DECO2

Document No.: 5DECO2/5A

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

OXYGEN CONCENTRATOR

USER MANUAL

DO NOT OPERATE THIS UNIT WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL!
SAVE THIS MANUAL FOR FUTURE USE.

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1、SAFETY NOTES

WARNING: For users requiring continuous oxygen, it's crucial to prepare backup power and oxygen source in case of power or oxygen supply failures. Please note that this device is designed for supplying oxygen and is not intended for life support or sustaining life.

WARNING: The use of the oxygen concentrator poses a fire risk due to oxygen enrichment. Do not use the oxygen concentrator or accessories near sparks or open flames.

WARNING: To ensure that you receive suitable therapeutic oxygen delivery tailored to your medical condition, the DECO2 Oxygen Concentrator must only be used under the guidance of a physician's order:

- used only after one or more settings have been individually determined or prescribed for you.
- used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer and that were used while your settings were determined.

WARNING: Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns.

WARNING: Do not lubricate fittings, connections, tubing, or other accessories of the oxygen concentrator to avoid the risk of fire and burns.

WARNING: Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.

WARNING: Use this device at an altitude above 13,123 feet (4000 meters) or above a temperature of 104 ℉ (40℃) or greater than 80% relative humidity may affect the flow rate and the percentage of

oxygen and consequently the quality of the therapy. Refer to specifications for details regarding parameters tested.

WARNING: Oxygen increases the risk of fire ignition and spreading. Avoid leaving the nasal cannula or mask on bed coverings or chair cushions when the oxygen concentrator is on but not in use, as oxygen can make these materials flammable. Remember to switch off the oxygen concentrator when not in use to prevent oxygen enrichment.

WARNING: If you experience discomfort or encounter a medical emergency during oxygen therapy, it is crucial to seek immediate medical assistance to prevent potential harm.

WARNING: Smoking during oxygen therapy is dangerous and can lead to facial burns or death. Smoking is prohibited within the same room where the oxygen concentrator or any oxygen carrying accessories is located.

WARNING: Open flames during oxygen therapy are dangerous and can lead to fire or death. Open flames are prohibited within 6.6 feet (2 meters) of the oxygen concentrator or any oxygen carrying accessories.

WARNING: The device is not intended for emergency use.

WARNING: It is not recommended to use the device in a mobile environment. Firstly, the device does not have an internal power supply. Secondly, the equipment is not suitable for use under transport conditions. It is recommended to carry the equipment to the destination and use it in a suitable place.

symbols	contents
	Indicates the foreseen risks (e.g., “Causes burns”, “Risk of explosion”, etc.).
	Indicates prohibited actions (e.g., “Do not open”, “Do not drop”, etc.).

	Indicates required actions (e.g., “Wear protective gloves”, “Scrub before entering”, etc.).

1.1 Important Information

 Electric shock risk

 DO NOT disassemble. Consult qualified service personnel for any servicing needs.

 DO NOT modify this equipment without the authorization of the manufacturer.

 Read the following information before operating the product.

1.2 Before Installation

 To prevent damage during transportation, always keep the concentrator in an upright position.

 If the electrical power source becomes unstable, stop using the device and seek an alternative power source.

 Only use stable and safe electrical power sources.

 The oxygen concentrator cabinet should ONLY be opened by an authorized equipment provider.

1.3 Placement

 You may choose a room in your house where using your oxygen concentrator would be most convenient. The concentrator can be easily rolled from one room to another on its casters.

 Do not place the oxygen concentrator in an area where its airflow may be blocked.

 Make sure to position the oxygen concentrator with a minimum

clearance of 4 inches (10 centimeters) on all sides, keeping it away from walls, draperies, furniture, or similar surfaces. Avoid placing it near deep-pile carpets, heaters, radiators, or hot air registers.

Do not place the device in a confined or small area.

The oxygen concentrator MUST be kept away from heat, fire and excessive water sources and conditions.

The oxygen concentrator should be positioned away from pollutants or fumes.

Do not place items on top of the concentrator.

NEVER block the air openings of the device or place it on a soft surface, such as a bed or couch, where the concentrator may tip or fall. Ensure that the openings remain clear of lint, hair, and similar debris.

The air intake and the exhaust of the oxygen concentrator should be positioned in a well-ventilated area.

1.4 Fire Warning and Explosion

Keep the concentrator away from flammable and explosive areas.

Users MUST NOT SMOKE while using this device. Keep all matches, lighted cigarettes or other sources of ignition out of the room in which this product is located. NO SMOKING signs should be prominently displayed. Textiles and other materials that are normally inflammable can ignite easily and burn intensely in oxygen enriched air. Failure to adhere to this warning can result in serious fire, property damage, and cause physical injury or even DEATH.

In high concentrations of oxygen, materials that can burn in regular air, and even some that typically wouldn't, can ignite easily and burn

quickly. For safety concerns, it is necessary that all sources of ignition be kept away from the product and preferably out of the room in which it is being used.

⚠ A spontaneous and violent ignition may occur if oil, grease, or greasy substances contact with pressurized oxygen. These substances MUST be kept away from the oxygen concentrator, tubing and connections, and all other oxygen equipment.

⃠ DO NOT use any lubricants unless recommended by the manufacturer.

1.5 Maintenance

⚠ The oxygen concentrator is intentionally designed to require minimal routine preventive maintenance, typically once per year. Preventive maintenance or performance adjustments on the oxygen concentrator should only be conducted by healthcare professionals or individuals with a comprehending understand of this process, including authorized or factory-trained personnel.

⃠ DO NOT service or maintain while patient in use.

❗ To achieve optimal performance, the manufacturer recommends running the concentrator continuously for a minimum of 30 minutes at a time. Operating it for shorter durations may potentially decrease the overall product lifespan.

1.6 Radio Frequency Interference

⚠ Most electronic equipment is influenced by Radio Frequency Interference (FRI). Always exercise CAUTION regarding the use of portable communications equipment in the area around such equipment.

⚠ The radio frequency (RF) energy emitted by this machine is exclusively intended for the operation of the device itself. Therefore, the RF emissions are minimal and should not disrupt the functioning of other nearby electrical equipment, including portable communication devices used in the vicinity of this equipment.

1.7 MR Unsafe

⚠ Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risk to the patient or damage to the oxygen concentrator or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.

⚠ Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID or electromagnetic security systems (metal detectors) as it may cause unacceptable stable risk to the patient or damage to the oxygen concentrator. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in device performance, unusual or harsh sounds, please disconnect the power cord and stop using the device. Contact your home care provider for further assistance.

⚠ This device is suitable for use at home and healthcare settings, with the exception of locations near active HF surgical equipment and the RF-shielded room of an ME system for magnetic Resonance imaging, where electromagnetic disturbance may be significant.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided as it may result in improper operation. In case where such use is necessary, it's essential to monitor both this equipment and other relevant devices to ensure that they are functioning normally.

⚠ Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the oxygen concentrator, including cables specified by the manufacturer. Failure to do so may lead to a deterioration in the performance of this equipment.

1.8 To Reduce the Risk of Burns, Electrocution, Fire or Injury to Persons.

⚠Avoid using the device while bathing. If continuous usage is required by the physician’s prescription, the concentrator must be in another room at least 2.5 meters (8.2 feet) from the bathroom.

⃠DO NOT contact the concentrator when your body is wet.

⃠DO NOT place or store this device in locations where it may fall into water or other liquid.

⃠DO NOT attempt to retrieve the equipment if it falls into water. UNPLUG IMMEDIATELY and call Qualified Service Personnel for examination and repair.

A product should NEVER be left unattended when plugged in.

⚠ This device should be used only as per the prescription of a physician and the guidelines outlined in this User Manual. If at any

point the patient or attendant believes that the patient is not receiving an adequate amount of oxygen, contact the provider and/or physician immediately. No adjustments should be made to the flow rate unless prescribed by a physician.

Close supervision is necessary when this product is used near children or individuals with physical challenges.

Use this product only for its intended purpose as described in this manual.

DO NOT use parts, accessories or adapters other than those authorized by the manufacturer. The use of certain humidifiers or accessories that are not designated for use with this oxygen concentrator may impair its performance.

If replacement parts used for the periodic servicing by an approved technician do not comply with the manufacturer's specifications, the manufacturer shall not be held responsible in the event of an accident.

DO NOT connect the concentrator in parallel or series with other oxygen concentrators or oxygen therapy devices.

In certain circumstances oxygen concentrators can be hazardous. The manufacturer recommends that you seek medical advice before using this product.

Avoid creation of any spark near medical oxygen equipment. This includes sparks from static electricity created by any type of friction.

If the concentrator has a damaged cord or plug, is not functioning correctly, or has been dropped or otherwise damaged, please contact Qualified Service Personnel for a thorough examination and any necessary repairs.

Keep the cord away from HEATED or HOT surface.

Do not move or relocate concentrator by pulling on the cord.

Do not insert or place any other objects into the openings of the equipment.

If you have any problems setting up, maintaining, or using this device, please contact the manufacturer or customer service. Please report to the manufacturer if any unexpected operation or events occur.

Don’t open or repair the device by yourself.

If the device experiences a drop, shock or any kind of impact that may result in changes in its performance, please get in touch with the service personnel. Don’t open or repair the device by yourself.

Do not use the device if it is damaged in any way. The continuous use of damaged equipment may cause injury, improper results, or serious danger.

Allow the equipment to warm up for at least 30 minutes from the minimum storage temperature before using it for its intended purpose.

Allow the equipment to cool for at least 30 minutes from the maximum storage temperature before using it for its intended purpose.

When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.

No service or maintenance while the equipment is in use.

Use this device only with the leads, electrodes, and accessories

that the manufacturer recommends.

Do not share the use of the parts, accessories or adapters with other equipment.

The parts placement of attachments is critical to the effectiveness of the therapy.

Delivery settings of the oxygen concentrator should be periodically reassessed for the effectiveness of the therapy.

Geriatric, pediatric or any other patients unable to communicate discomfort can require additional monitoring and/or a distributed alarm system to convey the information about discomfort or the medical urgency to the responsible care giver to avoid harm.

The proper placement and positioning of the interface is critical to the patient's therapeutic effect.

Example: *The proper placement and positioning of the prongs of the nasal cannula in the nose is critical to the amount of oxygen delivered to the respiratory system of the patient.*

1.9 ⚠ CAUTION

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from the FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf.

Call FDA at 1-800-FDA-1088 to report by telephone.

Reporting Form FDA 3500 is commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf.

2、FEATURES

2.1 Summary

Indications for Use: The DECO2 by Drive Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Intended patient population: The device is intended for use in adults.

Contraindication: Do not use on patients with oxygen allergy or oxygen poisoning.

Device Description: DECO2 oxygen concentrator is made up of mainframe and flowmeter. It is an electronically operated device that separates oxygen from ambient air. It provides high concentration of oxygen directly to patient/user through a nasal cannula or other methods.

The DECO2 by Drive Oxygen Concentrator is a Pressure Swing Absorption (PSA)type oxygen concentrator which takes 120V ~ power source as power source. The output of oxygen is 0.5 to 5 liter per minute.

Room air enters the piston type compressor via a series of filters for removing dust particles. The output compressed air is directed by a pneumatic valve into one of the two sieve beds which is full of adsorption material - molecular sieve. Nitrogen is adsorbed by the molecular sieve as the pressure increases; oxygen flows through the molecular sieve and concentrates at the sieve bed bottom. The enriched oxygen is divided into two streams; one stream enters a storage tank. The pressurized oxygen is regulated down to the suitable pressure, an adjustable flow meter and out to the patient At the same time the second bed is in exhausted status, the molecular sieve desorbs nitrogen as the pressure decreases; another oxygen stream from first bed enters the bottom of the second bed, promotes purging the nitrogen and is exhausted into the atmosphere. Two

sieve beds exchange the role of oxygen concentration and continue to produce 93% oxygen to the patient.

This user's manual will tell you about your concentrator and will serve as a reference as you use your concentrator.

2.2 Characteristics

- Oxygen concentrators consist of a mainframe and a flowmeter.
- Reliable, safe, complete plastic outer shell, with circuit breaker.
- The Display screen of elapsed time meter shows total elapsed working hours.
- Pressure safety valve helps to ensure operating pressure.
- Power loss alarm function.
- High- and low-pressure alarm function.
- Low oxygen concentration alarm function.
- Heat protection to ensure the safety of the compressor and concentrator.
- Low oxygen flow alarm function.

2.3 Specifications

1. Power supply: AC120V, 60Hz; Current: 3.5A; Power: 450VA.
2. At 3L/min: Sound pressure level: ≤ 50.5dB (A); Acoustic power level：58.5dB(A).

   At 5L/min: Sound pressure level: ≤ 50.5dB (A); Acoustic power level：58.5dB(A).
3. Maximum recommended flow: 5L/min.
4. Flow Range at Outlet Pressure of zero: 0.5~5L/min.
5. Flow Range at Outlet Pressure of 7 kPa: 0.5~5L/min.

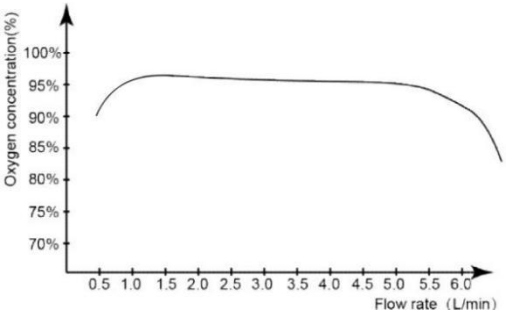
6. Change in maximum recommended flow when back pressure of 7kPa is applied: <0.5 L/min.

NOTE: Technical specifications of flowmeter are calibrated by manufacturer and tester. The user should use the device according to the manufacturer's instructions and the doctor's advice. The user is not allowed to adjust the device flow.

7. Oxygen Concentration: 90%±3% at 0.5L/min
93%±3% at 1 to 5L/min (after turning on for 5 minutes). Accuracy of oxygen concentration: ±3%in the flowrate range of 0.5-5L/min in the normal operating ambient.

8. OutputPressure:38kPa±5kPa.

9. When outlet pressure sure is zero, the change in oxygen concentration as a function of oxygen flow rate is presented as follows:



Flow Rate (LPM)	Oxygen Concentration
0.5	90%±3%
1	93%±3%
2	93%±3%
3	93%±3%
4	93%±3%
5	93%±3%

10. Release Pressure by machine operation:250kPa±50kPa.

11. Weight:16.1kg(35lbs)

12. Dimension:330×260×540mm(13"Wx10.2"Dx21.3"H).13. Height above sea level: The efficiency of oxygen

concentration will remain consistent up to 1828 meters above sea level. However, from 1828 meters to 4000 meters, the efficiency will decrease to less than 90%.

14. Safety System:
    ① Current overload or line surge shutdown.
    ② High temperature compressor shutdown.
    ③ High- and low-pressure alarm function.
    ④ Low Oxygen Concentration alarm.
    ⑤ Low flow alarm.
    ⑥ Pressure abnormal alarm.
15. Minimum Operating Time: 30 minutes.
16. Electric Classification: Class II equipment, Type BF applied part (Nasal oxygen cannula).
17. Mode of operation: Continuous duty.
18. Normal Operating Ambient:
    1. Temperature range: 5℃~40℃ (41℉~104℉)
    2. Relative humidity: 15%~80%
    3. Atmospheric pressure: 86kPa~106kPa (12.47psi~15.37psi)

NOTE: ① When the storage temperature is lower than 5℃, the equipment shall be laid in normal operation temperature environment for at least 4 hours.

② The lifetime of equipment will be affected, and the efficiency will be lowered if the equipment runs outside of the normal operating conditions.

19. Ingress Protection: IP21
20. Oxygen Output Temperature: Less than Ambient +6℃.

21. Tube: To prevent folding of tube, nasal oxygen is 2 meters, prolonged tube should be no longer than 15.2 meters (no flatting).
22. The Storage and transport Ambient:
    1. Temperature Range: 0℃~+55℃ (32℉~+131℉)
    2. Relative Humidity Range: 10%~90%
    3. Atmospheric pressure: 70kPa~106kPa (10.2psi~15.37psi)

    NOTE: The oxygen concentrator should be stored in area without erode gas; be avoided shaking and inversion in transportation.
23. This device is expected to work for a period of 6 years. If you intend to use it for a longer duration, please consult your Equipment Provider and physician.
24. Software version: Ver.1.1.0.20210518

3、INSTALLATION ANDOPERATION

3.1 Unpacking

NOTE: Unless the oxygen concentrator is to be used immediately, it is advised to keep the containers and packing materials for storage until the concentrator is used.

- Check for any obvious damage to the carton or its contents. If damage is evident, please notify the carrier or local dealer.
- Remove any loose packing materials from the carton.
- Carefully remove all the components from the carton.
- PACKING LIST
  Oxygen Concentrator: 1 unit
  User Manual: 1 piece

3.2 Inspection

- Examine the exterior of the oxygen concentrator for any nicks, dents, scratches or other damage.
- Inspect all components.
- Before using the oxygen concentrator, it's essential to check whether the oxygen concentrator can work properly including a qualitative test for system gas leakage and checking the gas flowrate at the application accessory. To do so, you can place the end of the nasal cannula under the surface of a half -full cup of water and observe for the presence of bubbles.
- Oxygen concentrator starting alarm system will automatically carry out functional self-check when you press power switch to the "|" position. During this time, the green, and yellow lights on the control panel will illuminate, and an audible alarm will sound, and the display is lit. Around 1 second later, only the green light will remain on, the display screen alternately displays the oxygen concentration and the cumulative time, indicating that the machine is functioning normally.

3.3 Storage

- Store the repackaged oxygen concentrator in a dry area.

  DO NOT place anything on top of the repackaged concentrator.

3.4 FEATURE VIEW

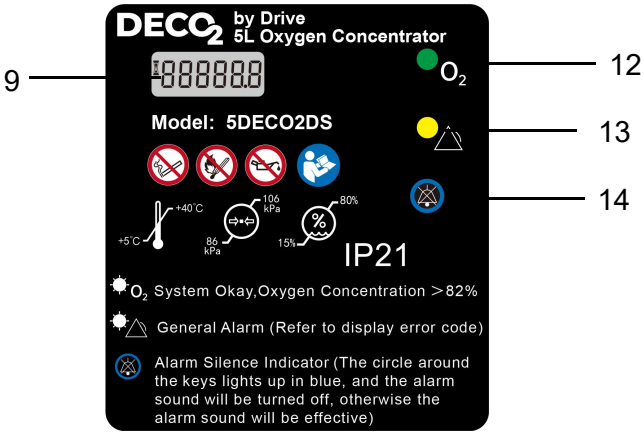


Figure 1

1--Flow meter

Setting oxygen flow rate by adjusting the knob.

2--Status indicator light

3--Oxygen tube

4--Outlet connector

5--Breaker

To protect the machine and user, the breaker will cut off power automatically when current ≥ 6A. After cooling, the machine can be turned on if push up the breaker.

6--Connection pipe of humidifier bottle

7--Humidifier bottle

For some users, dry oxygen inhalation may cause respiratory discomfort, humidifier bottle is used to humidify oxygen.

8--Power switch

9--Display screen

The oxygen concentration is shown; Record the total operation time, guide user to use device scientifically； Displays the error code.

Led Display Contents and Meaning

Symbol of Display	Meaning	Symbol of Display	Meaning
°C--95.6	Normal Oxygen Concentration	EF--0.4	Low Flow Alarm
123456	Cumulative Time	Et-56.0	Device High Temperature Alarm
Er--5t	Start-up Alarm	EPH132	High-Voltage Alarm
EC-82.0	Low O_2 Alarm	EPL102	Low-Voltage Alarm
E---P	Pressure abnormal alarm		

10--Power cord

11--Air intake filter

12--Green light. System is functioning properly, Oxygen Concentration≥82%.

13--Yellow light. Light up when the machine fails.

14--Alarm Silence Button used to temporarily silence an audible alarm. When the Oxygen Concentrator has a sound alarm, press the button to turn off the alarm sound. At this time, the button backlight will light up blue. To restore the alarm sound, press the button again, and the button backlight will go off.

Figure 2: Humidifier Features

Statement: The oxygen concentrator is not sold with accessories (i.e., nasal cannula, humidifier bottle).

DO NOT add water over the maximum water level. Pure water shall be added to the humidifier to between maximum and minimum water level in use.

- Mode of action: Pure water is added into the humidifier bottle to discharge oxygen in water through the PVC pipeline. After oxygen passes through the water, its water-containing concentration will be increased to prevent adverse reactions when users inhale dry oxygen.

- Recommended conditions of use: First, pure water is added to the humidifier bottle at a water level between maximum and minimum water level. Tighten the humidifier bottle cover and place the humidifier bottle on the humidifier bottle holder. Use PVC hose to

connect the air outlet of the oxygen concentrator to the air inlet joint of the humidifier bottle. Turn on the oxygen concentrator, then connect the nasal cannula joint to the air outlet of the humidifier bottle. The user can now start the oxygen inhalation process.

- Power switch "｜" indicates the power is on, "O" indicates the power is off. When the switch is set to "ON", if the power outage occurs, the oxygen concentrator will not operate, and an alarm sound will be triggered.

- Oxygen is obtained by passing through the humidifier. Pure water shall be added to the humidifier to a level between maximum and minimum markers. When the oxygen tube exiting the humidifier becomes stuck or blocked, the pressure inside the humidifier will rise to 25±5kPa, causing the safety valve to open and release the pressure.

- Expected service life of humidifier bottle: 3 years.

- Inspection of performance of humidifier：

  1. Use the PVC soft tube to connect the humidifier adapter and the oxygen outlet of the shell.

  2. Turn on the oxygen concentrator and adjust the flow to about 5L/min. Then, block the exit of humidifier. After about 5 seconds, the safety valve will open, releasing gas, and subsequently, the valve will close. This process confirms that the gas proofing of humidifier and safety valve are functioning as intended.

3.5 PREPARE WORK

3.5.1 Usual preparation

- Connect the other end of the cannula to the oxygen outlet connector.

- Plug in power supply：Ensure that the power switch is off; plug the

concentrator's AC connector into power outlet.

3.5.2 Preparing to connect the humidifier bottle

When the user feels uncomfortable inhaling dry oxygen, the humidification bottle can be used to humidify the oxygen.

Unscrew the cover of the humidifier, fill the purify water (or distill water) into the humidifier bottle between the maximum and minimum water level lines, and then screw the humidifier bottle. (If needed, add other medicine into the water, please according to the doctor's suggestion.)

- Screw the humidifier bottle absorbing connector into the cover of the humidifier, then insert the humidifier to the elastic belt on the front of the unit and connect the other end of the cannula to the oxygen outlet connector.

- Plug in power supply. Ensure that the power switch is off; plug the concentrator's AC connector into power outlet.

3.6 Turning the Concentrator ON

- Press the power switch to the " |" position. At this time, the green and yellow lights are on, the display is lit, indicating that the machine is functioning normally. After about 1 second, only the green light will remain on. The display screen alternately displays the oxygen concentration and the cumulative time.

- To properly read the flowmeter, identify the prescribed flow rate line on the flowmeter. Then, turn the flow knob until the ball rises to the line. Ensure that the ball is centered on the L/min line as specified (see Figure 3).

NOTE: Oxygenation time and the flow rate ranges are established and prescribed by your physician.

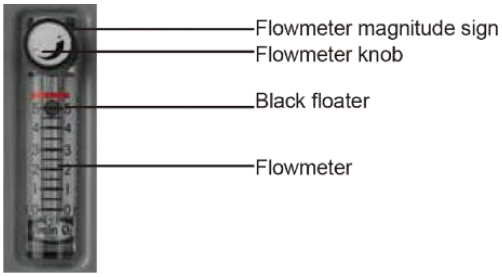


Figure 3

CAUTION: If the flow rate on the flowmeter is below 0.5L/min, check tubing or accessories for any signs of blocked or kinked tubing, or a potentially defective humidifier bottle.

3.7 Alarm System

- Initial startup of the concentrator

NOTE: Concentrator may be used during the initial warm-up time (approximately 5 minutes) while waiting for the O_2 concentration to reach its maximum level.

When the machine is running normally, the green light will illuminate (O_2 concentration greater than 82%±2%). 2 minutes after the machine is turned on, the oxygen sensor will operate normally. The explanations for the indicator light functions are as follows.

3.8 Alarm Signals

1. O_2 concentration is greater than 82%±2%, Green light illuminates. Normal Operation, the display screen alternately displays the oxygen concentration and the cumulative time.
2. High-Voltage Alarm:

When the AC voltage is above 10% of the nominal voltage (AC132V), the yellow light will illuminate, the display screen displays the "EPHi32 " error code, intermittent audible alarm sounds, Oxygen concentrator not operating.

3. Low-Voltage Alarm:

When the AC voltage is below 15% of the nominal voltage (AC102V), the yellow light will illuminate, the display screen displays the "EPLo02 " error code, intermittent audible alarm sounds, Oxygen concentrator not operating.

4. Start up fault alarm:

O2 concentration is less than 82%±2% after 120 seconds of startup, the yellow light will illuminate, the display screen displays the "Er--St" error code, intermittent audible alarm sounds.

5. Low oxygen concentration alarm:

When the oxygen concentrator running normally, O2 concentration is less than 82%±2%, the yellow light will illuminate, the display screen displays the " EC-820 " error code, intermittent audible alarm sounds.

(″82.0”, the number shows the current oxygen concentration data.)

6. Low flow alarm:

When the oxygen flow rate is lower than 0.5L/min, the yellow light will illuminate, the display screen displays the " EF--0.4 " error code, intermittent audible alarm sounds. ("0.4", the number shows the current oxygen flow data.)

7. High temperature alarm：

When the temperature is detected as exceeding the set high temperature alarm value, the yellow light will illuminate, the display screen displays the " E:-56.0 " error code, intermittent audible alarm sounds, Oxygen concentrator not operating.

8. Pressure abnormal alarm:

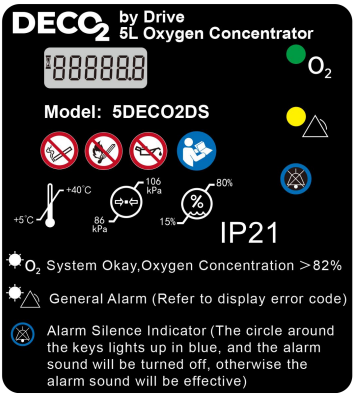
When the oxygen concentrator appears pressure is abnormal, the display screen displays the " E,---P " error code, intermittent audible alarm sounds, Oxygen concentrator not operating.

9. Power-off alarm:

When the oxygen concentrator does not have an AC power supply input, the yellow light will illuminate, the display screen stops working, intermittent audible alarm sounds.

10. When the oxygen concentrator is in alarm state, the operator can silence the alarm using the Alarm Silence button - the button backlight will light up in blue. This action only turns off the alarm sound but will not turn off the alarm state. To reactivate the Audio Alarm, press the button to turn off alarm sound again, and the button backlight will go off.

In order to facilitate the user's understanding, see the figure below:



Control panel

Alarm		Start-up fail alarm	Low oxygen concentration alarm	High Voltage alarm	Low voltage alarm	Low flow alarm	High temperature alarm	Pressure abnormal alarm	Power-off alarm
Alarm category		low priority	low priority	low priority	low priority	low priority	low priority	low priority	low priority
indicator light	Indicator color	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
	Flashing frequency	On	On	On	On	On	On	On	On
	Duty cycle	100% on	100% on	100% on	100% on	100% on	100% on	100% on	100% on
Auditory alarm signal		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Symbol of Display		Er--St	EC-82.0	EPH132	EPL102	EF--0.4	Et-56.0	Er--P	The display is not bright
Running state		The concentrator continues to operation	The concentrator continues to operation	concentrator does not work	concentrator does not work	The concentrator continues to operation	concentrator does not work	concentrator does not work	concentrator does not work
Alarm condition		Oxygen concentration is less than 82%±2% after 120 seconds of startup	Oxygen concentration drops below 82% volume fraction after start-upperiod	The AC voltage is above 10 % of the nominal voltage (AC132V)	The AC voltage is below 15 % of the nominal voltage (AC102V)	The oxygen flow rate is lower than 0.5L/min	The temperature is detected over 56℃	The oxygen concentrator has a pressure failure	Power supply interruption

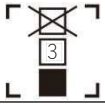
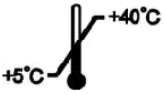
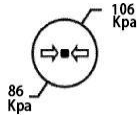
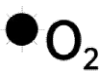
Alarm explanation

3.9 Turning the Concentrator Off

Press power switch to the “O” position and unplug the concentrator’s AC connector from the power outlet.

3.10 Symbols and Descriptions

Symbol	Meaning	Symbol	Meaning
~	Alternating current		Circuit Breaker
	Class II Equipment		Type BF applied part
O	OFF (power)	|	ON (power)
	No smoking		No open flame: Fire, open ignition source and smoking prohibited

	Height		Use no oil, Grease or Lubricants
	Serial number		Date of manufacture
	Up		Manufacturer
	Keep dry		Operation ambient temperature Range 5 to 40℃ (+41℉ to 104℉)
	Atmospheric Pressure Range 86 to 106 Kpa		System Okay, Oxygen Concentration ≥82% (Green Light)
	Alarm Sound ON/OFF Button		LOT Number
	Fragile, handle with care		System failure (Yellow Light)
	Operation ambient Relative humidity: 15%~80%		
	It is mandatory to read and understand the operating instructions prior to use. This symbol has a blue background on the product label.		
IP21	Ingress Protection-Protected against finger access to hazardous parts; protected against vertically filling water drops.		
	This device contains electrical and/or electronic equipment that must be recycled per EU Directive 2012/19/EU-Waste Electrical and Electronic Equipment (WEEE)		
℞ ONLY	Federal (U.S.A) law restricts this device to sale by or on the order of a physician.		
	Indicates a medical device that has not been subjected to a sterilization process.		

4、MAINTENANCE

DECO2 by Drive recommends using only original equipment manufactured parts and filters in order to guarantee reliable operation of the product.

⚠ **Warning:** Power should be disconnected before beginning maintenance on the concentrator.

⚠ **Warning:** Do NOT use lubricants, oils or grease.

⃠ DO NOT service or maintain while patient in use.

The concentrator regularly performs a self-check to verify pressure and oxygen concentration, no need extra maintenance on pressure and oxygen concentration. In addition, yearly maintenance by a qualified service professional is recommended for optimal performance. In high dust locations, maintenance may be performed more frequently.

4.1 Cleaning the Cabinet

Check the exterior of the cabinet every month and clean if it's visibly dirty.

- Turn off the power switch and unplug the concentrator's AC connector from the power outlet.
- Only the outside of the concentrator should be cleaned weekly. Use a damp cloth and then wipe it dry.

⃠ Do not use acetone, solvents, or any other inflammable products.

⃠ Do not spill liquid inside the cabinet.

4.2 Cleaning or Replacing the Filter (2 Types)

Clean cabinet filter and replace intake filter as often as specified

in the following paragraphs in order to protect the compressor and extend the concentrator's life.

DO NOT operate the concentrator without the filters installed, or when filters are wet. These actions could permanently damage the concentrator.

- Disassembly

Figure 4

(1) Cabinet filter

- The cabinet filter should be inspected periodically and cleaned as needed by the user or caregiver. Replace it if it's torn or damaged. To clean, these steps should be followed:

NOTE- Frequency of inspection and cleaning of filter may be dependent upon environmental conditions like dust and lint.

1. Remove the intake air filter.
2. Clean it in a solution mild dish soap (2 tbsp) and warm water (2 cups).
3. Rinse thoroughly with warm tap water and blow dry. The intake air filter should be completely dry before reinstalling (Figure 5).

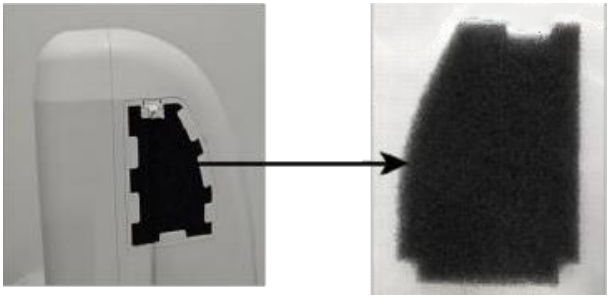


Figure 5

(2) Intake filter

- The intake filter access door is located on the left side of the concentrator. Using a small screwdriver, open the access door. Unscrew the block of cabinet filter holder. Remove the intake filter. (Figure 6)
- It's recommended to inspect the intake filter annually and replace if needed.
- More frequent inspection and replacement of filter may be required if operated continuously or in adverse conditions, such as a dusty or smokey environment.

⚠ The intake filter cannot be cleaned and can only be replaced.

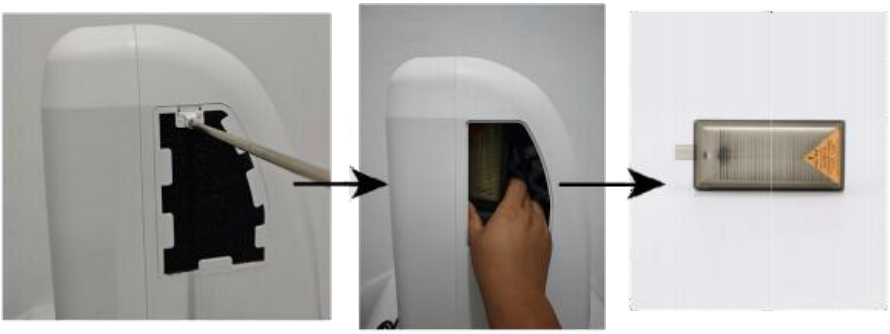


Figure 6

4.3 Cleaning the Optional Humidifier Bottle

- Change the water in the humidifier bottle every day.
- Cleaning: Wash the humidifier bottle weekly. First, wash the bottle with a solution of mild dish soap (2 tbsp) and warm water (2 cups), then rinse under running water and allow it to dry.
- Disinfection: Disinfect the humidifier parts by immersing them in a disinfection solution, such as a mixture of 1 part vinegar diluted with 10 parts water, then rinse the parts under running water and let it dry.
- Disassembly humidifier bottle.

(1) Unscrew the humidifier bottle. (Figure 7)

(2) Separate lid till the filtration end is outside the bottle. (Figure 8)

Figure 7

Figure 8

4.4 Oxygen nasal cannula (Available accessories)

Refer to the nasal cannula manufacturer's instructions.

4.5 Humidifier Tubing maintenance

The connection tube between humidifier bottle and humidifier bottle filter tube that can be contaminated by body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT

CONDITION. It is recommended to maintain/replace connection tube of humidifier bottle and humidifier bottle filter tube once a year.

Cleaning

	Recommended cleaning interval	Number of cleaning cycles*	Compatible cleaning method
Cabinet	7 days	300	Water, use only a damp cloth
Cabinet Filter	7 days	50	Mild dish soap (2 tbsp) and warm water (2 cups)
Humidifier Bottle	7 days	50	Mild dish soap (2 tbsp) and warm water (2 cups)

*Number of cleaning cycles determined by recommended cleaning interval and expected service life.

⚠Use of harsh chemicals (including alcohol) is not recommended. If bactericidal cleaning is required, a non-alcohol based product should be used to avoid inadvertent damage.

4.6 For each new patient

DECO2 by Drive recommends that at least the following procedures should be carried out by the manufacturer or a qualified third party when the equipment is transitioned from one patient to another.

If it's not feasible for a properly trained individual to carry out the entire procedures as described below; the device should not be used by another patient.

If it's time for maintenance, these procedures should be carried out in conjunction with the regular servicing procedures.

1. Use disinfectants safely. Always read the label and product information before use.

2. Always wear personal protective equipment when performing this procedure. Use suitable gloves and safety glasses. Cover exposed skin on the arms to prevent accidental contact with bleach solution applied to the concentrator.

3. Dispose of all accessories that are not suitable for reuse. This includes but may not be limited to the oxygen tubing, tubing connectors, nasal cannula and/or mask, and humidifier bottle.

4. Clean the exterior of the concentrator with a clean, lint-free cloth. For stubborn stains, a soft-bristled brush dampened with water can be used. Dry the concentrator with a clean lint-free cloth if water was used to remove soil.

5. Use 5.25% chlorine bleach (Clorox Regular Liquid Bleach or equivalent). Mix one (1) part bleach with four (4) parts water in a clean container. This proportion results in a solution where there is one (1) part bleach for every five (5) total parts (1:5). The total volume (amount) of solution required is determined by the number of concentrators in need of disinfection.

NOTE - An alternate suitable disinfecting agent (e.g. Mikrobac® forte or Terralin® Protect) may also be used. Follow the manufacturer's instructions for disinfection.

6. Apply the bleach solution evenly to the cabinet and power cord using a clean lint-free cloth. Ensure that the cloth is damp but not dripping with the solution. Do not use a spray bottle to apply the solution. Do not soak the device with the solution. Be cautious to prevent the solution from entering the vent areas on the concentrator base or the Auxiliary O_2 fitting area at the back of the unit. Avoid over-saturating the cabinet seams so that no solution residue is left in these areas. Avoid the caster wells

located on the bottom of the unit.

7. Exposure time of the disinfectant solution should be a minimum of 10 minutes and a maximum of 15 minutes.

8. After the recommended exposure time, all surfaces of the concentrator should be wiped with a clean lint-free cloth dampened with drinking-quality water, ensuring that the water is no warmer than room temperature. Use a dry, clean lint-free cloth to dry the unit. This step is to remove residue that may stain or leave a film on the unit, especially after repeated disinfections.

9. Check the cord, the plug on the back of the device, the power switch, the Circuit breaker, and the indicator lights for potential damage. Replace all damaged or worn components.

10. Replace cabinet filter on the left side of the equipment.

11. Check the oxygen concentration. If the device is within specification, the extended life intake bacteria filter does not need to be replaced between patients. If the oxygen concentration is not within specification, the provider should refer to the service manual section on Troubleshooting.

12. OPTIONAL INSIDE CLEANING: This operation is performed only by the qualified service personnel. The concentrator must be disconnected from the power supply for this step: Open the concentrator and remove all dust deposits inside the cabinet with an appropriate vacuum cleaner, then close the concentrator.

There is no portion of the gas pathways through the concentrator that could be contaminated with body fluids under normal conditions.

In some single fault conditions, such as an internal hose of the device becomes disconnected, there is a risk of the device's patient connection unintentionally becoming contaminated with expired gases. This condition will cause no flow out of the device and/or trigger an alarm. If this occurs, please consult the service manual for additional instructions.

Disinfection

The disinfection process can only be completed by the manufacturer or by a trained individual.

	Recommended disinfection interval	**Number of disinfection cycles**	**Compatible disinfection method**
Cabinet, power cord	Between patients	20	1:5 chlorine bleach (5.25%) and water solution, Mikrobac forte, Terralin Protect
Oxygen tubing, tubing connectors, nasal cannula/mask, humidifier bottle, cabinet filter	Do not clean, replace between patients	N/A	N/A
Optional - Inside cabinet	Between patients	N/A	Remove dust with a vacuum cleaner

5、TROUBLESHOOTING

Troubleshooting Guide

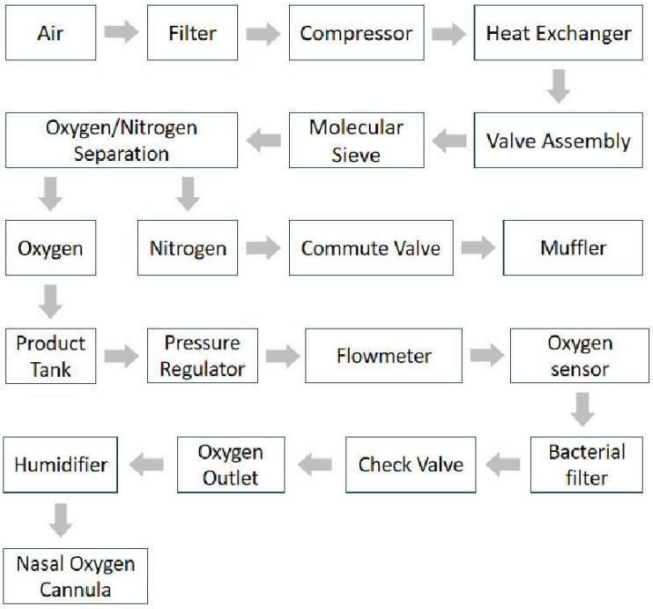
Symptom	Probable cause	Solution	Remark
Yellow light bright, intermittent audible alarm sounds, the display screen is not displayed	1.The power cord is not powered on.	1. Insert plug into outlet.	
	2. No power at outlet.	2. Inspect house circuit breakers. If problem recurs, use a different outlet.	
	3.Tripped circuit breaker.	3. Reset circuit breaker.	
Yellow light bright, intermittent audible alarm sounds, Oxygen concentrator not operating, the LED displays the "EPU02" or "EPH132"	1. Insufficient power at outlet.	1. DO NOT use extension cable. Move to another electrical outlet or circuit.	
	2.The input AC voltage is unstable.	2.Shut down the equipment, after voltage stability, operator intervention to restart the equipment.	
	3. Internal repairs required.	3 . Contact Equipment Provider immediately.	
Yellow light bright, intermittent audible alarm sounds, the LED displays the "Er--5L" or "EC-820" .	1. Low oxygen concentration due to blocked air intake.	1a. Remove and clean cabinet filter or replace intake filter. 1b. Move oxygen concentrator at least 4 inches away from walls, draperies or furniture.	
	2. Insufficient power at outlet.	2. DO NOT use extension cords. Move to another electrical outlet or circuit.	
	3. Flowmeter set exceeds 5L/min or higher.	3. Reset flowmeter to prescribed flowrate.	

	4. Fan inside the machine can't run or running rate turns slower causing the operating temperature too high.	4. Contact Equipment Provider immediately.	Repairs by qualified personnel
	5.Internal repairs required.	5. Contact Equipment Provider immediately.	
Yellow light bright, intermittent audible alarm sounds, the LED displays the" E--04 "	1. Flowmeter set at 0.5L/min or less.	1.Check flowmeter is set at 0.6L/min to 5L/min.	
	2.The intake filter is blocked	2. Remove and clean cabinet filter or replace intake filter.	
	3. Twisted or blocked tubing, cannula or humidifier.	3. Inspect for kinks or blockages. Rectify, clean, or replace the affected component.	
	4. Compressor failure or short circuit.	4. Contact Equipment Provider immediately.	Repairs by qualified personnel
	5.Internal repairs required.	5. Contact Equipment Provider immediately.	
There is water in the nasal cannula.	The water added in humidifier bottle is too much.	Water added should between the maximum and minimum of the liquid level.	
Yellow light bright, intermittent audible alarm sounds, concentrator not operating, the LED displays the " E---P ".	Internal repairs required.	Contact Equipment Provider immediately.	Repairs by qualified personnel
Yellow light bright, intermittent audible alarm sounds, concentrator not operating , the display screen displays the "E--SEN"	1.The air inlet or exhaust port of the device is blocked;	1. Keep the air inlet/ exhaust port of the device unblocked.	
	2.Internal repairs required.	2.Contact Equipment Provider immediately.	Repairs by qualified personnel

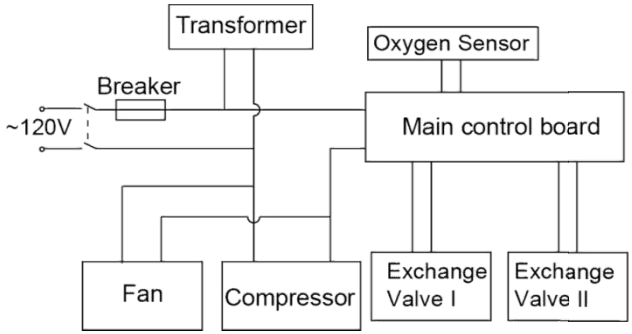
6、OTHER ATTENTIVE ITEMS

NOTE: If you experience a problem with your concentrator and are unable to service it yourself, contact the equipment provider from whom you purchased the concentrator.

6.1 GAS PATH OPERATION SKETCH MAP



6.2 Electrical Diagram



6.3 Post-marketing service

The equipment manufacturer warrants the Oxygen Concentrator under the conditions and limitations stated below. The warranty is 3 years from manufacture month in UDI label. This warranty is limited to the Buyer of new equipment purchased directly from Drive, or one of its providers, Distributors. Or Agents. During the warranty period, any defective parts or assemblies will be repaired or replaced at the sole discretion and determination of Drive, Routine maintenance items, such as filters, are not covered under this warranty, nor does it cover normal wear and tear. Upon verification of the warranty status, instructions will be issued. This warranty shall be voided and the manufacturer shall be relieved of any obligation or liability if:

- The device has been misused, abused, tampered with, or used improperly during this period.
- Malfunction results from inadequate cleaning or failure to follow the instructions. The equipment is operated or maintained outside the parameters indicated in the operating and service instructions.
- Unqualified service personnel conduct routine maintenance or servicing.
- Unauthorized parts or components (i.e., regenerated sieve mate- rial) are used to repair or alter the equipment.

6.4 Treatment of waste and residual

The treatment of waste and residual shall be conforming to law and regulations.

6.5 Accessories and spare parts

The accessories used must be oxygen compatible and biocompatible.

Note: The standard humidifier bottle, oxygen supply tube, nasal cannula or masks must be designed for oxygen therapy usage. These are not included in the set of accessories supplied with the device. Contact your equipment supplier to obtain these accessories.

6.6 Appendix EMC report

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment 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 this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Cellular technology (such as 5G wireless equipment) and wireless power transfer devices (such as Near Field Communications (NFC) and wireless charging devices, etc.) should be away from any part of the ME equipment when using oxygen concentrators to avoid possible interference.

Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014+A1:2020 standard for both immunity and emissions.

ESSENTIAL PERFORMANCE:

1. Flow Range at Outlet Pressure of zero: 0.5～5L/min; Flow Range at Outlet Pressure of 7 kPa: 0.5～5L/min.
2. Change in maximum recommended flow when back pressure of 7 kPa is applied:

＜ 0.5 L/min. Oxygen Concentration: When 0.5L/min,90%±3% and 1~5L/min, 93% ±3% (after turning on 5 minutes)

3. Output pressure: 38kPa±5kPa.

4. Power supply failure alarm; High pressure alarm; Low pressure alarm; Low Oxygen Concentration alarm. In case of voltage drop, the equipment starts the power-off alarm.

WARNING: If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

STATEMENT: For the purpose of its operation, the equipment has no wireless communication function.

a) The frequency used for radiated immunity test is 80 MHz to 2.7 GHz.

b) The following frequencies and modulations are used for proximity fields from RF wireless communications equipment.

Frequency (MHz)	Band (MHz)	Level (V/m)	Modulation
385	380-390	27	Pulse Modulation 18Hz
450	430-470	28	Pulse Modulation 18Hz
710	704-787	9	Pulse Modulation 217Hz
745		9	
780		99	
810	800-960	28	Pulse Modulation 18Hz
870		28	
930		28	

1720	1700-1990	28	Pulse Modulation 217Hz
1845		28	
1970		28	
2450	2400-2570	28	
5240	5100-5800	9	
5500		9	
5785		9	

WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies and use of nearby emitters at other frequencies could result in improper operation.

STATEMENT: The equipment should not be near high-frequency surgical equipment.

Table 1

Declaration - electromagnetic emission		
Emissions test	Compliance	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The oxygen concentrator uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The oxygen concentrator uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Clause 5	

NOTE 1 The EMISSIONS characteristics of this equipment make it suitable for use in a residential environment (for which CISPR 11 class B is normally required). If it is used in industrial areas and hospitals (CISPR 11 class A), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE 2 According to the scope of IEC 61000-3-3, it is applicable to electrical and electronic equipment having an input current equal to or less than 16A per phase, intended to be connected to public low-voltage distribution systems of between 220V and 250V line to neutral at 50Hz, and not subjected to conditional connection. Due to the rated input of EUT is AC 120V/60Hz, voltage fluctuations and flickers test is not applicable to the EUT.

Table 2

Declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV on AC power port	± 2 kV on AC power port
Surge IEC 61000-4-5	± 0.5kV, ± 1.0 kV line to neutral	± 0.5kV, ± 1.0 kV line to neutral
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles at 0°, 180°	0 % U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles at 0°, 180°
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the AC mains voltage prior to application of the test level.		

Table 3

Declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to Table 4	Refer to Table 4
Proximity magnetic fields IEC 61000-4-39	Frequencies 30 kHz, 8A/m, CW Frequencies 134.2 kHz, 65A/m, Pulse modulation 2.1 kHz Frequencies 13.56 MHz, 7.5A/m, Pulse modulation 50 kHz	Frequencies 30 kHz, 8A/m, CW Frequencies 134.2 kHz, 65A/m, Pulse modulation 2.1 kHz Frequencies 13.56 MHz, 7.5A/m, Pulse modulation 50 kHz

Table 4

Declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation : 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation : 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m
Note* - 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. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

STATMENT: The DECO2 Oxygen Concentrator is intended for use in the electromagnetic environments specified above. The customer or the user of the Oxygen Concentrator should ensure that it is used in such an environment, ensure that the essential performance of the device meets the requirements of the intended application.

Statement of the device's Essential Performance

Essential Performance as defined by manufacturer as following:

1． Flow Range at Outlet Pressure of zero: 0.5 ～ 5L/min; Flow Range at Outlet Pressure of 7 kPa: 0.5～5L/min.

2. Change in maximum recommended flow when back pressure of 7 kPa is applied: ＜ 0.5 L/min. Oxygen Concentration: When 0.5L/min, 90%±3% and 1~5L/min, 93%±3% (after turning on 5 minutes)

3. Output pressure: 38kPa±5kPa.

4. Power supply failure alarm; High pressure alarm; Low pressure alarm; Low Oxygen Concentration alarm. In case of voltage drop, the equipment starts the power-off alarm.

The Basic Safety of the equipment under test is as following:

Deviation from normal operation will pose an unacceptable risk to the patient or operator.

We, Drive DeVilbiss Healthcare, herewith declare that the stated above Essential Performance of the DECO2 Oxygen concentrator meets the requirement of EMC test in according with IEC 60601-1-2 Medical Electrical Equipment PART 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility.

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