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CASE STUDY

DELIVERING A CUSTOM OPTICAL SOLUTION FOR NON-INVASIVE MEDICAL DIAGNOSTICS - FROM COLLABORATION TO INNOVATION

INTRO

DELIVERING A CUSTOM OPTICAL SOLUTION FOR NON-INVASIVE MEDICAL DIAGNOSTICS

In the development of advanced medical technologies, precision, reliability, and adaptability are essential. When a medical device company approached us with the challenge of integrating a compact, non-invasive measurement system into their platform, our focus was not just on delivering a component, but on enabling the success of the end product.

This case study outlines our development process: from early-stage requirement analysis and technical exploration, through iterative prototyping and regulatory alignment, to final integration of the products. By working closely with the client's team, we ensured that every design decision supported the functionality, compliance, and usability of the final device.

Understanding the Requirements

Each project begins with an in-depth exploration of the client's specific needs and operating environment. In this case, the client was developing a medical device capable of real-time, non-invasive diagnostics at the bedside. To support this, they needed a spectroscopy-based solution that would integrate seamlessly with their system architecture and perform reliably in varied clinical environments.

We initiated the project with a comprehensive needs assessment, engaging in technical discussions with the client’s engineering and product teams. This allowed us to map out the key performance requirements, constraints, and environmental considerations early in the development cycle.

THE ENABLING NON-INVASIVE MEASUREMENT

Non-invasive diagnostics depend on the accurate interpretation of light-matter interactions, a domain where spectroscopy offers unique advantages. Our role was to convert the client's diagnostic requirements into an optical system capable of delivering stable, reproducible data in real time.

To achieve this, we worked closely with the client to translate clinical and functional goals into concrete technical specifications. This involved defining precise wavelength ranges, optimizing optical throughput, and tailoring the performacne to the expected signal dynamics of their application, all while ensuring the system remained compact, portable, and resistant to environmental interference.

FROM COMPONENTS TO INTEGRATED SYSTEM

The design process included prototyping and testing, where we fine-tuned the spectrometer, light source, and probe for compatibility not only with the target measurement task, but also with regulatory constraints and the client's broader device architecture. Key performance criteria and requirements included:

- **Optical performance:** ensuring wavelength stability, resolution, and signal-to-noise ratios met clinical thresholds.
- **Mechanical design:** tailoring form factors and mounting interfaces to fit within the client's housing constraints.
- **Regulatory alignment:** designing in accordance with CE/EMC and EN 60601-1-2:2015/A1:2021 standards to support FDA submissions.

Throughout the design process, we maintained a systemic view, which meant not just delivering isolated parts, but assessing how the components interacted within the larger device. This helped minimise integration risks and ensured optimal overall system performance.

NAVIGATING COMPLIANCE AND CERTIFICATION

Navigating regulatory requirements is a critical part of medical device development. We collaborated closely with the client's quality and compliance teams to align our development with FDA guidelines. While components from other vendors encountered certification challenges, the hardware we delivered passed regulatory scrutiny without issue. This outcome was the result of our proactive design-for-compliance approach and thorough documentation.

A COLLABORATIVE DEVELOPMENT PROCESS

Frequent and open communication formed the foundation of this project. From concept to completion, we maintained regular contact with the client's teams, facilitating:

- Rapid feedback integration
- Early identification of risks
- Adaptability to shifting requirements

This collaborative model enabled a fluid and transparent development process, helping both teams respond efficiently to technical or regulatory changes.

BEYOND DELIVERY: DEDICATED POST-DEPLOYMENT SUPPORT & OPTIMIZATION

Our involvement doesn't end at delivery. We provide post-deployment support to assist with integration adjustments, user feedback, and any additional optimisation needed in the field. This long-term engagement model ensures that the solution continues to evolve in step with the client's needs and the realities of the clinical environment.

PROJECT OUTCOME

The final product was a portable, spectroscopy-based diagnostic device, containing a custom spectrometer, light source and probe, that integrated seamlessly into the client's platform and supported their broader innovation goals. The solution enabled more precise, real-time patient monitoring while meeting the regulatory demands of the healthcare market.

The customer was very happy with the end products and said:
"***Thank you so much for the support throughout this project. The only hardware that did not give us any issue during the FDA certification was yours; great work!***"

CONCLUSION

This project illustrates how a structured, collaborative development process can bridge the gap between technical ambition and regulatory reality. By focusing on integration, compliance, and adaptability, we helped our client bring a high-impact medical device to market — one that not only performs reliably but also enhances patient care. We are proud to be a part of this innovation!

Our role as a development partner is defined by our commitment to understanding, adapting, and delivering solutions that serve the product's success and the user's needs.

Also in need of a custom solution? Feel free to contact us at www.avantes.com/contact

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CONTACT

WE'RE HAPPY TO HELP

Curious how spectroscopy will help you reveal answers by measuring all kinds of material in-line, at your production facility, in a lab, or in the field? Visit our website or contact one of our technical experts.
We are happy to help you!

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