

## Customer FAQ - E30 Ventilator

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## 1. Commercial

### 1. Who can order the E30 Ventilator?

The E30 ventilator will be offered directly to hospitals and health systems, local, state or federal health agencies, as well as non-governmental organizations (NGO) such as WHO, UNICEF, etc. The E30 will not be sold and distributed from our traditional DME/HCP or distributor partners. However, in countries where there is no direct channel, distributors are used to selling to hospitals and Governments.

### 2. How do you order the E30?

Work with your Philips Hospital Respiratory Care or Philips Sleep and Respiratory Care sales representative to determine if you have or need to create an account. It is recommended to work with your account representative to receive an E30 equipment and accessory quote, create and place your order.

### 3. Is there an allocation policy in place for the E30?

We will build to order, and if we need to allocate, will follow Philips guidance that is based on a fair and ethical approach.

### 4. Will we be putting any cancellation policies in place, aside from normal guidance?

Currently, a customer can cancel an order any time before the E30 ships. There is no return after 30 days.

### 5. What is the price of the E30, and will there be discounts?

For pricing, please check with your local sales representative. At this time, we do not intend to offer discounts on E30 device.

### 6. Does the E30 ventilator have CE mark?

The E30 does not have a CE mark. 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).

### 7. Is the E30 ventilator FDA cleared or approved?

The E30 is not cleared or approved by the FDA. However, the E30 is authorized for use by the FDA under the Emergency Use Authorization (EUA) for ventilators, which authorizes its use for the duration of the US Health and Human Services COVID-19 public health emergency declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

### 8. Can existing DreamStation devices be upgraded to an E30?

No. The E30 will be distributed as a complete hardware and software solution.



## 9. If I have a question about the E30, who do I contact for help?

If your customers have product related questions, please call your local Philips Respironics product support.

## 10. Can the E30 be used in the home?

The E30 is not approved for home use.

## 11. What are the terms of the warranty?

Respironics, Inc. warrants that the Philips Respironics E30 Ventilator will be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of 1 year from the date of shipment by Respironics, Inc. to the customer.

## 12. How long can you use the E30?

The 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).

## 13. Who is eligible for the \$1,000 credit program?

Customers with Trilogy Evo OBM, Trilogy EV300, Trilogy 202 and V60 orders existing in the approved backorder list (ordered through May 1, 2020) at time of the purchase of a Philips Respironics E30 ventilator:

- 989805664051 (INX9999H19) Philips Respironics E30 w/Humidifier, INTL
- 989805664021 (DSX9999H11) Philips Respironics E30 w/Humidifier, DOM

For every non-discounted E30 ordered, the program provides a discount of \$1,000/€885 on each Trilogy Evo OBM, Trilogy EV300, Trilogy 202 or V60 backordered ventilators. Contact your Philips Hospital Respiratory Care or Philips Sleep and Respiratory Care sales representative for complete details.

## 14. Can the E30 be serviced?

Respironics, Inc. warrants that the Philips Respironics E30 Ventilator will be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of 1 year from the date of shipment by Respironics, Inc. to the customer. If device fails within warranty period, it will be replaced by Philips. No repair kits, services, will be available after the warranty period, but a replacement could be purchased as long as the emergency authorization for the locale remains in place and Philips has inventory of E30.

## 15. This E30 looks like a DreamStation CPAP – why can't I use it as a CPAP?

The E30 includes invasive and noninvasive ventilation modes, alarms and oxygen therapy designed to treat patients with respiratory insufficiency. While the E30 cannot be used in the home as a CPAP, a treating physician could choose to use in CPAP mode in the hospital for the treatment of patients.

## 16. What does it mean for the supply of other CPAP devices?

During the COVID-19 crisis, Philips will make every effort to provide an uninterrupted supply of the full offering of respiratory care solutions. At this time, Philips is maximizing the delivery of solutions



to address the COVID-19 demand for ventilators, and this may result in temporary delays in other product categories.

**17. Does E30 have FAA approval?**

No, the E30 device is for hospital and field hospital use only. It is not intended to be used outside of a hospital setting.

**18. Where can I find the E30 device and accessory manuals and Quick Start Guide?**

Please visit [www.philips.com/hrcmanuals](http://www.philips.com/hrcmanuals), and select E30 from the left-hand menu.

## 2. Product / Technical

**19. Is the E30 a new product?**

Yes. The E30 Ventilator is a new solution that leverages the deep ventilation design experience of Philips intended to expand ventilator supply options during times of high census (e.g. COVID-19) of ventilated patients in acute care settings.

**20. What circuits can be used with the E30 Ventilator?**

Please refer to our Quick Start Guide (QSG) for circuit configuration options.

**21. Can this be used in the Intensive or Critical Care Unit?**

Yes.

**22. Is this for only spontaneously breathing patients?**

It is for respiratory insufficiency (as per intended use; but we have both ST and PC modes which can support patients that require a minimum breath rate)

**23. Does the E30 have remote monitoring capability?**

No.

**24. Does the E30 have visual and audible alarms?**

Yes. All alarms are both visual and audio-driven. The E30 has the following alarms:

- Circuit disconnection: off, 15, 60 seconds
- Apnea: off, 10, 20, 30, 40 seconds
- High respiratory rate: 1 to 60 BPM (in increments of 1)
- Low minute ventilation: 1 to 99 l/min (in increments of 1)
- Vent Inoperative
- Vent Inoperative - Inlet blocked. Check filter
- Vent Inoperative - Blocked Outlet
- Low Pressure
- High Pressure
- Low Motor Speed
- Low Voltage - Medium priority alarm
- Power fail – Uninterruptable power supply will alarm - initial shipment of devices (early April 2020)



- Power fail - External Alarm Module - high volume production

## 25. What do the visual indicators with the different colors mean?

Additional visual indicators have been included in the E30. The below outlines the visual indicators:



**Leak is less than MinVent**

- Leak and Minute ventilation monitoring highlighted in yellow: leak is less than minute ventilation, verify that the exhalation port isn't blocked.



**Leak is less than 0**

- Leak highlight in orange and Minute ventilation and tidal volume in yellow: the leak is less than 0, Reduce the O<sub>2</sub> flow or if unable to reduce the O<sub>2</sub> flow then increase the leak



**Excessive leak**

- Leak and tidal volume highlighted in yellow: excessive leak, Take appropriate steps to ensure the patient's mask is connected, and there is an appropriate seal

## 26. Will there be a roll stand?

While roll stands are currently being focused towards our preexisting ventilation platforms, our supply chain teams are evaluating other possibilities and will continue to communicate on this subject and need.

At the end of May 2020, we will offer an IV pole mounting solution for the E30. The E30 Pole bracket assembly can mount to an IV pole, and the E30 can be secured to the bracket assembly.

## 27. Does the E30 Ventilator provide direct access to the set-up menus?

The E30 Ventilator allows direct access to the set-up menus right out of the box. The E30 will start in Provider mode for ease of use and settings are changed in the therapy menu. The E30 can still be locked and/or changed to the patient mode.

## 28. Communication protocol? Is there a way to alert a nurse remotely?

At this time, there are no remote monitoring connections supported by the E30

## 29. Can I download the E30 device to review patient data (i.e. Care Orchestrator)?

No, the E30 is an EUA device and is not supported by systems that read device or patient data.

### 30. Does the E30 connect to hospital or patient data platforms?

This device does not support any Wi-Fi, Cellular or Bluetooth connections that would transmit data to a Philips or hospital-based system.

### 31. How should hospitals clean and disinfect their E30 devices?

Please follow the Cleaning Instructions and Disinfecting Instructions in the E30 User Manual and use only those cleaning and disinfecting agents per the process listed in this manual. These include 70% Isopropyl Alcohol (Device and O<sub>2</sub> Inlet Port), DisCide Towelettes (Device ONLY) and 10% Chlorine Bleach solution. Should a hospital choose to continue using agents detrimental to the enclosure plastic, cracks may appear, and the device may require replacement.

### 32. What if the E30 Ventilator is used on an infected patient?

To prevent patient or ventilator contamination, always use a main flow bacteria/virus filter on the patient gas outlet port, clean the external surfaces per instructions, and isolate the vents. Hospitals should follow their own published infectious disease control protocols.

### 33. How effective is the main flow bacteria filter (especially for viral issues like COVID-19)?

The bacterial/viral filter we offer has an efficiency rating of greater than 99.99%. To our knowledge, the filter has not been expressly tested with COVID-19.

12NC and PRD Part Number		Bacterial / Viral Filters	Box quantity
989805609521	342077	Bacteria/viral filters	10/pack
989805663481	C06418	Filter, bacterial, disposable	50/pack

### 34. How often should the bacterial/virus filter be replaced?

The duration of filter use will vary by patient and usage. As stated in the E30 User Manual, it is recommended to change the filter between patients and at regular intervals (or as stated by the manufacturer).

### 35. Will the exhalation filtration ensure 100% protection from patients' exhaled gas?

The filtered port will effectively filter (> 99.99% efficiency) the dispersion of gas that is forced out the exhalation port during the exhalation phase of a breath.

## 3. Clinical

### 36. What modes of ventilation are available on the E30 Ventilator?

The E30 has the following modes:

- Continuous Positive Airway Pressure (CPAP)
- Spontaneous (S)
- Spontaneous/Timed (S/T)
- Pressure Control (PC)

### 37. What is the CPAP mode?

CPAP mode is a spontaneously breathing therapy delivering a continuous pressure that supports the



airway.

### 38. What is the S mode?

Spontaneous (S) mode is a therapy in which all breaths are spontaneously triggered by the patient and the device delivers bi-level pressure support. In this mode, an Inspiratory Positive Airway Pressure (IPAP) is delivered during inhalation and a lower Expiratory Positive Airway Pressure (EPAP) is delivered during exhalation.

### 39. What is S/T mode?

In Spontaneous/Timed (S/T) mode, the device delivers bi-level pressure support. This mode provides Spontaneous and Mandatory breaths. A Mandatory breath is delivered if the patient does not spontaneously breathe within the prescribed Breath Rate (BPM) setting. This ensures that the patient receives a minimum number of breaths per minute. In this mode, an IPAP is delivered during inhalation and a lower EPAP is delivered during exhalation. The duration of a Spontaneous breath is determined by the patient effort. The duration of a Mandatory breath is determined by the inspiratory time setting.

### 40. What is PC mode?

In Pressure Control (PC) mode, the device delivers bi-level pressure support. This mode delivers Assisted and Mandatory breaths. This mode is similar to S/T mode, except that all breaths have a fixed inspiratory time.

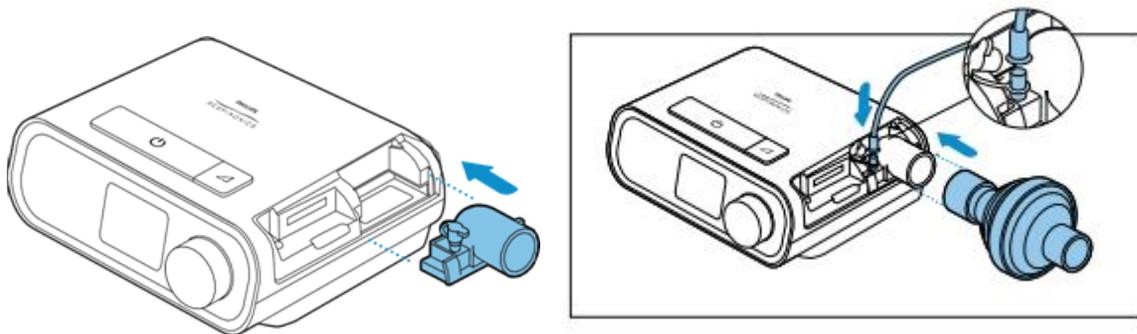
### 41. What are the default settings that the E30 is shipped with?

CPAP	10 cmH <sub>2</sub> O				
S	IPAP = 20 cmH <sub>2</sub> O	EPAP = 10 cmH <sub>2</sub> O			
S/T	IPAP = 20 cmH <sub>2</sub> O	EPAP = 10 cmH <sub>2</sub> O	BPM = 16	T <sub>i</sub> = 1.2	
PC	IPAP = 20 cmH <sub>2</sub> O	EPAP = 10 cmH <sub>2</sub> O	BPM = 16	T <sub>i</sub> = 1.2	

Note: settings can remain the same when moving from one patient to another as there is not a New Patient option that can be found in the Philips E30.

### 42. How can oxygen (O<sub>2</sub>) be delivered with the E30 Ventilator?

O<sub>2</sub> can be entrained through the inlet port on the E30 Ventilator or bled into the circuitry.



When using the O<sub>2</sub> inlet, the flow can be up to 1 to 60 lpm. When O<sub>2</sub> is bled in to the circuitry the flow can be up to 1 to 30 lpm.

#### 43. How do I estimate FiO<sub>2</sub> delivery without an oxygen analyzer inline?

Please refer to the digital whitepaper ([E30 Oxygen Entrainment and FiO<sub>2</sub>-Estimation Whitepaper](#)) and [training presentation](#) for more details, including graphs that can help you determine the estimated FiO<sub>2</sub> based on the liter flow of oxygen entrained. Please refer to the [Philips Respironics E30 ventilator web page](#)

Depending on the entrainment method used, up to 60lpm is possible with the E30, but many flowmeters in the hospital setting have indicators up to 15 lpm. That doesn't mean that they cannot deliver more flow, but only that the indicator stops at 15 lpm. If you continue to rotate the dial, additional flow can be supplied but without the lpm accuracy. For higher and better controlled lpm a second flowmeter can be used with the oxygen tubing outputs connected via a "wye" before attaching to the E30's O<sub>2</sub> inlet port. When you are using two flow meters, simply add the lpm indicators from each flowmeter together when referencing the FiO<sub>2</sub> estimation graphs.

#### 44. Can humidification be used with the E30 Ventilator?

The E30 Ventilator will be shipped with a humidifier, which can be utilized when treating with non-invasive ventilatory support. When treating with invasive ventilator support the humidifier should not be used. Instead, a dry circuit set up should be used with a heat moisture exchange filter (HME).

#### 45. Is there a tidal volume (Vt) setting on the E30 Ventilator?

No, there is not a setting for Vt on the E30 Ventilator. Vt can be monitored through the visual indicator.

## 4. Emergency Use Authorization and Dispositioning

#### 46. Given the E30 ventilator is authorized for use only during the COVID-19 pandemic under an emergency use authorization, what is Philips position on the use of the device post-pandemic?

Post-pandemic, Philips will advise all recipients of the E30 ventilators that the devices are no longer authorized for use after the COVID-19 public health emergency is declared ended in their country.

- The date of termination is specific to each country.
- Customers will be asked to confirm they have received this guidance from Philips, as well as their planned disposition of the E30 devices.

At the termination of the COVID-19 public health emergency in your jurisdiction, your customers should cease use of all E30 devices. There are two options for dispositioning. (NOTE: The following represent general options that may not be applicable for all jurisdictions, based on provisions of local Emergency Use Authorizations.) As noted in the above, customers will need to confirm they have received guidance on disposition from Philips as well as their planned disposition based on the following options:

##### OPTION 1: Destroy

- This option requires customers to render devices inoperable and to scrap all E30 devices locally. Healthcare facilities should destroy E30 devices in their possession on-site. If a healthcare facility



decides not to conduct on-site destruction of their E30 devices, they can contact Philips, and we will identify a recommended Third Party contractor to conduct the destruction.

## **OPTION 2: Retention**

- If permitted by local regulation, healthcare facilities may consider retention of E30 devices for potential use in future emergencies.

### **47. Are there countries that have different regulation than the Emergency Use Authorization that would permit continued use of E30 ventilators beyond pandemic and COVID-19 patients?**

There are varying country-specific conditions regarding the withdrawal of devices. Your local jurisdiction termination dates will be followed. If there aren't local jurisdiction termination dates, Philips will follow the US COVID-19 public health emergency termination date.