A Message to U.S. Congress members

The FDA Needs to regulate portable oxygen concentrator settings.

The setting numbers on Portable Oxygen Concentrators (POCs) should be equivalent to the Liters Per Minute (LPM) on my prescription. I need to know if a POC will fill the prescription I am required to have when purchasing one. Because the FDA has not regulated POCs setting numbers they have no meaning. My prescription is for 3 to 4 LPM which an Eclipse 5 POC will deliver. An Oxlife Liberty POC on a 4 setting is delivering the equivalent of less than 2 LPM, or 50% of what my prescription requires.

> A Pharmaceutical company would not be allowed to label one of their manufactured drugs in a way that obscures the medical dosage per pill.
>
> Currently POC manufacturers are purposefully obscuring the dosage of oxygen provided per setting on the portable oxygen concentrators they manufacture.

When I don't get the oxygen I need my health goes into a downward spiral just as it would if I wasn't getting the prescribed dosage on my other medications. If my health goes into a downward spiral, I will be prescribed more medications, have more doctor visits, and with COPD an increasing number of hospitalizations. The 1.5 billion dollar POC industry benefits from selling more POCS by misleading consumers (and Medical Professionals) to believe POC settings and LPM are equivalent because the FDA Licenses them. Medicare, Medicaid, Insurance Companies, and the people using POCs pay the increased medical costs!

In 2022 the POC industry had sales of $1.58 BILLION. By 2030 their sales are expected to at least double. If the FDA doesn't start regulating the POC industry the medical problems they create will also double. It will cost very little for the FDA to regulate POC settings so they are equivalent LPM and save Medicare, Medicaid, Insurance Companies, and the people using POCs Billions of dollars.

Continuous **F**low (CF) Medical oxygen is 99.5% pure oxygen and is measured in **L**iters **P**er **M**inute(LPM). An oxygen flow rate of 1 LPM means the patient will have 1 liter of oxygen flowing into their nostrils over a period of 1 minute. Approximately 1/3 of the oxygen flowing into their nose is inhaled and is the Inhaled Volume. The remaining 2/3 is not used. **P**ortable **O**xygen **C**oncentrators break a liter of oxygen into pulses of oxygen called boluses and send a bolus at the start of each breath using the liter of oxygen more efficiently. When comparing CF to pulse flow the inhaled volume divided by **B**reaths **P**er **M**inute (BPM) is the equivalent of a bolus.

A POCs maximum flow rate in **m**illi**l**iters per **min**ute (ml/min) is the amount of oxygen it is able to produce in 1 minute. For the purpose of comparing CF to pulse flow the maximum flow rate for CF is 1/3 of a LPM or 330 ml/min. Most POCs have a bolus size that is determined by dividing the maximum flow rate by the number of settings it has and then dividing that by **B**reathes **P**er **M**inute (BPM). A few larger POCs have a set bolus size and are able to deliver up to 2 LPM or 3LPM. The Eclipse 5 is a good example of this.

The following information on POC setting will show why POC settings have no meaning. Compare bolus sizes and see how they compare to Inhaled Volume for CF oxygen.

From – The Pulmonary Paper, Summer 2021, page 19

https://www.pulmonarypaper.org/summer-2021/

Prescriptions are written for LPM which is a measurement for CF oxygen. Inhaled Volume is needed to compare LPMs to settings. Inhaled Volume size is equivalent to Bolus size

1 LPM		2 LPM		3 LPM		4 LPM		5 LPM		6 LPM	
15BPM	30BPM	15BPM	30BPM	15BPM	30BPM	15BPM	30BPM	15BPM	30BPM	15BPM	30BPM
22 mL	11 mL	44 mL	22 mL	67 mL	33 mL	89 mL	44 mL	111 mL	56 mL	133 mL	67 mL

5 LPM @ 25 BPM = 66 ml Inhaled volume (Bolus) -- 6 LPM @ 25 BPM = 79 ml Inhaled volume (Bolus)

Pulse Mode Breath per minute - BPM **Pulse Mode** **Continuous Flow**

Inogen **Eclipse 5** **99.5 Pure Oxygen**

Setting	Flow Rate In ml/min	Bolus Size 15 BPM ml per bolus	Bolus Size 22 BPM ml per bolus	Flow Rate In ml/min	Bolus Size 15 BPM ml per bolus	Bolus Size 22 BPM ml per bolus	Flow Rate In ml/min	Bolus Size 15 BPM ml per bolus	Bolus Size 22 BPM ml per bolus
1	210	14	10	640	16	16	330	22	15
2	420	28	19	1,280	32	32	660	44	30
3	630	42	29	1,920	48	48	990	66	45
4	840	56	38	2,560	64	64	1,320	88	60
5	1050	70	48	2,960	80	80	1,650	110	75
6	1260	84	57	2,976	96	96	1,980	132	90

1,260 is the maxumum flow rate
Blolus size = flow rate ÷ BPM

2,976 is the maximum flow rate
Set bolus size

1,980 is the maximum flow rate
Blolus size = flow rate ÷ BPM

Oxlife Freedom - Page 28

Flow Settings & Pulse Volumes (ml)

Breaths per Minute	Setting 1	Setting 2	Setting 3	Setting 4	Setting 5
15	8.0	16.0	24.0	32.0	40.0
20	8.0	16.0	24.0	32.0	40.0
25	6.4	12.8	19.2	25.6	32.0
30	5.3	10.7	16.0	21.3	26.7
35	4.6	9.1	13.7	18.3	22.9
40	4.0	8.0	12.0	16.0	20.0

Oxlife Freedom and Liberty have the same bolus sizes. The bolus sizes are 24% smaller than Inogen One POCs and 51.5% smaller than the inhaled volume of CF.

Oxlife 5 Setting @ 25 BPM ÷ Inogen 5 Setting @25 BPM = Oxlife produces 76% of the oxygen or 24% less at the same setting.

32 ml (Oxlife 5 setting) ÷ 42 ml (Inogen 5 setting) = 76%

32 ml (Oxlife 5 setting) ÷ 66 ml (5 LPM Inhaled Volume) = 48.5%

A Oxlife Freedom or Liberty Setting 5 setting produces 51.5% less oxygen than 5 LPM of medical oxygen. (1 – 48.5% = 51.5%)

https://static1.squarespace.com/static/623b6406ecafe63ac597a73a/t/62421e5bddb56c004e782bf9/1648500317976/800-1049_rev_c_oxlife_freedom_user_manual.pdf

When a 5 setting on some POCs is 50% smaller than 5 LPM, POC settings have no meaning.

Oxlife Liberty – page 26

https://static1.squarespace.com/static/623b6406ecafe63ac597a73a/t/6499b2f1159e433809d3caf9/1687794418229/O2Concepts+Oxlife+Liberty+UserManual+800-1075+Rev+B+FINAL.pdf

Pulse Mode Bolus Volumes (mL)

Breaths per Minute	1	2	3	4	5	6	7	8	9
15	8.0	16.0	24.0	32.0	40.0	48.0	56.0	65.0	75.0
20	8.0	16.0	24.0	32.0	40.0	48.0	56.0	65.0	75.0
25	6.4	12.8	19.2	25.6	32.0	38.4	44.8	52.0	60.0
30	5.3	10.7	16.0	21.3	26.7	32.0	37.3	43.3	50.0
35	4.6	9.1	13.7	18.3	22.9	27.4	32.0	37.1	42.9
40	4.0	8.0	12.0	16.0	20.0	24.0	28.0	32.5	37.5

An Oxlife Freedom or Liberty Setting is 51.5% smaller than a LPM CF

51.5% × LPM = a Setting that is Equivalent to LPM

5 setting × 51.5% = 2.75 LPM

A 5 Freedom Setting should be changed to a 2.75 Setting to be equivalent to prescribed LPM

From COPD Foundation - https://www.copdfoundation.org/COPD360social/Community/Questions-and-Answers/Has-anyone-heard-of-the-POC-O2-Concepts-Oxlife-Liberty.aspx

Inogen One G5 - https://www.inogen.com/pdf/96-09302-00-01%20revA%20Technical%20Manual%20Inogen%20One%20G5.pdf - page 5

The following table summarizes the nominal bolus volumes (+/- 15%) delivered by the Inogen One G5 at 20C and sea level:

Flow Setting	Flow rate (ml /min)	10 BPM (ml/bolus)	17 BPM (ml/bolus)	25 BPM (ml/bolus)	30 BPM (ml/bolus)
1	210	21	12	8	7
2	420	42	25	17	14
3	630	63	37	25	21
4	840	84	49	34	28
5	1050	105	62	42	35
6	1260	126	74	50	42

Oxlife Independence – Page 18

https://www.oxygenconcentratorstore.com/blog/wp-content/uploads/manuals/portable/independence/Oxlife_Independence_Manual.pdf

Pulse Mode Setting	Bolus Volume (mL)
0.5	8
1.0	16
1.5	24
2.0	32
2.5	40
3.0	48
3.5	56
4.0	64
4.5	72
5.0	80
5.5	88
6.0	96

The Oxlife Independence has a set bolus size with the same bolus volumes as the Eclipse 5.

On set bolus POCs use the highest BPM and setting to find the maximum flow rate. Do the same on the Oxlife Liberty, which is 1.5 LPM, which gives it a maximum flow rate of 1,500 ml - 1.5 x 1,000 ml.

The Oxlife POCs are skimpy on details about the oxygen production of their POCs. It is like they don't want the consumers know what their POCs deliver.

Eclipse 5 - https://files.chartindustries.com/Eclipse%205%20Technical%20Manual%2020631679-F.pdf

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The Eclipse 5 settings are equivalent to LPMs for the first 6 settings when connected to AC power. On DC power setting 5 would be close and setting 4 is equivalent to LPM. I am sure the Oxlife Independence is the same and is misrepresenting their machine at the higher settings needed when ambulatory.

Pulse Dose Setting	Bolus Size (± 15%) mL	AC Power Supply and Power Cartridge (Battery)	DC Power Supply
		Max Breath Rate	Max Breath Rate
1.0	16	40	40
2.0	32	40	40
3.0	48	40	40
4.0	64	40	31
5.0	80	37	25
6.0	96	31	20
7	128	23	15
8	160	18	12
9	192	15	10

BOLUS VOLUME (+/- 15%)

NOTE: Bolus volume decreases as breath rate exceeds published range.

It is easy to see POC settings are not equal to LPM and the setting from different POCs are not equal to each other. Until the FDA regulates POC settings manufacturers will continue to use different POC settings to sell their machines and the companies that sell them will continue gas lighting the people they sell to.

Harsh but true.

If Inogen had been honest about their settings 9 years ago it would have saved me over two years of really struggling to stay active. My health also went downhill. For example, during the same time period my FEV1 went from 47% of expected to 30% of expected.

The following is from the bottom of - https://hors-sens.com/oxygen/needed_changes/settings.html

Your lungs and exercise

If you have a long-term lung condition, the thought of becoming quickly out of breath can be daunting and you may not feel motivated to exercise. It can be tempting to avoid exercise because you think it will make you breathless, but with less activity you become less fit and daily activities will become harder.

From - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4818249/pdf/EDU-ELF121.pdf

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I can shop with a 6 setting on the Eclipse 5 or 6 LPM continuous flow. With a 6 setting on an Inogen One G5 I really struggle and am less active.

Regular physical activity reduces hospital admission and mortality in chronic obstructive pulmonary disease: a population based cohort study

Conclusions

Subjects with COPD who perform some level of regular physical activity have a lower risk of both COPD admissions and mortality. The recommendation that COPD patients be encouraged to maintain or increase their levels of regular physical activity should be considered in future COPD guidelines, since it is likely to result in a relevant public health benefit.

From - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2117100/

An article on the American Thoracic Society website, "Portable Oxygen Concentrators (POCs) by Chris Garvey FNP, MSN, MPA, MAACVPR." It is a short read and offers good insights into pocs.

https://www.thoracic.org/patients/patient-resources/resources/portable-concentrators-garvey.pdf

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Portable oxygen concentrator manufacturers can easily change the setting numbers they use making a 3 setting the equivalent of 3 LPM on all new pocs. They could have a chart on their website to show what LPM a 3 setting would be on a poc already sold would be. Then anyone with a prescription could look at the new settings on a poc and know if it could fill their prescription. Physicians, respiratory therapists, family members and all concerned could look at the prescription and know if a particular poc could fill it.

It will cost portable oxygen concentrator manufacturers, but mainly from lost sales because the poc won't fill a prescription. But it will save Medicare, insurance companies and people with a prescription from buying a poc that won't fill the prescription. Some are now using a poc, like I did, that doesn't fill their prescription and it causes health issues and raises their medical costs, often paid by Medicare or other insurances.

Making poc settings equivalent to LPM will result in relevant public health benefits!

Ask medical professionals, your durable medical equipment supplier, or any one you are comfortable asking to contact their representatives in Congress and tell them about the need for the FDA to regulate pocs so settings are equivalent to LPM. Having the FDA regulate poc settings will raise the quality of life for those on supplemental oxygen and save Medicare money!

Thanks for your time,

Skip Miller

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I look forward to hearing from you, answering questions you may have or getting more information to you.

More POC specifications

SimplyGo Mini specifications

Product specifications

Oxygen concentrations*	At least 87% at all settings (maximum of 96%)

*Based on atmospheric pressure of 14.7 psia (101 kPa) at 70°F (21°C)

Outlet pressure	20 psig

Flow settings and pulse volumes

Setting	Nominal pulse volume at 20 BPM	Maximum minute volume output
1	11 ml	220 ml/min
2	22 ml	440 ml/min
3	33 ml	660 ml/min
4	44 ml	880 ml/min
5	50 ml	1,000 ml/min

+/- 25% or 6 ml, whichever is greater (average of 20 consecutive pulses) over the rated environmental range

SimplyGo Oxygen Concentrator

Oxygen Concentration*	87%-96% at all settings
Flow Settings and Pulse Volumes	**Pulse Mode** 1 = 12 ml; 1.5 = 18 ml; 2 = 24 ml; 2.5 = 30 ml; 3 = 36 ml; 3.5 = 42 ml; 4 = 48 ml; 4.5 = 54 ml; 5 = 60 ml; 5.5 = 66 ml; and 6 = 72 ml; +/- 15% or 4 ml, whichever is greater (Average of 20 consecutive pulses) up to a max of 2000 ml/min +/- 300 ml **Sleep Mode** Variable pulse volumes, based on breath rate, to maintain a constant minute volume per setting. 1 = 250 ml; 1.5 = 375 ml; 2 = 500 ml; 2.5 = 625 ml; 3 = 750 ml; 3.5 = 875 ml; 4 = 1000 ml; 4.5 = 1125 ml; 5 = 1250 ml; 5.5 = 1375 ml; and 6 = 1500 ml +/- 15% or 60 ml, whichever is greater (Sum of 20 consecutive pulses when the device is delivering at a 20 pulses per minute rate) **Continuous Mode** .5 = 500 ml/min; 1 = 1000 ml/min; 1.5 = 1500 ml/min; 2 = 2000 ml/min; +/- 15% or 150 ml/min, whichever is greater (3 minute running average) **Note**: Max recommended flow is 2 LPM (at nominal outlet pressures of 0 and 7 kPa).

Same company, different bolus sizes