CASE STUDY

Rapid Development of Intuitive LabVIEW-Based Software for a Touch Screen Medical Device

By Kit Yee Au-Yeung, Vice President, Products at Profusa, Inc.

The Profusa Lumee™ Oxygen Platform

Profusa is a start-up company made up of talented scientists and engineers working to develop a new generation of biosensors to monitor our body's unique chemistry in an unprecedented way. At Profusa, our goal is to help physicians salvage limbs of patients suffering from critical limb ischemia by providing them with a new way to continuously measure tissue oxygen before, during, and after surgical treatments. The Lumee Oxygen Platform, a breakthrough technology that has already received CE Marking for sale within the European Economic Area, enables physicians to monitor and improve blood circulation and administer the appropriate therapy before advanced symptoms may appear.*

At Profusa, we created the Lumee Oxygen Hydrogel biosensor, a tiny flexible fiber (3 mm to 5 mm long and approximately 500 microns in diameter) that is placed under the skin with a specially designed injector. The Lumee optical reader measures oxygen levels in the surrounding tissue by exciting the biosensor with light and

INDUSTRY
Medical Technology

OBJECTIVE
To develop an easy-to-use, commercial-grade touch screen software interface using NI LabVIEW System Design Software that will help bring our Lumee Oxygen Platform to market quickly, completing the project in less than four months.

APPROACH
To improve the existing LabVIEW software for clinical feasibility studies, implement industry-standard software engineering best practices for quality and traceability, and work closely with the Lumee product team to deliver professional software that meets strict regulatory and quality requirements, as well end-user (physician) workflow and usability needs, within a short time-frame.

HIGHLIGHTS

- Improved first-generation software for early R&D and clinical feasibility study in *less than one week*
- Defined software functional requirements based on physician needs in *just a few weeks*
- Created an intuitive and professional LabVIEW-based touchscreen user interface for physicians
- Developed robust product software that meets strict regulatory and quality requirements
- Delivered final, fully-tested software in *less than four months*, from concept to completion

**CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use*

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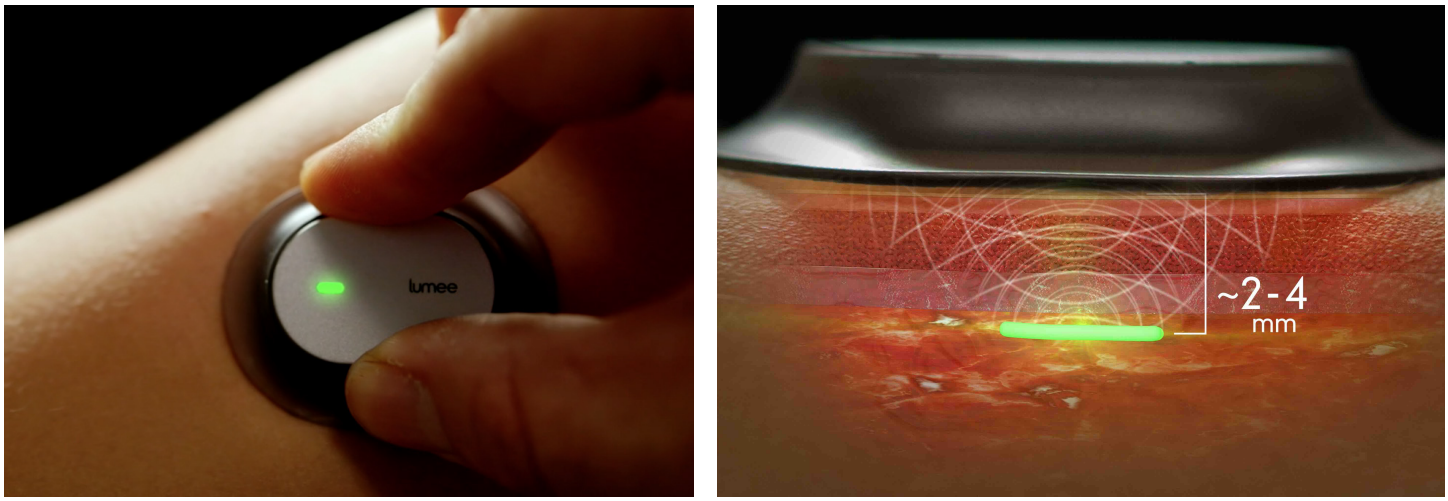
then measuring the emitted fluorescent light. Profusa's biosensors fully integrate with the body's tissue without any metal devices or electronics, avoiding the foreign body response for up to two years.

To achieve our clinical goal and get our technology in the hands of physicians, we needed to develop a commercial-grade software application to power our advanced hardware. We wanted the software to have an intuitive touch screen user interface for physicians to easily view critical information during patient data collection. This software application, called Lumee Live™, would be a key component of our Lumee Oxygen Platform product release.



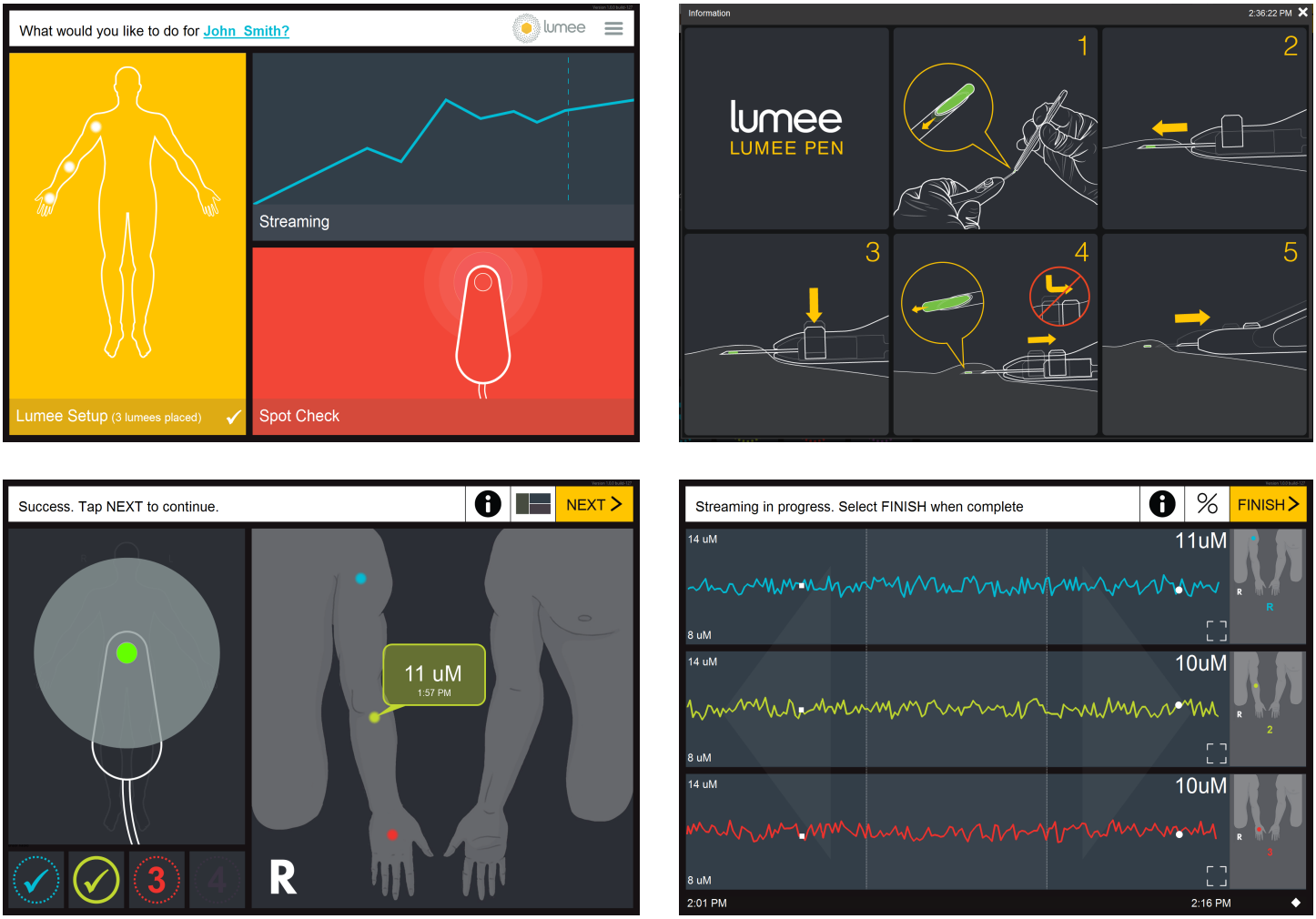
Profusa's Lumee optical reader excites and measures the signal from the Lumee Oxygen Hydrogel biosensor embedded 2 mm to 4 mm below the skin.

Enhancing the Software to Go Beyond the Lab

The first-generation LabVIEW software we developed for our first clinical feasibility study demonstrated the functionality of the system, but it lacked a critical piece needed to commercialize the Lumee Oxygen Platform: a user-friendly interface for collecting and displaying data. The software's interface had to be intuitive for physicians and able to run on a tablet computer so it would be easy to use in an operating room.

We wanted to build on our original LabVIEW-based software but realized we were limited by our lack of in-house LabVIEW development experience. We turned to the company we knew excelled in LabVIEW development: JKI.

JKI used LabVIEW to create a professionally designed mock-up of the user interface in just a few days, and proved to us that LabVIEW could provide a commercial-grade user interface that would provide all of the required functionality with a simple, user-friendly design. JKI's LabVIEW experts used engineering best practices to optimize our first-generation code, and made it more maintainable, reliable and scalable.



This compilation of screenshots shows the user-friendly software JKI developed with us for use by physicians and clinicians. The homepage (top left) leads to screens that allow the user to enable hydrogel biosensor placement (top right), spot check the sensor placement and measure signal levels (bottom left), and stream tissue oxygen signals onto a chart (bottom right).

Collaboration and Communication: Keys to Our Successful Partnership

At the beginning of this project, we met with JKI and shared our goals for our Lumee Live software. Through ongoing communication and an iterative process, JKI led the design and development of both the user experience and the software. JKI worked with our industrial designer to ensure the user-interface design was right for our product, and collaborated with our staff engineer on some aspects of the LabVIEW coding to ensure the software was well-integrated. Throughout this process, JKI made themselves available to answer any development questions that arose and even provided training in LabVIEW best practices.

Development responsibilities were divided to take advantage of each engineer's strengths, so JKI implemented a collaborative Agile Development process to keep the project on track to completion. Source code control tracked all revisions that were made between Profusa and JKI, and the traceability implemented by JKI helped us meet quality requirements more easily.

Future Plans: From Clinical Trials to Operating Rooms Around the World

Together Profusa and JKI designed and developed a modern, professional touch screen application for use on the Microsoft Surface, and had it ready to ship in just four months. JKI's ability to quickly deliver polished, commercial-grade software exceeded our expectations and provided tremendous business value to our stakeholders. Their work was key to allowing Profusa to launch our first product offering into the market with speed and impact, and was critical to our success.

We are excited to continue our work with JKI as we look to expand our Lumee Live software into the cloud. This expansion will give users the ability to share data (which may include protected health information) conveniently and securely via a web-based portal with custom analytics tools. Profusa has a vision to let users find, view, and analyze their health data from anywhere, and we are glad to have JKI as our valued partner in this endeavor.

I would definitely recommend JKI to my colleagues. JKI engineers are knowledgeable and fully capable of helping get LabVIEW-powered medical instruments to market fast. Next time I need to develop a piece of software using LabVIEW, I will absolutely turn to JKI.

Kit Yee Au-Yeung
VP, Products at Profusa

3687 Mount Diablo Blvd, Suite 208
Lafayette, CA 94549
888.891.7821
jki.net
info@jki.net

jki.net/blog
facebook.com/JKISoftware
twitter.com/JKISoftware