

Press Release

BiancaMed's Sleep Apnea screening technology receives FDA clearance

BiancaMed's sleep apnea screening technology has secured Food and Drug Administration (FDA) clearance enabling the *LifeScreen Apnea*[™] medical device to be marketed in the United States. BiancaMed is a medical technology company located in NovaUCD, the Innovation and Technology Transfer Centre at UCD. The FDA clearance was received by US based Del Mar Reynolds Medical who licensed BiancaMed's innovative technology to develop the *LifeScreen Apnea*[™] product.

LifeScreen Apnea[™] permits cardiologists to screen for obstructive sleep apnea using only the overnight recordings of a patient's cardiac signals recorded in the individual's home, which greatly reduces the cost and time involved in diagnosing the condition. Obstructive sleep apnea is a medical condition in which the breathing of an individual is interrupted while he/she is asleep, which can lead to daytime sleepiness, fatigue, and which is also a risk factor for serious heart disease.

It is estimated that there are up to 20 million sleep apnea sufferers in the US alone and 90 percent of these are undiagnosed. Similar numbers are estimated in Europe. The current market for sleep apnea diagnostic and screening technology is over USD100 million worldwide, and growing at an estimated 10 percent annual rate. The FDA clearance follows on from the award of the CE Mark for *LifeScreen Apnea*[™] received at the end of 2004, enabling the product to be sold throughout Europe.

Given timely diagnosis of sleep apnea, the outlook for sufferers is encouraging since an effective therapy exists. However, the biggest issue related to sleep apnea is to provide cost-effective and accurate diagnosis. Currently, diagnosis requires an overnight stay in a dedicated sleep laboratory, which is costly and many laboratories have long waiting lists. *LifeScreen Apnea*[™] overcomes both these problems as the cardiac signals are recorded while patients sleep in their own homes.



Speaking about this significant development for the company, Dr Conor Heneghan, Chief Scientific Officer, BiancaMed, said, "The clearance by the FDA of *LifeScreen Apnea*[™] marks an important milestone in BiancaMed's development as it successfully demonstrates our core belief in transferring leading-edge, university-based research in signal processing and pattern recognition into a real product." He added, "BiancaMed's focus is clearly set on the development of core intellectual property including know-how to enable the company to develop smart personalised health monitoring products, and this is another significant step in BiancaMed attaining that vision."

The algorithm technology used in *LifeScreen Apnea*[™] was initially developed by Dr Philip de Chazal and Dr Conor Heneghan based upon their research undertaken in UCD's Department of Electronic and Electrical Engineering. The pair co-founded BiancaMed in 2002 to commercialise the developed technology.

Using *LifeScreen Apnea*[™], the large world-wide customer base of Del Mar Reynolds Medical can now screen their patient's for sleep apnea using a routine 24-hour electrocardiograms (ECG) Holter scan. The product is integrated into the company's complete suite of cardiac analysis solutions for the medical profession. Del Mar Reynolds Medical is a leading supplier of Holter and non-invasive ECG solutions world-wide.

LifeScreen Apnea[™] was officially launched in the US at the Annual Scientific Session of the American College of Cardiology, which was held in Orlando, Florida in early March with an attendance in excess of 20,000.

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Editor's Notes

Del Mar Reynolds Medical is owned by Ferraris Group plc and was formed as a result of a merger between Reynolds Medical and Del Mar Medical. This merger formed the largest single supplier of Holter systems in the world. The combined product range encompasses resting ECG, stress testing, Holter, event monitoring, ambulatory BP and Information Management systems.

Dr Philip de Chazal is BiancaMed's Chief Technology Officer and has prime responsibility for design and implementation of biomedical signal processing algorithms and system architecture. He was a lead researcher in UCD's Department of Electronic and Electrical Engineering from 2000-2003. Prior to joining UCD, Dr de Chazal worked at Medcare Systems (Sydney, Australia), subsequent to completing his PhD at the University of New South Wales. He has particular expertise in signal processing and pattern recognition for biomedical applications specialising in the analysis of electrocardiograms.

Dr Conor Heneghan is BiancaMed's Chief Scientific Officer with responsibility for identifying clinical market opportunities and managing external research interactions. He is also a senior lecturer in UCD's Department of Electronic and Electrical Engineering. Prior to joining UCD, he was Director of Tele-Informatics at The New York Eye and Ear Infirmary and a post-doctoral researcher at Boston University. He completed his doctoral studies at Columbia University. His previous research work has included analysis of electrocardiograms and neural signals. His unique skills are in the area of signal analysis and feature detection.

NovaUCD is University College Dublin's EUR 10 million Innovation and Technology Transfer Centre. This purpose-built centre, nurtures new technology and knowledge-intensive enterprises. NovaUCD has over 40 incubation units and provides innovators and entrepreneurs with the necessary support and knowledge to take their ideas from proof of principle to commercial success. NovaUCD has been funded through a unique public-private partnership that includes AIB Bank, Arthur Cox, Deloitte, Enterprise Ireland, Ericsson, Goodbody Stockbrokers, UCD and Xilinx.

Seventeen high-tech, knowledge-intensive enterprises are currently located in NovaUCD including BiancaMed. Companies who recently located in NovaUCD include Lightwave Technologies, an environmental technology company and Duolog Technologies, a chip design



company. Only 12 of NovaUCD's incubation units are still vacant. NovaUCD would welcome proposals from the promoters of high quality, knowledge-intensive ventures who are interested in locating in NovaUCD and joining our growing community of entrepreneurs.