Rapid Injection Molding Reduces Prototype Process Risks for Oximeter

The Project: Quickly manufacture prototypes for the outside bumpers of a new pulse oximeter.

The Solution: Use rapid injection molding to evaluate three part batches for $3,000 per batch in 10 days per order.

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By Brad Cleveland
Medical device manufacturers always face very challenging product testing requirements and clinical trials before they can bring their products to market. This takes so much time that there is a continuous effort to accelerate all phases of the product design and development process. Case in point: design engineers from medical device manufacturer GE Healthcare recently reduced the time-to-market for a new product through use of an innovative process known as rapid injection molding.

GE Healthcare's product is a pulse oximeter dubbed the TruSat&#153 device. Pulse oximetry is used in a broad range of medical environments, including intensive care, operating rooms, emergency rooms, and even veterinary medicine, to provide early information to clinicians on problems in the delivery of oxygen to a patient's tissues.

The design goals for the pulse oximeter were to make it a tabletop device and to make it more durable and easier to use than similar products currently on the market. Along the way, GE Healthcare engineers faced a daunting product testing and approval process involving both internal and external country-specific regulatory agencies. And of course, there was pressure to get it done fast.

To make the initial devices, the engineers needed a way to quickly manufacture prototypes for the outside bumpers on the enclosure&#151plastic parts that protect the oximeter, hold it in place during use, and help provide easy plug-in access.

On past projects, they used stereolithography masters to produce urethane castings. Unfortunately, urethane parts aren't constructed of the same material and don't have the same color and feel as the final product. As a result, the company had difficulties demonstrating the part's functionality to customer prospects at trade shows and performing even the most basic functional testing.

In the case of the TruSat prototype, initial testing was as simple as setting it on a table and pushing buttons on the faceplate to determine if the bumper design would keep it from sliding on the flat surface during use. GE Healthcare engineers knew that if they used cast urethane bumpers, these would simply allow the device to slide across the table. They also knew from the start that urethane wouldn't meet their flammability requirements. For these reasons, a specific resin was needed to perform certifiable tests, which in turn drove them toward real injection molded parts in that specific resin.

Producing real injection molded parts in that specific resin, however, was a challenge because the conventional approaches for creating tooling take too long and cost too much. At this point, the engineers explored the rapid injection molding process available from The Protomold Co., Maple Plain, MN, which offers the ability to get real parts without conventional delays or costs. Protomold's rapid injection molding process utilizes proprietary software technology and high-speed CNC machining to produce real, plastic injection-molded parts from 3D computer-aided design (CAD) models in as little as three days. To check out this option, GE Healthcare submitted its 3D CAD design to Protomold via the company's website at www.protomold.com. Within 24 hours, the team received an interactive ProtoQuote&reg&#151a Web-based price quotation that suggests potential design improvements and demonstrates the effect different options have on price and delivery.

Using this online quoting tool, GE Healthcare engineers were able to interactively select their material, lead time, and surface finishes to determine pricing in real time. This was helpful in moving the process forward quickly, especially since obtaining quotes using traditional injection molding generally takes anywhere from a few days to a week.

Feedback from the ProtoQuote also served as a final design check, highlighting unexpected undercuts and surfaces in need of draft. To rectify these problems, the ProtoQuote illustrated where adjustments needed to be made to allow for part ejection from the mold. The design engineers easily changed the highlighted areas, and the first batch of bumper test parts was ordered.

To complete initial testing and finalize their design, GE Healthcare engineers worked with Protomold during the next few weeks to order three sets of parts, each with a different combination of material and design specifications. The team had its first set of parts in hand for testing within 10 days from placing the initial order. After the initial parts failed GE Healthcare's internal flammability testing, a second order was placed to create prototypes in a different flame-retardant chemistry.

After successfully meeting their flammability requirements with the second batch of parts, GE Healthcare engineers placed a third order, incorporating final design adjustments and color specifications. Because these were real injection molded parts, they proved strong enough to pass all remaining tests, including chemical resistance trials where the bumper is cut into sections that are soaked in cleaners and hospital antiseptics. The ability to test for such conditions enabled GE Healthcare engineers to draw reliable conclusions regarding material properties.

Traditional injection molding would have cost GE Healthcare around $60,000 and taken nine to 10 weeks for delivery of each batch. With rapid injection molding, GE Healthcare was able to receive and evaluate three separate part batches for roughly $3,000 per batch in a time frame of just 10 days for each order&#151around six times cheaper and seven times faster than conventional injection molding.

For GE Healthcare engineers, rapid injection molding allowed them to significantly accelerate the product development process by reducing the risks normally associated with multiple iterations. In addition, while waiting for their steel production molds, they were able to order approximately 500 “bridge tooling” parts from Protomold and get their product to market faster.

ONLINE

For additional information on the products and technologies discussed in this article, see *Medical Design Technology* online at www.mdtmag.com and the following websites:

&#149 www.protomold.com [1]

&#149 www.gehealthcare.com [2]

PULSE OXIMETER FACTS

Pulse oximeters provide clinicians with a non-invasive method of monitoring the percentage of oxygenated hemoglobin (Hb) in the blood stream, testing a patient’s entire respiratory system with one simple measurement. The devices generally use a probe attached to the patient’s finger or earlobe to monitor the percentage of oxygen in the blood. The device emits light at two wavelengths, using readings from light levels to calculate the proportion of Hb that is oxygenated. If a pulse oximeter detects oxygen levels below 90 percent, an alarm sounds to warn medical staff that the patient is entering serious hypoxia, a decrease in oxygen supply to the brain that occurs despite adequate blood flow.

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