



OPTIMIZING OPTICAL COMPONENTS FOR OPHTHALMIC INSTRUMENTS

The human brain is a powerful organ. Roughly a third of the brain's processing power is devoted to visual processing, indicating just how important vision is to human life. Yet our eyes — the source of visual information — are delicate, fragile organs susceptible to damage, prone to degradation, and subject to congenital deformity.

To help the ophthalmic industry overcome the challenges presented by the fragility of the eye, biomedical engineers and researchers create and continually improve instrumentation for ophthalmic imaging, illumination, and operation. While the performance of ophthalmic instruments is heavily dependent upon the integration of high quality optical components — lenses, mirrors, filters, prisms, objectives, light sources, and detectors — many companies find their time focused elsewhere, such as integrating mechanical and electronic assemblies and obtaining FDA clearance.

Specifying optical components often requires advanced knowledge in optical design or engineering. To ease potential burden on engineering staff and to accelerate the development process, many companies now rely on the optical design and manufacturing expertise of Edmund Optics®.

END-TO-END OPTICAL EXPERTISE

Lasers have reinvented ophthalmic surgery. Delivering precise amounts of energy to specific locations of the eye helps minimize tissue damage and improve patient recovery times. Procedures such as cataract removal surgery have replaced scalpels with lasers to neatly cut away the eye's corneal flap while minimizing risk to the patient. A laser can only be effective, though, when incorporated into an optical system optimized for the laser's unique attributes.

Recently, a leading manufacturer developing a laser ophthalmic surgical system came to Edmund Optics® for a design solution. The manufacturer needed a system capable of:

- Producing precise and accurate images of the eye
- Focusing and directing an accurately shaped beam to a specific location.

Since Edmund Optics® offers complete end-to-end capability to provide filters, lenses, and mirrors — off-the-shelf or of custom design — the instrument manufacturer leveraged Edmund Optics® knowledge to assist with the overall design and product selection process. This in turn

minimized the instrument manufacturer's number of suppliers, thus simplifying its supply chain process and FDA audits.

BUILDING EXPERTISE INTO THE SYSTEM

Providing proper ophthalmic care is a global concern, and with the help of Edmund Optics®, Forus Health is delivering an accessible, affordable ophthalmic solution to the burgeoning population of India. India's low ratio of ophthalmologists to population requires an accurate yet easy-to-use device for diagnosing preventable eye diseases. Additionally, the device must be usable without a doctor's involvement and be portable and easily deployable in both rural and urban environments. To fulfill the need, Forus Health developed the 3nethra prescreening device to detect signs of cataracts and glaucoma, along with diabetic retina, refraction, and cornea problems.

Edmund Optics® engineers collaborated with Forus Health to produce an optical system utilizing a combination of standard spherical optics and other off-the-shelf components, along with specialized mirrors and polarizers. EO's optical design expertise combined with its extensive manufacturing capability helped Forus Health produce a compact, high-quality ophthalmic device in a short time frame.

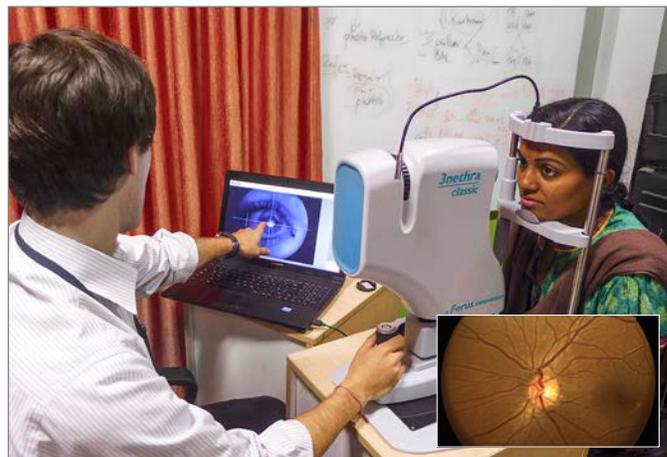


Figure 1: 3nethra, by Forus Health, plays a critical role in preventing treatable blindness worldwide.

In addition, EO recommended design modifications to extend the imaging capability into the near infrared: a key requirement for broadening the clinical effectiveness of the device. By controlling the entire process from design to prototype to production, Edmund Optics® could quickly implement Forus Health's feedback and simplify dialogue.

BEYOND STANDARD IMAGING

Although many diseases of the eye display outwardly visible signs, some diseases first affect internal layers of the retina and require detection methods that can see beneath the eye's surface. Retinal Optical Coherence Tomography (OCT) is such a method, and is used to extract information from the internal layers of the retina to provide the early and accurate detection of a variety of pathologies. Retinal OCT is an interferometric technique that recombines light reflected from the retina with an internal reference beam. The result of a Retinal OCT scan is a 3-dimensional map of the retina, which can reveal structural defects that are difficult to identify through traditional ophthalmic procedures. Retinal OCT is particularly helpful for conditions that primarily manifest in between retinal layers, such as age-related macular degeneration, central serous retinopathy, and cystoid macular degeneration.

The high sensitivity of interference techniques such as Retinal OCT produces high resolution, accurate images, but leaves such methods dependent upon the quality and arrangement of the optical components used within the instrumentation. For example, a manufacturer of an OCT instrument consulted with Edmund Optics® engineers to improve system performance; the use of standard plate and cube beamsplitters had been decreasing optical throughput, and image quality was being negatively affected by inconsistent polarization control. The EO team recommended replacing the existing beamsplitters with wiregrid cube beamsplitters, which allowed the manufacturer to maintain the instrument's form, fit, and nominal function while increasing efficiency and maintaining cost position.

Another equipment manufacturer relied on EO's expertise in optical coatings to improve an infrared retinal imaging system; ghost images within the system were causing false positive indications of retinal pathology. Edmund Optics® recommended replacing the existing optics and using a standard near infrared anti-reflection coating. Since both the optics and coating are produced by Edmund Optics®, EO could monitor the optical production and make adjustments as needed.

By partnering with Edmund Optics®, ophthalmic instrumentation manufacturers have been able to improve instrument performance while easily retrofitting existing equipment.

FROM ASTRONOMY TO OPHTHALMOLOGY

The best optical imaging system is still subject to aberrations introduced by the medium between the optic and the object under inspection, even if the medium appears transparent. Aberrations, or deviations in the direction of light travel, introduced by the gas or liquid medium distort and degrade the image, no matter how precise the optics are. A few decades ago, astronomers began using Adaptive Optics (AO) to detect and correct aberrations introduced as light from a distant object travels through the atmosphere. Since biological samples typically scatter light in the same way as the atmosphere, techniques created for astronomy are now being applied to medical imaging, including fluorescence microscopy and retinal imaging.

An adaptive optical system has two functions: to sense and correct distortions of the optical wavefront, commonly using a wavefront sensor

and deformable mirror. The effectiveness of both the sensing and correction can be limited by the imperfections of the other optical components within the system. For example, the scratches and irregularities of an optic can produce dim spots in the illumination pattern and degrade the performance of the wavefront sensor. In addition, the deformable mirror is only capable of correcting a finite amount of wavefront error. If a large amount of error is introduced into the system by other optical components, the deformable mirror will be unable to properly compensate for aberrations caused by the medium, such as the vitreous humor and other structures within an eye.

A manufacturer of an ophthalmic AO retinal scanning instrument requested that Edmund Optics® help minimize system performance inconsistencies. Edmund Optics® engineers evaluated the components used within the beam path — beamsplitters, mirrors, and lenses — and found issues with the quality of the original components. By replacing the existing components with higher precision optics, such as EO's TECHSPEC® Precision DUV Enhanced Mirrors, the EO team helped improve the beam quality and reliability of the retinal scanner without an expensive and time-consuming design overhaul.



Figure 2: TECHSPEC® Precision DUV Enhanced Mirrors provide excellent reflection from 170nm to the long-wave infrared.

FDA AND GOVERNMENTAL CLEARANCE

Medical equipment manufacturers must obtain and maintain approval from various regulatory bodies, which can be an arduous, time consuming process that may outlast the entirety of product development. By minimizing the number of suppliers used to develop and fabricate a medical device, instrument makers can reduce the cost and duration of approval. Since Edmund Optics® can design, manufacture, coat, and mount its optical components, every aspect of development and production is controlled and documented, simplifying approval and periodic audits for medical equipment manufacturers.

COLLABORATING IN YOUR DESIGN

Ophthalmic instrument designers juggle a wide range of responsibilities: electronic and mechanical integration, ergonomic and ruggedized packaging, algorithm development, and data presentation — to say nothing of the regulatory approvals. Optical component specification is just one among many tasks in which you need stellar performance, yet it is absolutely vital for system performance.

“At Edmund Optics we have one concern: helping customers get the right optical components to fill their specific application needs.”

We have helped designers produce or improve a wide range of ophthalmic instruments, and we’re prepared to apply that expertise and capability to your ophthalmic instrument design. Contact us today to see how we can help.

HOW EDMUND OPTICS CAN HELP YOUR OPHTHALMIC INSTRUMENT DEVELOPMENT

Ophthalmic instrument development can be challenging. Let Edmund Optics speed your product development by applying our expertise to your problem.

- Complete offering of off-the-shelf optical components speed proof-of-concept and prototyping
- Optical system design expertise removes uncertainty and builds confidence in design performance
- Affordable custom component development keeps costs under control
- Stock component modification service with quick turn around reduces time to market
- Seamless transition to volume production simplifies your product launch
- Optical assembly services to augment your internal capabilities
- Engrave or serialize parts for traceability
- Inspection reports confirm components meet published specifications and include data documenting performance to streamline regulatory audits
- State-of-the-art metrology services and ISO9001 certification ensure quality components meet your specifications and application needs

ADVANCED COMPONENTS IMPROVE PERFORMANCE

Cataract surgery illustrates many of the challenges of typical ophthalmic applications. This multistage process to remove and replace an eye’s biological lens with an artificial lens is performed differently depending on the surgeon. Yet, regardless of the instrument used, precision is critical in minimizing risk of injury to the patient. The eye presents a significant surgical hurdle. Since the cornea, capsule, lens, and cortex are optically

transparent, there is very little contrast between these different structures. Cataract surgery is both delicate and difficult, and surgeons need optimum illumination to maximize efficiency.

Instrument designers start from a set of requirements, such as angular distribution, uniformity of illumination, and wavelength range, and then translate the requirements into an optical design. Ophthalmic systems are complex, though, and can often require four or more unique lenses. One medical instrument manufacturer reduced the complexity by involving Edmund Optics® in the design process. Edmund Optics® engineers simplified a complex multi-lens system by using aspheric lenses. Aspheric lenses are more complex than traditional spherical lenses.

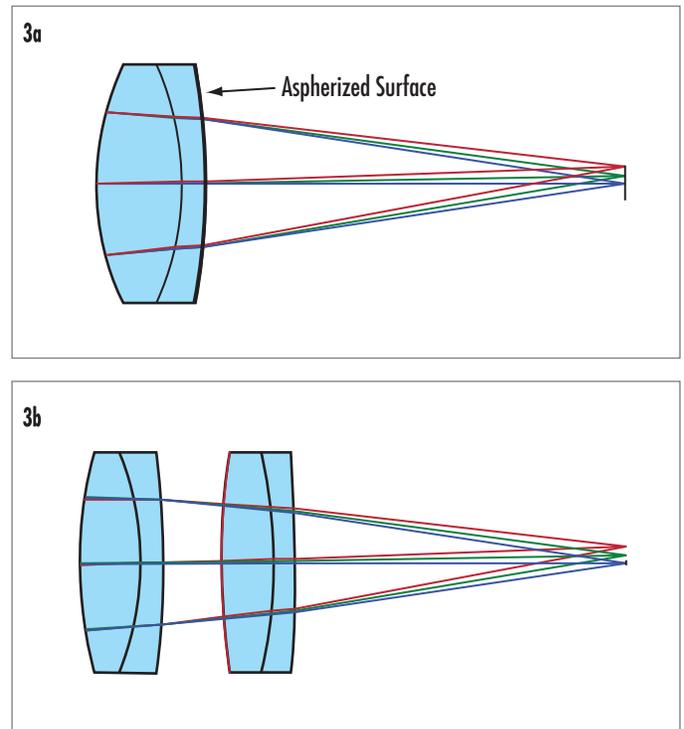


Figure 3: A single doublet with an aspherized surface (3a) outperforms two achromatic lenses (3b).

Whereas spherical lenses can be fabricated with relatively straightforward grinding and polishing processes, aspheric lenses require advanced processing equipment and the process knowledge to predict the tool movements needed to create a specified aspheric surface profile. Edmund Optics’ extensive experience in aspheric design and fabrication has drastically lowered both the design and fabrication cost associated with aspheric lenses and has enabled the adoption of aspheric lenses for low volume, less expensive applications.

When a cataract illumination system developer approached Edmund Optics with a need to develop a device capable of delivering a specific illumination level and pattern, EO helped design a system that paired an off-the-shelf aspheric lens with a custom one. With just two tightly-toleranced aspheric lenses, the system became capable of collimating and distributing light to specification. Although the tight tolerances increased the difficulty of the design, EO’s experience enabled the medical device to successfully reach mass production at the desired cost.