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Reaching Impact, Saturation, and Epidemic Control (RISE)

Standard Operating Procedure

Operation and Maintenance of Oxygen Concentrator

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Abbreviations

| | |
|------|---------------------------------|
| HEPA | High Efficiency Particulate Air |
| LPM | Liter per minute |
| LTOT | Long Term Oxygen Therapy |
| OC | Oxygen Concentrator |
| PSA | Pressure Swing Adsorption |
| SOP | Standard Operating Procedure |

Introduction

Oxygen therapy is an essential component of medical care. It is used in emergency care, for anesthesia, in surgery, and for managing acute and chronic respiratory conditions. However, the COVID-19 pandemic led to an unprecedented surge in the demand for oxygen supply, given its crucial role in treating COVID-19 patients. The respiratory complications due to COVID-19 can lead to hypoxemia in patients, a condition when the oxygen level in the blood is abnormally low. In such a condition, a patient requires oxygen therapy and access to quality-assured medical oxygen. Reliable access to quality-assured medical oxygen can mean the difference between life and death for patients.

Sometimes, even if oxygen is available, observations suggest that lack of oxygen access to patients in health care settings can be due to insufficient oxygen systems medical gas pipeline, medical grade oxygen generation plant, oxygen concentrators (OCs), low-quality and poorly maintained oxygen delivery equipment like ventilators, concentrators, CPAP, and BiPAP. Such shortcomings could be due to deficiencies in clinical and technical training and skills among clinical, technical, and administrative healthcare workers. Thus, creating awareness among the health care professionals and building their capacities to operate and maintain oxygen supply equipment efficiently is of paramount importance. Therefore, an enabling environment is required to streamline efforts to ensure that patients receive oxygen therapy, when needed. These efforts include safeguarding the quality of oxygen supplied by manufacturer, assuring its appropriate administration to the patient, and drastically improving the screening of hypoxemic patients.

Purpose of the Standard Operating Procedure (SOP)

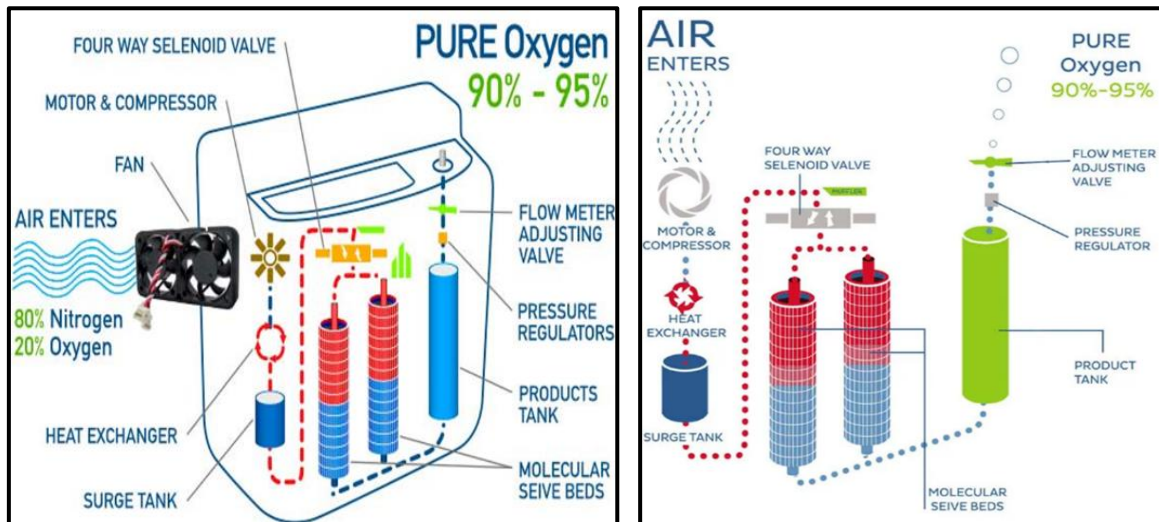
The document, titled “**Operation and Maintenance of Oxygen Concentrator**”, provides, in detail, the components and functioning of an OC. The SOP includes the following components: setting up (installing); handling the OC; concentrator accessories and consumables; cleaning and decontamination of concentrator; daily, weekly, and annual maintenance of oxygen concentrator; troubleshooting; basic dos and don’ts, etc. The SOP intends to bridge knowledge and skills gap among health care facility staff by providing in-depth information on the operation and management of an OC.

Scope

The specifications and guidelines in the “Operation and Management of Oxygen Concentrator (OC)” intend to support health facility administrators, clinical practitioners, procurement officers, planning staff, biomedical engineers, infrastructure engineers, and policymakers in the states and at the national level to select, procure, use, and maintain OC equipment. This document may also benefit health care workers, academics/researchers, development agencies, non-governmental organizations, regulators, and others involved in oxygen system management.

Background

An OC is a self-contained, electrically powered medical device designed to concentrate oxygen (up to 93% +/- 3 %) from ambient air, using pressure swing adsorption (PSA) technology. It is used to deliver oxygen at the bedside or within close proximity to patient areas. A single concentrator can service several beds using a flow splitter. On the other hand, two concentrators can be connected to each other using a Y-connector to deliver flow rates higher than their individual capacity. Concentrators with different maximum flowrate (liter per minute – LPM) capacity are available in the market such as 3 LPM, 5 LPM, 8 LPM, and 10 LPM.



(a) Components of Oxygen Concentrator (b) Functioning of Oxygen Concentrator

Types of Concentrators

1. Movement

- Stationary
 - Provide an uninterrupted oxygen supply with a flow ranging from 0.5 to 10 LPM.
 - Have a mean weight of about 10 kg.
 - Have several ergonomic handles built in to offer options for lifting or rolling the device.
 - The concentrator plugs into the main electricity supply at home, using 300 watts (or below) per hour (about the same as four light bulbs).
- Portable
 - Portable oxygen concentrators are the latest technology for long-term oxygen therapy (LTOT) users who desire a small, lightweight, and portable oxygen solution in a compact and mobile unit.
 - Portable concentrators vary in weight, size, oxygen flow settings, range of L.min⁻¹ and battery life as well as other components.



(a) Stationary Oxygen Concentrator (b) Portable Oxygen Concentrator

2. Flow wise

- **Continuous flow dose delivery** supplies a constant, steady, and reliable oxygen flow based on the setting number in L.min⁻¹.
- **Pulse mode delivery** delivers a pulsed “bolus” of oxygen when the user begins to take a breath. Initially, the individual flow setting should be adjusted.

Components and Functioning of Oxygen Concentrator

There are two main parts:

- **Compressor** - used to compress the air
- **Sieve bed filter** - used for adsorption of nitrogen

Other important parts are **the cooling system** that keeps the portable OC from overheating, **flowmeter adjusting valve, pressure regulators, surge and product tanks and the nasal cannula** that delivers the purified oxygen after the oxygen has been passed through all the sieve bed filters.

Working/Functioning of an OC

Step 1: Takes air from the room.

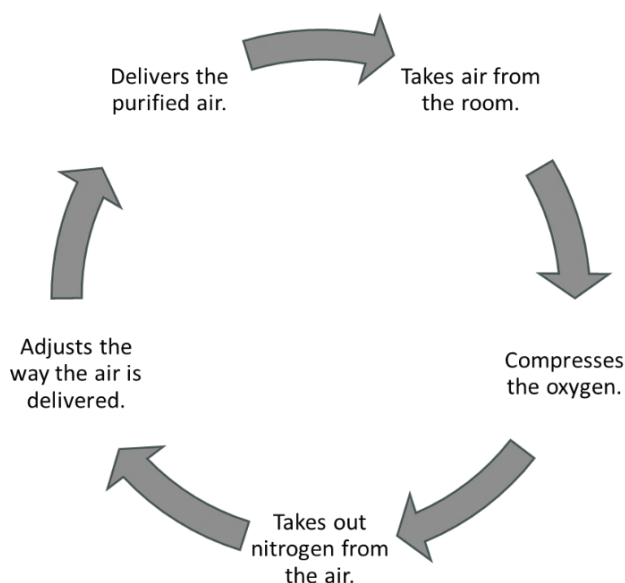
Step 2: Compresses the air and cools it.

Step 3: Takes out nitrogen from the air using adsorption.

Step 4: Adjusts the way the oxygen is delivered.

Step 5: Delivers the oxygen.

The compressor **compresses air that is filtered into the concentrator**, then delivers the air in a continuous stream. The **compressed air is cooled and then moves to the sieve bed filters**. The sieve bed filter plays an important role, as it is the component that **removes the nitrogen using PSA process** from the air. A material called **Zeolite**, which is a six-sided microscopic cube with holes on each side, is in the sieve bed which adsorbs the nitrogen from the air, leading to concentration of oxygen up to 96%.



Setting Up (Installing) and Handling a Concentrator

Steps to Set-up an Oxygen Concentrator

Step 1: Position the machine 6-7 inches from the wall and furniture.

Step 2: Connect the humidification bottle to the OC, if it is not provided with the machine and is prescribed. The location of the outlet of the humidification bottle will vary depending on the model.

Step 3: Attach the oxygen tubing to the humidification bottle.

Step 4: Make sure that the air filter is in place before operating the machine.

Step 5: Switch the power button ON of the machine and follow the instruction manual.

Step 6: Listen for an alarm on switching ON the machine.

Step 7: If applicable, make sure the machine's power button is in the OFF position before you plug it in the power socket. It could get damaged if it is already switched on.

Step 8: The machine will give alarm if the power flow is interrupted. Ensure the machine is connected to uninterruptible power supply (UPS)/diesel generator (DG) supply.

Step 9: Adjust the oxygen flow rate. Locate the LPM knob or switch on the machine and set the flowrate as prescribed.

Step 10: Connect the face mask or nasal cannula to the machine. Attach the one end of the tubing to the humidifier bottle/adaptor and the other end to the nasal prongs or face mask.

Step 11: Place the mask without any gap on the face and secure it by applying elastic band over the head or around the ears. Similarly, fit the nasal cannula upwards into the nostril for high levels of oxygen. Each prong should be curved up into the nostril.

Step 12: Ask the patient to breathe normally through mask or nasal cannula allowing the machine to supplement the oxygen.

Step 13: Switch off the power when the machine is not in use or has overheated.

How to Use an Oxygen Concentrator

Step 1

- Plug the machine into a grounded electrical outlet. If your outlet is not grounded, you will have to use a plug adaptor. Do not use an extension cord and do not plug any other items into the same outlet.
- Keep the concentrator 30 to 60 cm (1 to 2 feet) away from walls and furniture.
- Start the machine 15 to 20 minutes (or according to the manufacturer's instructions) before use to allow it to begin cycling the correct concentration of oxygen.



Step 2

- Fill and attach the humidifier bottle with distilled water or sterilized water (you can boil water for 3 minutes and let it cool). This will prevent the oxygen from drying out the nose/mouth of the user. Please do not forget to change the water in humidifier bottle once a day and after each user.
- Attach the tubing to the humidifier bottle.

Note: A humidifier bottle is typically meant as a single use item. If the manufacturer's instructions indicate that it can be reused, it shall be thoroughly cleaned with mild detergent and warm water after each user and completely dried.

In addition to the above steps, please go through the manufacturer operational manual.



Step 3

- Adjust the flow of oxygen according to the doctor's prescription. Most OCs have a maximum flow of 5 or 10 LPM.



Step 4

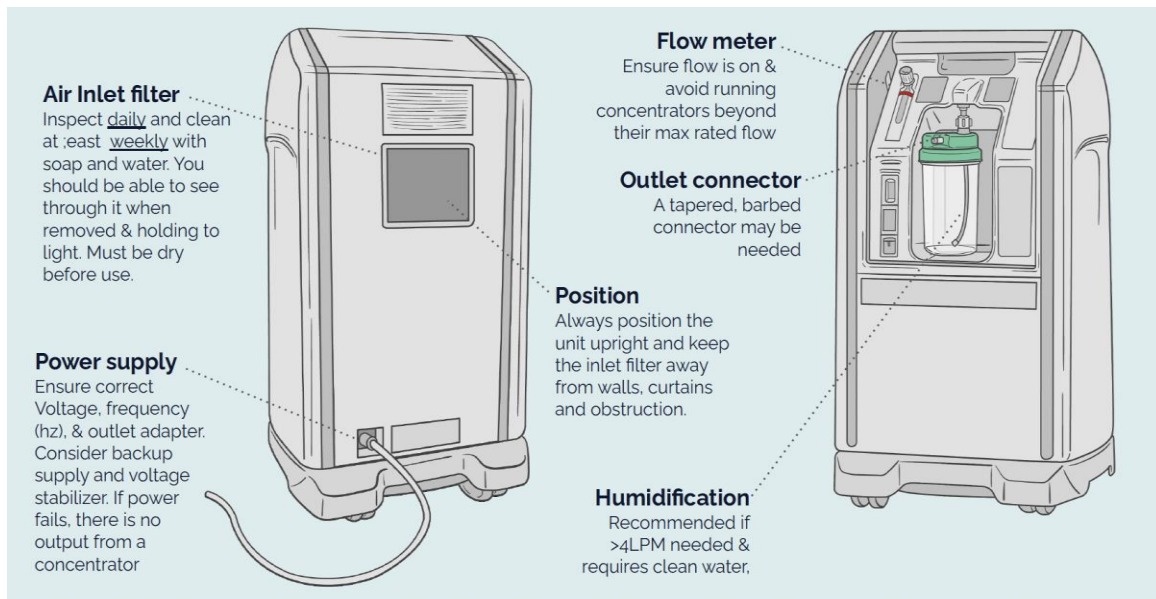
- Place the mask or nasal cannula on the patient and check to be sure they have air flow. Ask the patient to breathe normally.
- If using a mask, the concentrator must be running on a flow of 5 LPM to receive benefit from oxygen.

Note: A fresh set of oxygen tubing and nasal cannula or face mask must be provided for each individual user.



Step 5

- Switch off the power when the machine is not in use or has overheated.



Concentrator Accessories and Consumables

Therapeutic levels of oxygen are delivered to the patient via oxygen tubing and a breathing device such as nasal prongs, nasal catheters, or oxygen masks.

Nasal Prongs

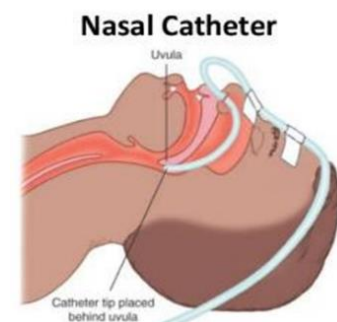
Nasal prongs and nasal catheters are consumables that are **not recommended for reuse** between patients by the manufacturer. If nasal prongs are to be **reused, cleaning and disinfection protocols** must be followed.

In children with hypoxic respiratory illness, it is recommended that nasal prongs are used. The distal prong diameter should fit well into the nostril (1 mm for premature infants; 2 mm for neonates up to 10 kg).



Nasal Catheters

If nasal catheters are used, French size 6 or 8 can be used in neonates and infants.



Oxygen Masks

Due to their relative inefficiency and low patient acceptance, oxygen masks are **not ideal in locations where oxygen is scarce** or for patients that require **prolonged oxygen therapy**.

Oxygen masks **require higher flows than nasal prongs or catheters** to achieve similar inspired oxygen concentrations, and if lower flows are used, carbon dioxide (CO₂) builds up in the mask and the patient will **re-breathe their exhaled CO₂**.



Humidifier Bottles

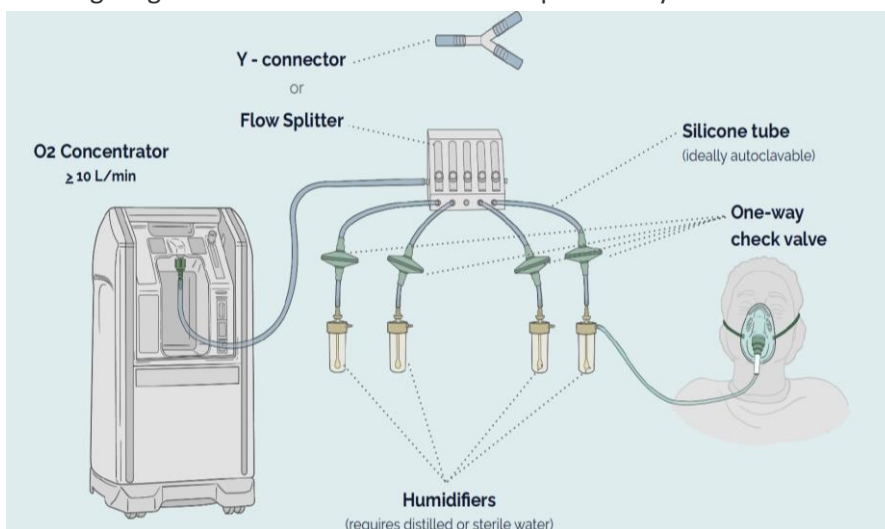
Humidifier bottles humidifies the oxygen supplied to the patients. The water used in humidifier bottles must be distilled or sterile. The water in the bottle must be changed regularly in order to prevent contamination.

How to connect one concentrator to multiple patients?

A **flow splitter assembly** can be used to split flow to supply oxygen to multiple patients using a single concentrator. Flow splitters **use nozzles** that deliver oxygen at a single fixed rate.

Important points to keep in mind when using a flow splitter:

- A flow splitter cannot deliver more oxygen than the max output of the concentrator.
- A low oxygen alarm may indicate need to reduce the flow to one or more patients (you are using too much flow).
- Changing the flow rate of any one patient on the splitter may affect the flow rates to other patients on the splitter.
- When titrating flow rates (or adding/removing patients from the splitter), check all flow meters and adjust as needed.
- If delivering humidified oxygen, always use distilled or sterile water. Do not attach the humidifier between the concentrator and the splitter.
- Limit total tubing length to less than 15 meters or as specified by the manufacturer.

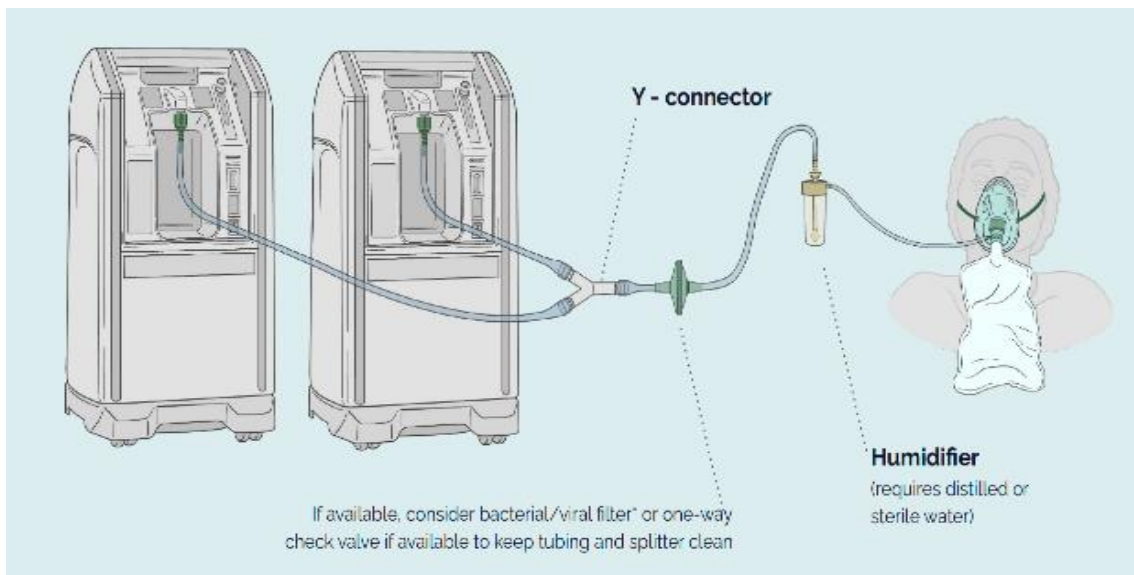


How to connect two OCs to one patient for increased oxygen flow delivery?

A Y-connector can be used to merge oxygen flow from two concentrators to obtain a higher flow rate which could be given to a single patient.

Important points to keep in mind when using a Y connector:

- Choose two concentrators with similar outlet pressure, and with desired combined flow output.
- Ensure power supply can handle more than one concentrator.
- Ensure tubing, connectors, and delivery devices are clean.
- Ensure secure connections (consider cable ties to secure tubing connections).
- Consider using humidifier if flows more than 1 LPM.
- Always use distilled water or sterile (filtered) water.
- If possible, check the flow rate and % oxygen after the Y-connector with an oxygen analyser or your finger.
- If flow is less than expected, check for leaks at all connections.



Cleaning and Decontamination of Concentrator

Exterior of concentrator

- Disconnect from power supply.
- Mop the external surface with mild detergent and water solution.
- Allow the solution to remain on the surface for 10 minutes.
- Mop the surface again with clean water only.
- Dry the surfaces with clean cloth.

Gross particle filter

- Clean the filter with mild detergent.
- Rinse with clean water, dry, and reuse.
- Replace visibly damaged filter.

- Use spare filter, if concentrator is to be used for another patient during cleaning of gross particle filter.

Nasal prongs

- Use single use nasal prongs.
- If reusable, clean with soap and water.
- Soak in 0.5% sodium hypochlorite solution.
- Dry in room air.
- If humidifiers are used, change the water in the bottle daily.
- Soak in 0.5% chlorine solution for 15 min in between patients and dry it.

Quick Tips

- Inspect and clean air inlet filter 1 to 2 times a week (a second air filter is needed to ensure continuous use while cleaning and drying one air filter).
- Replace humidifier water daily. Inspect humidifier bottle outlet for obstruction daily.
- Check tubing for kinks and leaks daily.
- Ensure air inlet filter is not obstructed daily.
- Check power and O₂ concentration alarms with each new patient or power up.
- Consider cable ties to secure connectors.
- Avoid running at or above max rated flow.
- Titrate O₂ flow using a pulse oximeter as frequently as possible.
- Avoid more than 15 meters of total tubing to the patient.
- Oxygen enrichment is a fire risk. Keep away from open flames, heat sources, and smoking.
- Do not overcharge the batteries. Never leave the charger plugged in with a fully charged battery.
- If not using the OC regularly, then use at least 10 hours per month so that internal components do not jam up.
- In the case of a portable OC, run them on batteries minimum of two hours a month.
- If you own multiple batteries, switch them every month, so that they are fully cycled and functional.
- An OC will alert you when it is time to replace the sieve bed columns. You will have 30 days to change the sieve beds.
- Always unplug the concentrator before cleaning.
- To avoid electrical shock, DO NOT remove cabinet during operation.
- DO NOT operate the concentrator without the filters installed.

Regular maintenance checks on the oxygen concentration output with a calibrated oxygen analyzer must be carried out by a trained technician at least once per year

Maintenance of Oxygen Concentrator

- Regular maintenance and specified service are vital for long-term operation and proper functioning of OCs.
- Compressor is the primary moving component and most subject to wear over time. It can be repaired or replaced.
- Regular maintenance by both clinical and technical staff is required.

- Maintenance should be scheduled, performed, and documented by a trained technician at least once per year (ideally every three to four months).
- Frequency of maintenance checks varies by model, use and environment, but should be done at least annually or every 5000 hours of use.
- More frequent maintenance is needed for hot, humid, and/or dusty operating environments.

Daily Maintenance Checks

- The OC's body and accessories should be cleaned daily to avoid dust accumulation.
- Replace humidifier water.
- Inspect humidifier bottle outlet for obstruction.
- Check tubing for kinks and leaks.
- Ensure air inlet filter is not obstructed.
- Check all screws, connectors, tubes, and parts are tightly fitted.
- Check oxygen flow before using it for clinical requirement.

Weekly Maintenance Checks

- Record the type of maintenance being performed and the elapsed operating hours.
- Check that the flow meter is set for the prescribed LPM flow rate.
- Remove the air filter and wash it in warm, soapy water, rinse thoroughly with warm tap water and allow it to dry.
- Clean the concentrator cabinet with a damp rag and mild detergent.
- Check for leakage, that is, hissing sound or reduction in pressure.

Annual Inspection

Outlet High Efficiency Particulate Air (HEPA) Filter and Compressor Inlet Filter

- To inspect the outlet bacterial filter, first remove the concentrator cabinet.
- Inspect the filter and change, if necessary, for example, if it looks dirty.
- Remove the plastic tubing from both ends and replace it with a new filter.
- Then reassemble the concentrator cabinet.

Oxygen Concentration Levels

- Check the oxygen concentration levels with an oxygen analyzer.
- Verify the concentrator supplying the prescribed level of oxygen, proper concentration percentage, and proper air pressure.
- Attach the analyzer to the cannula or a flexible tube, and then connect the cannula to the concentrator at the oxygen outlet barb to verify the readout for each measurement.

Power Loss Alarm

- Check the power loss alarm.
- Run the concentrator for at least one minute and then unplug the power cord.
- The power loss alarm should sound to indicate that it is working properly.

Troubleshooting of Oxygen Concentrator

| Problem | Remarks/Rectification Action |
|--|--|
| The concentrator does not turn on | Inspect and check power cord, electrical connections, circuit breaker (if equipped), internal fuse (if equipped; sometimes located on the PCB), on/off switch, PCB. |
| The concentrator operates, but the compressor shuts down intermittently | Check gross particle filter, cabinet fan, capacitor for the compressor, cabinet thermal switch (if equipped), valve(s), PCB. Compressor may have a faulty internal switch. |
| The concentrator's compressor does not turn on | Inspect and check electrical connections to the compressor, capacitor, and PCB. |
| The concentration is within specifications, but flow fluctuates | Check all filters and replace, if necessary. Flow meter needs to be adjusted, repaired, or replaced. |
| The concentration is within specifications, but the oxygen monitor indicates low concentration | Tubing to oxygen monitor could be kinked or oxygen monitor is faulty. Repair tubing or replace sensor. |
| The concentrator runs, but oxygen concentration is low | Check all filters and replace if necessary. Check compressor pressure and flow output. Replace or repair, if necessary. Sieve beds may be faulty and require replacement. |
| The concentrator overheats | Check ventilation fan operation. Replace, if necessary. Inspect and wash gross particle filter. Power may be in an overvoltage or undervoltage condition, check the UPS (if installed). |
| Oxygen does not flow out of the concentrator | Check system power. Inspect oxygen tubing and cannula for kinks or plugs. Check all filters and replace if necessary. Check internal tubing and fittings for leaks or kinks. Check compressor pressure and flow output. Replace or repair, if necessary. |
| Unit does not operate and the power failure alarm is sounding | Check to see that the plug is firmly in the socket. Check that there is power to the socket. Check circuit breaker on the concentrator and reset. Use back-up system until power is restored. |
| Limited air flow is coming through the tubing from the concentrator | Disconnect humidifier bottle and check flow. Replace, if necessary. Disconnect extension tubing and check for restored flow and replace, if necessary. Disconnect cannula from the extension tubing and check for restored flow and replace, if necessary. |
| Below Normal Light is on and concentrator is operating | Remove extension tubing and check flow rate setting is as prescribed. Adjust as necessary. Check for oxygen purity. |

Performing a Hard Reset

Turn the OC off and unplug it from the wall. Remove the battery pack and leave it for 30 minutes. After the allotted time, plug it back into the wall, turn it on, and put the battery pack in after 10 minutes.

- Check all vents and your cannula to ensure they aren't obstructed.
- Ensure your battery isn't loose or try replacing it with a backup.
- Check for physical damage on the system or the battery.
- Research any error message in your device manual.
- Take note of the error code and frequency of the issue you're experiencing.
- If you should need to contact the equipment provider for assistance, the error code or symbol will help them identify what is causing the issue.

Oxygen Concentrator Errors and Alerts

- If there is low oxygen alert, check to see whether the airflow is being blocked.
- If oxygen purity is lower than 80%, make sure the intake vent is not clogged or blocked. Turn the unit off and clean it, if necessary. The intake filter should be replaced or cleaned.
- If there is no breath detection, check that the cannula is properly positioned on the face and patient is breathing through the nose. Check for any twists and obstructions with tubing. If the breath is not detected for approximately 30 minutes, the device shuts down to conserve power.
- If the battery is low or empty, attach the external power supply to recharge the battery or exchange the battery.
- If the battery exceeds the temperature limit, it will stop working. If you are in a hot place, it makes the battery warm faster. Move to a cooler location.
- The OC will not produce oxygen when the temperature crosses the tolerance range. If the device is hot, move to a cooler area. On the other hand, if you are in a very cold place, move to a warmer place. Wait for at least two minutes for the device to warm up before turning it on. Check that the air inlet and outlet vent are clean and clear.

Basic Dos and Don'ts

Dos

- Keep the oxygen **at least three meters from** any open flame or heat source such as candles or a gas stove, or from anything that could cause a spark.
- **Avoid** using anything **flammable** near the oxygen including petrol, cleaning fluid, and aerosol cans or sprays such as fresheners or hairspray.
- Keep the oxygen equipment **clean and dust free**.
- Always plug your OC into a **grounded electrical outlet**.
- As the OC becomes hot when in use, place it in a **well-ventilated area**, away from curtains or drapes.
- **Inspect and service the OC** according to the supplier's instructions.

Don'ts

- Do not **smoke** or let anyone else smoke near the oxygen equipment.
- Do not allow **alcohol-based solutions, oil, or grease** to come into contact with oxygen supply devices.
- Never use an **extension cord or power board**.
- Do not **cover** the OC with a cloth or plastic while it in use.