

Press Release | August 19, 2020

Digital Diagnostics, formerly IDx, Expands Global Impact of Healthcare Autonomous AI with Acquisition of 3Derm Systems, Inc.

The Digital Diagnostics platform now holds the intellectual property for two key autonomous AI technologies focused on democratizing healthcare.

(CORALVILLE, IOWA, USA) August 19, 2020 – Healthcare access and inequity challenges have been exacerbated by the COVID-19 pandemic; members of at-risk populations around the world are increasingly delaying important specialist care. Today [Digital Diagnostics Inc.](#), a pioneering global healthcare autonomous artificial intelligence (AI) company formerly known as IDx, announces it has acquired 3Derm Systems Inc. of Boston, MA. This acquisition makes Digital Diagnostics the global leader in healthcare autonomous AI, where it is the sole holder of autonomous AI healthcare systems that are De Novo authorized by the U.S. Food & Drug Administration (FDA), enabling the company to close more care gaps widened by COVID-19.

Autonomous AI: Increasing Access to Specialty Care

This acquisition is an important milestone in the effort to use autonomous AI to improve healthcare quality, lower costs and reduce the suffering caused by disease progression. In “autonomous AI,” it is the computer, not the clinician, making the medical decisions, enabling patients to obtain diagnoses for serious conditions when and where they receive medical care. Obtaining an instantaneous diagnosis from frontline care physicians and other providers leads to better outcomes for patients, especially those from underserved populations.

The rebrand of IDx to Digital Diagnostics reflects its expanded platform of autonomous AI products in multiple medical specialties. The company’s flagship product, IDx-DR, was the first autonomous AI system De Novo authorized by the FDA in any field of medicine; it

diagnoses diabetic retinopathy and diabetic macular edema. With the acquisition of 3Derm, the Digital Diagnostics platform will immediately include telemedicine capabilities for dermatology, 3DermTriage,™ in preparation for FDA authorization of its autonomous AI skin cancer diagnostic system, 3DermSpot™.

“There is too much needless suffering from treatable illnesses, and this happens more in populations that do not have equitable access to healthcare, and particularly to specialist physicians,” observed Michael Abramoff, MD, PhD, founder and executive chairman of Digital Diagnostics. “Our autonomous systems allow frontline care providers to instantaneously diagnose serious conditions, refer patients who need specialist treatment faster, and improve long-term patient outcomes.”

How It Works: Instantaneous Diagnosis at the Front Line of Care

Digital Diagnostics was founded in 2010 by Dr. Abramoff, a practicing, fellowship-trained retina specialist ophthalmologist, neuroscientist and computer engineer who developed a unique, patented biomarker-based approach to build AI algorithms that perform cognitively complex tasks. These algorithms are integrated into easy-to-use systems that can make instantaneous clinical decisions in which the computer makes the medical decision. To make instantaneous diagnoses, both IDx-DR and 3DermSpot use high quality images of the eyes and skin coupled with autonomous AI; the system is operated by existing primary care clinic staff.

Digital Diagnostics products are in use by the largest and most prestigious health systems in the U.S. and globally. The company works closely with patient advocacy groups, federal regulators, and other quality of care and ethics-focused stakeholders to enable adoption of autonomous AI.

Milestones include:

- **February 2018:** IDx-DR receives Breakthrough Device designation from FDA.
- **April 2018:** First time FDA issues De Novo authorization for an autonomous AI, IDx-DR, in any field of medicine.
- **June 2018:** CMS introduces temporary bridge coding, CPT® code 92250-TC, for autonomous AI.
- **May 2019:** CPT® Editorial Panel creates the first CPT® category 1 code for autonomous AI, 9225X.
- **December 2019:** American Diabetes Association updates its Standard of Diabetes Care to include autonomous AI for the diabetic eye exam.
- **January 2020:** 3DermSpot receives Breakthrough Device designation from FDA.

- **July 2020:** NCQA updates HEDIS to support the use of autonomous AI for closing the diabetic eye exam care gap.
- **August 2020:** For the first time, U.S. CMS announces Medicare will pay for autonomous AI.
- **August 2020:** Digital Diagnostics acquires 3Derm Systems, clearing the path toward 3DermSpot availability in EMEA markets.

IDx-DR is present in 17 global markets, including:

- The Netherlands: Now used in multiple practices, The Netherlands hosted the first implementation of IDx-DR worldwide, under the Class IIa CE-mark.
- Poland: An entire voivodeship (province) diagnoses its diabetes population with IDx-DR.
- Austria: IDx-DR is deployed in multiple diabetes outpatient clinics in Vienna. Digital Diagnostics is working with a prominent university to obtain national reimbursement for IDx-DR.
- Germany: Digital Diagnostics completed a pilot and is working with insurance companies to introduce IDx-DR as a reimbursable healthcare service.
- Emerging markets also include United Arab Emirates (UAE) and Saudi Arabia (KSA).

“By using Digital Diagnostics’ autonomous AI platform, 3DermSpot decreases the time it takes to put their life saving device in the hands of frontline care providers,” said John Bertrand, CEO, Digital Diagnostics. “Expanding the specialties our products cover allows our customers to use our platform as their one stop shop for autonomous AI diagnostics at the point-of-care.”

“By working with primary care physicians and other healthcare providers, we will reach more people and diagnose diseases sooner, closing care gaps for at risk patients,” observed Seth Rainford, President and COO, Digital Diagnostics. “This allows specialists to practice at the top of their license to prevent blindness and treat skin cancer.”

“Improving access and empowering frontline care providers was core to our mission at 3Derm,” said Liz Asai, former CEO & Co-Founder, 3Derm Systems, Inc. and now VP of Dermatology, Digital Diagnostics. “We are thrilled to continue our work as part of a larger organization focused on doing AI the right way, and that offers a broad commercial platform.”

Healthcare Autonomous AI the Right Way

Digital Diagnostics is committed to autonomous AI the right way: with an unwavering focus on improving patient outcomes, safety, efficacy and equity. The company has worked collaboratively within the healthcare and regulatory systems of multiple countries, including U.S. federal agencies, to accelerate the acceptance and adoption of ethical, evidence-based, autonomous AI. Digital Diagnostics

About Digital Diagnostics Inc. (www.DXS.ai)

Digital Diagnostics Inc. (formerly IDx) is a pioneering AI diagnostics company on a mission to transform the quality, accessibility and affordability of healthcare. It was founded and is led by Michael Abramoff, MD, PhD, a practicing, fellowship-trained retina specialist ophthalmologist, neuroscientist and computer engineer. The platform includes two autonomous AI systems, IDx-DR and 3DermSpot. Digital Diagnostics is paving the way for autonomous AI diagnosis to become a new standard of care, contributing to democratizing healthcare and closing care gaps. The company works closely with patient advocacy groups, federal regulators, and other quality of care and ethics-focused stakeholders to enable adoption of autonomous AI.

About 3Derm Systems, Inc.

3Derm's skin imaging and diagnostics technologies increase patient access to dermatological care. 3Derm's teledermatology systems (3DermTriage™) and world-class machine learning algorithms expand the reach of dermatological care beyond the exam room for skin lesions and inflammatory diseases. Their autonomous AI system for skin cancer detection, 3DermSpot™, received two FDA Breakthrough Device designations and is currently under clinical investigation. 3Derm Systems is now a part of Digital Diagnostics.

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