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Balda Medical Monitors Cavity Pressure

**End-to-end process
monitoring for critical
medical moldings**

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**QUALITY
MOLDING**
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End-to-end process monitoring for critical medical moldings

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The CoMo Injection process monitoring system (below) with display screen (on the right, beside the operating panel) controls the reject gate for free-falling components at the front of the injection molding machine

"Safety first" is an important requirement for the injection molding of medical parts, which strictly demands 100% quality. Even minute defects of the molded component can lead to functional deficits and unreliable operation. Hence, Balda Medical GmbH & Co. KG of Bad Oeynhausen/Germany, analyzes all quality-related injection molding parameters before production start-up and as an integral part of the mold qualification process. The specialist decided to introduce a cavity pressure-based system made by Kistler in order to enhance the process analysis-based quality monitoring of its production of lancet holders and housings for blood sugar monitoring systems. This way, the company can guarantee 100% quality, removes defective parts from the production and avoids assembly problems. This approach also speeds up injection molding production start-up processes after mold changes.

Every year, Balda Medical continuously produces several million plastic components such as lancet holders for a lancing device that helps diabetics monitor their blood sugar levels. The lancet holders are made from teflon-modified polyoxymethylene (POM) and produced in a 4-cavity mold. The delicate technical component with several mechanical functions has many openings and operating elements. One element, a slender spring arm, is at particular risk of not being fully molded at the end of the flow path, which would cause a functional defect of the entire lancing device. While this defect can be quickly detected during subsequent component assembly at Balda's facility, it would lead to major disruptions

of the assembly process, with detrimental effect on the OEE (Overall Equipment Effectiveness).

A systematic analysis of all quality-related process parameters showed that there is a very complex correlation between material properties, drying conditions, process control and thermal effects. The extent of defects, however, was too insignificant to allow strategic process optimization by means of statistical methods as part of the six-sigma system. Hence, Balda approached the problem by using process data for on-line assessment of the component quality and by analyzing cavity pressure measurement as a method of gaining reliable answers. In order to achieve this, the mold was equipped with sensors and a Kistler monitoring system was installed. The technology was tested for several weeks so as to

gain insights into its potential benefits.

The display of the cavity pressure profile alone proved useful for the optimization and stabilization of the entire process. Andrej Gossen, process optimization expert, explains: "We increased the injection pressure, introduced a pressure-dependent switchover from injection to holding pressure, extended the holding pressure phase and, as a result, achieved a significant improvement of the component quality." After a few weeks, automatic production monitoring with a Kistler CoMo Injection monitoring system Type 2869A... showed the desired effect. Dr.-Ing. Oliver Pfannschmidt, Head of Engineering, remembers: "We tested several online quality



Injection molded in a 4-cavity mold, the delicate lancet holder is made from teflon-modified polyoxymethylene (POM) and part of a lancing device with mechanical functions, openings and operating elements

monitoring systems based on different process data. Only cavity pressure measurement delivered the desired results. No other system was able to provide such definite and reliable information on the resulting component quality."

After this experience, Balda Medical decided to equip each of the four cavities of both its production molds with a pressure sensor Type 6183A... . The sensors with a front diameter of 1 mm measure the pressure in the vicinity of a critical area of the component. The cables of all four sensors connect to a multi-channel plug connector Type 1708 located on the mold exterior. From there, one single cable transmits the sensor signals to the CoMo Injection process monitoring system, which analyzes the pressure profile, displays it on a monitor and controls the reject gate.

Process analysis with several evaluation functions

Balda defined the pressure profile displayed during the production of zero-defect parts with optimum quality as a master template for their production processes and set the parameters of the process monitoring system correspondingly. Two strictly required criteria are defined. These are based on the pressure profile and have to be met in all four cavities in order to lead to a positive quality assessment: the cavity pressure during injection must rise steeply within a specified period of time. This process is monitored with the help of "boxes", which describe a defined pressure range during a specified period of time. The pressure profile must pass through these boxes from bottom to top, while the holding pressure must exceed a predefined pressure minimum. A corresponding threshold is defined. If the pressure profile fails to pass through the box in the prescribed manner or the pressure maximum falls short of



A Kistler CoMo Injection Type 2869B2... (on the right, beside the injection molding machine) is monitoring the production of plug connectors



Housing shells for blood monitoring devices made from a PC/ABS blend with numerous interior contact surfaces and screw connection points such as screw bosses

Balda Medical GmbH & Co. KG

Balda Medical GmbH & Co. KG is one of the leading manufacturers of complex plastic products and system solutions for the pharmaceutical, diagnostics and medical engineering industry. Founded in 2002, the company specializes in the development, production and sale of solutions for medical engineering equipment, pharmaceutical packaging and disposable products. Balda supplies special handheld devices, disposables, packaging, drug delivery systems and functional assemblies exclusively by customer order.

Balda Medical covers the entire technical process chain from development and packaging right through to sterilization, if required. Consultancy, design and

development are carried out with the system and application expertise that is required by this specific market segment. The indispensable, standards-compliant and documented record of all performed services is provided as standard.

A subsidiary of Balda AG, the plastics processor Balda Medical with headquarters in Bad Oeynhausen/Germany is also integrated into the corporation's international network of facilities in the US, China and Malaysia. The production site in the immediate vicinity of the specialist's German headquarters consists of fifty small and medium-sized injection molding machines including extensive assembly and decoration systems.

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the threshold, CoMo Injection will identify the molded component as defective and will not transmit the signal for the passage of "IO" parts to the reject gate.

In order to reliably prevent any "NIO" parts from finding their way into the "IO" bin, the reject gate is generally switched to "NIO" and only temporarily changes to "IO" when the CoMo Injection process monitoring system transmits the corresponding signal during demolding of the lancet holder. This way, defective parts cannot be accidentally classified as "IO", even if the reject gate is broken or fails due to electricity cuts.

Despite the fact that the system analyzes and evaluates the process in real time, i.e. within fractions of a second, the responsible operator easily gains an insight into the process: on the touch screen, the pressure profiles of all four cavities can be superimposed, which allows an assessment of the process quality at a glance – thanks to the CoMo Injection monitoring system.

But process monitoring is not the only benefit of cavity-pressure based operation. "We also experience advantages during changeovers and setting processes," Rainer Koops, Head of Production, reports. "We benefit from faster start-ups, quickly achieve stable process conditions and experience less start-up scrap.", he says. Andrej Gossen explains: "Today, one glance at the pressure profile is enough to know whether the selected operating point has the best position in the defined process window."

Housing for blood sugar monitoring system

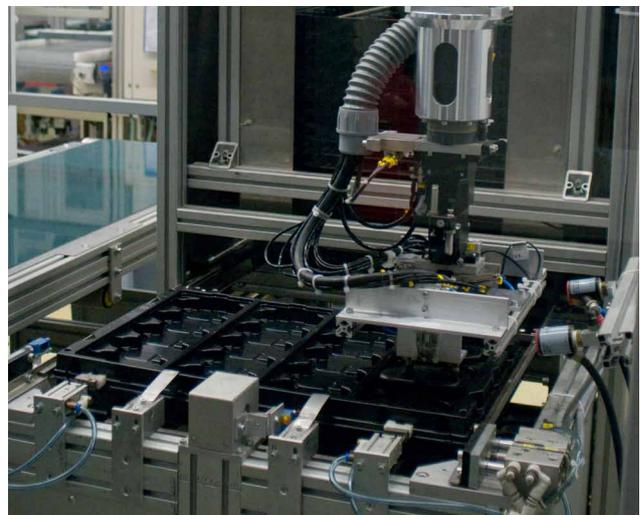
Balda has a strict focus on maintaining constant process conditions and eliminating defective parts. Despite the company's positive experience with cavity pressure monitoring, Oliver Pfanschmidt was careful to take one step at a time. "We have been working with Kistler pressure sensors for three years now and they have been proven to solve or even prevent problems. Pressure sensors definitely make a lot of sense, if the system is handled and maintained with the required expertise," he explains. "Hence, we delayed a comprehensive implementation, in order to acquire and accumulate the expertise that is essential for the process. We provided our employees with extensive training and the opportunity to make their own positive experiences with the system. Only then did we widely introduce the technology for sustained, long-term operation."

After the positive experience with the lancet holder production, Balda decided to also equip both cavities of a mold used for the production of two housing shells for a blood sugar monitoring device. These semi-shells were made from a PC/ABS blend and had numerous interior contact surfaces and screw connection points such as screw bosses. Flow simulation predicted potential problems and insufficient reproduction of these delicate structures.

The 2-cavity mold used for the production of the shells is operated on an all-electric Engel e-max 100 with impulse cooling and a downstream tray stacking system. The handling system is controlled via CoMo Injection to ensure that only parts that fail to comply with the required pressure profile are



The multi-channel plug connector located on the mold exterior integrates all signals in one cable and connects to the CoMo Injection system



If the CoMo Injection process monitoring system identifies a component as NIO, the robot will place it into the reject bin. IO parts are placed into stacking trays and transferred to the assembly station

removed. All parts identified as "IO" by the process monitoring system are placed into tray cavities and subsequently transferred to the fully automated in-house assembly station. Incomplete screw bosses would render assembly of the finished part impossible, leading to assembly line downtimes.

Andrej Gossen explains: "We invested a lot of time and money in optimizing the processes. The introduction of impulse cooling allowed us to cut the cycle times of six cooling circuits by 30%, while cavity pressure monitoring guarantees 100 % quality."

A strategy for reliable delivery capacity

Balda Medical uses two molds each for the production of lancet holders and housing shells, which are run in alternate operation. This way, one mold is always free for in-house maintenance and revision. The medical engineering specialist chose this approach to ensure reliable production and delivery capacity for its customers. If required, Balda Medical will themselves retrofit existing injection molds with pressure sensors, while new molds are ordered and fitted with sensors by external mold makers.

Critical products are equipped with pressure sensors

Will Balda Medical introduce comprehensive cavity pressure-based quality management? Oliver Pfannschmidt explains both extremes: "Several strategies are feasible. Either pressure sensors are only used in cases where defective components or process deviations are detected during active operation or all molds are equipped with sensors as a result of positive experience with cavity pressure monitoring."

Balda Medical will not implement either of these two extremes. "We have decided for a no-compromise middle ground, which is based on a risk-oriented approach," Pfannschmidt says. "We will analyze every molded component and make an individual decision on the need for monitoring based on the potential risk of defects." This approach will also be applied to a new, important system, which is made from more than twenty single plastic components: "All injection molding processes for the production of individual components have already undergone risk analysis. In cases where processes are too complex and fraught with risk, we will use cavity pressure sensors so as to accumulate process information, establish reliable processes and allow online analysis of the component quality."

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