



An excerpt from Medical Device Technology Alert 13 April 2007

GROUNDBREAKING TECHNOLOGY FOR CARDIAC DISEASE DIAGNOSIS

Cardiovascular disease (CVD) is a major international health problem, which accounts for 38% of all deaths worldwide. It is also estimated that the total cost of CVD in the United States alone is approximately \$400 billion and exceeds \$1 trillion worldwide.

The three primary indicators of the heart disease are electrical defects, mechanical defects, and biological markers of defects. Commonly, electrocardiography (ECG) is used to detect electrical defects, while stethoscopes (auscultation) and ultrasound echocardiograms are used to detect mechanical defects. While stethoscopes detect abnormal heart sounds, an ultrasound echocardiogram is a structural imaging technique, which indicates mechanical or structural abnormality. Biological markers are used to detect congestive heart failure and myocardial infarction.

While ultrasound echocardiogram is currently the favored diagnostic tool, it has many limitations. It requires skilled personnel to interpret results, its availability is limited, and is very expensive. It is estimated that four out of five echocardiograms are unnecessary for various reasons.

Stethoscopes on the other hand are inexpensive, universally available, allow rapid triage, and can diagnose many types of problems such as murmurs and regurgitation, septal defects, mitral valve prolapse, and stenosis. However, training in their use is difficult; results may be subjective and prone to human or environmental error, and furthermore, the heart sounds cannot be recorded or documented for later comparison or for research.

Currently, there are many therapies that can both prevent and effectively treat CVDs. Therefore, strategies to detect CVDs early have great potential to deliver benefits in reducing the burden of disease. Various diagnostic and biomarker strategies have been employed in this quest. One such approach is the use of the phonocardiographic characteristics of heart sounds to improve diagnostic accuracy.

Working in this direction, an Australia-based biotechnology company, HD Medical Group Limited, is leading the way to develop the world's first noninvasive heart failure predictive tool. The company has created groundbreaking patented and patent-pending technology in the area of mechanical heart sound analysis for early detection of cardiac diseases. In conjunction with Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australia's largest scientific research organization, the company plans to combine its own core technology with CSIRO's wireless vital signs sensor technology to revolutionize the early detection and management of heart diseases.



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HD Medical recently secured an exclusive worldwide technology license from CSIRO, for patent pending core radio frequency (RF) sensor technology to support this method. The research on this noncontact heart sensor technology was completed over a five-year period by a dedicated multidisciplinary team of ten researchers led by the late John Ables at the CSIRO Wireless Technologies Laboratory in Sydney, Australia.

The CSIRO technology is based on the principle of RF backscatter and does not require any contact with skin. By placing the sensor over the top of clothing, various signals are recorded, which appear to reflect either movement of the heart or intracardiac or intravascular pressure waveforms.

HD Medical has developed a device called the ViScope[®], which is an audio-visual auscultation tool for effective cardiac triage. Viscope[®] allows the physician to see, hear, and evaluate heart sounds to identify common pathologies. Specialized features include amplification and selective filtering of sounds.

HD Medical is planning to undertake 500 patient clinical trials in normal subjects and relevant disease populations, beginning in May 2007, to identify the signals obtained and to integrate the CSIRO technology into ViScope[®]. This integration of two breakthrough technologies will set a new gold standard for heart diagnostics, which could lead to the creation of a predictive tool for heart failure. The clinical trials are to be conducted at the Monash University Centre for Clinical Research Excellence based at the Alfred Hospital in Melbourne, Australia. The lead investigator of these trials is Professor Henry Krum, a world-renowned cardiologist who says, "These devices have the potential to revolutionize early detection and management of heart disease by utilizing technology that is completely noninvasive, able to be operated by non-medical personnel and, by collecting digitized information, able to be transferred remotely."

These simple noninvasive tests will have immediate application in rural and remote areas and in developing countries, as well as for the general population as a screening tool for use prior to more expensive and/or invasive diagnostic testing. HD Medical is partnering with the Indian government's national network of research laboratories to develop low cost digital medical equipment to be used at primary health care centers throughout India. The project is part of a rural telemedicine program sponsored by the Indian government.

Further research and clinical trials using ViScope[®], conducted at the University of California in San Francisco, has resulted in a research paper being accepted by the American Society for Echocardiography (ASE), which concludes that there is a linear correlation between the logarithm of calibrated intensity of the first heart sound and left



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ventricular ejection fraction. This abstract is to be presented at the ASE's 18th Scientific Sessions to be held in Seattle, Washington in June 2007.

The first generation ViScope[®] product will be available later in 2007 for doctors to use. ViScope[®] is designed to be user-friendly and portable, requiring no external PC. It delivers objective evidence for accurate triage, and enables detection of problems at an early stage. Doctors can be trained to use the system in a few hours and can use it without the need for technical support or interpretation of results by a specialist. It can also be seamlessly integrated with telemedicine technologies.

The ViScope[®] 100 Series product is the first of a pipeline of products, each subsequent version building on the technology of the previous ones. The company's plan is to move from triage to diagnosis to full pathology characterization--adding IP and innovation at each step.

HD Medical's products and technologies are backed by a strong Intellectual Property and the company is pursuing an active worldwide patent strategy. The company has pending and provisional patents for various other technologies such as gating for echo, MRI, and CT.

Funding for the CSIRO noncontact sensor technology development came from the Australian Federal Government. Subsequent to the results of the clinical trials, HD Medical will proceed to product development with the intention of developing international markets and applications.

HD Medical raised AUD \$3.35 million (US \$2.7 million) in 2005 to establish research and development facilities in India (Chennai) and the United States (San Francisco), and to facilitate product design and development activities. The company is currently undertaking a second round of capital raising to further its commercialization activities.

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