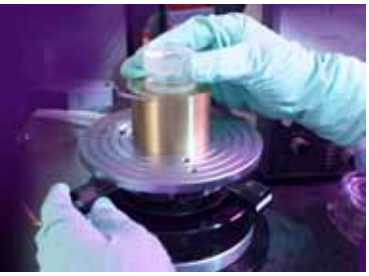
4 Big Mistakes in Developing Photonics-Enabled Medical Devices



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Photonics components have become key enablers in the design and development of next-generation medical devices and diagnostics. This trend has its roots in mature imaging technologies like optical microscopy and endoscopy/colonoscopy, which gained momentum with the recent rise of minimally invasive surgeries and molecular diagnostics. Now it's poised to accelerate, through emerging applications such as optogenetics, laser ablation therapy, and optical coherence tomography (OCT), among many others.

To get a sense of the technology's projected scale, consider that the global market for photonics in medical technology and life sciences is projected to nearly double during the current decade — increasing from approximately $32 billion in 2011 to $56 billion in 2020 — according to market research.[1]

However, the more widespread use of optics and photonics technologies in medicine presents certain difficulties for medical device original equipment manufacturers (OEMs). Integration of these complex, high-precision components must be considered and managed carefully, all the way from the earliest design phases through to production.

Zygo Corporation, an ISO 13485 and 9001 certified supplier of optical components and electro-optical assemblies, has been helping medical device OEMs successfully integrate photonics capabilities into their medical products for more than 15 years. Our extensive experience in optical design, assembly, and high-volume manufacturing equips us to not only supply precision optical components and systems on a build-to-print basis, but also to shepherd them all the way through the development process, from concept to production.

Following are four of the most common mistakes we see medical device manufacturers make, when attempting to incorporate optics and photonics into their designs.

A custom built photonic medical device: An assembled laser surgery objective with a cutaway view of the lens stack.

Mistake #1: Incomplete Tolerance Analysis

Tolerance analysis and budgeting is the process of determining the necessary design specifications for each component within the context of the entire system to ensure both the manufacturability and the optimal performance of the final product. In a system that involves photonic components, from source to imaging, with all the flat, spherical and aspherical precision optics in between, optical design tolerancing is critically important[2] — optical and mechanical engineers need to understand how tightly the size, surface figure, thickness, tilt, centering, and other parameters of the optics must be controlled. In addition, it is equally important to simultaneously analyze mechanical tolerances, to avoid having one aspect of the design "hoard" the available tolerance budget at the expense of the other.

Unfortunately, many medical device OEMs perform an incomplete tolerance analysis, failing to take into consideration all aspects of their designs. Sometimes they don't have the engineering background to fully understand all of their optical requirements and performance drivers for their particular system needs. Or perhaps they have an idea of what they are trying to achieve from a biologics standpoint, but they are not well equipped to convert that concept into

optical and mechanical requirements. In circumstances where design work is outsourced, the contractor may understand the nominal system performance requirements but may not be experienced in tolerancing a design for real-world assembly.

Regardless of the reason why it happens, incomplete tolerance analysis during design often results in problems. Under-specifying optical tolerances can cause performance shortfalls or issues during final assembly, either of which will require expensive and time-consuming design rework. And if the problem isn't identified until after clinical trials have begun — or, worse yet, concluded — the cost and time ramifications are amplified significantly, since every design change needs to be re-qualified by the Food and Drug Administration (FDA). Likewise, over-specifying optical tolerances can add unnecessary cost, complexity, and lead time to a project.

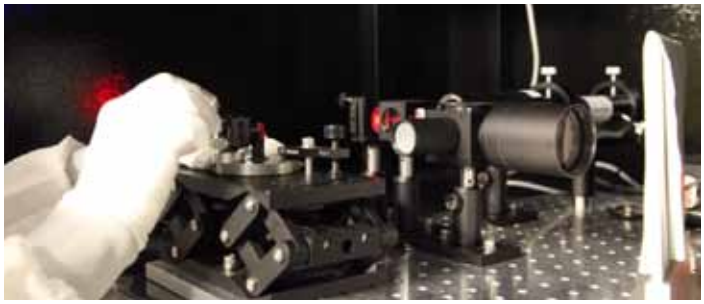
To avoid such situations, medical device OEMs need to work with someone (internally or externally) who not only understands optical and mechanical systems design, but can also translate requirements into specifications that can be defined, quantified, and measured throughout the different stages of development.

For example, we worked with a medical device manufacturer on two beam expanders and an objective lens for an ophthalmic application. The company had engineers on staff who understood optical system design very clearly, which made for a great working relationship. They clearly understood and communicated the technical performance requirements but handed over the entire optical design and tolerancing to us. We ended up designing, verifying, and building the assemblies for them. The product yield and performance had high success rates, and the OEM was able to get its product to market very quickly.

Mistake #2: Failing To Fully Inspect Components

Many medical device OEMs believe that if they submit a blueprint for a custom component to a machine shop — or review the datasheet for an off-the-shelf product (like optics or cameras) from a supplier — the parts they receive will precisely match what's on the documentation. They trust suppliers to deliver components to spec, and so they neglect to perform complete incoming quality control (IQC). Extremely subtle issues can be detected during the inspection process, but the fundamental goal is to ensure that the components will work together properly in the final product.

It is important for medical OEMs to have the capability to verify that what they are receiving is exactly what they asked for, especially when the components have tight optical and mechanical tolerances. We have dealt with machine shops that lack the necessary equipment to determine whether the finished opto-mechanical part matches the print. Even if a supplier does have the necessary inspection capabilities, it is incumbent upon OEMs to verify incoming part quality for themselves.



A measure of commitment and expertise: A custom-built interferometer may be what is needed to assure optical alignment of a lens assembly.

If they don't, they run the risk that the parts won't fit together in the product or achieve the alignment tolerances indicated by optical modeling. Imagine performing a final system test and finding that the product is missing its performance targets. It will be a mystery as to what specifically is causing the problem. Consequently, the production line will need to be shut down, and a root cause analysis will need to be performed, which can take a very long time. And once the faulty component is identified, the entire lot may need to be scrapped and replaced, and the design may need to be reworked.

We encountered such a situation when assembling a device for analyzing proteins for a diagnostic OEM. One of the components of the opto-mechanical design (which was developed by another firm) was an off-the-shelf, high-performance microscope objective lens. However, the OEM didn't develop screening criteria for these objectives and didn't inspect them upon receipt — they just expected that parts were going to work. We eventually discovered that there was too much variability with these parts and had to create our own optical inspection requirement (pass/fail criteria) to determine which could be used in the system and which could not. The results: a lot of wasted components and costly delays.

To fully inspect components, especially optical components, manufactures need to invest in expensive, specialized metrology equipment. Many medical device manufacturers — including some of the largest OEMs — choose not to bring that kind of capability in house. Instead, they work with a service provider that has the necessary equipment to verify that the components they receive are what they expected. If parts fail inspection, they can be sent back to the supplier long before they get to the production floor.

Mistake #3: Overlooking the Impact of Shipping

After going through the trouble of understanding the tolerance requirements and carefully inspecting optical components, it's crucial to consider the nature of the sensitive, precision-aligned product about to be shipped and how it should be packaged. To put it in perspective, when we do assembly of optics, the tolerance is at most about 10 microns of alignment precision. That's less than the width of a human hair — near the limit of human vision to see a detail. If that

It worked when it left the factory. What then?

optic moves more than ten microns before it reaches its destination, it is out of alignment and out of tolerance. That is the kind of risk manufacturers run when handing their product over to the shipping company.

OEMs should start thinking about the level of packaging that's required as soon as the opto-mechanical tolerances are understood. Once they know how much movement will be allowed in the alignment tolerance budget, they can determine how to constrain the optics and what level of packaging is required. The precision of the packaging design should be consistent with the capabilities of the system to offset shock and vibration during shipping.

The consequences of poor packaging design and misaligned optics can be severe. In the worst-case scenario, time may pass before the customer discovers that something is wrong with the product, which for medical devices could result in misdiagnosis, injury, or worse. Some customers have very sophisticated internal test capabilities and can quickly determine whether or not the product conforms to their requirements. If the product doesn't meet those standards, it will be shipped back to the OEM to assess what went wrong and to either repair or replace it (and ship it all over again).

When working with a design or manufacturing house, make sure that packaging design and analysis is part of the effort. For one medical customer, we predesigned a shipping container for the optical assembly we were building for them and tested it with a dummy part. That test revealed that the G-forces involved with the typical shipping and delivery system would compromise the bonding of the optical components in the assembly. So we ended up reworking the packaging to account for that shipping stress, and every product we shipped to that customer was in a specially designed shipping container. To date, there have been no failures due to shipping.

Mistake #4: Supply Chain Management Failure

Supplier selection is another area where manufacturers of photonic-enabled medical devices can go wrong. Many OEMs have procurement departments that handle supply chain management, but few of those groups possess the engineering knowledge to properly vet a supplier, particularly when it comes to optical components. They simply don't have the expertise on staff to understand what levels of precision a supplier is capable of achieving.

As a result, many OEMs end up assuming that just because the supplier is an established machine shop or optical fabrication house, they can produce the quality of lens necessary for the OEM's specific design. Worse, manufacturers fall into the trap of basing supplier decisions strictly on price. The old adage "you get what you pay for" certainly holds true when it comes to choosing an optics supplier.

The person (or people) making purchasing decisions must have an understanding of the processes used to manufacture the types of optical components their design requires. They need to know what questions to ask and how to validate the response (by conducting an on-site supplier audit, for example). What are the supplier's precision capabilities? What types of tolerances can they really hold? What can they measure? What type of equipment are they using? Do they have calibration certificates for those instruments? What technical resources do they have within their company? Does the project fall within their area of expertise?

It is also important to have dedicated resources that can receive (and inspect — see mistake #2 above) the finished components, and to be able to competently communicate with a supplier when problems arise. Errors will inevitably crop up, even with the best suppliers, and the procurement team needs to have the resources available to quickly determine the root cause and work with the supplier to resolve the issue.

On a related note, evaluating a supplier's ability to handle not only the current level of demand, but also future volumes, is critical. A small machine shop may be very precise and diligent when it comes to delivering a handful of prototype parts in a year, but will it be able to maintain that level of service when clinical trials have concluded and it's time to scale up to production volumes of hundreds or even thousands of parts per year? Changing suppliers at that point can be a major headache for a medical device maker, sometimes requiring revalidation of the product.

Sourcing parts externally involves surprisingly high levels of expertise in assessing vendors. This can be especially true in optics manufacturing.

We had an experience with a machine shop that was producing a high volume of components for one of our clients. After some time had passed, we started noticing failures during our incoming quality check. Our supplier engineering was sent to the shop and discovered that the supplier was manufacturing lens housings (that required very high tolerances) in an environment that was not temperature controlled, which meant that the components had little chance of being compliant. We ended up having to find a new supplier.

Conclusion

The path to market for photonics-enabled medical devices is fraught with peril. Before embarking on development of a new design, OEMs must first make sure they have the necessary expertise to perform a thorough tolerance analysis of the underlying optical components, effectively manage their supply chain, fully inspect incoming parts, and ship the finished product without misaligning the optics or otherwise degrading its performance. For those who lack the in-house resources, and wish to avoid these common pitfalls, the best option is to partner with an experienced firm that can help get new medical devices to the patients that need them as quickly and efficiently as possible.

About The Authors

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With a knowledgeable partner, optical subassemblies, or even final assemblies like this 3D dental imaging wand, including 20 optics and 3 imaging sensors in an autoclave compatible case, can be custom manufactured for you.

About Zygo Corporation

Zygo Corporation is a worldwide supplier of precision optics, electro-optical design and manufacturing services serving customers in the semiconductor capital equipment, bio-medical, scientific, and industrial markets, and optical metrology instruments.

Our Electro-Optics Group's facility in Tucson, Arizona boasts class 100 clean room capabilities, in-line production optical compensation, and Design for Manufacture and Assembly engineering services. The facility is ISO 9001:2008 and ISO 13485-2003 certified, and FDA registered; making it the ideal location for high precision system manufacturing. This facility is regularly audited to FDA standards by existing medical customers.

The Electro-Optics Group's Costa Mesa, California design and prototyping center is tightly integrated with both the Tucson assembly center and our high precision optical fabrication group in Middlefield, Connecticut. The center offers a wide range of engineering and program management service to take on the most demanding Life Science product development challenges.

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