

Friday 22<sup>nd</sup> August 2014

## **iSonea Strengthens its Leadership in Respiratory Mobile Health Technology**

### **FDA Grants Clearance for SonoSentry™1**

iSonea has achieved the first clearance of an Over-The-Counter (OTC) wheeze detection device in the United States.

The US Food and Drug Administration (FDA) have provided iSonea with a substantially equivalent letter for its SonoSentry™1 WheezeRate™ Detector device (K131285). iSonea is now clear to market this device in the United States as an OTC product instead of requiring a prescription for the purchase of the device from a medical practitioner.

SonoSentry™1 is a portable acoustic device for measuring and recording WheezeRate™. Whilst not smartphone enabled, the SonoSentry1 device uses a sensor head, iSonea's acoustic respiratory algorithms, and an LCD screen.

The additional benefit of this milestone is the establishment of the company's OTC predicate SonoSentry™1 WheezeRATE™ Detector, for future subsequent over the counter device submissions.

The SonoSentry™1 device is also suited for sale to consumers in developing countries where there is expensive, limited, or no internet access to connect to iSonea's cloud-based servers for analysis of recorded breath sounds.

As previously advised, the company is developing a new SonoSentry™2 stand-alone WheezeRATE™ Detector product with a similar sleek design to the company's AirSonea™ device, with a much lower potential production cost. The company is actively investigating commercialisation opportunities.



### **iSonea's Flagship Wheeze Monitor Device and App**

iSonea is now preparing a submission for its flagship AirSonea™ wheeze monitor device and App that uses a cloud-based server to acquire and process WheezeRATE™ recordings.

This device is best suited to developed markets with a high penetration of smartphones and Apps, and reliable, low cost accessibility to the internet allowing connection to our cloud-based servers for analysis of recorded breath sounds.



### **Patent Granted: Compliance Monitoring for Asthma Inhalers**

The US Patent Office granted and published an iSonea patent titled, “Compliance Monitoring for Asthma Inhalers.”

The granted iSonea patent addresses the multitude of inhaler types and regimes that an individual may use thus differentiating it from other patents in this area.

The patented medication compliance system consists of; a small profile multi-sensor that attaches to all types of inhaled Asthma medication delivery devices, a smart device App, and a backend server to communicate to pharmacy and physicians.

The system automatically recognises medication use from the multi-sensor, which in turn wirelessly communicates this information to an App on a smartphone or tablet in order to document the patients medication adherence, and based on the type and volume of the medication device, automatically monitor and reorder medication once the patient’s inhaler is nearing empty.

This device system will communicate with iSonea’s overall Asthma App management package which reminds patients to take their medicines, and notify physicians and pharmacists regarding patient recorded symptoms and measurements, and overall adherence to their medication plan.

This patent is significant because a major issue for the 300 million individuals worldwide with Asthma is compliance to their therapeutic plans. It is documented in medical literature that compliance to therapy regimes may provide a multitude of benefits including reduced health care costs, reduced health care premiums, improved pulmonary function and improved quality of life.

A system that can remind and document medication adherence has been demonstrated to increase medication compliance significantly.

This patent is significant for iSonea as it will enable pharmacy partners to develop this system for Asthma patient compliance, and it provides yet another demonstration of iSonea’s leadership in mHealth monitoring devices.

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### **Looking Forward Statements**

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