Prototype Used for Actual Surgeries Helps Physicians See its Value

July 8, 1998

EXECUTIVE SUMMARY

FDM® User	Logica, on behalf of Honeywell
Application	functional prototype of medical device
Products	Logica: design and prototyping services Honeywell: controls for homes, buildings, industry, space and aviation
Challenge	functional end product look-alike required to enable potential users to understand technology
Solution	built functional prototype using RP technologies including FDM
Results	• dramatically increased potential user understanding and acceptance of new medical technology • over two dozen actual surgeries performed with prototype device • increased strength and heat-resistance of prototype assembly by using FDM • successfully communicated design to management

Honeywell and Logica tested a new medical device technology using a functioning prototype built of RP parts, including FDM.

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For the first time, military surgeons have performed arthroscopic surgeries in the field, thanks to a new miniature color-display technology developed by Honeywell under DARPA sponsorship (Defense Advanced Research Projects Agency). Honeywell had the medical device prototyped using FDM in conjunction with other rapid prototyping technologies. Honeywell's new device replaces cumbersome CRT monitors, making it easier for surgeons to conduct minimally invasive surgeries in limited-space environments. The miniature display is mounted on a headset. It is used to view video images of a patient's internal geometry. During testing in both military and non-military surgical settings, surgeons wore a prototype headset assembled of various RP parts, including FDM. While many of the surgeons could not see the potential advantages of the device in early focus-group discussions, they immediately recognized its benefits when they put on the functioning prototype. It made the difference between being able to sell the concept to medical market leaders and losing funding for the program due to lack of understanding of the technology.

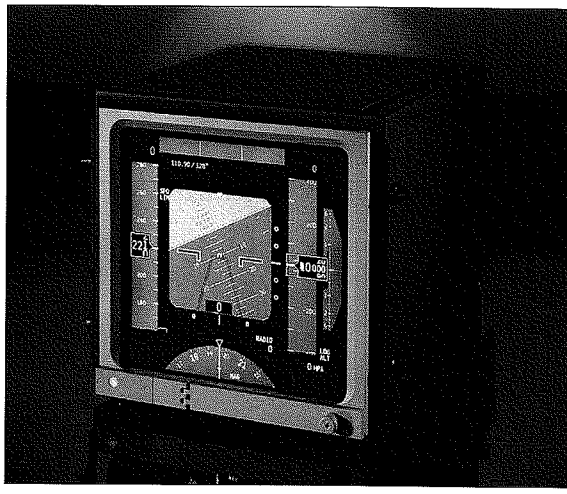
. . . in our markets there is no permanent advantage. No best stays best for long. Especially for a leader, a healthy dissatisfaction with the status quo is mandatory.

Michael Bonsignore
Chairman and CEO
Honeywell
(from the 1996 annual report)

Honeywell — The Authority in Control and Display Technologies

Honeywell was founded in 1885 with the invention of the automatic thermostat control for home heating. With over 50,000 employees in 95 countries, Honeywell achieved over seven billion US dollars in sales in 1996. The world's leading supplier of avionics systems for commercial, military and space use, Honeywell is also a recognized leader in militarized head-mounted display technology.

The company has one worldwide technology center focused on R&D, with branches in Prague, the Czech Republic; and Phoenix, Arizona and Minneapolis, Minnesota in the US. Some key strategies for the technology center have been to extend established industry and technology leadership positions; to penetrate global commercial, military and



Honeywell is well-known for its high-resolution flat panel displays, such as this display for a Boeing 777, as well as its head-mounted display technology.

Honeywell Control Systems Technology

controls
displays
processors
sensors
software
systems

space markets; and to apply commercial products and technology to government markets. To support these objectives, Honeywell spent $353 million on research and development in 1996 in the technology center and in its operational divisions.

Investing in Research and Development

The Honeywell Technology Center develops and evaluates advanced technologies, processes and product and service concepts for use in military and commercial settings. Honeywell is a leader in high-resolution, flat-panel displays for commercial, industrial and military applications. The technology center's display group develops both display processors and advanced display systems, including flat-panel and projection displays. Because of the display group's extensive experience with this type of technology, the US government approached them with a new concept for a miniature display.

Having identified a need for high-resolution miniature displays for its pilots and soldiers, DARPA funded the display group's efforts to investigate the technology and identify additional applications for it. According to Scott Nelson, staff scientist at the Honeywell Technology Center in Minneapolis, the military primarily uses monochrome head-mounted displays. Commercial markets require color displays. Both color and monochrome display systems, however, could be manufactured by the same production lines, translating into significant cost savings for the military. With DARPA funding, Honeywell identified a medical application for the technology that would benefit both military and private-sector users.

A Small Idea With a Big Impact

Surgeons use video endoscopes for minimally invasive surgical procedures such as arthroscopy and laproscopy. The endoscope has a miniature camera that transmits an electronic image to a CRT monitor. The monitor display is often located several feet away from the operating table, causing the surgeon to look away from the patient to view the image. Constantly turning one's head back and forth between patient and monitor is awkward, and looking in the opposite direction of the procedure can be disorienting.

Military surgeons face an additional challenge. They are deployed two or three times annually to combat support hospitals for training exercises and/or deployed troop support. The surgical teams are trained to be able to perform surgery within four hours of hospital deployment and to be fully deployed in just 48 hours. A typical combat support hospital has about 120 medical personnel, including three surgeons. The hospitals have about 350 beds and multiple tents and shelters. They handle everything from sprained ankles to trauma and intensive care. As well equipped as it

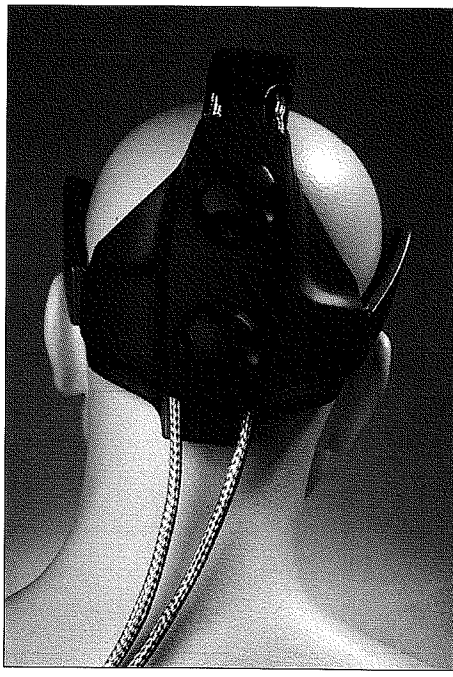
may be, the medical team is still limited in the types of procedures it can perform. There are restrictions on the weight and volume of equipment that can be transported to a field location. The CRT monitors used to conduct endoscopic procedures are large, heavy and fragile, making it nearly impossible to transport them. For this reason, the US military currently flies soldiers back to military hospitals for endoscopic surgery. This is very expensive and time consuming, and it can leave forces less prepared because they're short staffed.

Honeywell research scientists identified miniature head-mounted display technology as a solution for both ease-of-use and portability problems. After the technology had been under development for about a year, the Honeywell Technology Center brought in Logica, a Minneapolis engineering and industrial design firm to help design and prototype a stereoscopic head-mounted device that uses the miniature-display technology. Surgeons can easily adjust the headset to maximize comfort. Two miniature color displays are mounted directly in front of the eyes. They are individually adjustable, allowing each wearer to optimize the image. The video-display electronics are contained in a small pack worn by the surgeon.

The headset eliminates the need to look across the room at a monitor. "Using the headset is much less disorienting than using a CRT monitor because the surgeon can look toward the patient during the procedure," says Nelson. Lightweight, durable and compact, the headset is also easy to transport for military field deployments. By enabling military surgeons to perform endoscopic surgeries in the field, the headset will help maintain force readiness and improve surgical care in the field.

Without a prototype, the users couldn't see the potential benefit of such a sensory technology — so we couldn't get meaningful feedback on our design. The surgeons couldn't understand how the technology would help them in their jobs without actually trying it. That's when we turned to Logica for RP.

Scott Nelson
Staff Scientist
Honeywell Technology Center



Logica assembled this prototype with ABS parts built on an FDM system. Both the miniature color displays and the headband are adjustable.

Conducting Successful Focus Groups

A trait that sets the Honeywell/Logica team apart is the skill of finding the right focus-group participants. With the constant influx of new products into the market, the team's strategy has been to break through the clutter by reaching industry leaders who, in turn, influence the rest of the market. "We look for people who are leaders in their field — people who want to understand new technology and who are willing to test new products," remarks Dan Cunagin, Logica vice president of engineering. "If you gain the early adopters' acceptance, you can influence the followers as well." Cunagin says early adopters tend to have speaking engagements and give semi-

nars at which they mention new technologies and products, thus increasing awareness. Followers observe them to see what new technologies they support, and tend to feel more comfortable about investigating those technologies on their own.

"There are many followers and few leaders — especially in the conservative medical field," notes Cunagin. "Few people are willing to analyze a new technology and assess whether it would benefit them." In planning for focus-group testing for the miniature display technology, one of the challenges Honeywell and Logica faced was the high-quality color and resolution of the existing CRT equipment. Physicians require high-level image performance to operate. Because the miniature color-display technology was still in development during initial focus-group testing, the image quality was not as high as the traditional CRT the surgeons were accustomed to.

Nelson and Cunagin felt that a low-quality image would bias the surgeons' perception of the entire technology, so they began conducting early focus groups without prototypes. Sensory-type products such as the headset, however, often do not get an accurate assessment of their validity without prototyping. "Without a prototype, we quickly learned we could not get meaningful feedback on our design," maintains Nelson. "It wasn't until 1995 that the miniature-display resolution was anywhere near the quality of the CRT. Once we passed that milestone, we needed prototypes, but we couldn't justify tooling costs for focus groups. That's when we turned to Logica for rapid prototyping."

Using Rapid Prototyping to Facilitate User Input

About a year after the initial discussions with users, more focus groups were conducted — this time with functional prototypes assembled from FDM and SLA parts. Without rapid prototyping, Logica would have had to machine the parts out of plastic. According to Cunagin, machined parts would have been significantly less representative of production parts than RP parts, and they would have hindered efforts to get quality user feedback. Logica needs to conduct focus groups without the distraction of a prototype that's not up to par aesthetically. To achieve this, Logica requested several FDM parts for the assembly because the ABS material is easy to finish, and it approximates injection-molded plastics. "If we want the surgeons to give us input, we need to provide them with a prototype that looks as much like a real product as possible," Cunagin affirms. "With any wearable product, the design becomes very sensitive. If the physicians are embarrassed to put the headset on, they may not even get to the point where they're evaluating the technology. But if the prototype is well-built from an ergonomic and aesthetic standpoint, we're much more likely to get a fair technology assessment." Nelson adds, "We couldn't

By incorporating their feedback into the next prototype iteration, the surgeons actively participate in the design process.

Dan Cunagin
Vice President, Engineering
Logica

have achieved that without RP — especially FDM. Machined parts look machined. But with a little finishing work, FDM parts can look like injection-molded or cast parts — like the real product." Most of the headset parts will eventually be injection molded. A few of the smaller parts will most likely be die cast.

For testing purposes, the surgeons were videotaped using the headset for real surgical procedures. Logica interviewed the participants both during and after the procedures. The surgeons provided design input, suggesting enhancements and improvements. The product received dramatically different feedback — much more positive. "Once the physicians used a functioning prototype, the advantages became much more obvious to them," Cunagin recalls. "The same surgeons who said they weren't sure about the technology during earlier discussions could now see the benefits immediately."

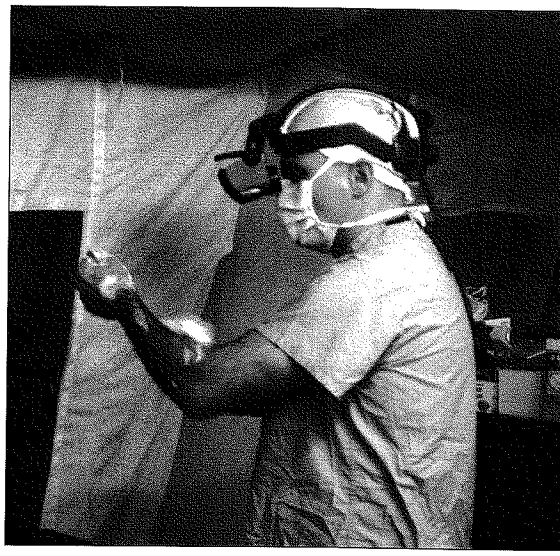
Surgeons test the miniature display technology using a prototype headset with ABS parts modeled on an FDM system. Over two dozen actual surgical procedures have been performed with prototype headsets.

Using rapid prototyping enabled Honeywell to get valuable user input at an early stage in design. Users evaluated the headset's weight, balance and adjustability. While they could view the display no matter how their head was oriented, their peripheral vision was also excellent, allowing them to see around the unit. "It's much easier to perform a procedure when your head is oriented toward the area you are working on," notes one of the doctors. "The benefits of this technology are very clear now that I've tried wearing the prototype during surgery." After testing the first functional prototype, user feedback was incorporated into the design, and more functional prototypes were built. This allowed users to participate actively in defining the product.

The Honeywell/Logica team also conducted functional testing during a military deployment exercise. Military surgeons tested the prototype headset in the field during arthroscopic knee surgeries. At less than 28 ounces, the headset is easy to transport, making minimally invasive surgical procedures possible in field deployment settings. Four functional headset prototypes have been built to date, with a combination of FDM and SLA parts. Over two dozen procedures have been successfully performed using the prototypes.

Choosing the Right RP Technology

Logica's challenge is to balance cost, performance and speed — to deliver the best prototype solutions to its customers. Depending on a client's needs and the prototype's intended use, Logica will select from several RP processes as well as die-cut foam, sheet-metal parts, machined parts — even purchased components. "Rarely can we take a concept and prototype it using just one process," says Cunagin. "It's always a combination of different processes, because each one has its individual strengths." Logica designers take an objective look at the different RP processes available and determine which process makes sense for each part they design. Cunagin believes that strategy serves Honeywell's needs best. Nelson relies on Logica to choose the right mix of RP for a particular assembly. "I'm familiar with the various RP technologies, but I leave those decisions to Logica," he remarks. "It's their job to know the best RP technology for our projects."



A military surgeon prepares to test the prototype during a real procedure.

"We look at the complexity and the size of the part," continues Cunagin. "We use FDM because we like Stratasys' ABS material properties. It's easy to finish, it's strong, and it approximates injection-molded plastic." Several factors influenced Logica's decision to go with FDM for portions of the headset assembly: the strength and heat-resistance properties of ABS, quick turnaround and ease-of-modification. The part across the top of the headset was prototyped using FDM because it's a contoured, curved part. Cunagin says interface-area accuracy on contoured geometry can be very difficult to achieve with other RP processes. The electronics pack that supplies power to the two displays was prototyped on the FDM system due to thermal considerations. The pack is very small (3 x 2 x 1 inches) and can generate a great deal of heat in its prototype form. It contains a very high-density PC board with the electronic equivalent of two television sets, plus video converters. "We chose FDM parts for the electronic covers and case housings, because the operating temperature was more than SLA or LOM could withstand," states Cunagin.

Other assembly parts were built on an SLA system. Demo units assembled entirely of SLA parts were given to marketing for review. Unfortunately, some of the SLA parts broke because the units were subjected to more rugged handling than Honeywell had planned. Nelson says that when more FDM parts are used for the headset assemblies they stand

We look at the complexity and the size of the part. We like to use FDM because we like the material properties of Stratasys' ABS. It's easy to finish, it's strong, and it approximates injection-molded plastic.

Dan Cunagin
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Logica

I've been impressed by what can be done with FDM technology since the first time I was exposed to it. We need the level of functionality that the ABS material provides.

Scott Nelson
Staff Scientist
Honeywell Technology Center

up to handling much better. Overall, Honeywell has been very pleased with Logica's prototypes. "I've been impressed by FDM technology since the first time I was exposed to it," maintains Nelson. "We need the level of functionality that the ABS material provides."

Cunagin indicates Stratasys' ABS material is in high demand because of its snap-fit capability, its strength, and the fact that it closely approximates injection-molded plastic. FDM prototypes can be finished to look very much like the end product. "The ability to finish the parts is critical," he states. "Some RP parts are easier to finish than others." According to Cunagin, there are limitations to the types of finishing work you can do to an SLA part. "You can't always add inserts because a photopolymer behaves more like a thermoset material. And it's brittle, too," he continues, "especially over time." Rather than heating an insert and sinking it into the SLA part, Cunagin says he would have to drill a hole in the SLA part and glue the insert with epoxy. "It's a lot easier to modify an FDM part, which is why we'll often choose FDM over SLA," Cunagin admits.

RP as a Business Advantage

It's very difficult for us to develop the types of products we do — within the schedules and budgets set for us — without RP. It's a given for us.

Dan Cunagin
Vice President, Engineering
Logica

Our program wouldn't be funded this year if we hadn't used RP technology last year. Upper management was amazed that we could do so much so fast — and have a prototype that looked like a real product. There's nothing that compares to putting hardware on the table.

Scott Nelson
Staff Scientist
Honeywell Technology Center

Logica has been in the engineering and industrial design business for over 30 years. "We added the engineering function to our design capabilities about 12 years ago," notes Cunagin. "For five years, it gave us a competitive advantage — a discriminator that set us apart." At the time, there were design firms and there were small engineering firms, but there were less than a dozen firms in the US offering both functions.

When other firms began adding engineering to their industrial design groups, Logica added seven seats of Pro/ENGINEER® — another discriminator. "We were one of the first users of Pro/E in the Minneapolis area," says Cunagin. "Because we were an early adopter of Pro/E, we had the advantage when RP technologies became available." Design firms without Pro/E had the extra step of building a solid model before they could generate an .STL file for an RP system. But Logica could export an .STL directly from Pro/E. Logica became one of the first design firms in the Midwest to incorporate RP into its design process in 1990, once again setting itself apart. For FDM parts, the company established a strategic relationship with Excell Models & Prototyping, a model shop located adjacent to Logica.

Cunagin considers RP to be an integral part of Logica's business and its process. "Without RP it's very difficult for us to develop the types of products we do — within the schedules and budgets set for us. It's a given for us," he adds. Each time Logica has incorporated a capability or service that its competitors don't have, the company has experienced strong growth.

"We always try to keep up on the latest RP tools," says Cunagin. "We probably spend over a million dollars annually on RP, which is

why Excell approached us when they were initially looking at bringing a rapid prototyping system in-house." Cunagin reviewed sample FDM parts with Excell Manager, Scott Krentz, and agreed that FDM would serve 50% of his RP needs.

Building a Functioning Prototype

Excell Models and Prototyping has an in-house FDM system, among other modelmaking equipment, including a CNC router, milling machine, and woodworking, moldmaking and molding equipment. "We bought our FDM system as a tool to bring in more business," says Krentz. FDM rapid prototyping is now 20-25% of his business. Krentz chose FDM over other RP technologies for several reasons. "I liked the fact that I didn't need to vent the system," he adds. "Not only would venting have been an added cost, but it would mean that the system wouldn't be portable." Krentz has already moved the FDM machine to another location in the shop and says it took just a few minutes to do.

Excell gets involved when Logica is in the concepting stage of design. "We're networked with Logica, so file transfer is easy," Krentz notes. "They can make changes on the fly, and we can run another FDM part immediately. We can start a part for them in less than half an hour." Excell modelmakers often run the FDM system overnight — something they can't do with their other equipment that requires an attendant. "This is a very competitive business," indicates Krentz, who has worked extensively with various forms of rapid prototyping. "We needed a fast, reliable system that produces parts in a durable material that's easy to sand and drill. Stratasys' FDM system fits our needs." He also says that injection-molded plastic is a common material choice for his clients. Cunagin adds, "We make decisions on Honeywell's behalf about which RP technology to use. FDM is an excellent solution to Honeywell's prototyping challenges."

The FDM system removes most of the human error potential from the situation; the CAD file you import is the model you get.

Dan Cunagin
Vice President, Engineering
Logica

How Honeywell Uses RP Technology

Rapid prototyping technology is very important to Honeywell as a company. The military and display groups at the Honeywell Technology Center use RP, but it's used even more extensively for the company's home and building control products, due to short product life cycles.

"We use RP as a design validation tool," Nelson remarks. "Designers tend to make certain assumptions as they go along. To a certain extent, you never really know what you've got until you see it in 3D. If you can identify certain points along the development path and stop to create something real for someone to touch and use, you can validate your assumptions much earlier." Not only does this strategy speed Honeywell's development process tremendously, but it also builds confidence throughout the chain of command and across functional groups. An FDM part

We push speed to market, because the faster we can get from defining customer requirements to quality delivery, the more likely we'll delight our customers. And delighted customers drive sustained, profitable growth . . . We've identified the best practices that will get us to market faster and to profit sooner . . . ***Rapid prototyping lets us quickly build and test models of products using computer technology.*** *(emphasis added)*

Honeywell '96 Annual Report

communicates a design much quicker than a 2D drawing or even a 3D CAD image. "It's always easier to put something in their hands than to show them a drawing and ask them to try to visualize the product. Our program wouldn't be funded this year if we hadn't used RP technology last year," maintains Nelson.

FDM gives Honeywell a much faster path to pre-production and production capability. Machining techniques don't allow Honeywell to go quickly from a few parts to hundreds of parts. "With RP, we can take the same CAD files from the RP domain, to the pre-production domain, to the high-volume production domain," continues Nelson. "Being able to transfer the same database easily from one domain to the next makes me feel more comfortable." Cunagin agrees, "When you're machining, there's always that human element involved. You're never quite satisfied that you're getting a good validation on your database. The FDM system removes most of the human error potential from the situation. The CAD file you import is the model you get," he concludes. "We see FDM as very cheap insurance, because it only takes the elimination of one or two relatively insignificant tooling changes to offset the cost of the RP iterations."

Bringing the Product to Market

Product development time at Honeywell varies quite a bit depending on factors such as design complexity and competitive development. As a medical technology, the headset will require FDA approvals and, therefore, a bit longer than other technologies to move from initial concept to product. But the goal is to shorten the timeline. "By using FDM technology, we get our parts in hours versus a week or two," says Nelson, "and they are much closer representations to the actual CAD file — much more accurate. It helps us improve our designs and complete them faster. In this case, the product concept was ahead of the available display technology. The miniature display technology is still improving, and it will catch up to headset concept soon. Not only will the product design have a very high-quality display, it will be easy to use and well-designed ergonomically and aesthetically. We will have incorporated a wealth of user input thanks to FDM rapid prototyping."

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Dan Cunagin
Vice President, Engineering
Logica

Stratasys, Inc.
+1.612.937.3000 (tel)
+1.612.937.0070 (fax)
www.stratasys.com (internet)
14950 Martin Drive
Eden Prairie, Minnesota
55344-2020 USA