

## Success story

# Global Health Care Company Increases Production Volume and Cuts Back Defects With Real-Time Release Solutions From the Umetrics® Suite of Data Analytics Solutions

*A global health care company has implemented multivariate analysis and real-time release for its injection molding process of medical device components using solutions from Sartorius Data Analytics. Since the implementation, the company has been able to increase its production volume substantially without any increase in headcount and has managed to eliminate delivery of defect components.*

**Real-time release the next step for improved quality**

More than a decade ago, the company had reached a stage in its injection molding process where they realized they could not get any further with statistical process control. Typically, in the production of small plastic components, production volumes can be a million pieces a day at a very low cost per piece. For these very low margin components, problems must be identified quickly. If defect components reach the next stage in the manufacturing process, the cost becomes exponentially higher.

Over the years, the company had been able to improve product quality continually, but to reach the next stage, just maintaining the present level of quality would not be enough to stay competitive. The company decided to go for real-time release in its injection molding process to ensure product quality and improve fault detection. To achieve that, the company needed real-time data analysis and easy-to-use visual tools for the operators to do real-time monitoring of the process.

**Discarding default cycles cheaper than adjusting the process**

The company's injection molding process has cycles of about 8-45 seconds, with each cycle producing 2-64 molded

components. The processes are usually very stable and a defect might only last a couple of cycles. Without real-time data, those defects are almost impossible to detect.

Using SIMCA and SIMCA-Q from the Umetrics Suite, the company has been able to create a multivariate fingerprint, or reference model, of the process for a machine at optimal performance. Real-time data from the process is then compared with the reference model. When a cycle looks different, the company found out that it was more efficient with an accept/reject signal rather than adjusting the process, and the components of that particular cycle are simply discarded automatically. On an aggregated level, data from thousands of machines are to be monitored simultaneously using Active Dashboard, which summarizes data from all production plants in one single dashboard.

**A challenge to process and store huge amounts of data**

Medical device production is regulated by the Food and Drug Administration (FDA) and all data relative to decisions, for example regarding accept/reject automated recommendations, have to be stored.

*"A challenge for the company has been the huge amount of data. They have several terabytes of accumulated data and*

*"The company realized that just maintaining the present level of quality would not be enough to stay competitive. They needed real-time monitoring of the process."*



*gigabytes added each day, which have to be aggregated in an intelligent way to create interactivity for the user,” says Johan Hultman, Global OEM Key Account Manager at Sartorius Data Analytics and the responsible project manager for the development and implementation. “The very essence of the project has been developing the Active Dashboard. But that has only been a small part of the project. The difficult part has been finding the best solution for data storage.”*

## Drastic drop of non-conformances

Implementing real-time release has saved the company up to 2000 hours per year in labor reduction for the first plant with this implemented. Instead of physically checking the components after the production, the system predicts product quality from the real-time data parameters while the components are being molded. Another time saver has been faster machine startup. Moreover, the company has seen a 26% increase in production volume over two years without any increase in headcount. Most importantly is, however, the reduction of non-conformances, with a more than 90% reduction of exceptions on some machines.

The system has also implied gained process knowledge that will be shared and available within the company.

*“By adding Active Dashboard to the Umetrics Suite we have something similar to Business Intelligence, but you could rather call it Production Intelligence,” says Johan Hultman.*

Since the implementation of the system, replace default with defective components delivered from the injection molding process have been eliminated. And if it is not producing high quality products, the company will not make a difference for the patients.



### The customer:

A global health care company.

### The challenge:

Implementing real-time release to improve quality and minimize defects in the company's injection molding process.

### The solution:

Implementing multivariate analysis and real-time release using solutions from the Umetrics Suite. The solution also visualizes the data from all production plants in one single dashboard.

### The result:

A 26% increase in production volume over two years without any increase in headcount and a 90% reduction of non-conformances in the process. Faster machine startup and increased process knowledge.

## Solution from Sartorius Data Analytics

SIMCA® Multivariate Data Analysis Solution, SIMCA®-Q, SIMCA®-online and Active Dashboard are all part of the Umetrics Suite of Data Analytics Solutions for real-time process monitoring and multivariate analytics.

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