

Press release

Zero tolerance for production defects

For insulin pens, one hundred percent reliability is absolutely essential

"Everybody makes mistakes now and then" – but in the demanding medtech sector where precision is paramount, that saying certainly does not apply. In the worst-case scenario, defects in the production of medical equipment could put patients' safety at risk. This is why high-precision monitoring of sensitive medical devices such as insulin pens is essential – and bad parts must be separated out promptly and reliably. This key task is performed by highly sensitive sensors connected to a comprehensive monitoring system.

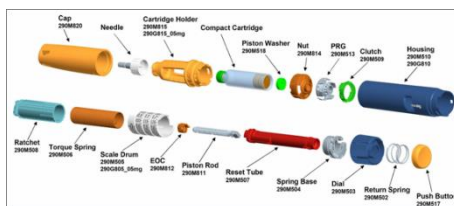
Any diabetic who needs insulin treatment is fully aware that the correct dose is critical for the success of their therapy. In the worst-case scenario, major errors in dosage could put life at risk, and even minor errors can cause permanent damage to the blood vessels. About 425 million people throughout the world use insulin pens regularly, and the trend is upwards. A pen is easier and safer to handle than a syringe, and the prick from the pen is gentler. A device that is straightforward for patients to use – but the production process for it is highly complex. In every pen, the interaction between about a dozen different plastic parts and two metal springs must be optimal. And each one of the various plastic components can only be allowed to deviate very slightly from the ideal dimensions and shape. Another challenge: the triggering mechanism, which must function precisely with the insulin capsule whenever the pen is used.

Like many other medical items made of plastic such as pipette tips, syringes and cannulas, the plastic parts for the insulin pen are manufactured using the injection molding process. To meet the demanding requirements for accuracy and quality, many manufacturers of these products opt for sensors and a process monitoring system from the Kistler Group. The sensors used in injection molding are pressure sensors: this means that they measure the cavity pressure at defined stages of the process – for instance, when the liquefied plastic is injected into the mold or when it is compressed. If the pressure applied at each of these stages matches the expected values, the plastic will be cured correctly. The sensors immediately send all the measured values to the process monitoring system, which automatically compares them with the setpoints – so any suspicious pressure deviations can already be identified while production is in progress. If the system detects a defect that could lead to problems such as trapped air bubbles or curvature of the plastic, it transmits an NOK (not OK) signal to the machine: this immediately prompts the machine to separate out the parts of inferior quality.

After injection molding, the next step is to assemble the large number of individual parts to produce a fully functioning insulin pen – and here too, sensitive sensors are needed to measure force and torque. They accurately capture the force that is applied when placing one part onto another. As in the injection molding process, the data is forwarded immediately to the linked process monitoring system for comparison with the setpoints. For example, this ensures that the pen caps will grip and engage correctly. The monitoring process also checks whether the spring in the triggering mechanism is correctly preloaded so the correct dose of insulin is released later on when the pen is used.

Whenever insulin treatment or infusions are given, when blood samples are taken or laboratory tests are performed, patients and users want to have 100 percent trust in the products. This reliability is ensured by end-to-end process monitoring – not only of the production of plastic parts by injection molding, but also of the process of joining them together to make a larger sub-assembly or the finished product.

Image material (please name the Kistler Group as picture source)



An insulin pen is a complex medical device consisting of 15 different plastic parts and two metal springs. All the functionally relevant parts must be tested at the earliest possible stage of the production process.



About 425 million users of insulin pens all over the world benefit from the simple handling of these devices.

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About the Kistler Group

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