Evaluation of Lifestyle P2 Portable Oxygen Concentrator

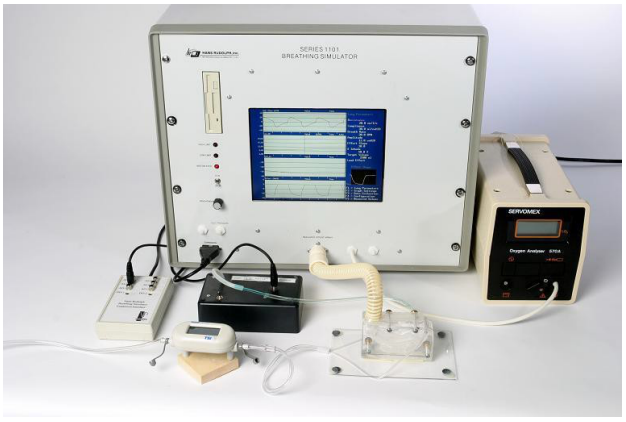
Testing Methods

Tested Devices

Tested portable oxygen concentrator (POC) for this report is the Qingdao Lifestyle Medical Science and Technology Co., Ltd P2 POC.

Additional Test Equipment

Series 1101 Breathing Simulator – Hans Rudolph, Inc.
570A Oxygen Analyzer – Servomex
BTC-II Miniature Diaphragm Pump – Hargraves Technology Corp. (not shown)
Model 24PC Pressure Sensor – Honeywell
Model 4140 Mass Flowmeter – TSI, Inc.
1104 7' Nasal Cannula – Hudson RCI
Breathing Simulator Expansion Interface – Valley Inspired Products
Artificial Nose – Valley Inspired Products
Clinical Oxygen Dose Recorder – Drive Medical



Portable Oxygen Concentrator Bench Testing Protocol

All POCs were tested in the same setup, described in the following conditions.

Lung and Data Acquisition Settings

For tests conducted in this evaluation, the following breathing patterns were utilized by the breathing simulator to simulate a patient:

Pattern	Resistance	Compliance	Rate*	Amplitude*	Slope	% Inhale	V_T
1	20	30	10	18.1	40	34	~500
2	20	30	15	20	40	34	~500
3	20	30	20	22.5	40	34	~500
4	20	30	25	26.0	40	34	~500
5	20	30	30	29.5	40	34	~500
6	20	30	35	33.0	40	34	~500
7	20	30	40	36.0	40	34	~500

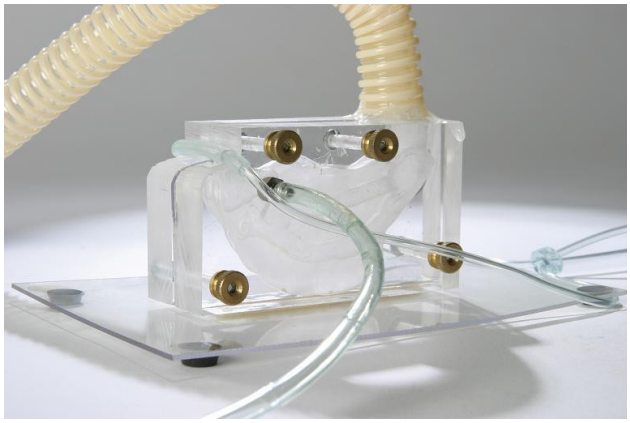
Note that the only adjusted parameters were Breath Rate and Amplitude. Amplitude could be further adjusted from shown values to ensure ~500mL V_t. Resistance and Compliance settings

resulted in restrictive lung conditions. Slope setting of 40 created a square inhalation curve to ensure device triggering. %Inhale setting yielded a 1:2 I:E ratio.

The breathing simulator was set to record data at 50 Hz (20ms intervals). Data acquisition channels were set to record simulated patient volume flow ATPD, oxygen flow (as read from the flowmeter via expansion interface), and nasal cavity pressure (as read from the external pressure sensor via expansion interface).

Pulse Flow Characteristics

The artificial nose was attached to the breathing simulator port and a nasal cannula was inserted into the nasal cavity. The 4140 flow meter was placed in line with the nasal cannula one inch below the cannula wye so that delivered oxygen from the device under test went through the flowmeter before being delivered into the nasal cavity.



Pulse flow characteristics were recorded at each of the device's integer settings over six consecutive breaths in each of the seven test patterns.

Pulse Volumes

Pulse volumes were calculated by integrating the raw oxygen flow data recorded from the flowmeter during the inhalation phase and/or pulse flow delivery that exceeded the inhalation cycle.

Flow Waveforms

Waveforms were created from the raw oxygen flow data.

Pulse Delivery Times

Delivery times were calculated by using the raw oxygen flow data to determine the time differential between the onset and cessation of oxygen flow from the device.

Delivered FiO_2%

The artificial nose was attached to the breathing simulator port and a nasal cannula was inserted into the nasal cavity. The diaphragm pump was set up to pull a gas sample from the breathing simulator bellows chamber to the oxygen analyzer. Delivered FiO_2% was recorded at each of the device's integer settings in all patterns, with a minimum of five minutes allowed to pass in each scenario for the concentrator's purity output to stabilize.

Oxygen Purity

The artificial nose was attached to the breathing simulator port and a nasal cannula was inserted into the nasal cavity. A tee was fitted to the oxygen analyzer inlet port, with the cannula tubing connector attached to the tee outlet perpendicular to the analyzer inlet port. A length of silicone tubing was used to connect the device's oxygen outlet to the tee, so the flow from the device was directed to the analyzer when triggered by the simulation.

Oxygen purity output was recorded at each of the device's integer settings in all patterns, with a minimum of five minutes allowed to pass in each scenario for purity output to stabilize.

Triggering Sensitivity

The artificial nose was attached to the breathing simulator port and a nasal cannula was inserted into the nasal cavity. The external pressure sensor was connected to the pressure sampling port of the artificial nose. The simulator settings were adjusted to match "Pattern 3", except Slope was set to 10 and % Inhale was set to 50%, creating a moderately shallow breath simulation. Amplitude values were adjusted (in integer increments) until the device did not consistently trigger breath-to-breath for a minimum of 60 seconds (to allow for any POC sensing algorithm to adjust sensitivity parameters). Amplitude was then set to the last setting prior to noting inconsistent triggering, and the simulation was allowed to stabilize. The nasal cavity pressure profile was recorded and the negative pressure in the nose at the onset of oxygen delivery was determined from the raw data file. If the device had multiple sensitivity settings, data was recorded for each trigger setting.

Dynamic Breath Rate Testing

Test setup was a combination of the pulse flow characteristics and delivered FiO_2% test setups, with the Clinical Oxygen Dose Recorder (CODR) placed in-line instead of the TSI flowmeter. A PC running the CODR software package was used for data collection. The breathing simulator was programmed to run a script based on breath rate data taken from an actual oxygen user, where the user was resting with a 1:2 I:E ratio, then active (1:1 I:E), then resting again (1:2 I:E). Using the breath rate data and adjusting the amplitude setting to maintain a static tidal volume throughout the test, the simulator script ran for a total duration of 19 minutes, with FiO_2% data as read from the oxygen analyzer taken every 30 seconds. The CODR and software recorded breath rate and pulse volume delivery on a breath-by-breath basis. Each unit was tested at settings of 2 and the maximum pulse setting available on the device. FiO_2%, pulse volume, and breath rate data as recorded by the CODR were synchronized and plotted after test completion.

Lifestyle P2 Portable Oxygen Concentrator

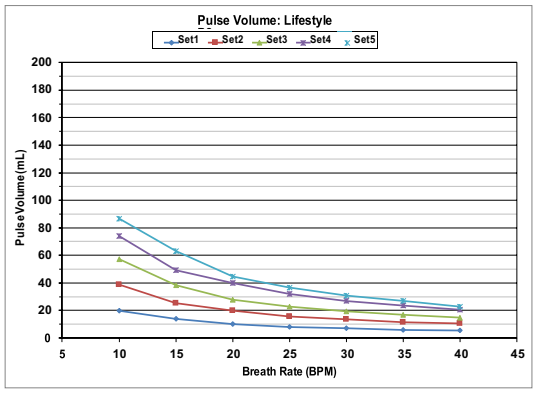
Tested Device Information

Model: P2; Serial Number: 20020881

Pulse Volumes

	Lifestyle P2 Pulse Volumes (mL)					
10BPM	20	38	57	74	87	10BPM
15BPM	14	25	38	49	63	15BPM
20BPM	10	20	28	40	45	20BPM
25BPM	8	16	23	32	37	25BPM
30BPM	7	13	19	27	31	30BPM
35BPM	6	11	17	23	27	35BPM
40BPM	5	10	15	20	23	40BPM
Average	10	19	28	38	44	Average
	Set1	Set2	Set3	Set4	Set5	
	Setting					

Pulse Volume Chart



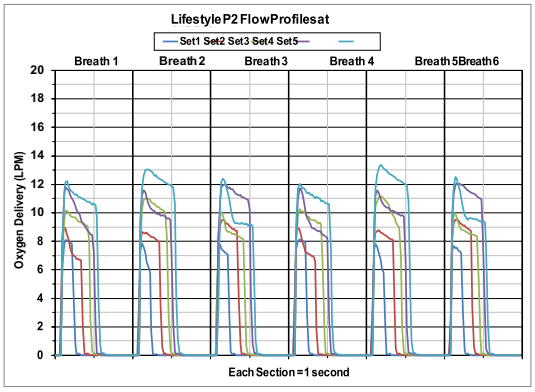
The P2 employs a minute volume delivery method at all settings and rates, reducing the delivered volume at a given setting as the user's breath rate increases. Users should expect to need to increase the pulse setting to maintain saturations as their respiratory rate increases with activity.

Product specifications describe pulse volumes at all device settings from 10 to 40 BPM (in increments of 5 BPM). All measured pulse volumes were within the +/- 15% specification noted in the product manual.

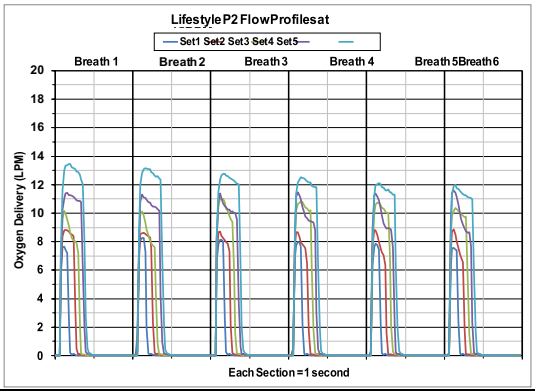
Flow Waveforms

Waveforms are charted for six consecutive breaths during the simulation.

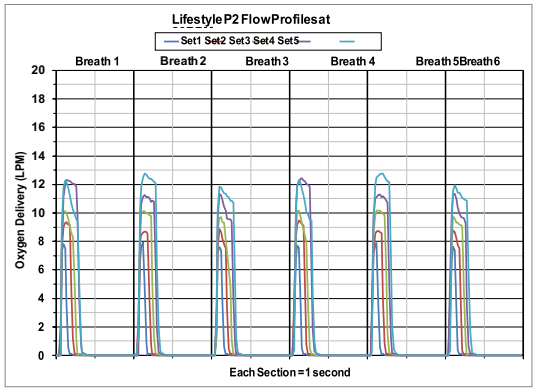
10 BPM:



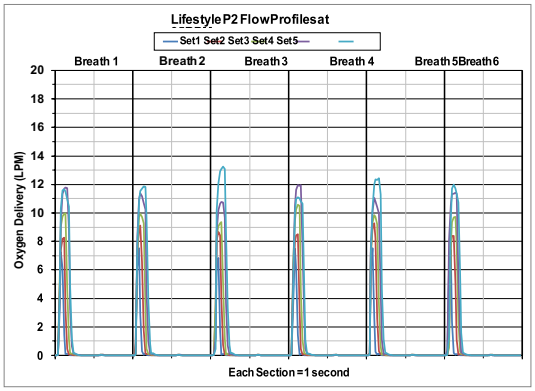
15 BPM:



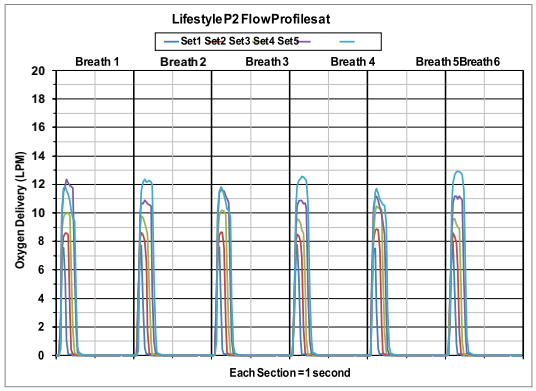
20 BPM



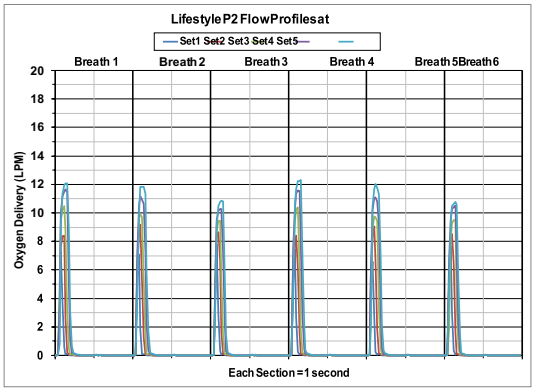
35 BPM



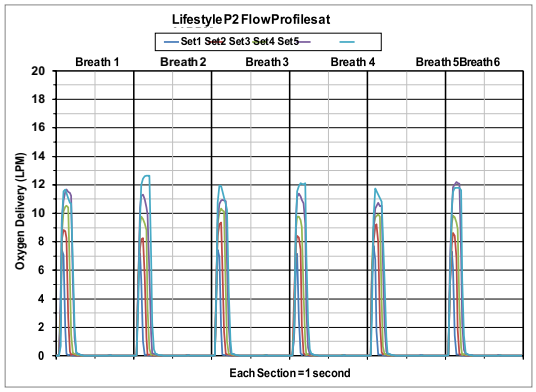
25 BPM



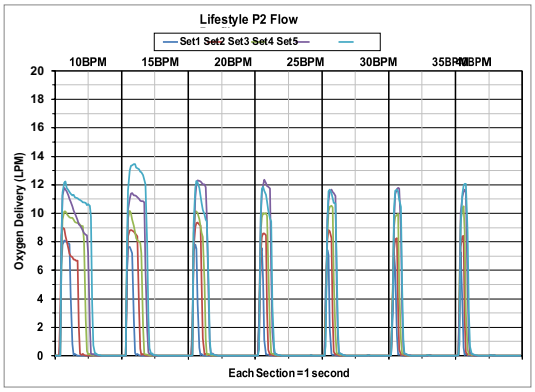
40 BPM



30 BPM



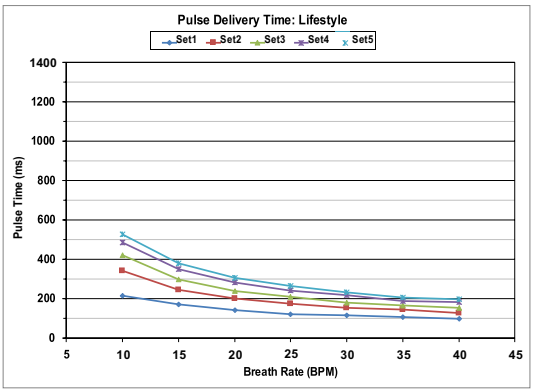
Waveforms charted by Breath Rate:



Peak oxygen flow at a given setting slightly varied on a breath-by breath basis with no observable reduction as the respiratory rate increased. Peak flows at "1" averaged 7-8 LPM, and at the maximum "5" setting peak flow averaged about 11-13 LPM.

Pulse waveform shapes were generally consistent at each setting/rate, with an early peak flow and slightly tapered delivery until the unit ceased pulse flow delivery. Breath-to-breath variability in waveform shapes may be attributed to where the unit was in its pressure cycle during flow delivery, among other mechanical factors. Waveforms shortened as breath rate increased, consistent with POCs that utilize minute volume delivery methods.

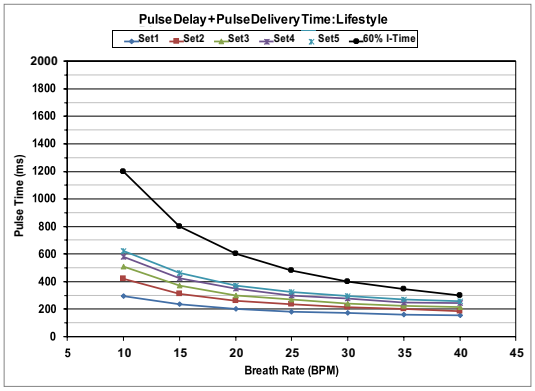
Pulse Delivery Times



As expected in minute volume delivery devices, pulse delivery times decreased with an increase in breath rate.

Delivering oxygen during the first 60% of inspiration is considered to be the most beneficial period to deliver oxygen and have that volume reach the distal air sacs in the lungs. Observing the recorded pulse delay (the time between breath initiation and onset of pulse flow) and pulse delivery times at rates up to 40 BPM, the data shows that the P2 delivers its full pulse volumes well within the initial 60% of the total inhalation time.

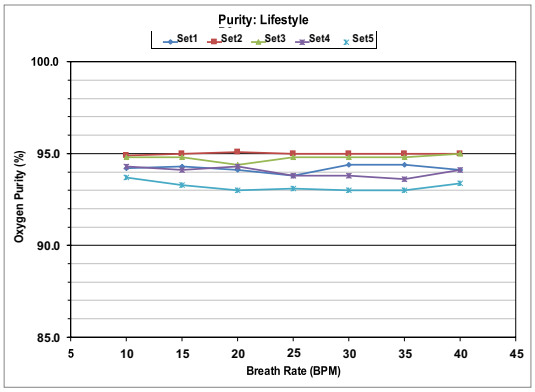
Pulse Delay + Pulse Delivery Times



Oxygen Purity

Lifestyle P2 Purity					
	1	2	3	4	5
10BPM	94.2	94.9	94.8	94.3	93.7
15BPM	94.3	95.0	94.8	94.1	93.3
20BPM	94.1	95.1	94.4	94.3	93.0
25BPM	93.8	95.0	94.8	93.8	93.1
30BPM	94.4	95.0	94.8	93.8	93.0
35BPM	94.4	95.0	94.8	93.6	93.0
40BPM	94.1	95.0	95.0	94.1	93.4

Measured oxygen purity at all tested settings and rates was well within the product specifications of 87-96%.



Oxygen Minute Volume

	Lifestyle P2 Minute Volumes (mL)					
10BPM	186	365	543	697	812	10BPM
15BPM	195	357	544	692	882	15BPM
20BPM	186	376	525	756	830	20BPM
25BPM	191	371	535	752	854	25BPM
30BPM	196	381	553	761	852	30BPM
35BPM	193	380	550	769	873	35BPM
40BPM	196	390	560	770	853	40BPM
Average	192	374	544	742	851	Average
	Set1	Set2	Set3	Set4	Set5	
	Setting					

Based on maximum delivered pulse volumes and the corresponding oxygen purity, maximum pure oxygen output of the P2 was around 850 mL per minute.

Dynamic Breath Rate Testing

The P2 was tested for pulse volume delivery and FiO2 at settings of 2 and the maximum 5 in an active breathing simulation while maintaining a static tidal volume.

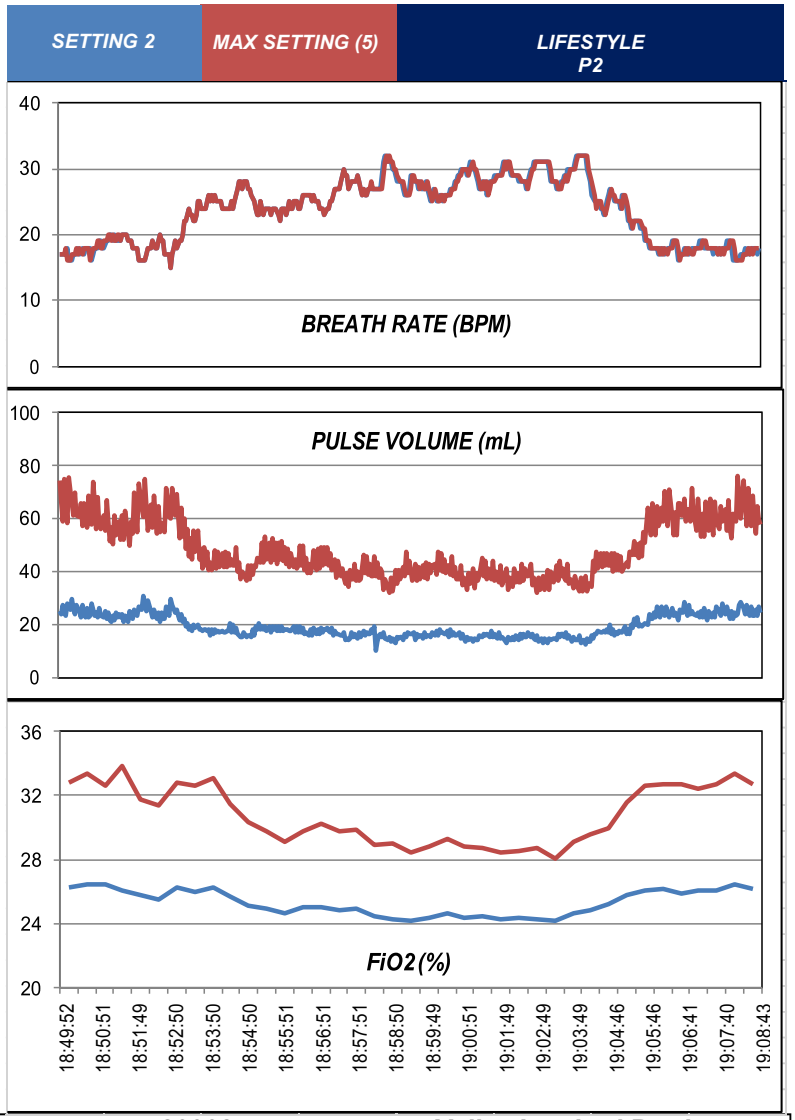
As expected, when the breath rate increased, pulse volume - and thus FiO_2% – decreased. At resting rates, pulse volume differentials between the 2 and maximum (5) setting were around 35-40mL, which corresponded to around a 5-7% difference in FiO_2%. At active rates these differentials decreased to about 20mL and 4% difference.

Triggering Sensitivity

The P2 does not have selectable sensitivity settings. Negative pressure required to trigger the device was as follows (values shown in cmH_2O):

Sens	P2	-0.07

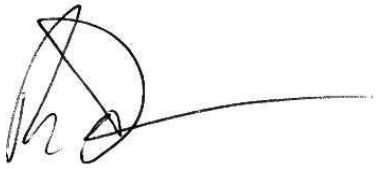
Measured trigger sensitivity was well within the specification of less than or equal to 0.12 cmH_2O.



Testing Information

Lifestyle P2 device tested and this report compiled from June-July, 2020.

Signed:



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