

NEWS RELEASE

IB CLINIC RECEIVES FDA CLEARANCE

For Immediate Release

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Elm Grove, WI – Imaging Biometrics, LLC (IB), a biotechnology company specializing in the development of software solutions for advanced visualization and analytics, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration for IB Clinic™, a post-processing perfusion, diffusion, and image analysis toolkit.

IB Clinic consists of three software modules: IB Neuro™, IB Diffusion™, and IB Delta Suite™. These modules accept DICOM image sets from common scanner modalities and generate various perfusion and diffusion-related parameters and image intensity differences.

IB Clinic is designed to make advanced image assessment, treatment consideration, and monitoring of therapeutic response easier and faster for trained physicians. For instance, using a patented algorithm called Voxel Intensity Calibration™ (VIC), IB Delta Suite can generate “Delta T1” (DT1) maps. These maps highlight areas of true enhancement on standard MRI images, thereby enabling radiologists to readily distinguish tumor from blood products. Another application allows the generation of perfusion magnetic resonance imaging (pMRI) fractional tumor burden (FTB) maps. These maps have been proven to reliably distinguish tumor recurrence from post-treatment radiation effects (PTRE). The validation and commercialization of pMRI-FTB maps are the result of close collaborative work between neuroradiologists and engineers.

IB Neuro accepts both magnetic resonance imaging (MRI) dynamic susceptibility contrast (DSC) and computed tomography (CT) perfusion datasets and performs data post-processing that provides clinicians with a robust way to make informed decisions in their approach to perfusion imaging of brain tumors and other brain disorders. Clinically validated, IB Neuro provides specific information about brain tumor biology and vasculature via the unique way it corrects for contrast agent leakage effects. Without this correction, confounding leakage effects provide widely varying results and may lead to erroneous treatment protocols. Moreover, IB Neuro incorporates Voxel Intensity Calibration – an exclusive way to reduce inherent image intensity variation thereby enabling easy comparison between images acquired at different time points and from different scanners.

IB Delta Suite generates maps of the differences in image intensity on voxel-by-voxel basis for two images acquired at different times or from different scanners. IB Delta Suite may enable easier identification of image intensity differences by applying VIC, an exclusively licensed technology proven to remove variability inherent with conventional imaging. IB Delta Suite also provides tools to co-register image series, generate regions of interest (ROIs) by setting image intensity thresholds, and export ROIs as DICOM images.

IB Diffusion generates apparent diffusion coefficient (ADC) maps used for the visualization of water movement in soft tissue throughout the body. It accurately generates maps from diffusion-weighted image series comprised of two or more b-value acquisitions.

Timothy Dondlinger, Chief Operating Officer, stated, “This latest clearance is an important milestone for our company and IB Clinic is our first step toward commercializing all IB-branded products in the US. The vendor-neutral, push-button generation of MR and CT perfusion and diffusion maps, coupled with a rapid clinical integration, makes the adoption of IB Clinic an easy choice for hospitals and imaging centers of all sizes.” “Ultimately, it’s a choice that will benefit patients,” added Dondlinger.

Renowned for their intuitive interface and rapid post-processing capability, IB-branded products are deployed in dozens of large and small healthcare facilities alike. “We are proud to have put these advanced imaging tools in the hands of clinicians at sites of all sizes,” says Dondlinger. “The rapid and proven results are aiding them in their treatment considerations on a daily basis”.

About Imaging Biometrics, LLC

Imaging Biometrics™ develops and provides medical image analysis solutions that enable clinicians to better diagnose and treat diseases with greater confidence. Through close collaboration with top researchers and clinicians, sophisticated advancements are translated into platform-independent software plug-ins which extend the base functionality of workstations, imaging systems, PACS and medical viewers. By design, IB’s advanced visualization software seamlessly integrates into clinical workflows. For more information about Imaging Biometrics, visit the company’s website at www.imagingbiometrics.com.