CASE STUDY

LASER INSTEAD OF FINGER PRICKS – DIAMONTECH USES OPHIR® PYROCAM™ TO DEVELOP NON-INVASIVE BLOOD GLUCOSE MONITOR

More than 500 million people worldwide live with diabetes. For them, the ability to measure blood glucose levels non-invasively (without piercing the skin) would be an enormous relief. Thanks to a patented development by DiaMonTech AG, this dream is on the way to come true for many people. The technology, which uses an infrared quantum cascade laser (QCL), has successfully completed a clinical study with a shoebox sized device. The next step is to integrate the technology into a smartphone sized device that can be handled by end users. To achieve this miniaturization without loss of quality, it is necessary to detect even minute changes in the laser beam. DiaMonTech uses the Ophir Pyrocam beam profiler to measure and characterize all their laser developments.

Product:
- Ophir Pyrocam pyroelectric array laser beam profiler

Field of application:
- Medical technology

Uses:
- Development of a non-invasive blood glucose meter

Benefits:
- Measures beam profiles quickly and reliably
- Universally applicable in both development and quality assurance
- Easy evaluation of the data with Ophir BeamGage software

Successful research

Many non-invasive methods for measuring blood glucose have failed because they were not accurate enough: Glucose values in body fluids such as tears, saliva or sweat do not correlate sufficiently with glucose values in blood. The situation is different for skin fluid (interstitial fluid – ISF). Measurements taken on ISF at body parts with good capillarization correspond well to the actual amount of glucose in the blood. DiaMonTech was founded in 2015, after years of research at the Goethe University Frankfurt, Germany. Based on this research, the company has developed a non-invasive blood glucose monitor.

Figure 1: D-Pocket, the non-invasive blood glucose meter from DiaMonTech

Measurement principle and clinical testing

The measurement works based on infrared spectroscopy, and specifically the principle of photothermic deflection. For this purpose, a quantum cascade laser (QCL) radiates mid-infrared pulses in wavelengths ranging between 8 and 11µm into the skin. The pulses of these wavelengths pass through the sensor element and excite the glucose molecules to oscillate briefly. With the fast relaxation a small amount of heat is given off to the environment. At the skin surface this results in a minimal increase in temperature. In the sensor element (internal reflection element – IRE), the thermal gradient causes a thermal lens effect. The probe beam of a red laser diode is deflected by this thermal lens as it passes through the IRE. The deflection is measured by a position-sensitive photodiode; the device calculates the glucose concentration based on the deflection. A clinical study with 36 subjects conducted at an external institute, which was concluded in 2024 shows results comparable to early stage continuous glucose monitoring devices (CGMs), that got approved by the FDA.

Miniaturization progress

The measuring principle has been validated with the D-Base device which is used as a technology carrier and demonstrator. Sergius Janik, COO at DiaMonTech, explains, why shrinking the device is the next goal: “People with diabetes want fast and compact measurement technology that they can easily use at home and on the road.” DiaMonTech currently focuses on finalizing the commercial handheld device called “D-Pocket”. As only a few manufacturers offer tunable QCLs - the core component for the devices – which are usually too big to be implemented in a handheld device and don’t match the fine requirements for accurate glucose sensing, DiaMonTech with its partners started developing their own QCLs specifically aimed at detecting bio molecules. These QCLs are small, energy efficient, mass manufacturable and ideal for handheld devices and with the new generations available for implementation into wearable devices DiaMonTech is currently testing and integrating these QCLs.

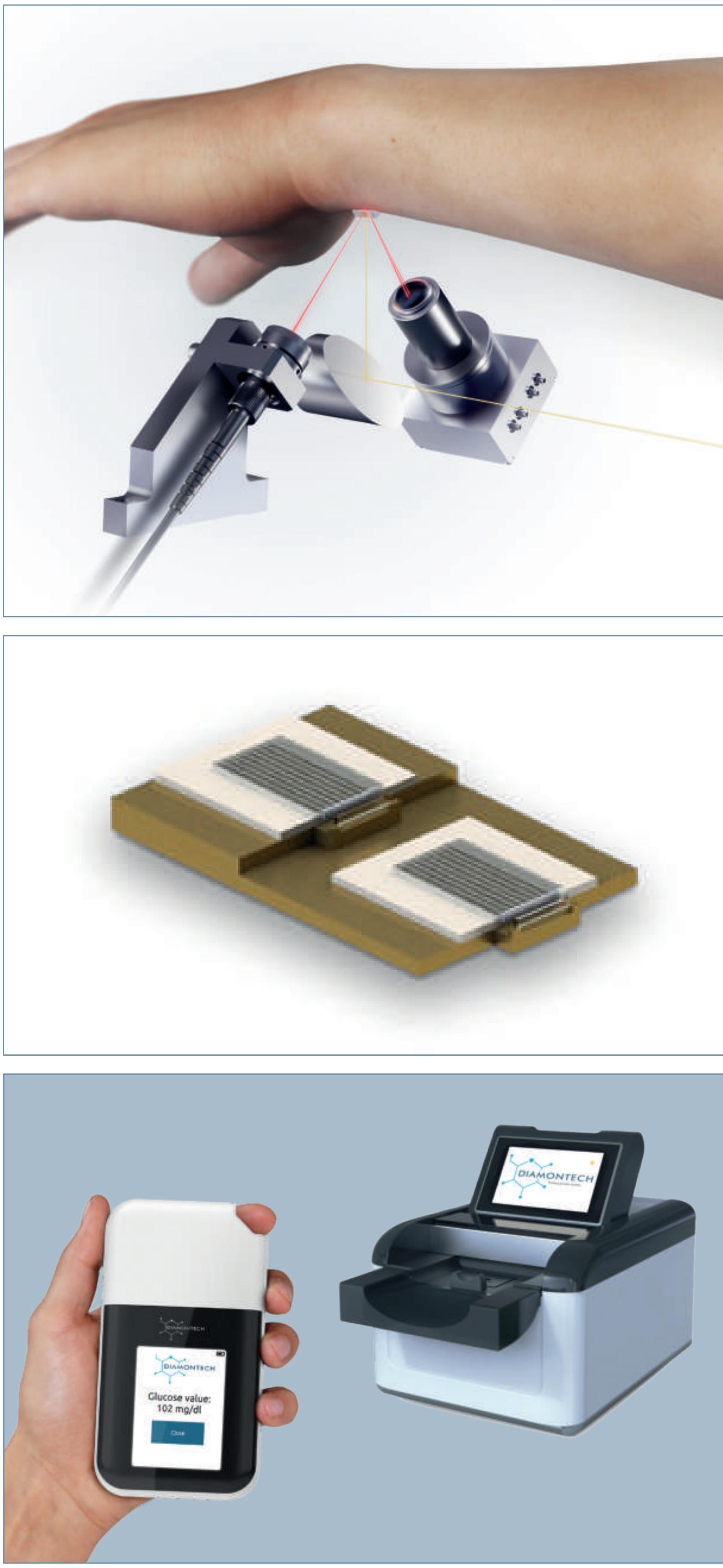

Figure 2-4: Functional principle of non-invasive blood glucose measurement by DiaMonTech. Core of the DiaMonTech developments are infrared quantum cascade lasers (QCL) as seen in fig. 3 (middle). After successful clinical studies with the shoebox sized D-Base device, the handheld device is under development.

Critical measurements

In order to evaluate the quality of a given QCL, the DiaMonTech laboratory conducts detailed measurements on all of them to answer the following questions:

- What does the laser beam profile look like?
- What is the output power of the laser?
- How divergent is the beam?
- What is the pulse repetition rate?
- What is the pulse-to-pulse stability and shape of the pulse?
- How large is the focal spot on the skin?

As the number of measuring points required is large for different QCL prototypes, utilization of a reliable and an easy to use tool is detrimental for development. After in-depth research and conducting an array of tests in their own laboratories, the experts from DiaMonTech decided on the Ophir Pyrocam-III-HR-C-A-PRO. Using this high-resolution pyroelectric matrix camera, the beam profile of an infrared laser can be measured both quickly and reliably. For the application at DiaMonTech, the camera was individually calibrated to the appropriate signal level. The camera data is then evaluated with the Ophir BeamGage software. Output power, beam profile and beam divergence can be determined by the camera in just a few seconds. Sergius Janik explains: "The Ophir Pyrocam is our key measuring device for characterizing the laser beam, and we use it every day. We use it not only for developing new prototypes, but also for quality assessment and troubleshooting. As necessary, we also make the Pyrocam available to our development partners, so they can make precise and reliable adjustments."

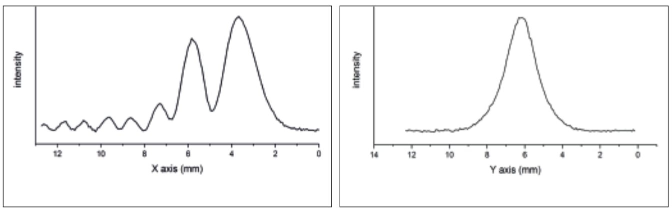

Figure 5: Left: Uneven energy distribution of a fragmented laser beam; right: expected gaussian beam profile

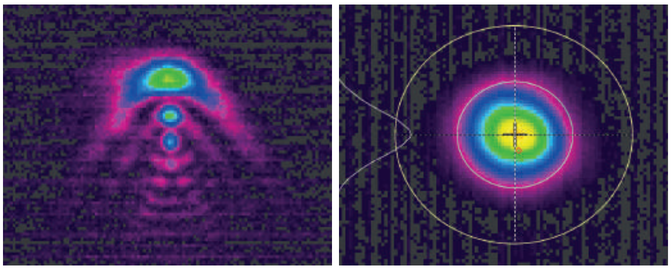

Figure 6: Imaging of the original beam profile using the Ophir Pyrocam: left is before, right is after lens adjustment.

Troubleshooting made easy

Sergius Janik describes a concrete application as an example of the enormous time savings achieved by the Ophir Pyrocam. During a series of tests conducted by the DiaMonTech lab on a new laser, the engineers were unable to focus the beam. The power distribution of the beam was very irregular, but the cause was not obvious at first glance. The images taken with the Pyrocam provided an explanation. Instead of the desired symmetrical Gaussian beam profile, the beam appeared strongly distorted (see Fig. 6, left). These results showed that the collimating lens of the beam was out of adjustment, which may have occurred during shipment. The laser system was sent back to the manufacturer, the lens was re-adjusted, and then the Pyrocam measurements showed a uniform beam profile, as in Fig. 6 on the right.

> "The Ophir Pyrocam makes our daily work easier. We get reliable results very quickly and can speed up the development cycles of the tested lasers."
>
> Sergius Janik, COO at DiaMonTech AG

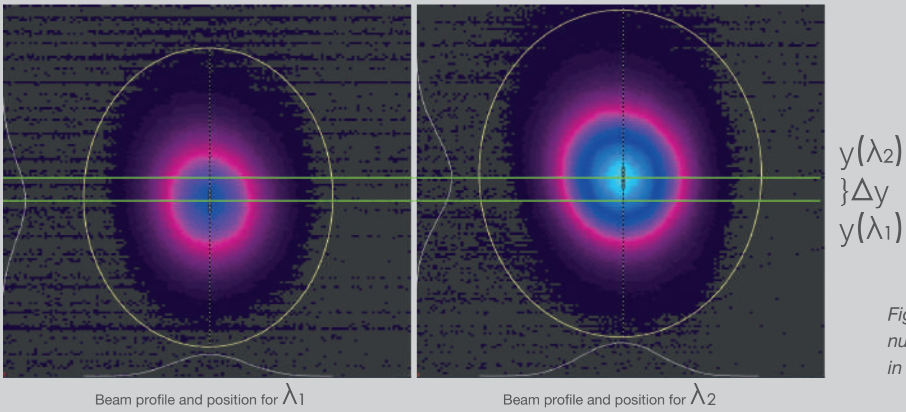

Figure 7: Beam profile for two different wave-numbers of a tunable QCL. The pictures show shifts in position and size of the beam profile.

Easy measurement of tunable lasers

Another challenge that arises when developing a compact blood glucose monitor is the different beam position for any given wavelength for off-the-shelf QCLs. To detect glucose in the skin, it is necessary to take measurements using a variety of wavelengths in the infrared range. But with a tunable laser, as soon as the wavelength is changed, the beam moves (a.k.a. "beam hopping"). For the newly developed QCL arrays it is necessary to test if all beams fulfill the positional and beam-shape requirements. In case of mis-aligned optics the beam enters the skin at slightly different positions (up to about ¼ mm) and – analogous to wrongly corrected vision – the thermal lens becomes blurred. When the DiaMonTech team changes the wavelengths, they use the Pyrocam to measure the focus position, which is marked with crosshairs. The BeamGage software records the changes in crosshair position for accurate tracking. The wavelengths that provide the most precise measurements can then be determined, based on the findings from these readings.

Faster measurements mean more efficient development along the road to miniaturization in non-invasive blood glucose monitoring, and there is no way around a camera-based measurement of the beam profile. Before purchasing a measuring device, DiaMonTech tested the solutions available on the market. The Ophir measuring device not only had a wavelength range suited to the purpose, it also provided the required performance range and offered very good value for the money. Sergius Janik appreciates the measurement technology: "The Pyrocam makes our daily work easier. We get reliable results very quickly and can speed up the development cycles of the tested lasers. This allows us to concentrate on the essential work of development and gets us faster to the final product."

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This case study was prepared in cooperation with DiaMonTech AG by Dagmar Ecker, MBE (Master of Business Engineering). Many thanks to DiaMonTech for providing the photographs and measurements used herein.