PHILIPS RESPIRONICS

E30

Ventilation solution

Philips Respironics E30 Ventilator oxygen entrainment and FiO_2 estimation

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Emergency Use Authorization

The Philips Respironics E30 Ventilator is not FDA approved or cleared. The Philips Respironics E30 Ventilator is provided globally for use under local emergency use authorizations, such as the FDA Emergency Use Authorization for ventilators, Health Canada Interim Order for use in relation to COVID-19, and waiver of CE marking, which authorize its use for the duration of the COVID-19 public health emergency, unless terminated or revoked (after which the products may no longer be used).

Table 1. ARDS oxygenation impairment in adults [3, 4]

Mild ARDS	200 mmHg < $PaO_2/FiO_2 \leq$ 300 mmHg (with PEEP or CPAP ≥ 5 cmH_2O, or non-ventilated)
Moderate ARDS	100 mmHg < $PaO_2/FiO_2 \leq$ 200 mmHg (with PEEP ≥ 5 cmH_2O, or non-ventilated)
Severe ARDS	$PaO_2/FiO_2 \leq$ 100 mmHg (with PEEP ≥ 5 cmH_2O, or non-ventilated)
When PaO_2 is not available, $SpO_2/FiO_2 \leq$ 315 suggests ARDS (including in non-ventilated patients)	

Introduction

In December 2019, the newly emergent coronavirus, a respiratory tract infection now referred to as the Coronavirus disease 2019 (COVID-19) was first recognized in Wuhan, China. While most people with COVID-19 develop only mild or uncomplicated illness, approximately 14% develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit.[1]

Building on evidence-informed guidelines developed by a multidisciplinary panel of health care providers with experience in the clinical management of patients with COVID-19, the WHO (World Health Organization) has put together a guidance on the clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. It is within this guidance that PaO_2/FiO_2 and SpO_2/FiO_2 ratios are utilized to classify the ARDS (acute respiratory distress syndrome) oxygenation impairment commonly associated with COVID-19.[2] (Table 1)

As COVID-19 continues to spread globally, healthcare providers are working diligently to treat soaring numbers of patients at a time when there are too few ventilators to provide care. Philips is responding to this pressing global need by quickly scaling production of the new Philips Respironics E30 ventilator with the needs of healthcare workers and COVID-19 patients in mind while also complying with medical device quality standards. The new E30 ventilator permits safe entrainment of oxygen (device inlet up to 60 lpm / patient circuit up to 30 lpm) to deliver high levels of inspired oxygen.

This white paper provides a reference for clinicians to estimate FiO_2 delivery based on the amount of oxygen (lpm) that is entrained into the device without an oxygen analyzer in the circuit. The theory and test data supporting the reference charts are also discussed.

Inlet Entrainment of Oxygen

The primary method to entrain oxygen into the E30 is through the dedicated oxygen inlet port (up to 60 lpm). (Figure 1) This accessory comes with each device and is simple and easy to connect (refer to the O_2 inlet port OIS or the E30 Quick Start Guide for details). Always ensure to place a bacteria/viral filter on assembly air inlet and keep this inlet free from blockages as any blockage could affect the oxygen delivery. (Figure 2)

When oxygen is entrained at the O_2 inlet of the E30, the mixture of gas provided to the patient is dependent on the total volume of gas provided by the ventilator. It can provide up to 100% FiO_2 when the rate of oxygen introduction meets or exceeds the average circuit leak rate. The equation for determining the FiO_2 when introducing oxygen at the inlet is as follows (assuming 100% pure oxygen for the low flow):

$$FiO_2 = \frac{100\% * Q_{O2(Inlet)} + 21\% * Q_{Air}}{Q_{Total}}$$

Where:

$\mathbf{Q_{O2(Inlet)}}$ is the low flow oxygen rate into the inlet of the device,

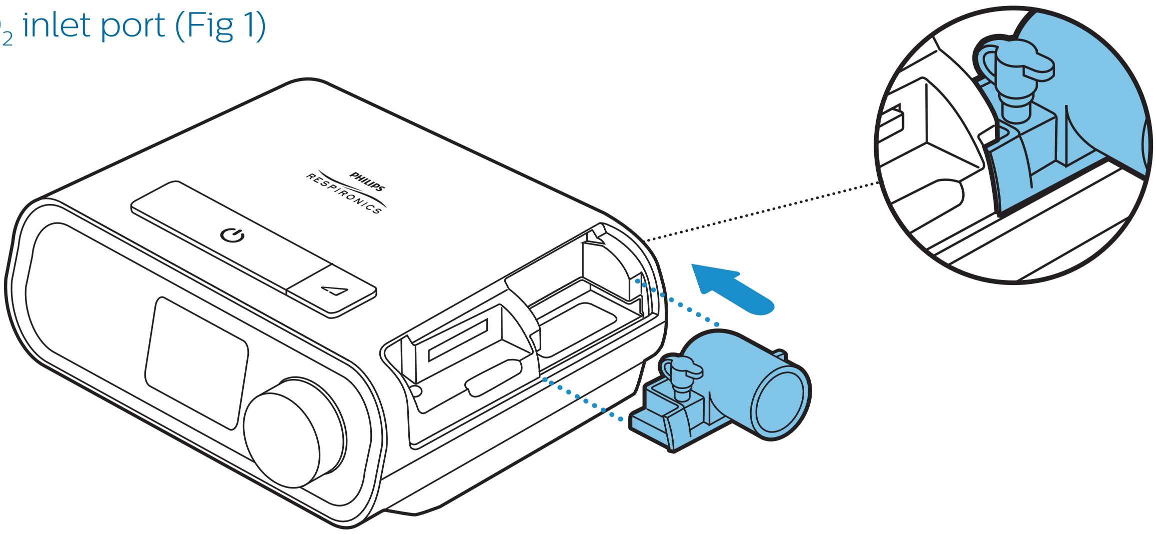
$\mathbf{Q_{Total}}$ is the average total flow from the outlet of the E30, represented as “Leak” on the front panel,

$\mathbf{Q_{Air}}$ is the flow rate of room air into the device ($Q_{Air} = Q_{Total} - Q_{O2(Inlet)}$).

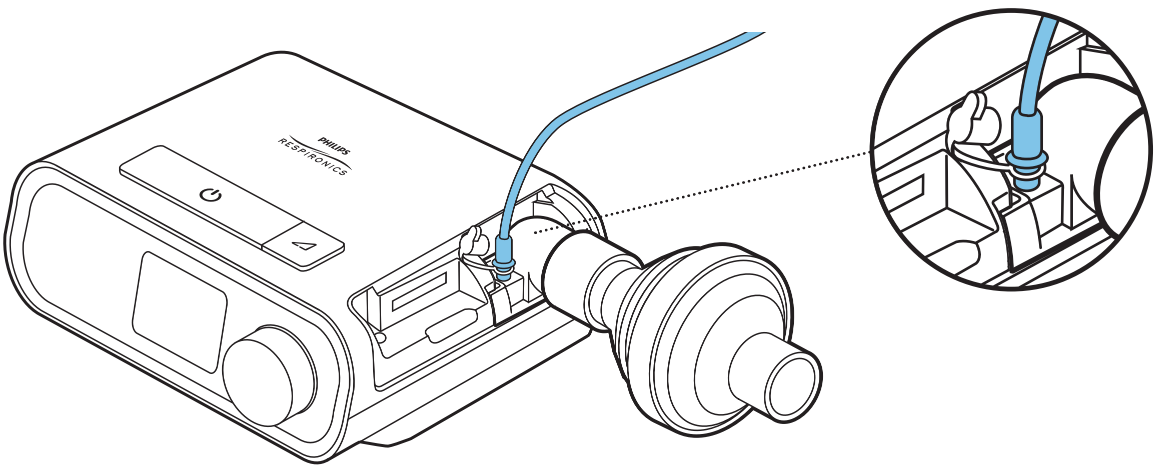
Note that $Q_{O2(Inlet)}$ cannot functionally exceed Q_{Total} (while the oxygen flowmeter can go higher, the excess oxygen flow will not be drawn into the device and will be wasted).

FiO_2 can be approximated at the hospital bedside by referencing the available charts based on either the Leak value (Figure 3) displayed on the E30 screen or the Mean Airway Pressure (MAP) (Figure 5).

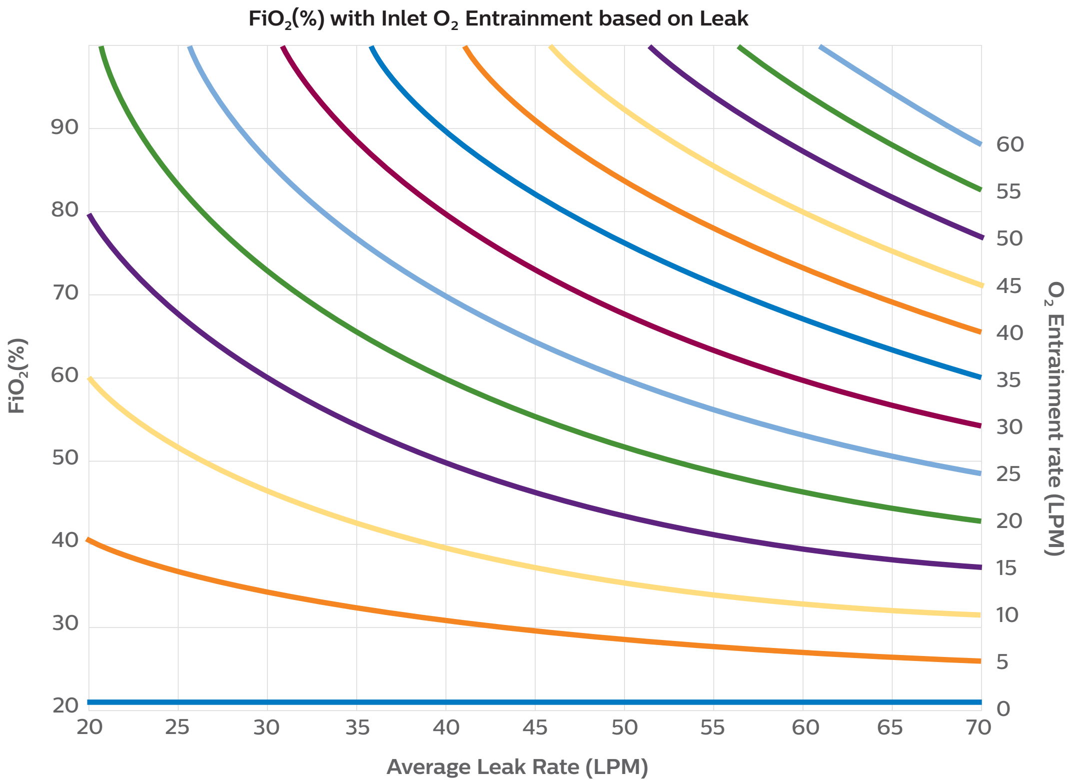
O_2 inlet port (Fig 1)



E30 with oxygen entrained at the dedicated O_2 inlet (Fig 2)



FiO_2 vs. leak for various rates of inlet O_2 entrainment (Fig 3)



If determining FiO_2 based on leak, simply look at the E30 screen (Figure 4) while delivering therapy to determine the current total leak (lpm). Use that leak value and the amount of oxygen (lpm) being entrained into the port to estimate the FiO_2 delivery to the patient (Figure 3). For example, with a leak of 30 lpm with 15 lpm of oxygen entrained into the inlet the estimated FiO_2 is 60%.

Example E30 ventilator screen image (Fig 4)

Another option for estimating FiO_2 is by using the mean airway pressure (MAP) which may be beneficial for oxygen prescription purposes. When using MAP it is assumed that the patient interface has little unintentional leak. (Note: rule of thumb is that [MAP = (IPAP/3) + (2*EPAP/3)] assuming an I:E ratio of 1:2. For example if IPAP is 24 and EPAP is 12, then using this formula the MAP would be 16). The E30 displays pressure during IPAP (inspiratory positive airway pressure) and EPAP (expiratory positive airway pressure) but does not display MAP.

FiO_2 as a function of MAP for various oxygen entrainment rates at the inlet (Fig 5)

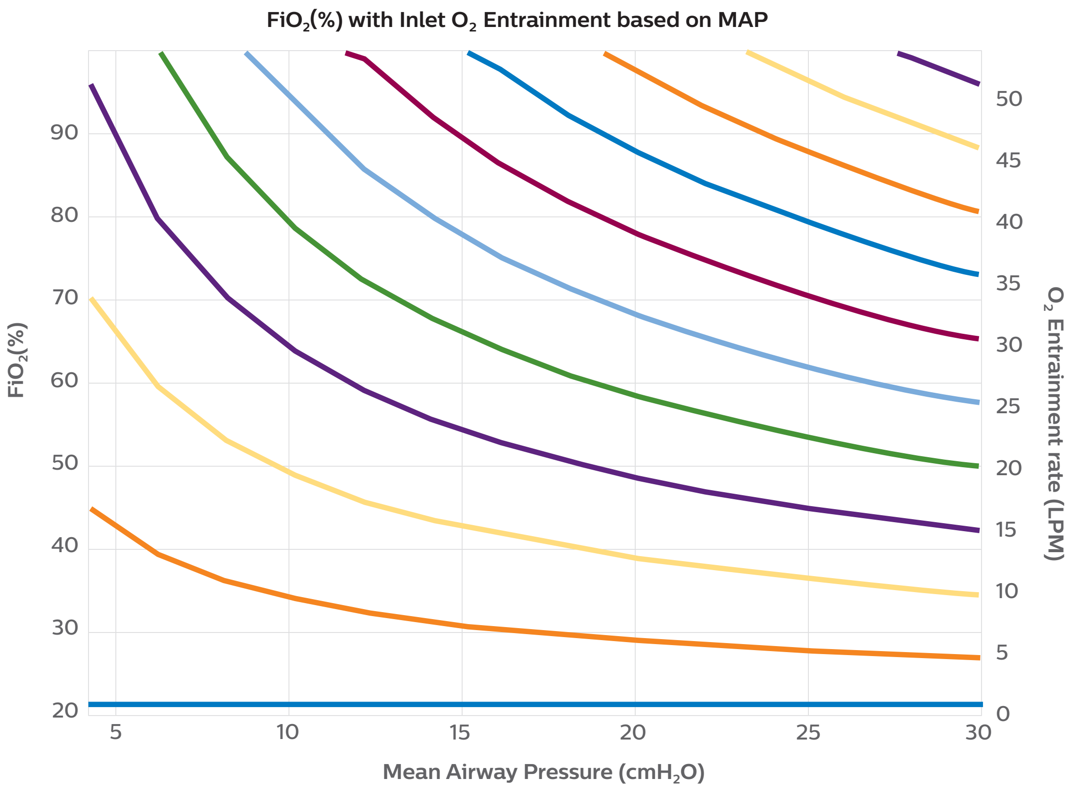


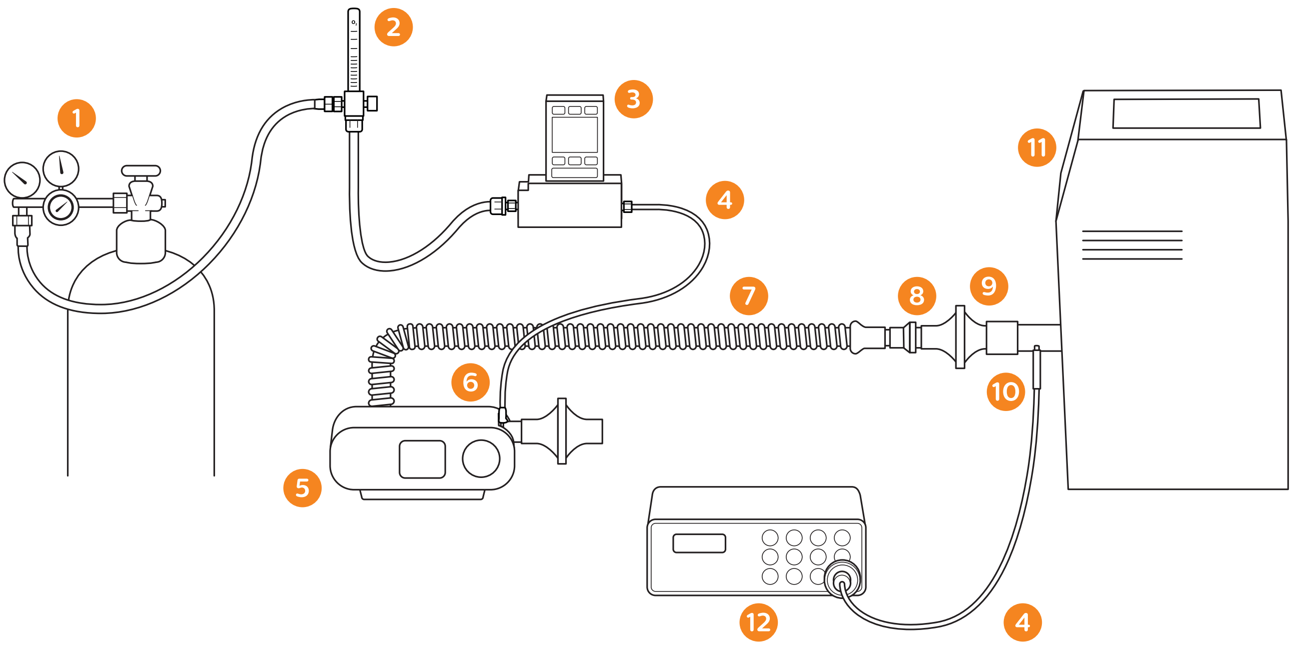
Figure 5: FiO_2 vs. mean airway pressure for various rates of inlet O_2 entrainment. This graph assumes an interface with the patient with minimal unintentional leak

Test Set-up

The Philips Respironics E30 ventilator was tested at a number of different pressure settings and leak rates, using an Alicat Flow meter to monitor the inlet O_2 entrainment flow rate and an Oxigraf Oxygen Analyzer to monitor the O_2 concentration at the inlet to the ASL5000 test lung (Figure 6). The ASL was set with an I:E ratio of 1:2, tidal volume of 400 ml with a breath rate of 15 bpm (Figure 7). The ASL was run in a flow pump mode in order to allow varying levels of pressure support with no change in tidal volume. In order to test a traverse range of desired leak either one or two Whisper Swivel II leak ports were used in the circuit.

The E30 device had a number of test cases in both S (spontaneous) and CPAP (continuous positive airway pressure) modes. The settings for S mode were: IPAP/EPAP of 8/4, 15/8, 25/12, and 30/8 cmH_2O while the CPAP test cases used CPAP of 10cmH_2O.* The inlet oxygen entrainment was varied from 10 to 60 lpm. Measured oxygen values were recorded as the median value across the breath cycle. All equipment was in valid calibration.

Test setup for inlet O_2 entrainment (Fig 6)



1. Oxygen cylinder
2. Oxygen flow meter
3. Alicat Mass flow meter
4. Oxygen tubing
5. E30 ventilator
6. Oxygen inlet port
7. 22 mm tubing
8. Exhalation valve
9. Bacteria/viral filter
10. FiO_2 port
11. ASL5000 active servo lung (connected to computer)
12. Oxigraf oxygen analyser

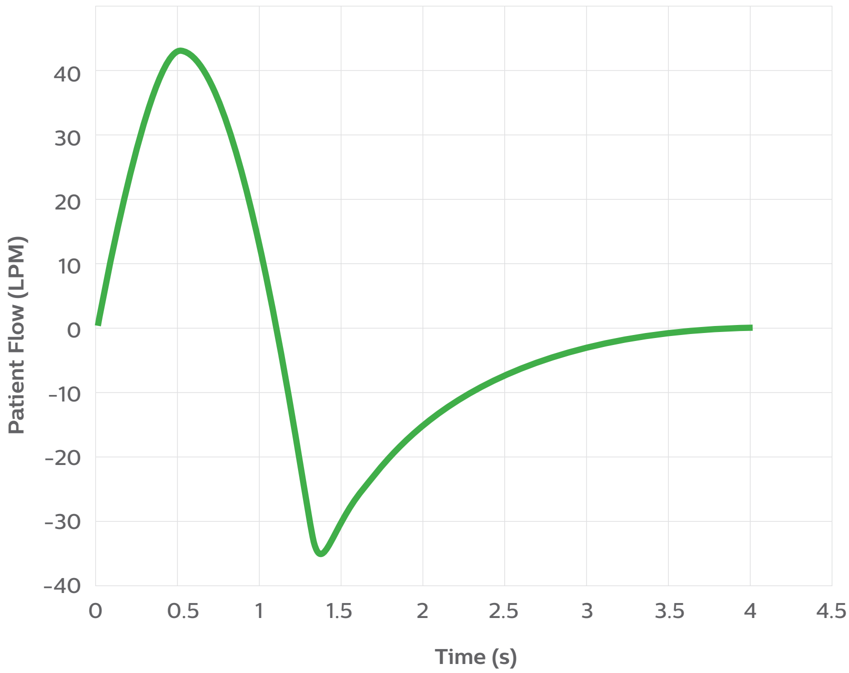
* ***Why were these settings tested?***

These settings were chosen as FiO_2 is functionally dependent on the leak and only the pressure to the extent that it impacts the leak. That is, different pressures will give the same FiO_2, as long as the leak is the same.

At the given test conditions, the test data differed from the model data by an average absolute error of 3.8%. Anecdotally, the error was greatest when the average leak matched the oxygen flow of the system, where some of the entrained O_2 was wasted during exhalation (total flow of the device was less than oxygen entrainment rate) and some room air entrained during inhalation (total flow of the device was more than the oxygen entrainment rate). Maximum error across all test conditions was 16%.

In the clinical setting, it should be noted that different breath profiles, patient metabolic rate, and significant mask leak can all cause actual FiO_2 to differ from predicted. All patients should have their SpO_2 carefully monitored by the clinician in order to ensure safety.

Typical breath profile (Fig 7)



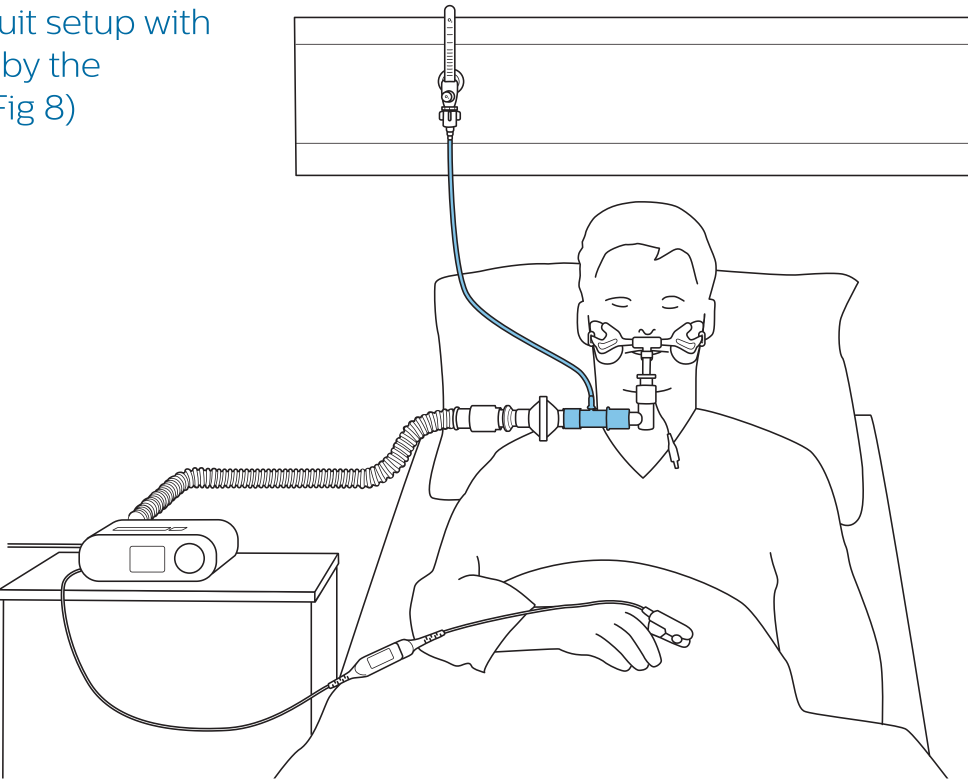
Oxygen Entrainment Near the Patient

A secondary method to entrain oxygen with the E30 is to add it directly into the patient circuit between the exhalation port and the patient interface (i.e. at or near the mask or endotracheal tube). This method is referred to as oxygen entrainment into the circuit or near the patient and has been tested up to 30 lpm (Figure 8).

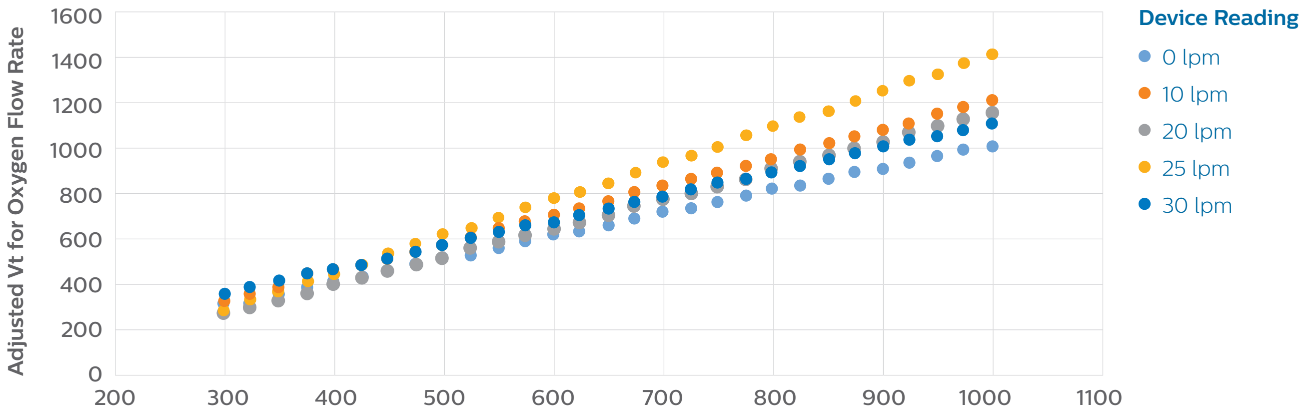
If accurate determination of FiO_2 is important, use of the primary method of O_2 entrainment via the dedicated inlet is strongly recommended over the method of entrainment in the circuit near the patient.

While entrainment of oxygen at the mask can be more efficient, many downsides do exist. Issues include: less reliable FiO_2 values across different patient interfaces and when additional leak exists between the patient and the interface, variable FiO_2 across different patient minute ventilations and I:E ratios, and impaired accuracy of estimated tidal volume when high amounts of oxygen are entrained in the patient circuit (e.g. >10 lpm) (Figure 9).

Example patient circuit setup with oxygen entrainment by the endotracheal tube (Fig 8)



Tidal Volume Adjustment for O_2 Flow Rate in patient circuit (Fig 9)



If using > 10lpm oxygen entrainment into the patient circuit, use the tidal volume adjustment for O2 Flow Rate graph available in the user manual.

In patient circuit oxygen entrainment scenarios such as the one shown in Figure 8, there is minimal mixing of the O_2 entrainment during inhalation, thus the FiO_2 can be modeled as a function of average inspiratory flow and oxygen entrainment rate.

$$FiO_2 = \frac{100\% * Q_{O2(Mask)} + 21\% * (\bar{Q}_{pt,insp} - Q_{O2(Mask)})}{\bar{Q}_{pt,insp}}$$

Where:

$\mathbf{Q_{pt,insp}}$ is the average inspiratory flow and $\mathbf{Q_{O2(Mask)}}$ is the rate of oxygen flow into/at the patient interface. In order to provide a usable model, an I:E ratio of 1:2 is assumed, and as such we can estimate the average inspiratory flow as:

$$\bar{Q}_{pt,insp} = \frac{V_T}{T_{insp}} = \frac{MV/BR}{\left(\frac{1}{BR}\right) * \%I} = 3 * MV$$

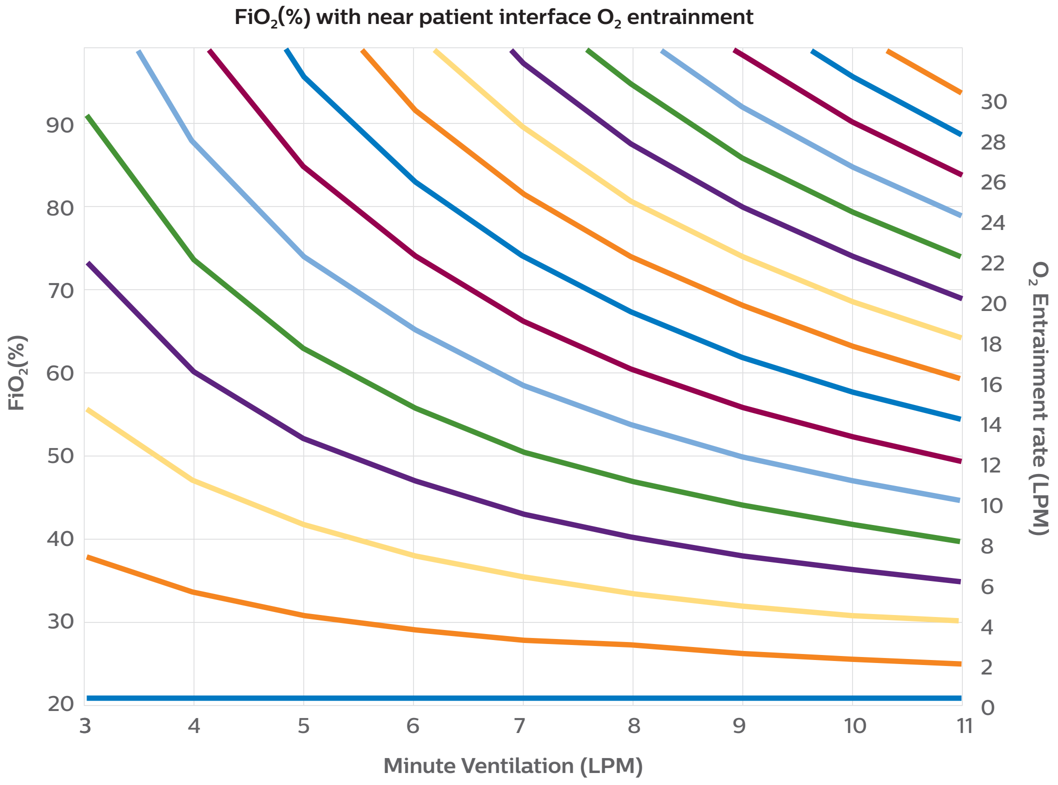
Where:

$\mathbf{V_T}$ is the tidal volume, $\mathbf{T_{insp}}$ is the inspiratory time, **MV** is the patient's minute volume, **%I** is the percent of the respiratory period in inhalation (1/3rd for I:E = 1:2), and **BR** is the breath rate. Thus, it simplifies the model to:

$$FiO_2 = \frac{100\% * Q_{O2(Mask)} + 21\% * (3 * MV - Q_{O2(Mask)})}{3 * MV}$$

With this final expression, we can generate a chart (Figure 10), suitable for a 1:2 I:E ratio and a patient interface with minimal O_2 mixing and minimal unintentional leak. It should be noted that unintentional leak at the patient interface and different I:E ratios will cause the actual FiO_2 to differ from the predicted.

FiO_2 vs. minute ventilation with O_2 entrainment near the patient interface (Fig 10)



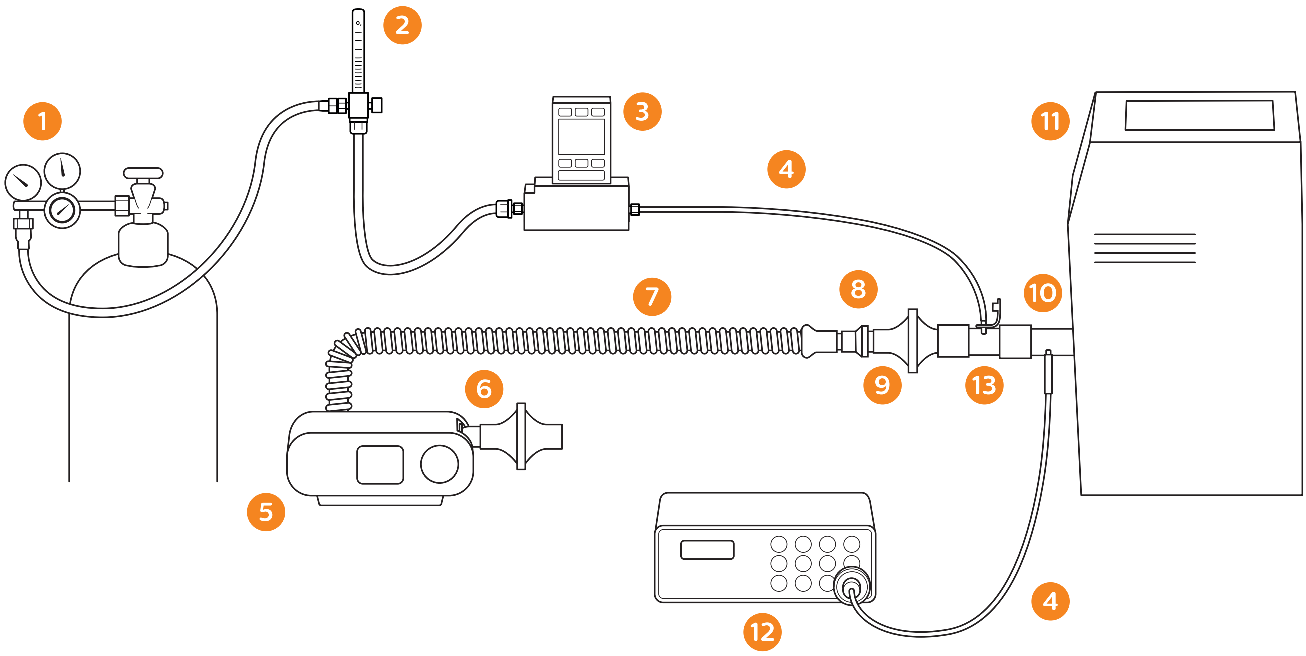
If determining FiO_2 based on minute ventilation, simply look at the MinVent value on the E30 screen (Figure 4) while delivering therapy. Use the MinVent value and the amount of oxygen (lpm) being entrained into the circuit to estimate the FiO_2 delivery to the patient. (Figure 10). For example, with a MinVent of 7 L/min and 8 lpm of oxygen entrained into the circuit the estimated FiO_2 is 50%.

Test Setup

In order to substantiate the FiO_2 results for oxygen being entrained into the patient circuit, a test setup utilizing the same equipment, but entraining the O_2 proximal to the test lung was used. Tidal volumes and breath rates were varied on the ASL5000 test lung, maintaining a 1:2 I:E ratio.

At the given test conditions, the test data differed from the model data by an average absolute error of 2.4%. In our experience, significant changes may occur with mask leak and with changes to I:E ratio when oxygen is bled into the mask. Additionally, if a NIV mask is used with a built-in leak port, significant loss of entrained oxygen may occur with the leak port and this model may be less reliable. It should be noted that different breath profiles, patient metabolic rate, and significant mask leak can all cause actual FiO_2 to differ from predicted. All patients should have their SpO_2 carefully monitored by the clinician in order to ensure adequate oxygenation.

Test setup for patient circuit O_2 entrainment



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9. Bacteria/viral filter
10. FiO_2 port
11. ASL5000 active servo lung (connected to computer)
12. Oxigraf oxygen analyser
13. Oxygen enrichment port

Conclusion

The Philips Respironics E30 ventilator supports oxygen entrainment both at the inlet of the device and in the patient circuit. The primary and preferred method of entraining oxygen at the inlet allows the E30 to meter all airflow to the patient and provide predictable FiO_2 and monitored tidal volumes. Entrainment of oxygen into the patient circuit as a secondary method could be more efficient in certain situations. But, entraining oxygen in this location can affect the accuracy of tidal volume measurements and yield somewhat less predictable FiO_2, depending on the variability of patient parameters, and therefore oxygen concentrations at the mask should be monitored.

If accurate determination of FiO_2 is important, use of the O_2 inlet is strongly recommended.

Using the charts provided in this paper may aid clinicians in obtaining estimated FiO_2 % that could be used in the management of COVID-10 patients.

References

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4. Riviello ED, Kiviri W, Twagirumugabe T, Mueller A, Banner-Goodspeed VM, Officer L et al. Hospital incidence and outcomes of the acute respiratory distress syndrome using the Kigali modification of the Berlin Definition. Am J Respir Crit Care Med. 2016;193(1):52-9. Epub 2015/09/10. doi: 10.1164/rccm.201503-0584OC. PubMed PMID: 26352116.

Appendix

FiO_2 vs. leak for various rates of inlet O_2 entrainment:

Numeric Table for Fig 3

	Leak Rate (L/min) from E30 Ventilator Display								
O_2 (lpm) entrained at inlet	20	25	30	35	40	45	50	55	60
0	21	21	21	21	21	21	21	21	21
5	41	37	34	32	31	30	29	28	28
10	61	53	47	44	41	39	37	35	34
15	80	68	61	55	51	47	45	43	41
20	100	84	74	66	61	56	53	50	47
25	100	100	87	77	70	65	61	57	54
30	100	100	100	89	80	74	68	64	61
35	100	100	100	100	90	82	76	71	67
40	100	100	100	100	100	91	84	78	74
45	100	100	100	100	100	100	92	86	80
50	100	100	100	100	100	100	100	93	87
55	100	100	100	100	100	100	100	100	93
60	100	100	100	100	100	100	100	100	100

Appendix (cont)

FiO_2 as a function of MAP for various oxygen entrainment rates at the inlet:

Numeric Table for Fig 5

	Mean Airway Pressure (cmH_2O)													
O_2 (lpm) entrained at inlet	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**	**20**	22	24	26	28	30
0	21	21	21	21	21	21	21	21	21	21	21	21	21	21
5	46	40	37	35	34	33	32	31	30	30	29	29	29	28
10	70	60	53	49	46	44	42	41	40	39	38	37	36	36
15	95	79	70	64	59	56	53	51	49	47	46	45	44	43
20	100	98	86	78	72	67	64	61	58	56	55	53	52	50
25	100	100	100	92	85	79	74	71	68	65	63	61	59	58
30	100	100	100	100	97	90	85	81	77	74	71	69	67	65
35	100	100	100	100	100	100	96	91	86	83	80	77	74	72
40	100	100	100	100	100	100	100	100	96	92	88	85	82	80
45	100	100	100	100	100	100	100	100	100	100	96	93	90	87
50	100	100	100	100	100	100	100	100	100	100	100	100	97	94
55	100	100	100	100	100	100	100	100	100	100	100	100	100	100
60	100	100	100	100	100	100	100	100	100	100	100	100	100	100

FiO_2 vs. minute ventilation with O_2 entrainment near the patient interface:

Numeric Table for Fig 10

	Patient Minute Ventilation								
O_2 (lpm) entrained in circuit near patient	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
0	21	21	21	21	21	21	21	21	21
2	39	34	32	30	29	28	27	26	26
4	56	47	42	39	36	34	33	32	31
6	74	61	53	47	44	41	39	37	35
8	91	74	63	56	51	47	44	42	40
10	100	87	74	65	59	54	50	47	45
12	100	100	84	74	66	61	56	53	50
14	100	100	95	82	74	67	62	58	55
16	100	100	100	91	81	74	68	63	59
18	100	100	100	100	89	80	74	68	64
20	100	100	100	100	96	87	80	74	69
22	100	100	100	100	100	93	85	79	74
24	100	100	100	100	100	100	91	84	78
26	100	100	100	100	100	100	97	89	83
28	100	100	100	100	100	100	100	95	88
30	100	100	100	100	100	100	100	100	93

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