ANALYZING MEDICAL DESIGN

Miles, Inc., Diagnostics Division, was challenged to introduce a new floor-standing automated blood analyzer, referred to as the Opera™ System. This new product was the successor of a previous instrument known as the Technicon RA 2000™ System, which was manufactured using sheet metal technology over the course of its 4-year history.

Design criteria for the new Opera System included:

- A contemporary appearance that would express technological leadership in an international marketplace.
- A design that would be distinctive and set a trend in the industry.
- A design suitable for a wide range of users, optimizing human factor considerations.
- A design requiring minimal tooling investment, which could be easily amortized during the first year of production.
- Tooling within 10 weeks.
- Easily assembled with minimum adjustments and alignment procedures.
- A design which would pass shipping tests.
- A design that insured manufacturing consistency and quality.

Miles initially planned to introduce the Opera using sheet metal technology with design features and a style similar to its predecessor. However, the Miles management team did not approve of that style, fearing it would appear dated.

In August 1993, Michael Campanelli, project director at Miles Diagnostics, contacted Integrated Design Systems, Inc., an industrial design firm located in Cold Spring Harbor, NY, to evaluate the criteria and provide alternative direction for the project. A design program was introduced that included new product designs based upon the use of a variety of materials, improved aesthetics, and human factor considerations. The design firm was chosen for the new project to assist Miles' management in introducing an entirely original program to its product line.

Concept Development

Numerous concepts were developed based upon 3-D Micro Station CAD layouts of the internal structure. Since many internal sheet metal structural parts for the Opera System were also used for the RA 2000 System, these 2-D Auto CAD drawing files were converted to 3-D Micro Station wire frames and assembled into a 3-D layout. These concepts were presented to Miles as full-color renderings of each alternative based upon actual spacial relationships.

Five different concepts, which could have been manufactured in either sheet metal, pressure formed ABS, structural foam, or any combination thereof, were evaluated based upon tradeoffs between aesthetics, tooling cost, and manufactured cost. Copies of three selected designs were distributed to focus groups throughout the world. Within 2 weeks, a decision was made to execute a new design.

After the concept was selected, sketches were made of each cover based upon the specifications of pressure forming, structural foam, and sheet metal. These sketches were distributed to selected vendors for preliminary evaluation. The following factors were analyzed during this phase:

- Comparative tooling lead times
- Tooling prices
- Estimated part cost
- Quality
- Tolerances
- Technical feasibility
- Suggested design alternatives

Information was analyzed in a spreadsheet program which included amortization, risk, and design trade-offs. The following decisions were derived from this analysis:

- All exterior covers would be molded in pressure-formed Kydex and then painted.
- All internal structural parts would be fabricated in sheet metal aluminum or steel.
- An insulated inner door was to be rotomolded in polyethelyne and filled with a 2 lb/ft³ density polyurethane foam.
- All gaskets were to be cut from standard profiles or sheets.
- A complicated molded bracket was to be cast in solid polyurethane.
- All hardware was to be standard and immediately available.

Vendors were interviewed and presented with a verbal description of the design objectives, including the tolerances, assembly methods, construction, aesthetics, and schedule.

After careful evaluation, Gregstrom Corporation of Woburn, MA, was chosen to provide Miles with the 21 molded parts. This selection was made because of Gregstrom's commitment to cutting all molds directly from data files.

Detail Design and Development

In January 1994, plastic skins, which had previously been defined in the CAD-based concept rendering, were further developed into fully detailed parts. Design concepts were continually critiqued and improved, based on invaluable manufacturing input from Dave Cheeseman, industrial manufacturing manager, Bayer Dublin, Ireland. Plastic parts and sheet metal inner structures were designed concurrently in order to optimize product design. The following design principles were applied:

- Design based upon an existing chassis.
- Sheet metal was to be used to provide a rigid structure, EMI shielding, and accurate mounting points.
- Plastic covers were to satisfy aesthetic details, were to be cost effective, lightweight, and provide thermal insulation where required.
- Adequate clearances were to be provided between all covers to permit their manufacture within standard industry tolerances.
- Covers were to be designed to fit onto the chassis without the need for adjustments, thus minimiz-

The newly-released version of the Opera System (right) with the old version (left).

The left door detail demonstrated the use of a secondary inner sheet bonded to the inside of the door for added strength, ducting, and aesthetics.

ing assembly time and field service problems.

- Each part was to be designed in preparation for later fixturing, referencing, and machining. This forethought permitted tight tolerances to be maintained where required.
- Aesthetics and structural integrity were to be integrated in all part designs.
- All hardware and fasteners were to be hidden.
- All hardware was to be readily obtained as standard off-the-shelf items.

As the parts were developed by Integrated Design Systems, CAD files were simultaneously sent by modem to Miles' model making department in Tarrytown, NY, and Dublin, Ireland. Within days, parts were cut and assembled into the first prototype set of skins and sheet metal structures. A fully-functional prototype was invaluable in evaluating assembly procedures, structural concerns, human factors, and overall appearance.

The entire product was evaluated by a team of managers and engineers from different departments. Problems were documented, evaluated, and eliminated by incorporating solutions into the 3-D layout. As these changes to the layout were being made, the prototype was updated and completed.

It was decided during this time that six sets of covers would be required within 5 weeks for alpha site field testing. General Pattern, located in Minneapolis, MN, was contracted to cast six sets of polyurethane covers (totaling 126 parts) from the original prototype parts. Rubber molds for these parts were cast from the first prototype and used to produce the six sets of covers within the course of 7 weeks.

Tooling and Production

Since the schedule required parts to be released for tooling before the entire design was completed, changes were made according to a prioritized list. During previous meetings with Gregstrom and their preferred tool maker, Beverly Pattern, of Beverly, MA, it was decided that vacuum cast aluminum molds would be best suited for these parts. Cast aluminum molds would provide the quickest, least expensive, and highest quality parts for this product. The benefits of cast aluminum molds over-machined and fabricated aluminum molds were:

- They are better suited to compound curved surfaces and details.
- They are less expensive than fabricated aluminum molds.
- They allow for better heat transfer due to contoured, molded-in cooling lines.
- They require shorter lead times to production than fabricated molds.

Integrated Design System, Inc.'s experience in tool design and machine programming using Master CAM allowed the 3-D design file to be structured in a manner suitable for Beverly Pattern to use.

Micro Station files for the lower set of covers were translated to IGES format, compressed, and sent by modem to Beverly Pattern. Within a few days, patterns were cut, completed, and prepared for casting. Delivery of tools to Gregstrom began in April. Throughout the month, parts were being molded simultaneously as tools were being completed. This process lasted through the end of May. By the last week of June, the first six sets of parts were formed. Trim fixtures were being fabricated at the same time, using the same 3-D design file that had been used to create the sheet metal and plastic parts.

The Opera System, which is assembled at the facility in Ireland, has recently been introduced to the market with great success. Miles' sales forecasts for the product have tripled as a result of improved performance and visual appeal.

The Opera System represents a breakthrough in the design of today's floor-standing, high-end medical instruments. It competes in a marketplace where visual impact, excellent quality, and low manufacturing costs are required. The integration of a variety of processes and materials, and a collaborative effort between Miles Diagnostics Division, Integrated Design Systems, Inc., Beverly Pattern, and Gregstrom, resulted in the successful launch. ■

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