Basics of Long-term Oxygen Therapy (LTOT)

A. Benefits of LTOT

1. Proven to increase survival and improves the quality of life of patients with chronic obstructive pulmonary disease (COPD)
2. Often improves cardiovascular morbidity, depression, cognitive function, exercise capacity, and frequency of hospitalization

B. Indications for LTOT (After Maximizing Medical Therapy)

Note: Measurement of the patient's oxygen level is key to documentation of chronic hypoxemia and subsequent management. Arterial blood gas (ABG) measurement of the partial pressure of oxygen (Pao_2), with its high degree of accuracy, is preferred for patients who are committed to lifelong supplemental oxygen. The arterial oxygen saturation (Sao_2) from the ABG is less helpful than the Pao_2. However, noninvasive pulse oximetry measurement (Spo_2) is accepted by payors to document need, especially during sleep. Most importantly, Spo_2 is a very reasonable and practical method to monitor ongoing therapy.

1. $Pao_2 \leq 55$ mm Hg or $Spo_2 \leq 88\%$
2. $Pao_2 \geq 55$ mm Hg or $Spo_2 \geq 88\%$, if there is documentation of pulmonary hypertension, cor pulmonale, or erythrocytosis (hematocrit concentration >55%)
3. May be prescribed during exercise if Pao_2 falls to < 55 mm Hg or Spo_2 falls to < 88% (no proven benefit in mortality, but may improve exercise tolerance)
4. May be prescribed for nocturnal oxygen desaturation to ≤ 88%

Patients whose oxygen levels decrease while sleeping and who are at risk for obstructive sleep apnea (OSA) should ideally be referred for a sleep disorder evaluation.

C. Responsibilities of the Health-care Practitioner Prescribing LTOT

1. Determination of need
   a. LTOT should be prescribed only when there is evidence of persistent hypoxemia in a clinically stable patient (on optimal medical therapy for at least 1 month).
   b. Clinically unstable patients should be prescribed oxygen therapy and reassessed at 1 to 3 months because up to 50% of patients will not require LTOT.

NOTE: Medicare and the Office of the Inspector General claims reviews demonstrate that 50% of all new patients receiving LTOT are discontinued from the therapy prior to 11 months, and nearly 40% are discontinued from the therapy before 6 months. Natural patient attrition may account for much more LTOT discontinuation then previously recognized.

2. Titrate to an adequate Spo_2 for each condition including rest, exercise, and sleep (when practical)
3. Completion of the Certification of Medical Necessity ([CMN] Form DME 484.03) as required by Medicare or other payors
4. Provide oxygen prescription for the durable medical equipment (DME) supplier
5. Ongoing assessment of patient's needs and compliance
    a. Assurance of patient education through DME provider with knowledge that LTOT must be used a minimum of 15 to 18 h/d; it is critical that the physician periodically reinforce reasons for LTOT need and importance of adherence
    b. Assessment of risk to the patient and family (eg, smoking while using oxygen creates a hazard to the patient and their environment)
    c. Periodic reassessment of oxygen prescription is advised, including oxygen titration by Spo_2 measurement because patient needs may change. The Centers for Medicare and Medicaid Services require that LTOT be recertified at 12 months but retesting of Pao_2 or Spo_2 is not necessary. The recertification should involve a face-to-face evaluation by the prescribing physician. Subsequent recertification is not necessary following the initial 12 months of use. The CMN should be revised, not recertified, after any substantial change in need occurs (eg, device, daily use).

D. Prescribing Oxygen

1. Optimal medical regimen for LTOT
    a. Optimal LTOT should be continuous oxygen therapy (24 h/d) with ambulatory capabilities for all patients that are actively mobile beyond the stationary delivery system.
    b. Ambulatory oxygen systems should ideally weigh less than 10 lb and preferably 5 lb to 8.5 lb. The 10-lb recommendation is not evidence based and derived from the Fifth Oxygen Consensus Conference. Similarly, there is no evidence regarding the 5 lb to 8.5 lb range, nor is this supported by expert consensus. Experts suggest the portable device be one that meets the patient's clinical and lifestyle needs, and one that provides oxygen at an equivalent of 2 L/min for > 4 to 6 h.
    c. Emergency supply of oxygen (usually E-cylinders) should be prescribed for the patient's home as an emergency backup. The accrediting agencies provide guidance on the type of emergency backup oxygen source, as well as the volume.
    d. An intermittent flow conserving device should be considered for patients who use a portable oxygen system if adequate Spo_2 is achieved with the specific device.

NOTE: Intermittent flow conserving devices do not give a flow rate (L/min). They actually administer a predetermined bolus (mL per breath), and the volume delivered in a given minute varies based upon respiratory rate, size of the bolus volume, and principle of operation for that specific device. Studies show that titrated intermittent flow conserving devices generally produce an Spo_2 equal to continuous flow for most stable users of LTOT; however, some patients may not adequately achieve targeted Spo_2. This can hold true for both rest and exercise conditions. A device setting (eg, 2) may not be an equivalent to the continuous flow of 2 L/min. The Medicare CMN form requires that the physician define liter flow (L/min) settings simply because reimbursement is tied to it; different reimbursement rates are based upon < 1 L/min, 1 to 4 L/min, and > 4 L/min requirements. However, regardless of oxygen delivery device, the LTOT prescription should focus on titration to a targeted Spo_2 because adequate oxygenation is the outcome, not L/min or a device-specific intermittent flow conserver setting. The established benefits of oxygen therapy in section A are based on the assumption that the prescribed LTOT setting results in adequate oxygenation and are based on studies performed prior to the introduction of intermittent flow conserving devices.

2. Oxygen flow rates

    a. Rest: The flow of oxygen (L/min and/or intermittent flow device setting) needed to correct hypoxemia should be determined by measurement of Spo_2 or Pao_2 when LTOT is initiated.

    b. Exercise: Higher oxygen flows are often necessary during exertion, so flow rates during exercise should be determined. The difference in oxygen flow necessary to correct hypoxemia at rest and during exercise may be magnified, or not achieved, by various types of intermittent flow devices. Oxygen titration should be performed with the patient wearing the specific conserving device.

    c. Sleep: While oxygen flow rate can be determined by nocturnal oximetry, oxygen flow rates are often increased by an estimated 1 L/min during sleep. If the patient develops signs of cor pulmonale despite adequate daytime oxygenation, nocturnal monitoring and titration should be considered. Intermittent flow devices are generally not recommended during sleep; however, there are device-specific studies supporting the nocturnal use of titrated intermittent flow devices in stable patients receiving LTOT.

    d. Target values: A Pao_2 of 60 to 65 mm Hg or an Spo_2 > 90% are acceptable.

A typical oxygen prescription for a mobile patient should provide:

1. Fifty feet of tubing and nasal cannula for home use when a stationary oxygen concentrator is used.
2. Portable oxygen system for mobility with an oxygen conserving device, with the patient's oxygen level titrated to an Spo_2 of > 90% during exertion and rest. The length of tubing should be specified by the manufacturer for a portable oxygen device.

Summary

A. Patient Selection Criteria for LTOT

- Stable course of disease on optimum medical therapy (bronchodilator, antibiotics, and corticosteroids)
- Arterial blood gas measurement or Spo_2 while breathing room air for at least 20 min
- Room air Pao_2 that is consistently ≤ 55 mm Hg (or Spo_2 ≤ 88%) or consistently 56 to 59 mm Hg plus clinically diagnosed pulmonary hypertension, cor pulmonale, or hematocrit concentration > 55%.
- Patients who have a normal oxygen concentration in whom Pao_2 falls to < 55 mm Hg or Spo_2 falls to < 88% with exercise. Decreased level of dyspnea and increased exercise capacity may be demonstrated with the use of supplemental oxygen.
- Patients with evidence of clinically significant nocturnal oxygen desaturation.
- Patients at risk for OSA should undergo a formal overnight sleep study.

B. Oxygen Dose

- Usually continuous flow by nasal cannula
- By intermittent flow device as long as adequate oxygen saturation is demonstrated
- Lowest oxygen setting to raise Po_2 to 60 to 65 mm Hg or oxygen saturation to > 90%
- Testing should be done during exertion, as well as during sleep, where practical. A good rule of thumb for sleep is to increase baseline liter flow by 1 L/min in such circumstances.

Matching oxygen equipment to the patient

A. How long it takes a patient to inhale?

With a pulse-dose setting, an oxygen conserving device delivers an oxygen bolus, or volume, during the initial part of inhalation, which might last a fraction of a second. How quickly that bolus is delivered is important. For example, for some patients, a bolus of 20 mL delivered at 400 milliseconds might not be adequate, and the bolus might have to be delivered in 300 milliseconds. Often, prescribing physicians are not aware of such issues.

The respiratory therapist must also know what the bolus and delivery times are for each unit in order to give a proper dose for the patient's respiratory mechanics. Therefore, all health-care professionals should coordinate closely, especially as oxygen delivery devices are becoming more sophisticated.

B. Is the patient's respiratory status deteriorating?

If the patient's respiratory status is rapidly deteriorating, an initial flow rate of 2 L/min may need to be increased to 4 L/min. In this instance, the health-care provider should choose a device that is able to scale to the patient's future needs.

C. Can the patient be sustained on a portable oxygen concentrator (POC)?

Some POCs on the market are pulse only or have a maximum continuous flow of 3 L/min, which might not be adequate for some patients. It is important to determine if the selected oxygen device can meet the clinical needs of the patient. Oximetry and titration must be performed at rest and while exercising.

D. Can the patient walk or exercise on a pulse setting?

Patients prefer portable oxygen devices that deliver pulsed oxygen because these are lighter and very portable. Such a device, whether a POC or lightweight cylinder, generally performs very well at rest, but upon exertion, the minute ventilation increases and respiratory rate (RR) may increase to 15/min or 25/min. Different POCs use different oxygen delivery methods. Some use a fixed minute volume such that, as the RR increases, the bolus decreases, similar to normal physiologic breathing. Other devices use a fixed bolus volume, and the minute volume increases as the RR increases. Some POCs may have a maximum oxygen production (ie, 750 mL/min) that is less than the patients F_{IO_2} demand and will not be adequate for use with exertion. In reality, the same risk occurs with continuous flow if the patient's oxygen level is not titrated at exertion.

E. Is the patient in a pulmonary rehabilitation program?

Patients often will join a pulmonary rehabilitation program. Usually, they are instructed to stow their POC and are given a different device provided by the program, and they exercise on a different device that provides a different amount of oxygen. Patients should exercise on their device instead.

F. Is the device portable?

Patients are demanding systems that provide them with more mobility; at the same time, oxygen suppliers are looking for ways to transition to a nondelivery oxygen business. These factors are increasing the demand for POCs, transfilling systems, and other lightweight ambulatory systems.

People requiring oxygen are generally elderly and have other comorbid conditions that limit their ability to transport or operate portable equipment. Portable, then, becomes a relative term; a full M6 cylinder weighing approximately 4 lb is clearly much lighter than a full E-cylinder weighing approximately 15 lb, with a cart. However, even 4 lb can be heavy and not at all portable to some people. Many patients prefer to pull their portable oxygen system on wheels, the same way many of us choose to transport luggage. Finally, portability also includes whether the patient can lift a POC. With higher, continuous-flow POCs, these devices become heavier at 16 to 22 lb. The patient needs to be able to lift this weight at least 2 ft off the ground to get the device into and out of a car.

Given the myriad of devices of varying size, shape, and weight, the "art" of portable LTOT becomes matching the patient's clinical and lifestyle needs to the device that best fits that patient. There is no agreement on what is portable for every patient under every circumstance.

NOTE: Medicare claims data and manufacturer data indicate that, for ambulatory delivery, traditional cylinders are still the primary system, followed by concentrator filling systems (eg, HomeFill; Invacare Corporation; Elyria, Ohio) that outsell POCs nearly 5:1, followed by POCs, then, lastly, liquid. Traditional cylinder and concentrator-filled cylinders generally use conservers.

LTOT in Pediatrics

Many of the delivery and specific oxygen systems apply to both pediatric and adult patients. The etiology of respiratory insufficiency and oxygen requirements may be different in pediatrics; however, the equipment, route and delivery mechanisms are similar.

- Ideally, oxygen saturation is kept ≥ 90; 90% of the time on oxygen is a reasonable starting point. The specific target saturations will change in some instances based on the diagnosis.
- The funding for oxygen equipment in pediatrics varies by state for Medicaid patients and depends on individual insurance carriers and company guidelines.
- Finally, extension tubing for small children and neonates should be no longer than 15 ft to avoid washout, especially in patients receiving low flow. At no time for older patients should the tubing exceed 50 ft.

LTOT Payment

Oxygen is a medication in gas form subject to precise administration and dosage. The system to deliver oxygen is the equipment. While the two should not be separated (it would be like paying for the syringe but not the drug inside it), most payors treat home oxygen therapy not as a therapeutic intervention but as an equipment need because this is how Medicare has classified oxygen equipment for decades. Attempts to have Medicare reclassify oxygen therapy as a therapeutic intervention or pharmacologic agent have so far been unsuccessful.

Payment for oxygen equipment and systems varies considerably between payers and Medicare. Medicare pays for a stationary unit to be used within the home and pays a separate payment for any system used for portable needs. Under the various categories of equipment that qualify for reimbursement are concentrators or liquid-based systems, portable systems of tanks or liquid oxygen (LOX) reservoirs, and systems that in some way combine the two separate types for a single comprehensive system.

Comprehensive systems are those that have a concentrator that also fills tanks for portable use, often referred to as "home cylinder filling" systems. Some patients can be adequately treated with a portable concentrator. Medicare will pay for such a system with a combined payment that equals the total of the separate payments for a stationary system plus a portable system.

Medicare and most payors are recognizing newer technology. Both concentrator-cylinder home filling systems (transfill portable concentrators) and POCs have a slightly higher allowable payment and different Healthcare Common Procedure Coding System codes. These are used by Medicare and are monitored by the Centers for Medicare and Medicaid Services. For example, certain transfilling devices, such as the HomeFill system, are identified as K0738, and POCs are identified as E1392. These codes allow nearly double the flat add-on payment for a standard cylinder or liquid portable unit.

Currently, Medicare pays for 36 months rental and then holds the supplying company liable to serve the patient without further payment (except for contents of tanks and LOX systems) for an additional 24 months before another 60-month billing/service cycle may begin. Coverage for oxygen equipment is according to the customary 80%/20% split of payment responsibility.

Private insurers tend to follow the Medicare model with some variation and, at times, increased reimbursement amounts. Individual benefits vary. Therefore, it must be ascertained how much service and equipment will be covered by insurance carriers and how much the patient may be liable for. It is possible that where benefits are selected in "cafeteria" plans, durable equipment coverage may not be a selected benefit. In such a case, an otherwise well-insured patient will have no coverage for oxygen therapy.

Uninsured or underinsured: If patients are uninsured or underinsured and are unable to pay the full price for oxygen equipment, most equipment suppliers will agree to a reduced payment plan or even provide equipment and services on a pro bono basis. Negotiation between the patient, physician, and the equipment provider usually yields a plan for oxygen supply.

NOTE: The oxygen supplier's responsibility is to supply the amount of oxygen as prescribed by the physician. If the patient is ambulatory, and if it is prescribed by the physician, the oxygen supplier is responsible for supplying portable oxygen equipment. The supplier may not be able to supply because patient's insurance plan only covers one type of equipment. The equipment must be cleared by the US Food and Drug Administration for use and recognized and covered under the Medicare and other insurance payor regulations. The supplier is not responsible for the weight, portability, or ease of use of the oxygen equipment. If the equipment meets the patient's oxygen requirement but not lifestyle, there may be little incentive to change. Whether lighter equipment is ultimately supplied to the patient depends on the supplier's resources and philosophy. For these reasons, it is of major importance that the physician becomes more involved in medical prescription writing to ensure that a patient's physical, social, and medical needs are met.

Air Travel With Oxygen

Patients who require oxygen at ground level will require it during flights and may need to increase their oxygen concentration while flying. It should also be recognized that those who do not use oxygen, but who have an Sa_{O_2} just above 90% on room air and at rest, may require oxygen during flights. This is due to the fact that air cabins are pressurized to 8,000 ft (about the elevation of the Grand Canyon). There are formulas to predict whether a patient's low, but acceptable, oxygen levels on the ground and at rest will desaturate while flying. Practically, these formulas are hardly used. Clinicians usually rely on their experience in prescribing oxygen to their patients who fly.

Patients who require in-flight oxygen must know their airline's policy regarding in-flight oxygen and whether the airline supplies oxygen because not all airlines do. Carriers will not allow oxygen tanks on flights unless they are empty. In this case, the carriers will supply the patient with oxygen at a charge per flight segment. A written request for the amount of oxygen must be obtained from the physician. Usually, the patient will contact the airline, who will then fax their documents to the physician's office. The physician's office will complete the documents and fax them back to the airline. This process could take a few days; therefore, planning is required.

POCs are allowed on most domestic flights, and they have revolutionized air travel for patients who can obtain them from their oxygen supplier. Passengers who require oxygen must also check with their airline to ensure their device is on the list of current, approved devices. Different airlines have different rules regarding what devices they will allow on their airplanes. Passengers must also be sure they have adequate battery power for the entire journey.

Another benefit of POC is that it can be used at the patient's destination without the need for oxygen set up. However, certain caveats must be noted. If the POC delivers both continuous-flow oxygen and pulse-dose oxygen, it will weigh 18 to 19 lb, and patients must be able to drag this weight. If the patient has a POC under 10 lb, then the patient must be using a pulse-dose oxygen device, and proper testing should have been performed to ensure delivery of adequate oxygen while the patient is awake at rest, upon exertion, and while he or she sleeping.

Some airlines require traveling with an adequate number of fully-charged batteries to power the POC for no less than 150% of the maximum flight duration. In many cases aircraft electrical outlets may not be reliable sources of power for electronic respiratory assistive devices, and some airlines do not permit passengers to use power outlets to use or charge these devices.

Due to increased security measures, patients may require a note from their doctor stating what the equipment is for and that it is needed for travel.

Appendix A

Home Oxygen Equipment

There are three types of equipment available for providing home oxygen therapy.

1. Liquid oxygen, which now makes up < 5% of home oxygen therapy and is not available in many markets, as a myriad of DME manufacturers have left the business
2. Concentrated compressed oxygen (oxygen concentrators), which compromises >90% of stationary systems
3. Compressed gas cylinders, which are used almost exclusively for ambulation

Concentrator (stationary electromechanical device) and concentrator filling system:

- > 85% oxygen purity (usually 92% - 96%)
- Requires only periodic check and service
- Electricity cost generated
- Heat generated during operation
- Noise generated during operation
- Portable accommodation is adjunctive equipment

Stationary Oxygen Concentrator

Cylinder filling system allows the patient to refill small cylinders in the home.

Supply is variable according to how much can be carried with the user when away from base

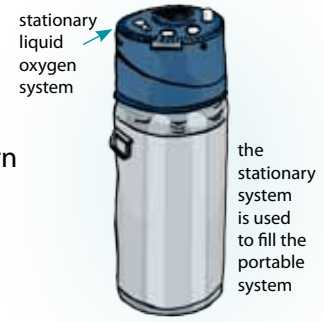
LOX + portable LOX devices:

Large reservoir stationary "base unit"

- Weighs 100+ lb

Requires regularly scheduled filling according to consumption pattern

- Flow range up to 6 L/min
- 99.9%+ oxygen purity



Stationary Liquid Oxygen System

Smaller portable devices

- Filled as needed from supply in stationary reservoir
- Weighs 3.5 to 15 lb
- Flow range up to 15 L/min
- 99.9%+ oxygen purity

Stationary Liquid Oxygen System

Oxygen concentrators + compressed gas cylinders or POCs

Stationary electromechanical device

Chemically separates nitrogen and oxygen from room air drawn into device – nitrogen "exhausted" to environment – oxygen compressed and stored for delivery as metered flow

- Weighs > 45 lb
- Electrically powered
- Flow range up to 10 L/min
- > 85% oxygen purity

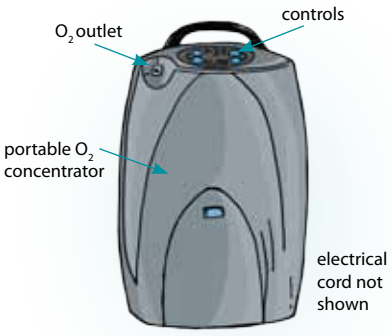
Compressed gas cylinders

- Commercially filled with 99.9%+ pure oxygen; OR
- Filled from concentrator with filling capabilities (85%+ oxygen purity)
- Weighs 3 to 15 lb
- Flow range up to 15 L/min (most up to 6 L/min)

POCs

Chemically separates nitrogen and oxygen from room air drawn into device – nitrogen "exhausted" to environment – oxygen compressed and stored for delivery as metered flow

- Weighs 7 to 20 lb
- A/C, D/C, and battery powered
- > 85% oxygen purity
- Only personal oxygen supply system approved for air travel



Portable O_2 Concentrator

LOX

- 99%+ oxygen purity
- Requires delivery of supply at intervals
  - No electricity
  - No operating noise
  - No heat generation
- Portable is filled from base unit
- Duration away from base is limited by portable supply and consumption rate

POC

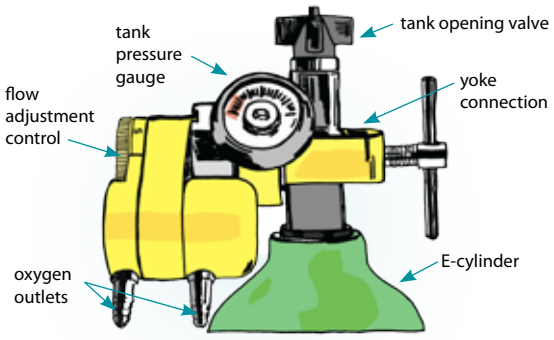
- > 85% oxygen purity (usually 92% - 96%)
  - Can serve as both stationary and portable supply for select users
  - Production capacity from 500 mL/min to 3 L/min
- Requires only periodic check and service
  - Electricity cost generated
  - Battery cost involved
  - Heat generated
  - Noise generated during operation
  - Portability is a feature of the system (limited by size/weight)
  - Duration is limited by power source availability

Oxygen Conservation Devices (OCD):

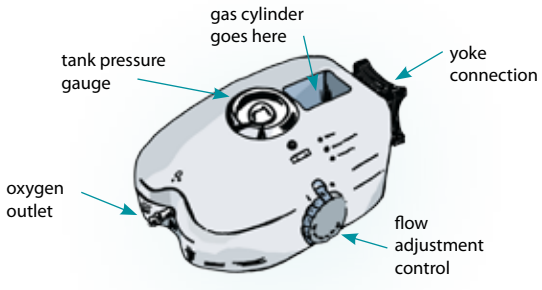
- Oxygen metered on demand – only during inspiration
- Flow range settings 0 to 6 L/min
- Some deliver fixed-volume bolus for each breath
- Some deliver variable flow on demand during each breath

One system can deliver multiple bolus volumes according to changes in the patient's respiratory rate

- Some are pneumatically regulated/controlled
- Some are electronically regulated/controlled



Pneumatic Oxygen Conserving Device



Electronic Oxygen Conserving Device

- Reduction in "wasted supply" compared with continuous flow devices
- Some devices can exceed dose-delivery of same setting as continuous supply
- Some devices fail to deliver doses equivalent to continuous flow at same settings

"Settings" between devices are NOT equivalent (2 L/min may not equal 2 L/min from one device to another)

- All oxygen systems include some number of OCD options
- There are more than 35 compressed gas cylinder-compatible OCDs
- Suppliers tend to stock multiple devices to cover the needs of a wider user population
- All LOX systems feature at least one portable device that is an OCD
- ALL POCs are also OCDs

Selection of a suitable OCD can ONLY be determined using "titration to desired saturation"

"Delivery-less" oxygen systems, also called "home filling" systems

Oxygen concentrator base unit with adjunct capacity to fill compressed cylinders for portable supply

Concentrator output > 85% oxygen purity (usually 92% - 96% purity)

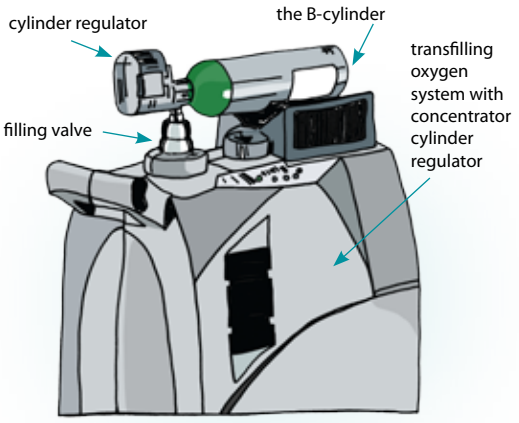
Concentrator filled cylinders are pressurized to 2,000 psi and filled with 93% +/- 2% (>90%)

All features of concentrator as stationary device + ability to produce portable supply

Fills compressed cylinders by redirecting a portion of flow OR using separate concentrator unit

Requires only periodic check and service

Requires no support/delivery service for portable supply



Transfilling Oxygen System With Concentrator Cylinder Regulator

All of these systems are suitable for delivery of oxygen using "low-flow" devices

- Nasal cannula
- Transtracheal catheter
- Reservoir cannulas and pendants
- Oxy-View (Oxy-View, Inc.; Engelwood, Colorado) glasses
- Some mask types

Remember:

- No system is inherently "better" than another. Each system has both positive and negative features.
- Oxygen systems should be tailored to the user based on: (1) supply needs – how much "flow (or volume)" is required and (2) handling – size and weight of portable adjuncts
- The higher the demand, the greater the limitations in equipment options.

Appendix B

Airline Web Sites

www.continental.com

Disability desk: (800) 228-2744

www.aa.com

Regular reservations: (800) 433-7300 (no disability desk)

www.jetblue.com

Regular reservations: (800)-JETBLUE or (800) 538-2583 (no disability desk)

www.delta.com

Regular reservations: (800) 221-1212 (no disability desk)

www.britishairways.com

Regular reservations: (800)-AIRWAYS or (800) 247-9297 (no disability desk)

www.airfrance.com

Regular reservations: (800) 237-2747 (no disability desk)

www.virginatlantic.com

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