while the battery is charging. The LCD display will indicate whether the device is operating on battery or external AC power.

The fully charged battery will retain some level of charge for up to thirty days in this device when not in use - see Caution below for battery removal/storage recommendation.

IMPORTANT: Battery damage may result if the concentrator's battery is allowed to discharge completely.

IMPORTANT: After 300 charge/discharge cycles, the battery capacity will be at least 80% of its original capacity. Replace the battery when the reduced battery life is affecting your mobility.

⚠ **CAUTION**: Remove battery if this device is not going to be used for more than seven days. Store battery in a cool, dry place.

⚠ **CAUTION**: Check that this device operates on battery after disconnecting from the power source.

IMPORTANT: When not using the battery inside the unit, be sure to store it in the protective sleeve that was provided with the original package.

6.3. NASAL CANNULA

Only use a nasal cannula with the following specifications:

- Length: 1.2m (4ft), 2.1m(7ft), 7.6m(25ft) or 15.2m (50ft)
- High flow
- Crush resistant
- Large internal diameter bore
- Suitable for up to 15 litres per minute (lpm) at a max. pressure of 3.6 psi
- Meets substance compatibility of IEC/EN 60601-1

⚠ A 15.2m (50ft) cannula must only be used when device is operating at a continuous mode setting.

⚠ **CAUTION**: Only use approved accessories with this device. Refer to the approved accessories guide for a complete list of accessories and cannula approved for use with this device. Using unapproved accessories or cannula may impair the performance of this device, including flow rate or oxygen purity.
Contact your distributor for updated information and accessories or if additional, optional, or replacement accessories are needed.

6.4. PULL CART

When using the device with a pull cart, attach and secure the concentrator with the straps as shown in Fig. 4.

IMPORTANT: It is recommended that patients use the pull cart to transport the device whenever possible.

Fig. 4

6.5. CONNECTING A HUMIDIFIER

WARNING: A humidifier may only be used in continuous mode!

Do not use a humidifier while the POC is in pulse mode or eco mode!

Do not overfill the humidifier!

Use humidifier only if prescribed by a clinician!

To attach the humidifier:

- Remove the cover on the humidifier bottle
- Fill the humidifier with distilled water
- Fill the humidifier bottle to the level specified by the humidifier bottle manufacturer mark then replace the cover.
- Attach the angle adapter directly to the humidifier bottle and - Place the assembled humidifier bottle into humidifier bag and attach the humidifier bag to the pull cart.

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- Connect the oxygen adapter hose (max 50 cm) to the angle adapter and fit the other end to the oxygen outlet on the concentrator. Make sure all connections are secure.
- Connect the nasal cannula to the humidifier bottle outlet and ensure oxygen is flowing through the cannula.
- The concentrator and the humidifier should always be used in an upright position to prevent water from entering the nasal cannula.

NOTE: Using only specified cannula.

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7. OPERATING ZEN-O™

IMPORTANT: Read Chapter 3 - Safety Instructions before using this device.
Zen-O™ Portable Oxygen Concentrator is designed for ease of use, with all functions accessed through just a few buttons on the control panel.

The device should be carried in its carry bag, placed on a cart and used when positioned upright on a table or on the floor while in the carry bag. The patient should be within the recommended cannula length during use.

IMPORTANT: Except during startup and shutdown sequences, the backlight on the display screen will remain off. Pressing any button will turn the backlight on briefly. The backlight will also remain activated during an unmuted alarm condition.

7.1. CONNECTING NASAL CANNULA

⚠ **CAUTION: Replace the cannula on a regular basis. Check with your home oxygen provider or clinician to determine how often the cannula should be replaced.**

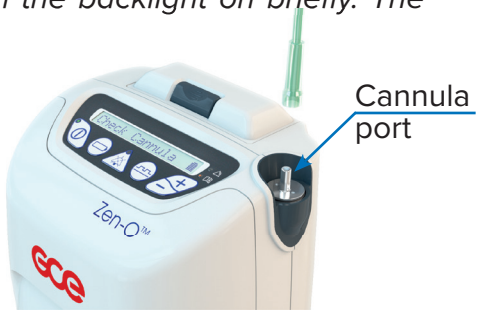

Fig. 5

⚠ **CAUTION**: Always follow cannula manufacturer's instructions for proper use.

Connect the tubing to the cannula port as shown in Fig. 5.

To connect the cannula to the patient, position the cannula tips in patient's nostrils and pass tubing over both ears and under chin. Follow manufacturer's instructions.

Slide adapter up tubing to adjust for comfort and fit.

Once the cannula is secured, breathe normally through the nose. Zen-O™ will detect a breath and deliver the oxygen during inhalation.

IMPORTANT: Improper cannula placement may result in the device being unable to detect all respiratory efforts of the patient. Ensure cannula is connected securely and it has been fully inserted.

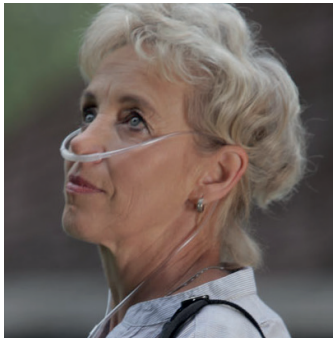
Fig. 6

7.2. TURNING ON

- To turn the device on, press the power button .
- The concentrator will chirp and the green, yellow, and red LEDs will flash once, while the screen displays the device name.

Red LED - indicates a warning danger and/or a need for urgent action

Yellow LED - indicates caution or attention required

Green LED - indicates device is on. The green LED will then stay lit.

IMPORTANT: No adjustments can be made until the startup sequence is completed.

7.3. CHOOSING A PREFERRED LANGUAGE

- While the device is on, hold down the plus and mute buttons together for about four seconds until it says “Language:”.
- Next cycle through the available languages using the plus or minus buttons.
- When the desired language is shown, press the mode button to select. The device will change the language and go back to the normal flow screen.

7.4. ADJUSTING SETTING

IMPORTANT: After powering on Zen-O™, the startup sequence will take approximately 35 seconds. Specified oxygen level will be reached within 2 minutes of use.

- The device starts working in the previous setting.

Use the mode button to alternate between pulse mode **Pulse X.X** and continuous flow mode **Cont. LPM X.X** .

- In pulse mode, the device will deliver a pulse of oxygen at the beginning of each of your inhalation.
- **Auto Mode:** If no inhalation is detected for 60 seconds when in pulse mode, the “Check Cannula” alarm will be activated and the device will automatically enter Auto-Mode and continue to deliver oxygen at a rate of 18 breaths per minute. When an inhalation is detected, the device will clear the “Check Cannula” alarm and exit Auto-Mode.
- In continuous flow mode, the device will provide a continuous flow of oxygen, but will consume more power and have a shorter battery life.

Setting the mode can be done as follows:

- Pulse mode of operation can be adjusted from 1.0 to 6.0 in 0.5 increments with the and buttons.
- Continuous mode of operation can be adjusted from 0.5 to 2.0 in 0.5 increments with the and buttons.

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IMPORTANT: If an air leak is suspected, leaks can be detected with a solution of soap and water applied to the cannula-concentrator connection point and looking for bubbles.

IMPORTANT: Flow can be verified by putting the oxygen concentrator in continuous mode and placing the end of the nasal cannula under the surface of a half full cup of water and looking for bubbles.

The current setting and power source (external power or battery; battery icon also shows approximate level of charge remaining) are shown on the display screen as shown in Fig. 7.

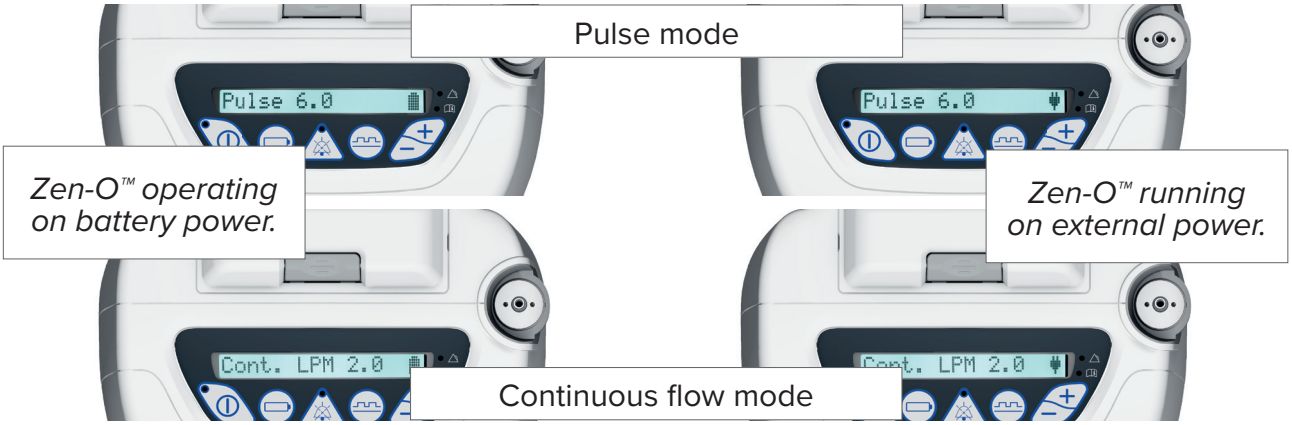

Fig. 7

7.5. ECO MODE

While the Setting screen is shown, press and hold the Battery button for approximately four seconds until it changes from “Pulse XX” to “Eco Mode”. Press and hold the Battery button again to return to Pulse Mode.

In standard Pulse Mode, the device will give you the same amount of oxygen every breath, regardless of your breath rate. This can consume more battery power at higher breath rates. In Eco Mode, the device will deliver a fixed volume of oxygen per minute regardless of breath rate, and will give an extended battery duration.

7.6. BATTERY BUTTON

The battery button allows you to check the status of the battery or batteries. Repeatedly pushing the button will cycle through all the information.

- First, the gauge information for both batteries (or one battery if only one is installed), will be shown **Charging NN%** .
- Next, the gauge for just the battery in the first slot **Batt1: NN%** , then the number of charge cycles on the battery in the first slot **Batt.1: N cycles** .
- Finally, the gauge and charge cycles for the battery in the second slot is shown **Batt2: NN%** **Batt.2: N cycles** .

If there is no battery in one of the slots, then a question mark will be shown instead of the fuel gauge and number of cycles. After the fifth push of the battery button, the display will alternate back to the main screen showing the current flow setting. It will also automatically exit the battery status menu and go back to the main flow setting display after approximately 15 seconds of no buttons being pushed.

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7.7. RESPONDING TO ALARMS

⚠ **CAUTION**: If you are unable to hear or see alarms, do not have normal tactile sensitivity, or cannot communicate discomfort, consult your clinician before using this device.

Pressing the alarm mute button ⚠ at any time will silence the buzzer. The length of the mute period depends on the severity of the alarm (see Chapter 9 - Alarm Indicators). During this mute period, the mute LED will remain illuminated, indicating the alarm buzzer is muted. Push the mute button again to un-mute alarms. Pressing the mute button when there is no active alarm will mute any future medium or low priority alarms for eight hours. See Chapter 9 - Alarm Indicators and Chapter 10 - Troubleshooting for additional information on alarms.

IMPORTANT: The alarm system is tested during the startup sequence. You should see all alarm lights briefly turn on and the audible alarm indicator chirp. If alarms are suspected of mis-operating, contact your distributor for verification that alarms are working correctly.

7.8. TURNING OFF

⚠ **CAUTION**: Always turn off this device when not in use.

To turn the Zen-O™ Portable Oxygen Concentrator off, press and hold the power button. The device will chirp and the screen will display a shutdown message **Shutting off** for approximately five seconds, then go into low-power mode.

IMPORTANT: Do not disconnect the AC power supply and remove the battery at the same time while the unit is running. Always use the power button to turn the device off. Wait until the device has completely shut down before disconnecting from power and removing the battery.

8. TRAVELING WITH THE ZEN-O™ POC BY AIR

8.1. PASSENGER PRE-FLIGHT PREPARATION

8.1.1. Required Labeling

Your Zen-O™ POC is suitable for aircraft use and has met all acceptance criteria of the United States Federal Aviation Administration (FAA). This is verified by the statement on the back of the POC that states, in red text, “The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft”. Prior to the flight, you may be asked to show this text on the POC to the flight attendant.

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8.1.2. Healthcare Provider Consultation

The FAA does not require a passenger to consult with a healthcare provider prior to using a Zen-O™ POC on board an aircraft. However, you, together with your healthcare provider, may wish to discuss the following:

- The effects of a pressurised cabin (cabin pressure altitude can reach 8,000 feet) on your oxygen needs.
  - Some Zen-O™ POC users need higher litre flow or litre per minute (LPM) setting for the Zen-O™ POC in the air because of cabin pressure altitude.
  - Some Zen-O™ POC users who use a Zen-O™ POC occasionally on the ground may need to use their Zen-O™ POC for the entire flight because of cabin pressure altitude.
- Your oxygen needs at the time of travel and whether your needs have changed since the Zen-O™ POC was first prescribed or during the most recent consultation with a healthcare professional.
- Certain button provisions in the Zen-O™ POC operating manual regarding oxygen delivery, indicators, warnings, and alerts, as well as setting/changing litre flow or LPM.
- All crewmembers (pilots and flight attendants (F/A)) receive training regarding the handling of in-flight medical events. However, the FAA does not require that air carriers or crewmembers provide medical assistance to passengers.

IMPORTANT: Additional information regarding passenger health and safety can be found at http://www.faa.gov/passengers/fly_safe/health/comprehensive/.

8.1.3. Determine a Sufficient Number of Batteries

You are responsible for bringing a sufficient number of batteries to power the Zen-O™ POC for the duration of the expected use of your Zen-O™ POC. You should consider at least the following in determining a sufficient number of batteries:

- Healthcare professional advice regarding duration of Zen-O™ POC use.
- Air carrier information regarding duration of the expected flight as well as any layovers and unanticipated delays.

IMPORTANT: You may be flying on multiple flights or multiple airlines, which could also involve extended periods of Zen-O™ POC use on the ground between flights.

- Zen-O™ owner's manual information regarding expected duration of battery power.

IMPORTANT: You should never rely upon available onboard aircraft electrical power during a flight.

- Air carrier requirements to carry a certain amount of batteries are typically available on each airline's web site.

IMPORTANT: Air carriers may require you to bring enough batteries to power the device for at least 150% of the expected maximum flight duration.

8.1.4. Documentation

You are responsible for the operation of the Zen-O™ POC on board the aircraft. For this reason, the FAA recommends that passengers carry with them, at minimum, this User Manual and any other written information provided by your healthcare professional regarding the Zen-O™ POC and its use.

8.1.5. Physician´s Statement

An air carrier may require a medical certificate from a passenger with a disability if there is reasonable doubt that the individual can complete the flight safely without requiring extraordinary medical assistance during the flight. Also, an air carrier may require a medical certificate from a person who needs medical oxygen during a flight. The FAA does **not** require passengers to obtain a physician's statement and present such statement to the operator or pilot in command (PIC) prior to Zen-O™ POC use on board the aircraft.

8.1.6. Spare Batteries

Battery damage and battery short circuit can result in battery overheating and fire. These events, in turn, can result in personal injury to passengers, and in the worst case for certain types of batteries, a catastrophic passenger compartment fire. Thus, spare lithium batteries carried on board aircraft must be individually protected from short circuit by placement in original retail packaging, by taping over exposed terminals, or by placing each battery in a separate plastic bag / protective pouch.

IMPORTANT: Spare lithium batteries are prohibited from being carried in checked baggage on an aircraft.

You are responsible for ensuring that all spare batteries carried in carry-on baggage are properly packaged. Zen-O™ POC equipment providers, some airlines, and freight forwarders specialising in small package shipments may provide this packaging service for you.

8.2. BOARDING AND IN-FLIGHT INFORMATION

8.2.1. Carry-on baggage

Your Zen-O™ POC is an assistive device. In this case, carriers shall not, in implementing their carry-on baggage policy, count the Zen-O™ POC toward a limit on carry-on items brought into the cabin by a qualified individual with a disability.

IMPORTANT: A bag with additional batteries that is required to power the Zen-O™ POC during the flight could also be considered an assistive device. However, there are restrictions on the Watt Hour (Wh) rating of the battery which is limited to 100Wh per battery. For your Zen-O™ POC, the Watt Hour (Wh) rating is less than 100Wh per battery maximum, therefore no limitation will be imposed.

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8.2.2. Zen-O™ POC as Checked Baggage

Your Zen-O™ POC may be carried on aircraft as a carry-on or as checked baggage. However, **spare lithium batteries are prohibited from being carried in checked baggage on an aircraft.**

8.2.3. Considerations Regarding Placement and Stowage of your Zen-O™ POC

In order for a Zen-O™ POC to work efficiently, the air/intake vents must not be blocked during use. Therefore, the area around the Zen-O™ POC should be clear of blankets, coats, and other pieces of carry-on baggage that may block the air/intake vents. If the air/intake vents are blocked, two things will occur. First, you will be alerted by warning lights and/or audible alerts that the oxygen concentration in the Zen-O™ POC output is insufficient. Second, when the temperature of the Zen-O™ POC internal components increases to a certain limit because the Zen-O™ POC is still trying to dispense oxygen, the Zen-O™ POC will automatically shut down to prevent overheating of the Zen-O™ POC and you will be alerted by warning lights and/or audible alerts.

Placement of Zen-O™ - Onboard an aircraft the Zen-O™ POC should be placed underneath the seat in front of you so that you or the flight attendant can see the warning lights and/or hear the audible warning. Placement directly under your seat and placement in a closed compartment would prohibit you from seeing the warning lights, as well as possibly prohibiting you from hearing audible warnings. Other placement locations may be acceptable as deemed acceptable by the flight attendant.

8.2.4. Seating Restrictions for Passengers who Plan to use a Zen-O™ POC On Board an Aircraft

Exit Row Seating - The FAA prohibits passengers that use any assistive device including Zen-O™ from occupying an exit seat.

Stowage during Aircraft Movement - During movement on the surface (pushback from the gate and taxi), take-off, and landing, the Zen-O™ POC must be stowed properly and in such a manner that it does not restrict passenger access to any exit or the aisle in the passenger compartment. Additional seating restrictions may be necessary to comply with these FAA safety rules. For example:

1. Some seats on an aircraft, such as bulkhead seats, may or may not have approved stowage space to accommodate a Zen-O™ POC during movement on the surface, take-off, and landing. Therefore, the Zen-O™ POC may not be able to be stowed properly during these phases of flight if the Zen-O™ user occupies those seats. In this case, a seating restriction may apply
2. During movement on the surface, take-off, and landing, the nasal cannula tubing that is used to dispense oxygen from your properly stowed Zen-O™ POC may not stretch across the row in such a way as to restrict passenger access or become a tripping hazard in an evacuation. You must not restrict another passenger's access during these phases of flight. In this case, a seating restriction may be required to comply with an FAA safety rule. For example, if all seats in the row are occupied, the appropriate seat for the Zen-O™ POC user would be a window seat.
3. An operator can only establish seating restrictions based on FAA safety rules. The examples above represent some, but not all, scenarios to consider.

IMPORTANT: A general airline policy that all passengers who board the aircraft with a Zen-O™ POC must occupy a window seat, without regard to the specifics of the individual situation, would be inconsistent with FAA requirements.

8.2.5. Cabin Depressurisation

There is no danger posed by a Zen-O™ POC that is operating during a loss of cabin pressure. However, in the case of loss of cabin pressure (rapid or slow), you should use the oxygen masks that deploy until the aircraft stabilises.

8.2.6. Use of Aircraft Electrical Power

There is no requirement for operators to provide aircraft electrical power to a Zen-O™ POC user. Electrical outlets on board aircraft are considered nonessential equipment and are not required by the applicable certification or operational rules. In addition, electrical malfunctions in aircraft systems may require the power source to these outlets to be deactivated on the ground or in flight for the safety of the flight. Due to this statement, the Zen-O™ POC should only be operated off battery power while on board aircraft. **You should never rely upon onboard aircraft electrical power being available during a flight**

8.2.7. Smoking

Smoking (including e-cigarettes) during oxygen therapy is dangerous and is likely to result in serious injury or death of the patient and others from fire. Do not allow smoking or open flames within 10 feet of the portable oxygen concentrator or any oxygen carrying accessories.

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8.3. TRANSPORTATION SECURITY ADMINISTRATION (TSA) REQUIREMENTS

Detailed information that is pertinent to passengers using respiratory devices, including Zen-O™ POCs, may be obtained from the TSA at *https://www.tsa.gov/travel/special-procedures*.

The following general security screening considerations apply to Zen-O™ POCs:

1. The limit of one carry-on and one personal item (e.g., purse, briefcase, or computer case) does not apply to medical supplies, equipment, mobility aids, and/or assistive devices carried by and/or used by a person with a disability.
2. If a person has medical documentation regarding their medical condition or disability, they can present this information to the screener to help inform him or her of the person's situation. This documentation is not required and will not exempt a person from the security screening process.

8.4. PLACING YOUR DEVICE IN AIRPLANE MODE

If you have the RS-00500C model (this is stated on the back of your device), this means your device is connected to GCE's Clarity platform. Clarity provides regular updates on your device's performance to your home oxygen provider, enabling them better support you and your device.

When travelling by air, you are required by international air travel regulations to disable communications features on your electronic devices on board the aircraft. If your Zen-O portable oxygen concentrator is enabled to work with GCE's Clarity platform you will need to place the device in Airplane mode.

You can do this in few easy steps:

1. To place in Airplane Mode: Press and hold both Mute and Minus buttons for 4 seconds.
2. The screen will display as follows:

and the power/battery symbol will alternate with "A":

3. If a button is pressed, the display shows as normal

and after 10 seconds it reverts to the continuously alternating "A"

4. To disable the Airplane Mode: Press and hold both Mute  and  Minus buttons for 4 seconds.

IMPORTANT: Activating or de-activating the Airplane mode does not affect the normal operating performance of your device, continue to use your device as normal.

9. ALARM INDICATORS

If the Zen-O™ Portable Oxygen Concentrator detects an alarm condition, it will indicate the alarm visually and audibly within 10 seconds. There are four levels of alarms: critical high priority, high priority, medium priority, and low priority.

Each is indicated differently by the backlit display; yellow, and red LEDs; and buzzer, as indicated below. In each case, the alarm message and power status will override the current display.

IMPORTANT: All alarm conditions and parameters are factory preset; conditions and parameters cannot be changed or adjusted by the user.

IMPORTANT: The alarm system is tested during the startup sequence. You should see all alarm lights briefly turn on and the audible alarm indicator chirp.

ALARM STATUS	AUDIBLE TONE	VISUAL INDICATOR	MUTE TIME
Critical high priority	Ten beeps per burst, a burst repeats every 3 seconds.	Solid red LED and device is automatically disabled	20 minutes
High priority	Ten beeps per burst, a burst repeats every 3 seconds.	Flashing red LED	20 minutes
Medium priority	Three beeps per burst, burst repeats every 8 seconds	Flashing yellow LED	8 hours
Low priority	Three beeps per burst, burst repeats every 10 minutes	Solid yellow LED	24 hours

IMPORTANT: If two alarm conditions exist at the same time, the highest priority alarm is indicated. If two or more alarm conditions of equal priority exist at the same time, the most recent one will be displayed.

IMPORTANT: The most recent alarms indicated by the device are logged for reference by service personnel. This log is maintained even if the device is powered down or if power is lost for any other reason.

IMPORTANT: If the mute button is pressed prior to an alarm condition (for example, to mute the device in a movie theatre), critical high priority and high priority alarms will override the mute function; medium and low priority alarms will be muted for eight hours and twenty four hours respectively from the time the button was pressed. Press the mute button off to display the last highest priority alarm. Press the mute button on again to reset the eight-hour timer.

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9.1. ALARMS

When the concentrator sounds an alarm, a corresponding message will be displayed on the screen. Take appropriate action as directed in the charts below.

9.1.1. Critical High Priority Alarms

IMPORTANT: These alarms will disable the device immediately.

ALARM MESSAGE	DESCRIPTION	ACTION
Charge battery	Battery needs charging.	Recharge the battery pack by plugging in to the power supply. Ensure all connections are made securely.
Invalid batt.	Battery is not an approved battery	Replace battery with an approved battery.
XX: Service!*	Service required.	Contact your distributor.

*Value: 01-20

9.1.2. High Priority Alarms

IMPORTANT: These alarms will allow the device to continue operating.

ALARM MESSAGE	DESCRIPTION	ACTION
Check Vents	Device is unable to maintain oxygen purity.	Be sure air inlet/outlet has not been blocked. If alarm persists, contact your distributor.
Low Battery	Estimated battery life less than 17 minutes.	Charge the battery pack by plugging in to power supply. *Important: The message will be automatically cleared when plugged in to power supply.*

XX: Service!*	Service required.	Contact your distributor.

*Value: 21-50

9.1.3. Medium Priority Alarms

ALARM MESSAGE	DESCRIPTION	ACTION
Check Cannula	No breath detected for 60 seconds	Check the cannula connection. Be sure to breathe through nose, If alarm persists, contact your distributor. *IMPORTANT: The message will be automatically cleared when breathing is detected.*
Low Flow	Continuous flow of oxygen is below specifications.	Check that cannula is not kinked and that patient filter is properly installed. If alarm persists, contact your distributor.
XX: Service!*	Service required.	Contact your distributor.

*Value: 51-70

9.1.4. Low Priority Alarms

ALARM MESSAGE	DESCRIPTION	ACTION
XX: Service!*	Service required.	Contact your distributor.

*Value: 71-99

9.1.5. Other Messages

MESSAGE	DESCRIPTION	ACTION
Power removed	External power has been disconnected; unit is now running on battery.	No action is required.
Shutting off	Displayed while unit goes through its power-down sequence.	No action is required.
No battery	Displayed as the battery menu item when there are no communications with the battery.	Verify that the battery pack is correctly installed. Contact your distributor if the battery is fully inserted and the message continues to be displayed longer than 30 seconds.
Batt NN%	Displayed percentage of battery charge if at least 10% and there is no external power connected.	Message is displayed when battery button is pressed.
Charging: NN%	NN% displays the current battery charge level. Displayed when battery charge is greater than 10% but less than 100% and there is external power connected.	Message is displayed when battery button is pressed.
Charging	Battery charge is less than 10% and there is external power connected.	Message is displayed when battery button is pressed.
Breath rate XX	The patient's average breath rate when the device is delivering the maximum amount of oxygen and the bolus is reduced. If no breaths are detected, the most recent breath rate is shown.	Reduced activity level. Be sure air inlet/outlet has not been blocked. *IMPORTANT: The message will automatically clear when the device returns to normal operation.*
Alarm cleared	A previously set alarm has been automatically cleared.	No action required.

10. TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	TROUBLESHOOTING
System becomes inoperative	• System may be disconnected from the power source. • System may be turned off. • Critical high priority alarm has occurred.	• Check that the system is connected securely to the power source. • Ensure the system is powered on. • Examine the system for damage or exposure to liquids. • If problem persists, contact your distributor.
Any alarm sound or either  or  LED lit	• See Chapter 9 - Alarm Indicators.	See Chapter 9 - Alarm Indicators.

Battery not charging	• Power is not connected.
	
	• Battery is not fully inserted.
	• Battery is inoperable.
		• Check connections to ensure:
		  • Round receptacles are secure in unit.
		  • Power cord is connected to AC/DC supply or automotive DC adapter is connected, if applicable.
		  • Power cord is connected to wall outlet, if applicable.
		  • Wall outlet has power.
		• Ensure battery is fully seated and battery cover is secure.
		• If problem persists, contact your distributor.

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11. MAINTENANCE AND CLEANING

11.1. ROUTINE MAINTENANCE

⚠ **WARNING: Do not use lubricants on this device or any of its accessories.**

⚠ **CAUTION**: Replace the cannula on a regular basis. Check with your distributor or clinician to determine how often the cannula should be replaced.

Device will indicate with an alarm when service is required. (Also, see Chapter 10 - Troubleshooting.)

No special maintenance needs to be carried out by the user. Contact your provider or manufacturer for help, in setting up, maintenance, or to report unexpected errors.

11.2. CLEANING AND DISINFECTION

⚠ **WARNING: Do not submerge this device in liquid. Do not expose to water or precipitation. Do not expose to dusty conditions.**

⚠ **CAUTION**: Do not use cleaning agents other than those specified in this manual. Allow the cleaning solution to dry from the cleaned surface before use.

⚠ **CAUTION**: Always disconnect power and turn off this device before cleaning.

Clean the exterior with a soft cloth slightly dampened with soapy water or with anti-bacterial wipes (Isopropyl alcohol 70% solution).

For disinfecting, use a MadaCide-FDW-Plus wipe or equivalent and follow the manufacturer's instructions. (Manufacturer - Mada Medical Products Inc., www.madamedical.com)

Important: The device should receive an external cleaning weekly, accessories should be cleaned as needed. The device exterior and accessories should be cleaned and disinfected and the patient filter replaced prior to delivering to a new patient. The device may become hot after operation, take additional care when replacing filters.

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

11.3. SERVICE LIFE

The expected service life of the device is 5 years, except for the sieve modules. The service life of the sieve modules will depend on the operating conditions. The sieve modules are an internal component of the device and should only be replaced by a trained person. If the intake and exhaust vents are not blocked and the check vents alarm is activated contact your distributor.

12. DEVICE REPAIR AND DISPOSAL

12.1. REPAIR

Do not attempt to repair the device. Contact your home oxygen provider or distributor for assistance (see Chapter 10 - Troubleshooting).

12.2. DISPOSAL

- Contact your distributor regarding disposal of the device.
- Dispose of battery according to local regulations or contact your distributor.

13. WARRANTY

GCE warrants every new Zen-O™ Portable Oxygen Concentrators and associated accessories (“Products”) to be free of defects in material and workmanship, subject to the following conditions:

All warranties on products, accessories, and components are from the date of sale as stated on the invoice issued by GCE. Warranties will not be extended based on any warranty work conducted within the warranty period. Out of warranty work will come with a standard 90-day warranty on parts and labour on the repair done.

PRODUCT DESCRIPTION	DEVICE WARRANTY
Zen-O™ Portable Oxygen Concentrator	3 years or 15,000 hours whichever comes first (For optimum performance, the Portable Oxygen Concentrator should be used for a minimum of 4 hours a day. Infrequent use may impact the life of the Sieve Assembly and will invalidate the warranty on the Sieve Assembly)
Accessories (Battery, Power supply packs, all bags)	1 year
Filters, cannula, and humidifier bottle	No warranty applicable

LIMITED WARRANTY POLICY SIEVE ASSEMBLY\MODULES

Model	Supplied with a POC	Supplied as a Spare Part
Zen-O Sieve Assembly	The Zen-O Sieve Assembly supplied in every unit is limited to 2 years or 15,000 hours whichever comes first from date of sale to the original purchaser	Sieve Assembly/Modules supplied as a spare part are limited to 1-year warranty from date of sale to the original purchaser

No other express warranties are made with respect to any product. All implied warranties, including warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth above. This warranty is not transferable and applies only to the original purchaser of the product from GCE.

If the purchaser believes that the product does not comply with the warranty as stated in this document, the purchaser should contact the distributor within 2 business days of receipt of the Product, providing a description of the problem and proof of the date of purchase. If directed by the GCE distributor, purchaser shall return the products, freight prepaid, properly packaged in GCE approved shipping container and identified by a Returns Material Number issued by GCE. GCE will not accept products not identified by a Return Material Number. Product without a Return Material Number shall be returned to the purchaser at the purchaser's expense.

GCE will at its sole obligation under this warranty, replace or repair at its option any Product that does not conform to this warranty. Products may be repaired or replaced with new or with refurbished items.

The limited warranty will be voided if the product(s) or components are;

- subject to inappropriate use, misuse, improper storage, accidental damage, neglect, physical damage, smoke (including tobacco or electric cigarettes), unauthorized modification or repair
- damaged due to ingress of sand, liquids, insects, animal fur or other foreign objects
- damaged due to unusual electrical stress or environmental conditions, such as, temperature, humidity, condensation outside the Product(s) or component specification.
- used or damaged in manner not considered fair wear and tear
- repaired or modified with components and materials not supplied or authorised by GCE
- damaged due to conditions not in the control of GCE.
- returned without a valid serial number as supplied by GCE or if the serial/batch number has been altered or damaged

This limited warranty does not cover defects in appearance, cosmetic, or decorative items, including any non-operative parts. The Product must be used and maintained as recommended in the relevant manuals, failure to follow the operating instructions in the user manual shall invalidate this limited warranty. UNDER NO CIRCUMSTANCES WILL GCE BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES UNDER THIS WARRANTY OR ANY IMPLIED WARRANTIES.

THESE REMEDIES ARE THE CUSTOMER'S EXCLUSIVE REMEDIES FOR BREACH OF WARRANTY.

14. TRADEMARKS AND DISCLAIMER

14.1. TRADEMARK

All trademarks are the property of their respective owners.

14.2. DISCLAIMER

The information in this document has been carefully examined and is believed to be reliable. Furthermore, the manufacturer reserves the right to make changes to any products herein to improve readability, function, or design. The manufacturer does not assume any liability arising out of the application or use of any product or circuit described herein; neither does it cover any license under its patent rights nor the rights of others.

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14.2.1. This Document

The information in this document is subject to change without notice. This document contains proprietary information that is protected by copyright. No part of this document may be reproduced in any manner, in whole or in part (except for brief excerpts in reviews and scientific papers), without the prior written consent of the manufacturer. Be sure to read carefully and understand all manuals provided with the product.

For Help

If you have questions about the information in these instructions or about the safe operation of this device, contact your home oxygen provider or distributor.

15. TECHNICAL DESCRIPTION

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Size:	212 mm (W), 168 mm (D), 313 mm (H) 8.3" (W), 6.6" (D), 12.3" (H)
Unit weight:	4.66 kg (10.25 lbs) (without carry bag and cart)
Power requirements:	AC adaptor: 100-240V AC (+/- 10%), 50-60 Hz in, 24V DC, 6.25A out. DC adaptor: 11.5-16V DC in, 19V, 7.9A out *(Important: see accessories list for model and part number of AC power supply.)*
Purity:	90% (+6/-3%) at all flow rates, over operating conditions
Setting:	User adjustable in 0.5 increments from 1.0 to 6.0 in pulse mode and from 0.5 to 2.0 in continuous mode.
Inspiratory trigger sensitivity:	-0.12 cm/H_2O
Setting indicator:	LCD display
Maximum oxygen discharge pressure:	20.5 psi
Humidity range:	5% to 93% ± 2% non-condensing for operating, storage and transportation conditions
Operating altitude:	0' to 13,000' (0 m to 4,000 m) relative to sea level, 1,060 down to 575 mbar
Sound level:	Sound Pressure level of 38 dB(A) at setting 2 in pulse mode, tested according to Prufmethode 14-1 03/2007 MHS-Hi Sound Pressure level of 46dBA/Sound Power level of 54dBA at setting 6 in pulse mode Sound Pressure level of 52dBA/Sound Power level of 60dBA at setting 2 continuous
Type of protection (electrical):	Class II
Degree of protection (electrical):	Type BF

Degree of protection (water):	IP22 in carry bag (protection against small objects and tilted dripping water) IP20 out of carry bag (protection against small objects and no protection against water entering the concentrator)

Technical Description

Degree of safety (flammable anaesthetic mixture):	Not suitable for use in the presence of a flammable anaesthetic mixture
Operating temperature:	Continuous operation at temperatures between 5°C (41°F) and 40°C (104°F).
Storage and transportation temperature:	Between -20°C (-4°F) and 60°C (140°F).
Alarm sound pressure level:	69 dB(A)
Alarm system delays:	Less than 10 seconds after detection (low oxygen alarms if oxygen is less than 82% volume fraction at specified environmental conditions)
Oxygen concentrator status indicator:	High priority alarm that indicates when oxygen concentration drops below 82%

Pulse mode bolus size (ml/breath) versus setting and breath rate

	SETTING					
BREATH PER MINUTE	1	2	3	4	5	6
15	11	22	33	44	55	66
20	11	22	33	44	55	66
25	11	22	33	44	55	66
30	11	22	33	44	55	66
35	11	22	33	44	55	57
40	11	22	33	44	50	50

All values +/- 15% over all operating conditions

Eco Mode bolus size (ml/breath) versus setting and breath rate

BREATH PER MINUTE	SETTING					
	1	**2**	**3**	**4**	**5**	**6**
15	11	22	33	44	55	66
20	10.5	19.8	31.5	42	52.5	59.4
25	8.4	15.8	25.2	33.6	42	47.5
30	7	13.2	21	28	35	39.6
35	6	11.3	18	24	30	33.9
40	5.25	9.9	15.75	21	26.25	29.7

All values +/- 15% over all operating conditions

Continuous Mode Flow (l/min) versus setting

SETTING	FLOW RATE
0.5	0.5
1.0	1.0
1.5	1.5
2.0	2.0

All values +/- 0.2 litres over all operating conditions

15.1. ELECTROMAGNETIC COMPATIBILITY (EMC) INFORMATION

Medical electrical equipment requires special cautions regarding electromagnetic compatibility (EMC). Portable and mobile radio frequency (RF) communications equipment can affect devices such as the Zen-O™ Portable Oxygen Concentrator. As such, the device should not be used adjacent to other equipment. If this is not practical, then observe the device to make sure it is operating properly at all times.

15.1.1. Guidance and manufacturer's declaration: electromagnetic emissions

The Zen-O™ Portable Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the concentrator should ensure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT/GUIDANCE
RF emissions CISPR 11	Group 1	The Zen-O™ Portable Oxygen Concentrator 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 concentrator 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	Complies	

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15.1.2. Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Zen-O™ is intended for use in the electromagnetic environment specified below. The customer or the user of the concentrator should ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT/GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 15kV contact ± 8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	± 2kV for power supply lines ± 1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Zen-O™ Portable Oxygen Concentrator required continued operation during power main interruptions, it is recommended that the concentrator be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT/GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 √P 150 kHz to 80 MHz d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5 Ghz	3 V/m	

IMPORTANT: At 80 MHz and 800 MHz, the higher frequency range applies.
IMPORTANT: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Zen-O™ is used exceeds the applicable RF compliance level above, the concentrator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the concentrator.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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15.1.3. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Zen-O™ Portable Oxygen Concentrator

The Zen-O™ Portable Oxygen Concentrator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The concentrator user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the concentrator as recommended below, according to the maximum output power of the communications equipment.

RATED MAX. OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE (M) ACCORDING TO FREQUENCY OF TRANSMITTER		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Important: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Important: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

15.2. FCC WARNING STATEMENT:

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
  (1) This device may not cause harmful interference, and
  (2) This device must accept any interference received, including interference that may cause undesired operation.
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.3. EU RED ARTICLE 10(10) RESTRICTIONS ON USE FOR MODEL RS-00500C:

Based on the information available from the European Communication Office (ECO) Frequency Information System (EFIS), Zen-O™ (model RS-00500C) complies with stipulated radio frequency radiation limits. The table below demonstrates compliance to Article 10 (10) of the European Union Radio Equipment Directive (RED) and confirms that there are no restrictions with regards to its use by patients in member states of the European Union;

RF Transmitter Information for device serial numbers beginning ZC, HY, DC:

FUNCTION / BAND USAGE	UPLINK / TRANSMIT (MHZ)	DOWNLINK / RECEIVE (MHZ)	MODULATION SCHEME	MAXIMUM EFFECTIVE RADIATED POWER (ERP/ EIRP)
EGSM 900	880.0 – 915.0	925.0 – 960.0	GMSK	+9.33DBM / 8.57MW
DCS 1800	1710.2 – 1784.8	1805.2 – 1879.8	GMSK	+18.79DBM / 75.68MW
GPS	N/A	1563 – 1587	CDMA / FDMA	RECEIVE ONLY
GLONASS	N/A	1593 – 1610	CDMA / FDMA	RECEIVE ONLY
GALILEO	N/A	1559-1610MHZ	/	RECEIVE ONLY
BTLE	2400 – 2483	2400 – 2483	GFSK/Π/4-DPSK/ 8-DPSK	-8.0DBM /0.158MW (EIRP)

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RF Transmitter Information for device serial numbers beginning 4C, 4Y:

FUNCTION / BAND USAGE	UPLINK / TRANSMIT (MHZ)	DOWNLINK / RECEIVE (MHZ)	MODULATION SCHEME	MAXIMUM EFFECTIVE RADIATED POWER (ERP/ EIRP)
LTE BAND 1 UMTS BAND 1	1920 – 1980	2110 – 2170	QPSK/16QAM	18.3 dBm / 68mW
DCS 1800 LTE BAND 3	1710 – 1785	1805 – 1880	GMSK/8PSK QPSK/16QAM	16.2 dBm / 42mW
LTE BAND 7	2500 – 2570	2620 – 2690	QPSK/16QAM	17.7 dBm / 59mW
EGSM 900 UMTS BAND 8 LTE BAND 8	880 – 915	925 – 960	GMSK/8PSK QPSK/16QAM	20.1 dBm / 102mW
LTE BAND 20	832 – 862	791 – 821	QPSK/16QAM	20.8 dBm / 120mW
LTE BAND 28	703 – 748	758 – 803	QPSK/16QAM	12.4 dBm / 17mW
GPS	N/A	1559 – 1610	CDMA / FDMA	RECEIVE ONLY
BLE	2402 – 2480	2402 – 2483	GFSK	8.0dBm / 6.3mW

15.4. RF EXPOSURE INFORMATION:

The RS-00500C model meets the applicable limits for radio frequency (RF) exposure, as determined by independent tests for the Specific Absorption Rate (SAR).

Specific Absorption Rate (SAR) refers to the rate at which the body absorbs RF energy. The SAR limit is 1.6 watts for kilogram in countries that set the limit averaged over 1 gram of tissue and 2.0 watts per kilogram in countries that set the limit averaged over 10 grams of tissue.

For RS-00500C, with serial numbers beginning ZC, HY, DC, Tthe highest SAR values measured in accordance with ICNIRP guidelines are:

Body SAR at 1g: 1.50 W/Kg

Body SAR at 10g: 1.70 W/Kg

For RS-00500C, with serial numbers beginning 4C, 4Y, the highest SAR values measured in accordance with ICNIRP guidelines for this device with a 4/5mm separation as provided by the system enclosure are:

Body SAR at 1g: 0.742 W/Kg

Body SAR at 10g: 0.834 W/Kg

During use the actual SAR values for this device are usually well below the values stated above, because for purposes of system efficiency operating power is reduced from full when not needed and the lower the power output the lower its SAR value.

16. GLOSSARY - EXPLANATION OF PACKAGING AND LABELLING SYMBOLS

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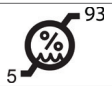
	See Instructions Before Use		Operating atmospheric pressure limitation 0´ to 13,000´ (0 Kpa to 50.2 Kpa)
	Type BF according to electrical safety requirements		Storage temperature limitation -20°C to 60°C (-4°F to 140°F)
SN	Serial Number		Humidity limitation 5% to 93% ± 2% non-condensing
REF	Catalogue Number		Handle with care
℞ only	U.S. federal law restricts this device to sale by or on the order of a physician		Separate collection for electrical and electronic equipment
	Do not use if packaging is damaged. See Chapter 6.		Manufacturer
	Use no oil or grease		Keep dry (This symbol refers to the IPX2 classification of the device)
	No open flame when device is in use or do not incinerate		Dispose of used battery properly
	Do not disassemble		No smoking
CE	Complies with applicable EU Standards		Class II symbol
EC REP	Authorized representative in the European Community		Suitable for homecare use
CH REP	Indicates the authorised representative in Switzerland		

CH REP

EUMEDIQ AG
Grafenauweg 8
CH-6300 Zug, Switzerland
www.eumediq.eu

Gas Control Equipment Limited
100 Empress Park, Penny Lane, Haydock,
St Helens WA11 9DB
United Kingdom

EC REP

EU importer:
GCE, s.r.o.
Zizkova 381,
583 01, Chotebor
Czech Republic

Manufactured for:
Gas Control Equipment Limited
By: GCE, s.r.o
Zizkova 381, 583 01 Chotebor
Czech Republic

CE 2460

Manufactured for:
Gas Control Equipment Limited
Jesus Siqueiros #652, 83170
Hermosillo, Mexico

Gas Control Equipment

Gas Control Equipment Limited
100 Empress Park, Penny Lane, Haydock,
St Helens WA11 9DB
United Kingdom
http://www.gcegroup.com

EC REP

EU importer:
GCE, s.r.o.
Žižkova 381, 583 01 Chotěboř
Česká republika
http://www.gcegroup.com

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