



Optovue Announces FDA Approval for Corneal Power Measurements

Using RTVue® to find a precise measurement of Total Corneal Power (TCP™)

FREMONT, CA; October 17, 2011 – Optovue, a pioneer in spectral-domain optical coherence tomography (SD-OCT), announces that the RTVue has received U.S. Food and Drug Administration (FDA) 510(k) clearance for Optical Coherence Tomography (OCT) measurements of central corneal power, curvature, and thickness in human corneas, pre- and post-cataract surgery.

The RTVue can be used to calculate the Total Corneal Power (TCP) of the cornea in eyes that have undergone corneal refractive surgery. Furthermore, the RTVue directly measures posterior corneal power and does not rely on good preoperative vision or previous clinical record(s). The success of IOL selection in cataract surgery is largely determined by corneal power. However, corneal refractive power has previously been very difficult to measure in post-refractive patients.

The OCT System can image the posterior corneal surface with very high resolution, allowing it to measure corneal power precisely. “That is what is needed in post-LASIK eyes,” states David Huang, MD, PhD, who has been using the RTVue to measure corneal power in multiple clinical studies sponsored by the National Institutes of Health (NIH). The RTVue uses a proprietary corneal segmentation algorithm that has been at least as effective, if not more effective, than other currently existing methods for measuring corneal power. The corneal power, curvature, and thickness measurements by OCT are repeatable within a visit, as well as for pre- and post-operative visits.

“As the segment of post-LASIK cataract patients grows, it is increasingly important that ophthalmologists have an accurate way to determine corneal power. This FDA clearance affirms that the RTVue is a precise and effective tool that provides value for the physician and the patient,” states Jay Wei, Optovue President and CEO. “We continue to leverage our experience in OCT product development and Fourier-domain technology to serve the needs to physicians and patients.”

RTVue was the first FDA cleared 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 RTVue provides an all-in-one solution for posterior and anterior high-speed, high-resolution OCT imaging, offering five-micron resolution, high-magnification imaging of the cornea, angle and anterior crystalline lens, pachymetry mapping, as well as retina and glaucoma scanning and analysis functions.

About RTVue®, iVue® and iStand™

RTVue was the first FDA cleared 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 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. iStand is a rolling floor stand option for iVue. When mounted to iStand, patients are able to be scanned in various positions including the supine position.

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 Germany.

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