

**Background:**

The VOCSN Multi-Function Ventilator by Ventec Life Systems received clearance through the U.S. Food and Drug Administration 510(k) Premarket Notification process on April 7, 2017.<sup>1</sup>

VOCSN, the first and only Multi-Function Ventilator, does not introduce a new therapy or provide experimental treatments - it simply combines existing therapeutic functionality into a single device: critical care ventilator, oxygen concentrator, mechanical cough assist, a suction system, and a nebulizer compressor for aerosolized medication administration. Each of these stand-alone therapies, housed in the Multi-Function Ventilator, are medically proven devices and validated by decades of use on patients.

The 510(k) clearance from the FDA declared VOCSN as equally safe and effective (substantially equivalent) as the five traditional devices it combines. However, “[a] claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use...”<sup>2</sup> The combination of these therapies from what is traditionally five separate devices to a single, integrated device provides inherent care benefits supported by existing research.

**VOCSN is Designed to Provide Integrated Respiratory Care with the Following Benefits:**

**Compliance with Prescribed Therapies:** The seemingly simple act of disconnecting from one device and connecting to another device, as occurs with suctioning or a separate cough assist device, can often be neglected by patients and caregivers due to the time required, patient-ventilator disconnection anxiety, and concerns about safety. Similarly, the inconvenience of carrying multiple devices and accessories often drives caregiver decisions on what equipment to bring when leaving the facility or home. Finally, traditional devices are incapable of automatically and absolutely tracking compliance with oxygen, cough, suction, and nebulizer therapies. The VOCSN Multi-Function Ventilator mitigates patient compliance and safety concerns by providing multiple therapies through the same circuit, without disconnecting the patient, and continually provides access to all five therapies in one device. Additionally, the use of all five therapies is stored on VOCSN and viewable by patient, caregiver, and clinicians to ensure and document compliance. The VOCSN combined therapies and single circuit makes it easier to administer each therapy in seconds rather than minutes. By making therapies easier and less time consuming, patient compliance may improve.

- As Dr. Jin, *et al* have found, “Complex treatment is believed to threaten the patient’s compliance.”<sup>3</sup> It is well supported that compliance to therapy is critical to patient outcomes. Furthermore, “therapeutic non-compliance has been associated with excess urgent care visits, hospitalizations and higher treatment costs.”<sup>4</sup> Satisfaction and ease of use of a nebulizer, for example, may in fact “reflect improved adherence or more correct use.”<sup>5</sup>

**Minimizes Circuit Disconnections Which Decreases Potential for Infection:** Switching between multiple circuits to provide different therapies using traditional devices (for example, switching circuits and devices between ventilation and cough assist therapy) requires frequent opening of the patient airway and exposes them to increased risk of bacterial infection. VOCSN is designed to reduce the risk of infection by providing advanced secretion clearance with cough assist and hospital grade suction at the touch of a button using a single circuit. The Ventec One-Circuit provides the following to each patient in a single circuit: 1) Oxygen Direct delivery internal to the circuit (tube within a tube); 2) uninterrupted ventilation through a single circuit that supports cough assist therapy; 3) ability to provide in line suctioning; and 4) in-line nebulizer that is flow and volume-compensated by the ventilator. Collectively, these features significantly minimize circuit disconnections.

- Management of the airway includes avoidance of circuit disconnections to prevent hypoxemia, loss of lung volume and reduce the incidence of VAP.<sup>6, 7</sup>
- “Closed suction caused fewer disturbances in patients’ hemodynamic condition, took shorter time, and is more economical.”<sup>8</sup>

**Promotes Cough Assist Frequency:** With the touch of a button VOCSN can alternate between Ventilation and Cough to provide cough therapy in seconds rather than minutes. This reduces the barriers<sup>9</sup> of stress and anxiety related to mechanical cough therapy as the patient does not need to disconnect from their life support ventilator. Once the cough therapy is complete, ventilation automatically resumes, uninterrupted. Unlike suction therapy, which often requires circuit disconnection, opens the airway to infection risk, and can potentially cause ancillary harm to the airway, research supports cough therapy as a more natural and effective means of secretion management for ventilator patients.<sup>10, 11</sup>

- Cough therapy “has been reported to be successful in avoiding hospitalizations, pneumonias, episodes of respiratory failure, and tracheotomy for patients with Duchenne muscular dystrophy, spinal muscular atrophy, and ALS.”<sup>12</sup>
- “Patients found MI-E [mechanical in-exsufflation or cough assist] significantly less irritating, less painful, less tiring, and less uncomfortable than endotracheal suctioning.”<sup>13</sup> Furthermore, cough assist has been shown to improve outcomes for neuromuscular disease patients with respiratory tract infections.<sup>14</sup>
- Comparing two MI-E protocols to suctioning alone, the 50S: MI-E (-50/+50 cmH<sub>2</sub>O) protocol reduced Ppeak and Raw and increased Cst immediately after its application and “this protocol provided the largest amount of removed secretions and held SBP, DBP and SpO<sub>2</sub> at basal values. The MI-E at high pressures promotes benefits to respiratory mechanics, is more effective in removing pulmonary secretions, and it does not lead to hemodynamic repercussions.”<sup>15</sup>
- In most conditions, VOCSN performed better than comparable devices.<sup>16</sup>
- The Clinical Practice Guidelines of the American Thoracic Society (ATS) strongly recommend cough augmentation to prevent respiratory complications in patients with neuromuscular disease.<sup>17</sup>

**Decreases Risk of Mistakes:** Rather than learning the operation of multiple systems, managing various devices and accessories, and understanding the alarm parameters of these devices, VOCSN streamlines care into a single circuit, an easy-to-use operating system, and a simple alarm platform to reduce the risk of mistakes when caring for complex patients with dynamic care needs.

- “[Lay users] may be overwhelmed by new...critical responsibilities associated with home care, including awareness of the potential for harm—to the equipment, to their loved ones, or to themselves—if they make an error.”<sup>18</sup>
- Additionally, it’s not uncommon for mistakes to lead to unplanned healthcare encounters, adding increased demands on an already burdened healthcare system. VOCSN, by employing the “Principles of Universal Design”<sup>19</sup> and thorough Human Factors Assessment<sup>20</sup> in its design, reduces patient and/or caregiver equipment anxiety, confusion, and errors with a single, easy-to-use operating system and a single device to manage.
- Alarm fatigue in patient care has been highlighted by clinicians and accrediting bodies for the past several years. “As the proliferation of technology in health care settings continues, so does the number of alarms related to these devices.”<sup>21</sup> Accordingly, having one device with one unique alarm system can serve to diminish this challenge.

**Increases Patient Mobility:** Mechanically-ventilated patients and their caregivers are often challenged with packing and moving multiple medical devices whenever patients leave the bedside of the facility or home. In the hospital environment, “[s]tatistically significant declines in health-related quality of life were identified in the domains of Mobility, Personal Care, Usual Activities...”<sup>22</sup>

- “Mobility is frequently an essential element of the plan of care of the patient. The mechanical ventilator system chosen for such a patient should allow mobility.”<sup>23</sup> Additionally “Children who rely on mechanical ventilators benefit from increased mobility to ensure that they receive the same levels of stimulation as children who breathe independently.”<sup>24</sup>
- In a patient-centered survey of mechanical ventilator users, 82% of the respondents indicated that ability to travel was either important or very important.<sup>25</sup> Furthermore, in another study focused on the quality of life of post-ICU patients requiring long-term invasive ventilation, “the topic most frequently reported as being unsatisfactory was mobility.”<sup>26</sup>
- Several studies identify the importance of early hospital mobilization of mechanically-ventilated patients. <sup>27, 28, 29, 30, 31</sup> “[Research] studies, and concomitant systematic reviews provide evidence that early progressive mobilization of adult ICU patients is feasible, safe, and may result in benefits including improved functional outcomes, and reduced ICU and hospital length of stay.”<sup>32</sup>

The VOCSN Multi-Function Ventilator, with five therapies in one 18-pound device, powered by a single battery and power cord, greatly facilitates freedom of movement for patients in the facility to leave the bed and for homecare patients to participate in work, school, and leisure activities, and/or regular health care visits.

**Standardizes Holistic Patient Monitoring:** The VOCSN Multi-View system is the first and only integrated data solution to trend information for all five therapies. Multi-View provides a holistic view of the respiratory care of each patient beyond the standard of care today which solely looks at trending data from traditional ventilators. This data may improve a medical professional's ability to proactively address exacerbations and prevent hospital readmissions and other unplanned healthcare encounters.

- “Accurate assessment of adherence behaviour [sic] is necessary for effective and efficient treatment planning, and for ensuring that changes in health outcomes can be attributed to the recommended regimen. However, when providers rate the degree to which patients follow their recommendations they overestimate adherence.”<sup>33</sup>
- When discussing how to help patients follow prescribed treatments, Haynes and colleagues stated, “One of the important difficulties in managing low adherence is lack of accurate and affordable measures.”<sup>34</sup>
- Remote monitoring and telemedicine are fast becoming a critical, efficient, and reliable standard of care.<sup>35, 36, 37</sup> With VOCSN Multi-View, accurate and actionable usage information is not only available for ventilation, but also for Oxygen, Cough, Suction, and Nebulizer.
- In a recent Healthbox report, remote monitoring was cited for providing significant value for the healthcare system. These include improved patient compliance, better outcomes, fewer emergency department visits and hospital admissions, and lower average lengths of stay.<sup>38</sup>

**Streamlines Transition from Hospital to Home:** The single, easy-to-use operating VOCSN system reduces training time for home caregivers and anxiety caused by the multiple traditional devices and operating systems that are replaced by VOCSN. VOCSN meets the international standards for critical care ventilation<sup>39</sup> and bridges the technology divide between the hospital and the home. Since VOCSN is suitable for patients between multiple care environments, it improves continuity of care for ventilator patients who frequently move throughout the healthcare continuum.

- “One of the problems associated with medical devices used in the home is that they often are not the same models as the ones used in formal health care settings.”<sup>40</sup>
- According to *HealthTECH*, “Many would consider that improved healthcare is the greatest result to come from technology.
  - Better equipment has allowed doctors to provide more comprehensive care.
  - Better treatments have increased the quality of life of a number of different people suffering from long-term illnesses.
  - And better medicine has completely wiped out the fear of some life-threatening illnesses of the past.”<sup>41</sup>

**Promotes Independence and Quality of Life:** Independence and quality of life improvements are well established for ventilator-assisted individuals cared for at home. Collectively, the published evidence points to how the operational simplicity, ease of change between therapies, and freedom of movement of VOCSN promotes, and perhaps expedites a patient's transition to home. VOCSN is designed to make care easier so that caregivers can spend less time working with machines and more time with patients. And this translates into improved patient satisfaction and quality of life.

- "Patients with progressive neuromuscular disease such as Duchenne muscular dystrophy and amyotrophic lateral sclerosis can also derive prolongation of life, palliation of symptoms and an improvement in quality of life."<sup>42</sup>
- Regarding patients with Duchenne muscular dystrophy and amyotrophic lateral sclerosis, "more than two-thirds of patients were satisfied with their lives. Eighty-four percent thought they had made the right choice."<sup>43</sup>
- Despite the fact that only 10% of amyotrophic lateral sclerosis patients choose mechanical ventilation, "90% were glad to have chosen home ventilation and would choose it again."<sup>44</sup>

**Summary:** The VOCSN Unified Respiratory System efficiently combines many of the significant medical and technological health care advancements into one simple, easy to use device. It does not introduce a new therapy or provide experimental treatments. Clinical and quality of life benefits for the patient range from greater independence and mobility to an increase in the standard of care resulting from therapy integration, which decreases the risk of mistakes and infection, promotes greater therapy compliance, and provides complete patient monitoring across multiple therapies. Simply, the aforementioned research supports that VOCSN is Simple, Mobile, and Care Changing.

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<sup>2</sup> <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>, Accessed October 28, 2019

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