

A SAFE WAY TO BETTER VISION

WaveLight relies on laser sources and laser beam analysis from MKS Instruments



There are many challenges in the development and production of laser systems for medical applications – and the safety requirements are significant. It's no wonder that medical technology manufacturers choose their suppliers very carefully. WaveLight GmbH, a subsidiary of Alcon and market leader in refractive surgery, successfully uses products from MKS Instruments in the development, production and maintenance of its high-quality laser systems. Spectra-Physics laser sources have been integrated into WaveLight® FS200 femtosecond laser systems for over ten years, and Ophir solutions for measuring laser power and energy, as well as for laser beam analysis, are employed throughout the process from development to maintenance. Millions of patients benefit from this collaboration.

Refractive surgery requires the very highest quality

The number of people with ametropia is on the rise, and many of them feel so restricted by it that they decide to have their vision corrected by laser treatment. Refractive surgery is thus becoming more and more important worldwide. One of the foremost companies in terms of modern diagnostic and surgical technologies for correcting refractive errors using eye lasers is WaveLight GmbH. A subsidiary of Alcon, in turn one of the world's leading ophthalmology companies, WaveLight develops and produces high-quality laser and diagnostic systems at three locations in Germany. Since the launch of the WaveLight® Refractive Suite, which consists of the WaveLight® FS200 femtosecond laser and the WaveLight® EX500 excimer laser, several thousand of these systems have been put into operation worldwide, and millions of patients have been operated on with the Refractive Suite.

Product:

- Spectra-Physics® laser source
- Ophir® BeamSquared®
- Ophir® 3A-FS sensor
- Ophir® SW
- Ophir® LT655
- Ophir® PE50U sensor

Field of application:

- Refractive surgery

Application, laser source:

- Part of the WaveLight® FS200 femtosecond laser

Application, measuring technology:

- Development, production, service of all WaveLight laser systems

Advantages, laser:

- Customized development of a laser source in the femtosecond range – highest precision & reliability

Advantages, measuring technology:

- High measuring accuracy
- Comprehensive SW functions





Fig. 1: WaveLight attaches great importance to precision and reliability in the production of its laser systems in Pressath/Bavaria.

This resounding vote of confidence is no coincidence: WaveLight attaches great importance to precision and quality in both development and production. Laser sources are tested and selected accordingly, so the requirements for the laser measurement technology are correspondingly high.

The long path from development to approval

An essential component of a laser system is the laser source itself. During the development of the WaveLight® Refractive Suite, the development engineers first combed the market to see if suitable laser sources were available as standard. For the cutting of the flap, i.e. the incision in the cornea, WaveLight was looking for a laser source in the infrared spectrum with a power of 1-2 watts and a pulse width in the femtosecond range. The developers found what they were looking for at MKS, selecting a Spectra-Physics laser source. After careful testing, the team decided on the standard pulsed laser source, which then had to be adapted to meet WaveLight's individual requirements. The dimensions of the laser, the integrated interfaces and the power supply were all optimized to meet WaveLight's needs – which is a process that should not be underestimated! It takes a few months to go from the experimental setup in the laboratory to the prototype, and it usually takes one to two years just to get the first pre-series product ready for testing. After five years, the laser system had been approved for Europe, and after a further three years, it even had worldwide approvals. An advantage here: The MKS production facility for Spectra-Physics lasers in Rankweil is certified according to the



Fig. 2: The WaveLight® Refractive Suite offers the fastest possibility to correct refractive errors with the highest precision.

general quality standards EN ISO 9001 and EN ISO 13485 for the design and manufacture of medical devices. Mario Klafke, Head of R&D Corneal Refractive at WaveLight adds: “You have to remember, it’s not enough just to have an excellent prototype. It’s essential to successfully complete the full approval process and to ensure that the product’s quality remains high when manufactured in series. But many processes can be greatly simplified if you have the right certifications. On the whole, we worked very closely with the MKS developers while setting up the first Spectra-Physics laser sources and thus avoided quite a few pitfalls.”

Metrological testing of the quality parameters

When it comes to assessing the quality of a laser source, the measurand generally used is the laser's ability to be focused, as described by the beam propagation ratio M^2 . Which is why there is an additional MKS product in use, not only for production and incoming goods inspection at Spectra-Physics but also for adjusting the laser source at WaveLight: Ophir BeamSquared. In less than a minute, this fully automated, camera-based instrument reliably measures the beam profile of continuous-wave and, as in this case, pulsed lasers. With regard to the laser source for the femtosecond laser system, there's an obvious advantage to using the same system for testing on both the manufacturer's and the customer's sides, but Ophir products are also used to measure the excimer lasers used for ablating the inner corneal tissue. Mario Klafke explains: "Our number one priority is the quality of our laser systems. Ophir measurement technology is therefore in daily use at our company — each and every laser system is meticulously tested, first in the manufacturing process and again during commissioning and maintenance. To do this, our worldwide service team uses exactly the same products as manufacturing does, ensuring comparable results every time." WaveLight uses Ophir 3A-FS thermal sensors and Ophir PE50U pyroelectric sensors to measure the laser power and laser energy, respectively. The latter have a higher damage threshold due to a special coating.

"Successfully creating a reliable laser system is not a sprint but rather a marathon. Once you've established the desired product quality, you have to ensure that it's maintained."

Mario Klafke, Head R&D Corneal Refractive

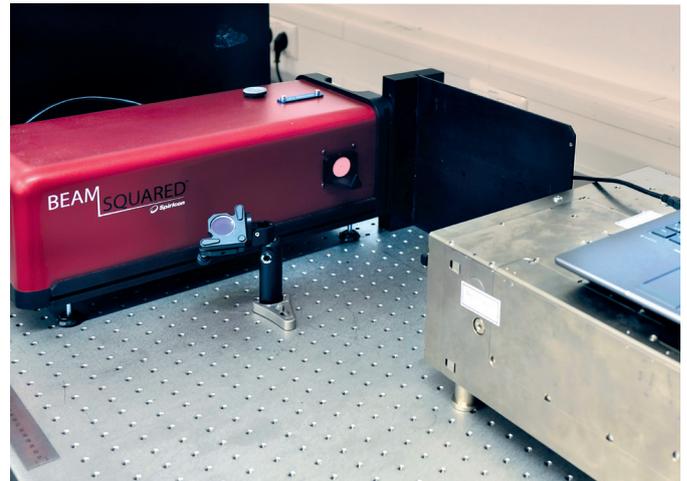


Fig. 3: The beam profile of the femtosecond lasers is checked with the Ophir BeamSquared analysis system.

At the same time, as OEM sensors, they're specifically calibrated to the employed wavelength of 193nm, further increasing their absolute measuring accuracy. To complete the measurement of the laser system, WaveLight relies on these camera-based instruments, with their large-format LT665 silicon cameras, to determine the beam profile. Ophir's comprehensive software was one of the key factors for choosing its measurement technology, as Mario Klafke puts it: "The measurement accuracy was an important criterion for us, and various functions of the BeamGage software plus the direct interface to the PC also made our work easier."

Continuous quality assurance

The WaveLight® Refractive Suite has now been on the market for more than ten years, and several million operations have been performed with these laser systems. Here, the basic requirement is their outstanding quality. This is where the intense collaboration between the development teams from WaveLight and Spectra-Physics, along with the meticulous measurements of the laser systems taken with Ophir measuring devices, has really paid off. "We view the cooperation with MKS as very positive. Of course, when dealing with any supplier, challenges will arise from time to time – but here they've always been resolved constructively and with a focus on service. By the way, this is not only true for Europe; on-site service in other regions also works very well," explains Mario Klafke.



WHY MKS?

CRITICAL TECHNOLOGIES	PROVEN PARTNER	OPERATIONAL EXCELLENCE	COMPREHENSIVE PORTFOLIO
World-class technology and development capabilities for leading-edge processes	Recognized leader delivering innovative, reliable solutions for our customers' most complex problems	Consistent execution across all aspects of our business	Extensive offering of products and services for the Semiconductor, Advanced Electronics and Specialty Industrial markets.

MKS Photonics Solutions

MKS Instruments helps businesses solve their hardest technology challenges. A trusted partner of the world's largest electronics and industrial companies, we leverage leading-edge science and engineering capabilities to offer solutions that improve process performance and productivity for our customers. Spectra-Physics, Ophir, Newport and ESI are brands within the MKS Instruments Photonics Solutions division. Spectra-Physics combines groundbreaking laser technologies with deep application expertise to deliver industry leading lasers for precision industrial and scientific research applications. Ophir specializes in laser and LED measurement products, including laser power and energy meters and laser beam profilers. Ophir also provides high-performance IR thermal imaging lenses and optical elements as well as optics for CO₂ and high-power fiber laser material processing. Newport provides a full range of solutions including precision motion control, optical tables and vibration isolation systems, photonic instruments, temperature sensing, optical and opto-mechanical components. ESI systems deliver market-leading solutions for Flexible PCB laser processing, high-speed MLCC testing, and CO₂-laser-based systems HDI PCB and IC substrate manufacturing. MKS Photonics Solutions enhance our customers' capabilities and productivity in the semiconductor, advanced electronics and specialty industrial markets.