The Interoperability Trap

Why the Industry Tried to Standardize the Device — When It Should Have Standardized the Platform

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The Promise of Continua

Around 2006, Intel and a group of major medical device manufacturers looked at the healthcare interoperability problem and came to a reasonable conclusion: if medical devices could all speak the same language, healthcare systems could connect to any device from any manufacturer and the data would flow seamlessly into the clinical record. No custom integration. No proprietary protocols. One standard. Universal interoperability.

The organization they created was called the Continua Health Alliance, formally launched in San Francisco on June 6, 2006. Intel had been developing the concept for about a year prior, and the idea was powerful enough to attract an extraordinary coalition. The founding members included Intel, Philips, Panasonic, GE Healthcare, IBM, Medtronic, Motorola, Cisco, Samsung, Sharp, and Welch Allyn, along with healthcare providers like Kaiser Permanente and Partners HealthCare. Eventually, nearly 240 companies — many of them Fortune 100 and Fortune 500 — joined the alliance, pledging to develop common standards and interfaces that would allow medical devices, wired or wireless, to communicate on a standardized data exchange layout. If you were building a blood pressure monitor, a glucose meter, a pulse oximeter, or a scale, you would implement the Continua standard. If you were building an EHR or a clinical platform, you would accept Continua-formatted data. The devices would talk. The systems would listen. The patient data would flow.

It was the right problem. It was an elegant vision. And it failed.

Why Device-Level Standardization Failed

The failure was not technical. It was structural. Three forces conspired to undermine the Continua vision from the inside.

The competitors did not want to help each other. The companies that joined Continua were, in many cases, direct competitors. The blood pressure monitor manufacturer sitting at the standards table was being asked to help create a protocol that would make it trivially easy for hospitals to switch to a competitor's device. The glucose meter company was being asked to eliminate the proprietary data format that locked clinics into its ecosystem. In theory, everyone benefited from universal interoperability. In practice, every company at the table had a business reason to slow the process down, water down the requirements, or ensure that the standard happened to favor its own architecture. The result was what always happens when competitors write standards together: the process became political, the timelines stretched, and the output reflected compromise rather than clarity.

The protocols became bloated. Standards written by committee have a gravitational pull toward complexity. Every participant wants their use case accommodated. Every edge case gets a field. Every optional feature gets a flag. The Continua protocols grew into elaborate, comprehensive specifications that were technically impressive and operationally impractical. The problem was physics. The devices that needed to implement these protocols were small, battery-powered, and built around tiny processors with minimal memory and storage. A blood pressure cuff running on a coin cell battery does not have the CPU cycles to negotiate a complex handshake protocol. A wireless scale does not have the storage to maintain a full Continua stack. The protocols that looked elegant on a whiteboard consumed more resources than the devices had to give. The specifications blew out the hardware budgets.

FDA clearance became a wall. This was the factor that most people outside the device industry did not understand, and it was the one that killed adoption most effectively. Medical devices are cleared by the FDA under specific configurations. The software, the firmware, the communication protocols, and the data formats are all part of the cleared configuration. When you change the communication protocol on a cleared device — when you replace a simple, proprietary Bluetooth

data packet with a complex Continua-compliant protocol stack — you have changed the device. And when you change a cleared device, you must submit a new 510(k) clearance to the FDA.

For a device manufacturer that has held FDA clearance for years, possibly a decade or more, this was not a minor inconvenience. It was an existential risk. Opening a cleared device for re-submission means months of regulatory process, hundreds of thousands of dollars in testing and documentation, and the possibility — however small — that the FDA finds something in the new submission that triggers additional requirements. A device that has been selling profitably for years, with a stable clearance, suddenly becomes a regulatory project with an uncertain timeline and an uncertain outcome.

No rational device manufacturer would accept that risk voluntarily. And most did not.

The result was an industry that agreed in principle that interoperability was essential and discovered in practice that the approach — standardizing at the device level — was architecturally wrong. You cannot solve interoperability by forcing every device manufacturer to change their hardware, their firmware, their protocols, and their FDA clearance. The cost is too high, the risk is too great, and the competitive incentives are misaligned.

The Insight: Standardize the Platform, Not the Device

The Continua experience taught those of us who were building connected health systems in that era a lesson that reshaped how we thought about architecture: the interoperability problem is real, but the solution is in the wrong layer.

Asking every device manufacturer to change their device is asking thousands of companies to modify thousands of products, each with its own engineering constraints, its own business model, and its own regulatory clearance. It is the hardest possible way to solve the problem. It requires coordinated action from competitors who have every incentive not to cooperate, implemented on hardware that cannot accommodate the complexity, and approved by a regulatory body that was not designed for rapid iteration.

There is an easier way. Instead of changing every device, you change one thing: the platform.

The platform sits between the devices and the clinical systems. It faces downward toward the devices and speaks their language — whatever language that is. Every proprietary Bluetooth protocol. Every manufacturer-specific data packet format. Every legacy serial interface and every modern BLE characteristic. The platform absorbs the diversity. It learns each device's native tongue.

Then the platform faces upward toward the clinical systems and speaks one language: a standardized, normalized, interoperable data format. Today, that format is FHIR — Fast Healthcare Interoperability Resources — the modern standard for healthcare data exchange. Every reading, from every device, from every manufacturer, arrives at the EHR in the same structure, with the same coding, in the same format. The clinician does not know or care which manufacturer built the blood pressure cuff. The data looks the same.

This is the architectural insight that Continua missed and that CloudCare was built on. The platform takes the hit, not the device.

How CloudCare Solves What Continua Could Not

CloudCare interfaces with more than 550 medical devices — and the number grows by the month. Blood pressure monitors from a dozen manufacturers. Glucose meters with proprietary data formats. Pulse oximeters that transmit over Bluetooth Classic, BLE, and cellular. Scales that send weight readings in kilograms and others in pounds. Thermometers with different precision ranges. Wearables with continuous data streams. Rapid diagnostic devices with binary results.

Not one of these devices has been modified to work with CloudCare. Not one manufacturer has been asked to change their protocol. Not one FDA clearance has been reopened. The devices ship exactly as they were designed, exactly as they were cleared, exactly as they have been for years. They do not know CloudCare exists.

CloudCare knows they exist. The platform's First Mile data pipeline includes a device abstraction layer that understands the native protocol of each connected device. When a reading arrives — in whatever format the manufacturer chose, over whatever wireless protocol the device supports — the abstraction layer translates it into a normalized internal format. That normalized data then flows through the CareSignals.ai analytics layer, through the Personalyze™ engagement engine, and up through the FHIR integration layer into the clinical system.

The clinician sees a blood pressure reading. It looks the same whether it came from an Omron, a Withings, a Welch Allyn, or a device from a manufacturer they have never heard of. The reading arrives with the correct LOINC code, the correct units, the correct patient reference, and the correct device reference. It drops into the EHR as if it had been entered by a nurse at a bedside terminal.

This is what interoperability actually looks like at scale. It is not a standard that every device must implement. It is a platform that absorbs every device's native behavior and outputs a common, standardized record layout. The complexity is centralized in one place — the platform — instead of being distributed across thousands of devices that cannot afford it, do not want it, and cannot survive the regulatory consequences of implementing it.

Why This Matters for the Convergence

The Continua story is not ancient history. It is a cautionary tale that the industry is at risk of repeating.

As AI transforms healthcare, there will be enormous pressure to standardize AI model interfaces, data formats, and integration protocols. Standards bodies will convene. Committees will form. Fortune 500 companies will pledge cooperation while protecting competitive advantage. The process will produce specifications that are comprehensive, complex, and impractical to implement on the systems that need them most.

The lesson of Continua is that standardization works when it happens at the platform layer, not at the endpoint layer. You do not ask every AI model to output data in the same format. You build a platform that accepts every AI model's native output and normalizes it. You do not ask every device manufacturer to implement the same protocol. You build a platform that speaks every device's language. You do not ask every EHR to accept data in the same way. You build a platform that translates into whatever format each EHR requires.

The platform absorbs the change. The platform absorbs the complexity. The platform absorbs the diversity. Everything above it and below it can remain exactly what it is.

This is not just an engineering principle. It is a business principle. A health system that adopts a platform-level interoperability approach is not locked into any single device manufacturer, any single AI model, or any single EHR vendor. They can swap devices when better ones emerge. They can upgrade AI models when new capabilities arrive. They can even change EHR systems — the most painful transition in healthcare IT — without losing their entire connected care infrastructure.

The device does not change. The AI model does not change. The EHR does not change. The platform shape-shifts to connect them all.

That is the lesson Continua taught us. That is the architecture CloudCare was built on. And that is why the platform layer — not the device layer, not the AI layer, not the EHR layer — is where the value accrues in connected healthcare.