

Case Study



When a product's architecture absorbs regulation: Building artificial intelligence and privacy by design into a contactless patient monitoring system

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When developing medical systems driven by artificial intelligence (AI), companies must navigate technical, market, privacy, and regulatory expectations. And during this process, regulations are often treated as constraints to be managed after product development. The Swiss health tech company QUMEA took a different approach when it developed its contactless patient monitoring system: it included regulation as a design parameter from day one. This approach shaped the system's architecture, capabilities, and market position. Moreover, integrating regulatory considerations from the beginning of the development process helped the company better tackle subsequent regulatory requirements and commercial decisions. In this case study, QUMEA describes how it turned regulatory requirements into a competitive advantage by treating them as design inputs instead of hurdles.

Laying the foundation for a successful design concept

QUMEA originated in one of the most challenging clinical monitoring settings: hospital wards caring for patients with delirium. These patients are amongst the most vulnerable and face an elevated risk of falls, pressure injuries, and rapid clinical deterioration. Therefore, they require close, continuous observation. Yet conventional monitoring approaches are problematic in ways that go beyond resource constraints.

The default solution is to use patient sitters, who are staff assigned to observe a single patient around the clock. This solution is not only costly and hard to staff but, more importantly, the visible presence of an unknown observer can trigger or reinforce paranoid ideation, agitation, and distress in patients experiencing delirium, making this approach clinically counterproductive. More modern approaches such as camera-based and optical monitoring systems also pose this problem: patients may still be aware of the device. The resulting sense of being watched can exacerbate the very symptoms the monitoring is intended to manage. In addition, substantial data protection and ethical concerns accompany any system that captures imagery in a clinical environment, especially where patients are most vulnerable.

The fundamental question at QUMEA was whether contactless, continuous, and clinically meaningful patient monitoring could be achieved without these negative effects: without the system producing personal data and without the patient feeling observed. At its core, this question – posed even before the first line of code was written – was about what ethical AI in a clinical setting requires.

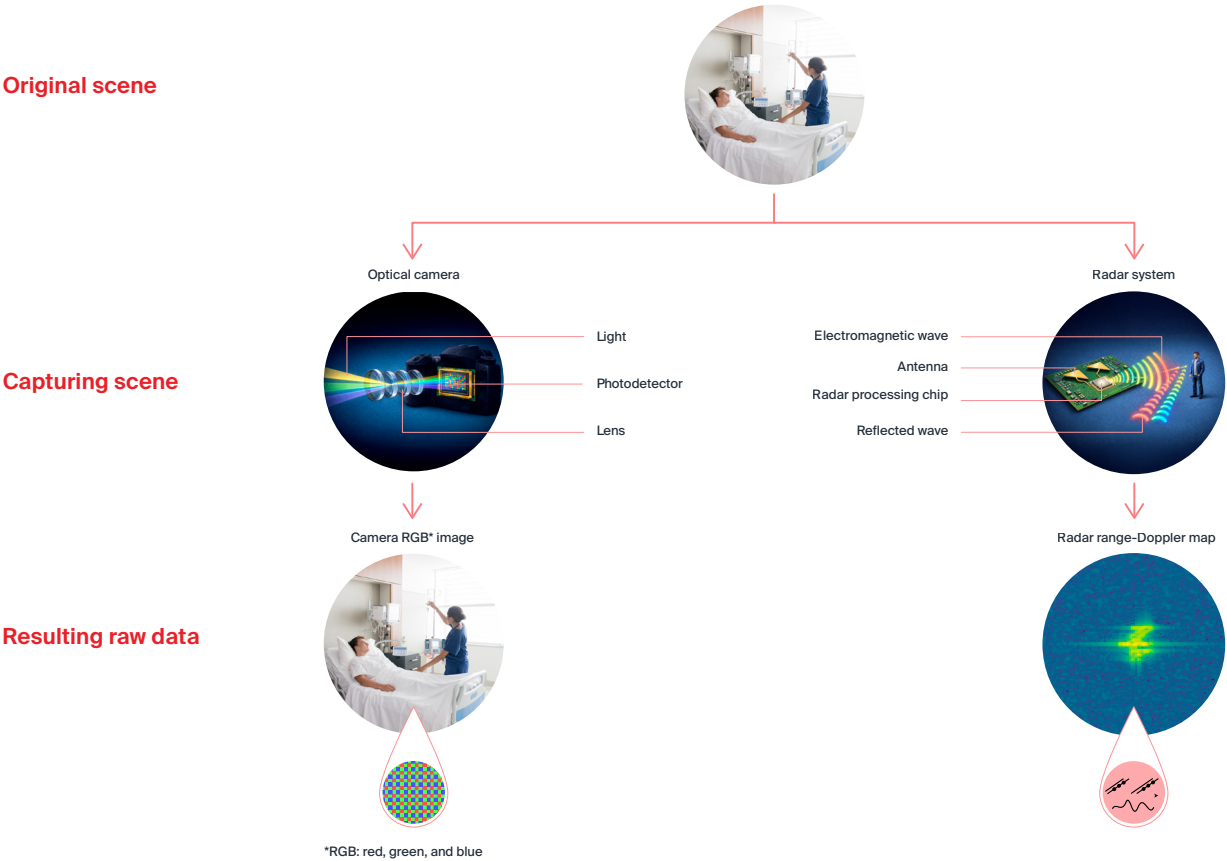
Radar: How one sensor shaped an entire system's architecture

To address the challenge of building a monitoring system that is intrinsically anonymous and that by design does not produce any personal data, QUMEA chose to use frequency-modulated continuous-wave (**FMCW**) radar sensors. FMCW radar transmits radio-frequency chirps and captures reflected signals across multiple antenna pairs. The raw output consists of range-Doppler tensors, which are complex numerical arrays that encode reflecting signal amplitude and phase of a moving surface across distance and velocity dimensions. These signals are not only extraordinarily rich in motion information but also, by their physical nature, intrinsically anonymous at the sensor level.

By design the sensors do not capture directly identifiable or biometric data or produce any data that enable identification without additional external context. This anonymity is not a processing choice; it is a measurement constraint. There is no path from the raw signal, which is physically limited by the wavelengths involved, back to a face or a body shape because that information is not captured in the first place. This gives radar a clear regulatory advantage over camera-based monitoring technology, which captures images and personal data so its raw data is not anonymous (see **Figure 1** for a comparison). This single architectural decision avoided structural compliance issues with the [General Data Protection Regulation \(GDPR\)](#), has enabled the company to build up a training dataset with over 25 million hours of patient movement recordings, and resulted in a proportionate [Medical Device Regulation \(MDR\)](#) Class I classification.

The problem of patients being aware of observation was addressed not only through the choice of technology (radar sensors do not have lenses or cameras that make them look like an observational device) but also through the sensor's physical design. Its small size and discreet form make the sensor's presence in a patient's room entirely unobtrusive, comparable to a smoke detector (see **Figure 2**).

Figure 1: Comparison of data capture in camera-based and radar-based technologies



Source: Adapted from [QUMEA AG](#) (2025), p.4¹

Figure 2: QUMEA's radar-based sensor



Source: [QUMEA AG](#)

From the sensor's initial application for fall prevention in delirium care, it has expanded to address a broader clinical need: continuous, objective insights into patients requiring close monitoring on general wards. The sensor is able to continuously record patients' mobility, activity levels, restlessness, reliable proxies to respiration, sleep, and emerging risks and can detect changes early, thus providing foresight. This results in more anticipation and less reaction. One example of such an application is the sensor's support of decubitus (pressure ulcers) prophylaxis.

AI: How a necessity became an opportunity

QUMEA added AI to its sensor not by choice but out of necessity. Range-Doppler tensors from multiple antenna pairs are high-dimensional, highly variable across patients and environments, and far too complex for rule-based interpretation at a clinical scale. This complexity in the sensing modality necessitated the use of AI to interpret the data.

Using AI created a productive dependency. Robust AI models demand large, diverse training datasets. Building such datasets in clinical environments requires a data architecture that can scale across institutions without prohibitive overhead for governance. Because QUMEA's sensor does not produce any personal data, it enabled exactly that. Today, QUMEA's models are trained on more than 25 million hours of movement recordings from patients' rooms. These training data were recorded by QUMEA sensors, accumulated in collaboration with clinical partners, and validated through structured feedback on system performance without the same consent and retention constraints that apply to identifiable data. The models' clinical performance was also independently assessed in a clinical study, which showed a significant decrease in falls of 49%.² In addition, QUMEA maintains a large, continually growing dataset of manually labelled and verified falls as well as other events against which its models are trained, validated, and tested. Rather than using a single general-purpose model, QUMEA operates several specialised models for specific tasks, such as determining whether a patient is alone. Moreover, many customers clinically validate the system in their own setting to prove the system's performance; this real-world data feeds

back into model development. Because all data are anonymous at source, neither this validation work nor the sensor's routine operation present the consent or data governance challenges that imaging-based approaches face. QUMEA relies on a dataset that is free from the complex consent frameworks, data minimisation constraints, and retention limitations that govern imaging-based alternatives.

These three elements – the sensor's architecture, the privacy properties it confers, and the AI capability it enables – were not the result of independent decisions made in sequence. Each determined the other: the use of radar in the sensor made anonymity structural, structural anonymity made the dataset possible, and the dataset made the AI clinically meaningful.

Turning regulatory compliance into a competitive advantage

For a multi-application clinical monitoring product, navigating the MDR begins with a fundamental question: for which applications is a product considered a medical device? The answer depends on an application's intended purpose, and the distinctions are consequential.

QUMEA's fall prevention application is intended to reduce the risk of injury – not to diagnose, monitor, or prevent a disease. Under the MDR, this places the sensor outside the medical device perimeter. This view is shared predominantly across the European Union (EU). QUMEA's supporting role in preventing pressure ulcers, by contrast, engages a clinical preventive function directly and is classified as a Class I medical device because it *supports* a clinical intervention without itself constituting that intervention.

Assessing an AI component in a clinical study context is a recurring challenge for medical device manufacturers: demonstrating algorithm performance, governing the training data, and providing the level of detail on the AI itself that regulators increasingly expect. Here too, the answer lies in the architecture. The regulated medical device function relies exclusively on deterministic machine learning rather than on generative or autonomously reasoning AI. By design, a given input yields the same output every time, so each output

remains a clinical signal, not a clinical decision. This reproducibility makes the models' behaviour traceable, testable, and auditable – properties that play a key role in clinical and regulatory assessments. Combined with data that are anonymous at source, it makes both the validation of the device and the ongoing governance of its data a structural property of the system rather than a procedural burden carried by approaches whose outputs are non-deterministic or derived from identifiable data.

Arriving at these distinctions required QUMEA to engage with the MDR text directly. Early in the sensor's development, QUMEA received widely divergent views from regulatory consultants. Rather than accepting that ambiguity, QUMEA read the regulation in full, developed its own classification rationale, and brought it to external advisors for validation. That investment produced not only a defensible classification but also added clarity to the product definition that has served every subsequent regulatory and commercial context.

Views diverged on the central question of whether fall detection constitutes a medical device at all. QUMEA's position – that preventing injury from falls (similar to a hospital handrail) is not a medical purpose and therefore falls outside the MDR – has been confirmed by external consultants and by the competent authorities in several countries, including Swissmedic and the Swedish Medical Products Agency. Under the EU's MDR (Art. 2(1)) and Switzerland's Medical Devices Ordinance (MedDO, Art. 3), the decisive factor is the manufacturer's intended purpose: prevention qualifies as a medical purpose only in relation to a disease, and a fall is not a disease. QUMEA's fall detection therefore remains outside the MDR irrespective of the patient population. A different classification would arise only from a genuinely medical claim, such as diagnosing or monitoring a condition.

When it comes to the GDPR, the system's architecture resolves compliance at the core: no personal data is produced, so data protection is a physical property of the system and not a procedural layer applied after the fact, as anonymisation or pseudonymisation procedures would be.

What QUMEA did not initially anticipate is how the MDR and GDPR – each demanding substantial effort from most medical device manufacturers – would combine into a competitive advantage. The sensor's true privacy-by-design architecture is, to QUMEA's knowledge, unique in the clinical monitoring market at scale.

Had a camera-based sensor been used, building a dataset of equivalent breadth under the same GDPR constraints would not have been possible. Deployment in the most privacy-sensitive settings, such as dementia care, psychiatric wards, palliative care, and even wet rooms, is substantially more straightforward when the system does not produce any data requiring protection. Because regulation was addressed at the level of the system's architecture, it became a source of product differentiation that is structurally difficult to replicate.

The evolving landscape of AI governance: The AI Act and proportionality

The EU's Artificial Intelligence Act (AI Act) now adds a horizontal governance layer alongside the MDR and GDPR. In June 2025, the EU's Medical Device Coordination Group (MDCG) clarified the interplay between regulations: a high-risk AI classification does not alter the MDR risk class, and documentation can be integrated into existing technical files.³ The principle of proportionality, which is central to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6(R3)) and increasingly important to AI governance more broadly, aligns with a system architecture built on anonymous sensing and human-in-the-loop design. Every output generated is a clinical signal, not a clinical decision, so the care team retains full decision-making authority. This satisfies the AI Act's human oversight requirements as naturally as it satisfies sound clinical practice.

Takeaway: Engaging with regulation can lead to innovative design decisions

QUMEA's development process – from a specific clinical need in delirium care to a radar-based AI foresight engine in use across multiple countries – was shaped at every stage by regulatory considerations. This was not because regulation constrained development, but because seriously engaging with it led to better design decisions. The sensor QUMEA chose, the AI it built, the classification it arrived at, and the product's market position are expressions of a single principle: the architecture of an AI medical device is inseparable from its regulatory architecture. In 2025, this approach – and the balance it achieves between AI capability, clinical utility, patient privacy, and regulatory clarity – was recognised with the Swiss Medical Technology Association's [Swiss Medtech Award](#), reflecting the broader community's recognition that using ethical AI in clinical settings represents a direction worth pursuing. For other teams navigating this space, the most important design question is no longer “How do we comply with regulations?” but “What product architecture inherently ensures compliance?”

References

- ¹ QUMEA AG (2025) Radar-based sensing vs. camera-based vision in healthcare: Why physics determines privacy, anonymity, and data protection (version 1.0 dated December 2025). Accessed 19 May 2026: <https://qumea.com/wp-content/uploads/251222-QUMEA-Whitepaper-Radar-Sensing-vs.-Computer-Vision.pdf>
- ² Eichenbrenner T et al. (2026) Falls and nursing workload in hospitalized older adults with delirium: A controlled trial of 3D-radar-based bed-exit monitoring versus contact mat. *Journal of the American Geriatrics Society* 0:1–8. doi: 10.1111/jgs.70635
- ³ Joint Artificial Intelligence Board (AIB) and Medical Device Coordination Group (MDCG) (2025) Interplay between the Medical Devices Regulation (MDR) & In Vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA). Accessed 5 May 2026: https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4_en?filename=mdcg_2025-6_en.pdf