

Topcon's Harmony Imaging Platform Users in Europe Now Have Access to IDx-DR

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IDx-DR, the first FDA-cleared AI system for the autonomous detection of diabetic retinopathy, is now available to Harmony users in Europe

OAKLAND, NJ and CORALVILLE, IA ? Topcon Healthcare Solutions (THS) announced today that it has partnered with IDx, a privately held AI diagnostics company, to expand the Harmony imaging platform to include IDx-DR, a state-of-the-art AI system that detects diabetic retinopathy in digital fundus images, for its European customers.

IDx-DR is the first AI-based diagnostic system with U.S. FDA clearance and a Class IIa CE mark for the autonomous detection of diabetic retinopathy, a complication of diabetes and a leading cause of blindness. In addition to being available as a stand-alone image-analysis solution, IDx-DR is now accessible in Europe via Topcon Harmony, THS? solution for ophthalmic data viewing, archiving, and clinical decision support.

?We are excited to provide Topcon Harmony customers in Europe with even greater value by expanding the platform?s offerings to include IDx-DR,? said John Trefethen, Vice President of Global Marketing and Product Design at THS. ?The Harmony application is designed to provide medical professionals with excellent usability, performance, and easy access to the tools they need to optimize their practice. With IDx-DR, we are continuing this commitment by providing customers with convenient access to cutting-edge automated image-analysis technology.?

IDx-DR analyzes images of the retina for the same signs of disease an ophthalmologist looks for, providing a reliable output for clinical decision-making. To administer the IDx-DR exam, clinic staff capture two images per eye with Topcon?s robotic fundus camera and then submit the exams to the IDx-DR client via a standard internet connection. In less than a minute, a disease output will populate. The software also provides immediate feedback on image quality to allow for more accurate disease detection and for poor quality images to be retaken while the patient is in the office. The system is currently used in clinical practices across Europe.

?Making IDx-DR available via Topcon Harmony will help improve the accuracy and efficiency of diabetic retinopathy screening for Harmony users in Europe,? said Arlette Goddijn, President of IDx Europe. ?IDx believes it is important to integrate with large platforms such as Harmony so that more healthcare professionals can leverage artificial intelligence to manage the rapidly growing number of people with diabetes.?

There are more than 58 million people with diabetes in the European region and this number is expected to grow to 71 million by 2040, according to the International Diabetes Federation.

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.

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 and EU class IIa certified AI-based diagnostic system designed for use at the front lines of care to detect diabetic retinopathy. IDx is developing additional AI-based diagnostic algorithms for the detection of macular degeneration, glaucoma, Alzheimer?s disease, cardiovascular disease, and stroke risk.

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Topcon Healthcare Solutions

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