

Venus 5

Portable Oxygen Concentrator

Model No.: OX-1A-E

User Manual

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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 OXTm 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 OXTm 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 OXTm Portable Oxygen Concentrator. "Patient" and "User" are used interchangeably.

1.2 Classification

This device is listed with an internationally recognized 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.

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:

A 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

	<u>-</u>			
Intended use Portable Oxygen Concentrator is intended to be used on a prescriptive basis for adult patients with chronic obstructive pulmonary disease (ILD) for oxygen therapy.				
Indications	Chronic obstructive pulmonary disease (COPD)			
IIIuications	Interstitial lung disease (ILD)			
Contraindication	COPD with moderate resting hypoxemia			
Side effect	Hypercapnia			
Side effect	Pulmonary toxicity			
Intended patient group Adult				
Note	It's suggested that patients should undergo a 6-min walk tests (6MWTs) before prescription using the device.			

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 OXTm Portable Oxygen Concentrator Venus 5 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 OXTm Portable Oxygen Concentrator Venus 5.
- 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 meters 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 1,300m, or outside the temperature range of 5°C (41°F) to 35°C (95°F), or outside the humidity range of 5%RH to 90%RH may adversely affect the flow rate and concentrator of oxygen and consequently the quality of therapy. When not in use, the device should be stored in a clean, dry environment between -40°C and 70°C (-40°F and 158°F). Use and/or storage outside of the valid conditions may damage the product. For more technical details see Chapter 14. Technical Description.
- 17. If feeling ill or experiencing discomfort while using this device, contact your clinician or seek medical assistance immediately to avoid harm.
- 18. 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.
- 19. The electrical cord and tubing could present a tripping or strangulation hazard. Keep away from children and pets.
- 20. 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 authorized personnel.
- 21. Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.

1 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 35°C (95°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.
- Patients with a fast breathing rate requiring a higher oxygen setting may require more oxygen than this device can produce see Chapter 14. Specification This device may not be appropriate in that case. Consult your clinician for alternative treatment.

- 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 flow rate.
- 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 5.1. 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 nebulizer. If a nebulizer 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 The cannula is disposable.
- 18 Only charge battery in an approved charger. (See approved accessories list.)
- 19 Do not use cleaning agents other than those specified in this manual. Allow the cleaning solution to dry from the cleaned surface before use.
- 20 Always turn off this device when not in use.
- 21 Always disconnect power and turn off this device before cleaning. See Chapter 10. Maintenance and Cleaning.
- 22 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.
- 23 Do not place objects on top of this device.
- 24 Keep away from children and pets to prevent damage to the device and accessories and/ or inadvertent setting changes.
- 25 Keep the device away from pets and pests.
- 26 This device is rated IP22 while used in the carry bag. Do not use in dusty or wet conditions.
- 27 Always use in a well-ventilated location.
- 28 Use caution when touching this device in high ambient temperatures.
- 29 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.

Overview of Important Information 3.3

- 1. Inhale through the nose for the concentrator to work most effectively. Inhaling through the mouth may result in less effective oxygen therapy.
- 2. This oxygen concentrator can operate in pulse delivery mode. Your clinician will provide you with specific instructions if applicable. See Chapter 14. Specification
- 3. This oxygen concentrator is prohibited to maintenance while the unit is operating.
- 4. Do not position the oxygen concentrator where is difficult to disconnection the device.

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 authorized by the manufacturer and has appropriate training, knowledge and experience.

For further information about training contact your home oxygen provider.

5. Product Description

5.1 Device and Accessories Description

The Venus 5 Portable Oxygen Concentrator, its features, and its accessories are described in detail in this manual. Read and understand it completely before operating the device. This manual applies to the following accessories:

• AC Power Supply



Power Output Plug (Plug into Concentrator)

AC Power Plug

Carrying Bag



Power Output Plug
(Plug into Concentrator)

DC cigarette lighter power plug

AWARNINGS

A warning represents the possibility of harm to the operator or patient.

- The operator should read and understand this entire manual before using the device.
- The device is not intended for life support. Where the prescribing health care professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternate source of oxygen should be available for immediate use.
- Geriatric or any other patient unable to communicate discomfort, or hear or see the alarms while using this device, may require additional monitoring.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- Do not use oil or grease on the concentrator or its components as these substances, when combined with oxygen, can greatly increase the potential for a fire hazard and personal injury.
- If you notice any of the following, discontinue use and contact your home care provider:
 - unexplained changes in the performance of this device
 - unusual or harsh sounds
 - dropped or mishandled device or the power supply
 - water spilled into the enclosure
 - broken enclosure
- Use only with Venus 5 AC power supply.
- Use only with Venus internal battery (Manufacturer: OXTm, Model: OX17P403A, Technical data: 6400mAh)
- Use only approved Venus 5 accessories.
- Repairs and adjustments must be performed by OXTm authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Periodically inspect electrical cords, cables, and the power supply for damage or signs of wear. Discontinue use and replace if damaged.
- To avoid electric shock, unplug the device before cleaning the bag. DO NOT immerse the device in any fluids.
- Your home care provider is responsible for performing appropriate preventive maintenance at the intervals recommended by OXTm.
- For proper operation, your device requires unobstructed ventilation. Always make sure any openings in the case are not obstructed by items which may impede ventilation. Do not place the device in a small closed space (such as a closet). The device should not be used adjacent to or stacked with other equipment. For more information, contact your home care provider.
- Do not use an extension cord.
- Device operation above or outside of the voltage, breath rate, temperature, humidity and/or altitude values specified may decrease oxygen concentration levels.
- Be aware that the electrical cord and/or tubing could present a tripping or strangulation hazard.
- Use only power cords supplied by OXTm for this device. Use of power cords not supplied by OXTm may cause overheating or damage to the device and may result in increased emissions or decreased immunity

of the equipment or system.

- Do not operate without the battery installed and working. If primary power is lost with no battery in place, the device will stop operating without warning the user. If the device must be operated without the battery, the user should be aware that there is no backup power and no warning if primary power is lost.
- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment. See the EMC section of this manual for distances to observe between RF Generators and the E2 device to avoid interference.
- Touched parts cause possible harms. If cause by heat, move away the unit if the vitiation is worse.

A Cautions

A caution represents the possibility of damage to the equipment.

- Do not immerse the device or allow any liquid to enter the enclosure.
- When the device is used in an automobile, disconnect it from the DC auto adapter outlet when the automobile is turned off. Do not operate the device in a non-running vehicle for an extended period of time, as this may deplete the vehicle's battery and prevent the vehicle from starting. Do not allow the device to be connected to the auto adapter outlet while starting the automobile normally or while you are starting the automobile with battery recharging cables. Wait until the automobile starts before connecting the device to the DC power outlet. Secure the device securely when used in any moving vehicle. (The same cautions apply if using the DC adapter outlet on a boat or recreational vehicle.)
- Turn off the device before removing the battery. The device should not be operated without the batteries installed. If the device is operated without the batteries installed, the standard shut-down routine will not be implemented when the power is disconnected prior to turning off the unit. This can result in damage to the device.
- Only use the supplied handle and shoulder strap to carry your device. With every use, verify that the case, shoulder strap and handle are in good condition.

Note: Additional warnings, cautions, and notes are located throughout the manual.

6. General Instructions Before Use

A variety of accessories can enhance the portability and use of the Venus 5 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 (Life time: 5 years)

• Carry bag (Life time: 3 years)

 AC power supply (Life time: 3 years) • DC power cable (Life time: 3 years)

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.

Spare parts

- AC power supply (OX17P408A) Input :100~240VAC, 50/60Hz, 2.0A, Output 12DC, 7A
- DC power cable (OX09P403A)
- Carry bag (OX17P503A)
- European power cord: European (OX02P408A) / North American (OX02P425A)
- Battery charger EU (OX02P612A- option)



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

6.2 Battery

Venus 5 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 External battery.

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

6.2.1 Charging the Battery

Check to make sure your unit's battery is fully charged before venturing out with VENUS 5 for the first time or upon subsequent use. To check the level of charge of the internal battery, press the POWER button on VENUS 5's keypad. The battery gauge/indicator(s) LEDs above the POWER button illuminate to indicate the level of internal battery charge (20-100%).

Note: The internal battery is charging whenever the unit is operating on AC or DC power. To charge the internal battery of Venus 5, simply connect its AC power supply or DC power supply into the unit's power connection inlet (as shown in Fig 4).

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. The concentrator is connected to a power source. The LCD display will indicate whether the device is operating on internal battery or external AC power.

IMPORTANT: Ensure power status icon (see Fig. 4) indicates power is connected. If not, check that cord is plugged in completely. (See Chapter 9. Troubleshooting for more information.)

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: 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.

6.3 Carry bag

When using the device with a carry bag, please check the status of unit is proper to fit into the carry bag. Ensure the unit is positioned for good exhaust of heat.

Fig. 1 The belt can be adjust the length for comfort with 4 ways usage.

IMPORTANT: It is recommended that patients use the carry bag to protect the device whenever possible.











Fig. 1

7. Operating your Venus 5

IMPORTANT: Read Chapter 3. Safety Instructions before using this device.

Venus 5 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. The patient should be within the recommended cannula length during use.

7.1 Connecting Nasal Cannula

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

Connect the tubing to the cannula port as shown in Fig. 2

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. Shown in Fig. 3

Once the cannula is secured, breathe normally through the nose. Venus 5 will detect a breath and deliver the oxygen during inhalation.

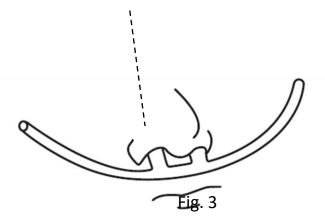
IMPORTANT: Improper cannula placement may result in the device being unable to detect all respiratory efforts of the patient. Ensure cannula is connected securely and it has been fully inserted.



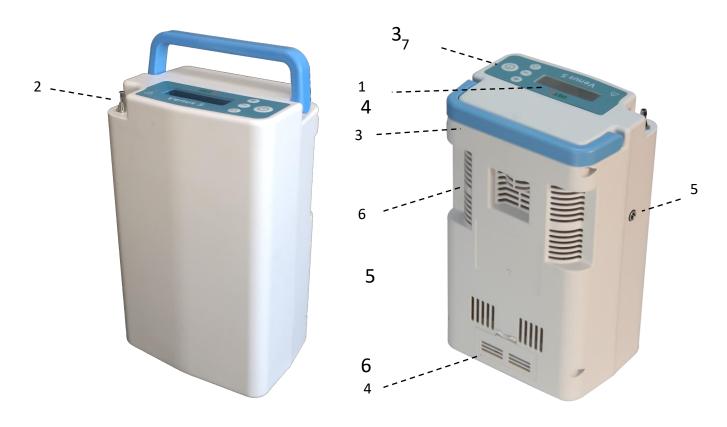


Fig. 2

Cannula to the nose

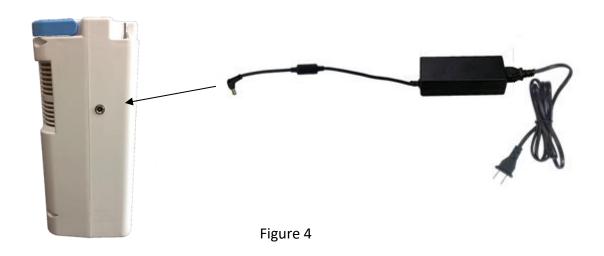


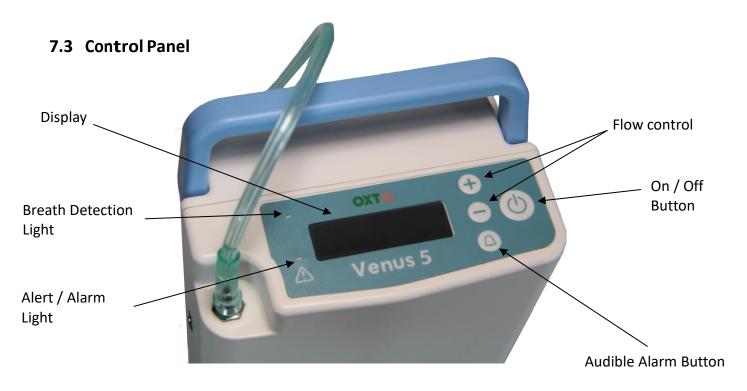
7.2 Device Overview



Item	Description	Function
1	Control Panel	Control switches and LCD display
2	Patient Cannula Connector	Oxygen output and connection point for patient cannula
3	Carrying Handle	Hand grip area for transporting the device
4	Filter Cover	For filter replacement
5	Power Input Connector	Connection point for VENUS 5 external power supplies: AC adapter, vehicle DC, external Battery
6	Air Exhaust Vent	Air outlet for enclosure ventilation fan
7	Power Switch	I =ON , O=OFF

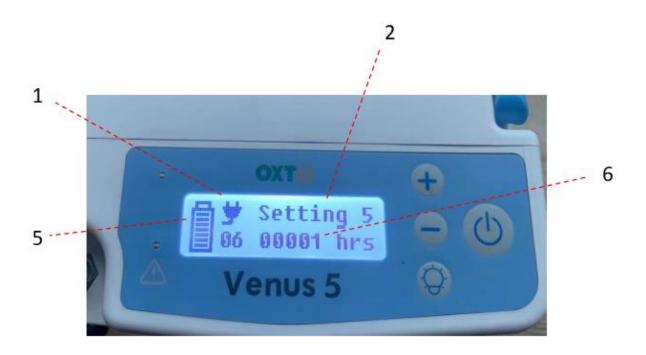
Important: Charge before operate start to use Venus 5

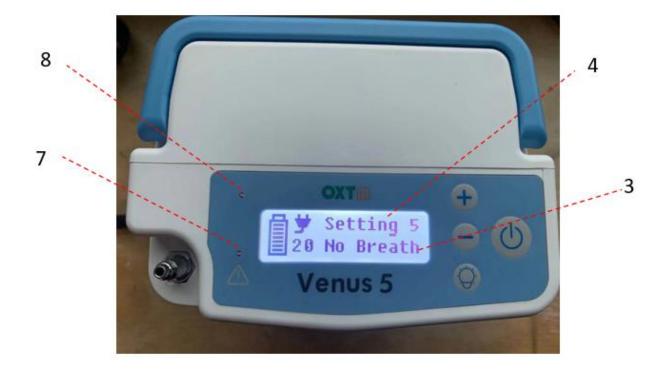




Item	Description	Function
1	Power	Turns the device On and Off
2	Operate	Select the setting to operate the device
		Shows information about the operating status of the device
3	Display Screen	
4	Plus (+)/Minus (–)	+ Increases the flow setting - Decreases the flow setting

7.4 Run Time Screen Description





Item	Description	Function
1	External Power Status	For detailed descriptions, refer to the
2	Operating Mode	" Alarm
3	Alarm Status	
4	Setting	Indicator and Screen Symbols section.
5	Battery Status	
6	Total Running times	
7	Audible Alarm Status	
8	Breath Indicator	

7.5 Turning On

To turn the device on, press the power key 2 seconds.



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

Expect time to operate unit from lowest stored temperature (-20° C) to 20° C (room temperature) : around 60 mins Expect time to operate unit from highest stored temperature (40°C) to 20°C (room temperature) : around 30 mins

7.6 Adjusting Setting

IMPORTANT: After powering on Venus 5, 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.
- In pulse mode, the device will deliver a pulse of oxygen at the beginning of each of your inhalation.

Setting the mode can be done as follows:

Note: When it is turned on, the device will automatically start at the flow rate setting used when the device was last turned off. As a precaution, each time you start the device, verify the flow setting. Use the – or + flow setting control buttons to select the setting as shown on the display. Flow settings will vary between 1-5.

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.

AWarning: It is very important to set your device to your prescribed level of oxygen flow. Do not increase or decrease your flow rate from your prescribed level until you first consult with your physician.

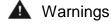
7.7 Responding to Alarms

Note: Pressing this button will toggle the Venus 5's breath detection audible alert on and off.

Breath Detection Alert Mode. The Venus 5 will alert with audible and visual signals for "no breath detected" when this mode is enabled and no breath has been detected for 20 seconds.

At 20 seconds, the device will enter into auto pulse mode and once another breath is detected, the device will exit auto pulse mode and deliver normally on inspiration. The display's mode indication area will show a bell icon, flashing red or yellow light depending on model, and display message when the alert is enabled.

If power is lost, the breath detection audible alert remains set in the user preferred mode.



Do not use the humidifier while the device is operated.

7.8 Turning Off



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

To turn the Venus 5 Portable Oxygen Concentrator off, press and hold the power key 2 seconds. The device will chirp and the screen shut down approximately five seconds later.

IMPORTANT: Do not disconnect the AC power supply 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.

8. Alarm Indicators and Screen Symbols

Visual, Audio Indicators	Description	Remedy	
Setting 5 37 Low 02 Venus 5	Low Oxygen Concentration Alarm The concentration < 82% after running up device > 300 second.	Medium Priority Alert Yellow light flash with auditory alarm	
Setting 4 On No Breath Venus 5	No Breath Alarm When a breath signal is not detected after 30 seconds.	Low Priority Alert Yellow light flash, short beep remind	
Setting 5 43 Hi Breath Venus 5	High Breath Rate Alarm The user's breath rate is over 40 times/ min	Low Priority Alert Yellow light flash, short beep remind	
Setting 5 00 LoBattery Venus 5	Low Battery Alarm Battery level less 20% remains. Remaining battery level in the range of 5%≤RSOC≤ 20% without connect adapter.	Low Priority Alert Yellow light flash, long beep remind. The empty battery symbol flashes.	
OXTM Igh TMP 988 Venus 5	High Temperature Alarm The device temperature excess 65 degree. The device will alarm and shut down within 10 second.	Low Priority Alert Yellow light flash, long beep remind	
Setting 5 20 Low 02 Venus 5	Breath Sensor Fail The breath sensor fail, no feedback signal to MCU.	Low Priority Alert Technical fault- Yellow light flash, no beep remind	

	Oxygen Sensor Fail	Low Priority Alert
Setting 5 20 Low 02 Venus 5	This alarm occurs when oxygen sensor fail, no feedback signal to MCU.	
Setting 5 20 Low 02 Venus 5	Gas Delivery Fail No delivery detected after dosing	Low Priority Alert Technical fault- Yellow light flash, no beep remind
Setting 5 20 Low 02 Venus 5	Gas Obstruction Pipe or nasal blocked	Low Priority Alert Technical fault- Yellow light flash, no beep remind
Setting 5 20 Low 02 Venus 5	System Startup Fail Lower concentration of oxygen than specified < 82% after 120s of system startup.	Low Priority Alert Technical fault- Yellow light flash, no beep remind
Setting 5 20 Low 02 Venus 5	Pressure Fail Compressor not work when device power on	Low Priority Alert Technical fault- Yellow light flash, no beep remind
Setting 5 20 Low 02	Compressor not work when device	Technical fault- Yellow light
Setting 5 20 Low 02 Venus 5 OXTM Setting 5 20 Low 02	Compressor not work when device power on Valve Fail Valves not work when device	Technical fault- Yellow light flash, no beep remind Low Priority Alert Technical fault- Yellow light

Alarm Condition Priorities

50	Onset of Potential Harm			
SQ	Alert	Display	Alert Priority	
1.	Low Oxygen concentration	Low O2	Medium Priority Alarm	
2.	No breath	No breath	Low Priority Alerts	
3.	High breath	Hi Breath	Low Priority Alerts	
4.	Low battery	Low Battery	Low Priority Alerts	
5.	High Temperature	High TMP	Low Priority Alerts	
6.	Breath Sensor Fail	Low O2	Technical fault	
7.	Oxygen Sensor Fail	Low O2	Technical fault	
8.	Gas Delivery Fail	Low O2	Technical fault	
9.	Gas Obstruction	Low O2	Technical fault	
10.	System Startup Fail	Low O2	Technical fault	
11.	Pressure Fail	Low O2	Technical fault	
12.	Valve Fail	Low O2	Technical fault	
13.	Power Supply Fail	Low O2	Technical fault	

9. Troubleshooting

IMPORTANT: The table below lists common problems and actions you can take. If you are unable to resolve a problem, please contact your home care provider.

Problem	Possible Cause	What You Should Do
Device Won't Turn On	Battery is depleted.	Use the AC or DC power cords to operate the device. If this does not resolve the problem, contact your home care provider.
	AC power connection is not correct	Re-install it correctly.
Device Will Not	Device is not turned on.	Press the power button.
Trigger A Pulse Of Oxygen	Cannula tubing is kinked or twisted.	Make sure the tubing is connected properly to the oxygen outlet port and that it is free of any obstruction.
	Device malfunction.	Contact your home care provider.
Oxygen Not At Full Concentration	Device is warming up.	Wait 5 minutes for the device to deliver oxygen at the prescribed concentration. If the condition persists, contact your home care provider.
Alarm Occurs	The device needs your attention.	See the Alarm Indicators and Screen Symbols section for information about specific alarms and what you should do.

10. Maintenance and Cleaning

10.1 Routine Maintenance

AWARNING: Do not use lubricants on this device or any of its accessories.

Device will indicate with an alarm when a filter or component needs to be leaned or

changed. (Also, see Chapter 9. Troubleshooting.)

Replace the filter every 1500 hours.

IMPORTANT: The cannula and 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.

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

The life time of device is five (5) years. Warranty is limited to three (3) years. Battery and oxygen generate system are limited to one (1) year warranty.

The carry bag is intended to make the POC easier to transport, prevent movement due to vibration and protect the device from minor mishaps.

13. Disclaimer

13.1 Disclaimer

The information in this document has been carefully checked and is believed to be reliable. The manufacturer reserves the right to modify any of these products to enhance readability, functionality or design. The manufacturer does not assume any liability arising from the application or use of any product or circuit described. It does not include any license under its patent rights or the rights of others.

13.2 This Document

The information in this document is subject to change without any notice. This document contains proprietary information for copyright protection. This document shall not be reproduced in whole or in any form without the prior written consent of the manufacturer (except for a brief excerpt of the reviews and scientific papers). Be sure to read and understand all the manuals provided by the product.

For help

Please contact your domestic oxygen supplier or distributor if you have any concerns about the information in this manual or the safety operation of the device.

14. Technical descriptions (Specifications)

Venus 5 Concentrator

Ovygon	87%~96% at all flow rates based on atmospheric of		
Oxygen			
Concentration	14.7psia(101 kPa) at 21°C		
Power requirements	AC adaptor:100~240V AC,50/60Hz in,12V DC ,5.42A out DC adaptor: 12.5~15V DC in		
SoundLevel	42dBA at setting 2 and 15 BPM (when measured at 1 m from front of device)		
Alarm type	 Low O2 No Breath High Breath Low Battery High Temperature Technical fault (Show Low O2) Breath Sensor Fail Oxygen Sensor Fail Gas Delivery Fail Gas Obstruction System Startup Fail Pressure Fail Valve Fail Power Supply Fail 		
Outlet pressure	≤16psi		
Operation Temp./Humidity/ Atmospheric pressure	5-35°C/ 5-90%RH/ 86kpa-106kpa		
Storage Temp./Humidity/ Atmospheric pressure	-20 -70 °C/5-90%RH/ 50kPa ∼ 106kPa		
Trigger sensitivity	≤0.18cm H2O		
Max Operational	up to 1300mm Higher altitudes may affect		
Altitude	performance		
Dimension(mm)	115(L) x 158(W) x 255(H)		
Weight (Kgs)	2.2 (with internal battery)		
Battery life	300 cycles		

Product lift	5 years
	,

Flow settings and pulse volumes(ml):

	Setting				
Breath per minute	1	2	3	4	5
15	11	22	33	44	55
20	11	22	33	44	50
25	8.5	17.5	26.5	35.5	40
30	7.5	15	22	29.5	33
35	6.5	13	19	25	30
40	5.5	11	16.5	22	25

^{+/-15%,} whichever is greater over the rated environmental range

15. Traveling With Your VENUS 5

With your Venus 5 and proper advance planning, you can enjoy traveling within your community and beyond. Before you leave, make sure you pack the following:

- Fully charged battery (and extra batteries for a long trip).
- AC power supply and connector cord
- DC power supply
- Carrying bag

Also, be sure to take the telephone numbers of your home care provider and physician in case of an emergency.

15.1 By Motor Vehicle

Use the Venus 5 DC power supply to plug in your device using the vehicle's cigarette lighter or DC power input. You can also use the Venus 5 device while it is running from a DC power source.

A

CAUTION: Make sure the vehicle has been started before plugging in your DC power supply. If you operate the device using the DC power cord while the vehicle engine is turned off, you could inadvertently drain the vehicle's battery.

15.2 By Bus or Train

Most bus and train lines allow passengers to use portable oxygen concentrators, but you may need to notify them in advance. When you make your travel arrangements, contact your carrier well before your departure for permission to bring your system and use it on board.

16. Symbols

T	
	General warning, caution, risk of danger Please read the instructions carefully before operating the product.
★	Type B applied part
	Class II equipment
SN	Manufacture's serial number
EC REP	Authorized representative in the European community
M	Date of manufacture
***	Manufacture
X	Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive) after over the valid term within 3 years, the machine should be treated on local law or regulation requirement. To avoid hurt users and pollute environment.
(€ ₂₄₆₀	The equipment bears CE mark CE02460 indicating its conformity with the provision of Council Directive 93/42/EEC concerning medical devices, and fulfills the essential requirement of Annex I of this directive.
Ţ	FRAGILE Contents of the transport package are fragile therefore it shall be handled with care.
<u>††</u>	THIS WAY UP Indicates correct upright position of the transport package.
*	KEEP AWAY FROM RAIN Transport package shall be kept away from rain.
(((•))	Non-ionizing electromagnetic radiation
[]i	Consult accompanying instructions for use
IP22	Drip proof equipment
	Do not use If package is damaged
	Keep away from open flames
	No smoking

17. EMCInformation

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Venus 5 is intended for use in the electromagnetic environment specified below. The user of Venus 5 should assure that it is used in such an environment.

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Venus 5 is intended for use in the electromagnetic environment specified below. The user of Venus 5 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic	±8 KV contact	±8 KV contact	Floors should be wood, concrete or
Discharge (ESD)	±2,4,8,15 KV air	±2,4,8,15 KV air	ceramic tile. If floors are covered with
IEC 61000-4-2			synthetic material, the relative humidity
			should be at least 30%.
Electrical Fast	a.c.power ports: ±2	a.c.power ports: ±2	Mains power quality should be that of a
Transient/Burst	KV	KV	typical home or hospital environment.
IEC 61000-4-4	100kHz Impulse	100kHz Impulse	
	Frequency	Frequency	
Surge	\pm 1 kV Line to Line	\pm 1 kV Line to Line	Mains power quality should be that of a
IEC 61000-4-5			typical home or hospital environment.
Voltage Dips, Short	0% U_T for 0.5 Cycle ${ m at}$ 0°,	0% U _T for 0.5 Cycle at 0°,	Mains power quality should be that of a
Interruptions and	45°, 90°, 135°, 180°, 225°,		typical home or hospital environment. If
Voltage Variations	270° and 315°	270° and 315°	the user of the Device required
on Power Supply			continued operation during power mains
Input Lines	0% U_T for 1 Cycle $at\ 0^\circ$	0% U _T for 1 Cycle at 0°	interruptions, it is recommended that
IEC 61000-4-11			the Device be powered from an
	70% U _T for 25/30 Cycles	70% U _T for 25/30 Cycles	uninterruptible power supply or battery.
	at 0°	at 0°	
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		antha a Cilia I an I a a I	environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 Note: UT is the A.C. r	0% U _T for 250/300 Cycles at 0° 30 A/m mains voltage prior to applic	at 0° 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Venus 5 is intended for use in the electromagnetic environment specified below. The user of Venus 5 should assure that it is used in such an environment.

Immunity Test	IEC 60601	Compliance	Electromagnetic Environment - Guidance
	Test Level	Level	
			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
Conducted RF	3 Vrms	3 Vrms	
IEC 61000-4-6	0.15MHz to	0.15MHz to	
	80 MHz	80 MHz	d = 1.2 P 150 kHz to 80 MHz
	6 Vrms is ISM	6 Vrms is ISM	
	and amateur radio bands	and amateur	
	between	radio bands	d = 0.35 P 80 MHz to 800 MHz
	0.15MHz to	between 0.15MHz to	d = 0.7 P 800 MHz to 2.5 GHz
	80 MHz	80 MHz	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).
Radiated RF	3 V/m	3 V/m	Field strengths from fixed RF transmitters, as determined by an
IEC 61000-4-3	80 MHz to	80 MHz to	electromagnetic site survey, a should be less than the compliance
	2700 MHz	2700 MHz	level in each frequency range. b Interference may occur in the
			vicinity of equipment marked with the $(((\cdot)))$
			following symbol:
Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by		
	absorption and reflection from structures, objects, and people.		
a	Field strength 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 Device is used exceeds the applicable RF compliance level above, the		
	Device should be observed to verify normal operation. If abnormal performance is observed,		
	additional measures may be necessary, such as re-orienting or relocating the Device.		
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		
С	Venus 5 incorporates a robust design and conforms with Radiated RF Immunity Test up to 10 V/m		
	between 80 MHz and 2.5 GHz while the test requirement is 3 V/m.		

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Device

Venus 5 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of Venus 5can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and Venus 5 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output	Separation Distance According to Frequency of Transmitter (meters)		
Power of Transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
(Watts)	d = 1.2 √P	d = 1.2 \\ P	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
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.

NOTE 1:	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.	
NOTE 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by the	
	absorption and reflection from structures, objects, and people.	

18. Declaration of Conformity



Oxytek Medical Technology Co., Ltd.

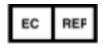
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