Oxygen Concentrator

Model: OX-10A

User Manual

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 OTM 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 Oxygen Concentrator. For the sake of brevity, the terms “concentrator”, “unit” or “device” are sometimes used in this document to refer to the OXTM 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+ A2: 2021, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- EN 60601‐1‐2:2015, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601‐1‐6:2010+A1:2015 Medical Electrical Equipment – Part 1‐6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
- EN 60601‐1‐8:2007+A1:2013 Medical Electrical Equipment – Part 1‐8: General Requirements for Basic Safety and Essential performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
- EN 60601‐1‐11:2015 General Requirements for Basic Safety and Essential Performance ‐ 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

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. Principle of Operations and Intended Use

2.1 Principle of Operations

The Oxygen Concentrator is a psa oxygen generator. The psa (pressure swing adsorption) oxygen generator is an air separation unit which is based on molecular sieves selective adsorption of nitrogen from air. It can continuously generate oxygen with the purity 90%±3% at ambient temperature. The adsorbed nitrogen can be desorbed by decreasing the adsorbed bed pressure resulting cyclical adsorption-desorption operation.

Pressure Swing Adsorption (PSA) processes rely on the fact that under pressure gases tend to be attracted to solid surfaces, or adsorbed. The higher the pressure, the more gas is adsorbed; when the pressure is reduced, the gas is released, or desorbed. PSA processes can be used to separate gases in a mixture because different gases tend to be attracted to different solid surfaces more or less strongly. If a gas mixture such as air, for example, is passed under pressure through a vessel containing an adsorbent bed that attracts nitrogen more strongly than it does oxygen, part or all of the nitrogen will stay in the bed, and the gas coming out of the vessel will be enriched in oxygen. When the bed reaches the end of its capacity to adsorb nitrogen, it can be regenerated by reducing the pressure, thereby releasing the adsorbed nitrogen. It is then ready for another cycle of producing oxygen enriched air.

2.2 Intended Purpose

OXTM Oxygen Concentrator is intended to provide supplemental low flow oxygen therapy for patients suffering from COPD.
The device is 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 use.

2.3Intended Use

OXTM portable oxygen concentrator is intended to provide supplemental low flow oxygen for patients suffering from COPD.
The device is 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 use.

Contraindications:

OXTM 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

Side-effect:

- Hypercapnia
- Pulmonary toxicity

Intended Patient's specification:

a) Population: adult
b) Age: above 18 years old
c) Health status: suffering from stage III (severe)or IV (very severe) of COPD with hypoxemia at rest or without hypoxemia.

Intended target groups:

Patients suffer from stage III (severe)or IV (very severe) of COPD with hypoxemia at rest or without hypoxemia.

Medical condition：

Medical fields concerned is providing supplemental low flow oxygen for patients suffering from at stage III (severe)or IV (very severe) of COPD with hypoxemia at rest or without hypoxemia

Clinical benefit:

The oxygen concentrator is intended to provide supplemental low flow oxygen therapy for patients suffering from COPD and correct use of Portable oxygen concentrator can benefit COPD patients by improving their exercise ability to walk more than 70m and by mitigating dyspnoea.

3. Safety Instructions

3.1 Intended user profile

Target user group: Patients and care givers who are trained by an experienced person who has been authorized by the manufacturer and has appropriate training, knowledge, and experience.

Operator	
Age	-Adult (above18 years old)
Knowledge	minimum: -Read and understand text and Arabic numerals; -Read this manual.
Linguistic	-English or local official language
Education	-At least 18 years old and 12 years intensive reading experience(school). -No maximum.
Experience	- be trained by an experienced person who has been authorized by the manufacturer - And has appropriate training, knowledge and experience.
Permissible impairments	-Mild reading vision impairment or vision corrected to log MAR 0,2(6/10 or 20/32). -Impaired by 40% resulting in 60% of normal hearing at 50 Hz to 2 kHz.

⚠ 3.2 Warnings Overview

1 There is a risk of fire associated with oxygen equipment and therapy. Do not use near sparks or open flames.

2 OX-10A is for single patient use only.

3 The settings of OXTM Oxygen Concentrator OX - 10A might not correspond with continuous flow oxygen.

4 The settings of other models or brands of oxygen concentrators do not correspond with the settings of OXTM Oxygen Concentrator OX - 10A.

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 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 10° C to 40° C, or outside the humidity range of 15% to 95% may adversely affect the flowrate 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 50° C. Use and/or storage outside of the valid conditions may damage the product.

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.

22 The operator should read and understand this entire manual before using the device.

23 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.

24 Geriatric or any other patient unable to communicate discomfort, or hear or see the alarms while using this device, may require additional monitoring.

25 Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.

26 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.

27 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.

28 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

29 Use only with OX‑10A AC power supply.

30 Use only approved OX‑10A accessories.

31 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.

32 Periodically inspect electrical cords, cables, and the power supply for damage or signs of wear. Discontinue use and replace if damaged.

33 Your home care provider is responsible for performing appropriate preventive maintenance at the intervals recommended by OXTM.

34 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.

35 Do not use an extension cord.

36 Device operation above or outside of the voltage, temperature, humidity and/or altitude values specified may decrease oxygen concentration levels.

37 Never drop or insert any object into any opening.

38 Be aware that the electrical cord and/or tubing could present a tripping or strangulation hazard.

39 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.

40 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.

41 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.

42 Do not use this device while sleeping unless prescribed by your clinician and use a pulse-oximeter to monitor the SpO2 of patient's.

43 Do not use this device over 14h with 95% concentration oxygen and consult with doctor before oxygen therapy.

⚠ 3.3 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 Don't position the equipment so that it is difficult to operate the disconnection device.

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 Always operate the device at the setting prescribed by a clinician. Do not alter the setting unless prescribed by a clinician. Periodic reassessment of the flow settings should be done by a clinician.

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

9 It is recommended for an alternate source of oxygen to be made available in the event of power outage or mechanical failure. Consult your home oxygen provider or clinician for an appropriate backup system.

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

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

12 If you are unable to hear or see alarms, do not have normal tactile sensitivity, or cannot communicate discomfort, consult a clinician before using this device.

13 If oxygen concentration drops below the specified level, an alarm will indicate this condition. If alarm persists, stop using this device, switch to an alternate source of oxygen, and contact your home oxygen provider.

14 Only use approved accessories or cannula 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 Replace the cannula on a regular basis. Check with your home oxygen provider or clinician to determine how often the cannula should be replaced.

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

19 Always turn off this device when not in use.

20 Always disconnect power and turn off this device before cleaning.

21 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.

22 Do not place objects on top of this device.

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

24 Keep the device away from pets and pests.

25 Always use in a well ventilated location.

26 Always follow the maintenance schedule as specified.

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

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

29 Do not immerse the device or allow any liquid to enter the enclosure.

3.4 Overview of Important Information

1 The patient is an intended operator.

2 Inhale through the nose for the concentrator to work most effectively. Inhaling through the mouth may result in less effective oxygen therapy.

3 If you have allergic reactions to nasal cannula, please contact your physician, therapist local or home care provider for assistance.

4 This oxygen concentrator can operate in continuous flow mode. See Chapter 14. Specification

5 Please contact with manufacturer and local competent authority if have any serious incident related with the oxygen concentrator.

6 Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of equipment that are designated by the manufacturer as repairable by service personnel.

7 2 hours is required for the oxygen concentrator to warm from -20° C between uses until the oxygen concentrator is ready for its intended use when the ambient temperature is 20° C, or, to cool from 50° C between uses until the oxygen concentrator is ready for its intended use when the ambient temperature is 20 ° C.

8 The circumstances in which the user should consult a healthcare professional：

a) Patients with a fast breathing rate (more than 20 breaths/min) requiring a higher oxygen setting may require more oxygen than this device can produce. This device may not be appropriate in that case. Consult your clinician for alternative treatment.

b) 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.

c) 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.

d) If your symptoms, such as headaches, drowsiness, confusion, fatigue or increased irritability, are not alleviated after inhaling oxygen, please consult your physician.
e) If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.

4. Instructions and Training

The Regulation (EU) 2017/745 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 OX - 10A Oxygen Concentrator, its features, and its accessories are described inn this manual. Read and understand it completely before operating the device. This manual a detail ipplies to the following accessories:

- AC Power Cable
- Intake Filter

Fig.1

Fig.2

6. General Instructions Before Use

A variety of accessories can enhance the portability and use of the OX - 10A 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:

- Oxygen Concentrator

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.

- AC Power Cable

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

6.2 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
- Suitable for adult
- Meets substance compatibility of IEC/EN 60601 - 1
- Have CE marking

Recommended: Disposable Nasal Oxygen Cannula RMK01 (Produced by Ningbo Runmai Medical Technology Co., Ltd)

⚠ **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 Humidifier

Only use a humidifier with the following specifications:

- Bottle humidifier: single person multiple use
- The pressure relief valve is 6Psi and

- The maximum water Level is about 240ml
- Oxygen flow rate can be suitable for prescription from patient.
- DISS Oxygen Inlet Connector
- Outlet Port: Tapered Outlet Accepts Universal Supply Tubing End Connector
- The material shall meet requirement of ISO 18562 series.
- Have CE marking

⚠ **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.

7. Operating OX-10A

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

OX－10A Oxygen Concentrator is designed for ease of use, with all functions accessed through just a few keys on the control panel.

7.1 Before Operating Your Oxygen Concentrator

1. Before operating your unit always checks to be sure the air filter (located on the back of your unit) is existed .

2.Attach the appropriate oxygen accessories to the oxygen outlet.

Oxygen Tubing Connection:

A. Attach the oxygen tubing directly to the connector.(Fig.3)

Cannula port

Fig.3

B.Oxygen Tubing Connection with Humidification:

WARNING:

- Do not overfill humidifier.
- Do not reverse the oxygen input and output connections. Water from the humidifier bottle will travel through the cannula back to the patient.

If your physician has prescribed an oxygen humidifier as part of therapy, follow these steps:

To attach the humidifier:

- Remove the cover on the humidifier bottle according to the instructions.
- Fill the humidifier with boiled tap water which has been left to cool or distilled water .
- Fill the humidifier bottle to the level specified by the humidifier bottle manufacturer mark then replace the cover according to the instructions.
- Connect the connector and the humidification bottle inlet fitting with a tube.(Fig.4)
- Attach the oxygen tubing directly to the humidifier bottle outlet fitting.(Fig.5)

Make sure all connections are secure.

Your physician has prescribed a nasal cannula, in most cases, it is already attached to the oxygen tubing. If not, follow the manufacture’ s instructions for attachment.

Remove the power cord completely from the line cord strap, Make sure the power switch is in the “Off” position, and insert the plug into the wall outlet; the unit is double insulated to guard against electric shock.

Fig.4

Fig.5

⚠ **WARNING:** Improper use of the power cord and plugs can cause a burn, fire or other electric shock hazards . Do not use the unit if the power cord is damaged.

7.2 Connecting Nasal Cannula

⚠ **CAUTION:** Replace the cannula on a regular basis.

Check with your home oxygen provider or clinician to determine how often the cannula should be replaced.

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

1. Without humidifier： Connect the tubing to the cannula port as shown in Fig.3 if no humidifier bottle is prescribed.
2. With humidifier： Connect the tubing to the outlet of humidifier bottle as shown in Fig.5 if humidifier bottle is prescribed.
3. 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.6

Once the cannula is secured, breathe normally through the nose. OX - 10A will deliver the oxygen during inhalation.

IMPORTANT: Ensure cannula is connected securely and it has been fully inserted.

Cannula

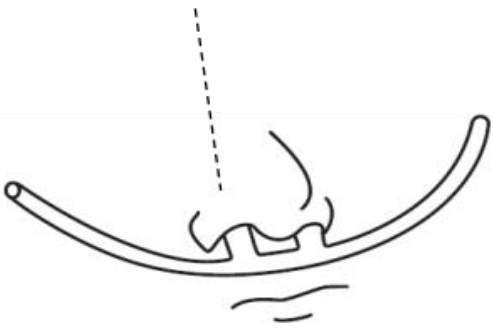


Fig.6

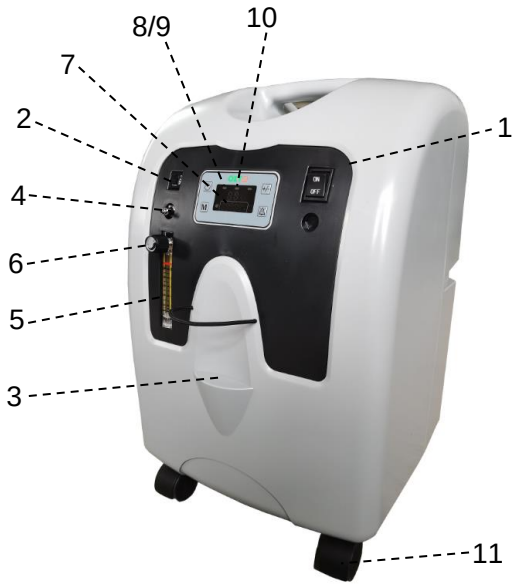
7.3 Device Overview

Please take time to familiarize yourself with your OX-10A oxygen concentrator before operating.

Before using this product, make sure you have the following items:

. 1 User manual.

. 1 Oxygen concentrator set.

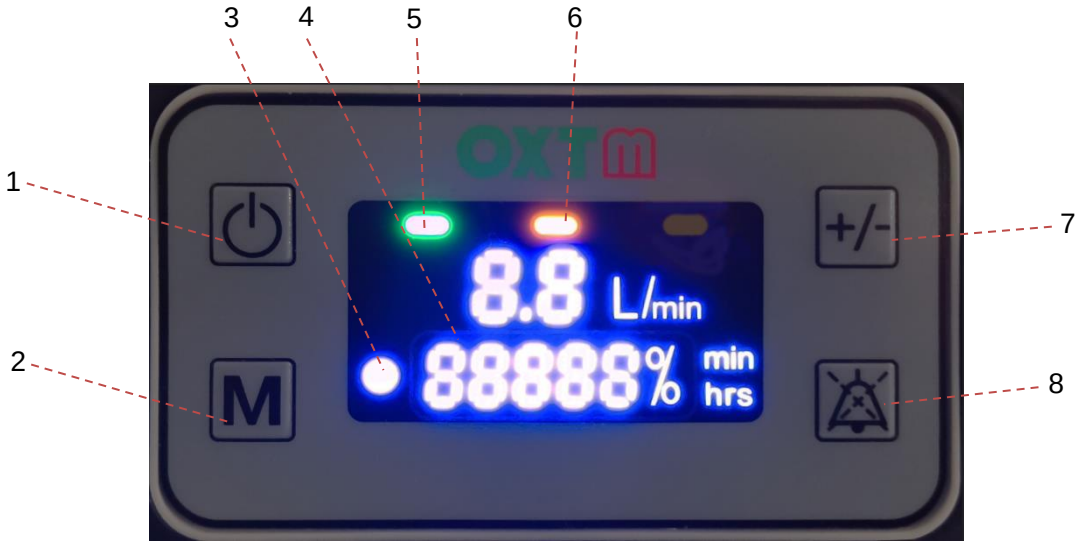


Front View

Rear View

Item	Description	Function
1	Power Switch	I =ON O=OFF
2	Circuit breaker	Resets the unit after electrical overload shutdown
3	Humidifier Holder	To hold the humidifier
4	Oxygen outlet	Oxygen is dispersed through this port
5	Flow meter	To display the flow rate
6	Flow meter knob	To adjust the flow rate
7	Monitor	Indicate the condition of oxygen purity status and hour meter
8	Green Power light	Illuminates when your concentrator is operating
9	Normal Oxygen (green) light	The LED display normal oxygen
10	Low Oxygen (yellow) light	The LED display low oxygen
11	Castor	
12	Air filter	Prevents dirt,dust and lint from entering your unit
13	Product specification label	
14	Exhaust	
15	Power cord and/or IEC power connector	

7.4 Control Panel

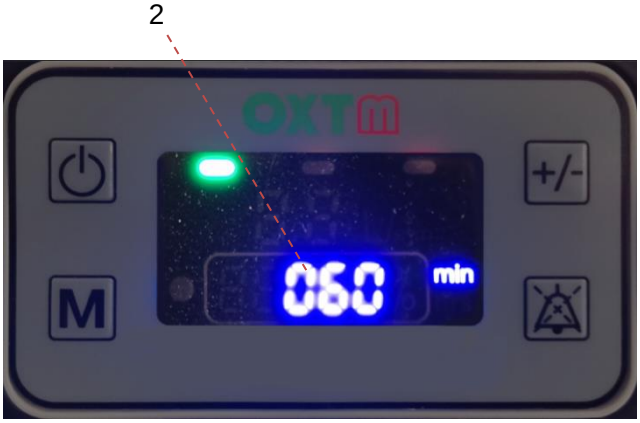


Item	Description	Function
1	Power	Turns the device On and Off
2	Mode	Selects one of the two possible operating states of the device
3	Indicator light	Indicates that the bell is temporarily cancelled or not
4	Monitor	Indicate the condition of oxygen purity status and hour meter
5	Green light	Illuminates when your concentrator is operating and the oxygen concentration > 82%
6	Yellow light	The oxygen concentration < 82% and indicates caution or attention required
7	Plus (+)/Minus (–)	Increases the time setting in-cycle
8	Bell,cancel temporary	Cancel the bell temporarily and/or reuse it

7.5 Run Time Screen Description

Normal mode

Timing mode



Item	Description	Function
1	Total Running times	Indicate the usage time
2	Countdown	

7.6 Turning On

- To turn the device on, Press the power switch to the “On” position.
- The concentrator will chirp and the green, yellow LEDs will flash once,

  Yellow LED - indicates caution or attention required

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

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

7.7 Adjusting Setting

⚠ **IMPORTANT:** After powering on OX-10A, the startup sequence will take approximately 35 seconds. Specified oxygen level will be reached within 10 minutes of use.

⚠ **IMPORTANT:** The device is for prescription use, the quantity of concentration of Oxygen(flow rate and use time) to delivered shall be set according to prescription from your physician.

Flow rate adjustment:

- Control the flow by adjusting the flowmeter knob according to a clinician’s prescription or direction

  -If turn clockwise ,the flow will decrease(and eventually will shut off the oxygen flow).

  - If turn counterclockwise, the flow will increase.

- Make sure the ball is centered on the line corresponding to the number of liters. The ball should not touch or exceed the red line(shown in Fig.7).Setting the flow higher than 10L/Min may cause the oxygen concentration decrease, serious may cause alarm E2(Low Oxygen Concentration Alarm).

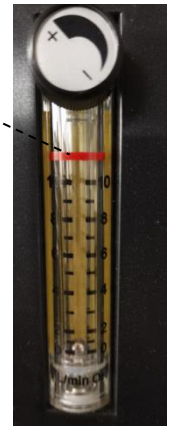


Fig.7

Running timing setting:

- The device starts working in the normal mode.
- Press “Plus (+)/Minus (-)  ”key ,the device will working in the timing mode.Press “Plus (+)/Minus (-)  ” key one time, the value of timing increase with the step 30 minutes.When the time is increased to be 480 minutes,press “Plus (+)/Minus (-)  ”key once again,the device will working in the normal mode.

⚠ **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.

⚠ **IMPORTANT:** Flow can be verified by putting the end of the nasal cannula under the surface of a half full cup of water and looking for bubbles.

7.8 Connecting the Humidifier

⚠ **WARNING:**

- Do not overfill humidifier.
- Do not reverse the oxygen input and output connections. Water from the humidifier bottle will travel through the cannula back to the patient.

To attach the humidifier:

- Remove the cover on the humidifier bottle according to the instructions.
- Fill the humidifier with boiled tap water which has been left to cool or distilled water .
- Fill the humidifier bottle to the level specified by the humidifier bottle manufacturer mark then replace the cover according to the instructions.
- Connect the connector and the humidification bottle inlet fitting with a tube.(Fig.4)
- Attach the oxygen tubing directly to the humidifier bottle outlet fitting.(Fig.5)

Make sure all connections are secure.

7.9 Responding to Alarms

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

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

7.10 Turning Off

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

Press the power key in panel,the device will chirp and the light will shutdown, then go into low‐power mode.

To turn the device off, Press the power switch to the “Off” position.

⚠ **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 and Prompt

8.1 Alarm

OX - 10A oxygen concentrator has 2 types of alarms according to different potential risks during the alarm active: Medium Priority and Low Priority.

When alarm occurs, it will remind the user by the alarm indicator light, alarm sound and alarm messages, different types of alarms have different alarm information as follows:

Alarm Code	Visual, Auditory	Description	Priority Alert	Alarm Condition	Alarm delay	Alarm Signal	Remedy
E2	 3 short beep every 11.2 seconds + yellow light flashes	**Low Oxygen Concentration Alarm** This alarm occurs when the oxygen concentration below 82%. Operator shall make instant on-time response.	**Medium**	**Technical Alarm**	**<5s**	**Visual + Auditory**	1.Change to another source of oxygen and contact your equipment provider. 2. Filter restricted: Clean or replace air inlet filter. Place your device so there is adequate air flow. 3.Restriction in humidifier or tubing: Repair or replace humidifier or tubing.
	 2 short beep every 16 seconds+yellow light on	**Power failure alarm** This alarm occurs when the power failure and the power switch is "ON".The alarm will disappear a few minutes after it occurs,and will no occur again until the device is powered on for 5 minutes. Operator shall pay attention.	**Low**	**Technical Alarm**	**<5s**	**Visual + Auditory**	Check whether the power supply is normal.

Sound pressure level range of the auditory is more than 65dB.

⚠ **IMPORTANT:** After running 5 minutes, disconnect the device from the power supply by unplugging the power cord, an audible alert sounds like "beep" and the yellow light on, which means the alarming system of the device works normally.

⚠ **IMPORTANT:** All alarms have been set and cannot be changed.

⚠ **CAUTION:** The operator needs to operate the oxygen concentrator in front of the control panel of the oxygen concentrator.

⚠ **CAUTION:** When the power failure,power failure alarm will occur and other alarms will disapper.If power is lost for less than or equal to 30s,power failure alarm will disapper and the alarm prior to the power lost will occur again.

8.2 Prompt

Prompt Code	Visual, Audio Indicators	Description	Prompt Signal	Remedy
E3		**High temperature** This prompt occurs when the temperature of the circuit board is greater than 60 ℃	**Visual**	Check whether the air inlet and outlet are blocked.It needs to be cooled naturally after half an hour, and the alarm will be released automatically.

⚠ **IMPORTANT:** All prompt have been set and cannot be changed.

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.

Symptom	Possible Cause	Remedy
A. Unit does not operate. Power light is off when the power switch is “on .”Audible alarm is pulsing.	1. Power cord not properly inserted into wall outlet.	Check power connection at the wall outlet. On 230 volt units, check the back of the unit.
	2. No power at wall outlet.	Check your home circuit breaker and reset if necessary. Use a different wall outlet if the situation occurs again.
	3.Oxygen concentrator circuit breaker activated (selected units).	Press the concentrator circuit breaker button (if equipped) located below the power switch. Use a different wall outlet if the situation occurs again.
B. Unit operates; the Power light is on when the Power switch is “On”. The yellow light flashes. Audible alarm sounding.	1. Air filter is blocked.	Check the air filter. If the filter is dirty, following the replace instructions on chapter 10.
	2. Exhaust is blocked.	Check the exhaust area; make sure there is nothing restricting the unit exhaust.
	3. Blocked or defective cannula or oxygen tubing.	Detach cannula. If proper flow is restored, clean or replace if necessary. Disconnect the oxygen tubing at the oxygen outlet. If proper flow is restored, check oxygen tubing for obstructions or kinks. Replace if necessary
	4. Blocked or defective humidifier bottle.	Detach the humidifier from the oxygen outlet .If proper flow is obtained, clean or replace humidifier.
	5.Gas leakage	Check connection between the device outlet and tubing, connection between the tubing and humidifier bottle, have any gas leakage. Replace if necessary.
	6.compressor failure	Contact your dealer/provider
	7.Sieve beds may be faulty or use up	Contact your dealer/provider
	8. Flow meter set too low.	Set flow meter to prescribed flow rate. If the above remedies do not work, contact your OXTM provider
	9.Other	Contact your OXTM provider
C. Unit operates the power light is on when power switch is “on “, audible low-frequency vibration sound is detected.		Turn your unit “off”, Switch to your reserve oxygen system, and contact your OXTM provider immediately.
D. If any other problems occur with your oxygen concentrator.		Turn your unit “Off”.Switch to your reserve oxygen system, and contact your OXTM provider immediately.
E. Both the green and the yellow lights are either on or off.	O.C.I malfunction	Contact your OXTM provider.
F. Yellow light is on and the intermittent audible Signal is sounding.	1. Flow meter is not properly yet.	Ensure the flow meter is properly set to the prescribed.
	2. Air filter is blocked.	Check the air filter. If the filter is dirty, wash it following the cleaning instructions on chapter 10.
	3. Exhaust is blocked.	Check the exhaust area: make sure there is nothing restricting the unit exhaust. If the above remedies do not work, contact your OXTM provider.
	4. Blocked or defective cannula or oxygen tubing.	Detach cannula. If proper flow is restored, clean or replace if necessary. Disconnect the oxygen tubing at the oxygen outlet. If proper flow is restored, check oxygen tubing for obstructions or kinks. Replace if necessary
	5. Blocked or defective humidifier bottle.	Detach the humidifier from the oxygen outlet .If proper flow is obtained, clean or replace humidifier.

	6.Gas leakage	Check connection between the device outlet and tubing, connection between the tubing and humidifier bottle, have any gas leakage. Replace if necessary.

10. Maintenance and Cleaning

10.1 Routine Maintenance

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

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

Device will indicate with an alarm when a filter or component needs to be cleaned or changed.

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

Air Filter and Oxygen Outlet Connector

The connector should not be cleaned at least once a week. To clean, follow these steps:

1. Remove the oxygen outlet connector (if used).

2. Wash in a solution of warm water and dishwashing detergent.

3. Rinse thoroughly with warm tap water and towel dry .The filter should be completely dry before reinstalling.

Air filter need to be replaced after device operates each 1000 hours. Air filter is disposable after used. Not replace the air filter regularly will affect the performance of concentration.

⚠ **CAUTION:** To prevent product damage, do not attempt to operate the unit without the air filter or while the filter is still damp.

10.2 Cleaning

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

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

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

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

⚠ **IMPORTANT:** The device should receive an external cleaning weekly, accessories should be cleaned as needed. And the device can be cleaned by bacterial wipes over 156 cleaning cycles.

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 3 years or 6,000 hours, except for the sieve beds. The service life of the sieve beds will depend on the operating conditions. Replace them in needed, indicated by the low oxygen concentration alarm. If intake and exhaust vents are not blocked and the low oxygen concentration alarm persists, contact your distributor for instructions on replacing the sieve beds.

Air Filter replacement time: 1500 hours.

11. Device Repair and Disposal

11.1 Repair

Do not attempt to repair the device. Contact your home oxygen provider or distributor for assistance .

11.2 Disposal

This device contains electrical and/or electronic components that must be recycled per EU Directive 2012/19/EU-Waste Electrical and Electronic Equipment (WEEE).

- Contact your distributor regarding disposal of the device.

12. Warranty

The device warranty is limited to one (1) years from date of manufacture or 6,000 hours of total use. All accessories are limited to one (1) year warranty.

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

13. 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.

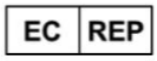
14. Specifications

No.	Item	Rating
1.	Delivery Rate (Lower delivery rates available for low application)	2 to10 LPM
2.	Outlet Pressure	8.5-13 psi (58.6-90 kpa)
3.	Electrical Rating	230 V, 50 Hz, 3.4A (Max.)
4.	Oxygen Percentage	2~9 LPM 93%±3%,10 LPM 90%±3%
5.	Average oxygen concentration	at 2 l/min: 93%±3%
6.	Maximum rated voltage	253V
7.	Backpressure	7Kpa if humidifier bottle attached 0 Kpa if no humidifier bottle attached
8.	Operating Environment Range	Temperature 10℃ to 40℃ Humidity 15% to 95% Atmospheric pressure 80~106 kpa (11.6~15.4 psi)
9.	Weight	19.2kg
10.	Sound Level (ISO 8359:1996 1M from front)	≤55dbA
11.	Dimensions	342mm(L) x368mm(W) x572mm(H)
12.	Operating System	Time Cycle / Pressure Swing
13.	Transport and Storage Conditions	Temperature -20℃ to 50℃ Humidity < 93% Atmospheric pressure 50~106 kPa (7.3~15.4 psi)
14.	Equipment Class and Type	Degree of Protection Against Electric Shock: Class II Degree of Protection Against Electric Shock: Type BF Applied Part (Nasal Cannula) Degree of Protection Against ingress of water and particulate matter: IP21 Model of Operation: Continuous
15.	Sieve Bed	Dimensions:234(L) X 93(W) X 425(H)mm Weight:3.2kg±1% Outlet Pressure:8.5-13 psi Outlet Size: ϕ7 Molecular Sieves: Specification/type:Z12-07,0.4-0.8mm Manufacturer: ZEOCHEM
16.	Total work hours	6,000 hours
17.	Lifetime	3 Years
18.	Warranty Period limit	1 Year or 6,000 hours of total use

OX-10A

FLOW L/M	2	3	4	5	6	7	8	9	10
%O_2	90~94%	90~94%	90~94%	90~94%	90~94%	90~94%	90~94%	90~93%	87~93%

15. Symbols

	Follow instructions for use
	Type BF applied part
	Class II equipment
	Bell, cancel temporary
	Stand-by button
	Machinery Directive
	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
IP21	Enclosure protection classification "2" means protection against solid foreign objects of ϕ 12.5 mm and greater "1" means protection against vertically falling water drops

	No sitting
	No smoking
	No open flame: Fire, open ignition source and smoking prohibited

16. EMC Information

⚠ **Warning:** Don't use the oxygen concentrator (model: OX-10A) near high-frequency surgical equipment, near magnetic resonance imaging equipment, or where the intensity of electromagnetic disturbances may be high.

⚠ **Warning:** Use of oxygen concentrator (model: OX-10A) near other equipment should be avoided because it could result in improper operation. If such use is necessary, oxygen concentrator (model: OX-10A) and the other equipment should be observed to verify that they are operating normally.

⚠ **Warning:** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of oxygen concentrator (model: OX-10A) and result in improper operation.

⚠ **Warning:** Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the oxygen concentrator (model: OX-10A), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
OX-10A is intended for use in the electromagnetic environment specified below. The user of OX-10A should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3- 2	Not applicable	
Voltage Fluctuations/Flicker Emissions IEC 61000-3- 3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
OX-10A is intended for use in the electromagnetic environment specified below. The customer or user of OX-10A should assure that it is used in such an environment.		
Anti-interference detection	**IEC 60601 Test Level**	**Compliance Level**
Electrostatic Discharge (ESD) IEC 61000-4- 2	Contact: +8 KV Air: +2,+4,+8,+15 KV	Same as the left
Electrical Fast Transient/Burst IEC 61000-4-4	The input a.c. power ports: ±2 KV The input d.c. power ports: ±2 KV Signal input/output ports: ±1 KV	Not applicable
Surge IEC 61000-4- 5	Input power ports: +0.5, +1.0 KV Signal input/output:+2.0 KV	Not applicable
Voltage dips IEC 61000-4-11	0.5 cycles for > 95% (sync angle (degrees):0, 45, 90, 135, 180,225, 270, 315)	Not applicable

	1 cycles for >95% UT (sync angle (degrees):0) 25 (50Hz)/30 (60Hz) cycles for 30% U T (sync angle (degrees):0)	
Voltage interruption IEC 61000-4-11	250 (50Hz)/300 (60Hz) cycles for >95% UT (sync angle (degrees):0)	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30A/m	Same as the left
Note: U_T is the A.C. mains voltage prior to application of the test level.		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power(W)	Distance (m)	IMMUNITYTESTLEVEL (V/M)
	385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
	450	430-470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
	710	704-787	LTE Band 13,17	Pulse modulation [b] 217 Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM800/900, TETRA800, CDMA850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
	5500						
	5785						

NOTE:
1. If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

17. Declaration of Conformity

Oxytek Medical Technology Co., Ltd.

ADDRESS: 10-2 , Guang Long Industrial Park, South 1st Rd, Chencun town, Shunde district, Foshan city, Guang Dong Province , China.

Product Designation: Oxygen Concentrator
Catalog Number: OX-10A

Tel： +86-757-2331-1740 **Fax : +86-757-2331- 1745**

Web: www.oxtm-o2.cn **Email: jenny@oxtm-o2.cn**

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Software version: OX10A-1.00

CE 2460

18. Reporting System of Serious Events

Please contact with manufacturer and local competent authority as below table once any serious incident related with the oxygen concentrator occurs.

Country	Contact information	Website
Belgium	**MDD AIMDD - IVDMD** Head of Vigilance Division: Th. Roisin **MDD AIMDD Vigilance: C. Driesmans** tel: +32 2 528 4418 **IVDMD Vigilance: J. Poels** tel: +32 2 528 4449 E-mail: vigilance.meddev@fagg-afmps.be **FAMHP- Federal Agency for Medicines and Health Products** Place Victor Horta 40, box 40, B - 1060, Brussels, fax:+32 2 528 4120	https://www.afmps.be/fr
Bulgaria	Executive Director of BDA: **Bogdan Kirilov, M.Pharm.** Head of Division 'Medical devices': **Todor Darakchiev** **Bulgarian Drug Agency** 8 Damyan Gruev Str., BG - 1303 Sofia, tel:+359 2 890 34 83, fax:+359 2 890 34 34 E-mail: todor.darakchiev@bda.bg, bda@bda.bg - Web site	https://www.bda.bg/bg/
Ceska Republika / Czech Republic	**Ivana Justová** **State Institute for Drug Control** Šrobárova 48, 100 41 Prague 10, Czech Republic, tel: +420 272 185 794, fax: +420 272 185 764 E-mail: urgent@sukl.cz , ivana.justova@sukl.cz	/
Hrvatska / Croatia	Krunoslav Kranjcec, Agency for Medicinal products and medical devices Ksaverska cesta 4, 10 000 Zagreb, tel: +385 1 4884 327, fax: +381 1 4884 110 E-mail: medpro@halmed.hr, Krunoslav.kranjcec @halmed.hr	https://www.halmed.hr/?ln=en
Danmark / Denmark	**Danish Medicines Agency** Axel Heides Gade 1, DK - 2300 - Kobenhavn, tel:+45 44 88 9595, fax:+45 44 88 9599 E-mail: med-udstyr@dkma.dk, Web sites: www.medicinskudstyr.dk	https://laegemiddelstyrelsen.dk/en/devices/
Deutschland / Germany	**AIMDD, MDD - Dr. Ekkehard Stößlein** - tel:+49 228 207 5384 **IVDMD - Prof. Dr. Rüdiger Siekmeier** - tel:+49 228 207 5360 **Federal Institute for Drugs and Medical Devices** Kurt Georg Kiesinger Allee 3, D - 53175 Bonn, fax:+49 228 207 5300 E-mail: medizinprodukte@bfarm.de	https://www.bfarm.de/DE/Home/_node.html https://www.pei.de/DE/home/home-node.html

Country	Contact information	Website
	IVDMD **Dr. Markus Funk** - tel:+49 6103 77 3115 **Jochen Halbauer -** tel:+49 6103 +77 3114 **Paul Ehrlich Institute**, Section Pharmacovigilance 2 Paul-Ehrlich-Strasse 51-59, D - 63225 Langen, fax:+49 6103 77 1268 E-mail: pharmacovigilance2@pei.de	
Eesti / Estonia	**Sofia Ratusnaja** - tel:+372 744 7425 **Health Board, Medical Devices Department** 1a Põllu st., EE - Tartu 50303 E-mail: mso@terviseamet.ee -	https://www.terviseamet.ee/en/medical-devices
Ireland / Eire	**Health Products Regulatory Authority** Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IE - Dublin 2 E-mail: devicesafety@hpra.ie	https://www.hpra.ie/
Ellada / Greece	**Eleni Papaioannou, MD** - tel:+30 213 20 40542, fax:+30 210 65 49585 E-mail: vigilancematerial@eof.gr **National Organization for Medicines** 284 Mesogion Ave, GR- 15562 Holargos, Athens	/
España / Spain	**Carmen Abad** **Carmen Valls** - tel: +34 91 822 5255, fax: +34 91 822 5289 **Agencia Española de Medicamentos y Productos Sanitarios** C/ Campezo 1, Edificio 8, ES - 28022 Madrid E-mail: psvigilancia@aemps.es	https://www.aemps.gob.es/
France	**Emilie Alliez** - tel:+33 1 55 87 33 46, fax:+33 1 55 87 37 02 **Agence nationale de sécurité du médicament et des produits de santé (ANSM)** 143-147 boulevard Anatole France, FR - 93285 Saint Denis Cedex E-mails: Exclusively for correspondence between authorities:medicaldevicesvigilance@ansm.sante.fr Other purposes: materiovigilance@ansm.sante.fr	http://www.afssaps.fr/
Italia / Italy	**Vigilance on Medical Devices** **Head of Unit 5 - Dr.ssa Lucia Lispi** - tel:+39 06 5994 2055 E-mail: dgfdm@postacert.sanita.it, vigilance@sanita.it, l.lispi@sanita.it **MDD AIMDD Vigilance - Dr.ssa Antonella Campanale - Dr.ssa Daniela Minella** tel: +39 06 5994 3038, +39 06 5994 3069 E-mail: dgfdm@postacert.sanita.it, vigilance@sanita.it, a.campanale@sanita.it; d.minella@sanita.it	/

Country	Contact information	Website
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Kypros / Kibris / Cyprus	**Ioannis Argyropoulos** – tel: +357 22 605785 **Cyprus Medical Devices Competent Authority** Prodromou 1 & Chilonos 17 Corner, CY - 1449 Nicosia, fax:+357 22 468427 E-mail: cymda@mphs.moh.gov.cy	/
Latvija / Latvia	Medical Device Evaluation Department - tel: +371 67 078 466, tel: +371 67078466 State Agency of Medicines, 15 Jersikas street, LV - 1003 Riga E-mail: info@zva.gov.lv	/
Lietuva / Lithuania	Director: **Nora Ribokiene** - tel:+370 5 261 51 77, fax:+370 5 212 73 10 **The State Health Care Accreditation Agency, under the Ministry of Health of the Republic of Lithuania** Jeruzales str. 21, LT-08420 Vilnius E-mail: vaspvt@vaspvt.gov.lt	https://vaspvt.gov.lt/
Luxembourg	Ministère de la Santé, Direction de la Santé - tel : +352 247 85612 Villa Louvigny - allée Marconi, L - 2120 Luxembourg E-mail: meddevices.vigilance@ms.etat.lu	https://sante.public.lu/fr/politique-sante/ministere-sante/index.html
Malta	**Malta Medicines Authority - Medical Devices Unit** **Medicines Authority** Sir Temi Żammit Buildings, Malta Life Sciences Park San Ġwann SĠN 3000, Malta Tel : +356 2343 9000 E-mail : devices.medicinesauthority@gov.mt	https://medicinesauthority.gov.mt/medicaldevices
Magyarország / Hungary	**Kornel Szerdi dr.**- tel:+36 1 886 9329, fax:+36 1 269 1255 **Health Registration and Training Centre, Department of Medical Devices** 1051, Budapest, Zrínyi street 3, Hungary E-mail: amd.vig@ogyei.gov.hu	/
Nederland /Netherlands	**Sietske Eerens, Esther Klinckenberg** - tel:+31 88 120 5000, fax:+31 88 120 5001 D**utch Health and Youth Care Inspectorate, IGJ Information Office (Meldpunt)** Visitors address: Stadsplateau 1 | 3521 AZ | Utrecht, postal address: Postbus 2518 | 6401 DA | Heerlen	https://www.igj.nl/

Country	Contact information	Website
	E-mail: meldpunt@igj.nl	
Österreich / Austria	**Federal Office for Safety in Healthcare - (BASG) Bundesamt für Sicherheit im Gesundheitswesen** **Institute for Surveillance, Department Medical Devices Surveillance** Traisengasse 5, A-1200 Vienna, fax: +43 50555 36409 E-mail: medizinprodukte@basg.gv.at	https://www.urpl.gov.pl/pl
Polska/ Poland	**Competent Authority** **Andrzej Karczewicz** - tel:+48 22 492 11 90, **Beata Koziozemska** - tel: +48 22 492 11 68 **Office for Registration of Medicinal Products, Medical Devices and Biocidal Products** Al. Jerozolimskie 181C, 02-222 Warsaw, fax:+48 22 492 11 99 E-mail: incydenty@urpl.gov.pl	https://www.urpl.gov.pl/pl
Portugal	**Raquel Alves** - tel: + 351 21 798 7297, tel:+351 21 798 7145, fax:+351 211 117 559 **Infarmed - National Authority of Medicines and Health Products, IP Unidade de Vigilância de Produtos de Saúde da Direção de Produtos de Saúde** Parque da Saúde de Lisboa, Av. do Brasil, nº 53, PT - 1749-004 Lisboa E-mail: dvps@infarmed.pt	https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/vigilancia-de-dispositivos-medicos
Romania	**Oana Arsenescu Georgeta Herta** tel: +40 21.222.86.52, +40 21 260.01.58, +40 21 260.01.59 fax: +40 21.222.86.83 **National Agency for Medicines and Medical Devices of Romania** 58, Sos. Nicolae Titulescu, sector 1, Bucharest E-mail: mdevice@anm.ro, georgeta.herta@anm.ro	https://www.anm.ro/
Slovenija / Slovenia	**JAZMP - Agency for Medicinal Products and Medical Devices of the Republic of Slovenia** Slovenčeva ulica 22, SI - 1000 Ljubljana - - tel: +386 8 2000 500 E-mail: info@jazmp.si, meddev.vigilance@jazmp.si	https://www.jazmp.si/en/medical-devices/vigilance-of-medical-devices/
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