



FOR IMMEDIATE RELEASE:

Assurance Biosense to Unveil Next-Generation Alar Sensor at the International Anesthesia Research Society Meeting

New Device Surmounts Shortcomings of Existing Fingertip Sensors

GLASTONBURY, CT (May 1, 2013) – Assurance Biosense, a subsidiary of Xhale, Inc., today announced that it will unveil its next-generation Assurance® Alar Sensor at the International Anesthesia Research Society (IARS) meeting in San Diego May 4-7, 2013. The IARS meeting is attended by more than 1,000 of the world's leading anesthesia educators and investigators and focuses on the latest advances in research and the best practices in anesthesia critical care.

The Assurance Alar Sensor, which recently received U.S. Food and Drug Administration (FDA) 510(k) clearance, monitors oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate from the nasal ala of adult and pediatric patients. The sensor measures blood flow at the nasal ala, the fleshy lateral part of the nares, and research has shown it to be more accurate and reliable than existing pulse oximetry devices using clip-on fingertip monitors. Moving the sensor from the hands to the ala improves patient comfort and allows patients greater freedom of movement.

The nasal ala is a superior measurement point because it is rich in vasculature and fed by both the external and internal carotid arteries, the same central blood supply as the brain. This multi-directional arterial supply provides strong, reliable signals that are highly responsive to change. This measurement site, unlike the fingertips, is unaffected by reductions in peripheral perfusion common in patients with cardio-respiratory comorbidities who are undergoing trauma-related shock, those receiving vasoactive drugs and those who are just cold as they are transported into the operating room for a procedure.

Additionally, the Alar Sensor's design and placement makes it immune to interference from ambient light, including sunlight, a common problem with fingertip sensors. Assurance Alar Sensors are compatible with a variety of monitors currently in the market, including all that use Nellcor OxiSmart II sensors.

“The Assurance Alar Sensor is the next generation pulse oximeter sensor,” said Richard J. Melker, M.D., Ph.D., CTO (Professor of Anesthesiology and Pediatrics at the University of Florida College of Medicine and co-founder of Xhale). “We believe that participants at the IARS meeting will appreciate its superiority over existing technology.”

The Assurance Alar Sensor improves patient safety because it detects signals even at low oxygen saturation, senses changes in oxygenation sooner and reduces false alarms that commonly occur with existing pulse oximetry devices using clip-on fingertip monitors to measure a patient's blood flow.

Pulse oximeters have become ubiquitous in hospitals for monitoring virtually all patients because they can give clinicians an early warning of low arterial blood oxygen saturation levels, known as hypoxemia. Early detection is critical because hypoxemia can result in brain damage or death in a matter of minutes.

However, conventional fingertip-measured pulse oximetry can lead to false readings that compromise the quality of patient care. Studies have found that more than 70 percent of the conventional pulse oximetry alarms outside the operating room are false.ⁱ In the operating room, studies show that in up to 9 percent of cases, conventional pulse oximeters fail to give any measurements due to low perfusion.

The Assurance Alar Sensor is designed for the continuous non-invasive monitoring of SpO₂ from the nasal ala of adult and pediatric patients (weighing >30kg). The sensor fits to the nasal ala without adhesives and is easily checked or repositioned by the clinician as necessary, allowing it to remain on the patient for the full length of stay. Studies at the Hypoxia Research Laboratory at the University of California San Francisco demonstrate the Assurance Alar Sensor's consistent accuracy throughout the ranges of 70-80 percent, 80-90 percent and 90-100 percent oxygen saturation.

"IARS is an ideal meeting to first show our Assurance Alar Sensor," said Andrew E. Kersey, President of Assurance Biosense. "Pulse oximetry is widely considered the fifth vital sign and is a critical component of assessing a patient's condition. We believe this sensor offers a unique solution to improve upon the measurement of pulse oximetry, providing faster and more reliable detection of oxygen saturation changes than conventional sensors."

About Assurance Biosense:

Assurance Biosense, a wholly owned subsidiary of Xhale, Inc., is committed to providing clinicians with easy-to-use, cost-effective diagnostic solutions that improve patient safety and reduce false alarms. Its Assurance® line of PPG/oximetry sensors monitor central blood through are uniquely designed to monitor by placement on the nasal ala, a region rich in vasculature, fed by the external and internal carotid arteries which also supply the brain. The unique physiology of the site provides a much stronger signal than that from a fingertip or extremity, delivering more robust pulse oximetry signals. Measurement from this

site will enable monitoring a range of critical physiologic parameters which cannot be monitored via conventional pulse oximetry. www.assurancebio.com

About Xhale:

Xhale, Inc., is a medical technology innovator, developing products that transform healthcare and save lives. The company is a world leader in the use of sensors that analyze vapor and exhaled breath and is focused on novel patient-centric monitoring solutions. Its two current product lines include SMART[®], the world's only definitive medication adherence monitoring system, and Assurance[®], a single-point-of-contact sensor that monitors multiple patient parameters more comfortably and conveniently than finger-based pulse oximetry with fewer false alarms.

(Note: Certain applications described above have not been reviewed by the FDA, and are therefore labeled for investigational use only.)

For more information, please visit www.Xhale.com or contact Investor Relations at the company at IR@Xhale.com or 352-371-8488.

ⁱ Wiklund L, Hok B, Stahl K, Jordeby-Johnson A: **Postanesthesia monitoring revisited: Frequency of true and false alarms from different monitoring devices.** *J Clin Anesth* 1994, **6**:182-188.