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DIGITALIZATION

OF CHINA MEDICAL DEVICE INDUSTRY



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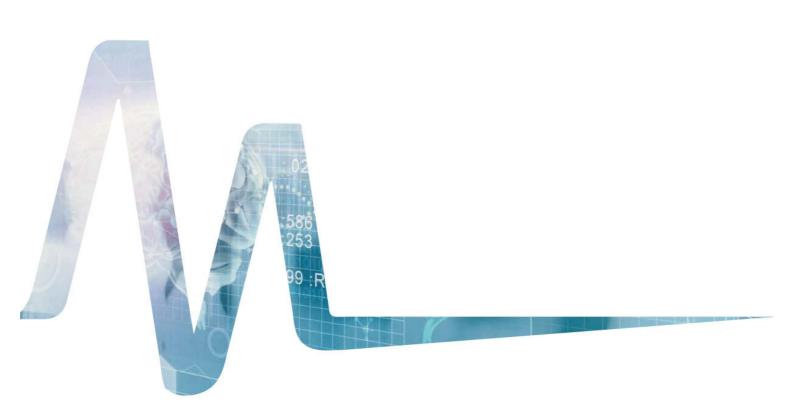
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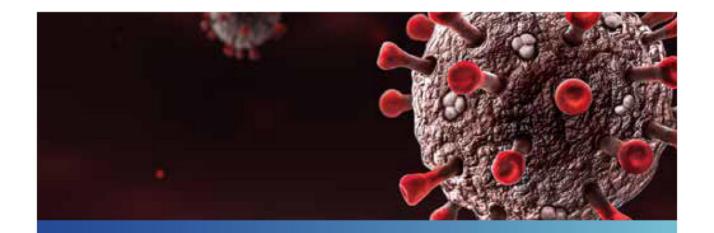
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01 INTRODUCTION





COVID-19 has ushered in a new era in patient diagnosis, treatment, and healthcare management, marked by the widespread adoption of digital technologies. Far from being a temporary phenomenon, the Chinese medical device industry is at the forefront of this digital revolution to integrate digital solutions at every step of the patient journey: physician- facing, patient- facing, and hospital- facing solutions continue to enhance the capabilities of the next generation of healthcare providers, to empower patients and to increase health care access.



Admittedly, digital transformation plays a vital role in revolutionizing medical products and improving customers' satisfaction. While it possesses enormous market potential, various challenges remain for medical device companies in China. In this white paper, we aim to paint an overall picture of digitalization in the medical device industry in China. Ultimately, we seek to help patients, physicians, industry partners, policymakers, and other members of the medical device community better master the digitalization dynamics and future trends.

OVERALL DIGITALIZATION LANDSCAPE



2.1 OVERALL EVOLVEMENT

The digitalization landscape in China has been evolving rapidly, and the path takes a hierarchical pattern across different stages. Based on the industry characteristics, the digitalization of China medical device industry can be broken down into three stages.

EMBRYONIC STAGE

2013 AND BEFORE

Digital medical device companies began to emerge. Triggered by worldwide technology transfer, early players emerged to provide healthcare operational applications for hospitals. During this period, the surgical robot industry was also transforming from academic research to commercialization.

DEVELOPING STAGE

2014-2018

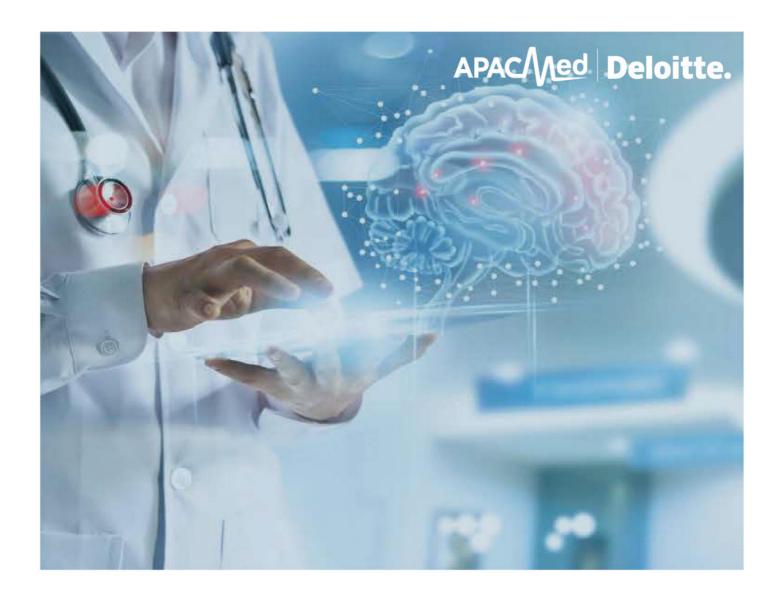
Triggered by a combination of multi-level policy incentives and the fast-growing China internet industry, players from divergent fields (e.g. Internet giants, hardware companies, medical device companies) began to engage themselves in competition, start-ups also sprang up to develop patient and physician- facing solutions.

ACCELERATION STAGE

2019-PRESENT

Digital medical devices have been widely adopted. After the outbreak of COVID-19 digital solutions in the healthcare industry have become the "new normal", and the advantage of preeminent patient & physician-facing solution providers has been further amplified.





2.2 KEY DRIVING FORCES

In recent years, policy evolvement, imbalanced supply & demand of health care resources, accelerated adoption of cutting-edge technologies, and the lasting impact of COVID-19 have become the drivers for digital medical device transformation.

DRIVING FORCE 1: POLICY EVOLVEMENT

Since 2011, a series of policies have strengthened the support for innovative medical devices, and the continuously refined regulatory system has accelerated the digitalization of the medical device industry.

O EMBRYONIC

DECEMBER 2011

The Ministry of Science and Technology issued the "12th Five-Year Plan" for digitalized medical device industry

JUNE 2016

General Office of the State Council issued "Guidance on the Development and Promotion of Big Data Applicationsin Health Care"

NOV 2018

National Medical Products Administration issued "Special Approval Process for innovative Medical Devices"

JULY 2019

NMPA issued "The Critical Points for Reviewing Deep Learning Assistant Decision-making Medical Device Software"

SEP 2020

General Office of the State Council issued "Opinions on Promoting the Development of New Types of Consumption with New Business Patterns"

DEVELOPING MARCH 2015

The Ministry of Science and Technology issued "Key & Special Implementation Plan for Digital Diagnostic & Treatment Device (Consultation Paper)"

APRI 2018

National Health Commission issued "Standards and Regulations of National Hospital IT Application (Trial)"

ACCELERATION —O MARCH 2019

National Health Commission issued "Grading and Evaluation System for Hospital Smart Services (Trial)"

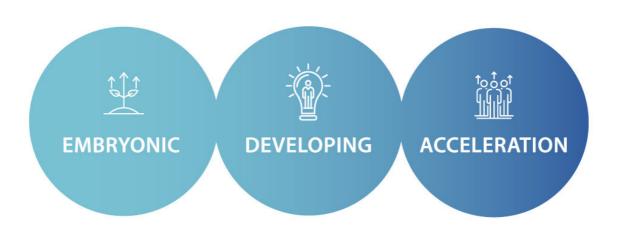
MARCH 2020

The National Development and Reform Commission and the Ministry of Industry and Information Technology jointly issued "The Notice on the Organization and Implementation of New Infrastructure Construction Projects in 2020"

JULY 2021

NMPA issued "Al Medical Software Product Classification Guideline"

DRIVING FORCE 1: POLICY EVOLVEMENT



In the embryonic stage, the Chinese government worked out several guidelines to bridge the gap between traditional medical device development and digital health innovation and spur the innovation of digitalized medical devices.

In the developing stage, the Chinese government started to set clear goals and metrics for adopting digitalized medical devices. By leveraging their growing experience and expertise across digital health and related domains, the government strengthened the requirement for hospitals to adopt intelligent products and created green channels for the registration and approval of qualified, innovative medical devices.

In the acceleration stage, the Chinese government further clarified the evaluation criteria and using standards of the digitalized medical devices.

DRIVING FORCE 2: IMBALATNCED SUPPLY & DEMAND OF HEALTH CARE RESOURCE

A large gap between the supply and demand of medical resources still exists. According to OECD, the total number of hospital beds per 1,000 inhabitants in China is 4.8, whereas this number reaches 12.84 in Japan, 12.44 in Korea, 8 in Russia, and 7.91 in Germany ①. Digital medical devices can help enhance the efficiency of hospital diagnosis and treatment and the accuracy of operation to alleviate the lack of medical resources in remote areas. There has been another long-standing problem of uneven distribution of medical resources across regions. According to the Statistical Bulletin on the Development of China's Health Industry in 2019, 2,749 Class III hospitals in China account for 11.60% of the total Class I-III hospitals. However, these hospitals provide 56.75% of medical services. Digitalization of medical devices can lessen the workload through supporting physicians in clinical diagnosis & screening, and treatment processes.

*①: Health equipment - Hospital beds - OECD Data

DRIVING FORCE 3:

ACCELERATED ADOPTION
OF CUTTING-EDGE TECHNOLOGIES

Machine learning (ML) and Artificial Intelligence (Al) have been more and more frequently used in medical image identification, data processing, and clinical diagnosis.

Physicians can reach actionable clinical treatment solutions more efficiently by leveraging the Internet of Things (IoT) and 5G technologies. Virtual reality (VR) technology is also widely used in surgical robots, practical medical training, and psychotherapeutics for mental illness. These technologies have enabled rapid digitalization for many organizations in the medical device industry.

DRIVING FORCE 4:

THE LASTING IMPACT OF COVID-19 ON PHYSICIANS AND PATIENTS

As mentioned, COVID-19 has ushered in a "new normal" marked by the widespread embracement of digitalized medical devices. China has experienced a substantial increase in physicians' frequency of interactions & treatments through digital channels. Patient awareness of digitalized medical devices (e.g. remote monitoring devices) experienced a substantial increase, and the government agencies are building the next generation of the regulatory system for digital solutions.



2.3 DIGITALIZATION LANDSCAPE BY COMPANY TYPES (TECH VS. DEVICE COMPANY)

Medical Device companies are time-honored players in the industry, whereas high-tech companies have recently stepped up their healthcare product development.



Non-traditional participants from technology and telecom (e.g. Apple, Huawei, and Xiaomi) are looking to address consumer and patient needs in line with healthcare consumerism. By leveraging their large customer base and the master of disruptive technologies, high-tech companies have been hatching innovative products tailored to customers. They have been also developing AI medical imaging solutions, clinical support systems, and digital therapeutics based on their advanced algorithm and continuously enriching user databases. Medical device companies are utilizing their industrial advantages, trust relationship with hospitals, extensive inputs from physicians to provide physicians with instantaneous answers about individual cases and enhance physician capabilities.

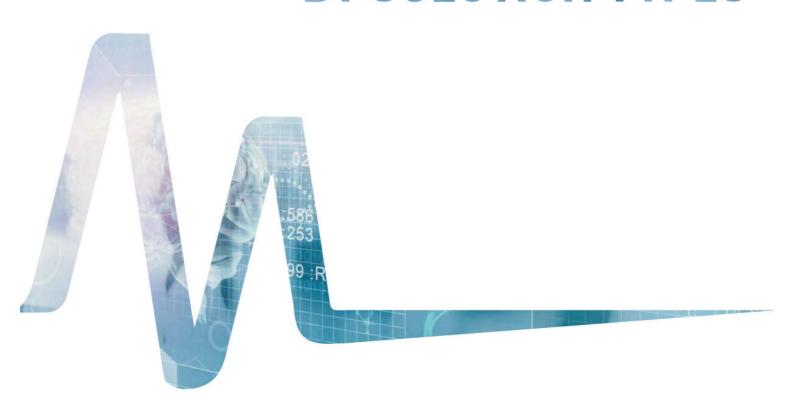
Early adopters of cutting-edge technologies (e.g. Resmed, Medtronic) have yielded various digitalized medical products.

Collaboration between tech and device companies for the development of digitalization was also observed. For example, Tencent established a strategic collaboration with DHC (DHC Software CO.,LTD). The two sides were committed to jointly building a digitalization solution for healthcare institutions (e.g. Al-powered APPs embedded in hospital information infrastructure). In the future, we believe collaboration and competition will co-exist between tech and device companies. The collective power will play a vital role in shaping the expanding landscape of digitalized medical device industry and will continue to enhance the capabilities of the next generation of healthcare providers.





DIGITALIZATION BY SOLUTION TYPES





3.1 OVERVIEW OF PHYSICIAN, PATIENT, AND HOSPITAL- FACING SOLUTIONS

These driving forces have created an environment in which the following three types of digital solutions flourish.



PHYSICIAN-FACING SOLUTIONS

Dedicated to reduce the workload of physicians and assist physicians in the diagnosis and treatment process

DIAGNOSIS SUPPORT DEVICE AND SYSTEM

CLINICAL DECISION SUPPORT SYSTEM

INNOVATIVE TREATMENT DEVICE



PATIENT-FACING SOLUTIONS

Dedicated to assist patients to achieve effective real-time health management

HOME-MONITORING & TREATMENT DEVICE

WEARABLE DEVICE

DIGITAL THERAPEUTIC



HOSPITAL-FACING SOLUTIONS

Dedicated to enhance the work efficiency of hospitals

SMART AND CONNECTED HOSPITAL EQUIPMENT (HOSPITAL INTELLIGENCE)

HEALTHCARE OPERATION SUPPORT



3.2 DEEP-DIVE INTO PHYSICIAN- FACING SOLUTIONS

There are three typical types of solutions within physician- facing solutions: diagnosis support device and system, clinical decision support system, and innovative treatment device.

DIAGNOSIS SUPPORT DEVICE/SYSTEM

























CLINICAL DECISION SUPPORT SYSTEM













INNOVATIVE TREATMENT DEVICE













DIAGNOSIS SUPPORT DEVICE AND SYSTEM

Many medical device companies are leveraging AI and big data to increase the accuracy and efficiency of the clinical diagnosis and treatment process. By July 2021, more than 15 Al-related diagnosis software received regulatory approvals in China across multiple TAs

(Therapeutic Areas). Major players include a batch of technology enterprises such as Infervision, Hologic and United Imaging. The offering portfolio primarily includes CT-based screening for pulmonary nodules, ischemic stroke assessment, X-ray-based examination for thoracic diseases, rapid cancer detection and evaluation using pathology images, etc.

The application of AI medical imaging solutions in China faces a challenging situation of a low adoption rate. Taking the screening of Diabetic Retinopathy (DR) as an example, although some companies in earlier research

claim that their algorithms were proved as accurate as trained ophthalmologists in detecting DR. In reality, the application rate of their solution is still meager in Class III hospitals and the fundus image generated by their future, providers are expected to concentrate their efforts on product launching and establishing business relationships with major hospitals.

We envisage that medical imaging companies can not . only empower Class III hospitals in top-tier cities, but also support confirmatory diagnosis for complex cases in lower-tier hospitals from remote areas. We foresee that 5G will help address the healthcare infrastructure and HCP knowledge gaps between top-tier and lower-tier hospitals.

CLINICAL DECISION SUPPORT SYSTEM



The leading players of clinical decision support system primarily include Biotronik, Shukun, Karl Storz and Tencent. Compared with Al medical imaging solutions, the data heterogeneity issue is significant for the clinical decision support system. The difficulty of data acquisition increases because it requires a more extended period of case data. The data are also poorly structured to contain various types of information, such as patient's medical histories and previous medical images (including those taken by patients and those taken by the hospital imaging department). The brand of the medical device or local demographics will also cause a reduction in the quality of the dataset. It is necessary to leverage Natural Language Processing technology to process the unstructured dataset and then train the model using machine learning technology.

As the government builds a standardized and regulated environment for the registration and using standards of clinical decision support system, we expect that tremendous clinical data will be structured under new regulations and industry standards in the future and the current algorithm of clinical decision support system will be savvy in analyzing a broader range of TAs (Therapeutic Areas) and applications.

INNOVATIVE TREATMENT DEVICE

SURGICAL ROBOT

Intuitive and Smith & Nephew led the market as the foremost surgical robot provider during the past ten years. In China, Tinavi is the most representative orthopedics surgical robot provider. We believe that the market potential for orthopedic surgical robots, pan vascular surgical robots, and transluminal surgical robots will surpass that of endoscopic surgical robots in the future. Robot-assisted NOTES is also expected to have endless potential due to advantages such as minimally invasive or noninvasive.

Currently, the technology import of some core components, such as a visual imaging chip, micro DC precision motor and optical positioning system are crucial to Chinese domestic providers. In the future, we anticipate that Chinese providers are giving top priority to the development of core technology.

REHABILITATION ROBOT

Some Chinese domestic technology companies are committed to providing the exoskeleton rehabilitation robot to those in need. However, the current rehabilitation robot was often time-consuming to equip, which caused great inconvenience for patients and care workers. The product positioning is relatively high-end, however, the budget of the rehabilitation department in hospitals is usually relatively low, resulting in a low customers' willingness to pay.

We expect the market to grow if companies are willing to provide the rehabilitation robot under a RaaS (Robot-as-a-Service) business model, where the hospital will only be paying according to the usage of the solution.



TINAVI 天智航

CASE STUDY FOR TINAVITIANJI® & IMC

♦ BACKGROUND AND STRATEGIC GOALS

China has an average of 20 million bone injury cases annually, with almost four out of five requiring surgical treatments. These injuries usually involve complicated structures and demand a high degree of steady surgical experience, with potential surgical risks caused by deep incision and high radiation exposure. TINAVI has been a forerunner in the medical robotics industry for over 10 years and has brought to market China's first homegrown orthopaedic surgical robot to improve safety and clinical results. TINAVI sets strategic goals to enhance product and solution competitive advantages in the short-term, become a leading market player in the mid-term, and grow to a global provider for orthopaedic robotics total solution in the long-term.

DIGITAL SOLUTION OVERVIEW

TINAVI TIANJI® is an orthopaedic robotic system that can help surgeons precisely position surgical instruments or implants during orthopedic surgeries for spine and trauma with its robotic arm. TIANJI® II version further enhances clinical usability and the remote surgery platform to achieve the mission of enabling healthcare equity and empowering doctors to conduct complex surgeries with higher efficiency.

USE CASES AND VALUE PROPOSITION

TINAVI TIANJI ®'s orthopedic guide and the unique intelligent algorithm for calculating screw trajectory allow precise design and stable execution of a surgical plan, even in a remote surgery setting. TINAVI also develops Digital Operation Center to achieve orthopaedic surgical teaching and telemedicine. Currently, under the support of NHC and MIIT, TINAVI is working on a surgical-robot-data-driven continuous improvement plan that initially focuses on improving surgical planning efficiency and expands to new use cases in the future.

These solutions make regular surgery precise and minimally invasive, improve the efficiency of complex

surgery and operation, and help distribute medical resources more equally as the technology provides a technical foundation to achieve the medical reform goal of tiered medical services and realize remote surgery that can significantly benefit primary care hospitals with limited clinical capabilities.

As a new solution to the market, TINAVI TIANJI®'s seed customers are leading Class III hospitals with clinical capabilities for executive referencing and advocacy development. As the market acceptance for surgical robots and brand recognition increase in the future, more demands for clinical capability improvement will come from primary care hospitals to conduct complex surgeries with safety, accuracy, and efficiency.

REVENUE MODEL

TINAVI follows the one-off purchase model as policies and regulations in the healthcare industry place barriers for a leasing model. At the same time, TINAVI is also exploring other revenue models such as scientific research support. The minimally invasive orthopedic surgery center built in 2020 charges medical institutions technical service fees based on the number of orthopedic robotic operations, which increases the accessibility of orthopedic surgical robots. However, these revenue models are still at the experimental stage and highly based on the customized needs of individual hospitals.

STRATEGIC PARTNERSHIP

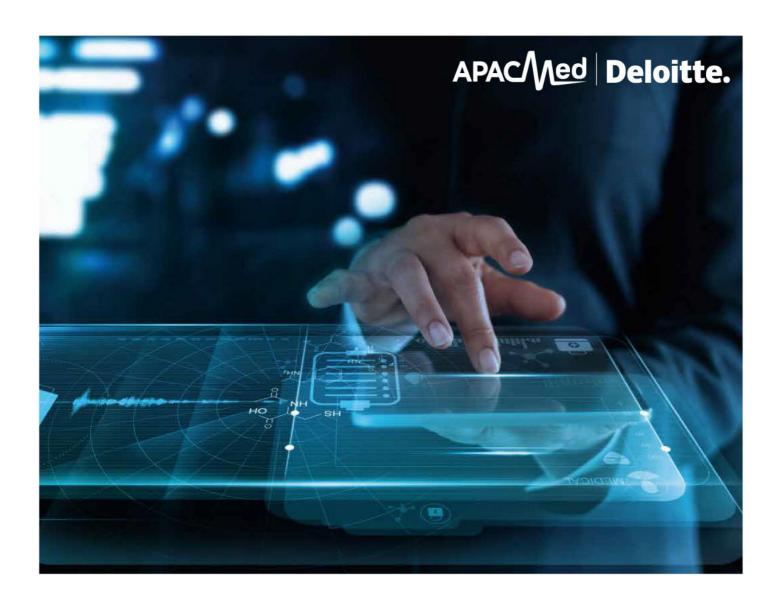
TINAVI actively engages with key stakeholders in healthcare ecosystem, including providers (esp. epicenters) for academic and clinical empowerment, associations and societies such as COA and CMDA-RAS for solution education, and recognition enhancement, universities for collaborative technology development and award winning through IUR, policymakers such as NMPA and NHC for better understanding of policy trends, as well as payers such as HSA for hospital charge code development, BMI reimbursement, and coverage expansion. In addition, TINAVI initiated Beijing Medical Robotics Innovation Center (IMC) with Tsinghua Industry R&D Institute and Zhongguancun Science City as an open innovation platform by incubating early medical robots projects and providing CDMO services for high-end medical equipment. As an integrated innovation platform harnessing the joint forces of the government, industry, academia, medical providers and investors, IMC is a national hub to accelerate high-end medical device growth. By forming an ecosystem for product R&D and industrialization, product incubation, innovation and CDMO business, IMC attracts high-quality teams and projects all over the world, with over 10 leading technology project teams landed successfully.TINAVI and IMC will continue to collaborate with worldwide organizations to contribute to medical robot ecosystem development.

KEY CHALLENGES FOR DIGITALIZATION

Access has long been a challenge for innovative solution launches in China. The first component of the access challenge is clinical acceptance without precedent referencing. It requires deep market understanding, continuous exploration, and stakeholder engagement to iterate solutions with enhanced usability, lower operation difficulty, and clear value positioning addressing clinical needs for safety, efficacy, and efficiency. The second component of the access challenge is commercial listing and reimbursement. Cost-effectiveness plays a significant role in hospitals' purchasing decisions and payers' charge code development and reimbursement decisions, requiring resource investment to generate and accumulate economic and clinical evidence.

ADVICE FOR COMPANIES INTERESTED IN DIGITALIZATION

It takes TINAVI over 10 years to concentrate on doing the right things to achieve today's position. Medical robotics is not an industry for the quick-return seeker and requires patience and tenacity to develop valuable products and solutions because of high clinical and technical thresholds. There are two directions to develop digital solutions, externally and internally. External one comes from doctors' digital unmet needs with actual clinical values. The internal one is driven by the company's own development goals and strategic ambitions.



3.3 DEEP-DIVE INTO PATIENT- FACING SOLUTIONS

There are three typical types of solutions within patient-facing solutions: home-monitoring solutions, wearable devices, and digital therapeutic (VR treatment for mental diseases).

HOME-MONITORING SOLUTIONS















WEARABLE DEVICES









oppo

DIGITAL THERAPEUTIC

ΔVΔNOS



MVisioner(妙智科技)





HOME-MONITORING SOLUTIONS



taking charge of their health now more than before. Home-monitoring devices may help patients identify potential risks before morbidity and monitor the progress of chronic to manage the risk of acute exacerbation, ultimately reduce the number of hospitalizations and control healthcare costs. Typical products include the sleep apnea product of ResMed, the Omnitest (blood sugar meter) of BBraun, and portable ultrasound monitor, allowing home patient monitoring and self-performance of specific vital sign measurements.

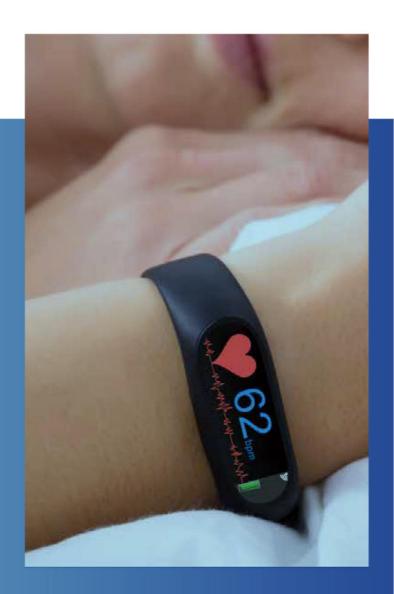
Unlike previous models of hospital-centered care, patients are

This increased use of digital health tools heralds a future heavy with digitally supported self-management, with the healthcare team getting involved only when needed. We advise home-monitoring devices providers to develop patient-facing service models to reduce friction and the number of steps along the patient journey. At the same time, providers should develop a set of patient-centric metrics in addition to traditional provider-centric metrics (e.g. readmission rate, mortality rate). With patient-centric metrics (e.g. response & waiting time, customization of suggestions, transparency of data usage), patients are more likely to acquire a user-friendly, personalized, trusted, and engaging home-monitoring solution.

WEARABLE DEVICES

Adding sensors to home wearable devices will enable the devices to track and capture healthcare parameters critical for clinical decisions and proper equipment operation to follow up. Patient daily monitoring allows this critical information to be communicable, measurable, and controlled with less risk of ignoring abnormal signals (e.g. abnormal heart rhythms)

However, most wearable devices can only monitor regular health indicators. Gaps still exist between the demands of clinical practice (e.g. highly accurate cardiovascular data) and the offerings of current wearable devices. Practical algorithms that meet medical standards are expected to be a critical breakthrough. For example, NMPA has approved HUAWEI Watch GT2 PRO ECG as a Class II medical device. The ECG of HUAWEI Watch GT2 Pro cannot be directly applied in diagnosis. However, it can record the electrical signal graph and find abnormal heart rhythm conditions such as AF, premature beat, and the heart health research cooperated by HUAWEI and Chinese PLA General Hospital will allow users to discover the high risk of cardiac rhythm earlier and manage their



Another use case for wearable devices may be early screening and disease prevention. Under the Healthy China 2030 and 14th five-year plan, the Chinese government prioritizes disease prevention, increasing large-scale community-based disease education and early screening programs. We foresee that wearable + IoT will expand into multiple therapeutic areas, especially chronic disease, and play a critical role in early screening and disease prevention.

DIGITAL THERAPEUTIC

Currently, there is a lack of innovative non-drug therapies for diseases/proper treatment or supplemental therapies improving compliance. Digital therapeutic devices can simulate experience through sense and perception with headsets to conduct medical education or facilitate effective physician-patient communication by creating intuitive settings.Representative players include but are not limited to Avanos, WonderLab, etc. The use cases of digital therapeutic, mainly in psychiatry, include anxiety treatment, PTSD treatment, and rehabilitation (esp. recovery in physical therapy such as stroke and traumatic brain injury). In the future, more pipelines and use cases are needed for digital therapeutic to cover broader conditions and be applied in more diversified scenarios, including schools and prisons.





CASE STUDY FOR ResMed

BACKGROUND AND STRATEGIC GOALS

Since the outbreak of COVID-19,remote treatment has become the focus of many hospitals and physicians across different therapeutic areas. ResMed captured this opportunity in this era and set up an ambitious goal to be a digital pioneer in the respiratory market. In the short term, ResMed commits to the digitalization of its core products and services, empowered by company digital capabilities and professional teams, to better engage strategic partners and customers. In the long term, following its global acquisition of Propeller Health, a leader in COPD (Chronic obstructive pulmonary disease) and asthma-connected health solutions,ResMed is looking to launch an advanced digital therapeutic solution and realize the complete digital transformation in China.

DIGITAL SOLUTION OVERVIEW

The current digitalization is a feature on CPAP(Continuous positive airway pressure) machines, precisely two software, MyAir and AirView™, for different parties. For patients, MyAir provides an online support program and mobile application that transmits data (e.g. usage hours, mask seal, event per hour, and pressure) from the machine to patient's device to help patients monitor their sleep condition. For physicians, AirView™ provides a cloud-based system that supports physicians in managing patients with sleep-disordered breathing and respiratory insufficiency. In addition to digital products, ResMed is building a virtual pathway for patients along journey through its Sleep Coach team with experienced medical professionals and third-party collaboration.

USE CASES AND VALUE PROPOSITION

ResMed is collaborating with Class III hospitals, China Sleep Research Society, and distributors to promote AirViewTM. Currently, AirViewTM is an additional feature for high-end CPAP machines, mostly applied on AirSense 10 Plus C for OSA(Obstructive sleep apnea) patients and Lumis for COPD patients. AirViewTM does not necessarily require connection with HIS because the health condition data is traced and available on AirViewTM. Therefore, it enables physicians to

quickly access patient data, share clinical insights with other health professionals, and reduce costs related to patient follow-up. Likewise, many physicians are enthusiastic about conducting clinical research of CPAP treatment, in which case AirView™ can render up-to-date real-world data for further analytics. MyAir enables patients to begin their therapy promptly and receive timely support at home throughout their treatment journey.

REVENUE MODEL

To differentiate itself from competitors, ResMed currently positions MyAir and AirView™ as free value-added services but looks forward to generating new sources of revenue in the future. ResMed will continue to update its technologies to strengthen its unique and premium brand position in the CPAP machine market. Once these digital tools appeal to numerous customers, ResMed will build SaaS(Software-as-a-Service) model based on that of which has already been running for years in the US market. Besides, ResMed will improve the chance of profitability by sensible planning, including registering digital tools as digital therapy solutions in the long term, in which case patients need to pay for the treatment like any other prescription.

STRATEGIC PARTNERSHIP

Digitalization may require a platform, which is extremely difficult for any player to build and operate independently. Therefore, seeking partnership is the key to success, and core partners include distributors and medical service providers. Distributors help ResMed cover a large group of patients and better engage with them, whereas physicians/medical service providers support disease diagnosis and treatment follow-ups for patient health management. To build a complete platform for digitalization, ResMed is also building a strategic partnership with high-tech device providers, specifically with oximeter wearable, and physical examination centers for OSA disease screening.

KEY CHALLENGES OF DIGITALIZATION

ResMed has encountered three main challenges along its digital transformation journey. The first challenge is involved with regulations and market supervision. The registration approval process is still developing in China, leading to the ambiguity of whether software could be registered as a medical device. The solution is to keep close communication with the NMPA for classification discussion to accelerate the whole approval process. The second challenge is on the company's internal operating level. Digital transformation would require a new organizational structure and operating model for a traditional medical device company. It is critical to find the right balance between overthrowing the previous business model and applying no change at all. ResMed has assembled an innovative digital team to work closely with its traditional medical team to empower a new operating model for customer adoption and engagement. Finally, shaping the mindset of external stakeholders could be challenging because ResMed's digital solutions may prevent patients from hospital visits, and not all stakeholders would recognize and understand the idea of digitalization. To overcome this challenge, ResMed has identified target physicians/KOLs, with high willingness to be part of digital transformation, as a pilot in the market and partnered with them to co-shape the digital environment and customer behaviors.

ADVICE FOR COMPANIES INTERESTED IN DIGITALIZATION

ResMed has put forward three proposals for companies looking forward to digitalization. Firstly, companies should actively explore the possibility of shaping the policy environment and engaging with policy makers instead of being reactive to situations. Secondly, transforming from a traditional business model to a digital business model will encounter fierce objections from both internal and external stakeholders. A company leader should stand firmly in his/her position and move forward with determination. Lastly, digitalization is not a task that a single company can complete. A company should know when to start the collaboration, whom to collaborate with, and what to do to maximize the collaboration outcome to ensure a smooth transformation towards digitalization.



3.4 DEEP-DIVE INTO HOSPITAL- FACING SOLUTIONS

There are two typical types of solutions within hospital-facing solutions: smart and connected hospital equipment, and healthcare operation support.

SMART AND CONNECTED HOSPITAL EQUIPMENT















HEALTHCARE OPERATION SUPPORT















Currently, most hospitals need to accommodate significant numbers of patients and most healthcare professionals are overloaded with routine work. Therefore, smart and connected hospital equipment has become more critical to improve hospital operations. Leading players in this field include BD, Medtronic, Steris, and Essniot, etc.

Medication management solution

Automatic medicine dispensing devices are designed to enhance the efficiency of the process and avoid human errors. In the future, device providers will reform the overall pharmacy management process according to the customized needs of hospitals and retail pharmacies, such as peak prescription volume, area of outpatient service, and to explore more use cases of digital solutions.

Digital operation solution

A digital operation room can reduce setup and preparation time, enabling efficient decisions and streamline treatment. We envisage that surgical robots will be incorporated the digital operation room in the form of a robotic arm, which can be integrated into a station and moved everywhere. These modular robotic arms are equipped with operational tools such as scalpels, graspers, and suturing instruments 2.

*2: Frost Sullivan, Growth Opportunities In Autonomous Mobile Robots, Robotic Grippers, Surgical Robots, AndDigital Manufacturing, Global Technology, Innovation, and Convergence Practice, January 2021

SMART AND CONNECTED **HOSPITAL EQUIPMENT**



HEALTHCARE OPERATION SUPPORT

The long-standing significant issue of hospital informatics is interoperability. The full potential of patient dataset in hospitals will only be realized when it begins to flow beyond the confines of single departments and even institutions. However, most of the time, it is still onerous for end-users to extract patients' data from diverse information systems and conduct a comprehensive analysis.

In the long run, we expect an FHIR (fast healthcare operability resources) model to create standards for different data elements so that innovative application providers can build application programming interfaces (APIs) to access datasets from different systems and provide in-depth analysis further using advanced algorithms. Under the FHIR model, hospitals will become a cloud platform connecting all medical terminals that otherwise would not communicate with each other (e.g., hospital imaging department, wearable devices, mobile apps) to enable health data to be quickly and efficiently exchanged. With the continuous expansion of patient databases, the quality of patient data sets will also be significantly enhanced.

End Users Radiologists Physicians Applications End Users App developers Radiologists Physicians Integrated Digital Solution Co-developed by Software Companies Applications Infrastructure Infrastructure

Solutions

 Innovative applications (e.g. Clinical support applications powered by AI algorithm) developed by technology partners based on patient dataset

Providers









Solutions

Patient dataset extracted from hospital IT infrastructure (e.g. HIS, LIS, HER, PACS systems)

Providers













BACKGROUND AND STRATEGIC GOALS

Patient Safety has long been a critical area of focus of the World Health Organization (WHO). According to the WHO, 4 out of 10 patients are harmed in primary and ambulatory care, and medication errors are a leading cause of injury and avoidable harm in the health care system costing the world US \$42 billion annually ③. BD, as a global leading medical technology company, commits to patient and healthcare worker safety. Since BD acquired CareFusion in 2014, BD has set goals to improve drug administration safety and lower medication errors. In the long run, BD aims to become a leader that sets a standard for medication management and optimizes precise drug administration.

DIGITAL SOLUTION OVERVIEW

BD RowaTM, a digital medication storage and dispensing solution brand for hospitals, retail pharmacies and pharmaceutical distribution centers, fits perfectly in the trajectory to fulfill BD's short- and long-term goals. In China, the concept of a "smart hospital" had not drawn the public's attention until the last ten years when the National Health Commission of the People's Republic of China (NHC) started to issue guidelines and notices for smart hospital construction. For example, "Grading and Evaluation System for Hospital Smart Services (Trial)" (March 2019) assesses hospitals' digital management and operations efficiency. These announcements have increased medical institutions' willingness to strengthen their digital capability, leading to the rise of BD RowaTM.

administration and the efficiency of the pharmacy workflow. With pharmacy automation, patient waiting time can be reduced by half which frees the pharmacists for clinical pharmacy research and service. More importantly, BD RowaTM improves the pharmacy precise management that ensures patient safety, such as full traceability of drug information (batch number, expiration date, etc.). One of BD's pharmacist clients stated that "my pressure can be relieved" since human error is now taken out of the equation. In addition, together with the embedded refrigerated system which meets the need of cold chain management of special drugs, BD RowaTM offers large volume unlimited SKU storage and management.

USE CASES AND VALUE PROPOSITION

BD Rowa™ in China can be found primarily in Class III & Class II hospitals, and a few Class I hospital & retail pharmacies. It automates the process from receiving prescriptions from physicians to handing medications to patients. When the prescriptions got sent to the hospital pharmacy via HIS (Hospital Information System), the "robots" will collect the exact SKU and dosage of prescribed medication from the storage and deliver it to the front-desk pharmacist for final check-up without human interference. The solution improves the precision of drug

REVENUE MODEL

BD RowaTM solutions are now installed under a project-based model, since each client has very different conditions for the solutions to fit in, such as pharmacy size and storage configuration. Customers will pay BD for the project depending on the selected models, the extent of customization, and other special requirements. Meanwhile, to better accommodate dynamic customer needs, BD may consider different models like leasing, product bundling, or data services, etc. once different forms of partnership are established.

STRATEGIC PARTNERSHIP

Currently, BD targets hospitals and SPD (Supply, Processing and Distribution) companies as distributors to expand its commercial coverage. With project-based installation, BD differentiates itself by providing hospitals solutions with premium quality and services that fulfill their needs, such as medication management process improvement and scientific research results sharing, etc. Moreover, BD works closely with SPD players by helping them strengthen connections with medical institutions. Meanwhile, BD is still exploring new scenarios and seeking collaborations with different types of partners such as retail pharmacies and e-commerce platforms.

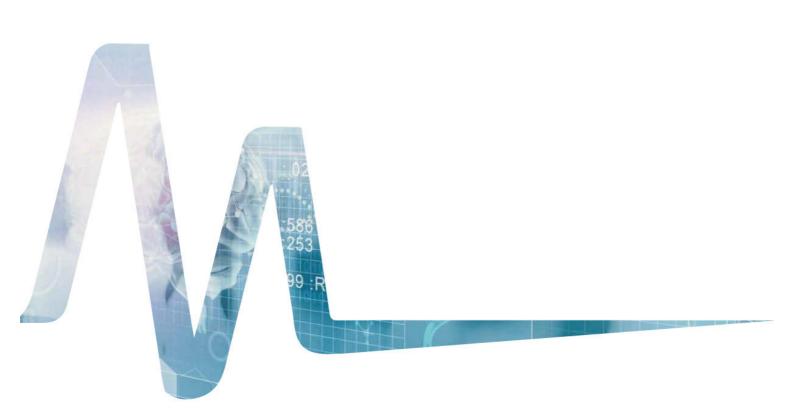
KEY CHALLENGES FOR DIGITALIZATION

Despite BD Rowa's growing presence in China, it still had challenges during the product's localization. To integrate with a variety of HIS systems in China, an evolving software customized for the Chinese market is mandatory, hence requires software-related talent investment. A local R&D team has been focusing on the development such software called MDIS (Medication Dispensing Information System) and its integration with the HIS systems. Another challenge is customer education. In the past, the priority has always been the speed of the dispensing system, therefore, the channel system with seemingly faster dispensing speed was preferred. However, such design compromises dispensing accuracy which becomes more & more important nowadays as related to patient safety. BD wants to promote the importance of precise drug administration as its core value proposition, that has a stronger connection to patient safety.

ADVICE FOR COMPANIES INTERESTED IN DIGITALIZATION

Looking forward, as policies promote smart hospitals and healthcare professionals emphasize the efficiency of hospital operations, undoubtedly more clinical and non-clinical digital solutions will emerge. BD suggests that providing a clear digitalization roadmap and establishing credibility are critical. When developing solutions for smart hospitals, companies need to clearly communicate the gap between the status quo and the ideal future state, then design a practical roadmap. Consequently, by doing the "right thing", solution providers' credibility can be established, and its sustainable market presence in China is secured.

04 FUTURE OUTLOOK





4.1 FUTURE TREND AND EVOLVEMENT



TREND 1

DIVERSIFY CHANNELS TO ACCESS HEALTHCARE SERVICES IN THE POST-PANDEMIC ERA

The COVID-19 has switched patient behaviors and the way they communicate with their physicians. Patients appreciated the more personalized interactions, the faster response time, and the convenience of managing and monitoring their care close-to-home. The virtual tools are becoming essential lifelines for communication and guidance for patients now administering their treatments at home. In the future, integrated EMR systems across different hospitals will streamline the treatment and patient transfer process to make close-to-home service possible. For example, an online hospital will become the first stop for a quick consultation and initial diagnosis. Patients will have access to multiple channels for close-to-home services for further diagnosis, treatment, and follow-up, supported by Al-diagnosis support tools connected to medical data.

TREND 2

EMERGENCE OF END-TO-END PATIENT MANAGEMENT SOLUTIONS DRIVEN BY CONNECTED PATIENT DATA

End-to-end solutions connecting patients and HCPs will emerge to provide diversified healthcare services to address pain points along the patient journey. Collaboration among pharma, device, tech companies, and medical institutions will build a connected digital ecosystem to better address unmet needs across disease stages of awareness, diagnosis, treatment, follow-up, and health management.





Diagnosis







Health management

Disease awareness

Reliable disease info and a real-time online consultation will be accessible on the digital platforms Empower diagnosis and clinical decision making process by Artificial

process by Artificial Intelligence/Machine Learning/Natural Language Processing technologies

Treatment

Tech-enabled solutions (e.g., medical devices, digital pills, and functional games via AR/VR) help increase compliance, control adverse reactions, and allow personalized treatment at home

Follow-up

Patients can conduct follow-up via online hospital or close-tohome institutions (CHCs/PE centers/pharmacies Innovations in medical devices and wearable devices enable better patient health condition monitoring and provide early warning for patients and their families



4.2 KEY HURDLES OF DIGITALIZATION IN THE MEDICAL DEVICE INDUSTRY

While digital solutions and AI-powered machines are attractive and trending areas of the medical and healthcare industry, companies must consider some critical hurdles before acting. The supporting policies for digital product registration approval have not yet been fully developed. Data-related issues, including collection, cleaning, and security, still require more time to adjust and optimize. Customer recognition and willingness to adopt this new technology are low due to product accuracy, reliability, and security. Companies also have internal challenges such as insufficient talent acquisition, an immature business model, and a long investment payback period.

EVOLVING REGISTRATION APPROVAL AND REIMBURSEMENT PROCESS

Policy and regulations are critical drivers for developing value-based healthcare, big data, and AI-empowered medical applications. The overall regulation and public health policy are still evolving with no clear standard for evaluation. While the NMPA official released "The Classification Guidelines for AI-related Medical Software Product" in July 2021, the detailed assessment process and standard for each classification have not been fully developed yet and limited acceleration approval process for digital products. Also, little policy support has been released to increase HCP adoption in recent years. Although the National Health Committee has issued guidelines to encourage more AI products on treatment and diagnosis adoption in 2018, no related policies from provincial governments make HCP largely unaware of digital medical devices. Therefore, the evolving registration approval and policy support are one of the key hurdles for the adoption of digital products and services. As for reimbursement, currently, there is essentially no reimbursement policies have been issued in some pilot cities.





DATA COLLECTION AND STANDARDIZATION ISSUES



- Data-related issues have always raised significant awareness and recognition in medical and healthcare Al innovative applications. The current debate on data privacy and ethical implications of Al centers on data ownership: whether the patient or provider owns the data and whether it can be shared or sold without the patient's consent. Although companies are investing more of their resources in data management, they might encounter the following hurdles.
- Data collection: Digital record is still not normalized in a large proportion of the hospitals, and some hospitals are hesitant to share data with other healthcare institutions for diagnosis and treatment purposes. The resulting fragmented dataset is causing a considerable challenge to access and collect data.

Data cleaning and standardization: Data cleaning is the first and most time-consuming process after having access to several large datasets, as they commonly have poor format consistency. The information systems of major hospitals in China are customized. The inconsistency causes the inability to run operations and promptly extract valuable insights from the dataset, potentially increasing human errors. Anonymizing, controlling access, and safely transferring healthcare data is a non-trivial and sometimes impossible task. Anonymized data from the electronic health record can appear innocuous and compliant, but just a few data elements may allow for patient identification.

Data privacy. Data privacy is the most sensitive and crucial part of a
company's business since health data are classified as personally
identifiable information. Providers need to trade-off between protecting
patients' privacy and the quality or performance of the dataset ①.

*④:Rieke, N., Hancox, J., Li, W. et al. The future of digital health with federated learning. npj Digit. Med. 3,119 (2020). https://doi.org/10.1038/s41746-020-00323-1

LOW CUSTOMER ADOPTION AND WILLINGNESS TO PAY OF DIGITAL TOOLS AND SOLUTIONS

Due to the lack of understanding and education of the AI tools and technologies, even though they have been used in clinical practices, many patients and HCPs still doubt the reliability, accuracy, and effectiveness. Accuracy is the first concern as there have not been enough domestic precedents of AI solutions. Some patients and HCPs are convinced that AI-powered machines can be susceptible to artifact-related errors. The second primary concern is that some patients and HCPs believe that digital products complicate the entire process. Some HCPs spend extra time and effort to reach out to patients to collect their compliance data regardless of using digital products. Some patients, especially elderly patients, find digital products challenging to use when they are on their own. Even though mentioned in the previous section, the last concern is data privacy and security. Patients have no other choice but to trust the technology provider not to leak their information after adoption. However, frequently reported cases of patient data leakage had damaged the reputation and trustworthiness of AI-empowered machines.

Some unique characteristics of the Chinese market increased the difficulty of adopting digitalized medical devices: There is intense competition in the medical device industry. Providers have to offer consumers or patients value-added services with a significant discount or even for free. The different consumer habits from those in other countries could be challenging for innovative medical device providers.

DIFFICULTY OF TALENT ACQUISITION

Company-level challenges should never be overlooked because if successfully resolved, the company would have a much more promising foundation for digital products and AI business innovation. The first challenge has always been talent acquisition. There is a shortage of talents who possess interdisciplinary education backgrounds in medical and digital-related subjects due to the flaws in course setup at education institutions. Therefore, the company would need to invest more in the talent acquisition and development of their professional know-how and skills.

UNCLEAR BUSINESS MODEL

Many healthcare companies fail to assess their genuine need for AI and whether their current capabilities can support them to achieve their goals and ambitions. Many companies are determined to develop their AI product portfolio, while there is a significant lack of technological infrastructure to establish primary conditions for AI solution implementation. The resulting poorly-designed business model is unable to generate profit and promising long-term business growth. Finally, adopting breakthrough technology requires a significant upfront investment, especially when the business model is immature. This situation would be challenging for the company as the investment payback period could be longer than expected.



4.3 NO-REGRET MOVES

One suggested action is to collaborate with trustworthy partners to shape policy-making and create a digitalization-friendly policy environment. We also recommend engaging with policymakers to understand the implication of related policies. Since digitalization and AI solutions are closely associated with and heavily rely on technology and data, companies should optimize the data collection and cleaning process for higher efficiency and pay extra attention to data privacy and security as this mainly concerns the consumer. We also advise that companies establish a customer-centric business model with its unique value proposition to ensure sustainable long-term growth and a healthy revenue stream.

CO-CREATE AN ENABLING ENVIRONMENT FOR DIGITALIZATION

Developing a friendly national digital health architecture for digital transformation is the top priority. Companies should consider shaping the policy-making process to accelerate the registration procedure of innovative digitalization products by engaging in partnership with domestic companies, MNC, and other healthcare institutions, and appeal for open-source health data standards and aim for reusable systems or assets, including interoperability of health information systems ⑤. Within the companies, spotting, attracting, and training valuable programming talent is a matter of cardinal significance. Also, raising public awareness and acceptance of innovative technology will create the domino effect as other customers will influence customers. Companies are suggested to actively engage with policymakers and regulators to raise public discussion on dataset's storage, use, and security.

ENSURE DATA PRIVACY AND SECURITY

Companies need to collaborate with hospitals and healthcare facilities to share data via the cloud for a more efficient collection process. This action would save time and effort to clean the collected data, minimize human errors, and finally lead to another highly encouraging initiative for data standardization. Having data standardization would allow faster and easier transformation and high overall data quality. Ensuring privacy and security is also critical. The Cybersecurity Law of the People's Republic of China issued in 2017, Personal Information Standard Specification issued in 2020, and Data Security Law of the People's Republic of China issued in 2021 show that the Chinese government aims to protect citizens' data security. Companies should strictly comply with these regulations and actively engage with government officials and policy experts to understand the policy implications.

DESIGN A SUSTAINABLE BUSINESS MODEL FOR SUCCESS

Companies should develop a sustainable business model with solid and unique value proposition. After establishing a clear value proposition, a company can build its products and services aligned with its vision. The transformation of scientific research into clinical practice is the lifeline for the survival of medical device and technology enterprises. Companies should consider the following factors to drive a healthy revenue stream and continuing growth: whether the core product can be approved as a Class II/III medical device by NMPA; whether the approved products can be commercialized; whether the company can successfully establish business relationships with major hospitals.

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APAC/Ned Deloitte.

| NAME OF THE COMPANY | SOLUTION | DESCRIPTION | DIGITAL HEALTH CATEGORIES | LINKS |
|------------------------|---|---|------------------------------------|---|
| ABBOTT | Cardiomems HF system | Heart failure remote monitoring device for pulmonary artery pressure | Healthsensors | https://www.cardiovascular.abbott/us/en/ hcp/proucts/heart-failure/pulmonary-pres- sure-monitors/cardiomems/about.html |
| ABBOTT | Confirm Rx™ with SharpSense™ technology | Insertable Cardiac Monitor for accurate, faster & easier diagnosis for arrythmias | Healthsensors | https://www.cardiovascular.abbott/us/en/hcp/prod- ucts/car- dac-rhythm-management/insertable-cardiac-monitors/ confirm-rx/about.html |
| ABBOTT | EnSite Precision™ | Cardiac Mapping System for diagnosis of arrythmias using smartphone remote monitoring | Companion diagnostics | https://www.cardiovascular.abbott/us/en/ hcp/proucts/heart-failure/pulmonary-pres- sure-monitors/cardiomems/about.html |
| ABBOTT | Freestyle libre sensor | Glucose sensor that allows current glucose reading on the patients' phone | Healthsensors | https://www.freestyle.abbott/us-en/home.html |
| ABBOTT | FreeStyle LibreLink app | Mobile app for the patient, allowing to read the results from current blood glucose levels from the Freestyle libre sensor | Mobile applications | https://freestylelibre.com.sg/freestyle-librelink-app.html |
| ABBOTT | Freestyle LibreLinkUp | Mobile app for the care-giver, allowing to read the results from current blood glucose levels from the Freestyle libre sensor | Mobile applications | https://freestylelibre.com.sg/freestyle-librelink-up.html |
| ABBOTT | Freestyle LibreView | Cloud-based diabetes management system | Big data | https://freestylelibre.com.sg/libreview.html |
| ABBOTT | Merlin.net™ Patient Care Network | Remote system that imports and manages cardiac information from the patients' implanted devices. | Big data | https://www.cardiovascular.abbott/int/en/hcp/prod- ucts/cardi- ac-rhythm-management/merlin-patient-care-network. html |
| ABBOTT | Merlin@home™ | Transmitter for Abbott implanted heart device monitoring any physician | Portable connected medical devices | https://www.cardiovascular.abbott/us/en/hcp/prod- ucts/cardi- ac-rhythm-management/merlin-home-transmitter.html |
| ABBOTT | myMerlinPulse™ App | Mobile app to transmit information from Abbott implanted heart device to patient's healthcare provider | Mobile applications | https://www.cardiovascular.abbott/us/en/hcp/prod- ucts/cardi- ac-rhythm-management/connectivity-remote-care.html |
| ABBOTT | NEUROSPHERE™ VIRTUAL CLINIC | Remote neuromodulation patient-care technology | Portable connected medical devices | https://www.abbott.com/corpnewsroom/prod- ucts-and-innova- tion/new-digital-prescription-for-pain-and-movement- disorders.html |
| ABBOTT | Proclaim™ Elite Recharge-Free SCS System | System that delivers spinal cord stimulation to help patients manage their chronic pain | Digital therapeutics | https://www.neuromodulation.abbott/us/en/prod- ucts/neurostimu- lators-chronic-pain/proclaim-elite-recharge-free-scs-s ystem.html |
| ABBOTT | St. JudeApp Medical Infinity™ | Provides patients with deep brain stimulation therapy to control their Parkinson's disease | Digital therapeutics | https://www.neuromodulation.abbott/us/en/hcp/prod- ucts/dbs-movement-disorders/st-jude-medical-infinity- dbs-system.html |
| ALCON | PHORCIDES with CONTOURA® Vision | Analytic Engine diagnostic software | Companion diagnostics | https://www.alcon.com/media-release/alcon-launch- es-lasik-inno- vations-new-planning-software-and-patient-interface |
| ALCON | SMART Suite DH PLatform or Cataract Surgery | Personalised, cloud based end to end care for cataract patients | Mobile applications | https://www.alcon.com/media-release/ alcon-develop-smart-suite-digital-health-plat- form-cataract-surgery |
| ALIGN TECH | Invisalign®Outcome Simulator Application | ITero scanners & Progress Assessment tool generated simulated outcome for patient treatment acceptance | Virtual and Augmented Reality | https://www.aligntech.com/solutions |
| ALIGN TECH | iTero®Timelapse software | Software that compares records over time, animated images to show oral changes | Virtual and Augmented Reality | http://www.iterotimelapse.com/ |

| NAME OF THE COMPANY | SOLUTION | DESCRIPTION | DIGITAL HEALTH CATEGORIES | LINKS |
|------------------------|--|--|---|--|
| B. BRAUN | DIABASS® Pro | Patient's diabetes data documentation software | SaMD (Software as a Medical Device) | https://www.diabass.com/en/ |
| B. BRAUN | Diasend® | Data sharing & synchronising patient's diabetes data with devices | Mobile applications | https://www-int.glooko.com/patients/ |
| B. BRAUN | Omnitest® app | Mobile app as digital diabetes diary with any glucose meter | Mobile applications | https://www.bbraun.com/en/products/b1/omnit- est-5-set-withbluetooth.html |
| B. BRAUN | Synchronized Intelligence™ | Platform collecting real-time data from patients' pumps and electronic reporting systems | Big data | https://www.baxter.com/healthcare-professionals/re- nal-care/amia-shares/synchronized-intelligence.html%2 3.html# |
| B. BRAUN | AMIA™ | Home peritoneal dialysis remotely connected with patient's healthcare provider | Portable connected medical devices | https://www.baxter.com/healthcare-professionals/re- nal-care/amia-sharesource-renal-care |
| B. BRAUN | Evo IQ ™ | Delivers infusion therapies, it integrates electronic medical records (EMR) systems and e-documentation | Portable connected medical devices | https://www.baxterhealthcare.co.uk/healthcare-professionals/hospital-care/evo-iq-infusion-system |
| B. BRAUN | EXACTAMIX™ | Compounder Software: automatically compound multi-ingredient sterile doses | SaMD (Software as a Medical Device) | https://ushospitalproducts.baxter.com/exactamix-com- pounder-0 |
| B. BRAUN | HOMECHOICE CLARIA™ | Automated peritoneal dialysis (APD) system with the SHARESOURCE remote patient management platform | Portable connected medical devices | https://renalcare.baxter.com/products/ho- mechoice-claria |
| B. BRAUN | KAGUYA™ | Automated peritoneal dialysis (APD) system with the SHARESOURCE remote patient management platform | Portable connected medical devices | https://renalcare.baxter.com/products/kaguya |
| B. BRAUN | PRISMAFLEX™ System integrating the DeviceConX platform | The DeviceConX platform connects the Prismaflex system to a hospital electronic medical record (EMR). | Big data | https://www.baxter.com/healthcare-professionals/criti- cal-care/prismaflex-system-critical-care |
| B. BRAUN | SHARESOURCE ™ Connectivity platform | A portal that clinician's can access to view data on demand for remote patient monitoring stores on a cloud based server | Big data | https://renalcare.baxter.com/products/sharesource |
| B. BRAUN | Spectrum IQ™ infusion system | Medication administration process with Electronic Medical Record (EMR) Integration | Portable connected medical devices | https://www.baxter.com.sg/healthcare-profession- als/hospi- tal-care/spectrum-iq-infusion-system-hospital-care |
| BECTON DICKINSON | BD Guardrails™ Suite MX | Software for the BD Alaris™ System, generates custom reports and graphics to help measure the effectiveness of a treatment | SaMD (Software as a Medical Device) | https://www.bd.com/en-us/offerings/capabilities/infu- sion-ther- apy/infusion-system-software/guardrails-suite-mx-soft ware |
| BECTON DICKINSON | BD™ Diabetes Care App | Mobile app for diabetic patients (data logging & emotional support) | Mobile applications | https://livingwithdiabetes.bd.com/bd-diabetes-care-app |
| BIOTRONIK | BIOTRONIK patient app | Mobile app for patient with heart conditions for home monitoring system update, symptom record, documentation, communication with physician & heart rate details | Mobile applications | https://www.biotronik.com/en-de/patients/patientapp |
| BIOTRONIK | CardioMessenger Smart | Portable monitoring device for patient with heart conditions to transmit information from implanted device to service center | Healthsensors | https://www.biotronik.com/en-us/prod- ucts/crm/transmitter/cardiomessenger-smart |
| BIOTRONIK | Home Monitoring® | A remote cardiac monitoring system to collect data from patient's device for physician review | Portable connected medical devices | https://www.biotronik-homemonitoring.com/ |

| NAME OF THE COMPANY | SOLUTION | DESCRIPTION | DIGITAL HEALTH CATEGORIES | LINKS |
|---------------------------|---|--|---|---|
| BIOTRONIK | SMART Detection® | Al helping in the diagnosis of heart conditions (sophisticated discriminator) | Companion diagnostics | https://www.heartrhythmjournal.com/arti- cle/S1547-5271(05)00800-3/fulltext |
| BOSTON SCIENTIFIC | Bionic Navigator™ 1.2 software | A software that allows setting and adjustment of stimulation parameters for Spinal Cord Stimulator system | SaMD (Software as a Medical Device) | https://www.bostonscientific.jp/content/dam/Manu- als/us/cur- rent-rev-en/91171765-02_Rev_A_Bionic_Navigator_1.2_ Software_Guide_DFU_en-US_s.pdf |
| BOSTON SCIENTIFIC | FreeLink™ Technology | Cordless Remote Control for Spinal Cord Stimulator system | Portable connected medical devices | https://www.bostonscientific.com/en-US/products/spi- nal-cord-stimulator-systems/precision_spectra/advanc ed-control.html |
| BOSTON SCIENTIFIC | Illumina 3D™ Programming Algorithm™ | Software that helps targetting and improving pain in spinal cord conditions | SaMD (Software as a Medical Device) | https://www.bostonscientific.com/en-US/products/spi- nal-cord-stimulator-systems/precision_spectra/advanc ed-control.html |
| BOSTON SCIENTIFIC | LATITUDE Consult™ System | Diagnostic data & access to technical analysis & expertise for efficient patient treatment | Telemedicine | https://www.bostonscientific.com/en-US/products/re- mote-pa- tient-monitoring/LATITUDE-Consult-System.html |
| BOSTON SCIENTIFIC | LATITUDE™ Home Monitoring System | Remote monitoring device for pacemakers & defibrilla- tors for updates to healthcare provider | Portable connected medical devices | https://www.bostonscientific.com/en-US/pa- tients/about-your-device/latitude-home-monitoring.html |
| BOSTON SCIENTIFIC | LATITUDE™ NXT | Remote monitoring device for accesss to patient's device data by healthcare provider | Portable connected medical devices | https://www.bostonscientific.com/en-US/products/re- mote-patient-monitoring/latitude-nxt.html |
| BOSTON SCIENTIFIC | LUX-Dx™ | Cardiac device programed with a dual stage algorithm that helps with diagnosis, providing insights & data verification | Healthsensors | https://www.bostonscientific.com/en-US/products/re- mote-patient-monitoring/LUX-Dx-ICM-System.html |
| BOSTON SCIENTIFIC | myLUX Patient App | Mobile app that collects data from the patient's cardiac implanted device | Mobile applications | https://www.bostonscientific.com/en-US/pa- tients/LUX-Dx-ICM-System/using-your-mylux-app.html |
| BOSTON SCIENTIFIC | ZOOM® LATITUDE™ Programming System | Portable cardiac rhythm management programming system | Portable connected medical devices | https://www.bostonscientific.com/en-US/products/re- mote-pa- tient-monitoring/ZOOM-LATITUDE-Programming-Syste m.html |
| CARDINAL HEALTH | Navista TS™ | Value based clinical decision for oncology practice | Analytics | https://www.cardinalhealth.com/en/services/special- ty-physician-practice/solutions/navista.html |
| CARDINAL HEALTH | RXID Select ™ Inventory Management | Cloud based solution to streamline inventory (retina meds) | Big data | https://www.draeger.com/en_sea/Products/Smart- Care-PS-The-automated-weaning-protocol |
| DRÄGER | SmartCare/PS | Automated clinical protocol designed to stabilise the patient's spontaneous breathing | SaMD (Software as a Medical Device) | https://www.draeger.com/en_sea/Products/Smart- Care-PS-The-automated-weaning-protocol |
| FRESENIUS MEDICAL CARE | TheHub | Applications that enable patients and care teams and providers to better collaborate and monitor patient treatments | Telemedicine | https://www.freseniusmedicalcare.com/en/news/frese- nius-medi- cal-care-launches-connected-health-platform-in-north- america/ |
| HEALTH CATALYST | Data Operating System (DOS™) | engineering approach that combines the features of data warehousing, clinical data repositories, and health information exchanges in a single, common-sense technology platform | Big data | https://www.healthcatalyst.com/healthcare-data-operat- ing-system-solution |
| HOLOGIC | C-View™ | Software that automatically generates synthesized 2D images from the tomosynthesis data without the need for a 2D scan | SaMD (Software as a Medical Device) | https://www.hologic.com/sites/default/- files/2017/Products/Im- age%20Analytics/PDFs/C-View-Two-Pager.pdf |
| HOLOGIC | Genius Al™ | Deep-learning based cancer detection (radiology) | Artificial intelligence | https://www.hologic.com/hologic-prod- ucts/breast-health-solu- tions/genius-ai-detection-technology |

| NAME OF THE COMPANY | SOLUTION | DESCRIPTION | DIGITAL HEALTH CATEGORIES | LINKS |
|------------------------|--------------------------------------|--|---|--|
| JOHNSON & JOHNSON | OneTouch Reveal® | Mobile app to monitor and analyze patients' blood sugar over time | Mobile applications | https://www.jnj.com/innovation/onetouch-reveal-mo- bile-app-gets-an-upgrade |
| JOHNSON & JOHNSON | RA-RA | Mobile app for remote monitering, symptom tracking & prognosis for Rheumatoid arthritis patients | Mobile applications | https://www.jnjmedicaldevices.com/en-US/ve- lys/knee/product/robotic-assisted-solution |
| JOHNSON & JOHNSON | VELYS™ Digital Surgery | Robotic Assisted Surgery (RAS) Platform powered by data insights from before, during, and after surgery (hip, knee & shoulder) | Robotic surgery | https://www.jnjmedicaldevices.com/en-US/velys |
| JOHNSON & JOHNSON | Zyrtec Allergy Cast | Propreity algorithm to anticipate onset of allergies, data tracking for patterns etc. | Mobile applications | https://www.zyrtec.com/allergy-forecast |
| LIMA CORPORATE | SMART Space | Humeral 3D positioner & Cubit Guidance system for Total Shoulder Arthroplasty | Portable connected medical devices | https://limacorporate.com/en/product-de- tail/286/smart-space.html |
| LIVANOVA | Symmetry | Recurrent & resistant Depression management by VNS Therapy | Portable connected medical devices | https://investor.livanova.com/news-releases/news-re- lease-de- tails/livanova-vns-therapy-system-symmetry-granted-c e-mark-difficult |
| LIVANOVA | VNS Therapy System | Implanatable device for drug resistant epilepsy with day-night & scheduled programming | Healthsensors | https://www.livanova.com/en-US/Home/Therapeu- tic-Areas.aspx |
| MEDTRONIC | CardioInsight™ Ecvue System | Electric data from sensors used to create 3D images of hearts electric activity | Healthsensors | https://europe.medtronic.com/xd-en/healthcare-pro- fessionals/- products/cardiac-rhythm/cardiac-mapping/cardioinsi ght-mapping-vest.html |
| MEDTRONIC | CARELINK™ SYSTEM | Diabetes therapy management software for healthcare professionals | SaMD (Software as a Medical Device) | https://www.medtronic.com/us-en/healthcare-profession- als/pro- ducts/diabetes/data-management-software/carelink.html |
| MEDTRONIC | GI Genius™ | Intelligent endoscopy module to address challenges of colorectal cancer | Artificial intelligence | https://www.medtronic.com/us-en/c/digestive-gastroin- testinal/gi-genius.html |
| MEDTRONIC | Guardian Connect System | External neurostimulator for interstim candidate evaluation | Healthsensors | https://www.medtronicdiabetes.com/products/guard-ian-connect-continuous-glucose-monitoring-system |
| MEDTRONIC | INTERSTIM™ EVALUATION SYSTEMS | Cloud based solution to streamline inventory (retina meds) | Healthsensors | https://global.medtronic.com/xg-en/healthcare-profes- sionals/- products/urology/sacral-neuromodulation-systems/inter stim-evaluation-system.html |
| MEDTRONIC | MAZOR X STEALTH EDITION™ | Robotic guidance system with preoperative & intraoperative planning | Companion diagnostics | https://global.medtronic.com/xg-en/healthcare-profes- sionals/- products/spinal-orthopaedic/spine-robotics/mazor-x-st ealth-edition.html |
| MEDTRONIC | Medicrea | Predictive modeling & sophisticated algorithms for spinal surgery | Artificial intelligence | https://newsroom.medtronic.com/news-releas- es/news-release-de- tails/medtronic-completes-acquisition-medicrea |
| MEDTRONIC | MiniMed™ 630G Insulin Pump System | Insulin pump system for diabetes management | Healthsensors | https://www.medtronicdiabetes.com/products/min- imed-630g-insulin-pump-system |
| MEDTRONIC | MiniMed™ 770G System | Real time glucose readings for personalisd insulin delivery system for diabetes management | Healthsensors | https://www.medtronicdiabetes.com/products/min- imed-770g-insulin-pump-system |
| MEDTRONIC | STEALTH AUTOGUIDE™ | Cranial robotic guidance platform | Companion diagnostics | https://global.medtronic.com/xg-en/healthcare-pro- fessionals/- products/neurological/cranial-robotics/stealth-auto guide.html |

| NAME OF THE COMPANY | SOLUTION | DESCRIPTION | DIGITAL HEALTH CATEGORIES | LINKS |
|------------------------|----------------------------|---|---|---|
| MEDTRONIC | Stealth3D™ | 3D Surgical navigation system | SaMD (Software as a Medical Device) | https://global.medtronic.com/xg-en/healthcare-profes- sionals/- products/ear-nose-throat/image-guided-surgery/ent-na vigation-solutions/related-navigation-products.html |
| MEDTRONIC | StealthStation FlexENT™ | Image guided surgery technology for ENT procedures | SaMD (Software as a Medical Device) | https://global.medtronic.com/xg-en/healthcare-profes- sionals/- products/ear-nose-throat/image-guided-surgery/stealt hstation-flexent.html |
| MEDTRONIC | Sugar.IQ | Cognitive app that helps detect patterns & trends for diabetics | Healthsensors | https://www.medtronicdiabetes.com/products/- sugar.iq-diabetes-assistant |
| MEDTRONIC | Thermosphere™ | Surgical navigation software for improved accuracy by creating predictable spherical blation zones (when used with ablation platform) | SaMD (Software as a Medical Device) | https://www.medtronic.com/covidien/en-us/prod- ucts/ablation-systems/emprint-ablation-system.html |
| MEDTRONIC | Vital Sync™ | Virtual patient monitoring nd clinical decision support solution | Companion diagnostics | https://www.medtronic.com/covidien/en-us/prod- ucts/health-in- formatics-and-monitoring/vital-sync-virtual-patie nt-monitoring-platform.html |
| MERIT MEDICAL | NvisionVLE® | Al algorithms to help clinician assessment & better informed course of treatment | Artificial intelligence | https://www.merit.com/wp-content/up-loads/2019/03/NVisionVLE-brochure.pdf |
| OLYMPUS | ENDO-AID | Ai powered platform for its endoscopy system | Artificial intelligence | https://www.olympus-europa.com/company/en/news/- press-releas- es/2020-10-09t08-30-00/olympus-launches-endo-aid- an-ai-powered-platform-for-its-endoscopy-system.html |
| QIAGEN | COSMIC | Somatic mutations in human cancer comprehensive database | Portable connected medical devices | https://digitalinsights.qiagen.com/products-over- view/cosmic/ |
| QIAGEN | Digital PCR | Single fully automated Nucleic acid quantification system | Artificial intelligence | https://www.qiagen.com/us/applications/digital-pcr |
| RESMED | AirCurve™ 10 S | Fixed pressure bilevel device for patient monitoring & engagement | Portable connected medical devices | https://www.resmed.com/en-us/healthcare-profession- al/products-and-support/devices/aircurve-10-s/ |
| RESMED | AirMini™ | Portable CPAP machine for sleep apnea | Portable connected medical devices | https://www.resmed.com/en-us/sleep-apnea/c- pap-parts-sup- port/sleep-apnea-full-products-list/cpap-machines/air mini-portable-cpap/ |
| RESMED | AirSense™ 10 CPAP | Portable CPAP & APAP machine for sleep apnea | Portable connected medical devices | https://www.resmed.com/en-us/sleep-apnea/c- pap-parts-sup- port/sleep-apnea-full-products-list/cpap-machines/air sense-10/ |
| RESMED | AirView™ | Cloud based patient management system for online patient management | SaMD (Software as a Medical Device) | https://www.resmed.com/en-us/healthcare-profession- al/prod- ucts-and-support/monitoring-and-data-management/ai rview/ |
| RESMED | Astral 150 | Remote monitering for invasive & non invasive ventilation using responsive algorithms to deliver personalised ventilaton | Portable connected medical devices | https://www.resmed.com/ap/en/healthcare-profession- al/products/devices/astral-150.html |
| RESMED | myAir™ | Online support program & app that sends data from machine to patient's device in form of sleep score | Mobile applications | https://www.resmed.com/en-us/sleep-apnea/c- pap-parts-support/myair-app/ |
| RESMED | Stellar™ series | Ventilator for invasive & non invasive ventilation at home/healthcare setting | Portable connected medical devices | https://www.resmed.com/en-us/ventilation/prod- ucts/stellar/ |
| ROCHE DIAGNOSTICS | mySugr app | Diabetes management app to store data from connected devices, integrations & manual entries | Mobile applications | https://www.roche.com/media/releas- es/med-cor-2017-06-30.htm |

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|-------------------------|----------------------------|--|---|--|
| ROCHE DIAGNOSTICS | NAVIFY® | A comprehensive patient profile consolidation system using solutions that include patient insights, data integration for treatment decision making | Artificial intelligence | https://www.navify.com/ |
| SIEMENS HEALTHINEERS | AI-Pathway Companion | A clinical decision support solution that enablees personalised & stanadardized care along care pathways in oncology, cardiology & infectious diseases. | Artificial intelligence | https://www.siemens-healthineers.com/en-us/digi- tal-health-solutions/digital-solutions-overview/clinical- decision-support/ai-pathway-companion |
| SIEMENS HEALTHINEERS | AI-Rad Companion | Al based sofware assistant for computed tomography | Artificial intelligence | https://www.corporate.siemens-health- ineers.com/press/releas- es/pr-20181125043shs.html |
| SIEMENS HEALTHINEERS | eHealth virtual visit | Virtual technology to support providers to improve delivery of care between patients & physicians for better decison making | Telemedicine | https://www.siemens-healthineers.com/digi- tal-health-solu- tions/digital-solutions-overview/patient-engageme nt-solutions/e-health-solutions- portfolio/virtual-visit |
| SIEMENS HEALTHINEERS | Mobile workflow solutions | Mobile apps that help document clinical data , keep it updated & secure | Mobile applications | https://www.siemens-healthineers.com/en-sg/digi- tal-health-solutions/digital-solutions-overview/pati- ent-engagement-solutions/e-health-solutions/ehea lth-solutions-portfolio/mobile-workflow-solutions |
| SIEMENS HEALTHINEERS | myCare Companion | Remote care management for chronically ill patients to design & adapt telemedicine programs | Telemedicine | https://www.corporate.siemens-healthineers.com/- press/releases/mycarecompanion.html |
| SMITH & NEPHEW | CORI Surgical System | Surgeon controlled hand held robotics assisted system for clinical decision making | Artificial intelligence | https://www.smith-nephew.com/professional/prod- ucts/robotics/cori-surgical-system/ |
| SMITH & NEPHEW | iADJUST | Mobile app for patient monitoring, adjustment schedules etc for use with taylor spatial frames | Mobile applications | https://www.smith-nephew.com/professional/prod- ucts/all-products/iadjust/ |
| STRYKER | BACS: spine innovations | A perioperative process managementb tool to improve patient outcome | Virtual and Augmented Reality | https://www.stryker.com/us/en/spine/prod- ucts/bacs-balance-acs/index.html |
| STRYKER | CODE-STAT™ | Data review software & service to improve patient outcome | SaMD (Software as a Medical Device) | https://www.strykeremergencycare.com/products/da- ta-solutions/code-stat/ |
| STRYKER | CranialMap 3.0™ | Navigation software for neurosurgical procedures for better patient outcomes | SaMD (Software as a Medical Device) | https://www.stryker.com/us/en/navigation/prod- ucts/cranial-map-3-0.html |
| STRYKER | MAKO™ Smartrobotics | Robotic arm assisted surgery including CT based planning, Accu Stop Haptics technology & data analytics for better surgical outcomes | Robotic surgery | https://www.stryker.com/us/en/joint-replacement/sys- tems/Mako_SmartRobotics_Overview.html#know-more |
| STRYKER | My SDC3™ iPad app | Digital capture accessories to edit & share surgical images & post operative recovery information with patients | Mobile applications | https://www.stryker.com/us/en/endoscopy/prod- ucts/my-sdc3-ipad-app.html |
| VARIAN | Ethos™ therapy | An adapative intelligence solution to generate adapted plans for physician review for quick decision making in patient care | Artificial intelligence | https://www.varian.com/products/adaptive-therapy- /ethos |
| InferVision | InferRead CT Lung | A CE marked, FDA cleared, NMPA approved AI solution to help radiologists with their diagnosis workflow, serving as a second pair of eyes. It is highly sensitive in assisting the user to quickly identify different types of lung lesions, providing detailed quantification information for each lesion, automatically generating a diagnostic report. InferRead Lung CT.AI is also capable of providing advanced analytics and visualizations, nodule malignancy prediction, and follow-up recommendations to assist providers in providing optimal patient care. | Artificial intelligence | https://us.infervision.com/product/19/ |

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|------------------------|---|--|------------------------------|--|
| InferVision | InferRead CT Pneumonia | A CE marked, NMPA approved, PMDA approved Al solution for real-time identification and alert of suspected pneumonia cases, for optimal protection of medical staff and timely treatment of patients. | Artificial intelligence | https://us.infervision.com/product/19/ |
| InferVision | InferRead DR Chest | A CE Marked (TB) Al solution designed to be used for the detection and notification of multiple diseases by analyzing chest X-ray images, including tuberculosis, fracture, pleural effusion and pneumothorax. High sensitivity in detecting various occult lesions such as ground glass density nodules and nodules obscured by soft tissue, etc. Supports both DR and CR modalities. | Artificial intelligence | https://us.infervision.com/product/19/ |
| InferVision | InferRead CT Stroke | An FDA cleared AI solution for accurate and fast triage of suspected hemorrhage, for optimal workflow and timely treatment of patients. | Artificial intelligence | https://us.infervision.com/product/19/ |
| InferVision | InferScholar Al-enabled Medical Research Platform | An easy-to-deploy Al-enabled medical research platform that provides a wide array of tools and modules (e.g. data management, annotation and labeling, radiomics and deep-learning, multi-center research), allowing users with limited or no coding experience in algorithm modeling to leverage advanced Al analytical tools and computing technologies in their research. | Artificial intelligence | https://us.infervision.com/product/21/ |
| InferVision | InferScholar Al-enabled Medical Application Platform | An Al-enabled medical application platform designed to close the gap between "research" and "application" by integrating the algorithm obtained through Al-enabled medical research into a software with user-friendly graphical interface that allows for straightforward user interaction and easy data input from standard information systems. | Artificial intelligence | https://us.infervision.com/product/21/ |



About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. In 2020, APACMed established a Digital Health Committee to support its members in addressing regional challenges in digital health. For more information, visit www.apacmed.org.