

Molding Technology Pays Off for Medical Manufacturer

Medical device manufacturers that collect and analyze patient data are developing innovative ways to integrate electronics and wireless technology into their products. These innovations often present new design and production challenges. That was the case for American TeleCare Inc., a leading developer of specialty patient monitoring devices.

The company's innovative "telehealth" medical devices enable patients to interact with their doctors from the comfort of their own homes, using a combination of audio and video-monitoring equipment. By sending data to doctors over a phone line, the device gives physicians real-time access to critical information such as heart rate and blood pressure.

Recently, American TeleCare, of Eden Prairie, MN., set out to produce a new audio-only monitor station called inLife™ to meet the needs of customers not requiring video monitoring. Due to time constraints, the company was having difficulty obtaining parts that were both cosmetically attractive and geometrically precise, until its engineers discovered rapid injection molding. With help from The Protomold Company, based in Maple Plain, MN., they were able to get the low-cost and dimensionally accurate prototypes and low-volume production parts they needed.

CONVENIENT, SECURE ACCESS TO PATIENT DATA

Most of American TeleCare's telehealth equipment uses live, two-way audio and video to relay a patient's vital information to medical providers, but research showed that patients and medical providers didn't always need full audio and video capabilities. As a result, the company wanted a more convenient, economical and less intrusive system for customers not requiring the video component. To meet this need, the company developed inLife — an audio monitoring station featuring an easy to use touch screen.

inLife guides patients through the health-monitoring process, gathering and recording such information as blood pressure, pulse, weight and glucose levels, as well as automatically adding a date stamp to each data record. Peripheral medical devices transmit data to the inLife monitoring station through either serial cables or a Bluetooth™ wireless adaptor module. The device also asks patients to respond to health-related questions of interest to their medical providers. The system then transmits the information via phone line to a server, which uploads it into the patient's record for physician review. inLife is ideal for patients, such as patients with congestive heart failure, who can benefit from at-home monitoring of vital information.

BREAKING OLD HABITS

To cost-effectively produce the inLife device, American TeleCare engineers needed an inexpensive way to create prototypes and low-volume production parts. Specifically, they needed an economical way to develop the product's key component — its enclosure box. They began by using a stereolithography (SLA) model to test their design concept, but knew they required more dimensionally accurate prototypes to move forward with material testing and verification.

"We needed prototypes that would allow us to test the accuracy of the enclosure's intricate fit dimensions," said John Blomberg, mechanical engineer, American TeleCare. "Without first verifying that the enclosure and circuit board geometries match, we couldn't proceed with mandatory product integrity testing."

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Company engineers explored several options, including room temperature vulcanization (RTV) molding, and steel tooling, for conventional injection molded parts. Both options posed problems. RTV molding limited the quantity of parts that could be created (25 to 50), while steel tooling was costly and required a long lead time. Neither option met the company's need for economical prototype and low-volume production parts. Then they looked into rapid injection molding developed by Protomold, which uses proprietary software and high-speed computer numerical control (CNC) machining to produce aluminum molds. The process creates real injection-molded parts from 3-D computer-aided design (CAD) models in as little as three days.

EXERCISING INNOVATION

The American TeleCare design team started by uploading its 3-D CAD file to Protomold's Web site at www.protomold.com. Within one business day, the team received Protomold's proprietary ProtoQuote®, an interactive Web-based price quote, including such useful information as lead-time options, pricing at various quantities, information on a wide range of molding materials, and even suggestions for design improvements.

“We’ve become accustomed to sending a design out and waiting up to a week to get a quote back from our prototyping vendors, which can sometimes be a roadblock because we often make design changes in the interim that necessitate re-quoting,” Blomberg said. “With Protomold’s online system, we made design alterations and checked the price and lead time conditions right away. Getting quotes back in a matter of hours really moved the development process forward, particularly compared to the turn-around timeframes other vendors offer.”

After submitting its initial design, the American TeleCare engineering team worked with Protomold design specialists to fit the enclosure’s design to rapid injection molding’s process capabilities. To stay within the 50-square-inch size limitation in effect at the time (Protomold can now support up to 75-square-inches) and maximum rib heights of 10 times the rib thickness, the engineers reduced the total product size to 49.5-square-inches and used an alternative mounting method to stay within the allowable rib heights.

“Protomold’s continuous and timely feedback was extremely useful and unique, especially compared to other prototyping vendors, who may not provide much, if any, feedback until the first parts are delivered,” Blomberg said. “Protomold helped us adapt our design to its process to create the best possible piece from the onset.”

After final adjustments to the design, American TeleCare engineers submitted their final prototype order to Protomold, who turned around 25 injection molded prototypes in 5 business days.

“Protomold delivered our prototypes within a week, while delivery from a standard molder would have been two to three months,” Blomberg said. “On top of that, Protomold’s quotes were typically one-half to one-third the price of conventional injection molders. This allowed us to save money while giving us extra time to hone our design and conduct product integrity testing.”

BENEFITING FROM PROGRAM IMPROVEMENTS

With prototype parts in hand, American TeleCare’s engineers proceeded with various products tests. Emissions and susceptibility tests of the new device are required by the Federal Communications Commission (FCC). Robustness was tested with rigorous Highly Accelerated Life Testing (HALT), which subjects a product to extremely high levels of mechanical and thermal stress. The rapid injection molded parts, cast in PC/ABS resin, withstood temperatures ranging from minus 70 to 200 degrees Fahrenheit without incurring any material failures, such as loose screws or broken ribs.

“With our demanding product development deadlines, it helped to have dimensionally accurate enclosure parts available for testing within a few weeks, versus waiting two months or more just to get prototypes,” Blomberg said. “In fact, the prototype parts from Protomold arrived before our circuit boards, which rarely happens.”

Adding to an impressive delivery time, the Protomold prototypes also improved cosmetic quality. While previous prototyping methods yielded parts that chipped when dropped and required painting to meet appearance requirements, the Protomold parts maintained a uniform exterior even if chipped or scratched.

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“We wanted a durable product that we could snap into place and test rigorously,” Blomberg said. “Rapid injection molded parts don’t require painting and hold up under long-term wear. Most importantly, they give us the ability to provide a product that will maintain its original cosmetic quality throughout its lifespan with the customer.”

FROM PROTOTYPES TO LOW-VOLUME PRODUCTION

Based on their positive experience with rapid injection molded prototypes—in terms of speed, price, and cosmetic quality—company engineers turned to Protomold for low-volume production.

“Before rapid injection molding, we were stuck between rapid prototyping and conventional injection molding,” Blomberg said. “To accommodate our need for 1,000 to 2,000 prototype parts, we could either make a lot of RTV molds or pay the high cost to create steel molds for injection molded parts. Either way, it’s an expensive process. Rapid injection molding fills the gap by giving us the ability to create 1,000 to 10,000 prototype parts in a timely, cost-efficient manner.”

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American TeleCare ordered parts for inLife’s official product launch in January 2005 and has the option of using Protomold for future production. Company engineers have worked with Protomold on a related telehealth product that incorporated Bluetooth technology, a wireless adaptor module, which it launched in 2003.

To learn more about American TeleCare products and service offerings, visit www.americantelecare.com. For more information about Protomold’s innovative rapid injection molding process, visit www.protomold.com.