



OPTOVUE RECEIVES FDA CLEARANCE ON NORMATIVE DATABASE

The largest FDA cleared Normative Database for OCT is now available for the RTVue FD-OCT from Optovue, Inc.

FREMONT, CA, September 16, 2010 – Optovue, the company that launched the first FDA cleared fourier/spectral domain OCT in the US, announced that it has received 510(k) clearance on its Normative Database (“NDB”) for the RTVue OCT device.

“This affirms that our protocols and management of this large international, multi-site normative population are at the level that FDA regulatory guidelines require,” stated Mike Sinai, PhD, Sr. Director of Clinical Research for Optovue. “Most importantly, this demonstrates the safety and efficacy of our NDB based on FDA current standard for its intended uses. This is the only normative database taking into account patient age, signal strength of scan, and even optic disc size in certain scan type. These factors along with the large normal sampling offer clinicians a high degree of confidence in our NDB as a reference tool in assessing retina nerve fiber thickness.”

The NDB for the RTVue system comprises over 600 eyes for the pending U.S. release, and is the largest FDA cleared NDB for an OCT device. Optovue plans on releasing the RTVue application update containing the newly cleared NDB for customers in the next several weeks.

About RTVue and iVue

RTVue was the first FDA cleared Fourier domain (also known as spectral domain) OCT launched in the United States, and also the first OCT cleared by the U.S. Food and Drug Administration for both corneal and retinal imaging. The iVue is the compact fourier-domain version of the RTVue OCT, offering the same scanning speed and resolution as the larger system, that includes scanning and reports for retina, retina nerve fiber and cornea assessment by the clinician.

About Optovue (www.optovue.com)

Optovue Inc. is a privately-held ophthalmic device company dedicated to working with eye care professionals and clinical researchers to lead the commercialization of new imaging modalities that improve diagnosis and therapy of ocular disease. Optovue has achieved widespread market success through a combination of unique data analysis design, a reputation for excellent customer service, and rapid innovation of its technology in response to physician feedback. The company is headquartered in Fremont, CA, with operations in Carlsbad, CA and European operations in Heidelberg, Germany.

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