LUISA®

Life Supporting Ventilation with High Flow Oxygen Therapy

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IN PARTNERSHIP WITH

LÖWENSTEIN
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PARTNERSHIP FOR BETTER PATIENT CARE

With over 60 years combined experience in respiratory care, Movair and Lowenstein Medical have partnered to deliver high-quality ventilation to the United States. The LUISA **non-invasive/invasive ventilator** with High Flow Therapy is a 3rd generation life supporting ventilator that represents the highest standards in German and U.S. product development, engineering, and manufacturing.

MŌVAIR
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Movair, formerly International Biophysics Corporation, innovator of the AffloVest has been in the cardiac surgery and respiratory market for over 30 years. Based in Austin, Texas, Movair advances life-empowering respiratory technologies that help people breathe better and live better.

LÖWENSTEIN
medical

Lowenstein Medical is a global market leader in respiratory care. They have been providing innovative solutions that improve the care of patients with over 30 years designing and manufacturing high performance ventilators used by patients ranging from neonatal to the elderly in over 130 countries worldwide.

PROVIDING LIFE SUPPORT FOR OVER 30 YEARS.

LUISA® AT A GLANCE

The LUISA from Movair and Lowenstein Medical is an advanced, easy-to-use, portable and compact home ventilator. LUISA has been globally recognized for multiple design excellence awards for intuitive, simplified everyday use.[1]

Movair is the exclusive sales, clinical and service partner for LUISA in the U.S.A.

- Targeted tidal volume, volume-assured pressure support, auto-EPAP (TTV-VAPS-AE) with unique Comfort Settings
  - Sensitive Inspiratory and Expiratory Triggers with **Inspiratory Lock Out Time**
  - Three Target Volume Speeds
  - Pressure Increase/Rise **and Pressure Reduction/Drop**
  - **Flow-Based Auto-EPAP**
  - Auto-Rate algorithm

- High Flow Therapy for invasive and NIV patients
- Lightweight at ~ 8 lbs.
- Ease of Use programming
- 10" angled touchscreen with horizontal or vertical device positioning
- 2nd alarm language
- SpO_2 and FiO_2 monitoring capabilities
- Up to 18 hours battery life[2]

HIGH FLOW THERAPY FOR YOUR VENTILATOR PATIENTS

The LUISA, with High Flow Therapy (HFT), is a home ventilator that offers all the potential benefits of HFT for patients that meet the clinical requirements for home ventilation. High Flow Therapy can deliver a high flow blend of air and oxygen, through a high-flow nasal cannula, which can improve oxygenation and decrease the workload of breathing in a wide array of patient populations.[3]

High Flow Therapy has been used in critical care, emergency departments, and is **now available to the ventilator patient at home.**

High Flow Therapy provides a flow rate that meets or exceeds a patient's inspiratory flow demand. This high flow rate can reduce the work of breathing and more closely match inspiratory demand through adjustable oxygen delivery and flow dependent clearance of carbon dioxide.[4,5]

Easy-to-use High Flow Therapy in LUISA has the potential to help manage nocturnally ventilated patients during the day with a less obtrusive oxygen flow delivery method that can potentially lead to:

- Enhanced oxygenation compared to conventional low-flow oxygenation[4]
- Improved work of breathing[5]
- Better secretion clearance[5]
- Increase in activities of daily living like eating, drinking and talking[5]
- Superior comfort and less anxiety or claustrophobia which could lead to better compliance[6]

The LUISA provides the flexibility of High Flow Therapy, for your patients that meet clinical requirements for home ventilation, invasive or non-invasive, with a flow range of 5-60 lpm.

LUISA offers all the benefits of High Flow Therapy for your ventilator patients in one device at home.

OPTIMAL CARE

TAILORED THERAPY

LUISA provides ventilator support and utilizes all standard volume, pressure and mouthpiece ventilation modes with the added benefit of High Flow Therapy. Ventilator modes include **LUISA's targeted tidal volume, volume-assured pressure support, auto EPAP (TTV-VAPS-AE)** with unique **Comfort Settings** designed to help patients be more comfortable and compliant.

PORTABILITY

Internal and external batteries offer long-lasting battery life with up to 18 hours of use[2]. LUISA is a lightweight and portable ventilator that offers two position functionality for flexibility of use at bedside, in an easy-to-carry durable bag or mounted on a wheelchair.

EASE OF USE

The LUISA with High Flow Therapy is designed for simple set-up and operation. A large, angled and rotatable 10-inch touchscreen provides an easy to view screen when programming the device through its' intuitive menu. It also provides easy visibility for patients from many angles while in use. The LUISA is a multi-purpose ventilator that does not require any adapters for different circuits.

CLOUD-BASEDREMOTE MONITORING

Device connectivity allows for personalized therapy data downloads through Movair's HIPAA-compliant[7], U.S.- based Microsoft Azure data center on the prisma CLOUD platform. The prisma CLOUD automatically ensures access to all relevant therapy data at all times. It can help manage your patients' treatment simply and securely.

prisma CLOUD with Modem Capability

- Remote reporting capabilities for DMEs and physicians
- Modem easily attaches to LUISA handle
- The modem goes where LUISA goes
- Plugged in and Powered by LUISA

SERVICE SIMPLIFIED

LUISA with High Flow Therapy provides long term care with easy serviceability. Routine patient maintenance consisting of only filter changes and a device wipe down provides uncomplicated upkeep.

With simple, routine maintenance and no adapters required between circuits, the LUISA provides clinicians and patients peace of mind with an all-encompassing system in a compact, home ventilator with the added benefit of High Flow Therapy.

LUISA® OVERVIEW

- HCPCS codes
  E0465/E0466 - invasive or non-invasive home ventilator
- High Flow Therapy
  invasive or non-invasive patients
- Connectivity
  remote monitoring for patient download reports
- Lightweight
  ~ 8 lbs.
- Uncomplicated
  no adapters, intuitive operation
- Battery run time
  up to 18 hours[2]
- Monitoring
  FiO_2 and SpO_2 measurement
- Safety
  alarm displayed in two languages
- Display
  10" angled touchscreen
- Responsive
  adjustable target volume speed
- Positioning
  vertical or horizontal; circuit orientation options (left or right side)

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.

SPECIFICATIONS

Positions to operate device	2
Number of programs/profiles	4
Weight (lbs.)	8.3 lbs.
W x H x D	11.8 x 5.1 x 8.2 in.
Display size	10” angled touchscreen
Min. V_T of patient	100 mL
Circuits (no adapters)	• Leakage • Single circuit with valve • Double circuit
Modes	TTV-VAPS-AE, HFT, S, ST, T, PSV, aPCV, PCV, P-SIMV, V-SIMV, aVCV, VCV, MPVp, MPVv, CPAP
Modes with target volume	TTV-VAPS-AE, S, T, ST, PSV, aPCV, PCV
IPAP pressure leakage circuits	4 - 50 cmH_2O
IPAP pressure valve circuits	4 - 60 cmH_2O
Ti min	0.5 sec
Ti max	4.0 sec
Frequency	2 - 60 bpm
Trigger inspiratory	Auto, 1 - 10
Trigger expiratory	5% - 95% of peak flow
Target volume	100 - 3000 mL
Target volume speed	Variable, with three selectable values
Low pressure O_2 inlet	Max. 30 l/min
FiO_2 measurement	Integrated, optional
Battery time	Up to 18 hours[2]
Internal battery service interval	4 years or 500 charge cycles
Alarm level	59 - 87 dB(A) (depending on priority level)
Noise level, dBA	Measurement according to ISO 80601-2-72 • at $V_T \geq 500$ mL: 38,5 dB(A) • at $V_T \geq 150$ mL: 37 dB(A)
Max. flow at 20 cmH_2O	>220 l/min
Alarm mute	120 sec
Boot time	• 12 sec when on battery • 1 sec when plugged in
Data storage	• 30 days detailed • 365 days statistics
Connectivity	Cellular modem or USB

For more information, please visit **movair.com/LUISA**

REFERENCES

1. iF Design Award for Design Excellence 2021 and Red Dot Award for Product Design 2021.
2. Utilizing 6 hour internal battery plus two optional external batteries at 6 hours each.
3. Dysart, K. et al. Research in High Flow Therapy: Mechanisms of Action. Respiratory Medicine. 2009. 103(10):1400-5.
4. Lodeserto, F. et al. High-Flow Nasal Cannula: Mechanisms of Action and Adult and Pediatric Indications. Cureus. 10(11):e3639.
5. Drake, M. High-Flow Nasal Cannula Oxygen in Adults: An Evidence Based Assessment. Ann Am Thorac Soc Vol.15(2):145-155.
6. Masclans, J. et al. The Role of High-Flow Oxygen Therapy in Acute Respiratory Failure. Medicina Intensiva. 2015; 39:505-515.
7. HIPAA stands for Health Insurance Portability and Accountability Act

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CE Marked as Class IIb medical device by TÜV Rheinland LGA Products GmbH

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