



FOR IMMEDIATE RELEASE:

Assurance Biosense Receives FDA 510(k) Clearance to Market Alar Sensor
- Unique Nasal Ala Pulse Oximetry Sensor -
- Alar Sensing Promises High-Levels of Accuracy, Stability and Monitoring Reliability –
- Sensor Compatible with Large, Existing Installed Base of Pulse Oximeters –

GLASTONBURY, CT – APRIL 16, 2013

Assurance Biosense, Inc., a subsidiary of Xhale, Inc., today announced receipt from the U.S. Food and Drug Administration (FDA) of 510(k) clearance to market its Assurance® Alar Sensor for monitoring of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate from the nasal ala of adult and pediatric patients.

The nasal ala, the fleshy part of the nose adjacent to the opening of the nares (nostril), is a region rich in vasculature and offers a unique monitoring site for pulse oximetry. This site is fed by both the external and internal carotid arteries; the latter also provides blood to the brain. This multi-directional arterial supply provides strong, reliable photoplethysmography signals that are rapidly responsive to changes in the patient's arterial oxygen saturation. This measurement site is less susceptible to patient movement or loss of signal due to variations in peripheral perfusion as are the extremities, and is easily accessed by an anesthesiologist during surgery.

The Assurance Alar Sensor is intended for the continuous non-invasive monitoring of SpO₂ from the nasal ala of adult and pediatric patients (weighing >30kg). The single patient use sensor attaches comfortably to the nasal ala without the need for adhesives at the placement site and can easily be checked and moved by the clinician as necessary, allowing it to remain on the patient for the full length of stay. The sensor is compatible with the large installed base of monitors compatible with the Nellcor Oxisensor-II sensor.

Andrew E. Kersey, President of Assurance Biosense, stated, "We are excited to receive clearance to market our unique Assurance Alar Sensor. We plan to begin initial shipments to select customers over the coming weeks. This revolutionary new sensor offers the benefits of reliable central monitoring while using existing legacy pulse oximeters and at no additional cost to that of traditional disposable finger-tip based oximeter sensors."

"Clinical testing has shown central monitoring of pulse oximetry to be an improvement over peripheral sites such as the finger-tips used by traditional sensors", Mr. Kersey continued, "further improving the measurement of this vital sign and improving patient care. Compared to monitoring at the finger-tip, central pulse oximetry has been shown to offer reliable measurements during extremely low perfusion, as well as faster detection of desaturation and resaturation events particularly during low perfusion. The nose is an excellent site for ease of access during surgery, while the hands are not readily available to anesthesiologists. This first product in our portfolio will be an important foundation upon which we will add future products that capitalize on the benefits of measurement at the alar site."

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 PPG/oximetry sensors monitor central blood flow to the brain through placement on the nasal ala, a region rich in vasculature, fed by the external and internal carotid arteries. The unique physiology of the site provides a much stronger signal than that from a fingertip or extremity, delivering more robust pulse oximetry signals, while simultaneously enabling the monitoring of a range of critical physiologic parameters which cannot be monitored via conventional pulse oximetry.



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 current product lines include SMART®, the world's only definitive medication adherence monitoring system, and Assurance®, a replacement for conventional finger-based pulse oximetry which will monitor multiple patient parameters from a single-point-of-contact sensor more comfortably and conveniently, and with fewer false alarms, than finger-based pulse oximetry.

For more information, please visit www.assurancebio.com or contact Investor Relations at the company at ir@xhale.com or 352.371.8488.

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