PEP Lacey
PRECISION ENGINEERED PRODUCTS

Ensuring Injection Molded Part Consistency

and Conformance through In-Mold Cavity Sensor Technology

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The use of plastic components has become increasingly prevalent in medical products, often displacing traditional metal components. Additionally, medical products continue to reduce in size to aid in decreasing patient recovery time through minimally invasive surgery, and the expectations with regard to the function of plastic components has increased. As medical devices continue to evolve, so are engineers designing smaller, more complex, and functionally more significant plastic components made from difficult-to-mold engineering resins. The envelope of expectations continues to get pushed, and molders that rise to the challenge become valuable.

For molders, the only solution is to innovate. That's why Lacey Manufacturing in Bridgeport, CT collaborated with PRIAMUS System Technologies and became the first scientific-based injection molding company in the United States to commercially use the PRIAMUS FILLCONTROL system in manufacturing.

Lacey Manufacturing, a unit of Precision Engineered Products, is a vertically integrated, FDA registered manufacturer of medical devices used in open and laparoscopic applications. PEP Lacey's 50 years in the medical field have been built on a tradition of integrating technologies that allow the realization of increasingly complex designs, while consistently improving reliability.

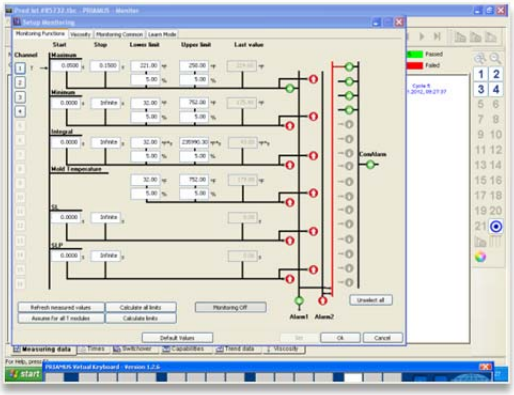
Only a few short years ago, injection molding parameter selection and adjustments were based primarily on experience. That approach, as we now know, runs the risk of unanticipated outcomes – essentially, failures. The incorporation of statistics and the use of Design of Experiments led to improvements in process control setting. But we still didn't know what was really happening within the cavity during injection; we could only approximate.

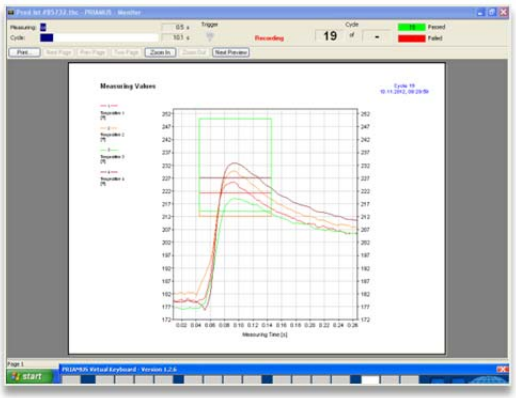
When molding parts with difficult geometries and difficult materials, it was essential for us to have real-time process insight during the injection cycle. We had to get into the cavity, right to the area where the part was being created, and "see" what the plastic was seeing by measuring outputs. This is the only way to truly know precisely what the process is producing. At the same time, we needed to do this without affecting the fit, finish, or function of the part itself.

The PRIAMUS FILLCONTROL system monitors, records, and controls temperature and pressure signals utilizing electrical signals generated by in-cavity sensors. The sensors are flush mounted on the mold surface so there is no functional or cosmetic impact to the molded part. The system is integrated with the molding machine control system. Each molding cycle initiates an accumulation of data which is stored and refreshed at the start of the next cycle.

In this fashion, critical data measured in-cavity is used to adjust important machine settings to assure consistency within the cavity to greatly minimize shot-to-shot variation. Many other systems rely on sensors that are in the runner system which only roughly approximate what the molten plastic inside the mold cavity might be experiencing. While runner-based systems are better than nothing, being

able to measure each cycle in the mold cavity provides feedback that is leaps and bounds ahead in terms of value.





PRIAMUS system screen shots

PEP Lacey and PRIAMUS agreed that Lacey would serve as the beta site for PRIAMUS in North America. After working together to integrate the PRIAMUS system on one molding machine, the technology was put to the test.

PEP Lacey had been trying to resolve balancing issues on a particularly hard-to-fill mold containing eight cavities. DOE work had been performed and the mold design was robust. However, due to the part geometry we could not consistently produce acceptable parts, despite our best efforts and applying the best science available at the time.

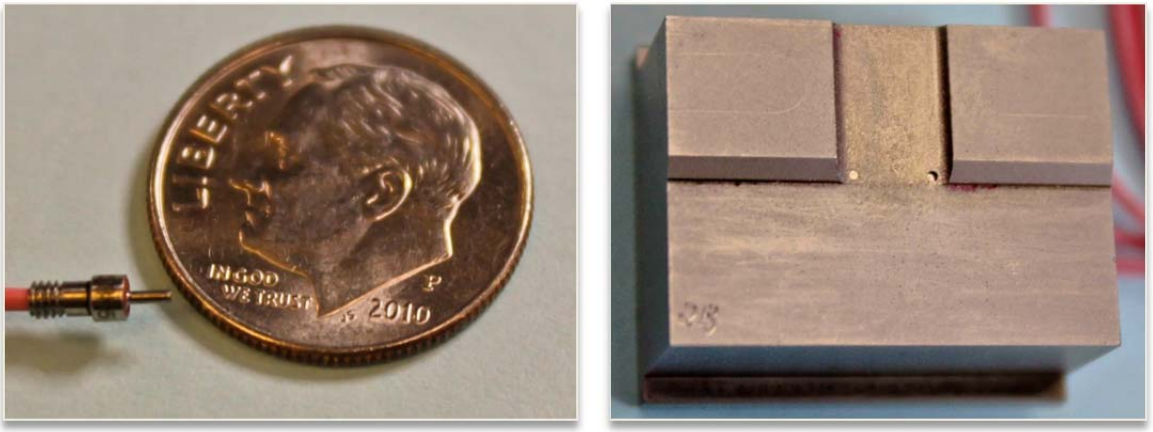
Utilizing flush-mounted cavity pressure sensors mounted in a position where the molten plastic last fills each of the eight cavities in the mold, the control system automatically adjusted nozzle tip temperatures in a fully closed loop manner, influencing the melt, so that all cavities filled equally at the same time. PEP Lacey accomplished process optimization using one flush mounted cavity pressure sensor in each cavity. The result was the ability to reliably produce conforming parts and also instantaneous feedback should any shift from optimized cavity flow occur.

Following this success story, PEP Lacey knew immediately this system offered tremendous advantage as it measured and controlled specific machine parameters using outputs that directly represented what each mold cavity was experiencing. We could finally "see" what the molding cavity was experiencing and continually influence the fill to get a good part every time!

In an effort to continuously improve, both PEP Lacey and PRIAMUS have continued to evolve the science. PEP Lacey continually provides valuable real-life feedback which aids in advancing control system effectiveness. For the past several years and continuing on an ongoing basis, PEP Lacey has theorized and tested new technologies and methods of in-cavity measurement and control. That first success, though effective, seems somewhat crude in comparison to the advances we have made.

The use of multiple sensors and the selection and placement of which types of sensors that are best suited to part specific challenges has resulted in the development of a tremendous knowledge base built on constantly pushing the science. The integration with machine controls has evolved as well, keeping up with the scientific advances made with sensor feedback. This has allowed the development of true closed loop systems that carefully and accurately evaluate and control the physical output of each molding cycle.

With the ever-expanding use of sensors in different types and components being molded at PEP Lacey, temperature sensors have become primarily favored over cavity pressure sensors (although pressure sensors still have use in specific situations). PEP Lacey prefers cavity temperature sensors, as generally speaking they prove a more reliable and cost effective alternative to using only cavity pressure sensors. Additionally, the smaller cavity temperature sensor dimensions (0.6 mm front diameter) allow for installation in critical areas where mounting other sensors is not possible.



Temperature sensor (L) and two sensors mounted in a cavity block (R)

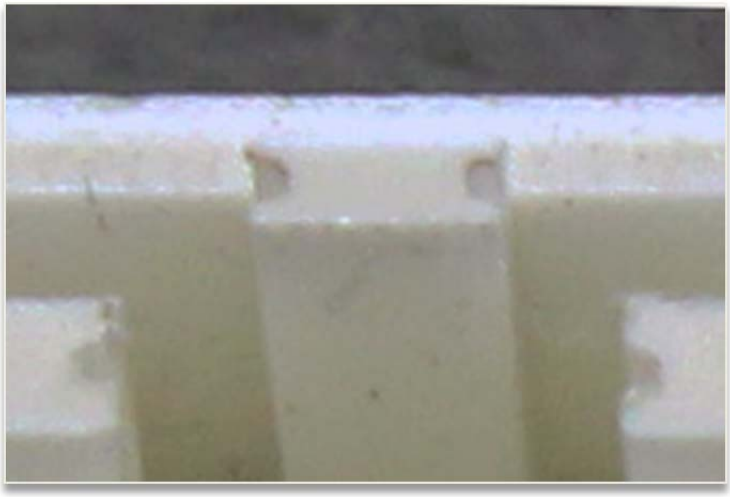
Currently, the temperature sensors, which are used in multiple critical locations on most mold cavities, have proven effective in producing a superior and much more consistent molded product. Using data from cavity temperature sensors placed at optimal locations, PEP Lacey has been able to minimize part variations that result in short shots and flash from single and multi-cavity medical molds. More importantly, the structural integrity of components which cannot always be ready measured is consistent and predictable.

During the establishment of mold parameters, the cavity sensors play an integral role in establishing robust processes using scientific methods. Establishing limits in this manner assures consistent and conforming parts and minimizes scrap, rework, and the ensuing guesswork due to a process going out of control. This is a major advantage when conducting Design of Experiments, the methods for which have also continued to evolve as new and ever-more-valuable outputs are developed.

In addition, mold set-up and mold start-up times have been dramatically reduced. Lot-to-lot material viscosity variations are compensated for automatically to achieve consistent part filling over numerous manufacturing cycles.

PEP Lacey also integrates the system with the machine and/or robotic part removal mechanisms which appropriately segregate the occasional part that does not meet the sensor output requirements and places the part into a reject bin. While reject levels are at an historical low, we err to the side of safety and remove parts that may be dimensionally conforming, but had "different" molding "signatures" than what we expected. We strive to ensure each part is as close to being exactly the same as the part before it, the part after it, and what was originally established.

PEP Lacey continues to set the pace as an industry leader in the area of process controls. PEP Lacey currently has over a dozen PRIAMUS monitoring systems in use for medical device and other industry injection molding processes in presses ranging from seven to 250 tons. PEP Lacey and, in turn, their customers, have come to rely on the consistency of the injection molded parts we supply.



Magnified detail shot of a thin walled section

The end result is a high level of confidence that each and every of the millions of molded parts we produce each year will perform exactly as expected. And with many of the parts we produce being at the centerpiece of the function of the products they go into, we are proud of our accomplishments and the positive impact our forward-looking thinking has had on patient outcome.

Through innovative drive and a willingness to be a leader in exploring technologies that better our processes, PEP Lacey and its customers realize tangible benefits that provide a high degree of confidence in the performance of the molded parts we produce. Because of our ongoing commitment to pushing the envelope of injection molding technology, Lacey enjoys a very real strategic advantage in providing the highest level of value to our customers that is head and shoulders above our competitors.