TECHNICAL NOTE

MKS SENSELINK QM™ MULTIVARIATE ANALYTICS FOR MEDICAL MICROMOLDING

INTRODUCTION

Molding processes are being developed for ever smaller components with increasing demand for micromolded parts in medical, electronic, micro-electromechanical systems (MEMS), and other industries. Micromolding processes are especially important in the production of many advanced medical components. These applications include, among others, ENT, wound closure, drug delivery devices, orthopedic implants, and devices for use in non-invasive surgery. Micromolded medical parts are typically very light (<1g), with detailed micron-scale feature sizes (wall thicknesses of 200 μm or less) and extremely tight dimensional tolerances (50 μm or less). Molding processes for such devices require high-speed, high-pressure injection, and exhibit limited effectiveness for control through variation in pack/hold stages, owing to rapid material solidification. Medical micromolding has some unique equipment and process characteristics. Medical micromolding equipment employs unusually small shot size barrels, as low as 2.0 cc and injection systems must deliver exceptional shot-to-shot accuracy, exact dosing, and high repeatability. As well, the small shot size and micron-scale feature sizes demand injection tools be capable of mass injection with very a rapid acceleration and deceleration response, within a few milliseconds.

Medical micromolders are being called upon to produce ever smaller and more intricate medical devices and this presents significant challenges. As the parts get smaller and more complex, process specifications become ever tighter and dimensional tolerances are dramatically reduced. Medical micromolding processes for smaller parts employ increased injection speeds and pressures, and this requires much faster response times in close-loop control of the equipment used in these processes. Smaller parts also mean more products per cycle and faster cycle times, which results in much higher throughput (i.e. hundreds of parts per minute) and increased risk of a defective part escaping detection. Product and process validation with higher throughput and tighter process and product specifications thus demands injection molding equipment with multiple accurate process monitors, extremely tight process control at high production speeds, and inspection equipment that matches production in measurement speed. In particular, the steady decrease in part size makes fast and accurate measurement of the dimensional tolerance problematic. Advances in medical micromolding processes and product quality therefore depend on expanding the capabilities and limits of process monitoring and control to produce smaller, more complex devices with tight dimensional tolerances. This drives the need for an advanced and highly capable statistics-based process analysis.

SOLUTION

MKS Instruments offers a solution for automated quality assurance with its SenseLink™ QM data monitoring system. SenseLink uses predictive, multivariate analytics (MVA) for process monitoring and control, fault detection, and part quality prediction. Many industries rely on MVA for effective automated process and product fault detection and process understanding; it is particularly well-suited for medical micromolding applications in which measurement of extremely small dimensional tolerances in the final product can be problematic. Medical micromolding processes generate significant quantities of real-time

process and machine-state data that can be analyzed and used for the prediction of product quality. MVA considers the correlation structure and relationships that exist between all variables being monitored in the micromolding process and models the micromolding to predict product quality (simply put, "If you can predict it, you don't have to measure it").

SenseLink QM is an integrated industrial computer platform that facilitates the use of Design of Experiments for the creation of a multivariate model of an optimized micromolding process that produces known good product. In operation, the SenseLink QM collects all available micromolding process data from analog, digital, and networked sources in real-time and uses the multivariate model to create a "current" process model which can be numerically contrasted with the previously-established optimized micromolding process model. Two relatively simple multivariate statistics, DModX and Hotelling's T^2, are generated from this comparison and they define the nature and extent of the deviation of the current process from the optimized process. This approach is a tremendous improvement over typical univariate SPC methods for real-time online fault detection in medical micromolding processes. SenseLink QM performs MVA on all process variables in real-time for each process cycle. Based on the results of this analysis, it can automatically identify defects such as short shots, voids, bubbles, flash, etc., and divert suspect product, avoiding further product loss through downstream product defects that are correlated with the original defect. Furthermore, MVA makes it possible to identify those process parameters that contribute to the production of defective product. This avoids the problem of defect measurement at micron scales and significantly reduces the time required for problem identification and correction in the micromolding process. Figure 1 shows the SenseLink QM data monitoring system showing the inputs and outputs for the system. The use of SenseLink QM for control in micromolding processes has been shown to provide typical quality assurance benefits in micromolding applications that include:

- Reduced routine visual inspection costs by 33%
- Reduced number of exceptions by 50%
- Reduced Mean-Time-To-Detect (MTTD) by over 50%
- Reduced machine downtime by 5%

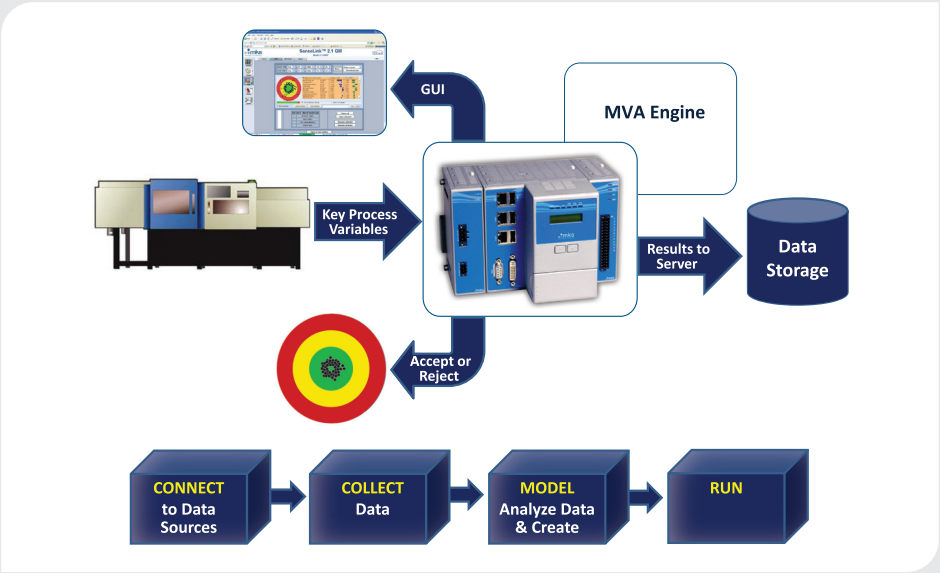

Figure 1. The SenseLink™ QM in-line quality detection system.

CONCLUSION

Medical micromolding processes present unique challenges for product fault detection and quality assurance in extremely small devices having dimensional tolerances at the micron scale. Traditional univariate SPC and product quality measurement methods are less effective for product quality assurance in these high-speed, small shot size injection processes. Multivariate analytics provide the required predictive ability for quality assurance in micromolding processes. MKS SenseLink QM data monitoring system provides a complete solution for process monitoring, fault detection, and part quality prediction in medical micromolding utilizing real-time MVA technology.

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