

Artificial Intelligence/Machine Learning Medical Device Market - A Global and Regional Analysis: Focus on Product Type, Clinical Area, and Country Analysis - Analysis and Forecast, 2022-2032

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Abstracts

Global Artificial Intelligence/Machine Learning Medical Device Market Industry Overview

The global artificial intelligence/machine learning medical device market was valued at \$4,011.7 million in 2022 and is anticipated to reach \$35,458.2 million by 2032, witnessing a CAGR of 24.35% during the forecast period 2022-2032. The market is driven by factors such as the presence of a large ecosystem of companies offering AI solutions, growing demand in the field of radiology and cardiology, growing demand for wearable sensors, and large number of government initiatives.

Market Lifecycle Stage

The global artificial intelligence/machine learning medical device market is highly fragmented, and the number of FDA and CE marked approvals of AI-enabled medical devices is increasing each year. This market still holds significant potential for growth as technological developments and investments into AI in healthcare are ongoing globally.

The opportunity for growth of the global artificial intelligence/machine learning medical device market lies in innovations in technology and the further development of AI-based medical devices enabling diagnostic accuracy and productivity.

Impact of COVID-19

Immediately after the outbreak of COVID-19, the focus of the healthcare systems

switched to managing the pandemic and related crises. This led to hospital budgets shrinking and thus resulted in the grim growth of AI. However, AI is being deployed in radiology departments across the globe to help fight COVID-19, and AI-based tools played an important role in fighting the COVID-19 pandemic. The adoption of AI in clinical settings increased during the pandemic owing to the numerous advantages of AI in tackling COVID-19.

Following the COVID-19 pandemic, the market is projected to exhibit rapid growth, primarily due to the increased adoption of AI-based solutions resulting from the pandemic. The market growth will also be driven by the surge in research activities surrounding AI-enabled solutions, advancements in deep learning and machine learning algorithms, introduction of new products to the market, emergence of local businesses, and growing adoption of AI-based solutions for various therapeutic applications.

Market Segmentation:

Segmentation 1: by Product Type

System/Hardware

Software-as-a-Medical Device

The global artificial intelligence/machine learning medical device market (by product type) is expected to be dominated by the software-as-a-medical device segment.

Segmentation 2: by Clinical Area

Radiology

Cardiology

Hematology

Others

The global artificial intelligence/machine learning medical device market (by clinical area) is expected to be dominated by the radiology segment.

Segmentation 3: Radiology (by Type)

Diagnostic Assistance

Imaging

Image Reconstruction

Others

The global radiology artificial intelligence/machine learning medical device market (by type) is expected to be dominated by the diagnostic assistance segment.

Segmentation 4: Cardiology (by Type)

Electrocardiography-Based Arrhythmia Detection

Hemodynamics and Vital Signs Monitoring

Others

The global cardiology artificial intelligence/machine learning medical device market (by type) is expected to be dominated by the electrocardiography-based arrhythmia detection segment.

Segmentation 5: by Region

North America - U.S., Canada

Europe - Germany, U.K., France, Italy, Spain, and Rest-of-Europe

Asia-Pacific - China, Japan, India, Australia, South Korea, and Rest-of-Asia-Pacific

Rest-of-the-World - Brazil, Mexico, Israel, and Rest-of-Rest-of-the-World

The global artificial intelligence/machine learning medical device market (by region) is dominated by the North America region.

Recent Developments in Global Artificial Intelligence/Machine Learning Medical Device Market

In October 2022, Koninklijke Philips N.V. received the U.S. FDA 510(k) approval for its AI-enabled MRCAT head and neck radiotherapy application.

In June 2022, Aidoc Medical, Ltd. raised a \$110 million Series D round investment to address the challenges faced by health systems by using AI.

In June 2022, Hyperfine Inc. received FDA 510(k) clearance for the MRI device Swoop. The Swoop system software uses deep learning to deliver clear images that aid in clinical diagnosis.

In April 2022, Clarius Mobile Health Corp.'s range of ultra-portable scanners, Clarius HD, was approved by Health Canada.

In March 2022, Clarius Mobile Health Corp. raised \$20.0 million in funding to expand its commercial-scale activities.

In December 2021, Hyperfine Inc. partnered with Brain Tumor Foundation to utilize Hyperfine's Swoop devices to provide neuroimaging worldwide.

In December 2021, Hyperfine Inc. announced the Health Canada licensing of Swoop as well as the launch of the imaging system in Canada.

In September 2021, Aidoc Medical, Ltd. and Subtle Medical partnered to bring end-to-end AI solutions to medical imaging.

Demand - Drivers and Limitations

The following are the drivers for the global artificial intelligence/machine learning medical device market:

Presence of a Large Ecosystem of Companies Offering AI Solutions Targeting the Diverse Range of Applications of AI in the Healthcare

Growing Demand in the Field of Radiology and Cardiology Increasing Adoption of AI-Enabled Solutions due to Their Ability to Shorten Waiting Times and Reduce Burden on Healthcare System

Growing Demand for Wearable Sensors to Increase Adoption of AI-Enabled Medical Devices for Home-Based Care

Large Number of Government Initiatives Advancing the Research and Development of AI-Enabled Medical Devices

The market is expected to face some limitations as well due to the following challenges:

Lack of Transparency and Concerns around Data Sharing Leading to Cybersecurity Concerns and Hindering Adoption of AI in Healthcare

Challenges Related to Identification and Minimization of Bias in AI Algorithms Leading to Concerns Surrounding the Reliability of Diagnosis and Thus Hindering the Use of AI-Enabled Solutions

How can this report add value to an organization?

Type: The clinical area segment helps the reader understand the different applications for which AI-enabled medical devices have been approved in the market. Moreover, the study provides the reader with a detailed understanding of the different types of systems and software-as-a-medical devices approved as AI-enabled medical devices globally.

Growth/Marketing Strategy: The global artificial intelligence/machine learning medical device market has seen major development by key players operating in the market, such as business expansion, partnership, collaboration, and joint ventures. Partnerships, alliances, business expansions, and regulatory activities accounted for the maximum number of key developments, i.e., nearly 65.00% of the total developments in the global artificial intelligence/machine learning medical device market.

Competitive Strategy: The global artificial intelligence/machine learning medical device market is highly fragmented, with over 250 players, including established companies and startups. Key players in the global artificial intelligence/machine learning medical

device market analyzed and profiled in the study involve established and emerging players that offer different AI-enabled medical devices. Additionally, comprehensive competitive strategies such as partnerships, agreements, and collaborations will aid the reader in understanding the untapped revenue pockets in the market.

Key Market Players and Competition Synopsis

The global artificial intelligence/machine learning medical device market is highly fragmented, with over 250 players, including established companies and startups.

Key Companies Profiled

Aidoc Medical, Ltd.

Canon Inc.

CellaVision AB

Clarius Mobile Health Corp.

General Electric Company

Hyperfine Inc.

Koninklijke Philips N.V.

Medtronic plc

Nanox.AI Ltd.

Paige.AI

RadNet, Inc.

Shanghai United Imaging Healthcare Co., Ltd.

Siemens Healthineers AG

Tempus

Viz.ai, Inc.

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