PHILIPS
RESPIRONICS

Trilogy Evo

Trilogy Evo Usability Study
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Background

Be it in a healthcare setting or the home, mechanical ventilation assists or replaces spontaneous breathing. Depending on the patient's condition, mechanical ventilation helps support or completely controls breathing through invasive or noninvasive means.[1] Invasive ventilatory support delivers via an endotracheal tube or tracheostomy, while noninvasive ventilatory support delivers primarily through a mask and/or mouthpiece.[2] Patients who have a tracheostomy but are otherwise medically stable may be required to remain in the hospital as long as they have the tracheostomy. This is especially important for people with spinal cord injuries, birth injuries, or other medical conditions who want to reclaim their quality of life by living in familiar surroundings.

Most clinicians are familiar with the features and operation of ventilators in the hospital or intensive care unit (ICU) setting. These devices typically deliver multiple modes of ventilatory support, have interactive displays, and must be tethered to an electrical outlet and a compressed gas source, but technological advances in portable ventilators have made them easier to use outside of the controlled setting of a hospital or medical center. A small, lightweight, and portable device is more practical for use in the home.

With training and practice, patients and their non-clinician caregivers and family members can learn how to operate a ventilator at home.

Nonprofessional or lay caregivers include individuals without formal medical training or education, such as adult patients and properly trained family members, who take care of ventilator patients in a chronic care setting, primarily in the home. Their interactions with the ventilators are generally limited to checking the patient's status on the user interface (UI) and performing routine tasks like changing circuits, charging batteries, and responding to alarms.

Non-respiratory clinicians are those who have medical training, such as home health nurses or medical transport personnel, but the training may not have been specific to respiratory care. Their interactions with the ventilator involve routine tasks similar to those of the lay caregiver.

The respiratory therapist (RT) is the clinician who has the most contact and interaction with the ventilator. The RT handles the initial setups and provides regular visits that include assessing the adequacy of ventilation, performing ventilator maintenance, updating prescriptions upon doctor's orders, and providing ongoing training and education.

A small, lightweight, and portable device, the Trilogy Evo ventilator was designed to be operated and used by patients, properly trained family and nonprofessional caregivers, clinicians (both respiratory and non-respiratory), technicians, physicians, and service providers. Trilogy Evo is a next-generation portable home ventilator that provides invasive and noninvasive positive pressure ventilation for the care of patients weighing ≥2.5 kg, and it is intended for use by qualified, trained personnel under the direction of a physician. Pressure and volume ventilation delivers through a controlled leak valve or a passive exhalation port. The ventilator can measure, display, record, and alarm for low-pulse oximetry values (SpO_2) and errors in the delivered oxygen concentration, as well as low or high exhaled carbon dioxide (CO_2) levels, respiratory rate, and pulse rate when integrated with the appropriate sensors and accessories. The ventilator is suitable for use in the home and in institutional and transport settings.[3]

Human factors evaluation

Successful operation of a life support device requires proper performance both of the device and by the operator so that no serious harm comes to the patient or user. The Trilogy Evo was tested under a series of critical tasks designed to evaluate its usability and functionality for each of the different types of users. A critical task is a user task that, when omitted or incorrectly performed, would or could cause serious harm to the patient or user, where harm is defined as compromised medical care.[4]

The aim of the study was to demonstrate with the final UI design that representative users can operate Trilogy Evo to perform critical tasks completely and correctly. Environments for the testing were in an actual or simulated home and in a hospital or institution. Trainers gave device training to all study participants prior to testing to remain consistent with actual usage.

A total of 49 participants were involved in the testing. Demographic information is presented in ***Table 1***. Testing was carried out in environments representative of typical home and clinical settings, including a long-term clinical care facility. Attention was paid to ambient conditions like lighting and noise, as well as other equipment that might be present (e.g., monitoring equipment, low-flow or high-pressure oxygen sources) when selecting the simulated use environments.

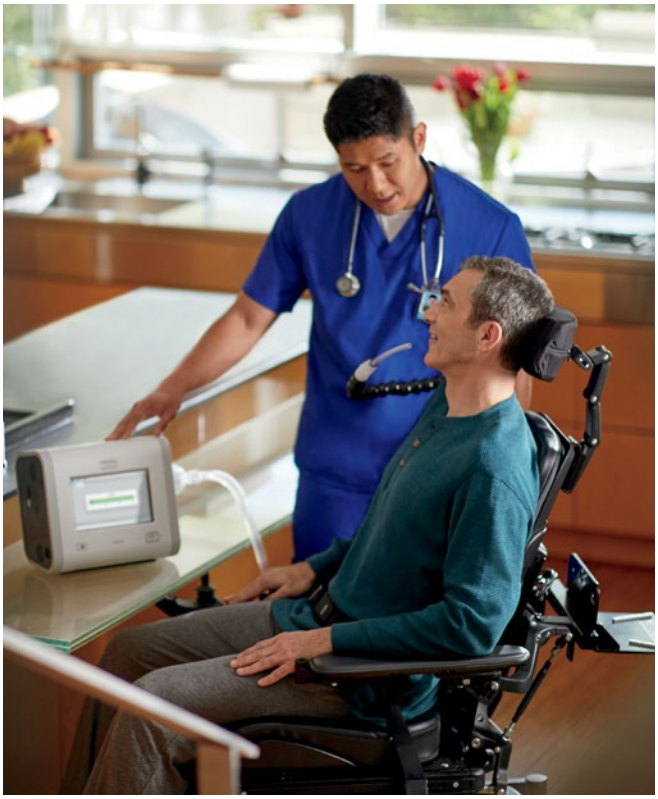


Table 1: Participant demographics

Participant group	N	Age	Ventilator experience
Nonprofessional or lay caregivers	18 (12 females)	25–50	2 to 21 years with different ventilators while serving as familial caregivers
Trilogy Evo usability study	15 (12 females)	31–58	1 to 24 years with different ventilators
Respiratory clinicians	16 (8 females)	26–66	5 to 41 years with different ventilators

Of the 21 critical tasks identified, 12 were classified as critical for all groups (nonprofessional or lay caregivers, non-respiratory clinicians, and respiratory clinicians), while the remaining 9 were deemed critical for the respiratory clinicians only. (***See Table 2***.) Critical tasks were executed during routine patient monitoring and care by the first two groups and as part of patient setup and monitoring by the respiratory clinicians.

Table 2: Trilogy Evo critical user tasks

All user groups
Set up the ventilator circuit
Position the ventilator for use
Lock/unlock the touchscreen to allow interactions
Switch from current prescription to another preset prescription
Respond to alarms
Put ventilator in standby mode
Power off the ventilator
Locate the battery icons and verify adequate battery capacity
Ensure circuit is securely connected
Properly protect the ventilator from liquids
Properly protect/maintain the ventilator to keep it from being damaged
Properly protect/maintain the AC power cord to keep it from being damaged

Respiratory clinician user group
Enter prescription from standby
Locate and observe monitored ventilation parameters
Locate and observe measured FiO_2
Locate and observe measured SpO_2 and $EtCO_2$
Adjust alarm limits based on monitored ventilation parameter values
Adjust alarm limits based on physiological or gas monitoring values
Switch between full and limited user interface access
Add new prescription and switch to it during therapy
Switch from current mode during therapy

Results

All of the user groups completed each of the critical tasks in an acceptable manner. Trilogy Evo was simple enough to allow for immediate fulfillment of the task or notified the user of an initial mistake that could be easily rectified.

Tasks completed acceptably by all user groups:

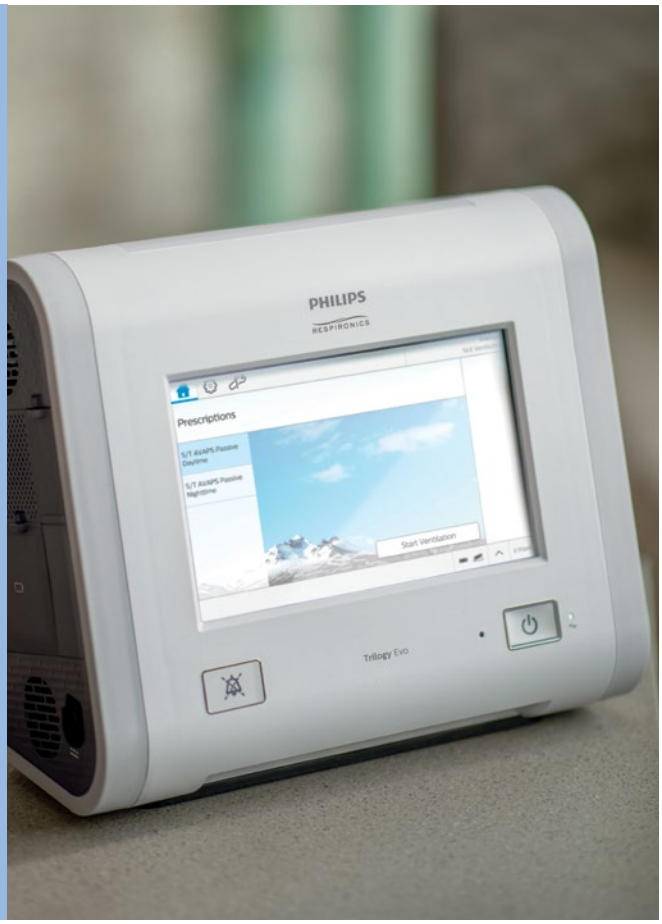
- Positioned the ventilator so that the air inlet was not blocked
- Switched therapy to another preset prescription
- Recognized and responded to alarm conditions
- Did not inadvertently place Trilogy Evo in standby mode or power it off
- Located battery icons
- Verified battery capacity

Tasks completed acceptably by the respiratory clinicians:

- Located and reported the monitored parameters on the user interface
- Located and reported the monitored SpO_2 on the user interface
- Adjusted alarm limits based on ventilation parameters and physiological or gas monitoring values
- Engaged and disengaged user interface screen lock without difficulty
- Changed therapy modes without difficulty

Tasks resolved appropriately by the respiratory clinicians:

- Connected the flow sensor when setting up a passive circuit, but when Trilogy Evo properly alarmed for "Circuit Mismatch," the user resolved the issue
- Did not connect the flow sensor when using a dual-limb circuit, but when Trilogy Evo properly alarmed for "External Flow Sensor Disconnected," the user resolved the issue
- Oriented the flow sensor incorrectly and in the wrong location, but when Trilogy Evo properly alarmed for "Flow Sensor Reversed," the user resolved the issue



Conclusion

In this human factors evaluation, representative samples of nonprofessional or lay caregivers, non-respiratory clinicians, and respiratory clinicians successfully completed critical tasks, set up the device correctly, and recognized and responded to alarms. These results indicate that the design of the device is appropriate for lay and clinical users.

References

1. Martin Tobin and Constantine Manthous, Mechanical Ventilation, American Thoracic Society, 2017.
2. Dean Hess et al., Respiratory Care: Principles and Practices, W.B. Saunders Company, 2002
3. Trilogy Evo Clinical Manual, 2018.
4. Applying Human Factors and Usability Engineering to Medical Devices, FDA Guidance, 2016.

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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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