

U.S. AI-enabled Ophthalmic Diagnostic Devices Market Size, Share & Trends Analysis Report By Component (Fundus Cameras, OCT/OCTA Systems, Ultra-widefield Imaging Systems, Slit Lamp Imaging Systems), By Application, By End Use, And Segment Forecasts, 2026 - 2033

<https://marketpublishers.com/r/UCAD0460C156EN.html>

Date: August 2026

Pages: 60

Price: US\$ 4,950.00 (Single User License)

ID: UCAD0460C156EN

Abstracts

The U.S. AI-enabled ophthalmic diagnostic devices market size was valued at USD 64.3 million in 2025 and is projected to grow from USD 72.5 million in 2026 to USD 267.2 million by 2033, at a CAGR of 20.5% from 2026 to 2033. The market is experiencing rapid growth as healthcare providers increasingly adopt artificial intelligence to address rising demand for early detection of retinal diseases, improve screening efficiency, and overcome shortages of ophthalmologists in primary care settings. AI-enabled retinal imaging systems have evolved from decision-support tools to autonomous diagnostic platforms capable of identifying diabetic retinopathy and other sight-threatening diseases without specialist interpretation.

One of the primary drivers of market growth is the increasing prevalence of diabetes and diabetic retinopathy (DR) across the U.S., creating a substantial need for scalable screening solutions. According to the CDC's Vision and Eye Health Surveillance System (VEHSS), an estimated 9.6 million Americans were living with diabetic retinopathy in 2021, including approximately 1.84 million individuals with vision-threatening diabetic retinopathy. The prevalence is projected to increase substantially, with 14.7 million Americans expected to be affected by 2050, highlighting the growing burden of diabetes-related vision impairment in the U.S. This growing disease burden is encouraging healthcare systems to implement AI-enabled retinal screening technologies that can accurately identify patients requiring specialist referral while improving screening

compliance in primary care settings.

Technological innovation and continued FDA clearances are further accelerating market expansion. In May 2024, the FDA cleared the Optomed Aurora handheld fundus camera integrated with AEYE Health's autonomous AI software (AEYE-DS), enabling portable diabetic retinopathy screening in virtually any healthcare setting across the U.S. The handheld system performs autonomous image analysis within approximately one minute, allowing screening to move beyond traditional eye clinics into primary care offices, pharmacies, and community health centers. This approval significantly broadened the accessibility of AI-enabled ophthalmic diagnostics and strengthened the commercialization of portable retinal imaging solutions in the U.S.

Moreover, AI-powered portable screening solutions are increasingly supporting early detection in primary care settings, reducing dependence on specialist availability while expanding access to vision care in underserved and remote communities. These innovations are strengthening the role of autonomous retinal diagnostics within routine diabetes management and preventive healthcare. To strengthen this trend, research presented at ENDO 2025 by investigators from the University of Texas Health Science Center at Houston introduced the Simple Mobile AI Retina Tracker (SMART), an AI-powered mobile retinal screening application capable of detecting and staging diabetic retinopathy with more than 99% accuracy in under one second. Designed to operate on internet-enabled devices, including basic smartphones, the solution enables primary care providers to incorporate retinal screening into routine diabetes care while expanding access to high-quality ophthalmic assessments in regions with limited specialist availability.

The market is also benefiting from growing clinical acceptance and supportive diabetes care guidelines. The American Diabetes Association (ADA) Standards of Care 2025 recognize FDA-authorized autonomous AI systems, including AEYE-DS (AEYE Health), EyeArt (Eyenuk), and LumineticsCore (Digital Diagnostics), as validated alternatives for diabetic retinopathy screening when appropriately implemented. The guidelines specifically recommend the use of retinal photography with remote reading or FDA-authorized AI algorithms to improve access to diabetic retinopathy screening, particularly in settings where access to eye care specialists is limited.

In addition, the ADA notes that prospective multicenter clinical trials have demonstrated the diagnostic accuracy of each of these autonomous AI platforms, supporting their integration into routine diabetes care. These AI-enabled screening services are also covered by most U.S. insurance plans, further reducing financial barriers to adoption

and facilitating broader implementation across primary care and endocrinology practices. As healthcare providers continue to prioritize preventive care, early disease detection, and workflow automation, AI-enabled ophthalmic diagnostic devices are expected to play an increasingly important role in improving vision care outcomes across the U.S.

U.S. AI-enabled Ophthalmic Diagnostic Devices Market Report Segmentation

This report forecasts revenue growth and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. AI-enabled ophthalmic diagnostic devices market report based on component, application, and end use:

Component Outlook (Revenue, USD Unit, 2021 - 2033)

Fundus Cameras

OCT/OCTA Systems

Ultra-widefield Imaging Systems

Slit Lamp Imaging Systems

Application Outlook (Revenue, USD Unit, 2021 - 2033)

Diabetic Retinopathy Detection

Age-related Macular Degeneration (AMD)

Glaucoma Detection

Diabetic Macular Edema

Others

End Use Outlook (Revenue, USD Unit, 2021 - 2033)

Hospitals

Specialty Clinics

Diagnostic Centers

Home Care

Academic Centers

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