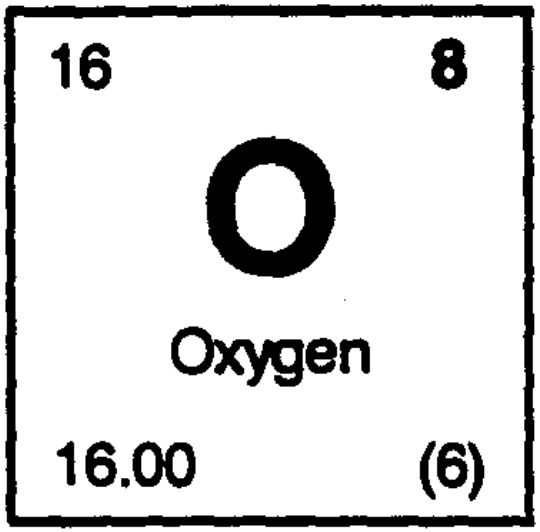


Options Available for Oxygen Users

Ryan Diesem, Valley Inspired Products

About Me

What I Am:

* 12+ years of experience at Valley Inspired Products
  * Research Manager/Technician for a variety of respiratory product testing projects since 2003
* Co-Author with Bob McCoy of 2007 Guide to Understanding Oxygen Conserving Devices
* Author/Presenter of various consumer articles and peer-reviewed abstracts

What I Am Not:

* Doctor, RRT, Pulmonary Specialist
  * I cannot recommend/prescribe therapy options or give informed clinical information on your health needs.
  * I am happy to discuss the equipment, their characteristics, and what to look for when considering oxygen delivery systems, but *technically* I cannot give you clinical advice.

Preview

This presentation will cover the following:

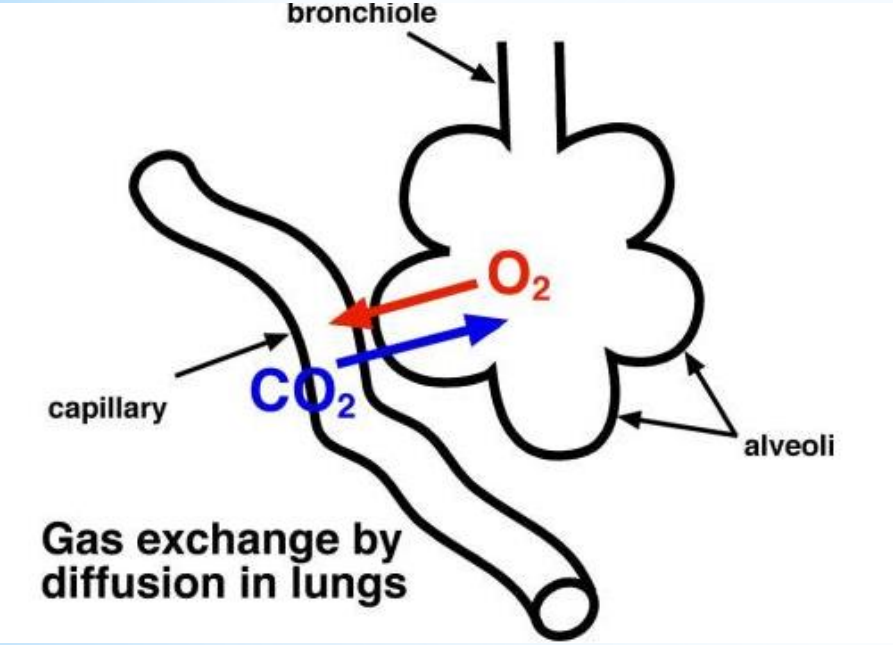
* Basics of Oxygen Therapy
* Brief History of Oxygen Equipment and Systems
* Discussion of Commonly Used Oxygen Equipment
  * Product Descriptions
    * Significant Differences Between Systems and Products
  * Extra Emphasis on Portable Concentrators (POCs)
    * Newest and Increasingly Popular Oxygen System
* What to Look For Based On Your Needs
  * Wide Product Variability – Know Capabilities Before You Buy

O_2 Basics

O_2 Basics

Why Oxygen Therapy?

* To raise/maintain users' oxygen saturations (SaO_2)
  * Lack of adequate oxygenation stresses heart, other organs
  * "Normal" SaO_2 : 96-99%
  * If SaO_2 <88%, O_2 prescribed
* Improves survival rates of those w/ $COPD_{1,2}$
* Helps reduce hospitalizations and lengths of $stay_{3,4}$



How Does Oxygen Therapy Work?

* Ambient air contains 20.9% O_2
  * For those with O_2 needs, this isn't enough
* Oxygen therapy increases the amount of oxygen in the air inspired by the user (FiO_2)
  * Inspired air can contain anywhere from 20.9% to 100% O_2 depending on delivery method
  * Increasing FiO_2 = Oxygen has greater capacity to reach gas exchange units in lung, where O_2 is transferred to bloodstream

O_2 Basics

How O_2 is Delivered

Continuous Flow (CF, or CFO)

* Oxygen delivered throughout entire breathing cycle.
* Can be delivered via cannula, mask, transtracheal (TTO)
* Wasteful- O_2 delivered during exhalation is not useful oxygen.

How O_2 is Delivered:
Intermittent Flow (IF, or Pulse)

* Oxygen "On Demand"
* Oxygen is delivered in specified volumes during inspiration.
* Two Common Methods:
  * Fixed Pulse Volume
    * At a given setting, pulse volumes is the same regardless of user's breath rate
  * Minute Volume
    * At a given setting, pulse volume is reduced as user's breath rate increases
* Oxygen is conserved, thus "oxygen conserving devices" (OCDs).
* Typically delivered via cannula, or TTO

O_2 Basics

Delivery Fundamentals – Fixed Pulse Volume vs Minute Volume

* Fixed Pulse – Pulse volume is not breath rate dependent

* Minute Volume – Pulse volume is breath rate dependent
  * Mimics CFO

* If you are using a minute volume delivery device, it is important you understand that if you leave the setting unchanged, you actually get less oxygen per breath at active breath rates than you do at resting breath rates.

Dose Volume Comparison Fixed Vs. Minute Volume Delivery			
	15 BPM		
	Unit 1	Unit 2	
Setting 2	*24 mL*	*33 mL*	Setting 2
Setting 4	*48 mL*	*67 mL*	Setting 4
Setting 6	*72 mL*	*100 mL*	Setting 6
	25 BPM		
	Unit 1	Unit 2	
Setting 2	*24 mL*	*20 mL*	Setting 2
Setting 4	*48 mL*	*40 mL*	Setting 4
Setting 6	*72 mL*	*60 mL*	Setting 6

Note that for Unit 1, dose volumes are fixed at both breath rates; For Unit 2 the volumes decrease as rate

O_2 Basics

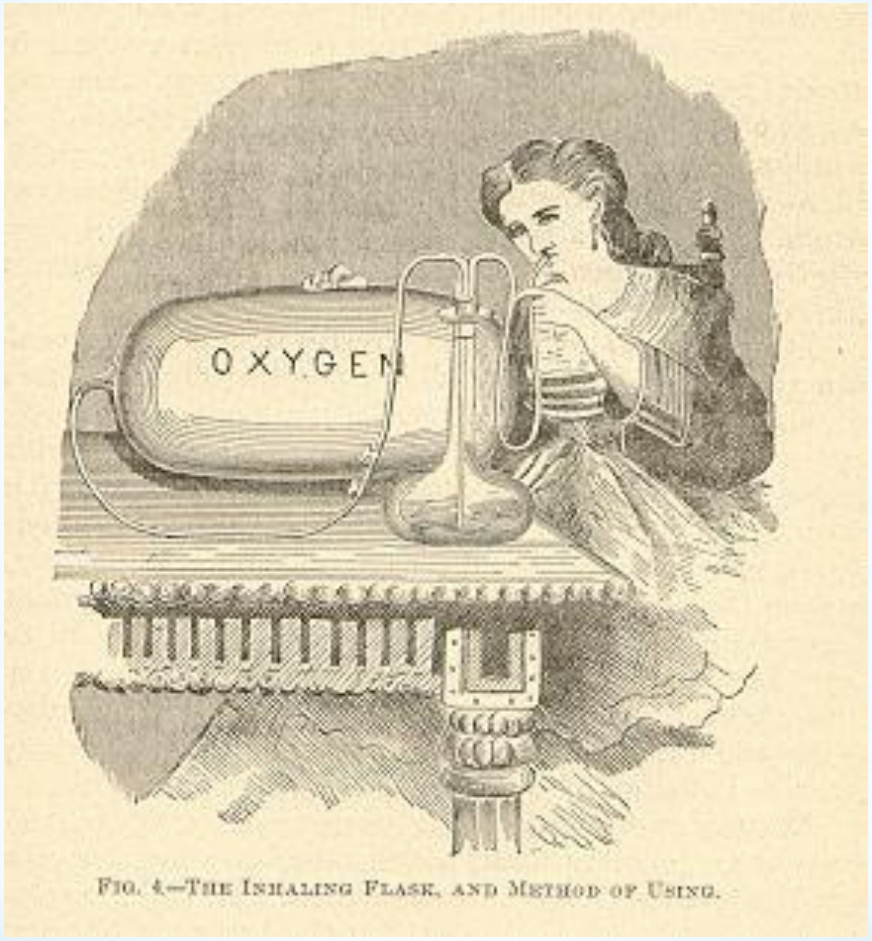


FIG. 4.—THE INHALING FLASK, AND METHOD OF USING.

History of O_2 Delivery Systems

History of O_2 Delivery Systems

Early Therapy Options

* From 1950s, O_2 therapy was typically administered in the hospital, though cylinders could be sent home with user.
* Continuous Flow only.
* O_2 usually used as a "last resort" to combat disease as opposed to supporting daily activities.[5]
* Mid-60s saw introduction of ambulatory (portable) options.
  * Cylinders, Liquid O_2 (LOX).
  * Heavy. 10-20lbs.
* Stationary Concentrators were introduced for home use in 1970s.
  * Very heavy- 90lbs.
  * "Low Flow" – up to 4-5 LPM.

1980s-2000s

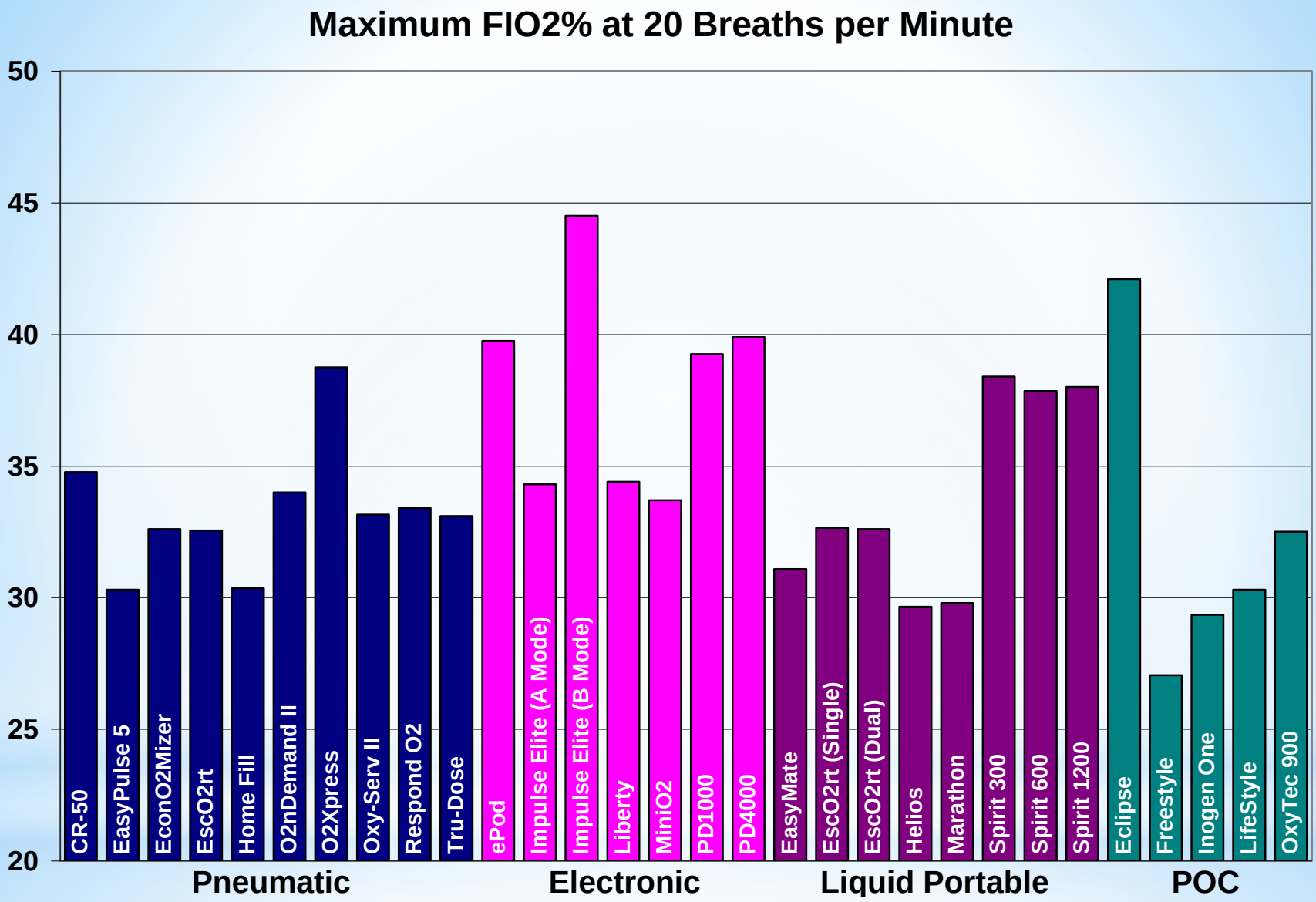
* Landmark NOTT Study shows LTOT improves COPD survival rates.
  * LTOT is no longer the “last resort”.
* Intermittent Flow devices introduced in early 1980s (OCDs)
  * OCDs applied to regulators and LOX portables, prolonging tank life and allowing for greater ambulation.
  * Introduced significant product-to-product performance variables

History of O_2 Delivery Systems

OCDs Crowd (and Cloud) the LTOT Marketplace

* By 2000 OCDs are common. They are often assumed to deliver O_2 "equivalent" to CFO. This is an incorrect assumption.
* Primary variables that determine FiO_2 in CFO therapy are O_2 flow rate, user breath rate, user tidal volume, and oxygen purity. FiO_2, then, is relatively predictable.
* OCDs add many additional variables that can affect FiO_2:
  * Dose volume, triggering sensitivity, and flow delivery characteristics (such as peak flow and delivery time) all will impact FiO_2.
  * Each product is different, with different capabilities, yet many assume one device will perform similarly to another.

History of O_2 Delivery Systems



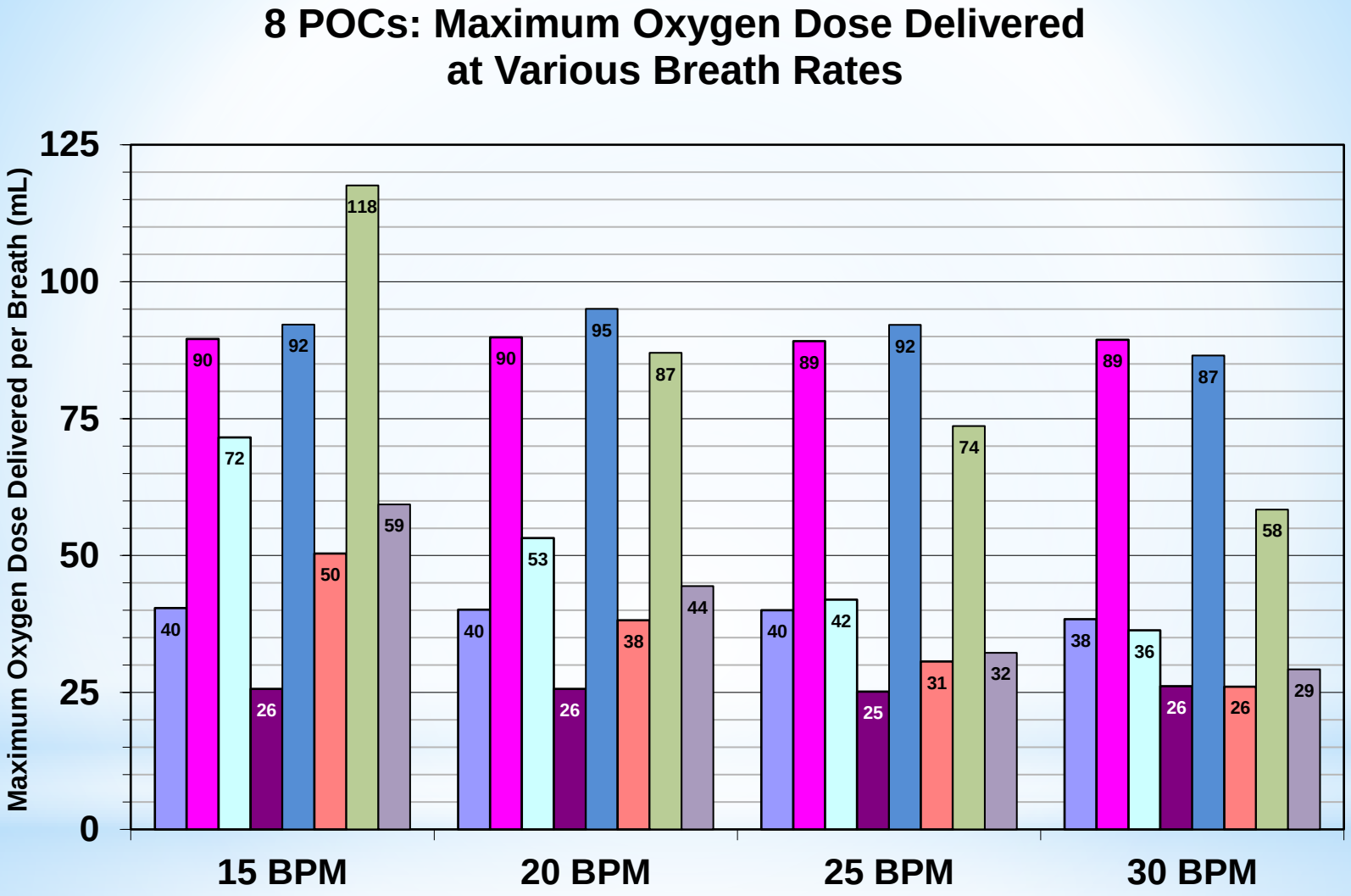
History of O_2 Delivery Systems

McCoy R, Diesem R. 2007 Guide to Understanding Oxygen Conserving Devices, Valley Inspired Products

2000s – The POC Era

* 2002- First modern portable oxygen concentrator (POC) introduced.
  * 10 lbs, w/battery, IF (pulse) only
* 2005 – First CF capable POC
  * 19 lbs, w/battery and cart, up to 3 LPM CF, up to 96 mL pulse
* 2007 – 2012: No less than 12 POCs released, ranging from 2 lbs to 18 lbs.
* As with OCDs, product capabilities widely vary. Education is vital.

History of O_2 Delivery Systems



History of O_2 Delivery Systems

Where We Are Today

* POCs are the “hot product” in LTOT, yet many users still receive the old standbys- stationary concentrators and compressed gas cylinders with CF regulators- as their only supplied O_2 equipment.

* Due to Medicare cuts and other fiscal concerns, LOX is being phased out by many providers- users needing LOX, especially users with high flow needs, are finding they have limited options.

* Product variability in O_2 systems is better understood today than even just 10 years ago, but many misconceptions still persist.

History of O_2 Delivery Systems

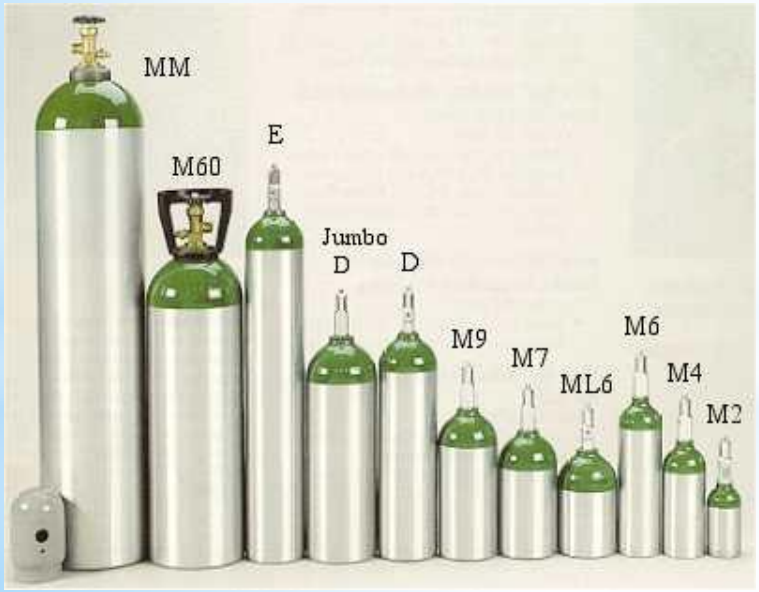
The Equipment

The Equipment

Stationary Concentrators

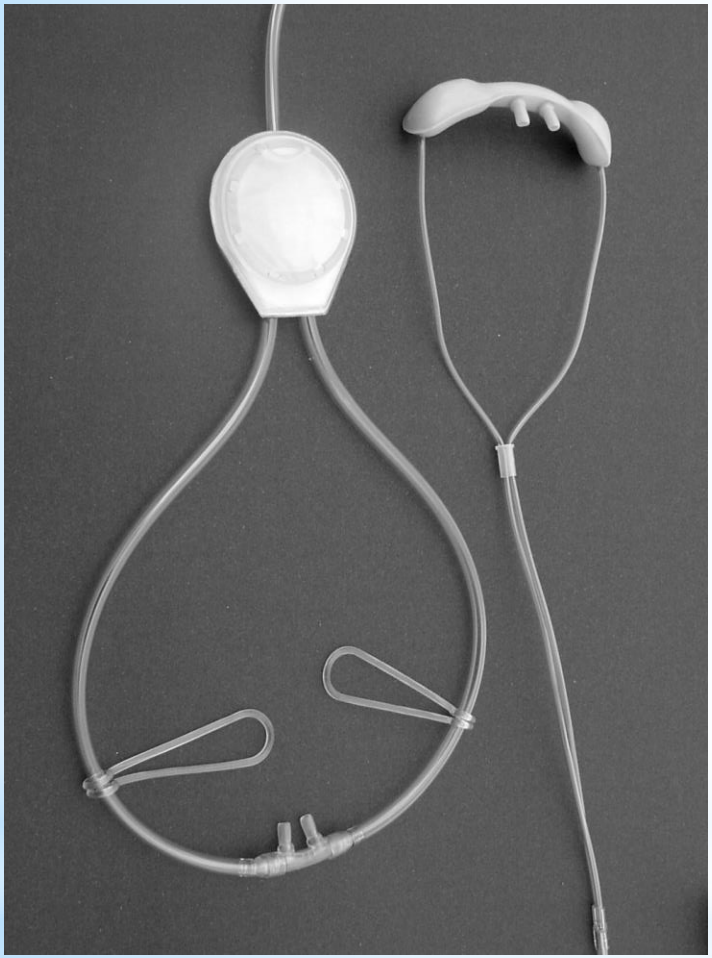
* Most O_2 users have one
  * Primarily used in home setting
  * Most weigh 25-50 lbs
  * Units *are* getting smaller, lighter
* Little variability in capabilities
  * CFO only, give 87-95% pure O_2 by separating O_2 from room air
* Most units 0-5 or 6 LPM, some up to 10 LPM; meet most users' needs
* Workhorses, typically need little maintenance
* Will increase electric bill!
  * Newer models more efficient

Compressed Gas Cylinders



* High purity oxygen – ~100%
* Fitted with CFO/OCD regulators
  * Can meet most users' needs if fitted with proper regulator and interface
  * Variety of tank sizes for portability
    * Operating time dependent on regulator setting!
    * Often used as "backup" O_2 source
* Need to be refilled
  * $$$, time, inefficient
* Bulky, heavy, cumbersome
  * "Portability" is in the eye of the beholder.

The Equipment



Reservoir Cannulas

* Stores volume of O_2 in reservoir during exhalation
  * ~20 mL stored
  * Extra volume inhaled along with regular CF flow
* Must be used with CFO
  * Pulse devices may not trigger
* Allows for greater FiO_2 at lower flows
  * Can reduce flow settings needed for high flow users

The Equipment

Liquid Oxygen Systems

* CF/IF Portable units paired with large “base unit” for filling
* Can meet most users’ O_2 needs
* Portables can be worn, carted
  * LOX systems last longer than similar sized cylinders – greater ambulation
    * Most efficient form of storage
  * Evaporates over time
* Prone to frosting, freezing
  * Environment, setting may impact use
* Expensive- costs for LOX, base refilling; Medicare cuts affecting availability to many users

The Equipment

Concentrator Transfill Stations

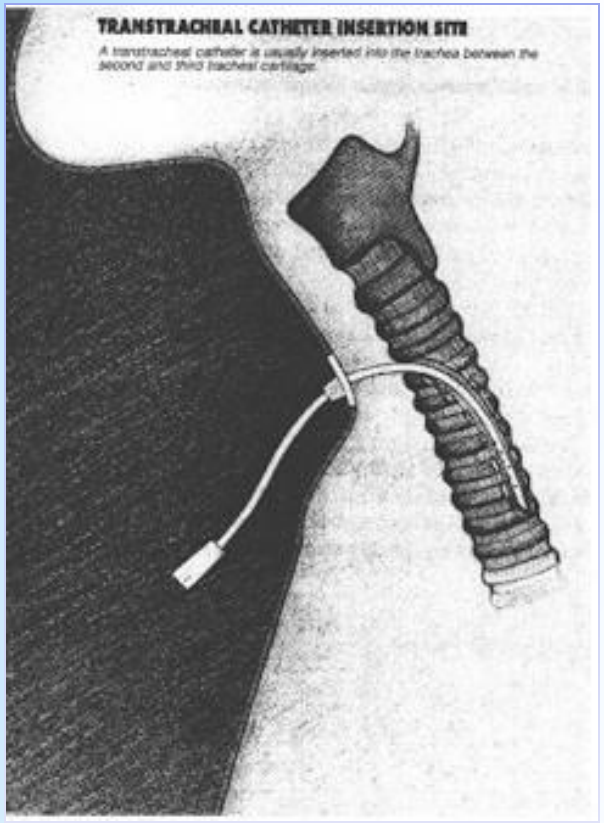
* Stationary unit fills gas cylinders
  * Users can fill portable cylinder as needed; may take a few hours each
  * In some cases, can be used simultaneously with O_2 therapy
* Some cylinders pre-fit with regulator/OCD; post-valve cylinders also available
* It's a cylinder, so not most efficient method of O_2 storage/delivery
* Eliminates need for provider refills
* Base unit not very portable

The Equipment

Concentrator O_2 Liquefier

* Takes O_2 from internal stationary unit and converts to LOX
  * Can produce 3 liters LOX/day
    * ~2600 L gas equivalent
    * 90-95% purity
* ~115 lbs, 3’ tall base unit
* Proprietary portable is provided
  * .3 L tank (similar to Helios/Spirit)
  * Pulse 1-4, 2 LPM CFO only
  * Cannot fill any other LOX portables on this device
* Not being marketed

The Equipment



Transtreacheal Oxygen Therapy (TTOT)

* Catheter inserted through a small hole made in the front of the neck and into the trachea
* TTOT can reduce O_2 flows/settings required to maintain SaO_2
  * O_2 delivered nearer to lungs
* Continuous and Pulse devices can be used with TTOT
  * Pulse device must use single lumen cannula
* No nose or ear discomfort due to cannula; face is clear of tubing

The Equipment

Non-Invasive Open Ventilation (NIOV)

* 1 lb. tidal-volume augmentation touch-screen ventilator
  * Requires compressed O_2 source
  * Increases FiO_2
  * Positive pressure generated by venturi effect; augments tidal volume, helps blow out CO_2 (similar to BiPAP delivery, but EPAP = 0)
  * Added volume dependent on setting, lung conditions
* Three activity level settings
  * O_2 delivery range of 50 – 250 mL
* Pillows-style nasal interface – larger than cannula
* 510(k) for homecare/institutional use, but no reimbursement code (yet) = expensive option

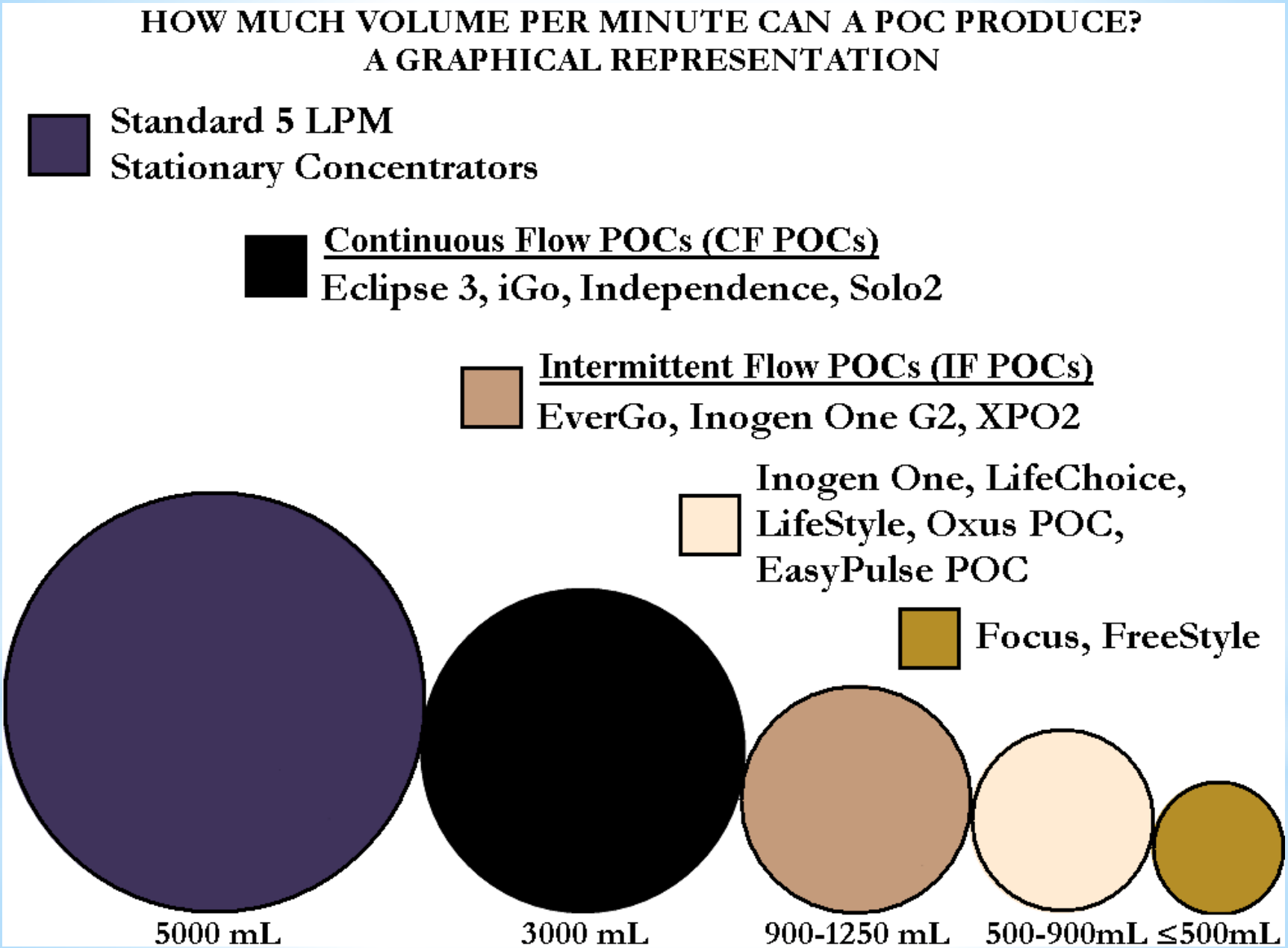
The Equipment

Portable Oxygen Concentrators

* Two types: IF POC and CF POC
* CF POCs feature both pulse and CF settings; IF POCs are Pulse ONLY
* IF POCs trade O_2 production for smaller size
  * Current IF POCs – 2-10 lbs
  * Current CF POCs – 10–18 lbs

The Equipment

HOW MUCH VOLUME PER MINUTE CAN A POC PRODUCE?
A GRAPHICAL REPRESENTATION



POC Portability

* All POCs come with rechargeable battery, AC/DC power cords (wall and car)
* Larger POCs have luggage carts; smaller POCs have straps (shoulder, waist)
* POCs are only O_2 system approved for flight travel, allowing users to bring equipment with them wherever they fly to

The Equipment

POC Limitations

* Battery operating life varies, can be unpredictable
  * CF delivery drains battery much faster than IF delivery
  * In IF modes, battery life dependent on setting and breath rate
  * If flying, the FAA requires enough batteries to last 150% of travel time- that could require a LOT of extra batteries.

* Accessories add 2-5 lbs or more to carrying weight
  * Batteries ~ 1-2 lbs, power cords/bricks 1-2 lbs, cart 1-2 lbs
  * CF POCs are larger than IF POCs and may be too cumbersome for some users to comfortably transport

* Users want smallest/lightest unit, but all POCs have different capabilities; the lightest unit may not meet users' O_2 needs

The Equipment

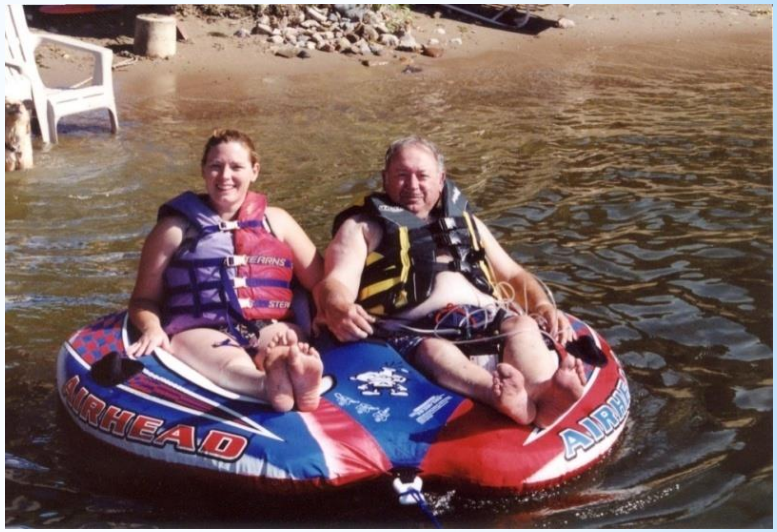
	Continuous Flow POCs						
	DeVilbiss iGo	Invacare Solo2	O2 Concepts Independence	Respironics SimplyGo	SeQual Eclipse 3/5	SeQual Equinox	
							
	Production and Delivery						
Maximum Oxygen Production (mL/min)	3000 mL/min (3.0 LPM)	3000 mL/min (3.0 LPM)	3000 mL/min (3.0 LPM)	2000 mL/min (2.0 LPM)	3000 mL/min (3.0 LPM)	3000 mL/min (3.0 LPM)	**Maximum Oxygen Production (mL/min)**
Available Settings	Pulse 1 to 6 Continuous 1 to 3LPM	Pulse 1 to 6 Continuous 0.5 to 3LPM	Pulse 1 to 6 Continuous 1 to 3LPM	Pulse 1 to 6 Continuous 0.5 to 2LPM	Pulse 1 to 6* Continuous 0.5 to 3LPM	Pulse 1 to 6* Continuous 0.5 to 3LPM	**Available Settings**
Pulse Delivery Type	Fixed Delivery 14mL per setting	Minute Vol. Delivery: Dose decreases as rate rises	Fixed Delivery 16mL per setting	Combination Fixed/Minute Vol. Delivery**	Fixed Delivery 16mL per setting	Fixed Delivery 16mL per setting	**Pulse Delivery Type**
	Dose Volumes per Breath*** 2 LPM Continuous Flow: 15 BPM: 44mL, 30 BPM: 22mL 4 LPM Continuous Flow: 15 BPM: 88mL, 30 BPM: 44mL 6 LPM Continuous Flow: 15 BPM: 133mL; 30 BPM: 66mL						
Maximum Delivered Pulse Volume	84mL	15BPM: 133mL 30BPM: 66mL	96mL	15BPM: 72mL 30BPM: 66mL	96mL*	96mL*	**Maximum Delivered Pulse Volume**
	Weight (Unit + Std. Battery); Add up to 10lbs for accessories						
Unit & Battery (approx.)	19 lbs	20 lbs	19 lbs (w/2 batteries)	10 lbs	19 lbs	14 lbs	**Unit & Battery (approx.)**
	Standard Single Battery Operation Times						
Approx. Battery Time at Pulse setting 2	4.7 hrs (20BPM)	3.5 hrs	2.9 hrs (20BPM)****	3.0 hrs (20BPM)	5.1 hrs (12BPM)	2.75 hrs (12BPM)	**Approx. Battery Time at Pulse setting 2**
	All Units Approved For Flight By FAA						
Max Altitude	13,123 ft	10,000 ft	13,123 ft	10,000 ft	13,123 ft	13, 130 ft	**Max Altitude**

	Intermittent Flow (Pulse Only) POCs								
	Airsep Focus	**AirSep FreeStyle 3**	**AirSep FreeStyle 5**	**Inogen One G2**	**Inogen One G3**	**Inova Labs Activox**	**Invacare XPO2**	**Oxus POC**	**Precision EasyPulse POC**
									
	Production and Delivery								
Maximum Oxygen Production (mL/min)	333 mL/min (0.33 LPM)	500 mL/min (0.5 LPM)	1000 mL/min (1.0 LPM)	1260 mL/min (1.26 LPM)	840 mL/min (0.84 LPM)	450 mL/min (0.45 LPM)	840 mL/min (0.84 LPM)	850 mL/min (0.85 LPM)	780 mL/min (0.78 LPM)
Available Settings	None Selectable	1 to 3	1 to 5	1 to 6	1 to 4	1 to 3	1 to 5	1 to 5	1 to 5
Pulse Delivery Type	Minute Vol. Delivery: Dose decreases as rate rises	Minute Vol. Delivery: Dose decreases as rate rises	Minute Vol. Delivery: Dose decreases as rate rises	Minute Vol. Delivery: Dose decreases as rate rises	Minute Vol. Delivery: Dose decreases as rate rises	Minute Vol. Delivery: Dose decreases as rate rises	Minute Vol. Delivery: Dose decreases as rate rises	Fixed Delivery 8.5mL per setting	Minute Vol. Delivery: Dose decreases as rate rises
	Dose Volumes per Breath* ** 2 LPM Continuous Flow: 15 BPM: 44mL, 30 BPM: 22mL 4 LPM Continuous Flow: 15 BPM: 88mL, 30 BPM: 44mL 6 LPM Continuous Flow: 15 BPM: 133mL; 30 BPM: 66mL								
Maximum Delivered Pulse Volume	15 BPM: 22mL 30 BPM: 11mL	15 BPM: 33mL 30 BPM: 17mL	15 BPM: 66mL 30 BPM: 33mL	15 BPM: 60mL 30 BPM: 30mL	15 BPM: 56mL 30 BPM: 28mL	15 BPM: 30mL 30 BPM: 15mL	15 BPM: 56mL 30 BPM: 28mL	43mL	15 BPM: 52mL 30 BPM: 26mL
	Weight (Unit + Std. Battery); Add up to 5lbs for accessories								
Unit & Battery (approx.)	3 lbs	4 lbs	6 lbs	7 lbs	5 lbs	5lbs	6 lbs	10 lbs	7 lbs
	Standard Single Battery Operation Times								
Approx. Battery Time at Pulse setting 2	1.5 hrs	2.5 hrs	2.0 hrs	4.0 hrs (est.)	3.0 hrs (est.)	4.0 hrs	2.5 hrs	3.0 hrs	3.2 hrs
	All Units Approved For Flight By FAA								
Max Altitude	10,000 ft	12,000 ft	12,000 ft	10,000 ft	10,000 ft	10,000 ft	10,000 ft	8,000 ft	9,000 ft

What To Consider In O_2 Delivery Systems

What To Consider In O_2 Delivery Systems

* Look for a device (or set of devices) that has the capability to adequately oxygenate at most or all daily activities
  * Resting, Exercising, Sleeping, Household Chores, Shopping, Traveling, etc.
* Remember, the smallest, lightest device may not meet most needs
* Think about the future – try to consider a product that can meet oxygenation needs today, and can meet them in the future when health conditions change



What To Consider In O_2 Delivery Systems

* Understand how the device delivers its oxygen
  * CF devices are less variable in their output than IF devices – 2 LPM is 2 LPM, whether from LOX or cylinders.
    * Purity – 100% VS. 90-95%, but FiO2 difference relatively minimal
  * Pulse devices widely differ in their output
    * "2" does NOT equate to 2 LPM, rather "2" equates to a certain volume delivered.
      * Ex. "2" on IF POC = 32 mL of ~93% pure oxygen, peak flow 5 LPM
      * "2" on IF OCD = 18 mL of 100% oxygen, peak flow 12 LPM
    * If the device uses minute volume delivery, know possibility that pulse setting needs to be increased at activity (higher breath rates) to maintain oxygen saturations

What To Consider In O_2 Delivery Systems

* Medicare cuts are affecting O_2 equipment availability
  * LOX users appears to be most affected- providers are dropping LOX
    * High flow oxygen users are especially affected- portable equipment options for high flow users are much more limited than for low flow users

* Be your own advocate – sadly, you cannot rely on providers or clinicians to understand oxygen equipment and how it may benefit you.
  * Educate yourself as much as possible
  * You may need to consider paying out-of-pocket for device you want

* One more time: Don't be tempted by smallest/lightest units that may not meet oxygenation needs- the first priority in selecting a device should always be that it oxygenates at most/all activities now and in the future.

Looking Ahead:

* No significant product developments foreseen in immediate future
  * Independence POC to 4LPM
  * New 5lb Respironics/SeQual POCs
    * Likely lower production than CF models
* Auto-adjusting delivery systems
  * Track SaO2, adjust pulse delivery as needed
  * Technology exists, patented, yet still in development limbo
* Advancements in oxygen separation/production
  * Membrane technology
  * Nanotechnology

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Thanks!

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