

China NMPA Accepts Registration for SpiroSonic Spirometers

- China regulatory acceptance for Uscom SpiroSonic devices
 - 4 devices accepted: AIR, SMART, MOBILE and FLO
- Research grade pulmonary function testing for hospitals and eHealth
- Addressing China's need for management of Asthma, COPD and COVID
 - Patented technology for digital ultrasonic spirometry

Thursday 21st July 2022: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) advises that Uscom China, a wholly owned subsidiary of Uscom Limited, has been granted regulatory NMPA acceptance for 4 devices in its range of SpiroSonic spirometry subject to the payment of a registration fee within 15 working days. The submission was initiated in January 2018 and will allow for the sale of Uscom Spirometers into the Chinese market for a period of 5 years once the approval is issued.

Background:

Uscom SpiroSonic spirometers are based on patented digital ultrasonic spirometry and comes in four models: the SpiroSonic FLO, SpiroSonic SMART, SpiroSonic MOBILE, and the SpiroSonic AIR. The SpiroSonic AIR can wirelessly interface with Uscom SpiroSonic APP to cloud-based or clinic-installed SpiroReporter software for remote archiving, analysis, trend analysis, and reporting with oversight from international expert diagnosticians.



World leading ultrasonic AIR technology provides wireless connection to APPs and remote servers delivering expert care in hospital, clinics and at home.

The SpiroSonic AIR, SpiroSonic APP, and SpiroReporter software combine as a world leading research-grade pulmonary testing solution for hospitals, clinics, home care, eHealth, and Pharma testing. These SpiroSonic technologies are specialised for precision diagnosis and management of asthma, COPD and long COVID.

Last year our international engineering team focused on the development of the SpiroSonic AIR technology, developing its specialised application in pulmonary research in Pharma and Long COVID, while finalising reviewers' questions for the FDA submission. The SpiroSonic AIR is a digital, multipath ultrasonic spirometer with a high-level viral disinfection system against COVID and Tuberculosis, both



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critical and emerging transmissible pulmonary infections worldwide. The SpiroSonic AIR, SpiroSonic APP and SpiroReporter can now display 46 advanced parameters of lung function using 48 different performance algorithms, has on board precision diagnostics and interactive user voice guidance. AIR's ultrasonic accuracy, software sophistication, and simplicity of use make the technology the world leader in spirometry and research-grade lung function testing. The AIR solution is currently approved in Europe and in regulatory process for FDA (US), NMPA (China), and a number of SE Asian countries.



The implementation model of wireless lung functions testing and management in an eHealth setting

This acceptance comes after more than 2 years of national testing and 3 months after a manufacturing and R&D agreement with Foxconn was executed for the manufacture of Uscom devices in Beijing. Foxconn is expanding its activities in high-level medical technology, and Uscom China is designated as a Chinese National High Technology Enterprise by the High Torch Industry Development Centre Ministry of Science and Technology, and currently has in the order of 37 active IP approvals or submissions covering novel devices and concepts for new products in China.

The new Beijing Uscom facilities in the Foxconn Technology Industry Zone will become the global manufacturing headquarters for Uscom Limited. Combined with our current administration and sales centre, this Foxconn partnership locates Uscom firmly in Beijing, China, a preferred centre for high technology development by the Chinese Government.

Uscom has recently lodged a PCT approval for a Spirosonometry patent covering a variety of new spirometry signal methods, feedback incentives and new patient guidance to optimise spirometry use. This patented technology increases the capabilities of spirometry and improves patient care in asthma, COPD and COVID.

Commentary:

Of China's 1.4b population, lung disease is a major public health problem responsible for approximately 1m deaths p.a. or 10% of all deaths, while approximately ~210m (15%) suffer from COPD, while ~40m people (3%) suffer from asthma. Asthma, COPD, air pollution, and smoking are the main causes of chronic respiratory diseases. COVID is an essentially pulmonary disease and the long-term incidence of pulmonary fibrosis is uncertain and likely to vary between different COVID variants, but many survivors may require chronic home monitoring of lung function to ensure no progress of Long COVID complications.

Executive Chairman of Uscom, Professor Rob Phillips said *"The NMPA acceptance of our SpiroSonic technologies in China is a significant commercial leap for Uscom into the most populous medical and medical consumer market in the world, and Uscom looks forward to activating our expanding sales teams to convert this opportunity into revenue. The SpiroSonic world leading technology provides research grade monitoring in a digital environment with an easy to use and disinfect technology suited to clinical and eHealth environments."*

The size and scale of the new manufacturing arrangements allow for concurrent manufacture of multiple products, for multiple markets and can accommodate expanded device manufacture volume as required. Products with existing regulatory approval will be given manufacturing priority.

References:

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About Uscom

Uscom Limited (UCM): An ASX listed innovative medical technology company specialising in development and marketing of premium non-invasive cardiovascular and pulmonary medical devices. Uscom has a mission to demonstrate leadership in science and create noninvasive devices that assist clinicians improve clinical outcomes. Uscom has three practice leading suites of devices in the field of cardiac, vascular and pulmonary monitoring; the USCOM 1A advanced haemodynamic monitor, Uscom BP+ central blood pressure monitor, and the Uscom SpiroSonic digital ultrasonic spirometers. Uscom devices are premium resolution, noninvasive devices which deploy innovative and practice leading technologies approved or submitted for FDA, CE, CFDA and TGA regulatory approval and marketing into global distribution networks.

The USCOM 1A: A simple to use, cost-effective and non-invasive advanced haemodynamic monitor that measures cardiovascular function, detects irregularities and is used to guide treatment. The USCOM 1A device has major applications in Paediatrics, Emergency, Intensive Care Medicine and Anaesthesia, and is the device of choice for management of adult and paediatric sepsis, hypertension, heart failure and for the guidance of fluid, inotropes and vasoactive cardiovascular therapy.

The Uscom BP+: A supra-systolic oscillometric central blood pressure monitor which measures blood pressure and blood pressure waveforms at the heart, as well as in the arm, information only previously available using invasive cardiac catheterisation. The Uscom BP+ replaces conventional and more widespread sub-systolic blood pressure monitors, and is the emerging standard of care measurement in hypertension, heart failure and vascular health. The Uscom BP+ provides a highly accurate and repeatable measurement of central and brachial blood pressure and pulse pressure waveforms using a familiar upper arm cuff. The BP+ is simple to use and requires no complex training with applications in hypertension and pre-eclampsia, heart failure, intensive care, general practice and home care. The Uscom BP+ is supported by the proprietary **BP+ Reporter**, an innovative stand alone software solution that provides a digital platform to archive patient examinations and images, trend measure progress over time, analyse pulse pressure waves and generate summary reports.

Uscom SpiroSonic digital multi-path ultrasonic spirometers: High fidelity, digital, pulmonary function testing devices based on multi path ultrasound technology. They require no calibration, are simple to disinfect, and are simple and accurate to use providing research quality pulmonary function testing in small hand held devices that can be used in research, clinical and home care environments. The devices can be coupled with mobile phone apps and proprietary SpiroSonic software, **SpiroReporter**, with wireless interfacing to provide remote tele-monitoring of pulmonary disease. The devices are specialised for assessment of COPD, sleep disordered breathing, asthma, occupational lung disease and monitoring of pulmonary therapeutic compliance.

VENTITEST digital ultrasonic ventilator testing solution is a new system for testing ventilators. All ventilators require calibration to maintain the accuracy with which they measure the pressure, flow and volume of air they deliver. VENTITEST and VENTITEST-S, based on advanced SpiroSonic technology provides a testing solution that provides for simple and accurate testing, archiving, analysis and reporting to optimise ventilation performance.

For more information, please visit: www.uscom.com.au

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This announcement is approved for release to the ASX by the Board of Uscom Limited.