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The role of The Life2000® Ventilation System, a novel NIV device, during a COVID-19 outbreak and national ventilator shortage

Background and Purpose

According to a February 14, 2020 report from Johns Hopkins Center for Health Security[1], there are approximately 8,900 stockpiled ventilators in the United States. American hospitals have an additional 62,000 fully featured ventilators and 98,000 ventilators that can provide basic functions in an emergency standard of care. Additionally, on March 15, 2020, Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, reported an updated number of 12,700 ventilators in the national strategic stockpile during a televised press-conference.[2]

Worldwide, there have been varying reports of the percentage of patients testing positive for COVID-19 requiring ICU admission (and presumably a fraction of those requiring mechanical ventilation) with 5% in China and 12% in Italy.[3] There are several reasons these countries could have seen differing percentages including co-morbidities (e.g., China with more male smokers and Italy with the world's second highest elderly population) and respective preparedness and response strategies to the outbreak.

Currently, the U.S has a population of 327.2 million people[4] and assuming that 40%-70% are estimated to contract the novel COVID-19 virus, there could be 130.8 million to 229 million infected Americans which could mean an estimated 6.5 million to 27.5 million people requiring hospital admission, potentially requiring ventilatory support in a fairly short period of time (weeks to months) for COVID-19 cases alone. As of the date this paper was published, according to the 2020 American Hospital Association (AHA) Hospital Statistics Report[5], there are about 55,663 med-surg ICU beds, 15,160 cardiac ICU beds, and 7,419 ICU beds classified as 'other' nationally. A report from the Imperial College of London[6] anticipates critical care bed capacity, in an unmitigated pandemic, would be exceeded as early as the second week in April 2020, with an eventual peak in ICU or critical care bed demand that is over 30 times greater than the maximum supply in the U.S.

These estimates pose several potential threats to the capacity of hospitals and healthcare providers' ability to source and utilize medical equipment. For this reason, clinicians will likely need to be especially judicious with decisions on when to initiate and wean mechanical ventilation (MV) and look to alternative modes of support, such as non-invasive ventilators (NIV) that offer similar ventilatory capacity sufficient to meet patient need in order to protect limited resources. NIV's apply end-expiratory positive airway pressure increasing functional residual capacity and opening collapsed alveoli, thereby improving ventilation–perfusion matching and reducing intrapulmonary shunt as well as improving lung compliance, thus reducing respiratory load.[7]

Description of Life2000 Ventilator

The Life2000 Ventilator is an FDA cleared volume-control ventilator for adult patients requiring partial or total life support and is indicated for invasive or non-invasive ventilation with a maximum positive end-expiratory pressure (PEEP) of 10 cmH_2O and peak inspiratory pressure (PIP) of 40 cmH_2O as seen in appendix 1. In the acute care setting, the device can use wall O_2, wall air, cylinders, or its own compressor. Fraction of inspired oxygen (FiO_2) is based on liter flow bleed-in or entrainment and supports spontaneous breathing for patients unable to drive their own respirations and can be delivered via nasal pillows, face mask, or ET tube (see Appendix Figure 1) in conjunction with a heat-moisture exchanger (HME) for humidification and can deliver FiO_2 no higher than 50% for stand-alone units and up to 90% if using supplemental bleed-in techniques. See Table 1 for technical specs and Figure 2 and 3 for FiO_2 adjustment in which Appendix.

Waveform comparisons of the Life2000 Ventilator to a nationally stockpiled MV, LTV® 1200, show similar performance capabilities across different patient lung types/needs: healthy, obstructive, restrictive, and spontaneous breathing (appendix 2). This demonstrates

that it can be used in patients needing ventilatory support who do not require ventilation that exceed maximum output capabilities of the Life2000® device.

Clinical Considerations for Applicability

- The Life2000 Ventilator's small form factor and low-profile nasal pillow interface allows for utilization across various acute care settings, including the following: ER/ED, Med/Surg Recovery, general floor, and post-ventilator weaning support.
- Traditional face masks have a limitation of anatomical dead space where CO_2 blow off can require higher PEEP settings. This limitation can be avoided with Life2000 nasal pillows that conform to the nostril, creating a seal that prevents leakage, while eliminating the risk of nasal bridge skin breakdown and the formation of mask pressure ulcers from prolonged periods of NIV usage.[8]
- The benefits of weaning patients from MV to NIV has been well established in clinical research and meta-analysis[9] and can significantly reduce risk for other nosocomial infections and lung injury. It is recommended that clinicians use best practices that are in line with their facilities' standards and professional guidelines.

ARDS Specific Considerations

- Patients who are at risk for developing Acute Respiratory Failure (ARF) or have mild respiratory distress may be appropriate candidates for Life2000 Ventilator initiation to prevent escalation to MV by setting a low tidal volume (6-8mg/kg of ideal body weight) and a high PEEP (relative to Life2000's capabilities) of 9-10 cmH_2O in accordance to American Thoracic Society (ATS) guidelines[10] and may prevent the patient from developing or advancing to more severe forms of Acute Respiratory Distress Syndrome (ARDS).
- Numerous professional organizations[10-11] and other peer-reviewed studies have suggested that lying a patient prone may help improve oxygen levels in the blood and increase survival in patients at risk or with mild to moderate ARDS. In a recent 2020 multicenter prospective cohort study[12], investigators combined the prone technique with the addition of High-Flow Nasal Canula (HFNC) or NIV treatment and found that when patients with pneumonia secondary to influenza and other viral infections were admitted to a hospital, those with mild ARDS had a reduced risk of progressing to invasive ventilation when using HFNC/NIV in combination with a prone position (PP) when position was maintained for a minimum of 2 hours a day and had significantly improved PaO_2/FiO_2 in comparison to respective standalone therapies. The unique Life2000 Ventilator configuration combines the benefit of nasal pillows to reduce dead space (typically seen in HFNC) and positive pressure therapy (reserved to NIV) that may assist in patient tolerance and therapeutic effectiveness.
- It is recognized that more moderate to severe cases of ARDS may exclude the use of NIV systems like Life2000 Ventilator due to the increased demand of PEEP ≥ 12 cmH_2O and a higher rate of NIV failure in these cases. Current recommendations from The American Thoracic Society (ATS)[10] state early predictors of NIV failure include higher severity score, older age, ARDS or pneumonia as the etiology for respiratory failure, or a failure to improve after 1 hour of treatment. This sentiment was recently reiterated by the Chinese Clinical Guidance for COVID-19 Pneumonia Diagnosis and Treatment Guidelines.[13] Clinicians should use careful considerations and best practice guidelines established by the American Association of Critical-Care Nurses (AACN), ATS, and other professional organizations when evaluating patients who are at risk for or are presenting with ARDS and mode of ventilation selected.

Conclusion

Thoughtful patient selection and NIV application can be extremely important in pandemic situations where there is a shortage of full capacity mechanical ventilators. At the core of the above clinical considerations should be interdisciplinary clinician driven protocols and guidelines that are consistent with best practices. Continued understanding of novel ventilation devices and their role in patient care is critical to improving clinician knowledge and improved patient outcomes in times of crisis. The distinctive features of Life2000 Ventilator may add clinical benefit in an acute care setting by reducing burden of more invasive forms of ventilation without compromising patient safety and outcomes.

Appendix 1: Waveform Comparisons

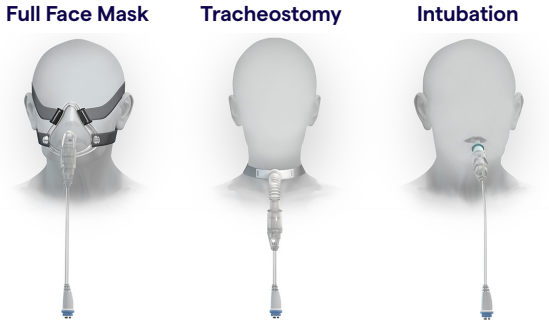
TABLE 1. LIFE2000® VENTILATION SYSTEM SPECIFICATIONS

FEATURES	LIFE2000
Product Code	NOU/CBK
Life Sustaining/Support Device	Yes
Patient Interfaces - Compatible	Nasal Cannula, NIV Masks, ET Tubes
Recognized Consensus Standards	ISO 80601-2-72 ISO 80601-2-12
Modes - Volume Mode	Proportional Open VentilationControl and Assit Control
Essential Performance Max. Inspiratory Pressure (cmH_2O) Tidal Volume (ml) Inspiratory Time (sec) Breath Rate (bpm) PEEP (cmH_2O) FiO_2 (%) Patient Trigger (Adjustable)	 0 to 40 50 to 2000 0.15 to 3.0 0 to 40 0 to 10 O_2 bleed in 1 to 9
Monitor/Alarms Peak Pressure (cmH_2O) Respiratory Rate (bpm)0 to 60 O_2 liter flow (L) High/Low Peak Pressure (cmH_2O) High/Low Breath Rate (bpm) High PEEP (cmH_2O) Breath Time Out (Apnea)	 0 to 50 0 to 60 Set PEEP + 7 60 sec

FIGURE 1. VENTILATION SYSTEM

COMPATIBLE INTERFACES

Breathe Pillows Interface®



Comfortable Breathe Pillows Interface

- Small-diameter tubing (5 mm vs traditional 22 mm)
- Patients can talk while wearing the noninvasive Breathe Pilows Interface
- Comfortable fit for around-the-clock use
- Available in multiple sizes

Breathe Universal Circuit® Connector

- Compatible with any third-party interface (including full face mask, tracheostomy tube, and intubation tube).

FIGURE 2: LIFE2000® - DELIVERED FiO_2

Delivered FiO_2 on a Life2000 is based on three elements

- Drive gas to the ventilator
  - Air - 21% oxygen
  - O_2 - 100% oxygen
- Entrainment Rate (R_E) - Varies w/ Peak Press. & set Peak Flow, Typically:
  - R_E = 3 when PIP ≤ 13 (Drive gas is 33% of total pat. gas)
  - R_E = 2 when 13 < PIP ≤ 26 (Drive gas is 50% of total pat. gas)
  - R_E = 1 when 26 < PIP ≤ 40 (Drive gas is 100% of total pat. gas)
- Liter flow of O_2 bled into the Inspire cannula
  - 0 to 30 lpm

FIGURE 3: LIFE2000 - RECOMMENDATIONS FOR DELIVERED FiO_2

For FiO_2 < 50%

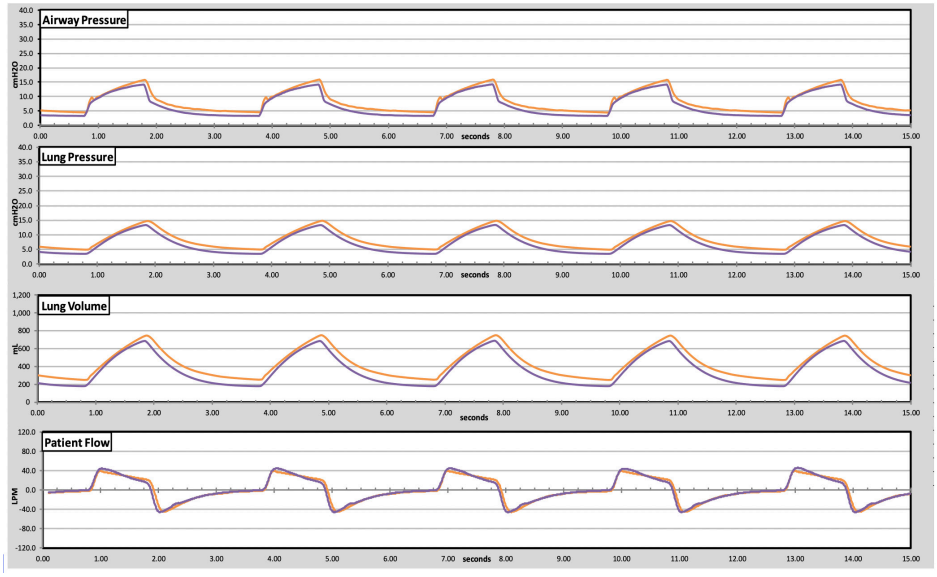
- Use Air as the drive gas
- Titrate O_2 bleed flow until delivered FiO_2 is achieved

For FiO_2 ≥ 50%

- Use O_2 as the drive gas
- Titrate O_2 bleed flow until delivered FiO_2 is achieved
- Note entrainment rate (R_E) affects FiO_2
  - R_E = 3; FiO_2 = 47% with no O_2 bleed flow
  - R_E = 2; FiO_2 = 60% with no O_2 bleed flow
  - R_E = 1; FiO_2 = 90% with no O_2 bleed flow

Appendix 2: Waveform Comparisons

TEST CASE 1 (HEALTHY): LIFE2000 VENTILATOR AND LTV® 1200

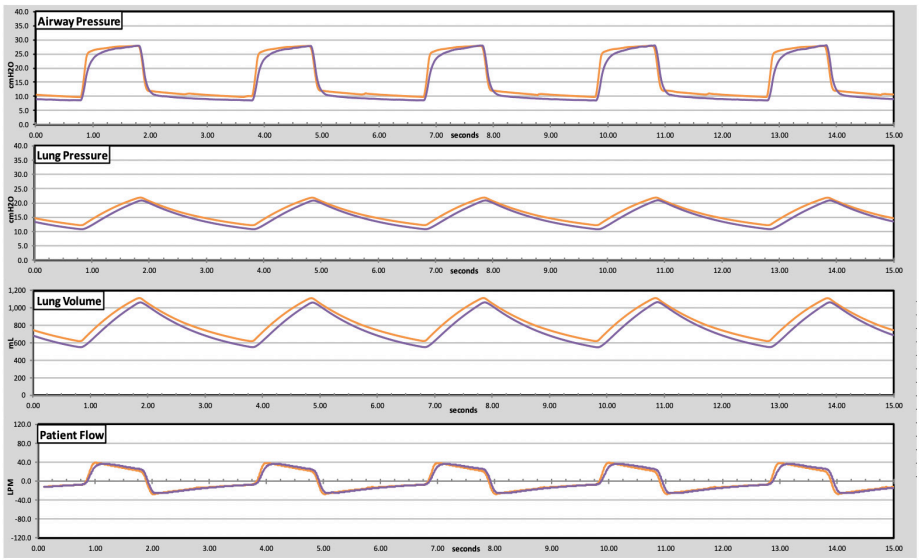


● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

PARAMETER	VALUE
Tidal Volume	500 ml
Peak Pressure (airway)	15 cmH_2O
Peak Pressure (lung)	15 cmH_2O
PEEP	5 cmH_2O
Peak Flow	40 lpm

TEST CASE 2 (OBSTRUCTIVE): LIFE2000® VENTILATOR AND LTV 1200

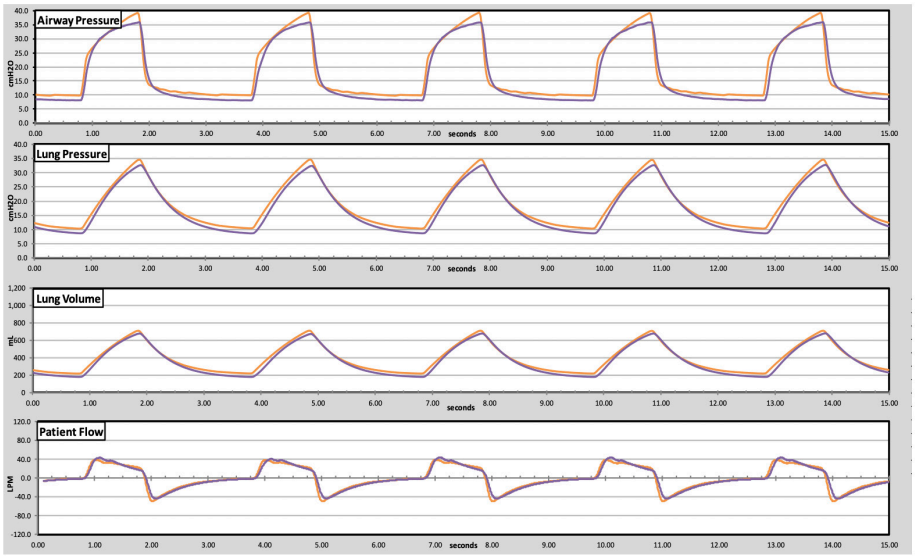


● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

PARAMETER	VALUE
Tidal Volume	500 ml
Peak Pressure (airway)	28 cmH_2O
Peak Pressure (lung)	21 cmH_2O
PEEP	10 cmH_2O
Peak Flow	40 lpm

TEST CASE 3 (RESTRICTIVE): LIFE2000 VENTILATOR AND LTV 1200

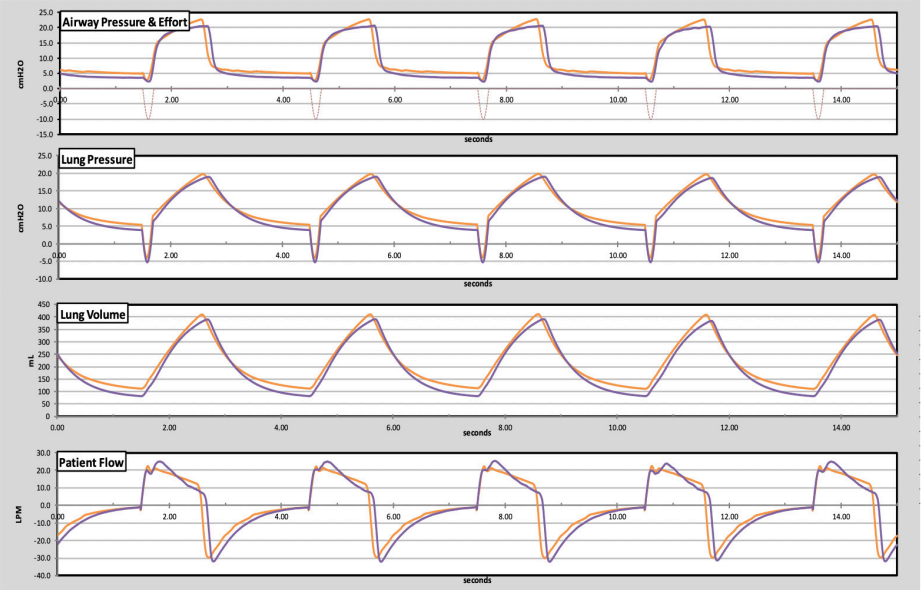


● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

PARAMETER	VALUE
Tidal Volume	500 ml
Peak Pressure (airway)	35 cmH_2O
Peak Pressure (lung)	35 cmH_2O
PEEP	10 cmH_2O
Peak Flow	40 lpm

TEST CASE 4 (SPONTANEOUS): LIFE2000® VENTILATOR AND LTV 1200



● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

PARAMETER	VALUE
Tidal Volume	300 ml
Peak Pressure (airway)	20 cmH_2O
Peak Pressure (lung)	20 cmH_2O
PEEP	5 cmH_2O
Peak Flow	25 lpm

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For more information, please contact your local Hillrom sales representative or call Hillrom Customer Service at 1-800-426-4224.

respiratorycare.hill-rom.com/Life2000

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