Zen-O™

Portable Oxygen Concentrator
Model: RS - 00500

User Manual

Gas Control Equipment

English

User manual: Zen-O™ Portable Oxygen Concentrator; Model: RS - 00500

EN

CONTENT

1. Foreword 3
1.1. General Information 3
1.2. Classification 3
1.3. Typographical Conventions 3
2. Intended Use 4
3. Safety Instructions 4
3.1. Warnings Overview 4
3.2. Cautions Overview 5
3.3. Overview of Important Information: 6
4. Instructions and Training 7
5. Product Description 7
5.1. Schematic Description 7
6. General Instructions Before Use 8
6.1. Accessories List 8
6.2. Battery 8
6.3. Nasal Cannula 10
6.4. Pull Cart 10
7. Operating Zen-O™ 10
7.1. Connecting Nasal Cannula 11
7.2. Turning On 11
7.3. Choosing a Preferred Language 11
7.4. Adjusting Setting 12
7.5. Battery Button 12
7.6. Responding to Alarms 13
7.7. Turning Off 13
8. Alarm Indicators 13
8.1. Alarms 14
9. Troubleshooting 16
10. Maintenance and Cleaning 16
10.1. Routine Maintenance 16
10.2. Cleaning 16
10.3. Service Life 17
11. Device Repair and Disposal 17
11.1. Repair 17
11.2. Disposal 17
12. Warranty 17
13. Trademarks and Disclaimer 17
13.1. Trademark 17
13.2. Disclaimer 17
14. Technical Description 18
14.1. Electromagnetic Compatibility (EMC) Information 19
15. Glossary - Explanation of Packaging and Labelling Symbols 22

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.

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 60601-1-2:2007, 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.
- CAN/CSA C22.2 No. 60601-1:14, Canadian Standard, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
- Medical Device Directive 93/42/EEC.

This equipment is classified as:

- Class II
- Class IIa according to the MDD 93/42/EEC
- Type BF
- IP22 with the carry bag

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 14. Technical Description.

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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

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 settings of Zen-O™ Portable Oxygen Concentrator RS-00500 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.**
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 2 metres 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. **Critical! 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.**

16. **Use of this device at an altitude above 2,700 m (9,000 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 14. Technical Description.**
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 9. 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.**

⚠ 3.2. Cautions Overview

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 14. 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.
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 humidifier or nebuliser. If a humidifier or nebuliser is used with this device, performance may be diminished and the device may be damaged.
16. Always follow cannula manufacturer's instructions for proper use.
17. Replace the cannula on a regular basis. Check with your home oxygen provider or clinician to determine how often the cannula should be replaced.
18. Check that this device operates on battery after disconnecting from the power source.
19. Only charge battery in this device or in an approved charger. (See approved accessories list.)
20. Remove battery if this device is not going to be used for more than seven days. Store battery in a cool, dry place.
21. Do not use cleaning agents other than those specified in this manual. Allow the cleaning solution to dry from the cleaned surface before use.
22. Always turn off this device when not in use.
23. Always disconnect power and turn off this device before cleaning. See Chapter 10. Maintenance and Cleaning.
24. 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.
25. Do not place objects on top of this device.
26. Keep away from children and pets to prevent damage to the device and accessories and/or inadvertent setting changes.
27. Keep the device away from pets and pests.
28. This device is rated IP22 while used in the carry bag. Do not use in dusty or wet conditions.
29. Always use in a well ventilated location.
30. Always follow the maintenance schedule as specified in Chapter 10.1. Routine Maintenance.
31. If this device indicates an abnormal condition, see Chapter 9. Troubleshooting.
32. Use caution when touching this device in high ambient temperatures.
33. The device can be re-used by a new patient. The device should be cleaned as indicated in section 10.2 of this user manual and, according to local laws and prescriptions prior to delivering to a new patient.

3.3. Overview of 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 14. Technical Description.*

4. Instructions and Training

The Medical Devices Directive 93/42/EEC states that the product provider must ensure that all users of this device are provided with the user manual and are fully trained in the use of the equipment.

⚠ **WARNING: Do not use the product without proper training! Patients and care givers must be trained by an experienced person who has been authorised by the manufacturer and has appropriate training, knowledge and experience.**

For further information about training contact your home oxygen provider.

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5. Product Description

5.1. Schematic Description

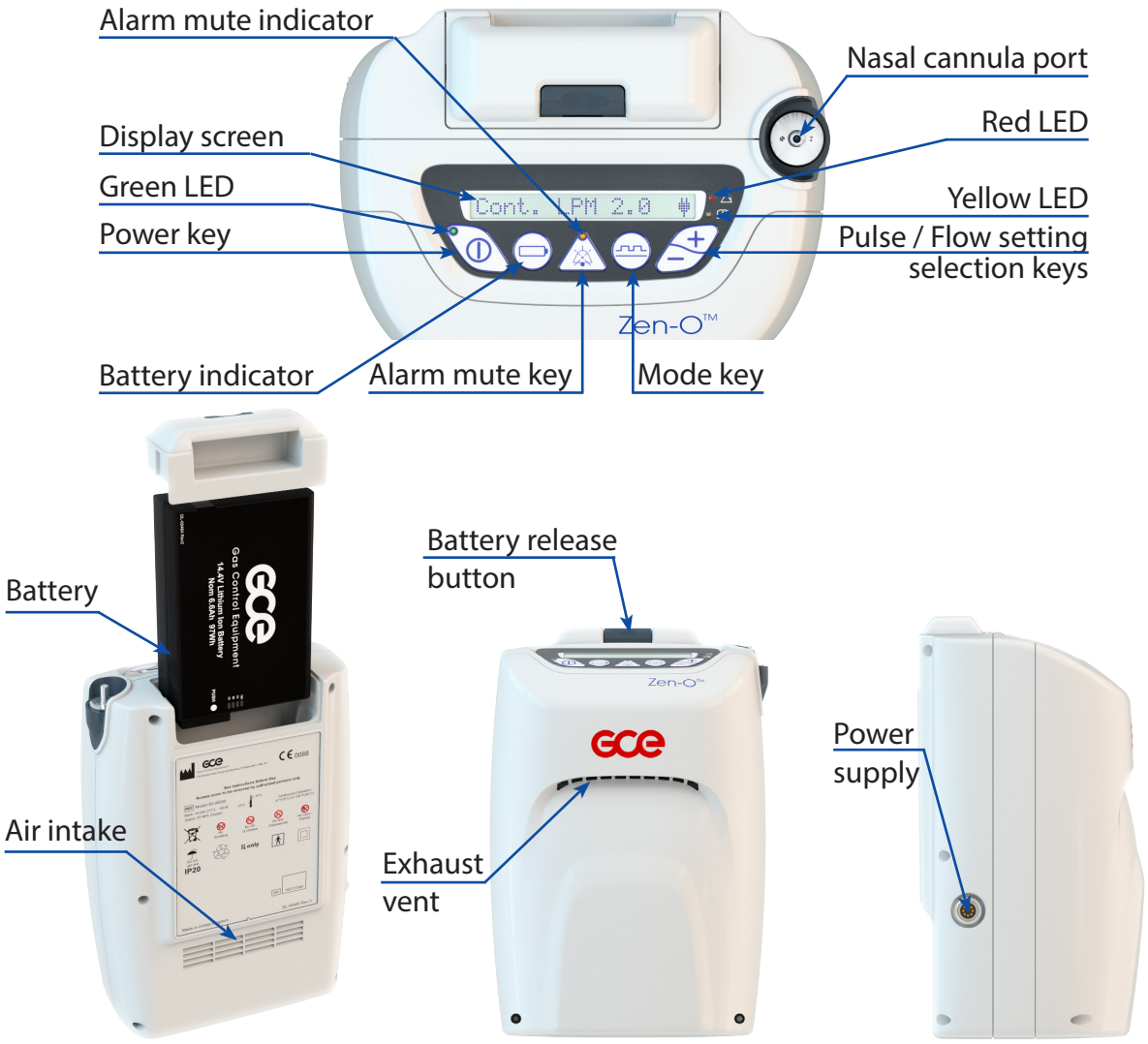

Fig. 1

6. General Instructions Before Use

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.

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

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

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)
- 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 - EU (RS-00516)
- External battery charger - US (RS-00515)

⚠ **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 Chapter 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 Chapter 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 receptacle 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%** .

Fig. 2

Fig. 3

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 one battery to charge for a minimum of three hours before use. Once completely charged, the device can run for up to 4 hours with one battery or 8 hours with two batteries in pulse mode, at 18 breaths per minute.

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 9. 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.

To maximise battery life and run time, avoid letting the battery deplete and use while connected to a power source whenever possible. The internal 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:

- 7ft (2.1 m) or 25ft (7.6 m) long
- High flow
- Crush resistant
- Large internal diameter bore
- Straight non-tapered tips
- 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

⚠ **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. The handle can be pulled out and adjusted for comfort.

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

Fig. 4

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 keys 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 key will turn the backlight on briefly. The backlight will also remain activated during an un-muted 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.

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

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

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.

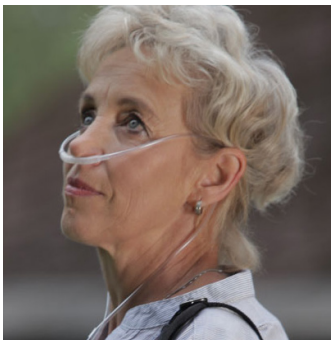

Fig. 6

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.

7.2. Turning On

- To turn the device on, press the power key .
- 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.

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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.
- 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 − keys.
- Continuous mode of operation can be adjusted from 0.5 to 2.0 in 0.5 increments with the + and − keys.

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.

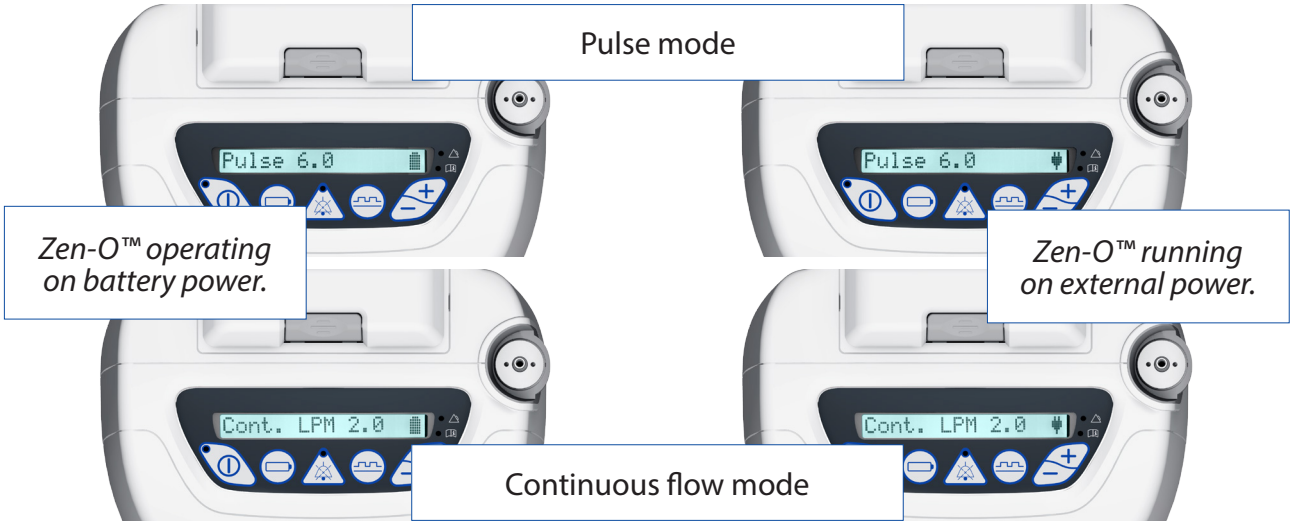

Fig. 7

7.5. 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 **Batt1: N cycles** .
- Finally, the gauge and charge cycles for the battery in the second slot is shown **Batt2: NN%** **Batt2: 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.

7.6. 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 key at any time will silence the buzzer. The length of the mute period depends on the severity of the alarm (see Chapter 8. Alarm Indicators). During this mute period, the mute LED will remain illuminated, indicating the alarm buzzer is muted. Push the mute key again to un-mute alarms. Pressing the mute key when there is no active alarm will mute any future medium or low priority alarms for eight hours. See Chapter 8. Alarm Indicators and Chapter 9. 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.

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7.7. 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 key. 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 key to turn the device off. Wait until the device has completely shut down before disconnecting from power and removing the battery.

8. 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, burst repeats every 3 seconds.	Solid red LED and device shuts of automatically	20 minutes
High priority	Ten beeps per burst, 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 key 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 from the time the key was pressed. Press the mute key off to display the last highest priority alarm. Press the mute key on again to reset the eight-hour timer.

8.1. 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.

8.1.1. 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

8.1.2. 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

8.1.3. Medium Priority Alarms

Alarm message	Description	Action
Check Cannula	No breath detected for 15 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

8.1.4. Low Priority Alarms

Alarm message	Description	Action
XX: Service!*	Service required.	Contact your distributor.

*Value: 71-99

8.1.5. 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 key 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 key is pressed.
Charging	Battery charge is less than 10% and there is external power connected.	Message is displayed when battery key 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.

9. 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  (red) or  (yellow) LED lit	• See Chapter 8. Alarm Indicators.	See Chapter 8. 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.

10 Maintenance and Cleaning

10.1. 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 a filter or component needs to be cleaned or changed. (Also, see Chapter 9. Troubleshooting.)

IMPORTANT: The cannula and patient filter can be contaminated from the patient, care in handling these components should be taken.

10.2. Cleaning

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).

Important: The device should receive an external cleaning weekly, accessories should be cleaned as needed. The device exterior should be cleaned and the patient filter replaced prior to delivering to a new patient..

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

10.3. Service Life

The expected service life of the device is 5 years, except for the sieve beds. The service life of the sieve beds will depend on the operating conditions. Replace them as needed, indicated by the check vents alarm. If intake and exhaust vents are not blocked and the check vents alarm persists, contact your distributor for instructions on replacing the sieve beds.

11 Device Repair and Disposal

11.1. Repair

Do not attempt to repair the device. Contact your home oxygen provider or distributor for assistance (see Chapter 9. Troubleshooting).

11.2. Disposal

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

12 Warranty

The device warranty is limited to three (3) years from date of manufacture or 15,000 hours of total use. All accessories including the batteries are limited to one (1) year warranty.

The standard warranty is only valid for products handled as stated in the user manual and in accordance with general industry good practice and standards.

13 Trademarks and Disclaimer

13.1. Trademark

All trademarks are the property of their respective owners.

13.2. 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.

13.2.1. 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.

14 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:	87% - 96% 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
Operating altitude:	0' to 9000' relative to sea level (0 km to 2.7 km), 1060 down to 700 mbar
Sound pressure level:	42 dB(A) at setting 2 in pulse mode, tested according to ISO 3744 38 dB(A) at setting 2 in pulse mode, tested according to Prüfmethode 14-1 03/2007 MDS-Hi
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)
Degree of safety (flammable anaesthetic mixture):	Not suitable for use in the presence of a flammable anaesthetic mixture

Technical Description (continue)

Operating temperature:	Continuous operation at temperatures between 5°C (41°F) and 40°C (104°F).
Storage temperature:	Between -20°C (-4°F) and 60°C (140°F).
Alarm sound pressure range:	65 to 85 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

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

14.1. 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.

14.1.1. 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 assure 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	

14.1.2. 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 assure 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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14.1.3. 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 monitor user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

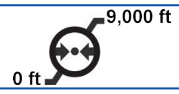
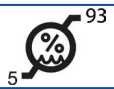
Rated max. output power of transmitter (W)	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
10	3.8	3.8	7.3
100	12	12	23

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.

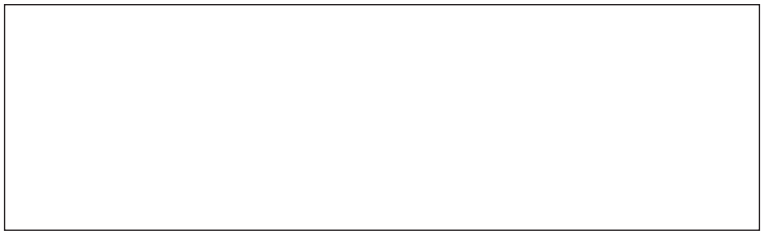
15 Glossary - Explanation of Packaging and Labelling Symbols

	See Instructions Before Use		Operating atmospheric pressure limitation 0´ to 9,000´
	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
Rx only	U.S. federal law restricts this device to sale by or on the order of a physician		Date of manufacture
	Do not use if packaging is damaged		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
	Separate collection for electrical and electronic equipment		Class II symbol
CE	Complies with applicable EU Directives including Medical Device Directive		Suitable for home care use
Power Input: 19 - 24 V⎓150 W		Power Input 19-24V DC, 150W	
Gas Output: 87%-96% oxygen		Gas Output = 87%-96% oxygen	

GCE Ltd,
100 Empress Park, Penny Lane, Haydock,
St Helens WA11 9DB
United Kingdom

CE 0088

Doc. Nr.: DL - 00466; Rev. 04; DOT 2015-11-04; TI: 200x200,COL(BAR), V1



Gas Control Equipment

http://www.gcegroup.com