



Press Release

Linshom Announces FDA Clearance of the Linshom Respiratory Monitoring Device (LRMD).

Baltimore – February 3, 2020 – Linshom announced today U.S. Food and Drug Administration (FDA) 510(k) clearance of the company's first product, a small, non-invasive respiratory monitor that addresses the growing need for continuous respiratory monitoring for patients susceptible to respiratory depression and compromise.

"Lack of continuous respiratory monitoring (CRM) is a major clinical problem as nearly half of all adverse events in hospitalized patients occur on the general care floor", says Ashish K. Khanna, MD, Associate Professor of Anesthesiology and Section Head for Research at Wake Forest Baptist Health. "Current general care floor monitoring consists of intermittent nursing checks every 4-8 hours, leaving patients unmonitored for most of their hospital stay. Clinical deterioration is often missed or belatedly recognized when the patient is in crisis".

The LRMD is a major advancement as it provides clinical staff an accurate measure of respiratory rate, seconds since last breath and relative tidal volume (RTV). RTV is a critical parameter previously unavailable outside of the operating room, intensive care unit or post anesthesia care unit.

"This is our first FDA clearance for the company, so it is a major milestone", says Linshom CEO Richard Hughen. "Clinically, this clearance brings us closer to commercial launch of a product that may reduce morbidity and mortality by monitoring respiratory rate and tidal volume continuously, thus allowing for prediction of impending respiratory failure and prompt intervention. Financially, this clearance provides current and future investors confidence that we hit our milestones and advance the value of the company with their investment".

Linshom is currently raising a series A round of funding that the company will use to improve the device and assemble evidence needed for clinical adoption and commercialization.

About Linshom:

Linshom is an early stage, privately held start-up company with a mission to provide continuous respiratory monitoring for patients and health care providers to reduce morbidity & mortality associated with respiratory depression and compromise.

Contact:

Richard Hughen – CEO
RHughen@LinshomForLife.com
443.994.1448

References:

Khanna et al. Automated continuous noninvasive ward monitoring: future directions and challenges. *Critical care*, (2019) 23:194

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6543687/pdf/13054_2019_Article_2485.pdf