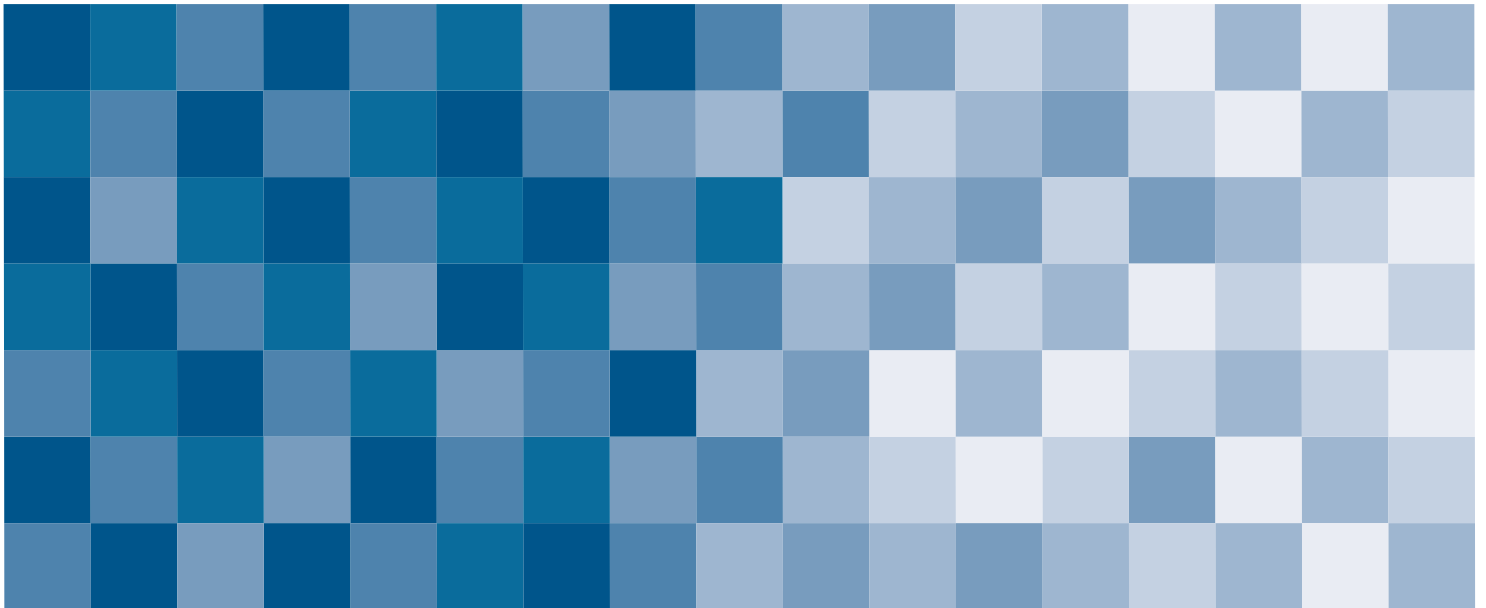


McKESSON

■ **Oxygen Concentrator**
portable

INSTRUCTIONS FOR USE



R_x ONLY

MFR # 146-125D



DANGER - NO SMOKING

MD



Approved for commercial aircraft use

QUICK START – OPERATING YOUR PORTABLE OXYGEN CONCENTRATOR



DANGER-NO SMOKING



Read the Important Safeguards and observe all Warnings and Cautions on the product and in the Instruction Guide. Follow all operating instructions. Refer to Operation section for more details.



IMPORTANT

Before using the device on battery power for the first time, the battery needs to be fully charged. Refer to Initial Battery Charge for details.



1. Install battery. Attach concentrator to AC or DC power. Battery must be installed for device to operate.



2. Connect cannula tubing to oxygen outlet.



3. Press and hold Power button to turn on concentrator.

NOTE- When the portable oxygen concentrator is turned on, the audible alert activates, and the display shows the hour meter for 3 seconds.



4. Use "+" or "-" buttons to set your prescription.



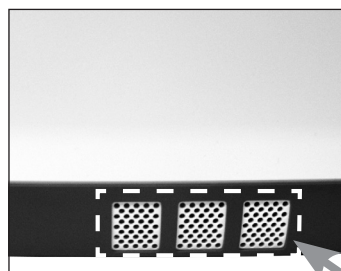
5. To use device in SmartDose mode, press SmartDose <SD> button.



6. Attach standard nasal cannula to your nose and face. Breathe normally through the cannula.



7. When finished using the device, press and hold the Power button until the concentrator turns off.



HOT



WARNING

This area can emit hot exhaust gas. Do not place near bare skin.

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SYMBOL DEFINITIONS

	Danger - No smoking near patient or device. i This symbol has a red circle and diagonal bar on the product label.		Catalog Number		Power Button		Green Oxygen Output within Specification
	It is mandatory to read and understand the operating instructions prior to use. i This symbol has a blue background on the product label.		Serial Number		Increase Prescription Setting Button		Yellow Low Oxygen, less than 86% O ₂
	Use no Oil, Grease or Lubricants i This symbol has a red circle and diagonal bar on the product label.		No MR (MR Unsafe) Unsafe for Magnetic Resonance Environment		Decrease Prescription Setting Button		Yellow Startup Low Oxygen, less than 86% O ₂
	RTCA / DO-160G Section 21 Category M and Section 20 Category T - The manufacturer of this Portable Oxygen Concentrator has determined this device conforms to all applicable FAA acceptance criteria for portable oxygen concentrator carriage and use on board aircraft. i Text shown with this symbol is red on the product label.		TUV Rheinland		Bluetooth connected to a smartphone (125X-BT Series Bluetooth Models Only)		Red Service Required Symbol
			Manufacturing Lot Code		Bluetooth not connected to a smartphone (125X-BT Series Bluetooth Models Only)		Red High Temperature (> 55 °C)
	Do not use near heat or open flames. i This symbol has a red circle and diagonal bar on the product label.		Manufacturer		SmartDose Enabled	Battery Charge Remaining i This battery symbol is illuminated with the following colors:	
	Do Not Disassemble i This symbol has a red circle and diagonal bar on the product label.		European Representative		Alarm Silenced button - Symbol Illuminates on display when an active alarm is silenced		Red Bar Graph when ≤ 5% battery charge
	Direct Current (DC Power)		European CE Mark		Hour Meter		Yellow Bar Graph when ≤ 10% battery charge
	Class II electrical protection – double insulated		Operating Temperature Range +15 to +35 °C (+41 to +95 °F)		Storage & Transport Humidity Range 15-93%		Green Bar Graph when 10% - 100% battery charge
	Type BF applied part		Storage & Transport Temperature Range -25 °C to +60 °C (-13 °F to +140 °F)		Medical Device		Battery Charging i Lightning bolt in the battery tip indicates battery is charging.
	CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.				General Warning i This symbol is used throughout this manual to indicate hazardous situations to avoid.		
	IP22 Ingress Protection - Protected against finger access to hazardous parts; protected against vertically falling water drops when enclosure is tilted up to 15°				Important Information i This symbol is used throughout this manual to indicate important information you should know.		
	This device contains electrical and/or electronic equipment that must be recycled per EU Directive 2012/19/EU- Waste Electrical and Electronic Equipment (WEEE)				Note and Information Symbol i This symbol is used throughout this manual to indicate notes, useful tips, recommendations, and information.		

BATTERY PACK MARKINGS

	Attention, Consult Instruction Guide		UL Recognized for Canadian and US market		Dispose of this product according to local regulations.
	Refer to Operating Instructions		Recycling Symbol Taiwan		For Canada & USA: Please call 1-800-822-8837 for information on how to recycle this battery
	Mark of conformity to applicable European Directives		UN Transportation Test		China RoHS
	Regulatory Compliance Mark of Australia and New Zealand.		Recycling Symbol		Regulatory Compliance Mark of Japan
	Battery Charge Status Gauge				

IMPORTANT SAFEGUARDS

Read this entire guide before using your McKesson portable oxygen concentrator. Important safeguards are indicated throughout this guide; pay special attention to all safety information. Imminently and potentially hazardous information is highlighted by these terms:



DANGER

Indicates an imminently hazardous situation which could result in death or serious injury to the user or operator if not avoided.



WARNING

Indicates a potentially hazardous situation which could result in death or serious injury to the user or operator if not avoided.

**CAUTION**

Indicates a potentially hazardous situation which could result in property damage, injury, or device damage if not avoided.

**IMPORTANT**

Indicates important information you should know.

**NOTES**

Indicates notes, useful tips, recommendations, and information.

READ ALL INSTRUCTIONS BEFORE USING.

**IMPORTANT**

The device is to be used only on the instruction of a licensed physician. It is intended for the administration of supplemental oxygen to oxygen patients > 10 kg as indicated by the physician. It is a transit-operable and body-worn device and is not intended to be used with other medical devices. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

**WARNING**

1. Electric Shock Hazard – Do not use while bathing.
2. Electric Shock Hazard – Do not immerse this device into water or any other liquid.
3. Electric Shock Hazard – Do not attempt to open or remove the cover; there are no user-serviceable internal components. If service is required, contact your equipment provider for instructions on obtaining service. Opening or attempting to service your device will void the warranty.

**DANGER****1. DANGER-NO SMOKING**

2. Oxygen causes rapid burning. Smoking 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 within the same room where the oxygen concentrator or any oxygen carrying accessories are located. Do not smoke while your oxygen concentrator is operating, or when you are near a person utilizing oxygen therapy.
3. If you intend to smoke, you must always turn the oxygen concentrator off, remove the cannula and leave the room where either the cannula or mask or the oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after you have turned off the oxygen concentrator before smoking.
4. There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.
5. Open flames during oxygen therapy are dangerous and are likely to result in fire or death. Do not allow open flames or hot, sparking objects within 2 m (6.5 feet) of the oxygen concentrator, cannula, or any oxygen carrying accessories.
6. Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on bed coverings or chair cushions if the oxygen concentrator is turned on but not in use; the oxygen will make the materials flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.
7. To prevent high concentrations of oxygen:
 - Do not leave device running when not in use. Do not leave cannula unattended while unit is delivering oxygen. High concentrations of oxygen can cause rapid burning.
 - Keep the equipment in a well-ventilated area.

**CAUTION**

McKesson recommends for optimal service life that the portable oxygen concentrator be operated for at least 30 minutes after it is powered on. Shorter periods of operation, operating in extreme temperature/humidity conditions or in the presence of contaminants, and/or handling and storage conditions outside those specified, may affect the long-term reliable operation of the product.

**WARNING**

1. Position your unit near an electrical outlet at least 6 inches (16 cm) from walls, draperies, or any other objects that might prevent the proper flow of air in and out of your device. The concentrator should be located so as to avoid pollutants or fumes and placed in a well-ventilated place so that the air inlet and exhaust are not blocked. Do not cover unit with a blanket, towel, quilt, or other covering, as the unit may overheat.
2. Do not lubricate fittings, connections, tubing, or other accessories of the oxygen concentrator to avoid the risk of fire and burns. No lubricants are recommended for use on this device.
3. 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.
4. The McKesson portable oxygen concentrators are equipped with a fire mitigating outlet fitting that prevents propagation of fire into the unit.
5. The accessories (nasal cannula, oxygen tubing, etc.) that supply oxygen to the patient must be equipped with a means that, in case of fire, stops the propagation of fire through the accessory for the safety of the patient and others. A fire activated flow-stop or thermal fuse device, if available, should be used with the oxygen supply accessories. These types of flow-stop devices stop the flow of oxygen to the patient in the event of fire. This means of fire protection should be located as close to the patient as practicable.
6. Improper use of the power supply, cord and plugs can cause a burn, fire, or other electric shock hazards. Do not use the unit if the power supply or cord/plug is damaged.
7. Locate oxygen tubing and power supply cords to prevent tripping hazards and reduce the possibility of entanglement or strangulation.
8. Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
9. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
10. When device is used under extreme operating conditions, the temperature near the exhaust vents on the bottom of the unit may reach 67°C (152.6°F). Keep bare skin away from this area.
11. Under extreme environmental conditions and a single fault condition occurs, the following device surface temperatures may exceed 41°C (106°F):

Description	Maximum Temperature		Maximum safe contact time
	°C	°F	
External surface of the portable oxygen concentrator	54.6	130.3	Less than 1 minute
Exhaust gas at discharge port	67.0	152.6	Less than 1 minute
DC jack	47.8	118.0	Less than 10 minutes
External power supply	44.3	111.7	Less than 10 minutes
Battery pack	53.9	129.0	Less than 1 minute

Keep bare skin away from this area.



WARNING

1. If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.
2. Geriatric, pediatric or any other patient unable to communicate discomfort can require additional monitoring to avoid harm.
3. Use of this device at an altitude above 3200 meters (10,500 feet) or above a temperature of 35°C (95°F) or greater than 93% relative humidity is expected to adversely affect the flow rate and the percentage of oxygen and consequently the quality of the therapy. Refer to specifications for details regarding parameters tested.
4. The oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories. It is very important to follow the prescription determined by your physician.
5. Your delivery settings of the oxygen concentrator should be periodically reassessed for the effectiveness of therapy.
6. To ensure you receive the therapeutic amount of oxygen delivery according to your medical condition, the oxygen concentrator must:
 - be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
 - be 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.
7. The settings of this portable oxygen concentrator do not correspond with continuous flow oxygen device settings.
8. The setting of other models or brands of oxygen therapy equipment do not correspond with the settings of this portable oxygen concentrator.



WARNING

There are many types of oxygen tubing and cannulas. Certain accessories may impair the device's performance. Use only standard nasal cannula with 25' or less of crush-proof oxygen tubing with this concentrator. Do not use pediatric (low-flow) nasal cannula or mask.

1. 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.
2. Some respiratory efforts of the patient might not trigger the conserving equipment.
3. Wind or strong draughts can adversely affect accurate delivery of oxygen therapy.
4. This device is not intended for use with a tracheostomized patient.
5. The rated range of delivered oxygen setting = 1 to 5
6. The rated range of breathing frequency = 4 to 40 breaths per minute (BPM)
7. Periodically inspect connection cords, connector tips and the power supply for damage or signs of wear. Discontinue use if damaged.
8. To minimize the ENVIRONMENTAL IMPACT of the 125 Series Portable Oxygen Concentrator during NORMAL USE, remove tubing and nasal cannula from the Portable Oxygen Concentrator, dispose the tubing and nasal cannula properly. Unplug the 125 Series Portable Oxygen Concentrator from AC power. Clean the cabinet as listed in the Portable Oxygen Concentrator (POC) CARE AND CLEANING section of this guide.



WARNING

1. Availability of an alternate source of oxygen is recommended in case of power outage or mechanical failure. Consult your physician for the type of back-up system required. Do not ignore alerts.
2. To avoid electric shock, do not remove the concentrator cover. The cover should only be removed by a qualified McKesson technician. Do not apply liquid directly to the cover or utilize any petroleum-based solvents or cleaning agents.
3. Before attempting any cleaning procedures, turn the unit "Off" and disconnect from AC or DC power.
4. Do not service or clean this device while in use with a Patient.
5. Use no lubricants, oils, or grease.
6. 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.



WARNING

This device contains electrical and/or electronic equipment. Follow local governing ordinances and recycling plans regarding disposal of device components.



MR Unsafe

1. 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 concentrator or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
2. Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, diathermy, RFID, and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the concentrator. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.
3. This device is suitable for use in home and healthcare environments except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
4. 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.
5. Use of accessories 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.
6. 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 concentrator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING

THE FOLLOWING BATTERY SAFETY WARNINGS MUST BE OBSERVED AT ALL TIMES:

1. Do not drop, hit, crush, or otherwise abuse the battery as this may result in the exposure of the cell contents, which are corrosive.
2. Do not subject battery to mechanical shock.
3. In the event of a battery leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
4. Do not expose the battery to fire or extreme heat. Do not incinerate. Exposure of the battery to extreme heat may result in an explosion. Avoid storage in direct sunlight.
5. Do not expose the battery to water, rain, or moisture of any type.
6. Do not expose to water, fire, or excessive heat.
7. Do not crush, disassemble, puncture or short circuit the connector terminals.
8. Do not open, disassemble, or attempt to repair the battery; there are no user-serviceable parts inside.
9. Do not short-circuit battery.
10. Do not store batteries haphazardly in a box or drawer where they may short circuit each other or be short-circuited by other metal objects.
11. Keep batteries out of the reach of children.
12. Keep batteries clean and dry.
13. Use only the battery in the application for which it was intended.
14. Charge the battery before initial use.
15. Recommended maximum time between charges = 1 year
16. Recommendation: Store the battery below 25°C (77°F), low humidity, no dust, and no corrosive gas atmosphere. Store fully charged if possible.
17. The battery must be recycled or disposed of properly.

INTRODUCTION

This instruction guide will acquaint you with the McKesson portable oxygen concentrator. Make sure that you read and understand this guide before operating your unit. Important safeguards are indicated throughout this guide; pay special attention to all safety information. Contact your McKesson equipment provider should you have any questions.

INTENDED USE

The McKesson portable oxygen concentrator is indicated for the administration of supplemental oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

INTENDED PATIENT POPULATION

The device is intended for the administration of supplemental oxygen to adult and pediatric patients with a body weight of greater than 10 kg as indicated by a physician.

INDICATIONS FOR USE / MEDICAL INDICATION

The McKesson portable oxygen concentrator will be used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Portable Oxygen Concentrator may be used in home, institution, vehicle and various mobile environments, indoors and outdoors. It is intended for the administration of supplemental oxygen to oxygen patients as indicated by a physician for use in a patient's residence, hospital, clinic or other facility.

CONTRAINDICATIONS

The device is not intended to be life support or life sustaining, nor does it provide any patient monitoring capabilities.

- Only use this product if the patient is capable of spontaneous breath (able to inhale and exhale without the use of a machine).
- Some respiratory efforts of the patient might not trigger the conserving equipment. Do not use on patients whose breathing during normal resting is unable to trigger the device.
- This device is not intended to be used with other medical devices. Do not use in parallel with other oxygen concentrators or oxygen therapy devices.
- The device is not intended for use with a tracheostomized patient.

ESSENTIAL PERFORMANCE

Essential Performance of the Oxygen Concentrator is to deliver oxygen enriched gas to the patient. Alarms indicate that the device is not meeting specification or a failure has been detected.

WHY YOUR PHYSICIAN PRESCRIBED SUPPLEMENTAL OXYGEN

Your body requires a steady supply of oxygen to function properly. Your physician prescribed supplemental oxygen for you because you are not getting enough oxygen from room air alone. Supplemental oxygen will increase the amount of oxygen that your body receives. Supplemental oxygen is not addictive. Your physician prescribed a specific oxygen flow to improve symptoms such as headaches, drowsiness, confusion, fatigue, or increased irritability. If these symptoms persist after you begin your supplemental oxygen program, consult your physician.

The oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories. Your delivery settings of the oxygen concentrator should be periodically reassessed for the effectiveness of therapy.

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.

HOW YOUR MCKESSON PORTABLE OXYGEN CONCENTRATOR WORKS

A concentrator separates oxygen from room air which allows high-purity supplemental oxygen to be delivered to you through the oxygen outlet. Although the concentrator filters the oxygen, it does not affect the normal amount of oxygen in your room. This pulse concentrator delivers the full dose (bolus) of oxygen on each breath, right at the start of inhalation.

If the unit is on and no breathing is detected, the device will go into AutoBreath™ mode and dispense oxygen at regular intervals until breathing is detected again or battery is depleted.

During AutoBreath mode, the unit dispenses a bolus of oxygen at a rate of 20 BPM. The oxygen bolus volume is dependent on the setting and is indicated in the Standard and SmartDose Mode Oxygen Bolus Dispense Table. AutoBreath mode is a backup solution to ensure some oxygen is delivered to the patient in the event that the device is unable to detect patient breathing.

HOW SMARTDOSE® TECHNOLOGY WORKS

When enabled, patented SmartDose technology automatically adjusts the oxygen dose in response to changes in your breathing pattern. It delivers more oxygen when needed to help you stay active and saturated, thus giving you the freedom and confidence to live a more active life.

When you are active, a higher oxygen dose helps reduce feelings of breathlessness and keep you active. After you set the flow rate to your prescribed dose, there is no need to manually change the oxygen flow rate during the day— SmartDose technology does it for you.

PORTABLE OXYGEN CONCENTRATOR OVERVIEW

UNPACKING AND CONTENTS

First, unpack your concentrator and identify all items.

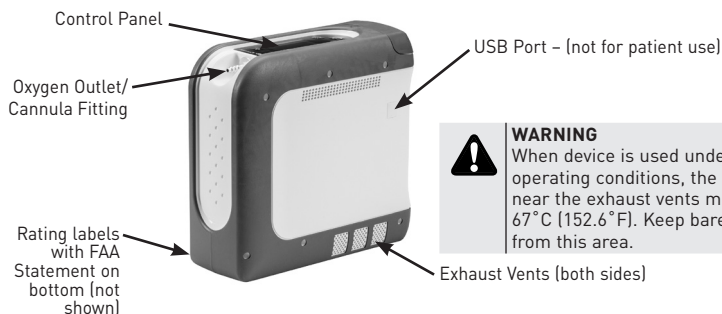
1. McKesson Portable Oxygen Concentrator
2. Single Battery Pack
3. Carrying Case
4. Power Supply (AC/DC Adapter)
5. AC Power Cord
6. DC Power Cord (Auto Adapter)
7. Instructions for Use (this document)

NOTE— Contents vary by model. Please refer to the contents list on the device carton for items specific to your model.

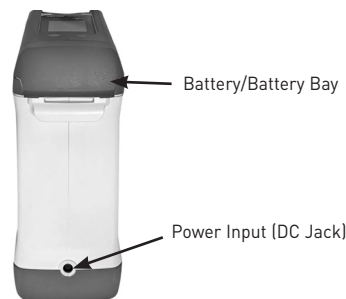


IMPORTANT PARTS OF YOUR CONCENTRATOR

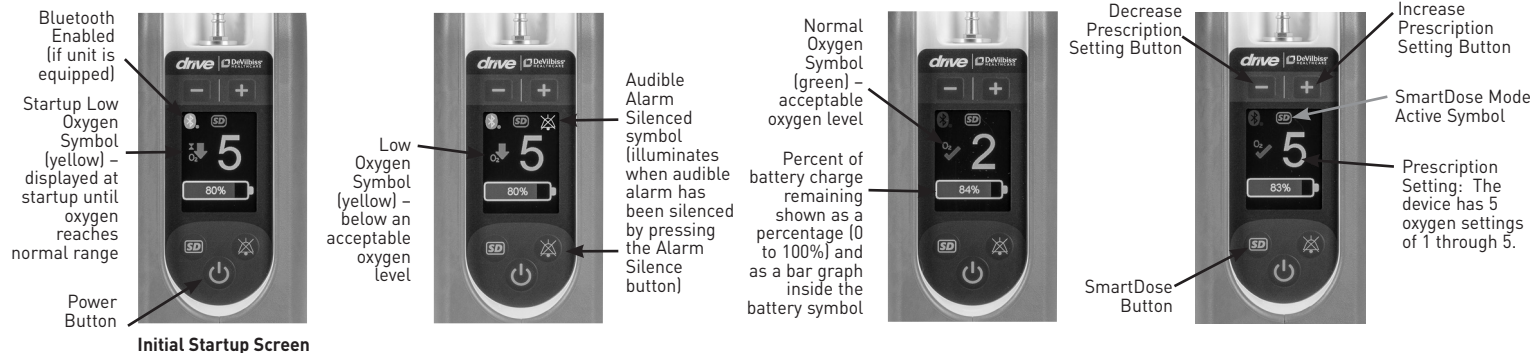
Portable Oxygen Concentrator



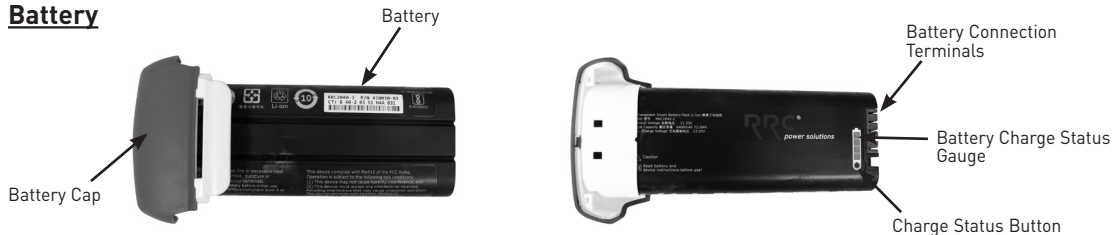
WARNING
When device is used under extreme operating conditions, the temperature near the exhaust vents may reach 67°C (152.6°F). Keep bare skin away from this area.



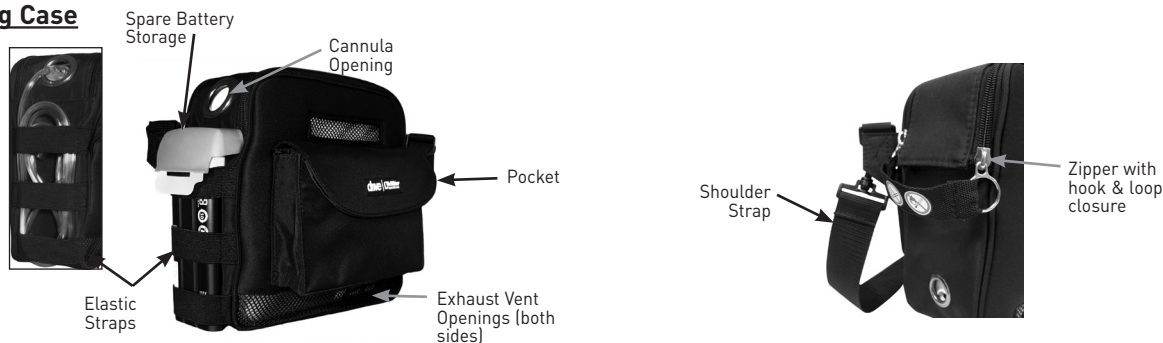
Control Panel



Battery



Carrying Case



PORTABLE OXYGEN CONCENTRATOR OVERVIEW

SYSTEM ASSEMBLY

1. Unpack device and all components. Refer to Overview – Unpacking and Contents.
 2. The device ships in the carrying case; unzip the end for access to the battery bay.
 3. Remove battery from packaging and insert into battery bay.
- NOTE**– Before using the device on battery power for the first time, the battery needs to be fully charged. Refer to Battery – Initial Battery Charge for details.
4. Attach the shoulder strap to the carrying case by clipping it to the D rings on each side.
 5. Attach the power supply and cord to power source to charge the concentrator. Refer to Battery - Initial Battery Charge (page 11).
 6. Connect cannula tubing to oxygen outlet.
 7. The portable oxygen concentrator is now ready for use; it can be operated inside the carrying case or removed if desired.



NOTE– The carrying case has several openings for proper airflow. Never block the air openings. Never use a carrying case other than one approved by McKesson.

STARTUP

At startup, the device beeps once and briefly illuminates the home screen showing the logo and hour meter. Verify beep is heard and display illuminates on startup. Yellow Startup Low Oxygen Symbol stays illuminated until oxygen is in normal range (up to 10 minutes) after which green normal oxygen symbol illuminates.



OXYGEN PRESCRIPTION SETTING

The oxygen prescription setting is displayed on the main device screen. The portable oxygen concentrator has five oxygen delivery settings of 1 through 5. If SmartDose is enabled, the screen will show 1 through 5 with the SD logo illuminated to indicate SmartDose mode.

To change the Portable Oxygen Concentrator oxygen setting:

Press either '+' Increase or '-' Decrease Setting button on the control panel to adjust the oxygen setting higher or lower. To turn SmartDose on or off, press the SmartDose <SD> button.



OPERATION

DAILY OPERATION

NOTE– Ensure the power cord is fully inserted into the concentrator connector and the power cord plug is completely inserted into a fully functioning AC wall outlet. Failure to do so may cause an electrical safety hazard.

NOTE– Before using the device on battery power for the first time, the battery needs to be fully charged. Refer to Battery – Initial Battery Charge for details.

1. Ensure battery is charged or attach concentrator to AC or DC power to check battery charge level.

NOTE– Battery must be installed for device to operate regardless of power source.

2. Connect cannula tubing to oxygen outlet.
3. Press and hold the Power Button to turn on device.
4. Check the Prescription Setting. Press "+" Increase or "-" Decrease Setting buttons to adjust the flow to your prescription setting. To turn SmartDose on or off, press the SmartDose <SD> button.

NOTE– For your safety, the oxygen concentrator must be used according to the prescription determined by your physician.

5. Attach recommended nasal cannula to your nose and face. Breathe normally through the cannula.

NOTE– Do not use pediatric (low-flow) nasal cannula or mask.

NOTE– To check that your device is functioning properly during use, simply watch for the green normal oxygen symbol to blink upon inhalation. You can also pinch the tubing for 3-4 seconds then release it, and feel a dose delivered at the cannula.

NOTE– Upon startup, it will take up to 10 Minutes for the oxygen output content to be 90% +/- 3%. During this time, the yellow start-up low oxygen symbol will be illuminated but the device can be used.

NOTE– The McKesson POC has an oxygen sensing device (OSD®) to monitor oxygen purity once the oxygen stabilization process is complete (after approximately 10 minutes of operation). Once stabilized, the OSD monitors the oxygen purity and will alert if purity falls below an acceptable level.

6. To change the battery during operation: Turn off the device. Grasp the battery cap and pull straight up, then insert a charged battery and press until it clicks into place.

NOTE– The device will operate for a minimum of 3.5 hours at a setting of 2 at 20 BPM (breaths per minute) using a new fully charged battery.

7. When finished using the device, press and hold the Power Button for 2 seconds to turn off the concentrator.

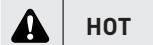
NOTE– The device should not be used on battery power when sleeping; the battery will not provide a long enough run time for a full night's sleep. Attach concentrator to AC or DC power for overnight use.



OPERATION

WEARING THE DEVICE

1. The carrying case allows you to easily take your portable oxygen concentrator with you while on the go. Simply place the Portable Oxygen Concentrator in the case and adjust the shoulder strap to the desired length.



HOT



WARNING
This area can emit hot exhaust gas. Do not place near bare skin.

SILENCING ALARM CONDITION

To silence an audible alert during operation, simply press and release the Alarm Silence button on the control panel. The Alarm Silenced symbol will remain on the display until the alarm condition is corrected.

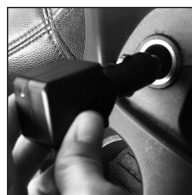


POWER OPTIONS

Your portable oxygen concentrator can be used on the 3 following power sources:

1. Battery Power – Your device must always have a battery installed to operate. The portable oxygen concentrator will use battery power if no other power source is present. However, if AC or DC power is connected, the device will run on that power source thus conserving battery charge level. If the other power source is disconnected, the device will automatically switch to battery power. The device will operate for a minimum of 3.5 hours at a setting of 2 at 20 BPM (breaths per minute) using a new fully charged battery
2. AC Power (for use at home or where standard AC power is available) – Attach the universal AC Power Supply to the concentrator and an AC power outlet using the AC Power Cord
3. DC (car charger) Power
 - a. **START YOUR VEHICLE.**
NOTE– DO NOT leave the concentrator or Power Supply plugged into the vehicle without the engine running or attempt to start the vehicle while either is connected to the vehicle. This may drain the vehicle's battery.
 - b. Attach Power Supply to the device and to the vehicle accessory power port using the DC power cord.
 - c. Secure the portable oxygen concentrator and Power Supply in your vehicle and make sure the air inlet and exhaust vents are not blocked.

NOTE– Battery will not charge if plugged into power source less than 13.8V but the device will function correctly.



STORAGE

When not in use, your device and batteries should be stored in a cool, dry location within the specified storage parameters (refer to Specifications).

- Do not store batteries haphazardly in a box or drawer where they may short circuit each other or be short-circuited by other metal objects.
- Do not store batteries longer than 1 year without recharge.
- Lithium-ion batteries can be stored from -4°F to 140°F (-20°C to 60°C) at up to 90% relative humidity.
- Recommendation: Store the battery below 77°F (25°C), low humidity, no dust, and no corrosive gas atmosphere. Store fully charged if possible. Avoid storage in direct sunlight.

High temperature storage (above 104°F / 40°C), such as in a hot car, may degrade battery performance and reduce battery life. Low temperature storage may affect battery performance.

The best battery charge conditions are within a temperature range of 32°F to 113°F (0°C to 45°C) at up to 90% relative humidity. If the battery temperature exceeds 113°F (45°C), the device will not charge the battery. Charging will be resumed when the battery temperature drops to 111°F (44°C) or below.

LONG TERM STORAGE

Do not store batteries longer than 1 year without recharge.

NOTE– Using the Portable Oxygen Concentrator more frequently will prolong sieve bed life. If the Portable Oxygen Concentrator has been stored for an extended period of time, it may take up to 30 minutes of operation to recover sieve beds to their full potential.

NOTE– Run the device for 20 minutes every 6 weeks while in storage for optimal performance.

BATTERY

The display shows the battery charge level as a percentage (0 to 100%) and as a bar graph inside the battery symbol.

The concentrator will operate for a minimum of 3.5 hours at a setting of 2 at 20 BPM (breaths per minute) using a new fully charged battery.

NOTE - The battery may have 75% of its initial capacity after 300 charge/discharge cycles; in this case, you can expect up to 2.5 hours of runtime at a setting of 2 and 20 BPM.

INITIAL BATTERY CHARGE

Before using the device on battery power for the first time, the battery needs to be fully charged. Optional spare batteries purchased should also be fully charged before first use.

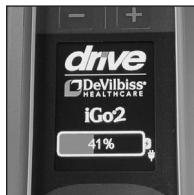
- To charge portable concentrator battery, simply attach the power supply to the device and an AC or DC power source using the appropriate power cord.
- The Battery Charging Icon illuminates on the display during charge and goes off when the battery is fully charged.

NOTE - If you purchased spare batteries for backup, insert into the concentrator one at a time and charge as above.

BATTERY CHARGING

When an external power source is attached and the battery is charging, the Battery Charging Icon illuminates on the display. The charging icon is not visible when the battery is fully charged.

NOTE - The best battery charge conditions are within a temperature range of 32°F to 113°F (0°C to 45°C) at up to 90% relative humidity. If the battery temperature exceeds 113°F (45°C), the device will not charge the battery. Charging will be resumed when the battery temperature drops to 111°F (44°C) or below.



To charge portable concentrator battery:

- Using AC Power - attach the power supply to the concentrator and an AC power source using the appropriate power cord.
- Using DC Power - Your concentrator includes a DC Cord that allows the concentrator to operate from DC accessory power port outlets such as those found in motor vehicles.
 - START YOUR VEHICLE.**

NOTE - DO NOT leave the concentrator or Power Supply plugged into the vehicle without the engine running or attempt to start the vehicle while either is connected to the vehicle. This may drain the vehicle's battery.
 - Attach Power Supply to the concentrator and to the vehicle accessory power port using the DC power cord.
 - Secure the portable oxygen concentrator and Power Supply in your vehicle and make sure the air inlet and exhaust vents are not blocked.

NOTE - Battery will not charge if plugged into power source less than 13.8V but the device will function correctly.

TYPICAL BATTERY RECHARGE TIME

The typical time to recharge your battery from a fully discharged condition is less than 5 hours dependent upon the setting.

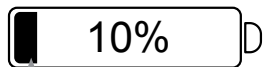
NOTE - Battery will charge in less than 3 hours from fully discharged state with device off and plugged into AC power; or less than 4 hours when using DC power. While using the concentrator, charge time will be less than 5 hours from fully discharged state using either AC or DC power.

NOTE - Battery will not charge if plugged into power source less than 13.8V but the device will function correctly.

BATTERY CHARGE LEVEL

Display (installed battery)

The display shows the battery charge level as a percentage (0 to 100%) and as a bar graph inside the battery symbol.



- * Green Bar Graph = 10 to 100% charge remaining
 - * Yellow Bar Graph = ≤ 10% battery charge remaining
 - * Red Bar Graph with Audible Alert = ≤ 5% battery charge remaining
- Device Shutdown = within 2 minutes of reporting 5% charge remaining. Plug in device or change battery to continue use.

Spare Battery (not installed)

To check the charge level on a spare battery, simply press the Charge Status Button on the individual battery.



Flashing = 10% remaining

NOTE - Each segment of the battery charge status gauge indicates 25% of total charge capacity.

BLUETOOTH AND SMARTLINK02 APP

Portable Oxygen Concentrator Models with Bluetooth® (125 BT series ONLY)

This section provides an overview of the Bluetooth model portable oxygen concentrator when used in conjunction with the SmartLink02 App by Drive DeVilbiss Healthcare available in the App Store (iPhone) or Google Play Store (Android) for your smartphone.

- Download the App by searching for "SmartLink02" in the store and installing on your smartphone.
- Log into the SmartLink02 login page using your email and password. If you need an account, click "Register" button.
 - To register your account: Enter your info in each registration field, including the password you want to use, then click "Register" at the bottom of screen.
- When you log in the first time, you will be prompted to Pair Your POC to the SmartLink02 App:



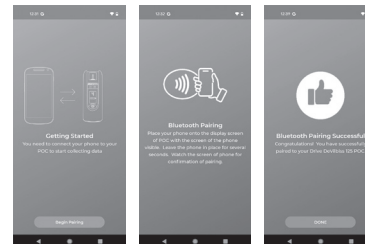
IMPORTANT

Before you begin the pairing process, be sure the Bluetooth option is turned on in your phone or tablet. Refer to your phone's instructions for details.

- At the bottom of the Getting Started screen, select the button "Begin Pairing" and Pairing Wizard will guide you through the process.

NOTE - Android users may be prompted to enable location permissions; if so, Select "While Using The App" and proceed.

- The Pairing Device screen will appear. Place your smartphone directly onto the portable oxygen concentrator display screen for several seconds, and the portable oxygen concentrator will send a pairing request to your phone. When prompted, select "Pair" to confirm the pairing request.



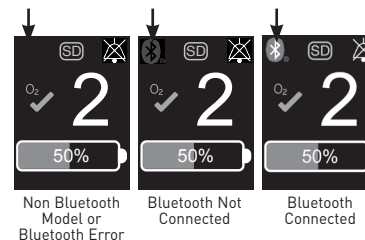
IMPORTANT

You must select "Pair" on your smartphone to proceed with Pairing. If you do not want to proceed, select "Cancel" to end the pairing request.

- A Pairing confirmation will display on your smartphone screen.

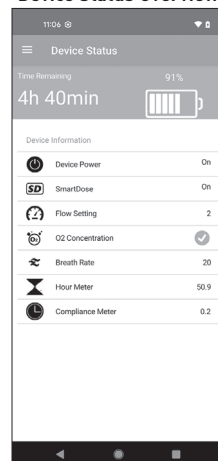
NOTE - The portable oxygen concentrator can only be paired to a single phone. If you wish to change the paired phone, download the app on your new smartphone and repeat the above steps.

- Within the SmartLink02 App, the Menu button located in the upper left corner lets you navigate to:
 - Device Status Overview:** allows you to control or view your portable oxygen concentrator device settings.
 - Settings:** contains your personal information, pairing options, device information, and options to select your provider if desired. The Support menu with helpful videos and FAQs is also located on this screen.

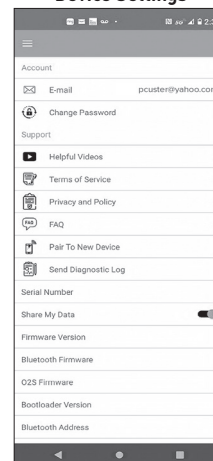


DEVICE STATUS OVERVIEW		DEVICE SETTINGS	
	Screen Selector Tool allows you to switch between Device Status Overview and Device Settings screens		Email address associated with your SmartLink02 app account
	<p>Battery Time Remaining:</p> <p>NOTE - Run time projections are estimates based on your flow setting and can be used as a general guideline. If you change the flow setting on the POC, you will need to refresh the app Device Status screen to see the most accurate battery runtime estimate.</p> <ul style="list-style-type: none"> Time Remaining shown in hours/minutes. <p>NOTE - If the POC is unable to determine the time remaining, the app will show "****" (four stars). The Time Remaining estimate may take up to 2 minutes to recalculate.</p> <p>Time Remaining indicated as a percentage and colored graph showing Green when battery is 10% - 100% charged, Yellow when battery has a 5% - 10% charge, and Red if the charge is below 5%.</p>		Password allows change of password associated with account
	Helpful Videos shows list of videos available to view		Terms of Service for using the application with your portable oxygen concentrator unit
	Device Power shows ON when the POC is running, shows OFF when the POC is turned off.		Privacy and Policy Terms for using the application with your portable oxygen concentrator unit
	When SmartDose is ON, the POC is ready to deliver the next higher O ₂ setting when the unit detects an increased demand. When SmartDose is OFF, the device is operating in standard mode.		Shows list of Frequently Asked Questions
	Flow Setting displays the POC oxygen output setting from 1 to 5.		Pair to New Device is used to connect a new portable oxygen concentrator
	O ₂ Concentration displays a Green Check for oxygen purity >= 86% or a Yellow Down Arrow for oxygen purity < 86%.		Diagnostic Log is used to send a log to support personnel if requested
	Alarm Silenced symbol shows On when an active alarm condition has been muted via the Alarm Silence button on the portable oxygen concentrator keypad, and shows OFF when Alarm Silence is not active.		
	Breath Rate shown in Breaths per Minute (BPM). One breath consists of one inhale and one exhale.		
	Hour Meter displays the number of hours the unit has been in operation.		
	Compliance Meter displays the number of hours of patient breathing on device.		

Device Status Overview



Device Settings



TRAVELING WITH YOUR PORTABLE OXYGEN CONCENTRATOR

While the McKesson portable oxygen concentrator sets you free to go everywhere and makes travel far more streamlined than other oxygen delivery methods, here are some things to keep in mind – no matter how you're getting there and back. We recommend you keep your physician and provider contact information with you in case of an emergency.

NOTE– Before starting a trip, check with your McKesson provider for options (e.g. extra battery/AC Power Cord for use at destination, etc.). Refer to Replacement Items/Spare Parts for appropriate power cord part numbers.



IMPORTANT

Always check to ensure your battery and/or spare battery is fully charged before beginning a trip or when you may not have access to other power sources.

The concentrator will operate for a minimum of 3.5 hours at a setting of 2 at 20 BPM (breaths per minute) using a new fully charged battery. However, a variety of factors such as age of battery and flow rate, can impact the duration of operating time. For longer operation time, we suggest keeping 1 or more spare batteries on-hand and charged.



CAUTION

When transporting the portable oxygen concentrator, care should be taken to avoid excessive shock.

ON THE GO WITH PORTABLE OXYGEN CONCENTRATOR



IMPORTANT

When using public transportation (plane, train, bus, ship), notify your carrier(s) when making travel arrangements. They will have specific details about requirements for oxygen use during flight/trip. Most carriers require advance notice and many have rules regarding the minimum battery operation time you must have. Some carriers may require confirmation of need from your physician.

AIR TRAVEL

RTCA / DO-160G Section 21 Category M and Section 20 Category T– The manufacturer of this portable oxygen concentrator has determined this device conforms to all applicable FAA acceptance criteria for portable oxygen concentrator carriage and use on board aircraft.

The concentrator will operate for a minimum of 3.5 hours at a setting of 2 at 20 BPM (breaths per minute) using a new fully charged battery. If you will be using the device during air travel, ensure you have enough charged batteries for 1½ times the expected maximum flight duration.



CAUTION

The portable oxygen concentrator should be taken as a carry-on item if traveling by air; medical devices do not count toward carry-on luggage limits. If you plan to check the device as luggage:

1. The portable oxygen concentrator with 1 battery installed can be checked.
2. The portable oxygen concentrator should be packed in a protective case. The carrying case does not provide adequate protection if checking the device.
3. The FAA does not allow spare batteries to be checked; spare batteries must be protected from short circuit and kept in your carry-on bag.



IMPORTANT

Per FAA Regulations, spare batteries must be protected from short circuit by placing in original retail packaging or by placing each battery in a separate protective pouch. Refer to the FAA Advisory Circular 120-95A regarding portable oxygen concentrators for complete details
https://www.faa.gov/documentLibrary/media/Advisory_Circular/AC_120-95A.pdf

BUS / TRAIN TRAVEL / CRUISE SHIPS

Make sure you have sufficient battery life before beginning your trip.

- Power outlets may not be available on buses although they may be accessible in some transportation terminals.
- Portable oxygen concentrators should be able to operate a minimum of four hours without available onboard electrical power (in the event of a power disruption onboard the train).



NOTE– You should travel with 1 or more spare batteries to meet this requirement.

- Generally cruise ships supply electrical outlets allowing you to recharge your battery.

MOTOR VEHICLE TRAVEL (Refer to page 10, Power Options – DC (Car Charger) Power, for details regarding motor vehicle travel.)

Your concentrator includes a DC Auto Adapter that allows the concentrator to operate from DC accessory power port outlets such as those found in motor vehicles.

1. START YOUR VEHICLE. DO NOT leave the concentrator or Power Supply plugged into the vehicle without the engine running or attempt to start the vehicle while either is connected to the vehicle. This may drain the vehicle's battery.
2. Attach Power Supply to the device and to the vehicle accessory power port using the DC power cord.
3. Secure the concentrator and Power Supply in your vehicle and make sure the air inlet and exhaust vents are not blocked.

NOTE– Battery will not charge if plugged into power source less than 13.8V but the device will function correctly.

CAMPING / OVERNIGHT STAYS

Battery should be charged using AC or DC Power in the camper. The concentrator can be operated on the battery power when other power sources are not available. If overnight oxygen use is required, you should have AC/DC Power available because the battery will not last overnight.

TRUCKING INDUSTRY

Recommended setup for truckers is to have the concentrator plugged into AC or DC power to be charged while the truck is running. Then when the truck is turned off, the concentrator will run on battery power. If overnight oxygen use is required, you should have AC/DC Power available because the battery will not last overnight.

INTERNATIONAL TRAVEL

International carriers may have additional requirements; be sure to contact each carrier regarding their rules and necessary documentation.

REPLACEMENT ITEMS/SPARE PARTS

The following items can be purchased separately as replacement items or spare parts for your 125 Series McKesson POC:



WARNING

Certain oxygen accessories not specified for use with the portable oxygen concentrator may impair the performance. ONLY use recommended oxygen delivery accessories. Do not use a humidifier; this device is not intended for use with, and will not function with, a humidifier. Only manufacturer approved power supplies, cords, and adapters must be used with this product to ensure proper operation and safety.

Power Supply 120 Watt (AC/DC adapter)	DV68-620
USA Power Cord	DV51D-606
Continental Europe Power Cord.....	DV51D-607
UK Power Cord	DV51D-608
Australia Power Cord.....	DV51D-609
China Power Cord.....	DV51D-614
DC Power Cord (auto adapter)	DV6X-619
Carrying Case	125D-670
External Battery Charger	
Charging Station – US.....	125CH-613
Charging Station – Continental Europe.....	125CH-614
Charging Station – UK	125CH-615
Spare Battery	125D-613
Sieve Bed Package.....	125D-619
Cabinet Screws (6).....	125D-621

There are many types of oxygen tubing and cannulas. Certain accessories may impair the device's performance. Use only standard nasal cannula with 25' or less of crush-proof oxygen tubing with this concentrator. Do not use pediatric (low-flow) nasal cannula or mask. Your homecare provider should also give you advice on the proper usage, maintenance, and cleaning.

The accessories (nasal cannula, oxygen tubing, etc.) that supply oxygen to the patient must be equipped with a means that, in case of fire, stops the propagation of fire through the accessory for the safety of the patient and others. A fire activated flow-stop or thermal fuse device, if available, should be used with the oxygen supply accessories. These types of flow-stop devices stop the flow of oxygen to the patient in the event of fire. This means of fire protection should be located as close to the patient as practicable.

PORTABLE OXYGEN CONCENTRATOR CARE AND CLEANING



WARNING

To avoid electric shock, do not remove the concentrator cover. The cover should only be removed by a qualified McKesson technician. Do not apply liquid directly to the cover or utilize any petroleum-based solvents or cleaning agents.

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.

Use no lubricants, oils, or grease.

Before attempting any cleaning procedures, turn the unit OFF and disconnect from AC or DC power.

Do not service or clean this device while in use with a patient.

EXTERIOR COVER & BATTERY

Clean the concentrator exterior cover and battery as needed:

1. Ensure battery is installed while cleaning the cover.
2. Use a damp cloth or sponge with a mild household cleaner on the exterior cover and wipe it dry. If battery is removed, wipe battery bay with a dry cloth only.



CAUTION

Do not apply liquid directly to the cover.

3. Wipe battery with a dry cloth as needed.

CARRYING CASE

The carrying case should be cleaned as needed. To clean, follow these steps:

1. Remove the device from the carrying case before cleaning.
2. As needed, clean the case by using a damp cloth with a mild household cleaner and wipe dry.



POWER SUPPLY, AC POWER CORD, DC POWER CORD

1. Disconnect cords from the device and power source before cleaning.
2. Clean the cords as needed by using a damp cloth with a mild household cleaner and wipe dry.



CANNULA AND TUBING

Clean and replace the cannula and tubing according to the manufacturer's instructions.

NOTE- To minimize the environmental impact of the 125 series portable oxygen concentrator during normal use, remove tubing and nasal cannula from the portable oxygen concentrator, dispose the tubing and nasal cannula properly. Unplug the 125 series portable oxygen concentrator from AC power. Clean the cabinet as listed in the PORTABLE OXYGEN CONCENTRATOR CARE AND CLEANING section of this guide.



CLEANING

	Suggested cleaning interval	Number of cleaning cycles *	Compatible cleaning method
Outer Cabinet	7 days	260	Mild dish soap (2 tbsp) and warm water (2 cups)
Power Supply and Cords	7 days	260	Mild dish soap (2 tbsp) and warm water (2 cups)
Carrying Case	7 days	260	Mild dish soap (2 tbsp) and warm water (2 cups)
Battery	7 days	260	Wipe with dry cloth only

* number of cleaning cycles determined by suggested cleaning interval and expected service life

TROUBLESHOOTING & ALARM SYSTEM

TROUBLESHOOTING

The following troubleshooting chart will help you analyze and correct minor malfunctions. If the suggested procedures do not help, switch to your reserve oxygen system and call your McKesson homecare provider. Do not attempt any other maintenance.



WARNING

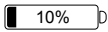




To avoid electric shock hazard, do not remove the covers. There are no user serviceable internal components. The covers should only be removed by a qualified McKesson provider/McKesson homecare technician.

SYMPTOM	POSSIBLE CAUSE	REMEDY
Unit does not operate. Display is not illuminated and nothing happens when power button is pressed and held	1. Power button was not held.	1. Press power button and hold for 2 seconds.
	2. No battery installed.	2. Battery must be installed for device to operate regardless of power source.
	3. Battery depleted or defective battery.	3. Install charged battery or contact provider for replacement.
	4. External power not attached and battery is depleted.	4. Check cord connections to device, power supply, and power source.
	5. No power at wall outlet.	5. Check your home circuit breaker and reset if necessary. Use a different wall outlet if the situation occurs again.
	6. Faulty power supply, AC power cord or DC power cord.	6. Contact your oxygen provider.
	7. Faulty DC accessory power port outlet.	7. Check automotive fuse.
	8. Unit malfunction.	8. Contact your oxygen provider.
Unit is on; audible alert is sounding; no visual alarm	1. No breathing detected.	1. Apply cannula and breathe on device.
	2. Cannula is not adjusted properly.	2. Check all cannula connections to make sure they are tight, and adjust the cannula to fit comfortably in your nose. Ensure tubing is not kinked.
	3. Tubing/cannula too long.	3. Replace with shorter tubing/cannula. Cannula and tubing length cannot exceed 25'.
	4. Low flow cannula being used.	4. Replace with standard cannula.
	5. Unit malfunction.	5. Contact your oxygen provider.
Cannot adjust/change the oxygen prescription setting	1. Unit malfunction.	1. Contact your oxygen provider.
Unit not triggering properly	1. Sensor needs recalibrated.	1. Turn unit ON, but do not use it for 5 minutes to auto-calibrate the sensor.
Battery fuel gauge symbol is yellow or red.	1. Battery is nearing depletion. • Symbol is yellow <10% • Symbol is red <5% with audible alert	1a. Charge battery by connecting device to AC or DC power source. 1b. Install optional backup battery. Device will automatically shut down within 2 minutes of reporting 5% charge remaining.
Yellow startup low O ₂ symbol is on	1. Start up period.	1a. Wait until startup period is done (about 10 minutes). 1b. If after 15 minutes of operation the yellow low O ₂ is still on, this indicates that service might be required. Contact your oxygen provider and switch to your reserve oxygen system.
Yellow low O ₂ symbol is on with or without audible alert	1. Sieve bed error	1. Run the unit for at least 15 minutes to recover sieve beds to full potential. If after 15 minutes of operation the yellow low O ₂ symbol is still on, this indicates the sieve beds may need to be replaced. Contact your oxygen provider and switch to your reserve oxygen system.
	2. The oxygen concentration is falling: a. Symbol is on below 86% b. Audible alert sounds below 85%	2. If after 15 minutes of operation the symbol is still on and/or the audible alarms sounds, this indicates the sieve beds or other components may need servicing. Contact your oxygen provider and switch to your reserve oxygen system.
Red high temperature symbol is on with audible alert	1. Unit overheated.	1. Ensure vent holes are not blocked. Allow unit to cool and try again. If this doesn't resolve the problem, contact your oxygen provider and switch to your reserve oxygen system.
Red service required symbol is on with audible alert	1. Unit malfunction.	1. Contact your oxygen provider and switch to your reserve oxygen system.
Battery status lights never indicate fully charged	1. Using the DC auto adapter but there is not enough power to fully charge battery.	1. Battery will not charge if plugged into power source less than 13.8V but the device will function correctly.
Unit is plugged in showing external power connected icon, battery is less than 100%, but not charging (no lightning bolt)	1. Battery is too hot.	1. Let battery cool to room temperature.
	2. Battery is too cold.	2. Let battery warm to room temperature.
	3. Input voltage is too low.	3. Change external power source.
	4. Other battery charge condition.	4. Wait a few minutes, battery management circuit may cause a slight delay before charging begins.
Unable to pair portable oxygen concentrator with smartphone	1. Portable oxygen concentrator does not have Bluetooth.	1. ONLY 125 BT series portable oxygen concentrator Models include Bluetooth®.
	2. Smartphone is too far away from portable oxygen concentrator.	2. Refer to page 12 in this guide and follow instructions in SmartLinkO2 App.
If any other problems occur with your portable oxygen concentrator		1. Turn your unit OFF and switch to your reserve oxygen system. Contact your oxygen provider immediately.

OVERVIEW OF ALARMS

This device contains an alarm system which monitors the state of the device and alerts of abnormal operation, loss of essential performance or failures. Alarm conditions are shown on the LCD display. The alarm system functions are tested at power up by lighting all visual alarm indicators and sounding the audible alarm (beep). All alarms are low priority technical alarms.

To mute the audible alarm, press and release alarm silence button. The alarm silenced symbol will appear on the display until the alarm condition is corrected. To reactivate the audible alarm (beeping), press the alarm silence button again.

Alarm Condition	Display Shows	Visual Alarm Signal Meaning	Audible Alarm Signal	Visual Alarm Signal Cleared by	Action to Take
Battery nears depletion		YELLOW = Battery is <10% RED = Battery is <5%	Yes, when battery is < 5%	Turn off device or switch to alternate power source	Charge battery, change battery, or switch to alternate power source
Low oxygen concentration		YELLOW = Oxygen concentration is <86%	Yes, before oxygen drops below 85%	Turn unit off unless the device is still in startup period	Call provider and switch to reserve oxygen.
Start-up period		YELLOW = Device and systems are tested at power up	No	Once oxygen reaches at least 86%	Wait until startup is finished (up to 10 minutes)
High temperature		RED = Device has overheated	Yes	Move unit to cooler location and allow it to cool.	When unit is cool, it can be restarted. If condition persists, call provider and switch to reserve oxygen.
Malfunction		RED = Service Required symbol indicating malfunction	Yes	Turn unit off	Call provider and switch to reserve oxygen.
No breathing detected	None	More than 60 seconds between requested dispense cycles.	Yes	Turn unit off or breathe on device.	Resume breathing. If no breathing is detected, device enters AutoBreath™ mode and dispenses oxygen at regular intervals until breathing is detected again.

RESERVE OXYGEN SYSTEM

As a precaution, your McKesson provider may supply you with a reserve oxygen system. If your unit loses power or fails to operate correctly, the alarm system will sound to signal you to switch to your reserve oxygen system (if provided). Contact your McKesson provider.



WARNING

Availability of an alternate source of oxygen is recommended in case of power outage or mechanical failure. Consult your physician for the type of back-up system required. Do not ignore alerts.

RETURN AND DISPOSAL

After use of the device, please return the device to the provider for disposal. The equipment, including accessories and internal components, does not belong in your regular household waste; such equipment is manufactured from high-grade materials and can be recycled and reused. The internal motor, PC board and wiring should be removed from the unit and recycled as electronic waste. The adsorbent columns (sieve beds) are not hazardous waste since they have been used only for separating oxygen from air. There are no chemical contaminants in the used adsorbent columns and they may be disposed of in municipal waste, never dispose by means of public sewers or drainage. The disposal of infectious accessories (e.g. nasal cannula from an infected user) must be made via an approved waste disposal company. Names and addresses can be obtained from the local municipality. The remaining plastic components should be recycled as plastics. The European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) requires that electrical and electronic equipment be collected and disposed of separately from other unsorted municipal waste, with the aim of recycling it. The crossed-out waste bin symbol indicates that separate collection is required.

DISPOSAL OF LITHIUM-ION BATTERIES

Lithium-ion batteries should be recycled. Some states have specific laws regarding the disposal of lithium-ion batteries. You should contact your local Government Household Hazardous Waste Agency for information on state battery disposal regulations. For information on where you can recycle your batteries at no cost, visit www.call2recycle.org or call 1-877-723-1297.

Recycle batteries according to national and local regulations. Contact your local representative for assistance. The batteries must be disposed only in a discharged state at the collection center. In case of not fully discharged batteries, provide for a risk against short circuits. Short circuits can be prevented by isolating the terminals with tape.

MAINTENANCE

There is no routine or scheduled maintenance required for the portable oxygen concentrator.



WARNING

Do not attempt to open or remove the cabinet; there are no user-serviceable internal components. If service is required, contact your equipment provider for instructions on obtaining service. Opening or attempting to service your device will void the warranty. Disconnect supply before servicing.

EXPECTED SERVICE LIFE

- Oxygen Concentrator - 5 years
- Compressor - 3 years
- Sieve Beds - 1 year
- Battery - 300 charge/discharge cycles

Expected service life of the unit, and in particular the sieve beds and compressor, may vary based on the operating environment, storage, handling, and the frequency and intensity of use.

There is no portion of the gas pathways through the concentrator that could be contaminated with body fluids under normal or single fault. A bacteria filter is used in the connection to prevent contamination of the system and does not require routine maintenance within the expected service life.

SIEVE BED CHANGE

Sieve beds are replaceable items that can be changed in less than 10 minutes by your McKesson provider. If you experience an issue that troubleshooting refers to sieve bed replacement, please ask your provider to order 125D-619. At that time, you and your provider can discuss the best replacement option for your situation.

PROVIDER INFORMATION

PROVIDER'S CHECKLIST

i NOTE– If the unit fails to operate properly, oxygen concentration is not within specification, or external/internal damage is found, contact McKesson for instructions. Service instructions will be available to qualified McKesson providers; please request through customer service. Run the device for 20 minutes every 6 weeks while in storage for optimal performance.

1. Upon arrival, check the portable oxygen concentrator for damage that may have occurred during shipping and notify McKesson of any damage. (Obvious shipping damage should be reported to McKesson within 10 calendar days after arrival.) Do not use damaged equipment. Save the carton, noting the position of the unit and placement of the packing material for possible future return.
2. Instruct the user on the safe operation of the portable oxygen concentrator; review the important safeguards and observe all Warnings and Cautions on the product and in the instruction guide.
3. Leave a copy of this instruction guide with the user.

i NOTE– McKesson recommends leaving a reserve oxygen supply with the patient when setting up the portable oxygen concentrator, and instructing the patient to always keep reserve oxygen on hand.

Under a highly improbable single fault condition, the device patient connection may unintentionally become contaminated with expired gases. This failure condition will cause the device to continually alert for no breath detection and will need to be repaired by McKesson and/or an authorized service center. The design of the concentrator allows removal of the patient connection for cleaning and/or replacement during service and repair.

CLEANING & DISINFECTION WHEN THERE IS A CHANGE OF PATIENT

The portable oxygen concentrator should be cleaned and disinfected between patients as follows:

1. Dispose of all accessories that are not suitable for reuse, particularly the oxygen tubing and nasal cannula.
2. Clean the device, battery, and components as described in the care and cleaning section.
3. Disinfect the surfaces of the device, battery, and components using DisCide® Ultra Disinfecting Spray, DisCide® Ultra Disinfecting Towelettes, CleanSmart™ Disinfectant Spray, or equivalent and follow the disinfectant manufacturer's instructions. Avoid wiping the battery terminals.

i NOTE– The disinfection process can only be completed by the manufacturer or by an appropriately trained individual.

DISINFECTION

	Recommended disinfection interval	Number of disinfection cycles *	Compatible disinfection method
Cabinet, battery, power supply & cords, carrying case	Between patients	60	DisCide® Ultra Disinfecting Spray, DisCide® Ultra Disinfecting Towelettes, CleanSmart™ Disinfectant Spray
Oxygen tubing, nasal cannula	Do not clean, replace between patients	N/A	N/A

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

SPECIFICATIONS

Dimensions (H x W x L)	8.4"H x 3.5"W x 8.6"L (21.3 cm x 8.9 cm x 21.8 cm)
Weight	4.95 ± 0.1 lb. (2.25 ± 0.05 kg)
Oxygen Output.....	90% + 4/-3 over entire operating range
Oxygen Prescription Settings	1 to 5
Operating Temperature Range	+5 °C to +35 °C (+41 °F to +95 °F)
Operating Humidity Range	15% to 93%, non-condensing
Operating Atmospheric Pressure Range	700 hPa to 1060 hPa [approx. 10,500 ft. to 1300 ft below sea level @ 35°C]
Transport & Storage Temperature Range	- 25 °C (-4 °F) without relative humidity control to +60 °C (+140 °F) at a relative humidity up to 93%, non-condensing
Transport & Storage Humidity Range	15% to 93% non-condensing
Transportation and Storage Atmospheric Pressure (at nominal temperature and humidity)	640 hPa - 1060 hPa
Maximum Limited Pressure	24 psi
Maximum Breathing Rate	40 BPM
Sound Level	37.5 dBA typical at setting 2 (MDS-Hi)
Measured Sound Pressure Level (ISO 80601-2-69:2014)	< 45 dBA
Measured Sound Power Level (ISO 80601-2-69:2014)	< 53 dBA
Measured Sound Pressure Level Range of Alarm (IEC 60601-1-8:2012)	> 59 dBA

Power Quality Requirements

AC Mains Input.....	100-240 VAC, 50/60 Hz, 140 VA
DC Input	13.8 to 17 VDC
The battery will charge as long as the DC input voltage is higher than the battery voltage. The device will charge the battery to full capacity if the DC input is at or above 13.8V DC.	
OSD Set Points.....	> 86% - Normal Oxygen Symbol (Green) < 86% - Low Oxygen Symbol (Yellow) < 85% - Low Oxygen Symbol (Yellow) and Audible Alert

Device Classification Class 2, Type BF Applied Part, IP22

The McKesson portable oxygen concentrator meets RTCA DO-160G Section 21 Category M and Section 20 Category T Airline Use.

Patented Breath Sensing with SmartDose Technology – US 8061353

Patented PulseDose Technology – US 4519387 and US 4457303



CAUTION

When moving the portable oxygen concentrator from an extreme environment, allow time for the device to acclimate to the recommended operating environment. Operating your concentrator outside the recommended operating environment may impact performance, cause damage, and will void the warranty.

Specifications subject to change without notice.

Audible Alerts:

- Low Battery
- Low Oxygen Output
- No Breath Detected
- High Temperature
- Unit Malfunction

TABLE 1 – STANDARD AND SMARTDOSE® MODE PULSEDSE® OUTPUT

Standard and SmartDose Mode Oxygen Bolus Dispense Table							
Setting	Total Volume per Minute (ml/min)	Bolus Volume @ 15 BPM (ml)	Bolus Volume @ 20 BPM (ml)	Bolus Volume @ 25 BPM (ml)	Bolus Volume @ 30 BPM (ml)	Bolus Volume @ 35 BPM (ml)	Bolus Volume @ 40 BPM (ml)
1	260	17.3	13.0	10.4	8.7	7.4	6.5
2	440	29.3	22.0	17.6	14.7	12.6	11.0
3	725	48.3	36.3	29.0	24.2	20.7	18.1
4	880	58.7	44.0	35.2	29.3	25.1	22.0
5	1014	67.6	50.7	40.6	33.8	29.0	25.4
5 SD	1100	73.3	55.0	44.0	36.7	31.4	27.5

TABLE 2 - OXYGEN FLOW EQUIVALENTS

Pulse Setting	PulseDose Bolus Volume (mL) @ 20 BPM	Equivalent Oxygen Flow Setting (L/m)	Oxygen Output
1	13.0	1.0	90% +4 / -3
2	22.0	2.0	90% +4 / -3
3	36.3	3.0	90% +4 / -3
4	44.0	4.0	90% +4 / -3
5	50.7	5.0	90% +4 / -3

NOTE– This comparison is theoretical, based on typical patient breathing pattern assumptions, and is only a recommendation. This is not intended to replace titration. The patient should be titrated to the portable oxygen concentrator at rest and with activity.

Per ISO 80601-2-67

+/-15% at Standard Temperature and Pressure (tested @-933 hPa, 25 °C +/- 5 °C)

+/-25% over entire operating range

The above chart shows oxygen output delivered at each of the settings during normal use. When SmartDose technology senses the need for more oxygen, your oxygen setting will temporarily be increased by up to 1 setting to help keep you active and saturated.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

If the device performance is lost or degraded due to electromagnetic disturbances, a visual and audible alarm indicates that the device is not meeting specification or a failure has been detected.



WARNING

MR Unsafe

1. 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 concentrator or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
2. Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, diathermy, RFID, and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the concentrator. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.
3. This device is suitable for use in home and healthcare environments except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.



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.

CABLES AND MAXIMUM LENGTHS OF CABLES

- DC power cord (cigarette lighter adapter) #DV6X-619 maximum length = 2.2 meter (7.2 ft)



WARNING

Use of accessories 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 concentrator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC AND INDUSTRY CANADA STATEMENT

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

The output power of this device is less than 20mW. The SAR test is not required. When using it, ensure that the antenna of the device is at least 20cm away from all persons.

This Class B digital apparatus complies with Canadian ICES-003.

NOTE– *The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications or changes to this equipment. Such modifications or changes could void the user's authority to operate the equipment.*

NOTE– *This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:*

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference; and (2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Radiation Exposure Statement: This product complies with the US portable RF exposure limit set forth for an uncontrolled environment and is safe for intended operation as described in this manual. Further RF exposure reduction can be achieved if the product is kept as far as possible from the user body or is set to a lower output power if such function is available.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

This device complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Radiation Exposure Statement: The product complies with the Canada portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The minimum separation distance for portable use is limited to 15mm assuming use of antenna with 2 dBi of gain. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

Bluetooth® Module Contains FCC ID: BL652, Contains IC: 3147A-BL652

EUROPEAN UNION STATEMENT

This device complies with the essential requirements of the 2014/53/EU – Radio Equipment Directive (RED). The following test methods have been applied in order to prove presumption of conformity with the essential requirements of the 2014/53/EU – Radio Equipment Directive (RED):

- EN 62368-1:2014/A11:2017: Safety requirements for audio/video, information, and technology equipment
- EN 300 328 v2.2.2 (2019-07): Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive
- EN 62311:2008 | EN 50665:2017 | EN 50385:2017: RF exposure
- EN 301 489-1 v2.2.0 (2017-03): Electromagnetic compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- EN 301 489-17 V3.2.0 (2017-03): Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2,4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment
- EU 2015/863 (RoHS 3): Declaration of Compliance – EU Directive 2015/863; Reduction of Hazardous Substances (RoHS)

This device is a 2.4 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in France and Italy where restrictive use applies.

In Italy the end-user should apply for a license at the national spectrum authorities in order to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services.

This device may not be used for setting up outdoor radio links in France and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz. For detailed information the end-user should contact the national spectrum authority in France.

CE DECLARATION

Hereby, DeVilbiss Healthcare LLC, declares that this portable oxygen concentrator device with Bluetooth is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. The declaration of conformity may be consulted at <https://drivemedical.com/us/en/service/declarationconformity>.

The Bluetooth® word, mark, and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by DeVilbiss is under license. Other trademarks and trade names are those of their respective owners.

125x-BT Series Portable Oxygen Concentrator Basic Pneumatic Diagram

i NOTE– There are no operator-detachable parts.



WARRANTY

Drive DeVilbiss Healthcare warrants the Drive DeVilbiss portable oxygen concentrator under the conditions and limitations stated below. Drive DeVilbiss warrants this equipment to be free from defects in workmanship and materials for five (5) years from date of factory shipment to the original purchaser (typically the healthcare provider) with the exceptions of the compressor (warranted for 3 years), sieve beds (warranted for 1 year), and battery (warranted for 1 year). The carry case is excluded from this warranty. These warranties are limited to the buyer of new equipment purchased directly from Drive DeVilbiss, or one of its providers, distributors, or agents. Drive DeVilbiss' obligation under this warranty is limited to product repair (parts and labor) at its factory or at an authorized service center. Items that undergo normal wear and tear are not covered under warranty.

WARRANTY CLAIMS SUBMISSIONS

The original purchaser must submit any warranty claim to Drive DeVilbiss or to an authorized service center. Upon verification of the warranty status, instructions will be issued. For all returns, the original purchaser must (1) properly package the unit or parts in a Drive DeVilbiss approved shipping container, (2) properly identify the claim with the return authorization number, and (3) send the shipment freight prepaid. Service under this warranty must be performed by Drive DeVilbiss and/or an authorized service center.

i NOTE– This warranty does not obligate Drive DeVilbiss to provide a loaner unit during the time that an oxygen concentrator is undergoing repair.

i NOTE– Replacement components are warranted for the unexpired portion of the original limited warranty.

This warranty shall be voided, and Drive DeVilbiss 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 Drive DeVilbiss operating and service instructions.
- Unqualified service personnel conduct routine maintenance, servicing, or repairs.
- Unauthorized parts or components (i.e., regenerated sieve material) are used to repair or alter the equipment.
- Unapproved filters are used with the unit.

THERE IS NO OTHER EXPRESS WARRANTY. IMPLIED WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY AND TO THE EXTENT PERMITTED BY LAW ANY AND ALL IMPLIED WARRANTIES ARE EXCLUDED. THIS IS THE EXCLUSIVE REMEDY AND LIABILITY FOR CONSEQUENTIAL AND INCIDENTAL DAMAGES UNDER ANY AND ALL WARRANTIES ARE EXCLUDED TO THE EXTENT EXCLUSION IS PERMITTED BY LAW. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, OR THE LIMITATION OR EXCLUSION OF CONSEQUENTIAL OR INCIDENTAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

i NOTE– International warranties may vary.

ORDERING AND RETURNING PARTS

Drive DeVilbiss Customer Service Contact Information

Customer Service (USA): 800-338-1988

International Department: 814-443-4881 / DHCinternational@DeVilbissHC.com

ORDERING NON-WARRANTY REPLACEMENT PARTS

Order non-warranty parts and literature from your McKesson provider.