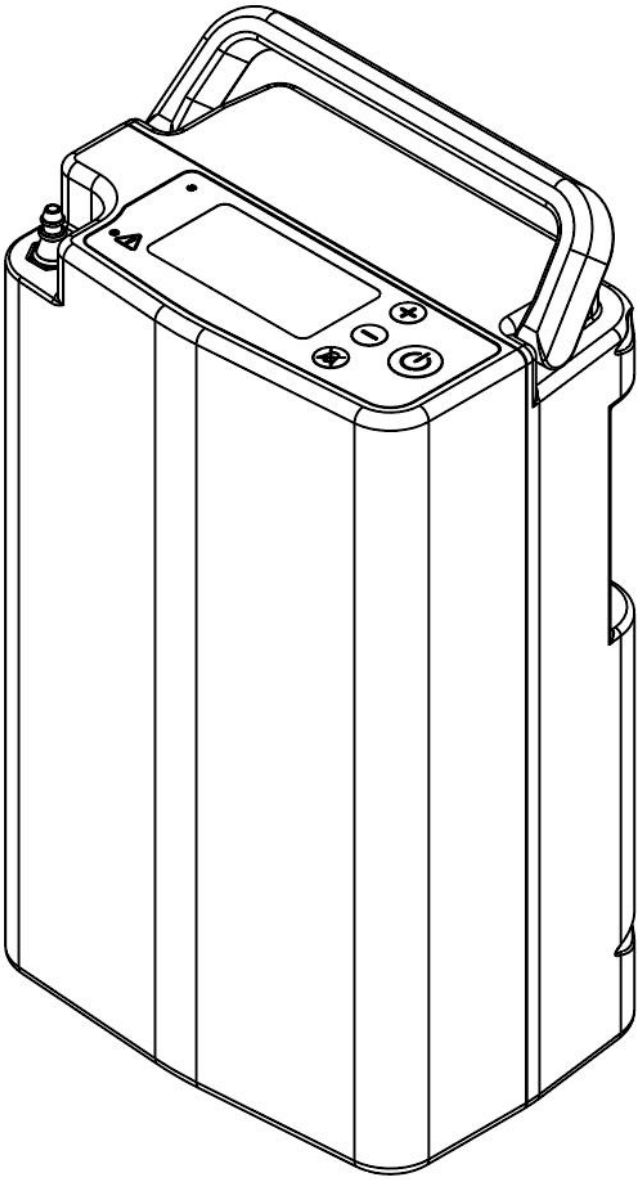
Venus 5

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:

- EN 60601-1:2006+ A1:2013+AC:2014+A12:2014+A2: 2020, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- EN 60601-1-2:2015+A1:2021, Medical Electrical Equipment-Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- EN 60601-1-6:2010+A1:2015+A2:2020, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
- EN 60601-1-8:2007+AC:2014+A11:2017+A2:2021, 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.
- EN 60601-1-11:2015+A1:2021 Medical Electrical Equipment - Part 1-11: General Requirements for Safety– Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
- ISO 80601-2-69 Medical electrical equipment- Part 2: Particular requirements for the basic safety and essential performance oxygen concentrator equipment.

Medical Device Regulation (EU) 2017/745.

This equipment is classified as:

- Class II
- Class IIb according to the REGULATION (EU) 2017/745
- Type BF
- IP21 without 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

OXTm 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.
OXTm 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

OXTm 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 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 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 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 -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. If feeling ill or experiencing discomfort while using this device, contact your clinician or seek medical assistance immediately to avoid harm.
18. The electrical cord and tubing could present a tripping or strangulation hazard. Keep away from children and pets.
19. 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.
20. 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 OX-1A-E for single patient use only.

3 The display may be difficult to read under bright lighting conditions (sunlight, interior lights, etc.), move away from direct light for viewing the display.

4 Keep away from lint or other loose material that could block the intake vents.

5 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.

6 Non-prescribed oxygen therapy can be hazardous under certain circumstances. Use this device only when prescribed by a clinician.

7 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.

8 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.

9 Do not use this device while sleeping unless prescribed by your clinician.

10 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.

11 This device may not reach specified oxygen concentration purity until it has been in use for up to 2 minutes at set flow rate.

12 This device is designed for use by one patient at a time.

13 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.

14 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.

15 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.

16 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.

17 Always follow cannula manufacturer's instructions for proper use.

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

19 Only charge battery in an approved charger. (See approved accessories list.)

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

21 Always turn off this device when not in use.

22 Always disconnect power and turn off this device before cleaning. See Chapter 10. Maintenance and Cleaning.

23 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.

24 Do not place objects on top of this device.

25 Keep away from children and pets to prevent damage to the device and accessories and/ or inadvertent setting changes.

26 Keep the device away from pets and pests.

27 This device is rated IP22 while used in the carry bag. Do not use in dusty or wet conditions.

28 Always use in a well-ventilated location.

29 Always follow the maintenance schedule as specified in Chapter 10.1. Routine Maintenance.

30 If this device indicates an abnormal condition, see Chapter 9. Troubleshooting.

31 Use caution when touching this device in high ambient temperatures.

32 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. 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.

Side effects:

Oxygen therapy may occur some side effects below, please check with your physician for evaluation before use oxygen concentrator.

- Oxygen is dissolved in the blood plasma, which enables a compensating change to occur where oxygen supports neurons that may be starved of oxygen, as well as reducing inflammation and post stroke edema in the brain.
- The therapy has occasionally caused seizures but due to the effect of dissolved oxygen on neurons, the seizure is not usually followed by any further negative effect. Such seizures usually occur as a result of oxygen toxicity.
- High levels of oxygen can induce overgrowth of the blood vessels in the eye and lead to blindness. This condition is referred to as retinopathy of prematurity (ROP).
- Patients with chronic obstructive pulmonary disease are at a particular risk of accumulating carbon dioxide. Patient needs to be carefully monitored to prevent supplemental oxygen becoming dangerous rather than beneficial.

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.**

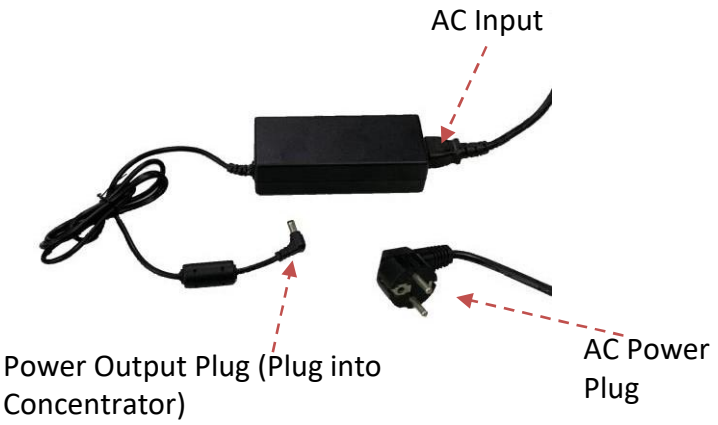
For further information about training contact your home oxygen provider.

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



- Carrying Bag

- DC Power Cable

⚠ WARNINGS

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..
- 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 and remove the batteries 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.
- Never drop or insert any object into any opening.
- 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. The alarm active before 30 mins of battery drain out.
- 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.

⚠ 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
- Carry bag
- AC power supply
- Cannula
- DC power cable

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 6800 mAh
- AC power supply Input :100~240VAC,50/60Hz, 2.0A,Output 20VDC, 5A
- DC power cable
- Carry bag
- External battery (option)
- power cord: European/ North American
- Battery charger

⚠ 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

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

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. The display will illuminate to indicate the level of internal battery charge (10- 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). Be certain to first properly align the power cord to this inlet. To do this, take note of the plug of both the power cord connector and the Venus 5's inlet connection.

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.

6.3 Nasal Cannula

Only use a nasal cannula with the following specifications:

- 7ft (2.1 m) long
- High flow
- Crush resistant
- Large internal diameter bore
- Straight non-tapered tips
- Suitable for up to 15 liters 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 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 2 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 NasalCannula

⚠ **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. 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.

Cannula connect to outlet

Fig. 2

Cannula to the nose

Fig. 3

Item	Description	Function
1	Carrying Handle	Hand grip area for transporting the device
2	Control Panel	Control switches and LCD display
3	Patient Cannula Connector	Oxygen output and connection point for patient cannula
4	Power Input Connector	Connection point for VENUS 5 external power supplies: AC adapter, vehicle DC, external Battery
5	Air intake	Air enter the unit from here
6	Product specification label	
7	Air Exhaust Vent	Air outlet for enclosure ventilation fan
8	Air filter	Prevents dirt,dust and lint from entering your unit

Important: Charge before operate start to use Venus 5

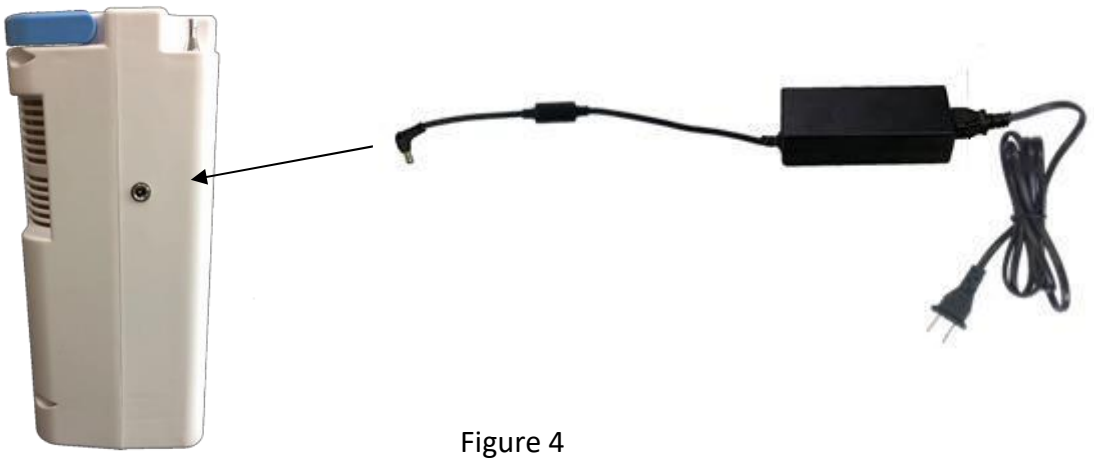
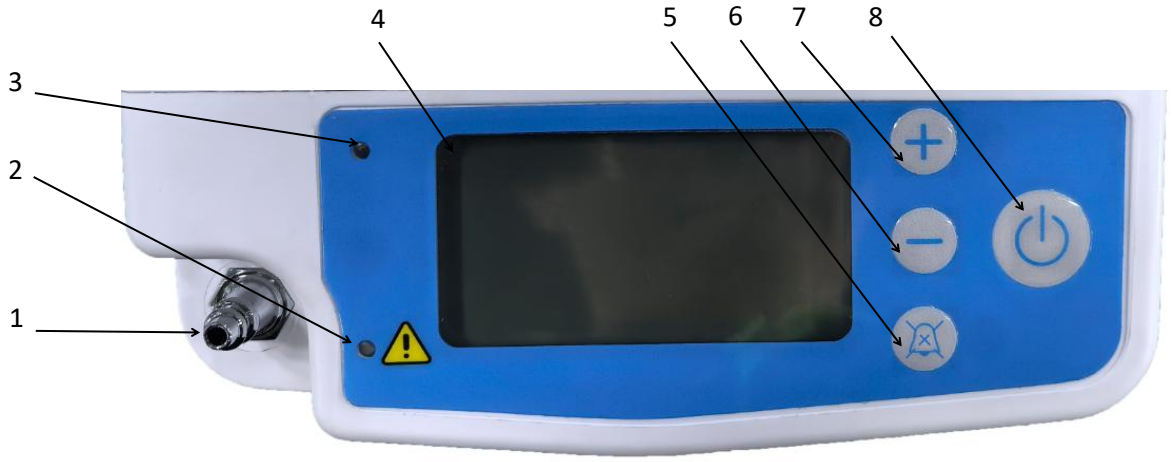


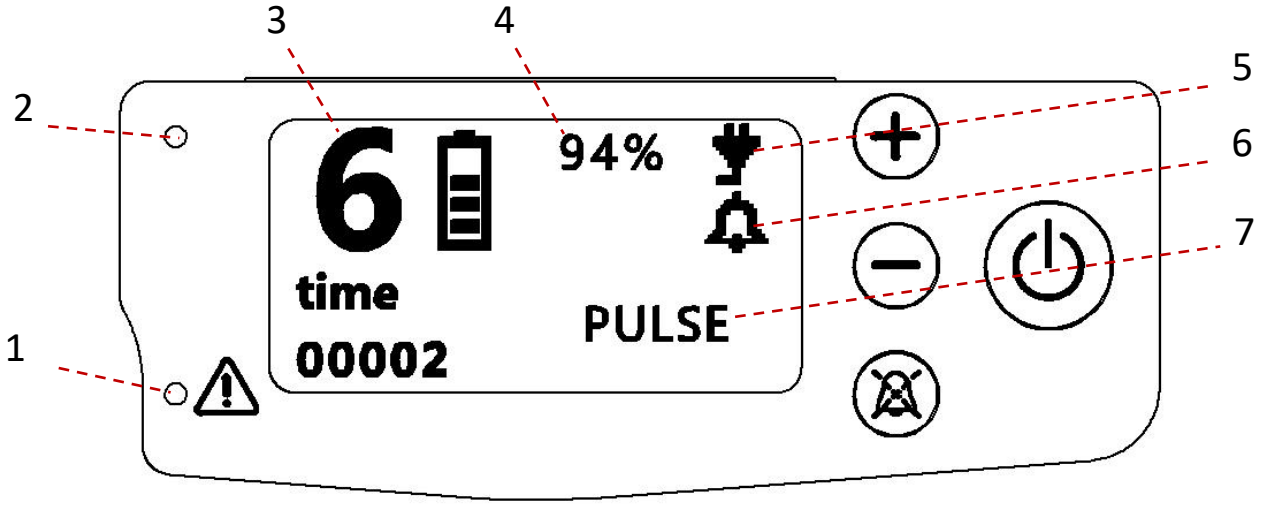
Figure 4

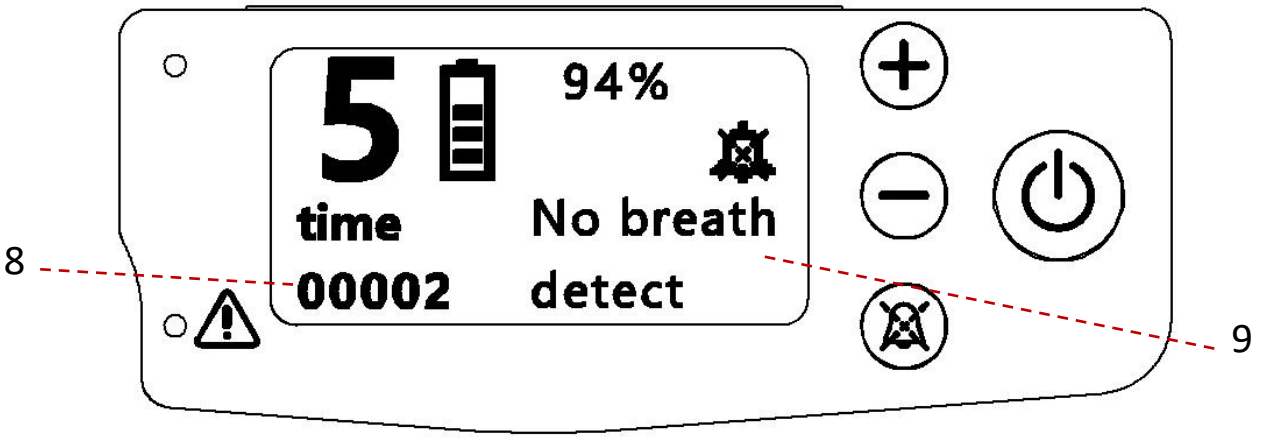
7.3 Control Panel



Item	Description	Function
1	Oxygen outlet	Oxygen is dispersed through this port
2	Yellow light	Alert/Alarm light
3	Green light	Breath detection light
4	Monitor	Display information on the running status of the machine
5	Bell cancel temporary	Cancel the bell temporarily and/or resue it
6	Minus(-)	Decrease the flow setting
7	Plus(+)	Increase the flow setting
8	Power	Turns the device On and Off

7.4 Run Time Screen Description





Item	Description	Item	Description
1	Breath detection light	2	Alert/Alarm light
3	Pulse flow setting status	4	Battery level display
5	External power supply status	6	Bell status
7	Operation mode/status	8	Total running time
9	Alarm status		

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.

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 1-6.

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.

⚠ **Warning:** 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 30 seconds.

At 30 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.

⚠ Warnings

- Do not use the humidifier while the device is operated.

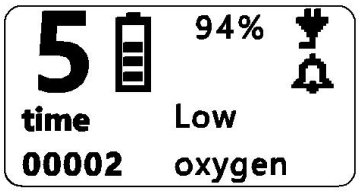
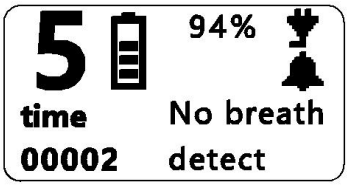
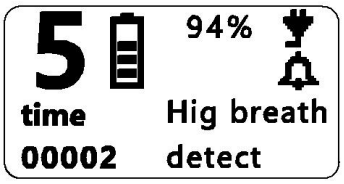
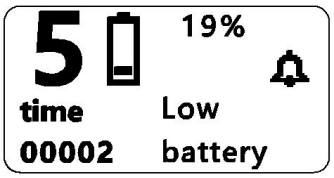
7.8 Turning Off

⚠ 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
 3 short beep+1 long beep + red light flash	**Low Oxygen Concentration Alarm** **Medium priority alert** This alarm occurs when the device is delivering a lower concentration of oxygen than specified(82%±3%)	1.Reset the correct pulse flow setting. 2. Check the intake filter. If it is blocked or has been used for more than 1500 hours, please replace it. 3. Check the air outlet to ensure that nothing is obstructing the machine's heat dissipation. If the alarm still appears after the above method of handling, please contact your supplier
 1 short beep + red light lights flash	**No Breath Alarm** **Low priority alert** This alarm occurs when a breath is not detected for a period of 30 second or more. This alarm becomes silent as soon as a breath is detected.	Check the connection from the cannula to the device. Make sure the nasal cannula is properly positioned on your face and that you are breathing through your nose. Make sure the cannula tubing is not kinked or obstructed.
 1 long beep + red light flash	**High Breath Rate Alarm** **Low priority alert** This alarm indicates that the user's breath rate is exceeding the capacity of the device.	The indicator resets itself when the breath rate is over 40 times. If this indicator regularly occurs, contact your home care provider.
 2 short beep +1 long beep + red light flash	**Low Battery Alarm** **Promt** This alarm occurs when when the battery level is below 20%. Remaining battery life is dependent on your device settings and your activity level.	Replace connect to a power source.
	**High Temperature Alarm** **Promt** The internal temperature of the unit is too high.No operation can be performed before the unit cools down	1. Place your device at least 1.6 meters away from walls, fabrics, or other objects 2. Check the air outlet to ensure that nothing is obstructing the machine's heat dissipation

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 trigger a pulse of oxygen	Device is not turned on.	Press the power button.
	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

⚠ **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 leaned or changed. (Also, see Chapter 9. Troubleshooting.)
The intake filter to be checked every three (3) months. Suggest replace the filter every 6 months or each 1500 hours after replacement. (according to 8 hrs x 30 days x 6 months for usage)
IMPORTANT: The cannula 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 beforecleaning.

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 two (2) years or 8000 hours of use(whichever comes first). Battery and sieve bed 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

Oxygen Concentration	87%~96% at all flow rates based on atmospheric of 14.7psia(101 kPa) at 21℃
Power requirements	AC adaptor:100~240V AC (±10%),50-60Hz in, 20V DC, 5A out DC adaptor : 13~20V DC in
SoundLevel	42dBA at setting 2 and 15 BPM (when measured at 1 m from front of device)
Alarm/Prompt type	low oxygen concentration,No breath, High breath rate, Low battery, High Temperature
Outlet pressure	8.5~15 psi
Dosing Sensitivity	<-0.15cmH_2O
Operation Temp./Humidity/ Atmospheric pressure	5~35℃/ 5~90%RH/70~106 kpa
Storage Temp./Humidity/ Atmospheric pressure	-20~70℃/ 5~95%RH/70~106 kpa
Dimension(mm)	115(L) x 158(W) x 255(H)
Weight (Kgs)	2.2 (with internal battery)

Flow settings and pulse volumes(mL):

	Setting					
Breath per minute	**1 200mL**	**2 400mL**	**3 600mL**	**4 800mL**	**5 1000mL**	**6 1200mL**
15	**13**	**26**	**40**	**53**	**66**	**80**
20	**10**	**20**	**30**	**40**	**50**	**60**
25	**8**	**16**	**24**	**32**	**40**	**48**
30	**7**	**13**	**20**	**26**	**33**	**40**
35	**6**	**11**	**17**	**22**	**28**	**34**
40	**6**	**10**	**15**	**20**	**25**	**30**

+/-15%(include the manufacturer measurement uncertainty: +3.9%) , 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

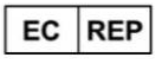
Use the Venus 5 DC power supply to plug in your device using the vehicle's cigarette lighter or DC power input. You can also use the Venus 5 device while it is running from a DC power source.

⚠ **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

	General warning, caution, risk of danger Please read the instructions carefully before operating the product.
	Type BF applied part
	Class II equipment
	Manufacture's serial number
	Authorized representative in the European community
	Date of manufacture
	Manufacture
	This device contains electrical and/or electronic components that must be recycled per EU Directive 2012/19/EU-Waste Electrical and Electronic Equipment (WEEE).
	The equipment bears CE mark CE 02460 indicating its conformity with the provision of Regulation(EU) 2017/745 concerning medical devices.
	FRAGILE Contents of the transport package are fragile therefore it shall be handled with care.
	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
	Follow instructions for use
IP21	Enclosure protection classification (without bag) "2" means protection against solid foreign objects of ϕ12.5 mm and greater "1" means protection against vertical dripping water(condensation)
	Do not use If package is damaged
	No open flame: Fire, open ignition source and smoking prohibited

17. EMC Information

ELECTROSTATIC DISCHARGE – TEST SPECIFICATION	
Basic Standard	: IEC6100-4-2:2008
Test Port	: Enclosure port
Discharge Impedance	: 330ohm / 150 pF
Discharge mode	: Single Discharge
Discharge Period	: One second between each discharge

RESULT & PERFORMANCE				
Product	Oxygen concentrator		Mode	ON
Model/Type reference	OX-1A-E		Temperature	22°C
Power	AC 230V / 50HZ		Humidity	50%
Discharge Method	**Discharge Position**	**Voltage (±KV)**	**Min. No. Of Discharge per polarity (Each Point)**	**Meet the immunity Performance Criteria**
Contact Discharge	Conductive Surfaces	8	10	EUT Operated as intended, no degradation of function
	Indirect Discharge VCP	8	10	
	Indirect Discharge HCP	8	10	
Air Discharge	Slots, Apertures, and Insulating Surfaces	2,4,8,15	10	
* There was no obervable degradation in performance.				

RADIO FREQUENCY ELECTROMAGNETIC FIELD – TEST SPECIFICATION	
Basic Standard	: IEC 6100-4-3:2006 + A1:2007+A2:2010
Test Port	: Enclosure port
Step Size	: 1%
Modulation	: 1kHz, 80%AM
Dwell Time	: 1 second
Polarization	: Horizontal & Vertical

RESULT & PERFORMANCE			
Product	Oxygen concentrator	Mode	ON
Model/Type reference	OX-1A-E	Temperature	23°C
Power	AC 230V / 50HZ	Humidity	55%
Frequency (MHz)	**Position**	**Field Strength (V/m)**	**Meet the immunity Performance Criteria**
80 – 2700	Front, Right Back, Left	3	EUT Operated as intended, no degradation of function
* There was no obervable degradation in performance.			

PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATION EQUIPMENT				
Frequency (MHz)	**Position**	**Modulation**	**Field Strength (V/m)**	**Meet the Immunity Performance Criteria**
385	Front, Right, Back, Left	Pulse Modulation, 18Hz	27V/m	EUT Operated as intended, no degradation of function.
450		FM, ±5kHz deviation, 1kHz sine	28V/m	
710, 745, 780		Pulse modulation, 217Hz	9V/m	
810, 870, 930		Pulse modulation 18Hz	28V/m	
1720, 1845, 1970		Pulse modulation, 217Hz	28V/m	
2450		Pulse modulation, 217Hz	28V/m	
5240, 5500, 5785		Pulse modulation, 217Hz	9V/m	
* There was no obervable degradation in performance.				

ELECTRICAL FAST TRANSIENT / BURST – TEST SPECIFICATION	
Basic Standard	: IEC6100-4-4:2012
Test Port	: Input AC power port
Impulse Frequency	: 100kHz
Impulse Wave-shape	: 5/50ns
Burst Duration	: 0.75ms
Burst Period	: 300ms
Test Duration	: 2 minutes per polarity

RESULT & PERFORMANCE			
Product	Oxygen concentrator	Mode	ON
Model/Type reference	OX-1A-E	Temperature	24˚C
Power	AC 230V / 50HZ	Humidity	56%
Coupling	**Voltage (kV)**	**Polarity**	**Meet the immunity Performance Criteria**
L+N+PE	2	±	EUT Operated as intended, no degradation of function
* There was no obervable degradation in performance.			

SURGE – TEST SPECIFICATION	
Basic Standard	: IEC6100-4-5:2005
Test Port	: Input AC power port
Wave-Shape	: Open Circuit Voltage – 1.2 / 50 us Short Circuit Current – 8 / 20 us
Pulse Repetition Rate	: 1 pulse / min.
Test Events	: 5 pulses (positive & negative) for each polarity

RESULT & PERFORMANCE			
Product	Oxygen concentrator	Mode	ON
Model/Type reference	OX-1A-E	Temperature	24˚C
Power	AC 230V / 50HZ	Humidity	56%
Coupling Line	**Voltage (±kV)**	**Phase Angle**	**Meet the immunity Performance Criteria**
L – N	05, 1	0°, 90°, 180°, 270°	EUT Operated as intended, no degradation of function
* There was no obervable degradation in performance.			

CONDUCTED DISTURBANCES INDUCED BY RF FIELDS – TEST SPECIFICATION	
Basic Standard	: IEC6100-4-6:2013
Test Port	: Input AC power port
Step Size	: 1%
Modulation	: 1 kHz 80% AM.
Dwell Time	: 1 second

RESULT & PERFORMANCE			
Product	Oxygen concentrator	Mode	ON
Model/Type reference	OX-1A-E	Temperature	24˚C
Power	AC 230V / 50HZ	Humidity	56%
Inject Line	**Frequency (MHz)**	**Voltage Level (V r. m. s.)**	**Meet the immunity Performance Criteria**
Power Line	0.15 – 80	3	EUT Operated as intended, no degradation of function
		6*	
* There was no obervable degradation in performance.			

POWER-FREQUENCY MAGNETIC FIELD – TEST SPECIFICATION	
Basic Standard	: IEC6100-4-8:2009
Test Port	: Enclosure port
Power Frequency	: 50Hz / 60Hz
Duration	: 5 Min
Direction	: X axis Y axis Z axis

RESULT & PERFORMANCE			
Product	Oxygen concentrator	Mode	ON
Model/Type reference	OX-1A-E	Temperature	24˚C
Power	AC 230V / 50HZ	Humidity	56%
Direction	**Field Strength**	**Duration**	**Meet the immunity**

	(A / m)	(Min)	Performance Criteria
X axis	30	5	EUT Operated as intended, no degradation of function
Y axis	30	5	
Z axis	30	5	
* There was no obervable degradation in performance.			

VOLTAGE DIPS, INTERRUPTIONS, AND VARIATIONS – TEST SPECIFICATION	
Basic Standard	: IEC6100-4-11:2004
Test Port	: input a.c. power port

RESULT & PERFORMANCE					
Product	Oxygen concentrator			Mode	ON
Model/Type reference	OX-1A-E			Temperature	24°C
Power	AC 230V / 50HZ			Humidity	56%
Test Level % UT	**Reduction (%)**	**Cycle**		**Phase Angle**	**Meet the immunity Performance Criteria**
		(50Hz)	**(60Hz)**		
0	100	0.5	0.5	0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	EUT Operated as intended, no degradation of function
0	100	1	1	0°	
70	30	25	30	0°	
0	100	250	300	0°	
* There was no obervable degradation in performance.					

IEC 60601-1			
Clause	Requirement	Result	Verdict
6	Classification of me equipment and me systems		
6.1	Class ll me equipment, externally powered	Class ll when powered by adapter	P
6.2	Internally powered me equipment	Internally powered equipment when powered by battery	P
6.3	Equipment with means of connection to a supply mains complied with class l or class ll me equipment requirements when so connected, and when not connected to supply mains with internally powered me equipment requirements.		P
6.4	Enclosures classified according to degree of protection against ingress of water and particulate matter as per IEC 60529		P
6.5	Me equipment and me systems intended for use in an oxygen rich environment classified for such u se and complied with 11.2.2	Refer to chapter" Intended Use" in user manual	P

18. Declaration ofConformity

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