

Philips Respironics E30 ventilator device training presentation

Julie Yarascavitch, Sr. Global Clinical Applications Manager

April 11, 2020

Emergency Use Authorization

The Philips Respironics E30 Ventilator is not FDA cleared or approved. 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).

Philips Respironics E30 ventilator fills the critical hospital ventilation shortage for COVID-19 patients

The ventilator is authorized for use to treat patients with respiratory insufficiency

Intended to provide invasive and noninvasive ventilatory support for individuals with respiratory insufficiency



Intended Use: The Philips Respirations E30 ventilator is intended to provide invasive and non-invasive ventilatory support for individuals with Respiratory Insufficiency. It is specifically for the care of adult and pediatric patients >7 years of age and >18kgs. It is intended to be used in the hospital or other institutional healthcare environments, as well as spaces converted for the care of large numbers of COVID-19 patients (e.g. convention centers, university dormitories, motels). The Philips Respironics E30 ventilator is intended for use by qualified, trained personnel under the direction of a physician.



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 to medical device quality standards.

This global ventilator solution, can be purchased by governments and hospitals who are experiencing ventilator shortages. The Philips Respironics E30 ventilator can be used when there is limited access to a fully featured critical care ventilator.

Designed for mass production by a team deeply experienced in respiratory care, the Philips Respironics E30 ventilator meets numerous important needs.

Key ventilation features

Interface modality: Noninvasive and invasive (respiratory insufficiency) **Integrated heated humidification** (noninvasive use) **Ventilation modes:** CPAP, S, S/T, PC Passive circuit **Pressure range: IPAP:** 4 to 30 cm H₂O **EPAP:** 4 to 25 cm H_2O **CPAP:** 4 to 20 cm H_2O **Patient settable alarms:** Circuit disconnection: Off, 15, 60 seconds Apnea: Off, 10, 20, 30, 40 seconds Low minute ventilation: 1 to 99 IPM **Breaths per minute settable:** Off, 1 to 30 (1-breath increments) Supplemental low flow oxygen: Patient circuit -up to 30 lpm / device inlet - up to 60 lpm



Designed for your safety Easy to use Optimized oxygen delivery Key monitoring and alarms



Easy to use

Quick set-up and simple operations allowing healthcare providers with a wide range of skill sets to treat and monitor patients.

Device overview

- Device front with humidifier
- Removing the humidifier
- Device back

Device overview: Device front with humidifier

- 1 Therapy On/Off button
- 2 Ambient light sensor (not active)
- 3 Ramp button
- Door, air entrainment port (filters and O₂ inlet)
- 5 Display screen
- 6 Control dial
- 7 Humidifier



Device overview:

Detaching the humidifier

- Ensure that the E30 is switched off before disconnecting the humidifier.
- Pick up the system, placing one hand on the E30 and the other on the humidifier.
 Press the humidifier release button and gently pull each component apart.



Device overview:

Device back

- 1 Humidifier connector
- 2 Door, accessory access (SpO₂)
- 3 Air outlet port
- 4 Power inlet



Setting up the device power

- Configuration A External Alarm Module (EAM)
- Configuration B Uninterrupted Power Supply (UPS)

Device power:

Configuration A

- Ensure the E30 ventilator is turned off. To prevent accidental disconnection, route the power supply cord through the cord clamp.
- Plug the external alarm module connector into the power inlet on the E30 ventilator. Clamp the cord securely to the E30 ventilator enclosure.
- Plug in the power supply to supply power to the E30 ventilator. Ensure both cables are secured with cord clamps and verify that the E30 ventilator and External Alarm Module are operating properly.



Device power:

Configuration B

- 1 Ensure the therapy device is turned off.
- Plug in the AC-DC adaptor into the E30 ventilator. Clamp the cord securely to the E30 ventilator enclosure.
- Plug the AC-DC adaptor into the UPS backup outlets row and then in the power supply.





Navigating the menu

• Adjusting therapy settings

Navigating the menu:

Adjusting therapy settings

- Rotate the control dial to navigate to the 'Therapy' tile, then press the control dial to enter.
- Choose a therapy mode before editing the settings. Whilst the 'Mode' tile is highlighted green press the control dial.
- 3 Rotate the control dial to select the mode you intend to use for therapy. Press the dial to make the selection.
- 4 Rotate the control dial to navigate to the therapy setting you wish to adjust. Press the dial to select the setting and then rotate the dial to adjust value.
- Once you've finished adjusting the therapy settings, press the 'Therapy on/off button' to start therapy.
- Press the 'Therapy on/off button' again to review the ventilation data for this therapy session.





Designed for your safety

Recommended circuit set-ups contain a bacterial/viral filter to minimize exposure for healthcare providers when used invasively or noninvasively with example accessories that may be used, such as a full-face, non-vented (without integrated leak) mask, or helmet.

Example Circuit options

These circuit set-ups and accessories are examples provided for information purposes only as not all have been validated for use with the Philips Respironics E30 ventilator.



Circuit set-up:

Using helmet

- 10 External Alarm Module
- **1** Uninterrupted Power Supply
- 2 E30 ventilator
- 3 Bacterial/viral filter
- 4 Tubing
- **5** Oxygen analyzer (optional)
- ⁶ SpO₂ module
- 7 SpO₂ sensor
- 8 Helmet
- 9 Exhalation valve
- 0 Cap end
- 11 Oxygen tubing
- 12 Oxygen flow meter



Circuit set-up: Using non-vented mask

- 13 External Alarm Module
- **1** Uninterrupted Power Supply
- 2 E30 ventilator
- 3 Tubing
- 4 O₂ inlet port
- **Bacteria/viral filter**
- ⁶ SpO₂ module
- 7 SpO₂ sensor
- 8 Exhalation valve
- 9 Non-vented mask
- 0 Oxygen tubing
- 11 Oxygen flow meter



Circuit set-up:

Invasive use

- External Alarm Module
- **1** Uninterrupted Power Supply
- 2 E30 ventilator
- 3 Tubing
- O₂ inlet port
- Bacteria/viral filter
- 6 SpO₂ module
- 7 SpO₂ sensor
- 8 Exhalation valve
- 9 Closed suction catheter
- 10 ETT holder
- 11 Oxygen tubing
- 2 Oxygen flow meter
- 13 Trach adaptor without closed suction catheter
- Optional HME (not shown)





Optimized oxygen delivery

Safe entrainment of oxygen (device inlet up to 60 lpm / patient circuit up to 30 lpm) to deliver high levels of inspired oxygen.

O₂ delivery set-up: Primary Option: O₂ inlet port

- Confirm that the E30 ventilator is powered OFF then open the door on the right side of the unit.
- 2 Remove the blue filter.
- Removing the door is optional. If this is desired, pinch the hinges inward and lift the door up and off.
- Install the O₂ assembly into the slot where the filter was. Push the assembly completely in to ensure it's flush to the surface of the unit.
- Attach the air filter to the O₂ assembly. Remove the cap of the O₂ inlet port and connect the tubing from your oxygen source.

 \sim

Keep the O₂ inlet with the bacteria/viral filter on it free from blockages.

O₂ delivery set-up: Secondary Option: Patient circuit entrainment

Oxygen can also be added to the circuit using the oxygen enrichment port in the location highlighted on the right between the patient interface and the exhalation valve.

Both oxygen delivery options can be used for patients with noninvasive or invasive interfaces. This circuit set-up and accessories are examples provided for information purposes only as not all have been validated for use with the Philips Respironics E30 ventilator



O₂ delivery set-up comparison

	O ₂ inlet port	Patient Circuit entrainment
Oxygen entrainment	up to 60 lpm	up to 30 lpm
Compensation for delivered pressure	Yes	No
Tidal Volume adjustment needed	No	Yes, if oxygen > 10 lpm Refer to chart on the next slide

If accurate determination of FiO₂ is important, use of the O₂ inlet is strongly recommended

FiO_2 estimation O₂ inlet port using leak

For example, with a leak of 30 lpm and 15 lpm of oxygen entrained into the inlet the estimated FiO_2 is 60%.

↑ ●000		Therapy	
cmH₂O 10.0	Leak 30	MinVent 7	
Vt 440	RR 16	SpO2 96%	
-^- PC			



FiO₂ estimation O₂ inlet port using MAP

Assumption: patient interface has little unintentional leak

MAP = (IPAP/3) + (2*EPAP/3) assuming an I:E ratio of 1:2

For example, IPAP = 24 and EPAP = 12, then MAP = 16

₹ ●000		Therapy		
	cmH₂O 10.0	Leak 30	MinVent 7	
٦	Vt 440	RR 16	SpO2 96%	
	≁ РС			



Vt adjustment Patient Circuit O₂ Entrainment

If using > 10lpm oxygen entrainment into the patient circuit, use the tidal volume adjustment for O_2 Flow Rate graph

No tidal volume correction is required when using the O₂ inlet port

Tidal Volume Adjustment for O₂ Flow Rate in patient circuit



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

FiO₂ estimation Patient Circuit O₂ Entrainment using MinVent

For example, with a MinVent of 7 L/min and 8 lpm of oxygen entrained into the circuit the estimated FiO_2 is 50%.

↑ ●000		Therapy	
cmH₂O 10.0	Leak 30	MinVent 7	
∨t 440	RR 16	SpO2 96%	
∽- РС	:		

Entrainm $FiO_2(\%)$ ent rate (LPM) Minute Ventilation (LPM)

 $FiO_2(\%)$ with near patient interface O_2 entrainment



Key monitoring and alarms

On-screen respiratory monitoring (pressure, tidal volume, RR, Minute Ventilation, leak and SpO_2) as well as visual and audible alarms to provide pertinent therapy information.

Therapy modes

- CPAP
- S
- S/T
- PC

Therapy modes: **CPAP**

Continuous Positive Airway Pressure

- 1 Patient triggered and cycled breaths.
- Pressure delivered during both inhalation and exhalation is the CPAP pressure setting.
- 3 All breaths are spontaneous





Therapy modes: s

Spontaneous

Patient triggered support.

 Breaths are spontaneous (patient triggered and cycled) and pressure supported.





Therapy modes: st

Spontaneous / Timed

Patient triggered support with a breath rate. In this example the breath rate is set to 10 breaths per minute (every 6 seconds)

- Pressure supported breath, patient triggered and cycled.
- 2 Mandatory breath, machine triggered and cycled.





Therapy modes: PC

Pressure Control

Patient triggered support with a minimum breath rate and fixed inspiratory time on all breaths. In this example the breath rate is set to 10 breaths per minute (every 6 seconds)

- 1 Assisted breath, patient triggered and machine cycled.
- 2 Mandatory breath, machine triggered and cycled.





Time

Key monitoring

- Therapy delivery
- SpO₂ connection
- Alarm options

Key monitoring:

Therapy delivery

- Press the 'Therapy on/off button' to start therapy.
- Press the 'Therapy on/off button' again to review the ventilation data for this therapy session.

E30	 € ●000 Therapy CmH₂O Leak MinVent 10.0 30 7 Vt RR Sp02 440 16 ✓ PC 		
		-	

Key monitoring:

SpO_2 connection

- Connect the SpO2 accessories: link module, xpod or similar approved and then the oxygen sensor
- SpO₂ is visible on the bottom right in the monitored parameters view
- Acknowledge the SpO₂ message on screen by clicking the control dial



Key monitoring:

Alarm options

- 1 Turn the control dial to the Alarms Menu
- 2 There are three settable audible/visual alarms: Patient Circuit Disconnect; Apnea; and Low Min Vent
- In this example we set the Low Min Vent to 5
- If appropriate acknowledge the silence alarm message by clicking the control dial.
- 5 Once appropriate click to clear the alarm message with the control dial



Visual alarms

- Leak is less that Min Vent
- Leak is less than 0
- Excessive leak

Visual alarms: Leak is less than Min Vent

Situation:

When leak is less than minute ventilation the two cells on the data screen will be highlighted yellow.

The leak in the circuit should be equal to or greater than the volume of air exhaled by the patient (MinVent) to adequately remove CO_2 enriched air.

Action and resolution:

- Verify that the leak port isn't blocked

If the indicator still remains and oxygen is entrained through the patient circuit:

- Reduce the $\rm O_2$ flow or
- Increase the leak in the circuit.

Once the balance is adequately restored the yellow highlights will disappear.



Visual alarms: Leak is less than 0

Only applicable when oxygen is entrained directly into the patient circuit

Situation:

When leak is less than 0 the cell will be highlighted orange. As per the indication above, Min Vent will be highlighted yellow because the minute ventilation is greater than the leak. Tidal volume will also be highlighted yellow because the negative leak reduces tidal volume accuracy.

A negative leak indicates extra oxygen in the circuit that is being wasted and not utilized by the patient.

Action and resolution:

- Reduce the $\rm O_2$ flow or

- if unable to reduce the O_2 flow then increase the leak.

Once the balance is adequately restored the color highlights will disappear.



Visual alarms:

Excessive leak

Situation:

When leak is excessive the leak and tidal volume cells will be highlighted yellow.

The patient's mask may be too loose or disconnected possibly leading to unfiltered exhaled gases.

Tidal volume is highlighted yellow because the excessive leak reduces tidal volume accuracy.

Action and resolution:

Take appropriate steps to ensure the patient's mask is connected and there is an appropriate seal.

Once leak returns to a stable value the yellow highlights will disappear.





Additional Information

Provider Access Humidifier Use

Provider Access (default)





If locked, Provider mode can be accessed by following these steps:

- 1. Supply power to the device (if not already).
- 2. Once the device is powered, press and hold both the Control Dial and the Ramp button on the device for at least 5 seconds. (will give you temporary access)
- 3. Then navigate to the Device menu and turn the Provider Mode back on

Patient Access

If you lock provider access in the Device Menu then you will be in the Patient Mode with the following menus available





Using the Humidifier (noninvasive only)



Comfort





Fixed or Adaptive (A) humidification

Fixed applies a constant heat on the humidifier heater plate. Under certain conditions and settings, this mode can allow condensation to occur in the tube.



Adaptive adapts the heater plate temperature to the ambient conditions in the room, and is designed to not allow condensation to occur in the tube.

Using the Humidifier (noninvasive only)



Comfort



Humidifier Setting

This setting allows you to choose the desired humidity setting for the humidifier: 0, 1, 2, 3, 4 or 5.



Easy to use

Designed for your safety

Optimized oxygen delivery

Key monitoring and alarms



