

VolparaAnalytics™ Breast Imaging Quality Assurance Software Registered with FDA

Knowledge of Volumetric Measures from an Objective Measurement Tool Provides Context for Quality Assurance Analytics

PHOENIX, September 18, 2013 – Matakina International today announced registration of a new Class I software medical device, VolparaAnalytics™, with the U.S. Food & Drug Administration (FDA). The company made the announcement today at the ARRS Breast Imaging Symposium, September 18-21, 2013 at the JW Marriott Phoenix Desert Ridge Resort and Spa, Phoenix, AZ.

VolparaAnalytics assists in quality assurance by monitoring and recording critical elements of the breast imaging process, and then generating key imaging performance metrics to help understand the performance of technologists, readers and mammography machines.

For each image received, VolparaAnalytics automatically extracts information about the x-ray physics parameters used, records mammography and technologist identifiers, and computes various novel metrics from that data, including volumetric breast density and pressure. Real-time alerts and reports can demonstrate, for example, whether one technologist is compressing too much, or if one mammography unit is operating differently to the others. This comparative information can help determine whether additional training or re-calibration is required.

“The measurements have already proven effective in identifying issues at several facilities and have enabled us to resolve them in a timely manner. This is a very useful tool and the volumetric context is critical to understanding how a particular unit functions,” said Vikas Patel, PhD from Upstate Medical Physics, A Landauer Medical Physics Partner.

“Imaging performance metrics, such as average force, can only be properly interpreted in context of the volumetric characteristics of the patient population. For example, one site might apply far more force because the breast size is higher, a fact that becomes very evident when you consider pressure applied, not force,” said Ralph Highnam, CEO of Matakina International

In the study “Practitioner compression force variation in mammography: A 6-year study” recently published in the *British Journal of Radiology*, Mercer et al established that there is a wide variation in compression force and breast thicknesses for the same patient when they are imaged by different technologists. Clinical implications of this range from

variations in dose exposure to potential variations in image quality and lesion visibility. “Thus it is critical, that your technologists are operating to approximately the same level, and that is what we seek to demonstrate with VolparaAnalytics,” added Highnam.

In another recent study “Screening mammography recall rate: does practice site matter?”, recently published in *Radiology*, Rothschild et al questioned “the utility of a universal recall rate goal and suggest that targets have to be adjusted on the basis of local population factors.” With VolparaAnalytics, clinics can now consider their recall rates in the context of knowing their volumetric context. According to Highnam, “a particular site might have far more recalls than another because the patient population at that site is far denser. Similarly, a radiologist who primarily reads fatty mammograms from a more obese neighborhood may seem to outperform another radiologist whose patients are predominately younger or slimmer women with dense breasts.”

Cleared by the FDA, HealthCanada, the TGA and CE-marked, VolparaDensity™ is in use at sites across the globe, helping radiologists assess breast density more objectively. The volumetric numbers derived by VolparaDensity™ are at the heart of VolparaAnalytics™. VolparaAnalytics™ supports most of the major digital mammography systems and the results can be displayed via browser or via real-time email alerts.

About Matakina

Founded to enable radiologists to give women the most accurate information possible regarding their breast health, Matakina International, Limited is the wholly owned sales and marketing arm of Matakina Technology Limited of New Zealand. Volpara’s founders and Board of Directors includes John Hood, PhD, former Vice Chancellor of the University of Oxford, UK; Ralph Highnam, PhD, former CEO of Mirada Solutions, one of the University of Oxford’s most successful spin-outs of recent times and co-author of the seminal book *Mammographic Image Analysis*; and Professor Sir Michael Brady, a serial entrepreneur who recently retired from the University of Oxford where he was Professor of Information Technology for 25 years.

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