

Rhythm Healthcare R&D Testing Laboratory	Title: Evaluation of Rhythm Healthcare P2-E7 Portable Oxygen Concentrator	
Release date: Jan 22,2024	Revision date:	File No: 240122
		Revision:

Evaluation of Rhythm Healthcare P2-E7 Portable Oxygen Concentrator



Test Methods

Tested Devices

Tested portable oxygen concentrator (POC) for this report is the P2-E7 distributed in the United States by Rhythm Healthcare | SN 24CBB000640

Test Equipment:

PWG-33BT Breathing Simulator - Piston Medical Ltd

Micro Intelligent Oxygen Analyzer - Xi'an Beegas Electronic Technology Co., Ltd.

Mass Flow Meters - Alicat Scientific Inc

Certifier FA Plus 4088J Pressure Sensor – TSL

PWG-33-HUM Artificial Nose Simulator - Piston Medical Ltd

NOC-DAW0721 7' Nasal Cannula - Ningbo Runmai Medical Ltd.



Breathing Simulator Parameter Settings

Pattern	Rate	Inspiratory rate (mL/s)	V _T (mL)
1	10	250	500
2	15	376	500
3	20	500	500
4	25	625	500
5	30	758	500
6	35	876	500
7	40	1000	500

By adjusting the respiratory frequency and inspiratory rate to ensure that each inspiratory volume is controlled at 500 ml, the breathing simulator creates a square curve waveform of the respiratory ratio (1:2 I:E) to ensure triggering breathing.

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).

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Flow Pulse Characteristics

The Device is connected to the nasal oxygen tube, the nasal oxygen tube is connected to the flowmeter, the other end of the flow meter is connected to the artificial nose, and the artificial nose is connected to the breathing simulator, placed all in a straight line.

Pulse Volumes

Trigger breathing through a breathing simulator, control each inspiratory volume at 500 ml, and record the pulse flow flowing through the flow meter during the test to calculate.

Flow Waveforms

calculated the device for six consecutive breaths at different breathing rates (10 /15 / 20 / 25 / 30 / 35 / 40).

Pulse Delivery Times

Calculated by pulse flow, the time difference between the start and end of the flow.

Delivered FIO2%

The nasal oxygen tube of the Device is connected to the artificial nose, the artificial nose is connected to the breathing simulator, and the front end of the breathing simulator is connected to the oxygen analyzer to ensure that the gas passes through, and the Fio2 data is recorded after the device is running stably.

Oxygen Purity

The artificial nose is connected to the breathing simulator, a tee is installed at the entrance of the oxygen analyzer, the Device nasal oxygen tube is connected to the tee, and the other port of the tee is connected to the artificial nose, the pulse flow will be guided to the oxygen analyzer when breathing is triggered at different breathing rates and all settings of the Device, all gears need to be tested, and the data will be recorded after the operation is stable.

Triggering Sensitivity

The artificial nose is connected to the breathing simulator, a three-way connection pressure sensor, nasal oxygen tube and artificial nose, adjust the parameters of the breathing simulator, create a suitable breathing waveform, trigger the breathing of the Device, and find the right and stable breathing by controlling the inhalation volume Trigger the breathing data of the Device, record the pressure value at this time, and the pressure difference between the front and rear of the pressure sensor is the pressure that triggers breathing.

Dynamic Respiratory Rate

The oxygen nozzle of the Device is connected to the flowmeter, the flowmeter is connected to the artificial nose, the artificial nose is connected to the breathing simulator, the front end of the simulator is connected to the oxygen concentration meter.

The parameters of the breathing simulator are set to create a suitable breathing waveform, and the breathing simulator is programmed In order to run according to the breathing rate of the user's actual situation, to simulate the user's breathing, the user rests according to the breathing ratio (1:2 I:E), and then performs activities according to the breathing ratio (1:1 I:E), and again according to (1: 2 I:E).

Take a break to verify whether the Device can follow the breath, the simulator runs for about 19 minutes, read the data of Fio2 every 30 seconds, and record the pulse flow.

Unit was tested at settings of 2 and the maximum pulse setting available on the device. FiO2%, pulse volume, and breath rate data were synchronized and plotted after test completion.

Rhythm Healthcare P2-E7 Portable Oxygen Concentrator

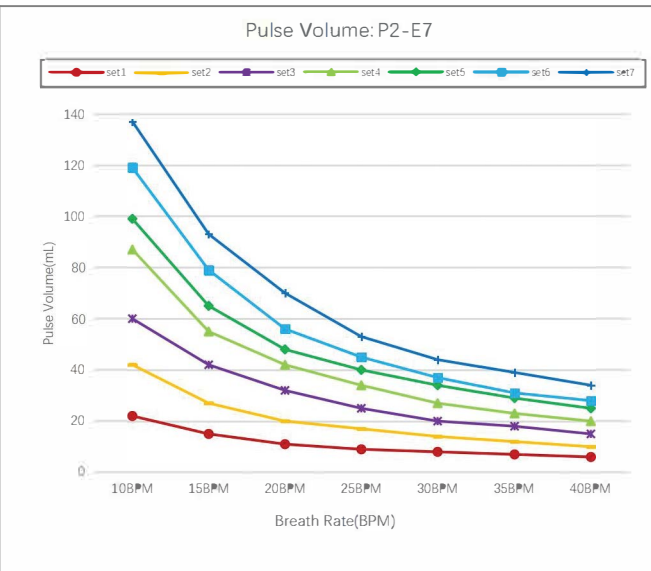
Test Device information

Model: P2-E7 | Serial Number: 24CBB000640

Pulse Volumes

Rhythm Healthcare P2-E7 Pulse Volumes (mL)							
Rate	Setting 1	Setting 2	Setting 3	Setting 4	Setting 5	Setting 6	Setting 7
10 BPM	22	42	60	87	99	119	137
15 BPM	15	27	42	55	65	79	93
20 BPM	11	20	32	42	48	56	70
25 BPM	9	17	25	34	40	45	53
30 BPM	8	14	20	27	34	37	44
35 BPM	7	12	18	23	29	31	39
40 BPM	6	10	15	20	25	28	34
Average	11	20	30	41	49	56	67

Pulse Volume Chart



P2-E7 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.

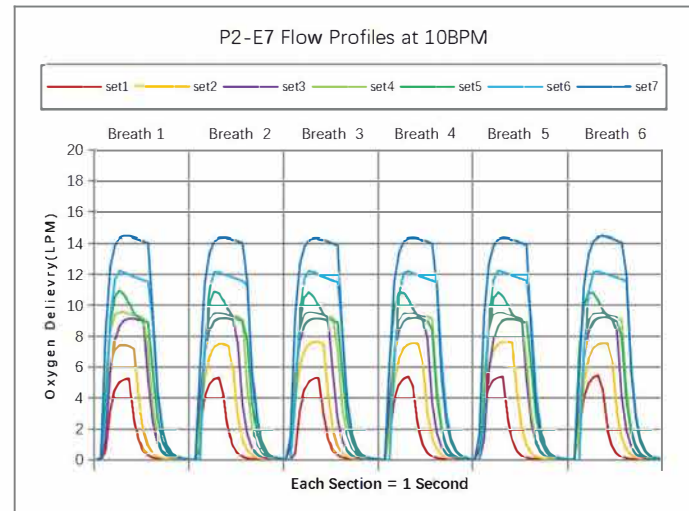
Specifications describe pulse volumes at all settings from 10 to 40 BPM (in increments of 5 BPM).

All measured pulse volumes were within the +/- 15% specification noted in the manual.

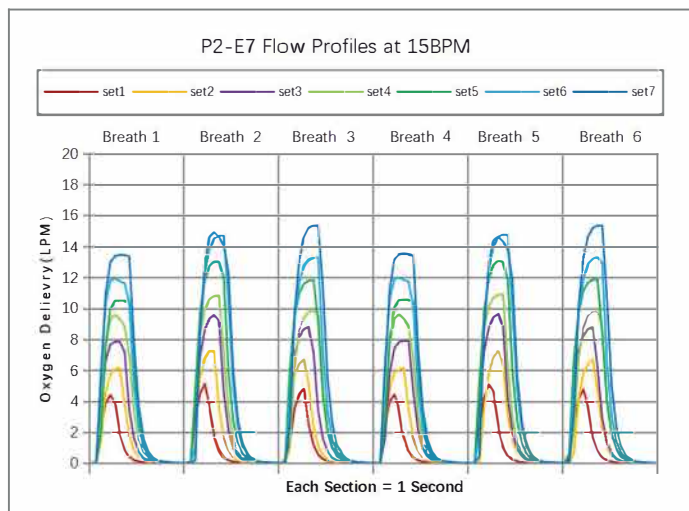
Flow Waveforms

Waveforms are charted for six consecutive breaths during the simulation.

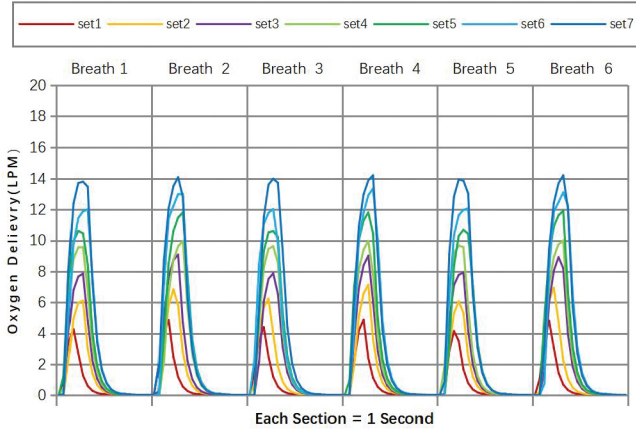
10 BPM



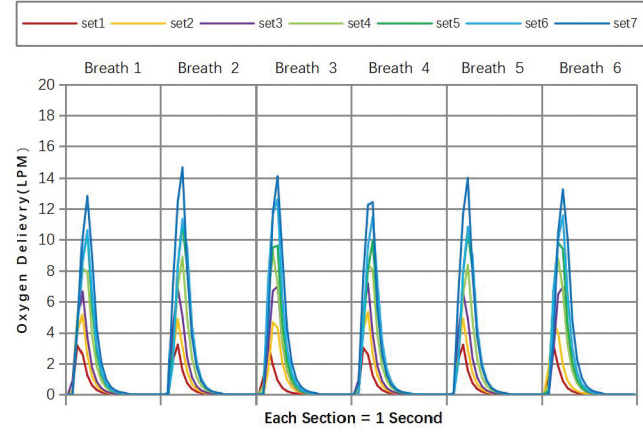
15 BPM



P2-E7 Flow Profiles at 20BPM



P2-E7 Flow Profiles at 35BPM



20 BPM

25 BPM

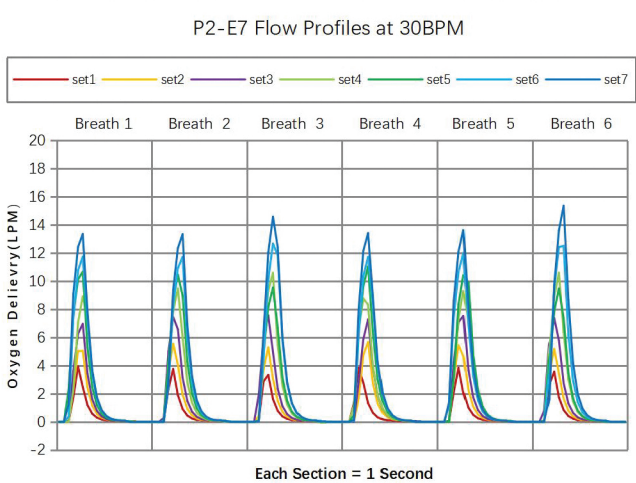
30BPM

35BPM

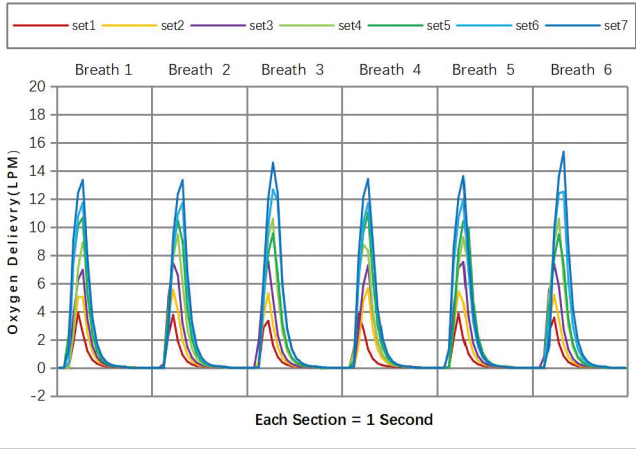
40BPM

Waveforms charted by Breath Rate

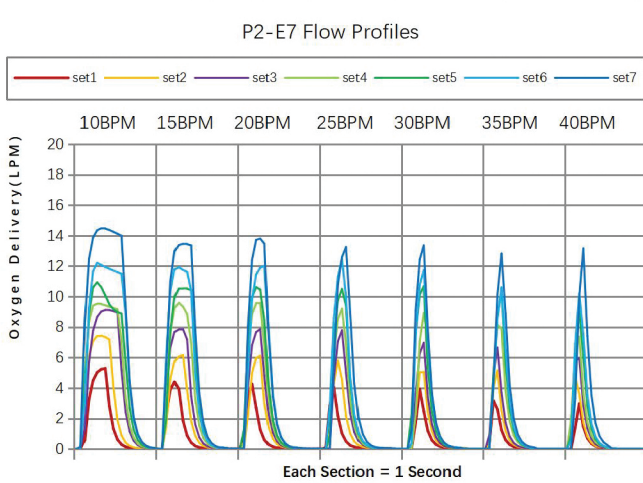
P2-E7 Flow Profiles at 25BPM



P2-E7 Flow Profiles at 30BPM



P2-E7 Flow Profiles at 40BPM



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 3-5.5 LPM, and at the maximum “7” setting averaged about 13-15 LPM.

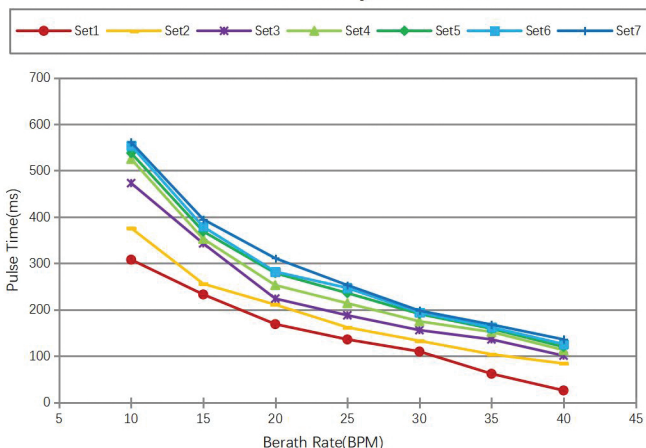
Pulse waveform shapes were generally consistent at each setting/rate, with an early peak flow and slightly tapered delivery until the unit ceased pulse flow delivery.

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

Pulse Delivery Time: P2-E7

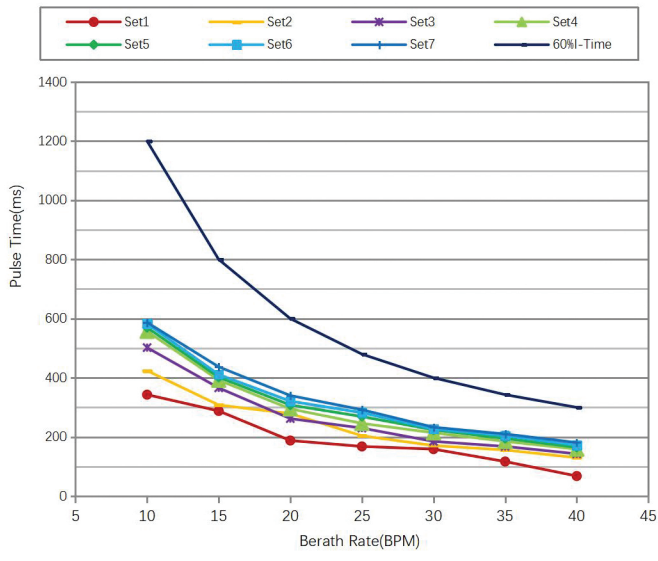


As expected in minute volume delivery devices, pulse delivery times decreased with an increase in breath rate.

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-E7 delivers its full pulse volumes well within the initial 60% of the total inhalation time.

Pulse delay + Pulse Delivery Time: P2-E7

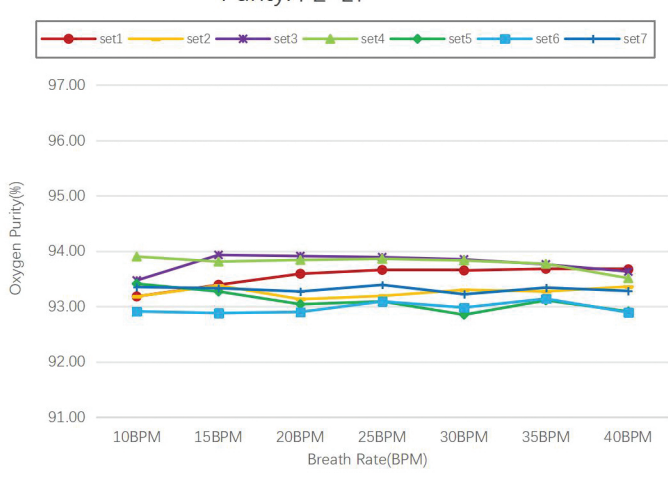


Pulse Delay + Pulse Delivery Times

Rhythm Healthcare P2-E7 Purity (%)

Rate	Setting 1	Setting 2	Setting 3	Setting 4	Setting 5	Setting 6	Setting 7
10BPM	93.18	93.18	93.47	93.90	93.41	92.91	93.35
15BPM	93.39	93.38	93.93	93.81	93.27	92.88	93.33
20BPM	93.59	93.13	93.91	93.84	93.04	92.90	93.27
25BPM	93.66	93.19	93.89	93.86	93.09	93.09	93.39
30BPM	93.65	93.30	93.85	93.83	92.85	92.98	93.22
35BPM	93.68	93.27	93.76	93.77	93.11	93.14	93.34
40BPM	93.67	93.36	93.63	93.51	92.91	92.89	93.28

Purity: P2-E7



Oxygen Purity

The Oxygen concentration measured at all tested settings and rates was above 92.8%, which was well within the product specifications of 87-96%.

Pure Oxygen Minute Volume

Rhythm Healthcare P2-E7 Minute Volumes (mL)							
Rate	Setting 1	Setting 2	Setting 3	Setting 4	Setting 5	Setting 6	Setting 7
10BPM	206	411	591	811	912	1107	1256
15BPM	220	398	604	782	916	1103	1230
20BPM	220	399	600	803	990	1109	1234
25BPM	220	400	592	783	952	1094	1253
30BPM	221	399	600	781	962	1109	1279
35BPM	222	400	591	786	953	1104	1281
40BPM	219	401	582	791	970	1114	1260
Average	218	401	594	791	951	1106	1256

Based on maximum delivered pulse volumes and the corresponding oxygen purity, maximum pure oxygen output of the P2-E7 was around 1281mL per minute at setting 7, and around 411 mL per minute at setting 2.

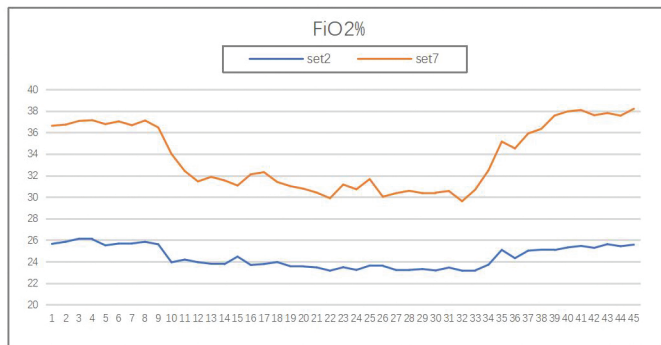
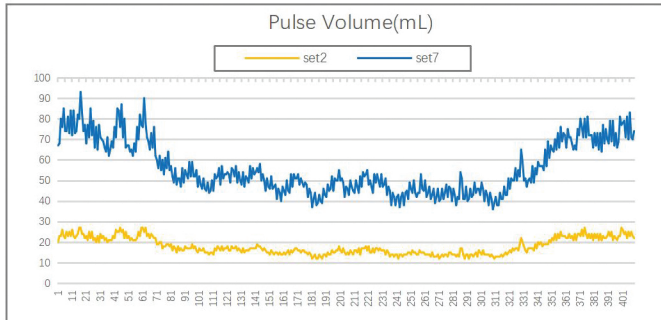
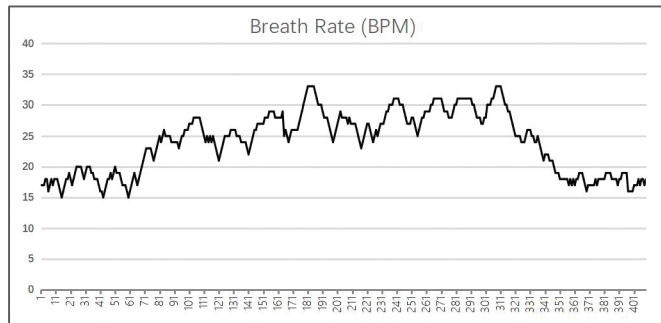
Dynamic Breath Rate Testing

During the breathing simulation with the breathing simulator, the P2-E7 tested the flow and FiO2 data at Setting 2 and Setting 7.

As expected, when the breath rate increased, pulse volume and thus FiO2% decreased.

At resting rates, pulse volume differentials between the 2 and maximum (7) setting were around 66mL, which corresponded to around a 12.6% difference in FiO2%.

At active rates these differentials decreased to about 40mL and 8.5% difference in FiO2%.



Trigger Sensitivity

Sensitivity settings	Trigger sensitivity (Pa)	Remark
1	6.5	
2	5.5	
3	4.8	Factory Default Settings
4	4.2	
5	4.0	

P2-E7 factory default setting trigger pressure Pa, provide 5 levels of sensitivity setting, the lowest trigger pressure Pa;

All measured Trigger sensitivity were within the specification noted in the manual.