



CLIENT CASE STUDY

How Restera Met Critical Clinical Trial Deadlines
with Dojo Five's Embedded Expertise

CLIENT BACKGROUND

Restera, a medtech startup developing an innovative obstructive sleep apnea treatment, needed to complete firmware for their External Pulse Generator ahead of a critical clinical trial in Australia.

With only two internal developers and strict regulatory requirements, they required highly specialized embedded expertise—fast.

PERFORMANCE & COMFORT IN WEARABLE DESIGN

Restera is developing a wearable, wireless system to treat obstructive sleep apnea, designed for comfort, ease of use, and high patient compliance.

Wearable & Wireless

Lightweight design adheres gently to the skin, avoiding the bulk and discomfort of CPAP machines.

Intelligent Neurostimulation

Addresses the root cause of sleep apnea with a less intrusive, more comfortable alternative to existing devices.

Broader Patient Reach

User-friendly design may serve patients who avoid or cannot tolerate traditional therapies.

Clinical-Stage

Ongoing trials with regulatory approval in progress.

Accurate Detection & Analysis

Performs comparably to polysomnography (PSG) in measuring sleep stages and detecting apnea events.

E-cacy & Compliance Focus

Aims for CPAP-level performance with higher compliance than other neurostimulation devices like Inspire and Nexo.



CHALLENGES

Tiny Internal Team

- › Only 2 developers, no bandwidth for additional hiring.

Specialized Tech Need

- › Deep knowledge of Nordic Semiconductor's nRF52840 and nRF5340 microcontrollers, Nordic BLE, and low-power firmware in a medical context.

Tight Deadline

- › Clinical trial schedule could not slip.

Regulatory Compliance

- › Build needed to meet medical device standards from day one.

SOLUTIONS

Restera partnered with Dojo Five after connecting at the Sensors Converge conference:

Why Dojo Five?

- › Proven experience with Nordic BLE and nRF microcontrollers.

Medical Device Regulatory Knowledge

- › Allowed our team to avoid compliance rework.

On-Demand Model

- › No full-time hiring, immediate ramp-up.

Agile Processes & Seamless Integration With Restera's Team

- › Iterative cycles kept development on track.



IMPLEMENTATION

The collaboration between Restera and Dojo Five was characterized by:

SEAMLESS INTEGRATION:

Dojo Five worked closely with Restera's internal team, effectively becoming an extension of their development capabilities.

REGULAR COMMUNICATION:

Weekly meetings were established to ensure alignment, track progress, and address any emerging issues promptly.

AGILE METHODOLOGY:

The teams adopted an agile approach, allowing for quick iterations and adaptations as the project progressed.

KNOWLEDGE TRANSFER:

Throughout the engagement, Dojo Five shared insights and best practices, enhancing Restera's internal capabilities.



RESULTS

The partnership yielded significant benefits for Restera:

ACCELERATED DEVELOPMENT:

Dojo Five's expertise allowed Restera to complete their External Pulse Generator development in time for critical clinical trials in Australia.

COST-EFFECTIVE SCALING:

By leveraging Dojo Five's on-demand resources, Restera avoided the costs and commitments associated with full-time hires while still accessing top-tier embedded development skills.

RISK MITIGATION:

Dojo Five's experience in testing and BLE technology helped reduce both timeline risks and potential patient safety issues, critical factors in medical device development.

ENHANCED QUALITY:

The combination of Dojo Five's expertise and Restera's internal knowledge resulted in a high-quality product ready for clinical trials.

REGULATORY READINESS:

Dojo Five's familiarity with medical device regulations helped ensure the product was developed with compliance in mind from the start.

KEY TAKEAWAYS & RECOMMENDATIONS

Strategic partnerships:

For startups in specialized fields like medical devices, partnering with experts can significantly accelerate development and reduce risks.

Communication is crucial:

Regular, structured communication (e.g., weekly meetings) is essential for maintaining alignment and addressing issues proactively.

Internal champion:

Having an internal resource who can effectively liaise with the external team ensures continuity and enables quick decision-making.

Flexible resourcing:

On-demand access to specialized skills can be a game-changer for startups, offering expertise without the overhead of full-time hires.

Look beyond local:

While Restera appreciated the ease of working with an onshore team, they recommend considering expertise and fit as primary factors when selecting development partners.

CONCLUSION

Restera's partnership with Dojo Five demonstrates how strategic collaboration can empower medical device startups to punch above their weight.

By leveraging specialized embedded development expertise, Restera was able to accelerate their product development, manage risks effectively, and progress towards bringing their innovative sleep apnea treatment to market.

This case study illustrates the potential of flexible, expertise-driven partnerships in driving innovation in the medical device industry.

WHY CHOOSE US?

By partnering with Dojo Five, companies can access advanced embedded software development expertise, enabling them to meet aggressive timelines while laying a solid foundation for long-term project success.



Visit DojoFive.com to learn more about what Dojo Five can do for your embedded project.
Or emails us at hello@dojofive.com.