

AI-enabled Medical Devices Market Size, Share & Trends Analysis Report By Component (Software, Hardware), By Technology (Machine Learning, NLP), By Therapeutic Area, By End Use, By Region, And Segment Forecasts, 2025 - 2033

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Abstracts

AI-Enabled Medical Devices Market Summary

The global AI-enabled medical devices market size was estimated at USD 13.67 billion in 2024 and is projected to reach USD 255.76 billion by 2033, growing at a CAGR of 38.5% from 2025 to 2033. Growing adoption of personalized and precision medicine, medical imaging and diagnostics advancements, and a supportive regulatory and reimbursement landscape contribute to market growth.

In addition, increasing healthcare digitalization and rising investments and industry collaborations are some other factors fueling market growth further. Personalized medicine drives the adoption of AI-enabled medical devices by enabling tailored healthcare based on individual genetics, environment, and lifestyle. By analyzing genomic data, imaging scans, and clinical records, AI systems deliver actionable insights for precision therapies. These technologies facilitate early disease detection, risk stratification, and treatment monitoring aligned with personalized medical protocols.

Furthermore, advanced predictive analytics empower clinicians to manage patient health, proactively improving clinical outcomes. For instance, in January 2025, Lunit received FDA 510(k) clearance for its Lunit SCOPE IO, an AI-powered tissue analysis software designed for immuno-oncology. The solution helps identify tumor-infiltrating lymphocytes (TILs) in cancer tissues, supporting precision immunotherapy decisions.

Moreover, the evolution of AI algorithms, including deep learning, natural language processing, and computer vision, propels AI medical device capabilities. Improved algorithm accuracy enhances diagnostic precision and reduces error rates. These technological improvements facilitate expanded applications, including AI-assisted imaging, predictive risk modeling, and automated patient monitoring. For instance, in June 2025, Clairity, Inc. became the first FDA-authorized AI platform for breast cancer prediction, receiving De Novo authorization for CLAIRITY BREAST. This innovative platform predicts a woman's five-year risk of developing breast cancer using only routine screening mammograms.

Global AI-enabled Medical Devices Market Report Segmentation

This report forecasts revenue growth at global, regional, and country levels 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 global AI-enabled medical devices market report based on component, technology, therapeutic area, end use, and region:

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

Software

Hardware

AI-enabled Medical Devices

Smart Wearables

Services

Technology Outlook (Revenue, USD Million, 2021 - 2033)

Machine Learning

Deep learning

Supervised

Unsupervised

Others

Natural Language Processing (NLP)

Computer Vision

Context-Aware Computing

Therapeutic Area Outlook (Revenue, USD Million, 2021 - 2033)

Cardiology

Neurology

Radiology

Oncology

Mental and Behavioral Health

Ophthalmology

Others

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

Hospitals & Clinics

Diagnostic Centers

Ambulatory Surgical Centers (ASCs)

Home Care Settings

Others

Regional Outlook (Revenue, USD Million, 2021 - 2033)

North America

U.S.

Canada

Mexico

Europe

Germany

UK

France

Italy

Spain

Denmark

Sweden

Norway

Asia Pacific

China

Japan

India

South Korea

Australia

Thailand

Latin America

Brazil

Argentina

MEA

South Africa

Saudi Arabia

UAE

Kuwait

This report can be delivered to the clients within 3 Business Days

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