# Evaluation of Rhythm Healthcare P2-E6 Portable Oxygen Concentrator

## Test Methods

Tested Devices

Tested portable oxygen concentrator (POC) for this report is the P2-E6 distributed in the United States by Rhythm Healthcare, unit SN 23EBB024663.

## Test Equipment:

PWG-33BT Breathing Simulator - Piston Medical Ltd

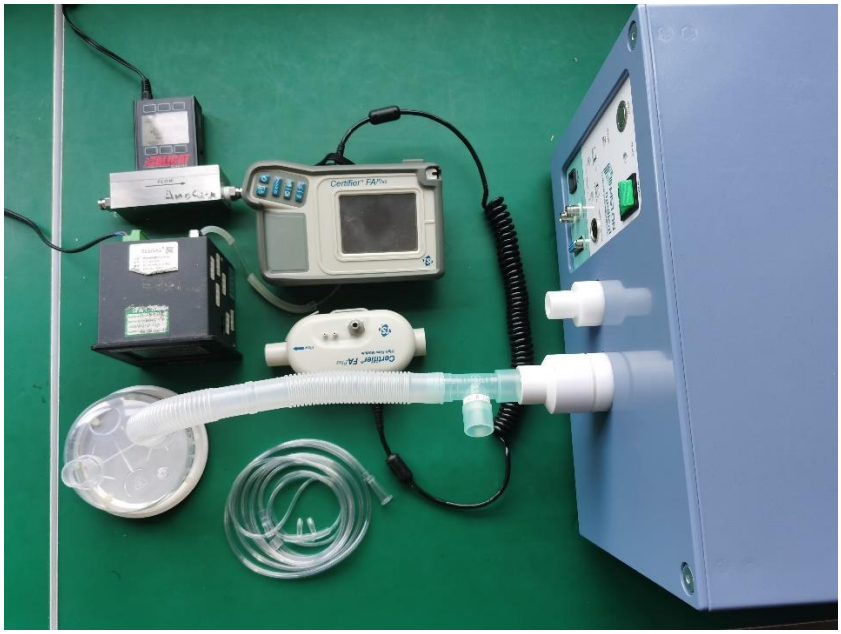
Micro Intelligent Oxygen Analyzer - Xi'an Beegas Electronic Technology Co., Ltd.

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).

## 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 -E6 Portable Oxygen Concentrator

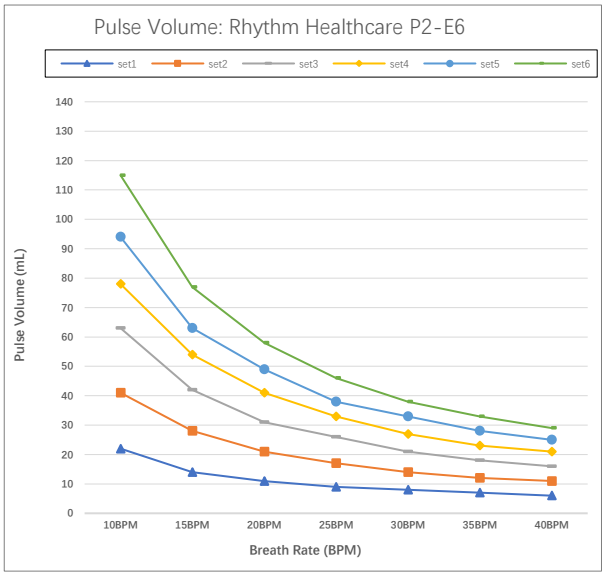
Test Device information

Model: P2-E6; Serial Number: 23EBB024663

## Pulse Volumes

| Rhythm Healthcare P2-E6 Pulse Volumes (mL) | | | | | | |
|---|---|---|---|---|---|---|
| Rate | Setting 1 | Setting 2 | Setting 3 | Setting 4 | Setting 5 | Setting 6 |
| 10 BPM | 22 | 41 | 63 | 78 | 94 | 115 |
| 15 BPM | 14 | 28 | 42 | 54 | 63 | 77 |
| 20 BPM | 11 | 21 | 31 | 41 | 49 | 58 |
| 25 BPM | 9 | 17 | 26 | 33 | 38 | 46 |
| 30 BPM | 8 | 14 | 21 | 27 | 33 | 38 |
| 35 BPM | 7 | 12 | 18 | 23 | 28 | 33 |
| 40 BPM | 6 | 11 | 16 | 21 | 25 | 29 |
| Average | 11 | 21 | 31 | 40 | 47 | 57 |

## Pulse Volume Chart




P2-E6 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.

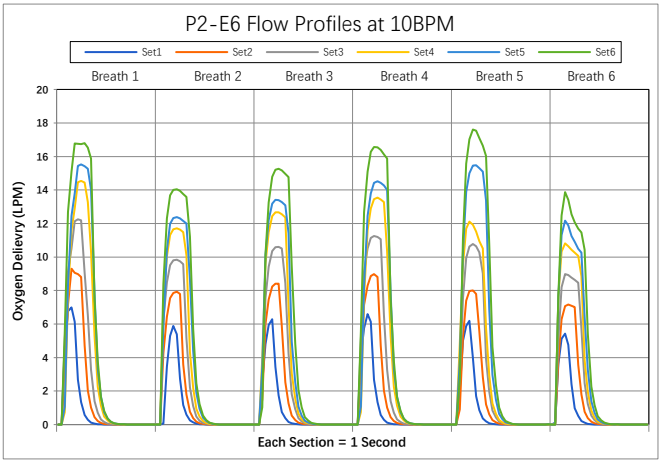
Specifications describe pulse volumes at all settings from 10 to 40 BPM (in increments of 5 BPM).

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

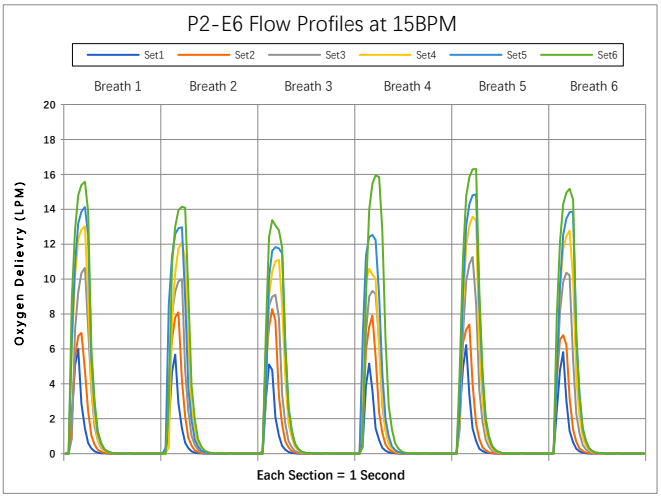
## Flow Waveforms

Waveforms are charted for six consecutive breaths during the simulation.

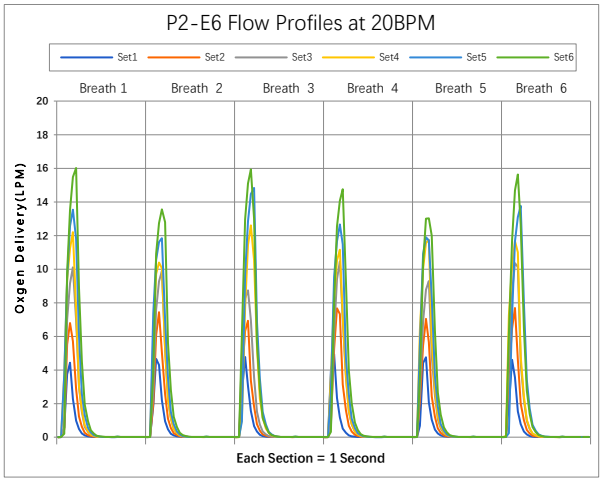
### 10 BPM



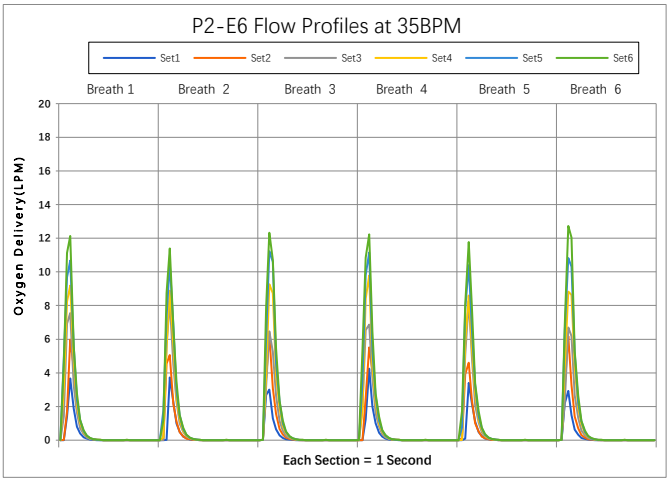

### 15 BPM



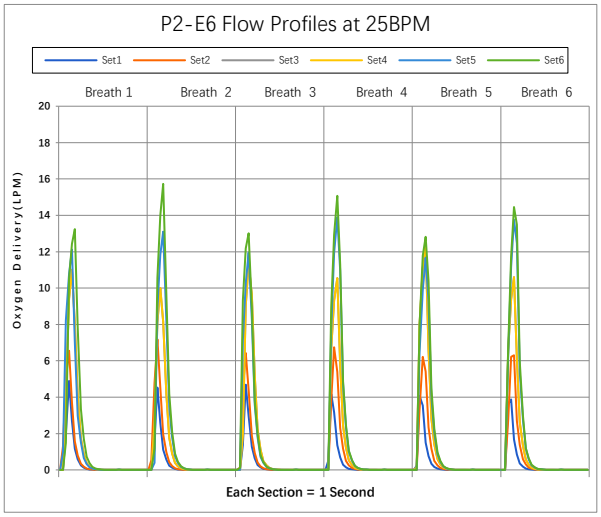
## 20 BPM



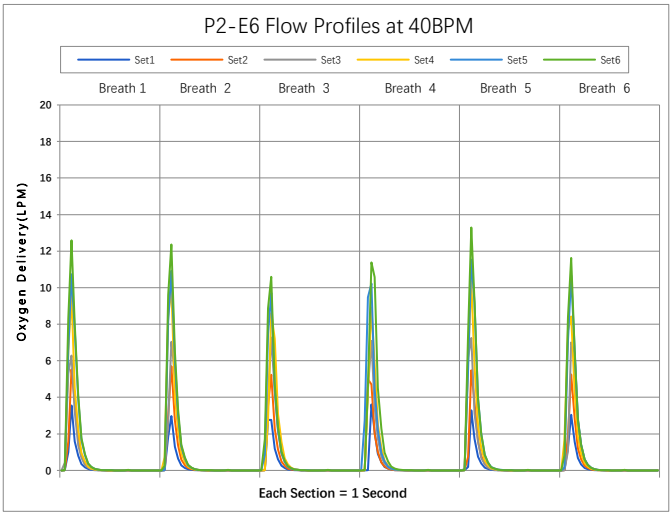

## 35BPM



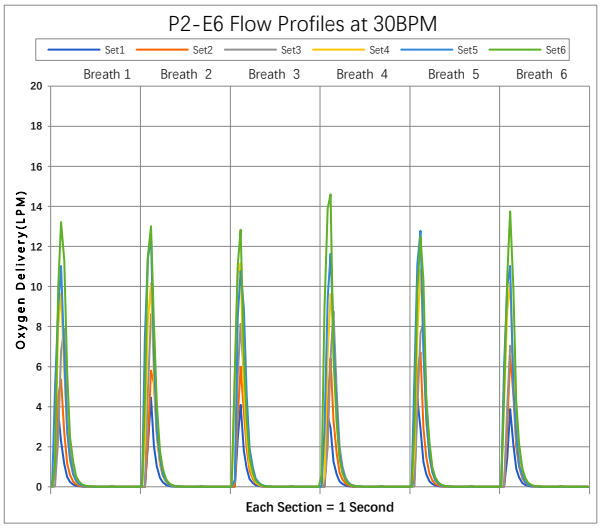

## 25 BPM



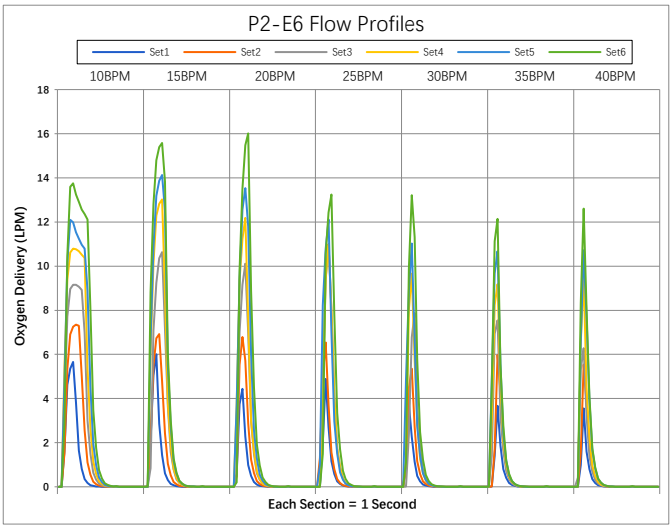

## 40BPM




## 3 0BPM




## 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.

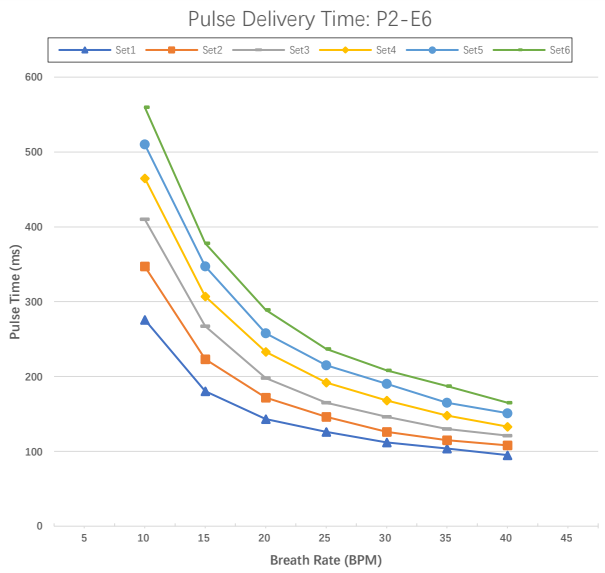
Peak flows at “1” averaged 4-6 LPM, and at the maximum “6” setting averaged about 12-16 LPM.

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

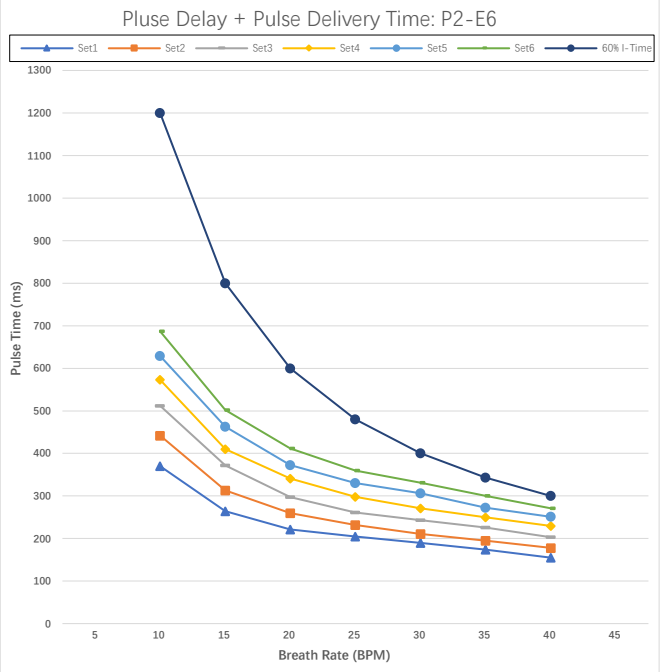



As expected in minute volume delivery devices, pulse delivery times decreased with an increase in breath rate.

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.

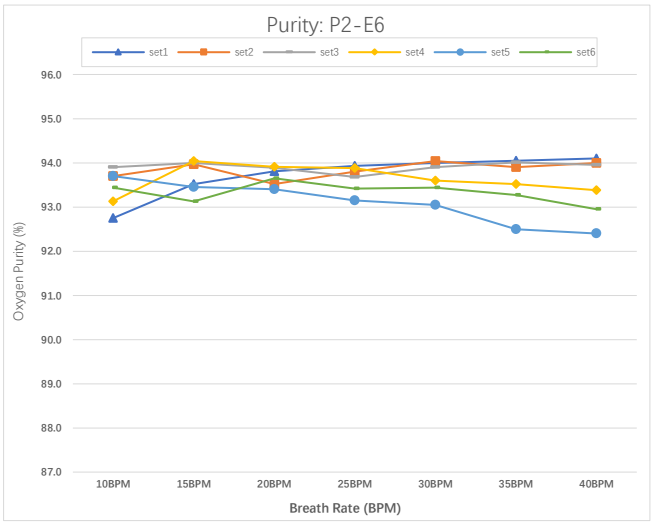
Observing the recorded pulse delay (the time between breath initiation and onset of pulse flow) and pulse delivery times at rates up to 40 BPM, the data shows that the P2-E6 delivers its full pulse volumes well within the initial 60% of the total inhalation time.

## Pulse Delay + Pulse Delivery Times




## Oxygen Purity

| Rhythm Healthcare P2-E6 Purity (%) | | | | | | |
|---|---|---|---|---|---|---|
| Rate | set1 | set2 | set3 | set4 | set5 | set6 |
| 10BPM | 92.75 | 93.70 | 93.90 | 93.13 | 93.70 | 93.44 |
| 15BPM | 93.52 | 93.97 | 94.00 | 94.04 | 93.45 | 93.13 |
| 20BPM | 93.81 | 93.52 | 93.89 | 93.91 | 93.40 | 93.65 |
| 25BPM | 93.93 | 93.80 | 93.68 | 93.88 | 93.15 | 93.42 |
| 30BPM | 94.00 | 94.04 | 93.90 | 93.60 | 93.05 | 93.44 |
| 35BPM | 94.05 | 93.90 | 94.01 | 93.5 | 92.50 | 93.27 |
| 40BPM | 94.10 | 94.00 | 93.95 | 93.38 | 92.40 | 92.95 |




The Oxygen concentration measured at all tested settings and rates was above 92%, which was well within the product specifications of 87-96%.

## Pure Oxygen Minute Volume

| Rhythm Healthcare P2-E6 Minute Volumes (mL) | | | | | | |
|---|---|---|---|---|---|---|
| Rate | set1 | set2 | set3 | set4 | set5 | set6 |
| 10BPM | 196 | 385 | 585 | 731 | 880 | 1080 |
| 15BPM | 205 | 384 | 596 | 770 | 915 | 1080 |
| 20BPM | 210 | 387 | 596 | 771 | 920 | 1088 |
| 25BPM | 216 | 391 | 600 | 770 | 933 | 1087 |
| 30BPM | 220 | 393 | 602 | 778 | 951 | 1090 |
| 35BPM | 222 | 397 | 604 | 779 | 940 | 1089 |
| 40BPM | 226 | 411 | 609 | 780 | 955 | 1084 |
| Average | 213 | 393 | 599 | 768 | 928 | 1086 |

Based on maximum delivered pulse volumes and the corresponding oxygen purity, maximum pure oxygen output of the P2-E6 was around 1090 mL per minute at setting 6, and around 390 mL per minute at setting 2.

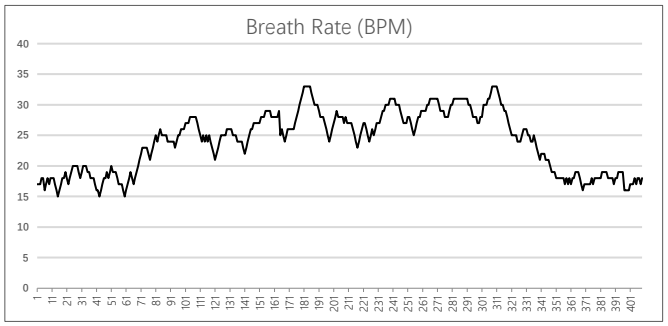
## Dynamic Breath Rate Testing

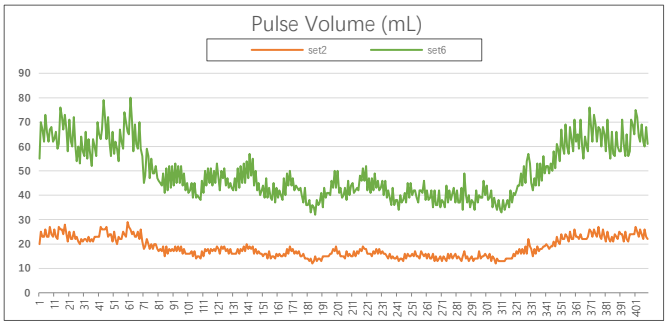
During the breathing simulation with the breathing simulator, the P2-E6 tested the flow and FIO2 data at the setting 2 and setting 6.

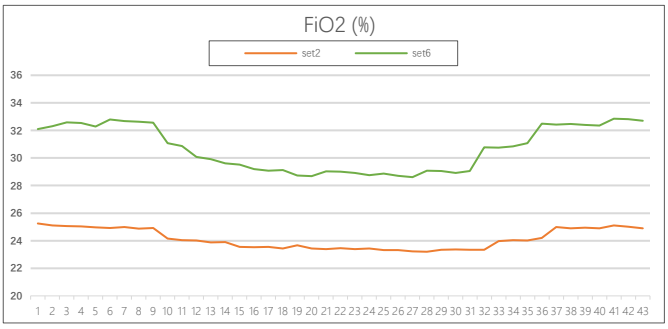
As expected, when the breath rate increased, pulse volume and thus FiO2% decreased.

At resting rates, pulse volume differentials between the 2 and maximum (6) setting were around 30-35mL, which corresponded to around a 6-7% difference in FiO2%.

At active rates these differentials decreased to about 22mL and 5% difference in FiO2%.




## Trigger Sensitivity

| Sensitivity settings | Trigger sensitivity (Pa) | Remark |
|---|---|---|
| 1 | - 10.7 | |
| 2 | - 8.8 | |
| 3 | - 6.7 | Factory Default Settings |
| 4 | - 6.1 | |
| 5 | - 5.3 | |

P2-E6 factory default setting trigger pressure

-6.7Pa, provide 5 levels of sensitivity setting, the lowest trigger pressure - 5.3 Pa;

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