Isansys Lifecare Achieves CE Mark for World’s First Cloud-Ready Medical Device

Isansys Lifecare Limited **[1]**, the provider of complete real-time physiological patient data services and systems, has announces that it has achieved CE certification for its LifeTouch Patient Surveillance System, comprising the LifeTouch HRV011 intelligent body-worn wireless sensor and associated Patient Gateway. The LifeTouch is the world’s first cloud-ready medical device of its kind, and the first to be certified as a Class IIa medical device under the European Medical Device Directive (MDD). The LifeTouch system is now ready for clinical use in the EU and other countries that recognise the CE mark.

Enabling a complete ‘Vitals as a Service’ clinical solution, the LifeTouch System provides continuous real-time information for automated patient surveillance, for early warning scores and track and trigger indicators, and for predicting adverse events. Through its low cost and highly scalable architecture, LifeTouch offers the opportunity for continuous surveillance of all patients regardless of whether they are in hospital, other care facilities, or at home. For the first time, it is economically viable for healthcare providers not only to improve patient safety and enhance clinical outcomes, but also to massively reduce costs associated with avoidable patient deterioration, medical errors, readmissions to intensive care wards, and admissions (and readmissions) to hospital.

The ultra-low profile and lightweight LifeTouch HRV011 sensor measures and analyses the ECG signal of every heartbeat in real-time to provide data for Heart Rate Variability (HRV) methods with unprecedented accuracy. Robust algorithms in the HRV011 extract key ECG parameters from which Heart Rate and Respiration Rate are continuously derived. These key vital signs, together with the HRV data, may be viewed directly via a local network on the Patient Gateway web server interface, or forwarded into a secure cloud-based electronic patient record that is updated continuously and in real-time.

The LifeTouch System is an entirely new type of medical device that has been specifically and uniquely designed to operate in a network and be 'cloud'-ready. The

LifeTouch enables robust and clinically relevant data to be simply and unobtrusively captured from a patient, analysed in real-time, merged with other data in the patient's electronic health record and securely delivered to authorised personnel – anytime, anywhere.

Commenting on the announcement, Isansys Lifecare CEO Keith Errey said: "This CE certification marks a major milestone on the road to global pervasive adoption of these kinds of essential devices. Our LifeTouch system – the world's first cloud-ready medical device and, now, the first single-use smart patch device to achieve a CE mark – is in the vanguard and now ready for full-scale deployments. The LifeTouch System is addressing the core quality of care and patient safety needs of healthcare providers with an approach that is totally unique in this market and defined by a clear understanding of how clinical environments actually function."

Rebecca Weir, Isansys Director of Business Development added: "We are now focussed on another significant industry 'first' – building the Isansys Healthcare Cloud to deliver the scalability, accessibility and affordability benefits of cloud-based technology to the clinical market for the first time. We are working to create this brand new ecosystem and secure clinical network infrastructure that will match the very special characteristics and requirements of healthcare providers and patient care environments. We will be making some very exciting announcements about this in the near future."

The LifeTouch HRV011 sensor has been designed to be as low cost as possible while incorporating the very latest generation components and state-of-the-art functionality. As a single-use, semi-disposable device with the low-cost body contacting parts being disposable and the electronics modules being refurbished, it leads to a new paradigm in affordable high quality medical devices. Key target markets for Isansys' solution outside of Europe include developing economies where the system offers healthcare providers the ability to leapfrog many of the expensive medical devices currently in use. The LifeTouch system incorporates enormous intelligence, providing scope for additional functionality in the future that will open up vast new opportunities for low-cost screening and targeted monitoring of specific cardiac conditions. The LifeTouch System is covered by patent applications relating to construction, use and functionality, and is available through the Isansys service offerings or under license from Isansys.

For more information, please visit www.isansys.com [1].

Posted by Ron M. Seidel, Editorial Intern

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