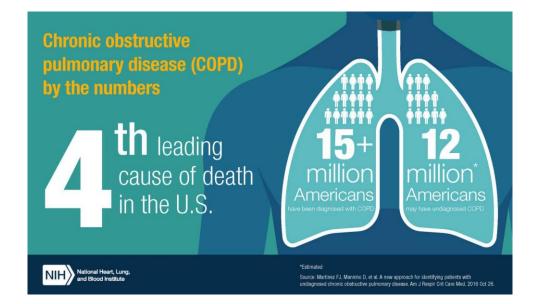
# Why NIV?



### Why is NIV Important?





With COPD being a leading cause of death in the United States, early treatment adoption is an important factor

#### NIV at home is still not widely utilized

• Less than 5% of eligible COPD-CRF patients are using NIV at home<sup>1</sup>

#### **Benefits of NIV at Home**



NIV treatment at home is associated with:



\*For those that are readmitted,

NIV treatment can extend time to readmission by 33% which allows for more symptom free days<sup>2</sup>

1 Elliott, M. Domiciliary NIV for COPD: Where Are We Now? The Lancet Respiratory Medicine. July 2104.

2 Suh, E. et al. Home Mechanical Ventilation for Chronic Obstructive Pulmonary Disease: What Next After the HOT-HMV Trial? Respirology 2019 (24) 732-739.

3 Frazier, W. et al. NIV at Home Improves Survival and Decreases Healthcare Utilization in Medicare Beneficiaries with COPD with Chronic Respiratory Failure. Respiratory Medicine, December 2020. Vol. 177.



The LUISA® home ventilator is a 3rd generation ventilator that offers all the standard ventilation modes, including TTV-VAPS-AE, with the added benefit of High Flow Oxygen Therapy at home.

The LUISA incorporates two therapies in one device. For patients that meet the requirements of home ventilation, LUISA offers NIV at night and the option of High Flow Oxygen Therapy during the day.



The LUISA has been authorized by the FDA under an EUA but has not been FDA cleared or approved. The LUISA is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. U.S. federal law restricts this device to sale by or on the order of a physician.

#### **Key Differentiating Features:** *Patient Comfort Settings*



The LUISA offers several unique features to help patients stay compliant with their therapy:

- Three Target Volume Speeds
- Flow-Based Algorithm
- Sensitive Inspiratory and Expiratory Triggers
- Inspiratory Lockout Time
- Pressure Rise/<u>Pressure Drop</u>
- Auto-Rate Algorithm

#### and

• HIGH FLOW OXYGEN THERAPY

#### Key Takeaways



- Along with TTV-VAPS-AE, LUISA offers patients the flexibility and effectiveness
  of HFT for daytime use. Both modes are available simultaneously in one device.
- With the High Flow Oxygen mode, LUISA offers One device, Two Therapies
- With several adjustable comfort settings and up to four individual prescriptions, LUISA
  is NIV therapy designed to be tailored to your patient's unique needs and disease state.
- A long-lasting battery life and a weight of 8 lbs. allows LUISA to be easily transported to MD appointments, pulmonary rehabilitation, family visits and other daily activities
- Best-in-class 10" angled, rotating touchscreen and vertical or horizontal positioning allows LUISA to be placed on either side of the bed or room and be easily seen by patients and caregivers.

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#### Quick Talk Track

Who are you talking to and What do they care about



### **Start with THE WHY**



- Nearly every physician or clinician cares about at least one of these three things:
  - Reducing readmission rates
  - Decreasing ER and hospital visits
  - Increasing patients quality of life and days of living
- So, start with the data. NIV initiated early can
  - Decrease risk of hospital readmission by ~50%
  - Decrease overall risk of hospitalization by ~28%
  - Decrease mortality rate by ~64%





- However, 2 things must happen for those outcomes to become reality
  - 1. Patients need to be started on therapy early because the longer we wait the benefits begin to wane
  - 2. Patients need to adhere to NIV therapy. NIV therapy that can be adjusted to meet the patients comfort standards is more likely to drive compliance

### **Neuromuscular Doc & Clinics**



- Sensitivity Settings and Inspiratory Lockout
  - Inspiratory sensitivity is able to be adjusted as the patients status declines
  - The ability to set it extremely sensitive is important as the disease progresses
  - Inspiratory lockout allows that extreme sensitivity without the risk of breath stacking and desynchrony with the vent

## **Pulmonary Docs & Clinics**



- Sensitivity Settings and Inspiratory Lockout (positioned differently)
  - Inspiratory sensitivity is able to be adjusted as the patients status changes
  - The ability to set it extremely sensitive may be most important when your patients have been deconditioned by long hospital stays and would benefit from the ability to trigger a breath very easily
  - Inspiratory lockout allows that extreme sensitivity without the risk of breath stacking and desynchrony with the vent

### **Pulmonary Docs & Clinics**



- Pressure Drop
  - The ability to change the slope of decline in pressures can be very beneficial for COPD and Obesity Hypoinflation Patients
  - Allowing the patient to have pressure decline more slowly allows the COPD patient to have more pressure to exhale against, providing for a more complete exhalation
  - Mimics pursed lip beathing. This is a technique the patient is likely familiar with and can provide much more comfort
  - For OHS patients it can act as a sort of lung recruitment as well

## **Pulmonary & Sleep Medicine**



- EPAP Algorithm
  - The ability to provide a comfortable nights sleep is one of the goals. The auto rate algorithm on the LUISA is flow based and assures the patient will not feel a flutter or oscillation during the rise from EPAP min to max. Forced oscillation can be very uncomfortable and inhibit patient compliance
  - The flow based algorithm ensures a smooth rise in pressure in the event the airway patency decreases

## **Pulmonary & Sleep Medicine**



- Auto Rate Algorithm
  - LUISA learns the patients normal respiratory pattern by calculating 2 factors – Minute Ventilation and Respiratory Rate
  - This helps to ensure that in the event a back up rate is needed, it is more physiologically comfortable for the patient

#### **Additional Overall Benefits**



- Speed
  - Can be set to ensure patient comfort based on patients sensitivity to pressure changes
  - Patients who are very sensitive to pressure increases will often feel as if the machine is 'just ramping up and going crazy', which leads to a mistrust of the device. The ability to set that so that the pressure increases minimally every 5-8 breaths can increase compliance

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#### LUISA

#### The Next Generation of Home Ventilation



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