

# Software-as-a-Medical-Device (SaMD) & Connected Health

## PHARMACEUTICAL & MEDICAL DEVICES INDUSTRY

Healthcare is shifting from episodic treatment to continuous, data-driven care. In this new paradigm, software is no longer an accessory to medical devices—it is a core clinical asset. The rapid rise of Software-as-a-Medical-Device (SaMD) and connected health ecosystems is transforming how care is delivered. Devices such as smart inhalers, insulin pumps, and wearable diagnostics now generate real-time patient data, feeding into clinical systems to enable proactive intervention and personalized treatment.

At the same time, regulators are increasing scrutiny on cybersecurity, data integrity, and AI governance—including global frameworks like the EU AI Act. Organizations must now balance innovation speed with clinical-grade trust and compliance. A leading healthcare technology company recognized that future competitiveness would depend on its ability to evolve from hardware-centric products into integrated, software-driven care platforms.



### Real-Time Monitoring

Continuous patient data from connected devices



### Recurring Revenue

Performance-as-a-Service business models



### OTA Updates

Continuous software delivery over the air



### AI Decision Support

AI-enabled clinical intelligence at scale

Transforming devices into continuous, intelligent care systems — **Fortis & Peak**



# The Strategic Challenge

The organization could build devices—but could not transform them into connected, intelligent care platforms. Five critical barriers stood between their hardware-centric model and the future of digital health. These challenges spanned technology architecture, regulatory compliance, data strategy, and operational scalability—each compounding the others and limiting the organization's ability to compete in an increasingly software-defined healthcare landscape.

## The Core Problem

A hardware-centric business model with limited post-sale engagement meant the organization had no mechanism to deliver ongoing value, capture patient data, or evolve its products after deployment. Devices were sold, not sustained.

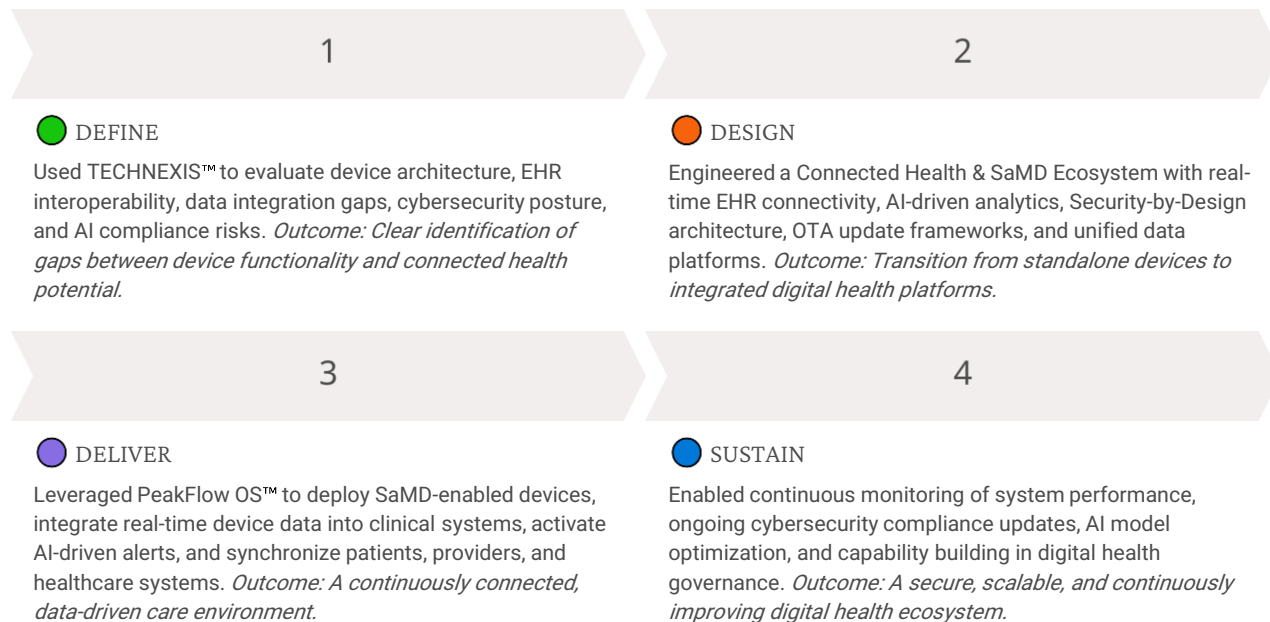
Without interoperability between devices, software, and clinical systems, fragmented patient data limited clinical insights and prevented the kind of proactive, personalized care that modern healthcare demands.

## Five Critical Barriers

- **Hardware-centric model** with limited post-sale engagement
- **Lack of interoperability** between devices, software, and clinical systems
- **Increasing cybersecurity** and regulatory requirements
- **Fragmented patient data** limiting clinical insights
- **Difficulty scaling** software updates and AI capabilities safely

# Transformation Powered by 3D&S + TECHNEXIS™ + PeakFlow OS™

Fortis & Peak deployed a structured four-phase transformation methodology—Define, Design, Deliver, Sustain (3D&S)—powered by two proprietary platforms: TECHNEXIS™ for digital health engineering and PeakFlow OS™ for real-time care orchestration. Together, these tools enabled a comprehensive evolution from standalone hardware to an intelligent, continuously connected care ecosystem.



# Core Platforms & Transformation Architecture

Three integrated layers power the full transformation—from engineering and orchestration to execution. TECHNEXIS™ serves as the digital health engineering engine, PeakFlow OS™ as the real-time care orchestration platform, and 3D&S as the overarching execution framework. Together, they replace the traditional reactive care model with a continuously intelligent one.



TECHNEXIS™

## Digital Health Engineering Engine

- Designs secure, interoperable SaMD architectures
- Embeds cybersecurity and compliance into system design
- Integrates devices, software, and clinical systems seamlessly



PeakFlow OS™

## Real-Time Care Orchestration Platform

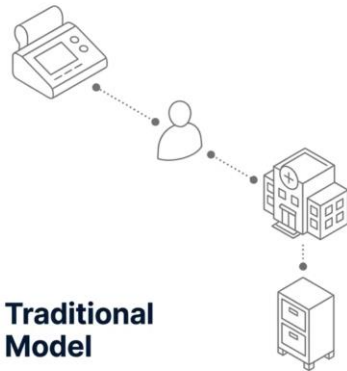
- Enables continuous data flow between devices and healthcare systems
- Coordinates real-time monitoring, alerts, and interventions
- Supports scalable, patient-centric care delivery



3D&S Framework

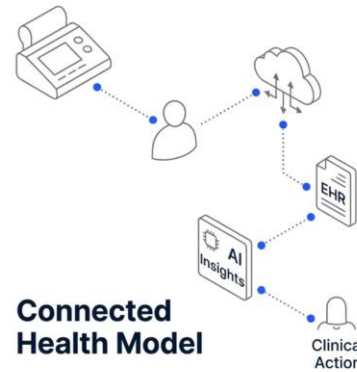
## The Execution Methodology

- DEFINE: Identify digital health and interoperability gaps
- DESIGN: Architect SaMD and connected care systems
- DELIVER: Deploy real-time, AI-enabled health platforms
- SUSTAIN: Continuously optimize performance and compliance



## Traditional Model

Periodic Visits, Limited Data,  
Reactive Care



## Connected Health Model

Real-Time Data, EHR,  
AI Insights, Clinical Action

# Measurable Impact & Strategic Positioning

FORTIS & PEAK

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The transformation delivered measurable outcomes across clinical, operational, and commercial dimensions. Patients benefit from continuous monitoring and early intervention, improving outcomes and deepening engagement with their care teams. The organization successfully transitioned to recurring, service-based revenue models—unlocking long-term commercial value beyond the point of sale. Enhanced compliance with global cybersecurity and regulatory standards reduced risk, while a scalable platform positioned the organization for future AI-driven healthcare innovation.

In the future of healthcare, value is not delivered at the point of care—it is delivered continuously, through intelligent systems that monitor, predict, and intervene in real time.

## ✓ TECHNEXIS™ Creator

Digital health and engineering innovation platforms that architect secure, interoperable SaMD solutions

## ✓ PeakFlow OS™ Owner

Real-time healthcare orchestration systems enabling continuous, patient-centric care delivery

## ✓ 3D&S Methodology

Execution-driven transformation framework: Define, Design, Deliver, Sustain

## ✓ AI-Powered Healthcare

A leader in enabling secure, AI-powered, and platform-driven healthcare at scale



Fortis & Peak transforms medical devices into connected, intelligent care ecosystems – positioning clients as leaders in the next generation of digital health. Contact: [info@fortisandpeak.com](mailto:info@fortisandpeak.com) | [www.fortisandpeak.com](http://www.fortisandpeak.com)

