



For Immediate Release

IDx and Topcon sign exclusive AI platform agreement for the U.S. market

IDx, the company behind the first and only FDA-cleared autonomous AI diagnostic system, joins forces with Topcon, a pioneering ophthalmic device manufacturer, to tackle preventable blindness

CORALVILLE, IA and OAKLAND, NJ, October 22, 2018 – IDx, a leading AI diagnostics company, and Topcon, one of the world’s leading ophthalmic device manufacturers, have signed an exclusivity agreement that will allow the companies to scale delivery of AI-based diagnostic solutions in the U.S. market.

The agreement grants exclusive rights to IDx in the U.S. as the only autonomous AI company permitted to sell its products with the Topcon NW400 – an easy to use, robotic fundus camera. Topcon continues to collaborate with other partners in the AI space for solutions that fall outside of this autonomous agreement.

In turn, IDx has agreed to assign Topcon’s NW400 as the only robotic desktop fundus camera with less than a 55 degree field of view to be integrated with IDx-DR, an autonomous AI system that instantly detects diabetic retinopathy in fundus images.

“The importance of ease of use and consistently high image quality to successfully implement autonomous AI diagnostics in the front lines of care cannot be stressed enough,” said Michael D. Abramoff, MD, PhD, founder and CEO of IDx. “Topcon is truly the innovative market leader in developing highly automated, consistent and easy to use retinal imaging systems. Together we can prevent visual loss and blindness by ensuring the safety, accessibility, and affordability of early disease detection.”

Both companies have a history of innovation. IDx received FDA clearance for IDx-DR in April 2018, marking the first time the FDA has cleared an autonomous AI diagnostic system that does not require a physician to interpret images or results. Topcon introduced the first commercial back-of-the-eye spectral domain (SD) and swept source (SS) optical coherence tomography (OCT) systems and more recently announced the widely successful Maestro and Triton OCTs.

“Our partnership with IDx further solidifies our position as a pioneer in the eye care business,” said Fumio Ohue, Managing Executive Officer of Topcon. “Our efforts to deliver better workflow solutions, imaging technology, and AI tools to eye care providers will be complemented by our work with IDx to bring autonomous diagnostics to a growing population of people with diabetes.”

The recent FDA clearance of IDx-DR followed a clinical trial that demonstrated the autonomous AI system’s ability to safely deliver specialty-level diagnostics in primary care settings. Novice operators received minimal training on how to capture images using the Topcon NW400 and IDx-DR’s image quality AI. They successfully produced a diagnostic result 96% of the time by consistently capturing the high-quality images needed for IDx-DR to make a disease assessment.

Topcon recently announced the release and class II clearance of Topcon Harmony, a diagnostic data management application with vendor-neutral connectivity that enables software providers like IDx, EHRs and third-party manufacturers to seamlessly integrate diagnostic results into one central location for eye care providers.

About IDx

IDx is a leading AI diagnostics company on a mission to transform the quality, accessibility, and affordability of healthcare. Founded in 2010 by a team of world-renowned clinician scientists, the company is focused on developing clinically-aligned autonomous algorithms that detect disease in medical images. By enabling diagnostic assessment in primary care settings, IDx aims to increase patient access to high-quality, affordable disease detection.

The company's first product, IDx-DR, is an FDA-cleared AI-based diagnostic system designed for use at the front lines of care to detect diabetic retinopathy. IDx-DR is intended for use by health care providers to automatically detect more than mild diabetic retinopathy in adults (22 years of age or older) diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400, an easy to use and highly accurate robotic fundus camera.

IDx is developing additional AI-based diagnostic systems for the detection of macular degeneration, glaucoma, Alzheimer's disease, cardiovascular disease, and stroke risk. Prior to this current round, IDx had been funded by a group of private angel investors since the company's founding in 2010.

About Topcon

Topcon is a comprehensive ophthalmic device manufacturer within the worldwide ophthalmic community. It introduced the world's first commercial back-of-the-eye spectral domain (SD) and swept source (SS) optical coherence tomography (OCT) systems, which have driven innovation in eye-care.

More recently, Topcon Healthcare Solutions started to enhance not only its hardware but also its software solutions. To become the leader in diagnostic software, Topcon has developed a new strategic division whose primary objective is to create world-class software solutions for the eye-care industry and beyond. The company's products enable the collection and visualization of a wide range of imaging and clinical data while providing quantitative and clinical analysis capabilities.

Topcon's software gives clinicians access to patient exam data captured from OCTs, Visual Fields, Fundus cameras, and other Topcon and third-party devices. Topcon leverages its image management software called Synergy, where practitioners gain access to DICOM and non-DICOM information stored in a central, cloud-based environment. Additionally, Topcon now provides an integrated service that connects practitioners to an extensive network of reading services to assist in the management of sight-threatening eye diseases.

IDx

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