

Press release

Process-integrated quality assurance – the new approach to risk management at K 2025

Kistler presents AI-supported automated quality control in injection molding for MedTech

Winterthur, September 2025

Quality assurance in medical technology is undergoing a radical change: away from random sampling and toward automated 100% inspection. This involves automated quality control of each individual part using AI-supported calculation of key product characteristics. The inspection is based on data, such as cavity pressure, which is taken directly from the injection molding tool. Find out more about innovative solutions from Kistler at K 2025 (Düsseldorf, October 8-15, hall 10 / booth F51).

New medications are available to treat diseases such as diabetes and Parkinson's – and more people who depend on them. As a result, the demand for certain medical devices, such as auto-injectors, is rising. The medical device industry needs rapid ramp-ups of additional production capacities to keep pace with the growing demand without compromising quality. If, for example, an insulin pen does not work reliably, the consequences can be life-threatening. Manufacturers need to protect themselves as well: in case of a malfunction, they must provide proof that they have exhausted all technical possibilities to prevent production errors. State-of-the-art technology now offers significantly more thorough options than statistical process control via physical sampling, which is still widely used in the medical device industry.

Advanced quality assurance in injection molding for MedTech

In automated 100% inspection, every single part is checked. An AI model uses data from sensors in the mold to calculate important quality parameters such as the dimensions and weight of each individual produced part. In plastic injection molding, the well-established cavity pressure measurements and contact temperature form the basis for these calculations. Often, switching to the new method is merely a question of software and a change in the interaction between production and quality assurance. "We at Kistler are seeing more and more manufacturers from the medical industry turning to state-of-the-art production processes with automated quality control to ensure maximum safety during rapid ramp-ups. Our experts provide support in implementing this new form of quality assurance as quickly and efficiently as possible," explains Dr. Oliver Schnerr, Head of the Business

Unit Plastics at Kistler.

Successful, automated quality control with AI

Kistler will be showcasing its complete measurement chain for automated quality control at this year's K – from sensors to process monitoring and control to data documentation. Among other things, visitors will be able to see the smallest combined cavity pressure and temperature sensor (6188). The data collected by the sensor is evaluated and analyzed by Kistler's ComoNeo process monitoring system, which collects pressure and temperature data in real time throughout the entire injection molding cycle. By comparing it to reference curves, ComoNeo reliably detects deviations.

A suitable solution for automated quality control is the additional software feature ComoNeoPREDICT in combination with the STASA QC software, which performs model analyses for process validation. Based on these analyses, ComoNeoPREDICT uses artificial intelligence to calculate the quality of each individual part. The AkvisIO process data management platform documents the results and consolidates them with data from other sources. In addition to documenting processes and quality, AkvisIO allows process data to be analyzed over longer production runs and periods of time. This enables medical technology manufacturers to perfect their processes while ensuring that they comply with the highest FDA and MDR standards and deliver safe products to their customers.

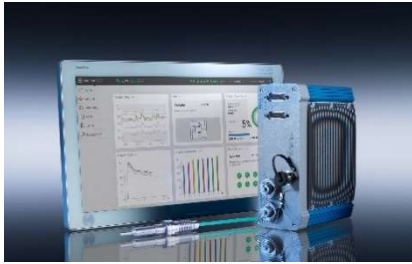
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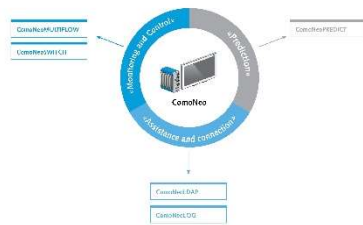
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Automated quality control of all parts during the production process ensures complete traceability in medical technology.



Kistler's ComoNeo process monitoring and control system forms the basis for advanced quality assurance in injection molding for MedTech.



The ComoNeo PREDICT software feature uses artificial intelligence to calculate important quality parameters for injection molding for MedTech.



The STASA QC software from Kistler provides model analyses for process validation – an important step for subsequent automated quality control of all parts.

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About the Kistler Group

Kistler is the global market leader for dynamic pressure, force, torque and acceleration measurement technology. Cutting-edge technologies provide the basis for Kistler's modular solutions. Customers in industry and scientific research benefit from Kistler's experience as a development partner, enabling them to optimize their products and processes so as to secure sustainable competitive edge. Unique sensor technology from this Swiss corporation helps to shape future innovations not only in automotive development and industrial automation but also in many newly emerging sectors. Drawing on our extensive application expertise, and always with an absolute commitment to quality, Kistler plays a key part in the ongoing development of the latest megatrends. The focus is on issues such as electrified drive technology, autonomous driving, emission reduction and Industry 4.0. Some 2,000 employees at more than 60 facilities across the globe are dedicated to the development of new solutions, and they offer application-specific services at the local level. Ever since it was founded in 1959, the Kistler Group has grown hand-in-hand with its customers and in 2024, it posted sales of mCHF 448. About 9 percent of this figure is reinvested in research and technology – with the aim of delivering innovative solutions for every customer.