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Global Software as a Medical Devices Market - 2024 -2031

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Abstracts

Software as a Medical Devices (SaMD) Market is segmented By Device Type (Wearable Device, PCs/Laptop, Smartphone/tablets), By Application (Diagnostic, Clinical Management), By Deployment Method (Cloud-based, On-Premise), By Region (North America, Europe, Asia Pacific, Middle East, and Africa) – Share, Size, Outlook, and Opportunity Analysis, 2024-2031

Report Overview

Software as a medical devices (SaMD) market is estimated to reach at a CAGR of 69.31% during the forecast period (2024-2031).

The term Software as a Medical Device External Link Disclaimer is defined by the International Medical Device Regulators Forum (IMDRF) as 'software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device'

Market Dynamics

The software as a medical devices market growth is driven by the rapid product launches and rising adoption of the Internet of Things (IoT) and connected devices in the healthcare sector. Moreover, ease in regulations for the certification of the SaMD will further boost the market. Additionally, rising investments by the companies for SaMD will allow market players to flourish during the forecast period.

The rising adoption of the Internet of Things (IoT) in the healthcare sector, is expected to drive growth in the forecast period

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The increasing adoption of IoT in the healthcare sector is expected to significantly influence the growth of the Software as a Medical Device market over the coming years. Various smart devices, such as sensors, smartphones, and wearables, collect necessary data from the devices, further utilized to enhance customers' experience. The increasing need for data analysis and analytics integration is expected to propel the Internet of Things market utilization over the forecast period. Some IoT applications in healthcare include continuous monitoring of the blood pressure, heartbeat, body temperature, respiration rate, continuous collection of certain parameters in case of chronic illnesses, and providing remote assistance, among other applications. For instance, in 2018, the FDA approved the electroCore, Inc gammaCore Sapphire hand-held device for the acute treatment of migraine pain in 2020 for the preventive treatment of migraine.

Moreover, in February 2020, Cisco announced enhancements to its IoT portfolio that enable service provider partners to optimize cellular IoT environments and new 5G use-cases. New wireless technologies such as 5G, Wi-Fi 6 – would lead to more devices, and new IIoT use cases give service providers the tools to create competitive cellular IoT offerings for their customers.

Lack of data privacy of patients is likely to hamper the market growth

The privacy of the patient's health data, such as their details, confidential information, family history, sensitive medical history, etc., may be at stake as a data breach is highly prevalent in the industry. There are no stringent laws for data privacy, making the users apprehensive about adopting the software as a medical device technology. This may, in turn, hamper the overall growth of the market during the forecast period.

COVID-19 Impact Analysis

The Covid-19 pandemic resulted in a huge shortage of vacant beds in hospitals worldwide. The patients suffering from chronic illness were advised against visiting hospitals physically for treatment due to the fear of being infected. This trend encouraged the aggressive use of software as a medical device across the globe to ensure no patient suffers due to a shortage of healthcare infrastructure. Thus, the pandemic greatly accelerated the growth of the software as a medical device market.

Market Segment Analysis

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The diagnostic segment is expected to hold the largest share in this market segment

The diagnostic segment accounts for the largest market share, owing to the uncertain risk of heart stroke with a sedentary lifestyle that has offered demand for wearable medical devices. Along with increasing disease prevalence, advancements in cardiac disease diagnosis and management have provided immense growth opportunities. Healthcare professionals are also adopting wearable technologies to remotely monitor patients' heart health and offer on-time treatment with early abnormalities. Additionally, developing novel devices, including patches and wearable defibrillators, allows continuous cardiac activities and critical care tracking. For instance, a wearable necklace ECG monitor has been developed to detect abnormal heart rhythm called atrial fibrillation.

Moreover, vital sign devices are wearable devices that can continuously collect vital signs such as body temperature, blood pressure and heart rate over an extended period. While these wearable monitoring devices cannot transmit data to receivers, healthcare professionals can analyze the collected biometric data for treatment effectiveness; hence wearable vital sign monitors are primarily used in hospitals. The wearable type monitor includes a flexible thermometer strip, an inflatable bladder on a wearable cuff, or a pulse oximeter sensor that measures the patient's oxygen levels by focusing on skin colour changes.

The cloud-based segment is expected to hold the largest share in this market segment

Cloud-based SaMD is expected to hold a significant share due to the rising popularity and greater functionality and scope compared to on-premise-based devices. It is also anticipated to show multiple growth opportunities in the coming years owing to the rising penetration of IoT in healthcare. For instance, In June 2019, Zoll Medical launched Zoll HFAMS, a patch-based wearable heart management system. Moreover, cloud-based software also allows for high performance on lower-tier hardware, which many healthcare technology giants are taking advantage of to develop high-performance devices through innovations and their research and development. For instance, Singapore-based Biofourmis recently received FDA clearance for its cloud-based AI software RhythmAnalytics, a part of its digital therapeutics program.

The wearable devices segment is expected to hold the largest share in this market segment

Wearable technology, an emerging trend, integrates electronics into daily activities and

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addresses the changing lifestyles with the ability to be worn on any part of the body. Wearables have gained significant traction, owing to the boom in the fitness trend across consumers. According to Cisco Systems, the number of connected wearable devices is expected to increase from 593 million in 2018 to 1,105 million in 2022. The smartwatch category is experiencing a rise, owing to additional features, like the brand that suits the everyday lifestyle. For instance, Embrace2 of Empatica is the first wrist-worn wearable in the field of epilepsy to be cleared as a medical device for detecting patterns that may be associated with convulsive seizures in children & adults. In September 2020, Apple announced the launch of the Apple Watch Series 6 equipped with revolutionary blood oxygen allowing users to track accurate details of overall wellness. This has broadened its portfolio as well as contributed to the company's revenue growth.

Market Geographical Analysis

North America region holds the largest market share of global software as a medical device's market

North America is projected to hold the largest market share owing to several companies are getting FDA clearances for their software coupled with the burgeoning investment in the healthcare industry by major countries such as the U.S. and Canada. For instance, in July 2020, Channel Medsystems has announced that it had obtained FDA clearance for its next-generation Cerenecryotherapy product to treat menstrual bleeding. In addition, in May 2020, Arterys Inc. raised $28 million to accelerate the delivery of artificial medical intelligence to practices worldwide. In the latest round of Series C investment, they received the seventh USA FDA clearance from a syndicate led by Benslie Investment Group and Temasek Holdings, with participation by Fosun, Revelation Partners, Emergent Medical Partners and Varian Medical Systems.

Market Competitive Landscape

Software as a medical device market is highly competitive with the presence of global companies. Some of the key players which are contributing to the growth of the market include Arterys Inc., Paragon Biosciences (Qlarity Imaging LLC), Viz.ai, Inc., VitalConnect., Apple, Inc., iSchemaView, inc. (RAPID), IDx Technologies Inc., MaxQ AI, Ltd. Greenfinch Technology, Siemens Healthineers AG, and Koninklijke Philips N.V. The major players are adopting several growth strategies such as product launches, acquisitions, and collaborations, which are contributing to the growth of the software as a medical device globally. For Instance, In December 2020 MaxQ AI, Ltd. launched a

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second-generation ACCIPIO clinical platform for the healthcare industry to enhance physicians to provide “smarter care” with enhanced clinical workflow.

Market Key Companies to Watch

Paragon Biosciences

Overview: Qlarity Imaging is a portfolio company of Paragon Biosciences. Paragon Biosciences is a global life science leader that creates, builds, and funds innovative biology-based companies in three key areas: cell and gene therapy, adaptive biology, and advanced biotechnology. The company’s current portfolio includes Castle Creek Biosciences, CiRC Biosciences, Emalex Biosciences, Evozyne, Harmony Biosciences, Qlarity Imaging, Skyline Biosciences, and a consistent flow of incubating companies created and supported by the replicable Paragon Innovation Capital model.

Product Portfolio: Qlarity Imaging assists radiologists in diagnosing breast abnormalities with AI-driven technology. QuantX is the first FDA-cleared computer-aided diagnosis software and helps improve radiologist performance during breast MRI interpretation.

Key Developments: On August 2, 2021, Qlarity Imaging and Blackford partnered to bring QuantX Diagnostic AI to more breast radiologists via Blackford Platform to help more patients in need.

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