[High Priority] - S0404 : [COVID-19] Philips— Respironics E30 Ventilators: ECRI Assessment of Emergency Use Authorization Device [ECRI Exclusive Special Report]

Medical Device Special Report

Published: Thursday, May 21, 2020

UMDNS Terms:

- Positive Airway Pressure Units [20742]

Product Identifier:
[Capital Equipment]

Product	Philips Healthcare Model
Ventilators	Respironics E30

Geographic Regions: Worldwide

Manufacturer(s): Philips Healthcare3000 Minuteman Rd, Andover, MA 01810, United States

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Infection Control, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Staff Education, Materials Management

Background:

1. ECRI is providing our perspectives about the Philips Respironics E30 ventilator in response to inquiries from members regarding use of the device for COVID-19 patients.
2. The E30 ventilator is built on the DreamStation platform, which is primarily used to treat obstructive sleep apnea in the home, but it is also indicated for hospital/institutional use.
3. Philips has received authorization from the FDA under the Emergency Use Authorization (EUA) to temporarily sell the E30 ventilator during the COVID-19 pandemic. When the EUA or the COVID-19 public health emergency is terminated or revoked, the E30 may no longer be used.
4. The intended use statement authorized by the FDA says that the E30 can “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 >18 kgs. 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."
5. In basic functionality and modes, the E30 is comparable to an invasive pressure controlled ventilator, like the Philips Respironics V60. However, unlike such devices that are primarily used in a hospital setting, the E30 lacks some key features present in devices that provide life support. ECRI has identified the following concerns and limitations of the E30 compared to an ICU ventilator.

Concerns and Limitations to Consider:

1. Performance:
    1. Limited range of settings.
        1. The E30 cannot provide the same range of inspiratory pressures, positive end-expiratory pressure (PEEP), or respiratory rate as an ICU ventilator.
        2. The maximum inspiratory pressure setting is 30 cm H_2O.
        3. The maximum PEEP setting is 25 cm H_2O in all pressure control modes. Maximum CPAP setting is 20 cm H_2O.
        4. The maximum respiratory rate setting is 30 breaths/min.
        5. These settings are adequate for some patients requiring invasive ventilation, but insufficient for the sickest patients.
    2. No tidal volume control modes.
        1. The E30 provides pressure control modes.
        2. Users will not be able set a specific tidal volume, which some clinicians prefer when ventilating patients within the mL/kg range based on the ARDSNet protocol.
        3. As with any pressure control mode, as the patient's lung compliance changes, the delivered tidal volumes will also change unless inspiratory pressure settings are adjusted.
    3. No direct control of FiO_2.
        1. The E30 does not have an air/oxygen blender.
        2. Instead, oxygen can be bled into the flow at one of two places:
            1. Up to 60 liters per minute at the air inlet to the device with the use of a custom adapter provided by Philips. This is the preferred location, because introducing the oxygen here allows the device to measure the total flow of gas going to the patient.

        2. Up to 30 liters per minute at the patient interface. Introducing oxygen here will affect that the accuracy of tidal volume measurements and yield somewhat less predictable FiO_2 depending on the variability of patient parameters.
    3. The user cannot directly control FiO_2. Instead, the user must adjust the flow of oxygen via the oxygen flowmeter.
    4. Insufficient oxygen delivery could lead to patient deterioration. This is especially likely with COVID-19 patients.
    5. Philips has provided a chart with estimated FiO_2 at different device settings and oxygen flow rates.
2. Safety:
    1. No internal battery.
        1. The E30 does not have an internal battery or an integrated alarm if line power is lost. It comes with an optional uninterrupted power supply (UPS) or an external alarm module to mitigate the loss of line power.
        2. Loss of power leading to cessation of ventilation could lead to serious patient injury or death. Philips states the UPS will power the E30 for longer than 90 minutes on a full charge.
        3. The option offered (UPS or external alarm module) depends on supply availability and market requirements.
    2. The volume of alarms.
        1. The E30 alarms are quieter than typical hospital devices and may not be heard in a busy ICU.
        2. The alarm volume is not adjustable.
        3. The E30 does not offer any remote alarm annunciation capability, such as the ability to connect to nurse call.
        4. Missed alarms could lead to serious patient injury or death.
3. Workflow:
    1. Unfamiliar breathing circuit setup.
        1. The E30 has an unusual breathing circuit arrangement.
            1. As with any single limb passive circuit, the E30 does not have an exhalation valve that opens and closes. Instead, it relies on the exhalation port to allow passive flushing of exhaled CO_2.
            2. To control the spread of the coronavirus, the breathing circuit for COVID-19 patients should have an exhalation port with a bacterial/viral filter.
        2. For clinicians unfamiliar with the proper setup of the E30 breathing circuit, Philips provides an online version of the Quick Start Guide (QSG), as well as a training presentation, training video, and webinar available on the E30 website.
        3. Assembling the breathing circuit improperly could lead to increased staff exposure to coronavirus (if a non-filtered exhalation port is used) or potentially dangerous amounts of rebreathing by the patient (if the exhalation port is accidentally or excluded/obstructed).
    2. Small screen.
        1. The 2.25-inch color display on the E30 is significantly smaller than the screen on modern ICU ventilators and most transport and home care ventilators.
        2. Because the screen is so small, it can only display six settings and/or parameters at a time. Waveforms cannot be displayed.
        3. Because of the small screen size, clinicians will have to be relatively close to the device (and, therefore, the patient) to perform regular vent checks. This may require more use of scarce PPE compared to ventilators with screens that can be read from outside the patient's room.

Manufacturer's Corrective Action/Recommendations:

1. Although the E30 does not offer volume modes, users can monitor tidal volumes on the user interface. Philips has created a ventilation parameter's calculation tool as a means to help clinicians ventilate within the ARDSNet protocol (see Resources on the E30 Product Webpage).
2. Depending on the oxygen flow rate, the E30 can deliver up to >90% FiO_2. Philips has created a white paper to assist the user in estimating the delivered FiO_2 without the need of an inline oxygen analyzer (see Resources on the E30 Product Webpage).
3. The E30 is equipped with visual indicators that alert the user when various leak conditions occur (i.e., too much leak, not enough leak through the exhalation port), as well as the suggested actions and resolutions in training materials.

ECRI Recommendations:

1. If you are experiencing or expecting a large surge of patients that require ventilatory support, refer to ECRI's strategies for mitigation .
2. Note that the E30 is a modified home BiPAP sleep apnea therapy device, so it should be considered only if all of the more sophisticated devices have been or are expected to be deployed. Refer to the above article for a comprehensive list of types of devices and the order in which they should be considered.
3. Before purchasing and using Philips Respironics E30 devices, ensure that a plan is in place to address the limitations of the device:
    1. Limited range of settings, no volume control modes, no direct control of FiO_2:
        1. Ensure that clinicians are aware of the limitations of the E30.

2. Whenever possible, use more capable ventilators for patients who require more aggressive settings.
3. Consider keeping a copy of the FiO_2 estimation chart provided by Philips near each E30 device so clinicians can easily refer to it.

2. No internal battery:
    1. Use the UPS provided by Philips as an external battery.
    2. Obtain an external power loss alarm module from Philips when they are available.
    3. Plug the E30 into emergency backup power outlets.
3. Alarms are not very loud:
    1. If possible, use E30s only in areas where background noise is minimal.
    2. Consider unorthodox methods, such as using consumer baby monitors for remote alarm annunciation.
4. Unfamiliar breathing circuit setup:
    1. Train staff on the unique characteristics of the E30 breathing circuit arrangement, including:
        1. Non-vented masks for noninvasive ventilation.
        2. Inclusion of the exhalation port (also referred to as valve in QSG) between the patient interface and breathing circuit. Failing to include this exhalation port will result in potentially dangerous levels of rebreathing by the patient.
        3. Ensuring that exhaled gas is filtered appropriately.
    2. Consider keeping a copy of the breathing circuit arrangement pictures provided by Philips near each E30 device so clinicians can easily refer to them.
5. Small screen:
    1. If possible, use E30s only in areas where the device can easily be seen from outside the patient room.
    2. Consider unorthodox methods, such as using consumer video baby monitors to view the screen from outside the patient room.

4. Create a plan for removal from use of the E30 upon EUA termination. The device will only be approved for use for the duration of the COVID-19 emergency.

Manufacturer's Perspectives or Comments:

1. Philips describes the product as:
    - Easy to use with 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 with 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. It offers safe entrainment of oxygen to deliver high levels of inspired oxygen. Key monitoring and alarms with on-screen respiratory monitoring as well as visual and audible alarms to provide pertinent therapy information.

References & Source Documents:

1. FDA Emergency Use Authorization Product Listing, including intended use: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
2. E30 Comparison to other Philips Ventilation Products: https://www.usa.philips.com/c-dam/b2bhc/master/landing-pages/experience-catalog/sleep-and-respiratory-care/how-philips-is-globally-addressing-the-coronavirus-covid-19/e30/e30-ventilator-comparison-chart.pdf
3. The E30's online manual and quick start guide may be found here: https://www.philips.com/hrcmanuals
4. The E30 training website may be found here: https://www.usa.philips.com/healthcare/medical-specialties/covid-19/sleep-and-respiratory-care-covid-19/e30-ventilator

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 May 21. ECRI researched report