PHILIPS

RESPIRONICS

E30

Ventilation solution

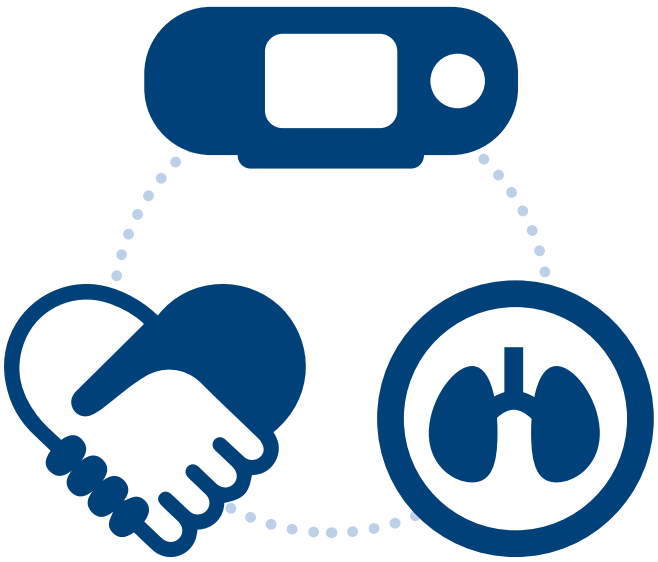
E30 ventilatory support during COVID-19

As COVID-19 continues to exist globally, health care providers are working diligently to treat the numbers of patients with the most appropriate respiratory care. Ventilatory support recommendations have been presented to provide guidance on the care of the critically ill.

The COVID-19 pandemic has progressed since first reported in China. Individuals of all ages are at risk for infection and severe disease, but the probability of fatal disease is greatest in > 65 years of age. Others at risk are of any age with underlying conditions of:[1]

- **Hypertension**
- **Cardiovascular disease**
- **Diabetes**
- **Chronic respiratory disease**
- **Cancer**
- **Renal disease**
- **Obesity**

Illness can range from asymptomatic infections to severe pneumonia with acute respiratory distress syndrome (ARDS) and death. In a summary of 73,314 China patients, it was found that 81% of the cases were mild, 14% were severe and 5% were critical.[1] A report of 1,482 confirmed COVID-19 patients in the United States found the most common symptoms to be: cough (86%), fever or chills (85%), shortness of breath (80%), diarrhea (27%), and nausea (24%).[2]



Ventilatory support

Adults with COVID-19 and acute hypoxemic respiratory failure prescribed O_2 therapy alone, may not be treated sufficiently. Determination from non-COVID clinical trials, non-invasive ventilation (NIV) and high flow therapy (HFT) are deemed preferable treatments for improving oxygenation. Pre-pandemic research has suggested that HFT had a non-significantly longer time to intubation than NIV from 24 days compared to 22 days respectively.[4] Respiratory management in guidelines have been published by several organizations that list the use of NIV, such as PAP therapy, for varying degrees of acute hypoxemic respiratory failure.[5, 6, 7, 8, 9]

Intubation, in a controlled setting to ensure the safety of both the patient and health care worker, may be appropriate if signs of early respiratory decompensation are seen. Options for respiratory support may be limited and therefore intubation should be performed appropriately.[3] The World Health Organization (WHO) guidelines for the management of respiratory failure in COVID-19 does advocate the use of NIV for COVID-19 treatment as long as personnel are provided the appropriate personal protective equipment (PPE).[6]

Early intubation and mechanical ventilation of those with known or suspected COVID-19 could result in the intubation of patients that may have otherwise improved on NIV or had initially been suspected to have the coronavirus but test negative. As well as, unnecessary intubation may deny the life-saving treatment for others. Depending on the severity and current step in the coronavirus process that the patient is in can help in the flexibility of treatment that can start with NIV.[10]

Illness ranges and treatment[3]

COVID-19 Stages	Description	Treatment
Asymptomatic	Test positive but have no symptoms	Self-isolation
Mild Illness	Symptoms of fever, cough, sore throat, malaise, headache, or muscle pain without shortness breath, dyspnea, or abnormal imaging	Self-isolation, close monitoring in case of a rapid decline
Moderate Illness	Clinical assessment or imaging demonstrates evidence of lower respiratory disease and an oxygen saturation (SaO_2) > 93% on room air at sea level	Hospitalization, antibiotics to treat the pneumonia
Severe Illness	Respiratory rate > 30 breaths per minute (bpm), SaO_2 < 93% on room air at sea level*	Oxygen (O_2) via nasal cannula, high flow therapy (HFT), noninvasive (NIV) ventilator support with low tidal volumes (Vt 4-8mL/kg of predicted body weight) and plateau pressures < 30 cmH_2O
Critical Illness	Respiratory failure, septic shock, and/or multiple organ dysfunction	Managed as one would with other life-threatening Infections with intubation using a higher PEEP strategy over a lower PEEP strategy, proning may be added to improve oxygenation and reduce the heterogeneity of lung ventilation

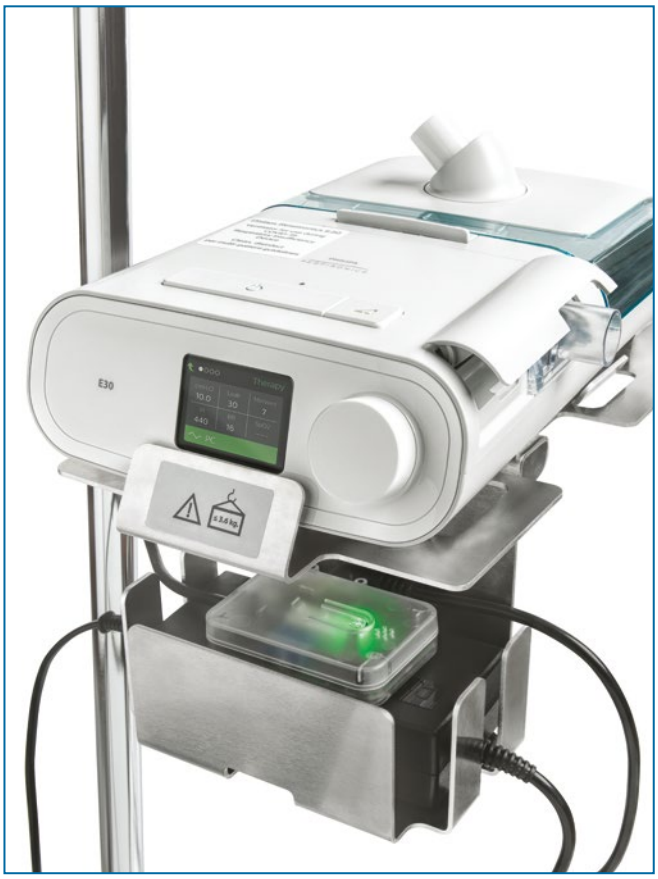
*COVID-19 Guidelines from France and Germany[11, 12] recommend SpO_2 < 92%

Philips Respironics E30

Under the Emergency Use Authorization (EUA), Philips Respironics released the E30 ventilator designed to support the needs of COVID-19 patients with the healthcare worker in mind while also complying with manufacturer medical device standards.

The Philips Respironics E30 ventilator is intended to provide invasive and noninvasive ventilator support for individuals with respiratory insufficiency. It is specifically for the care of adult and pediatric patients > 7 years of age and > 18 kgs. Deployment can be within 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). Qualified, trained personnel under the direction of a physician are the intended to manage the operation of the device.

With the current shortage of critical care hospital ventilators, the E30 fills the need for those in the moderate or severe stages of the illness as described by the NIH, where utilization of NIV can save the critical care units for those that need it the most. Even in field or rural hospitals, where the critical care ventilator may not be available. The E30 is not only an NIV unit but can also be used invasively with the invasive circuit configuration therefore meeting the ventilatory support needs of the critical illness patient when other ventilators are not available. Both audible and visual alarm capabilities of the device provide safety and security and differentiate the device from positive airway pressure (PAP) therapy that is also delivered non-invasively.



Clinical Benefits

Oxygen delivery: Safe entrainment of oxygen up to 60 LPM to deliver high levels of oxygen

Key monitoring and alarms: On-screen respiratory monitoring (Pressure, Tidal Volume, Respiratory Rate, Minute Ventilation, Leak and SpO_2 with a separate sensor) as well as visual and audible to provide pertinent patient therapy

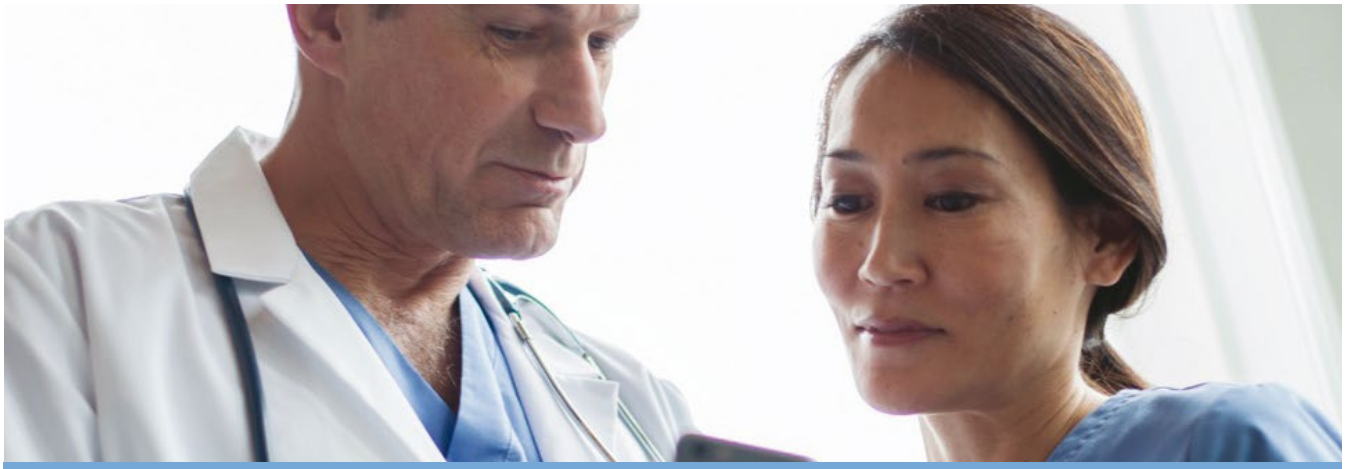
Clinician Benefits

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

Designed for your safety: Recommended circuit set-ups contain a bacterial/viral filter to minimize exposure for healthcare providers when used invasively and non-invasively

Confidence: Designed, engineered and mass manufactured by a team deeply experienced in respiratory care with a passion for patient care

The Philips Respironics E30 ventilator is suited to treat the COVID-19 patients that are in need of non-invasive and invasive ventilatory support within hospitals and field hospitals, whilst the pandemic demands an increase in ventilator usage.



Emergency Use Authorization

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). This device is not FDA cleared or approved.

References

1. Wu, Z., McGoogan, JM., Characteristics of and important lessons from the coronavirus disease 2019 (COVID 19) outbreak in China: summary of a report of 73,314 cases from the Chinese Center for Disease Control and Prevention. JAMA, 2020

2. Garg, S., Kim, L., Whitaker, M., et al, Hospitalization rates and characteristics of patients hospitalized with laboratory-confirmed coronavirus disease 2019 – COVID-NET, 14 states, March 1- 30, 2020, MMWR Morb Mortal Wkly Rep. 2020;69(15):458-464

3. Gulick, Roy M., Lane, H. Clifford, Masur, Henry, et al, NIH COCID-19 Treatment Guidelines, **https://covid19treatmentguidelines.nig.gov , April 21, 2020**

4. Frat, JP, Thille, AW, Mercat, A, et al. High-flow oxygen through nasal cannula in acute hypoxemic respiratory failure, N Engl J Med, 2015;372(23):2185-2196

5. American Association of Respiratory Care, Guidance Document" **https://www.aarc.org/wp=content/uploads/2020/03/guidance-document-SATS-COVID19.pdf**

6. Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim Guidance March 13, 2020. World Health Organization. **https://www.whoint/publiciations-detail/clinical-management-of-severe-acture-respiratory-infection-when-novel-coronovirus-(ncov)-infectin-is-suspected**

7. Alhazzi,W. et al, Surviving Sepsis Campaign: guideline on the management of critically ill adults with Coronavirus Disease 2019 (COVID-19), Intensive Care Med (ESICM)

8. COVID-19 Ventilation Guidelines, **https://www.esicm.org/resources/coronavirus-public-health-emergency/#GUIDELINES**

9. Poston, J, Patel, BK, Davis, AM, Management of Critically Ill Patients with COVID-19, JAMA Clinical Guidelines Synopsis, March 26, 2020. **https://jamanetwork.com/jurnals/jama/fullarticle/2763879**

10. Arulkumaran, N, Brealey, D, Howell, D, Singer, M, Use of non-invasive ventilation for patients with COVID-19: a cause for concern? Lancet, April 20, 2020, **https://doi.org/10.1016/s2213-2600(20)30181-8**

11. Rabec, C. et al, Procedure de prise en charge pneumologique ors reanimation des patients hospitalises dans le cadre de la pandemie COVID 19, RespiPre REA-SPLF GAVO2avril 2020

12. Pfeifer, M. et al, Position Paper for the State of the Art Application of Respiratory Support in Patients with COVID-19, German Respiratory Society, Pneumologie, online April 22, 2020

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Caution: U.S. federal law restricts these devices to sale by or on the order of a physician.

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