



# **A CXO's Handbook for Navigating the Future of Healthcare Technology**

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# Introduction

With the latest advancement in technologies such as wireless communication, sensors, data storage, and semiconductors, there is a revolution in “state-of-the-art” methodology or working models across industries. The healthcare industry is no exception to this revolution, and this effect is most visible in the industry’s adoption of *digital* technology.

The healthcare industry is a leader in continuous innovation and developing robust solutions. With the rise of *Connected Healthcare*, the industry is set to usher in the next wave of transformation. Projections by market.us estimate that the connected healthcare market will expand to USD 520.6 billion by 2032, growing at a CAGR of 25.2%. This growth is expected to be fueled by wireless communication enabled medical devices monitoring and analyzing patient data in real time, alongside telemedicine for quality healthcare at home, indicating a shift towards a patient-centered healthcare model.

This eBook is an invitation to explore the future of healthcare, where technology empowers individuals, revolutionizes patient care, and paves the way for personalized well-being. Within its pages, you’ll discover the latest advancements in medical devices such as the role of edge AI, non-invasive diagnostics, and robotic-assisted surgery. We will explore some compelling case studies such as FDA Class II Telehealth Examination Device, Point of Care Ultrasound Diagnostics Device, and AI-based Edge-to-Cloud Unified Healthcare Platform. We will also delve into the power of digital healthcare and witness the transformative potential of connected healthcare with Internet of Medical Things (IoMT).



# An Outlook on the Latest Innovations in Medical Devices

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- Technological Advancements Paving the Way for Smart Medical Devices
- Beyond the Cloud: Real-Time Decision-Making with Edge AI
- The Era of Non-Invasive Diagnostic Devices
- Case Study: FDA Class II Telehealth Examination and Diagnosis Device
- Robots in Operation Theaters: The Future of Surgery
- The Future of Medical Imaging: Powered by AI & ML Technology
- Case Study: Image Control Technology for Minimally Invasive Spine Surgery
- Compact Devices, Large Data: Addressing the Design Challenges of Medical Devices

# Technological Advancements Paving the Way for Smart Medical Devices

The development and use of smart medical devices are gaining momentum across various healthcare applications. This trend is expected to continue, with the smart medical devices market projected to reach a valuation of USD 76 billion by 2028, growing at a CAGR of 19.2%.

## Computer Vision

Advancements in computer vision technology significantly enhance the functionality of medical devices, especially by improving diagnosis accuracy through sophisticated image analysis. This technology plays a crucial role in detecting severe conditions, such as tumors and hemorrhages, providing a critical tool in medical diagnostics.

## Extended Reality

The integration of Augmented Reality (AR), Virtual Reality (VR), and Mixed Reality (MR) is transforming surgical and emergency response training for medical professionals. Additionally, these technologies offer therapeutic benefits for patients experiencing vision problems, or suffering from autism and depression, showcasing their versatile application in enhancing both medical training and patient care.

## AI in Medical Devices

Artificial Intelligence is powering the advancement of medical devices - enabling remote diagnostics, telemedicine, and data-driven decisions. AI's capability to analyze health data for early disease detection is reshaping preventive healthcare, making diagnostics more efficient and effective.



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# Beyond the Cloud: Real-Time Decision-Making with Edge AI

Imagine how many lives would be saved if doctors and caregivers could receive real-time alerts about any abnormality or fall instances in patients. Edge AI can make this a reality!

Edge AI processes data locally without the need for data transmission. It saves cost, reduces latency, and enables real-time decision-making. The localized processing is also energy efficient, consuming less energy than a power-hungry data center.

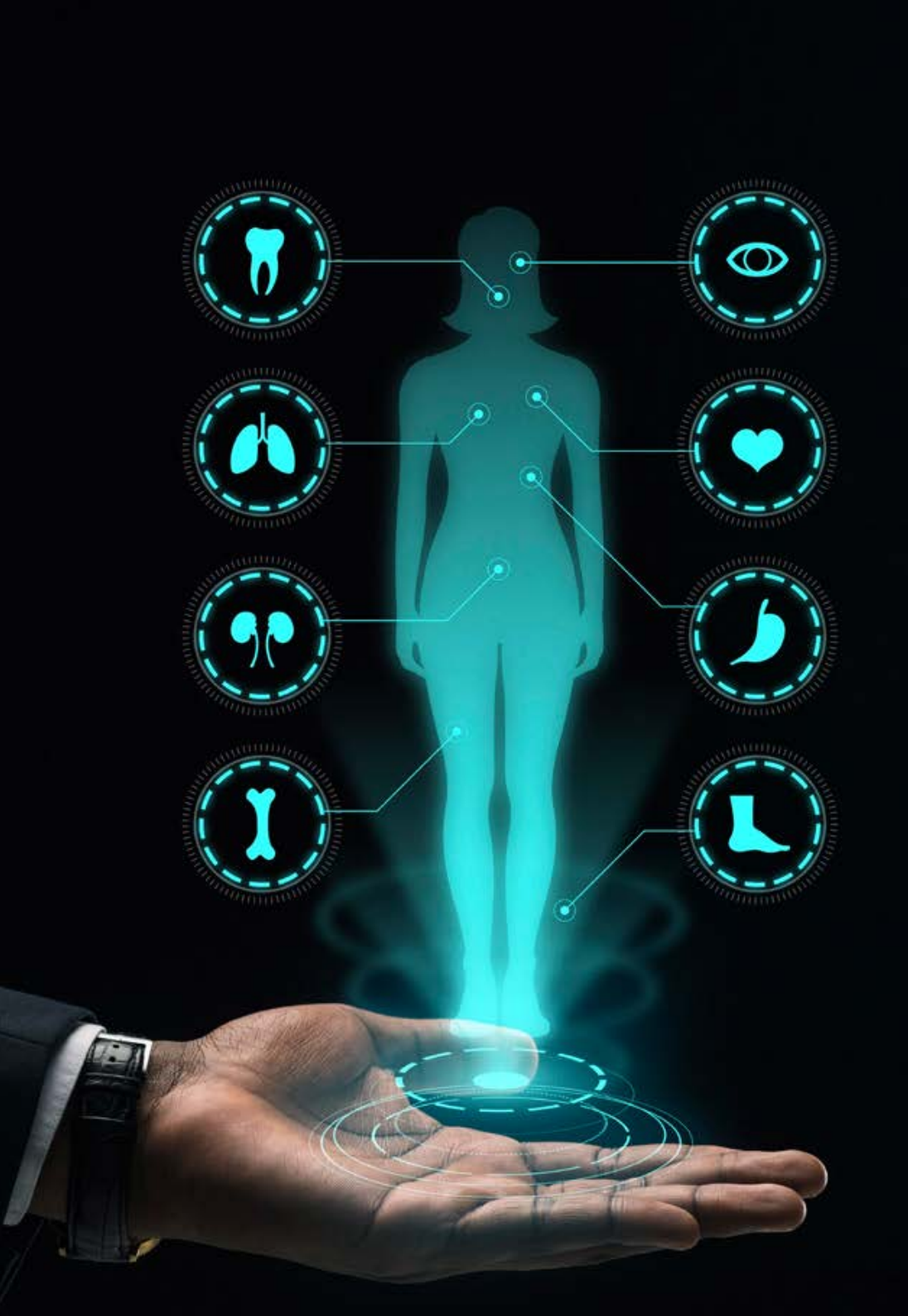
The use of edge AI in fall detection can be lifesaving for patients; medical

devices can analyze sudden movements, detect falls, and send real-time alerts to caregivers. This approach also acts as a preventative measure by predicting situations where falls might occur, thereby enhancing patient care and safety.

Leading chip manufacturers, including Nvidia, Qualcomm, and Intel, are at the forefront of edge AI technology, crafting specialized chipsets and software to unlock its full potential across industries. This development heralds a new era of accessibility and innovation for edge AI applications.

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# The Era of Non-Invasive Diagnostic Devices

Wouldn't you like to know what's happening inside your body at any given time? It's not science fiction any more, but reality made possible with non-invasive diagnostics.

Leveraging modern medical devices, patients or even healthy individuals can keep track of key health parameters. Today, it is possible to track blood sugar levels, cholesterol, and enzyme levels painlessly.

Non-invasive diagnostic devices are medical tools that diagnose health issues without puncturing or cutting the skin. Advancements in technology are expanding their capabilities beyond glucose monitoring to monitor various health indicators seamlessly. These devices offer

benefits such as increased patient comfort, reduced infection risk, and improved accessibility, revolutionizing connected healthcare.

Non-invasive imaging techniques like CT scans, MRI, and ultrasound scans provide structural and functional images for diagnosis without invasive procedures. They also play a vital role in cancer diagnosis and prevention, enhancing detection accuracy and lessening the social burden of the disease.

The future of non-invasive technology looks bright, especially with regulatory efforts actively prioritizing stringent evaluation, keeping the patient's safety above all else.

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## CASE STUDY

# FDA Class II Telehealth Examination and Diagnosis Device

Our client wanted to recreate the experience of an in-person clinician visit through a portable, modular telehealth examination device. The challenge involved achieving a compact form factor while integrating a dual-camera setup. A key objective was to capture detailed, high-resolution digital images of both the throat and the ear canal.

To achieve seamless connectivity between patients and clinicians, eInfochips worked with the client to develop a portable home examination kit. This innovative device featured multiple external adapters enabling comprehensive examination of the heart, lungs, skin, throat, ears, and body temperature. The telehealth solution was based on the Qualcomm® Snapdragon™ 410 processor and had a cloud-based repository for sharing and storing examination data.

The device hardware development encompassed the creation of schematics, layout files, PCB fabrication, and assembly, spanning the Alpha and Beta phases. The device achieved FDA class II compliance and adhered to stringent medical standards and processes.

### Regulatory & Compliance Support

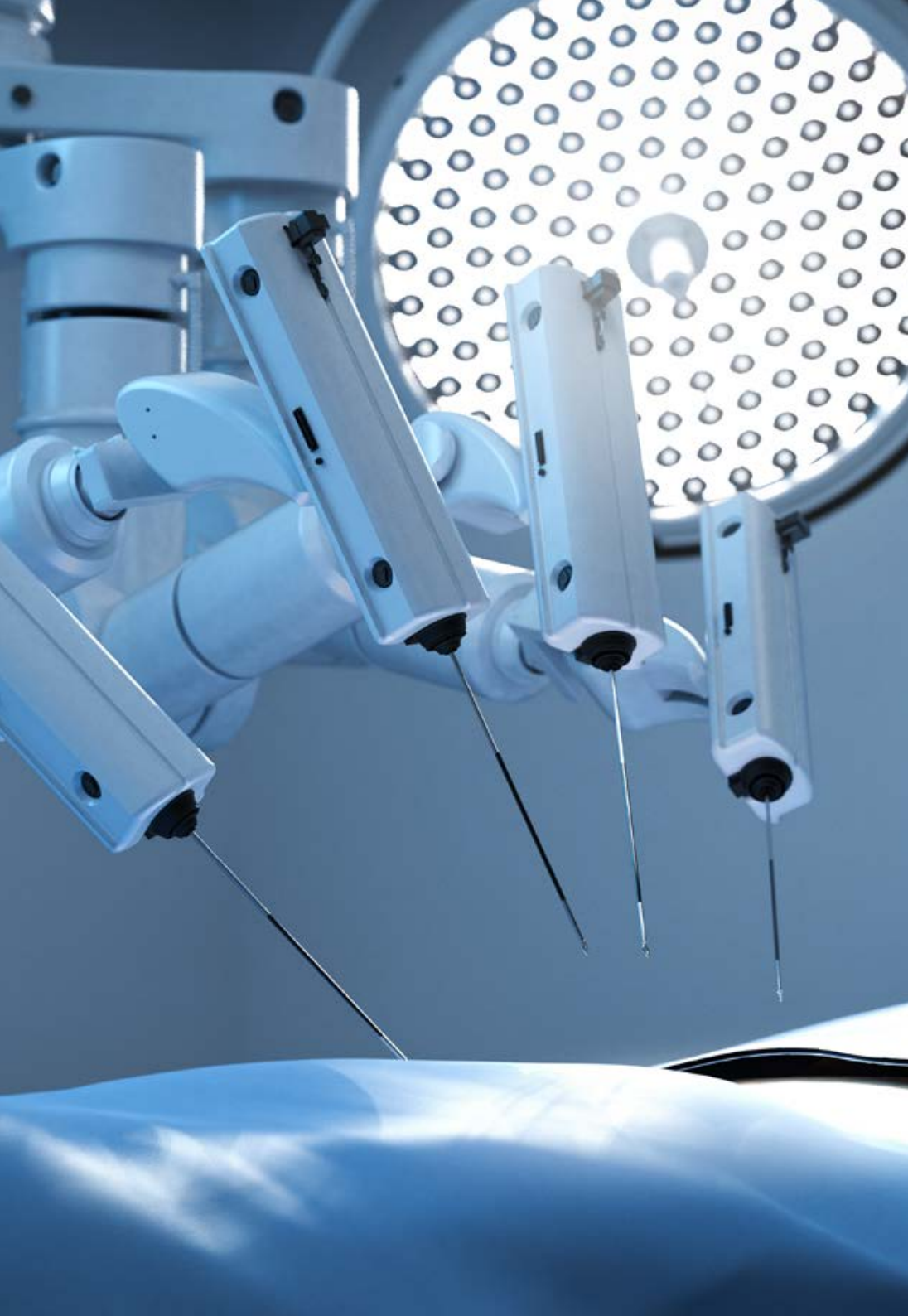
- ISO 13485:2016 (QMS for Medical Devices)
- IEC 62304 (Software Lifecycle Processes for Medical Devices)

### Benefits

- Shortened product development life cycle by leveraging in-house image tuning lab
- Episodic and longitudinal care delivered at home

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# Robots in Operation Theaters: The Future of Surgery

The medtech industry is undergoing a significant transformation with the rise of robot-assisted surgery (RAS), where computer-controlled surgical robots assist surgeons in performing minimally invasive procedures.

According to reportlinker.com, the market size of robotic-assisted surgery systems is expected to grow to USD 15.75 billion by 2028. A clinical trial led by scientists at UCL and the University of Sheffield displayed how RAS could be used for bladder cancer removal, and reconstruction. This resulted in patients spending 20% less time in the hospital.

A typical robotic-assisted surgery system comprises three main components:

- **Surgeon's Console:** Provides a magnified, high-definition view of the surgical site.

- **Patient Cart:** Positions the patient and holds the robotic arms.
- **Robotic Arms:** Equipped with surgical instruments that the surgeon manipulates from the console.

## **Benefits of Robotic-Assisted Surgery**

The system allows surgeons to operate with greater precision and control due to enhanced visualization and improved dexterity of the robotic instruments. This translates to potential benefits for patients, including faster recovery times, reduced risk of infection, less blood loss, and minimally invasive procedures with smaller incisions.

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# The Future of Medical Imaging: Powered by AI & ML Technology

Artificial Intelligence (AI) enables radiological systems to automate image processing workflow. AI algorithms not only improve anomaly detection by minimizing human errors, but also prove invaluable in early disease detection, especially for asymptomatic patients. Machine Learning (ML) algorithms further assist radiologists in achieving faster diagnoses by highlighting the potential issues in medical scans.

AI/ML algorithms can classify complicated datasets and images in a few seconds, compared to the hours spent in manual examination. Deep learning algorithms perform segmentation tasks in medical imaging analysis. They also help automate complex tasks performed by expert human observers.

While challenges such as ensuring data privacy, interoperability of AI models, and robust validation processes exist, the integration of AI/ML in medical imaging holds immense promise.

Additionally, radiomics, combined with machine learning techniques, can empower advanced decision-support systems for tasks like patient stratification, disease prediction, and prognosis. These advancements have the potential to revolutionize healthcare by enabling earlier diagnoses, more personalized treatment plans, and ultimately, improved patient outcomes.

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## CASE STUDY

# Image Control Technology for Minimally Invasive Spine Surgery

Achieving lower latency and handling the processing burden for high-quality imaging are the major challenges when it comes to developing image control devices. To address these challenges, a US-based healthcare company engaged eInfochips to develop an image control device for minimally invasive spine surgery. The goal was to achieve better visualization with minimal disruption for enhanced surgical outcomes.

eInfochips helped by translating the proof-of-concept (POC) into a commercial product. The team took complete ownership of the design and development including product architecture, hardware

design, firmware development, BOM analysis, and pre-compliance testing. The team worked on a custom carrier board design and integration with Qualcomm QCS8250 SOC.

### Regulatory & Compliance Support

- IEC 60601-2 (Electromagnetic Compatibility for Medical Devices)
- ISO 13485:2016 (QMS for Medical Devices)

### Outcomes

- Attained high-performance imaging latency of 4k@30 capture
- Achieved minimal glass-to-glass latency of <110ms
- Enhanced surgical outcome and patient safety



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# Compact Devices, Large Data: Addressing the Design Challenges of Medical Devices

As more people shift towards healthier lifestyles, there is a boom in the adoption of personal health devices and patient-focused applications. These medical devices enable consumers to monitor body vitals, diagnose symptoms, and manage daily medication.

According to the Grand View Research report, the portable medical device market size is expected to reach USD 85.3 billion by 2025 at a CAGR of 8.7%.

## **Miniaturization & Manufacturing**

While miniaturization improves portability and opens up new design possibilities, it presents numerous challenges: integration of smaller components, efficient power management, and manufacturing for mass production. Advancements in electronics design technologies such as multi-layer PCB design,

power management ICs, and wireless connectivity modules help to achieve reduced device size.

## **Multiple Sensor Integration**

Sensors are the key components of portable and at-home diagnostic kits. Integrating multiple sensors in a portable form factor is another major challenge in medical devices. Camera-enabled devices require effective image tuning for improved display of high-resolution images for diagnostic purposes.

## **Low Power Consumption**

Personal health devices such as wearables or connected therapeutic devices work on battery power. It is possible to achieve efficient power consumption by reducing the discrete design components. To ensure power saving, the firmware application design should enable regular sensor data transfer to the mobile application or cloud.

## **Wireless Connectivity Options**

To ensure seamless communication, medical devices use Bluetooth and LTE to send patient data to the cloud for analysis. However, this necessitates including multiple connectivity options in a small device and achieving reliable communication with limited power posing a challenge for design developers.

## **Security**

Portable medical devices need to be secure as they capture, store, and transmit the personal health information of an individual. These devices are prone to cyber-attacks as they are majorly used in the home or public network environments.

eInfochips can support device developers in resolving these challenges.

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# Internet of Medical Things and Connected Healthcare

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- Delivering Better Care with a Connected Ecosystem
- Case Study: Remote Monitoring Device for Incontinence Detection
- Securing Patient Data in the Age of Connected Devices
- Case Study: Edge AI Based Point of Care Ultrasound Diagnostic Device



# Delivering Better Care with a Connected Ecosystem

Internet of Medical Things (IoMT) creates a connected healthcare ecosystem, enabling the existing healthcare system to be more proactive. Connected healthcare holds immense potential to improve healthcare outcomes, reduce healthcare costs, and elevate the overall quality of care.

Connected healthcare makes remote and at-home diagnosis a reality, extending the horizon of doctors beyond the four walls of the hospitals. It enables continuous monitoring and streamlines communication between patients and healthcare providers.

IoMT is not just a boon for patients; it also offers a host of advantages to the healthcare industry. It helps streamline hospital operations, simplify insurance claim processes, and accelerate medical research.

From MRI and CT scanners to blood pressure and glucose monitoring devices, the applications of IoMT are vast and far-reaching. With each passing day, the healthcare sector inches closer to a new era of groundbreaking applications that will revolutionize the way we approach health and wellness.

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## CASE STUDY

# Remote Monitoring Device for Incontinence Detection

A UK-based digital-enabled homecare service provider wanted to develop an IoT device for incontinence detection. The device aimed to improve patient care and response time by sending alert to caregivers when incontinence was detected.

The client chose to work with eInfochips to implement an edge-to-cloud solution that ensured 24/7 monitoring and detection for urine and fecal incontinence. The project's scope included the complete hardware and mechanical and industrial design. The firmware was developed on the NXP ARM architecture MCU.

eInfochips leveraged a First Order Derivative (FOD)-based algorithm for ammonia level detection in the room. Azure cloud infrastructure enabled the analysis of real-time telemetry streams from medical devices. Additionally, the team leveraged the cross-platform React Native framework to develop a mobile application that provides a digital interface to manage devices, users, and tenants.

### Benefits

- 50% boost in staff efficiency
- Real-time alerts on the caregiver's mobile
- Improved hygiene outcomes for patients
- Reduced TCO with fully managed Azure PaaS services



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# Securing Patient Data in the Age of Connected Devices

The increasing use of Internet of Medical Things (IoMT) in the healthcare ecosystem opens new cybersecurity challenges as these devices are vulnerable to cyber-attacks. While connected medical devices offer convenience and quick access to care, there are a lot of challenges in the security of these devices.

Home care and telemedicine devices have default passwords and lack firewalls. Moreover, these devices are present in unsecure network environments making them vulnerable to cyber-attacks. Vital patient data is transferred from telehealth devices to hospitals via the Internet and thus, implementing communication security methods for secure data transfer is important.

Hospital care devices such as infusion pumps, ventilators, patient monitors, and

imaging systems, are also at risk of being hacked. Legacy devices with outdated operating systems are particularly vulnerable as they were not designed for exposure to external networks.

The article cites two real-world examples: the Ripple20 Vulnerabilities that affected millions of IoT devices, including medical devices, and the CT-GAN demonstrating how compromised hospital networks can lead to manipulation of 3D imagery.

Endpoint security, communication security, and version updates in legacy devices can help to achieve a secure environment for the medical device's ecosystem. By following these best practices, eInfochips can help healthcare companies secure their devices in the healthcare ecosystem.

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## CASE STUDY

# Edge AI Based Point of Care Ultrasound Diagnostic Device

A US-based medical devices company with expertise in AI-enabled scanning solutions developed the world's thinnest ultrasound tool. The challenge at hand was to develop a connected cloud platform and revamp the existing Android application, along with the need to use an open-source operating system supporting touchscreen devices.

eInfochips implemented an azure based cloud platform to enable deep-learning algorithm development. For the front end, the team developed an Android application to display high-level imaging on a touchscreen medical tablet.

The solution included a remote device management platform that

enabled rapid provisioning and OTA firmware updates of the device in the field. A machine learning-based diagnosis recommendation feature was also implemented on the platform. In addition, a HIPAA-compliant web portal was designed for remote ultrasound test reviews, managing education workflow, and providing performance analytics.

### Benefits

- 60% reduction in cloud consumption costs compared to traditional solutions
- 10x Improvement in Image Quality at 1/10th of the Cost
- 54% reduction in test cycle time through automation, with 65% feature coverage
- Expanded product deployment to 4+ diverse geographies



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A person's arm is shown wearing a purple smartwatch. The watch is surrounded by several semi-transparent digital health data overlays. At the top center, a red heart icon is next to the text '78 bpm'. Below this is a white ECG waveform. To the right, there is a bar chart with the number '23' below it. Further right, a clock icon is next to some small, illegible text. On the left side of the watch, a white box contains a line graph and the text 'MIN: 62 bpm' and 'MAX: 162 bpm'. To the right of the watch, another white box contains a red heart icon and the text '117 bpm'. The background is a solid blue color with some faint white dots.

# Digital Health: A New Reality in Healthcare

- How the Digital Shift is Improving Access to Care
- The Growing Impact of mHealth Solutions on Patient Care
- Case Study: Healthcare Mobile Application Development and Cybersecurity Testing
- Key Considerations for Implementing Unified Digital Health Platforms
- Enabling Advanced Diagnostics with Software as a Medical Device
- Case Study: SaMD Platform for Connected ICUs



# How the Digital Shift is Improving Access to Care

The rise in chronic diseases, growing elderly population, and shortage of healthcare professionals have led to an amplified strain on the healthcare systems globally. Additionally, with the penetration of technology in our day-to-day lives, patients seek a more customized healthcare experience.

The adoption of smartphones and wearable devices are also driving digital health innovation. Wearable devices enable patients to track their health data in real-time and actively take part in their well-being.

Digital health offers numerous benefits across the healthcare ecosystem. Telehealth systems

make appointment scheduling and communication with doctors accessible and convenient for patients. They benefit patients by enabling care from home or on the go, saving time and money.

This digital shift in healthcare empower doctors to quicken the diagnoses and make data-driven healthcare decisions. The transformation can help healthcare institutes optimize workflows, improve operational efficiency, and scale down the ever-increasing workload.

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# The Growing Impact of mHealth Solutions on Patient Care

mHealth or mobile health refers to healthcare applications that serve both patients and healthcare providers equally. They allow patients to check their symptoms, track vitals, access data through wearables, and seek medical assistance virtually. These apps also help doctors in enhancing the diagnosis, monitoring, and treatment of patients.

The market for mHealth solutions is booming, driven by increasing smartphone use, remote care needs, and improved internet connectivity. There are diverse types of mHealth applications available based on their application and target audience.

**Telehealth apps** virtually connect patients and doctors - anytime, anywhere. These applications help patients to schedule appointments and receive treatments, eliminating travel and wait time.

**Remote monitoring apps** capture real-time patient data through medical devices or wearables, allowing healthcare providers to track vitals and intervene when necessary.

**Treatment adherence apps** help patients stay on track with daily medication doses, can schedule reminders, and can even teach patients to use inhalers or injectors.

The development of mHealth applications comes with a range of challenges that need to be addressed. Firstly, these apps must be able to work seamlessly with various third-party devices and healthcare IT systems, enabling interoperability for effective use. Secondly, given that these apps handle sensitive health information of individuals, data security becomes paramount and should be implemented rigorously to safeguard patient privacy. Lastly, it is crucial to design the apps in a user-friendly manner, taking into consideration the needs of elderly patients and making

sure they are easily accessible and intuitive to navigate.

eInfochips can help health companies develop native and cross-platform mobile applications in diagnostics, monitoring, and telehealth domains.

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## CASE STUDY

# Healthcare Mobile Application Development and Cybersecurity Testing

A US-based pharmaceutical company wanted to create a mobile app that would serve as a patient assistant, providing features like:

- Reminder setup for medication adherence
- Treatment tracker to monitor progress
- Report generation for easy data sharing with healthcare providers

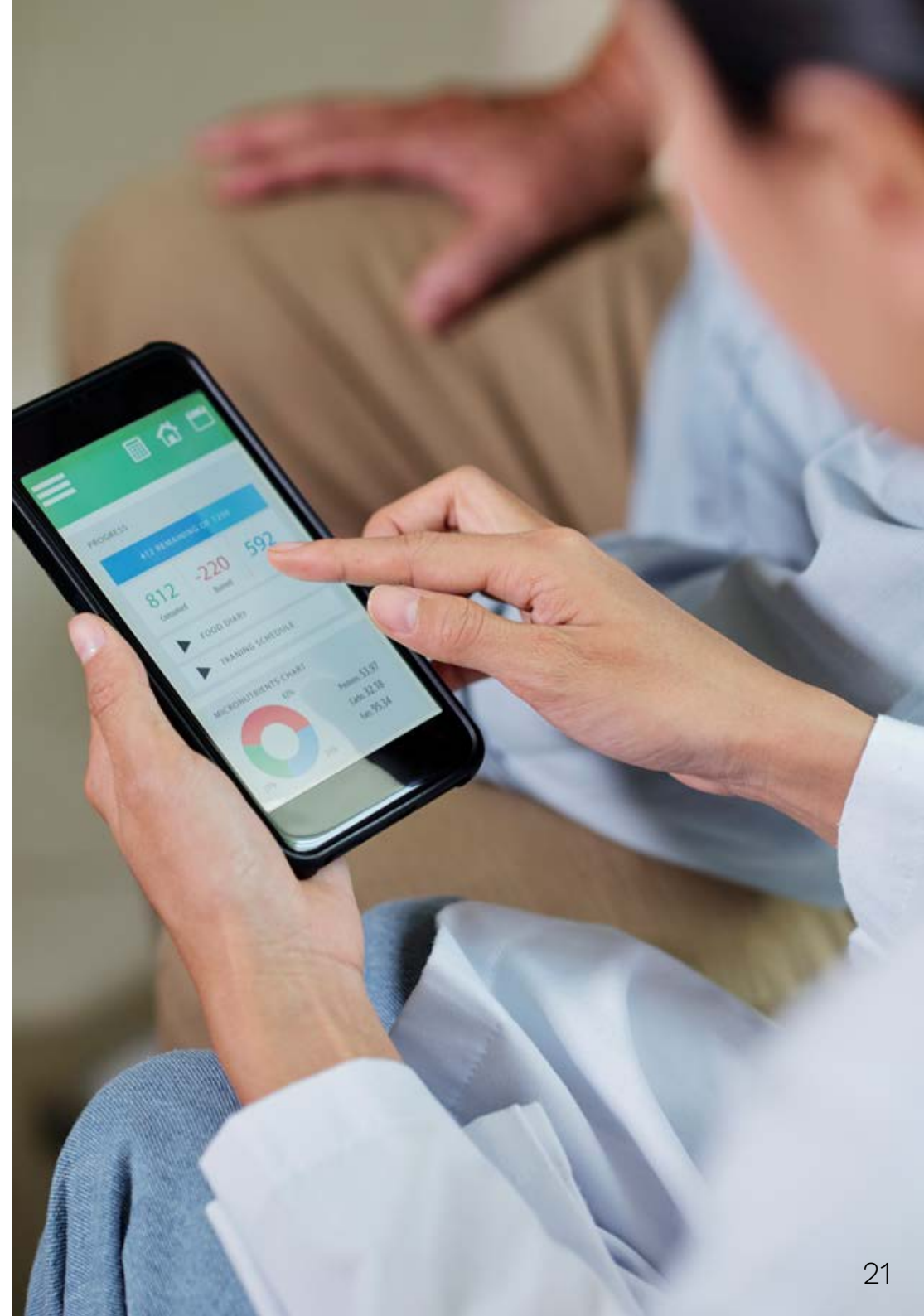
Infochips developed a native mobile application for both Android and iOS platforms. The team prioritized security by conducting thorough testing using Threat Modeling and Vulnerability Assessment & Penetration Testing (VAPT). This ensured compliance with critical regulations, including Pharmaceutical Good Practices (GxP) and OWASP security standards.

### Tailored for Patients with Respiratory Conditions

Recognizing the target audience's needs, the app incorporates an additional feature: displaying location-specific Air Quality Index (AQI) data fetched via the ClimaCell API. This empowers patients to make informed decisions about medication use based on environmental conditions.

### Benefits for Patients

- **Extended useful life of inhaling devices:** Improved adherence can lead to more efficient use of medication.
- **Enhanced patient experience:** User-friendly features promote better medication management.
- **Improved clinical outcomes:** Better monitoring and adherence can lead to positive treatment results.



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# Key Considerations for Implementing Unified Digital Health Platforms

Digital health platforms seamlessly integrate patient data from various devices into the cloud. This data is then analyzed to provide real-time insights, improve decision-making, and ultimately deliver better care.

However, the successful implementation of a digital health platform requires careful consideration, especially when choosing a cloud platform. Here are some factors to keep in mind:

## **Cloud Partner Selection**

Choosing the right cloud platform is crucial to avoid possible pain points down the line. Considering factors such as security, compliance, migration strategy, support services, and cost, can help in sound decision-making.

## **Cross-Domain Expertise**

A dedicated team with expertise across software development, cloud architecture, regulatory compliance, and data security is essential to developing a digital health platform.

## **Quality Management System (QMS) and Documentation**

A robust quality management system ensures that the platform meets regulatory requirements and facilitates a smooth market launch. Additionally, it is essential to create and maintain documentation of design history and risk management files, in compliance with ISO 13485, IEC 62304, and FDA SaMD standards.

## **External and Partner System Integration**

A core function of digital health platforms is the seamless integration with various external systems such as EHRs, insurance provider systems, payment institutions, and supply chain systems. The platform should support different data formats and be compatible with HL7 standards to ensure smooth data flow.

## **Data Privacy and Security**

Digital health platforms manage sensitive patient data. The platform must prioritize robust security measures and ensure adherence to data privacy regulations such as HIPAA and GDPR.

## **Maintenance and Scalability**

As the platform scales, maintaining a secure and reliable environment becomes a challenge. The platform should be able to manage the large cloud infrastructure and ensure end-to-end security, reliability, and uptime.

eInfochips provides end-to-end services to develop digital health platforms for applications such as remote patient monitoring, home diagnostics, wearables, consumer health devices, and many more.

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# Enabling Advanced Diagnostics with Software as a Medical Device

Software as a Medical Device (SaMD) is a term first coined by the International Medical Device Regulatory Forum (IMDRF). In simple terms, SaMD is software designed for medical purposes, independent of any device, and is categorized based on (i) the significance of the output for medical decisions and (ii) the criticality of the conditions.

SaMD can leverage AI/ML technology to analyze a variety of multi-modal data. SaMD can analyze image streams from various sources like X-ray scans, CT scans, and MRIs to detect abnormalities and guide initial treatment decisions.

SaMD's potential extends beyond images. They can also analyze non-image data streams like audio recordings and biochemical test results. By analyzing this diverse medical data, SaMD can even predict life-threatening conditions.

Recognizing the importance of patient safety and data transparency, regulatory bodies are actively developing guidelines and best practices for SaMD development.

Read the full article to explore this evolving field in more detail and discover the key considerations shaping the future of SaMD.

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the full article





## CASE STUDY

# SaMD Platform for Connected ICUs

A Germany-based global pharmaceutical and life sciences conglomerate wanted to develop a digital solution to bring together patient's vital parameters, imaging, non-imaging lab reports, and diagnostics devices. The goal was to enable a real-time critical care clinical decision support system to provide adequate care and reduce mortality and morbidity.

To address the challenge, elfnochips crafted a solution blueprint that included architecture design, an implementation roadmap, and a comprehensive regulatory compliance strategy. A real-time dashboard was designed to display pre-conditions,

recommendations, alerts, notifications, and medical history snapshots. The team integrated hospital data pipelines to develop a web application prototype to create insight-driven visual dashboard for medical practitioners. By utilizing cloud-native services, data protection and security were achieved.

### Benefits

- Enabled swift diagnosis
- Quick access to critical illness case details and history

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## The Road Ahead

A Perspective on the Future of Medical Devices and Healthcare

# Smart Healthcare Wearable Devices to Improve Patient Care & Clinical Efficacy

Since 2020, the smart healthcare wearable market has been witnessing a 25-30% YoY growth. Medical devices such as smart watches, wearable monitors, and fitness trackers help in continuous monitoring of vitals and seamless data streaming for healthcare analytics. In a connected ecosystem, this data plays a key role in enabling Remote Patient Care, Robotic Assisted Surgeries (RAS), AI-based healthcare solutions, and AR/VR based healthcare solutions.

Smart wearables not only require silicon, digital, and embedded domain experience, but they also require expertise in miniaturization,

low-power electronics, and regulatory compliance. This makes product development complex and challenging.

Our partnerships across the ecosystem from silicon to cloud, help us simplify this journey for our client. These partnerships grants us early access to technology, as well as insights and deep tech support from our partners. This in turn means we can help you shorten the product development lifecycle (PDLC).

Infochips has in-depth experience in product design and development of FDA Class I and Class II medical devices for monitoring, diagnostics

& imaging, wearable health, and telemedicine. Our in-house Quality Management System (QMS) is ISO 13485 Certified and we are in the process of being FDA 21 CFR Part 820 compliant.

I invite you to have a conversation with me and my colleagues to explore how we can accelerate and simplify your product development journey.

## Anal Dharamshi

Subject Matter Expert  
- Healthcare





# Thriving in the New Healthcare Landscape with Comprehensive Solutions

Around the globe, the healthcare sector is undergoing a seismic shift. In contrast to being passive care receivers, patients are taking a more active role in managing their health.

Companies in the healthcare ecosystem face challenges of rising costs, traditional model disruptions due to digital technology, and evolving patient expectations. These scenarios present a significant challenge but offer a golden opportunity for healthcare companies to excel. To thrive in this rapidly transforming sector, healthcare organizations must prioritize digital solutions and build a collaborative ecosystem.

elnfochips stands at the forefront of this exciting new era by driving patient-centered healthcare through data-powered solutions.

Our dedicated team of healthcare domain experts had developed cutting-edge medical devices and secure digital health platforms with a proven track record of success in delivering innovative solutions to clients.

Our focus on innovation, quality, and scalability helps clients accelerate time-to-market, enhance product performance, and navigate the ever-changing healthcare landscape.

As a turnkey engineering service provider, elnfochips is committed to supporting healthcare organizations in building a more patient-centered, efficient, and accessible healthcare system for all.

**Purva Shah**

Product Marketing Manager  
- Healthcare



# A Peek into the Capabilities of eInfochips in the Healthcare Domain



## Product Engineering Service Offerings



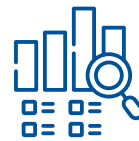
### Create

- Ideation & Engineering
- Certification Support
- Manufacturing



### Connect

- Digital Backbone
- Connected IoT Platform
- Cloud



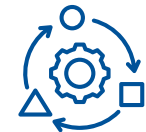
### Analyze

- AI/ML
- Edge Computing
- Data Science
- BI & Dashboards



### Manage

- CloudOps
- DevOps
- Device
- Firmware



### Sustain

- L2-L4 Support
- Enhancements
- Localization
- VA/VE

Risk Assessment, Threat Modelling, Vulnerability Analysis, Penetration Testing, SOC

# Regulatory and Process Expertise

## Development Processes

### ISO 13485:2016

Medical Devices QMS

### ISO 14971

Risk Management

### IEC 62304

Medical Device Software Lifecycle

### IEC 62366

Usability Engineering

### FDA 21CFR 820.30

Design Control Requirements



## Regulatory Standards

### IEC 60601-1 & Collateral Standards

Safety and Essential Performance of Electrical Medical Equipment

Particular Standards like:  
IEC 80601-2-26 for EEG

## HIPAA Compliance



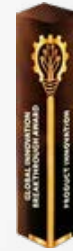
# Awards & Accolades Received by eInfochips



“The Premier Healthcare Alliance Award” winning solution for Drug Delivery & Management



ISG Digital Case Study Awards™ 2022 and 2023 for our best-in-class Digital Healthcare Solutions



NASSCOM Spotlight Awards 2023 for Connected Healthcare Solution



Award winning Point-of-Care Telehealth Solutions for Remote Patient Diagnostics




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## About eInfochips

eInfochips, an Arrow Electronics company, is a leading provider of digital transformation and product engineering services. eInfochips accelerates time to market for its customers with its expertise in the areas of IoT, AI/ML, security, sensors, wireless, cloud, and power. eInfochips has been recognized as a leader in Engineering & R&D services by many top analysts and industry bodies, including Gartner, Zinnov, ISG, IDC, NASSCOM, and others.

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