



**Proven safety and  
quality – from design  
to production**

## **Medical device manufacturing**

Comprehensive process monitoring for the production  
and quality testing of medical devices



# Kistler: your partner in the medical devices market – today and tomorrow

Manufacturers of medical devices have to meet demanding market requirements. They have to comply with large numbers of national and international standards in order to guarantee a product's safety and quality. Kistler is present throughout the world with a comprehensive portfolio of solutions for sensors and process monitoring systems: your ideal partner in every phase of medical device manufacturing – from the design concept, product development and qualification phases all the way through to production.

Are you interested in achieving zero-defect production, 100% process transparency and enhanced process stability through automated monitoring of process limits? Are you aiming for product traceability with reduced outlay on documentation in your manufacturing facility? The experts at Kistler are always on hand to help you maintain your successful presence in the highly regulated medical market!

Compliance with national and international standards and regulations is the essential and fundamental requirement for the manufacture of products in the medical technology sector.

#### Regulations

- EU: MDR
- USA: FDA
- 21 FDA 820
- Country-specific regulations

#### Good Manufacturing Practice (GMP)

#### Standards

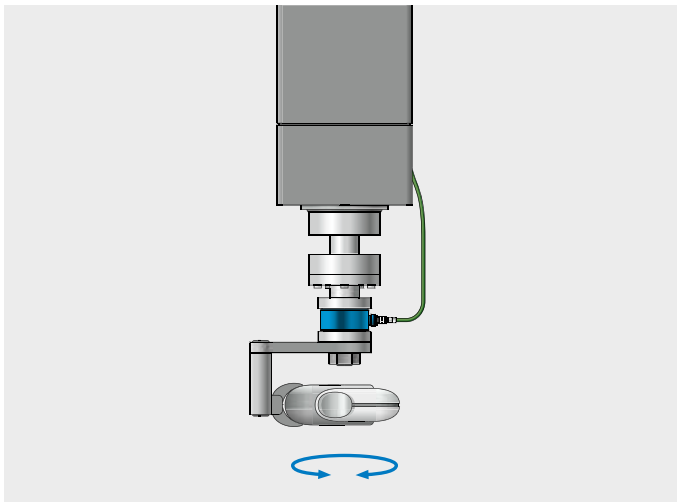
- ISO 9001
- ISO 13485

# The right solution for every application

No matter which application area your medical device is intended for: Kistler supplies solutions precisely tailored to your objectives – solutions that deliver enhanced process transparency and end-to-end documentation.

## Practical example 1: Disc inhaler

In disc inhalers, the mouthpiece is closed with a protective cap that only fits correctly if the cap is placed in position with a specified torque during production. This mounting process can be monitored and recorded with sensors and systems from Kistler. Your benefits: significantly improved process reliability and product quality.



Kistler torque sensors verify that the sealing cap on a disc inhaler closes correctly

## Practical example 2: Insulin pen

Insulin pens pose two production challenges: molding of several plastic parts with tight tolerances as well as the accurate assembly and the joining of those with an expensive medical compound to guarantee a 100% functionality. Early application of Kistler's products even in the design phase improves clients process understanding to meet the specified functionality. In addition, Kistler products guarantee a holistic quality control even at large quantities and lead to reduced scrap in production. The direct benefits for the client are reduced quality cost and a complete process documentation over the whole value chain.



Process monitoring on an insulin pen production line: quality assurance underpinned by process-integrated inspection and documentation

### Benefits for manufacturers of medical devices

- Zero-defect production
- Compliance with all standards and regulations
- Reduced quality costs
- Optimized process efficiency
- Rapid amortization (RoI)
- Data backup and optimization

### More application areas

- Surgical instruments
- Pipettes
- Laboratory equipment
- Dental equipment
- Electromedical equipment
- Ophthalmic equipment and products (contact lenses, etc.)





Source: Riegler GmbH & Co. KG

## Maximum quality – from the produced single components through to final acceptance

**Kistler systems create the conditions for manufacturing medical devices of impeccable quality – equipping companies to meet future challenges and enhancing patients quality of life through safer products.**

### **Production**

Cavity pressure measurement makes it possible to decide whether a produced part is good or bad while the injection molding process is still under way. Kistler's process monitoring and control system ComoNeo analyses obtained cavity pressure data in real-time.

### **Assembly**

In processes where various components are assembled to produce a medical device, different Kistler sensors are deployed – as appropriate to the application area – to ensure that the product is assembled correctly.

### **Function test**

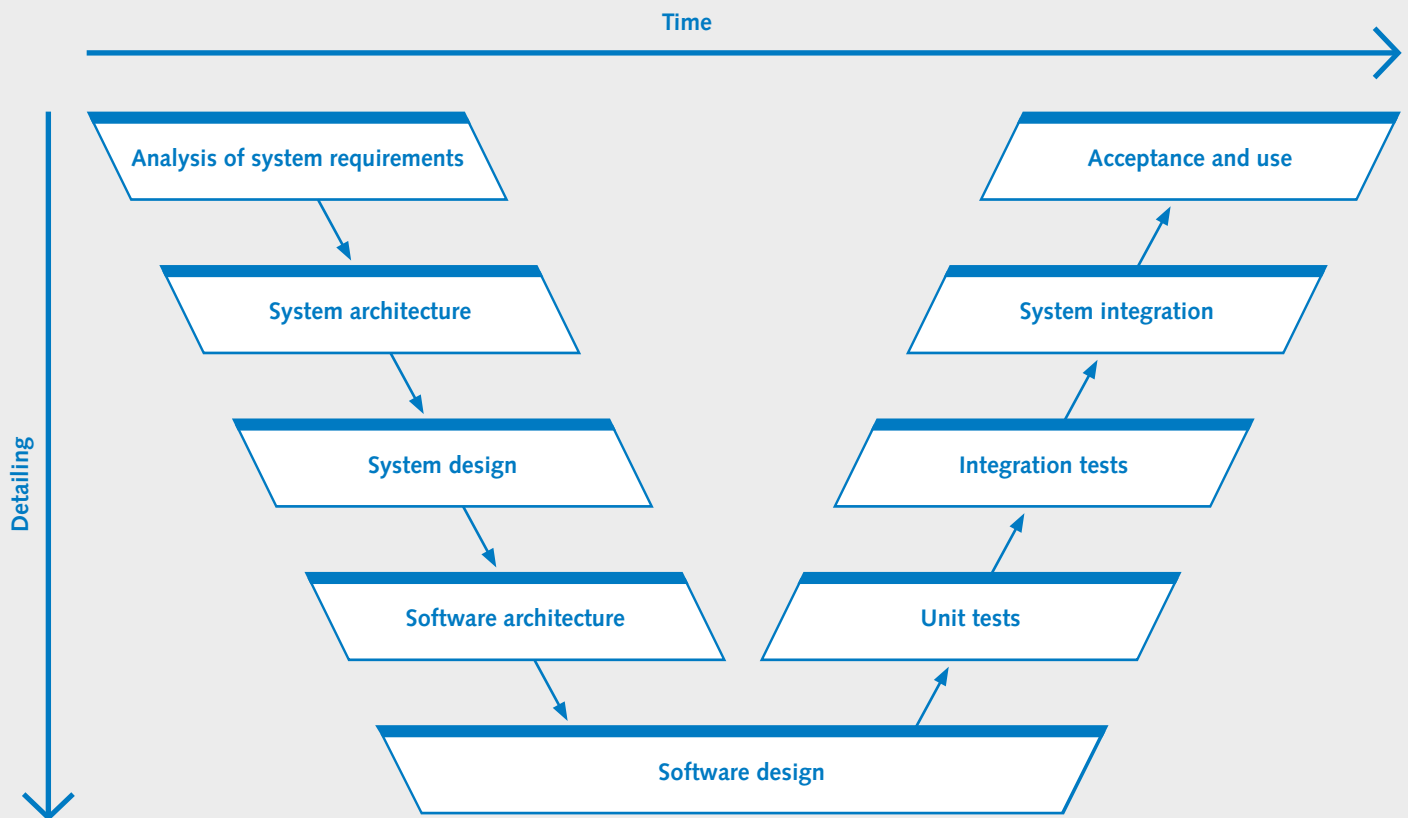
All the functions have to be verified to ensure that the medical device can be used with absolute safety. On the insulin pen, for example, Kistler sensors test the spring force of the triggering mechanism to prevent incorrect dosage of the medication.

### **Documentation and data storage**

Measured values and obtained process data in the preceding steps are processed as appropriate and made available to the customer. In conjunction with a direct manipulation-proof connection to the customer's quality database, Kistler technology ensures that all quality-related data is stored securely.

### **Calibration service**

Kistler offers its customers a special service so they can efficiently meet the strict requirements for the manufacture of medical devices: the small force and torque sensors used for these applications can be calibrated directly on-site. This minimizes costly machine downtime and also eliminates complex acceptance procedures for the plant after the sensors have been calibrated.



We are thoroughly familiar with the complex process that medical devices undergo – from the design phase through to production. No matter where you need our support – we are on hand, across the globe, to offer you our know-how and expertise.

#### 1 Design

We assist you with selecting the right measuring chain and positioning the sensors correctly so that you obtain meaningful measurement results.

#### 2 Development

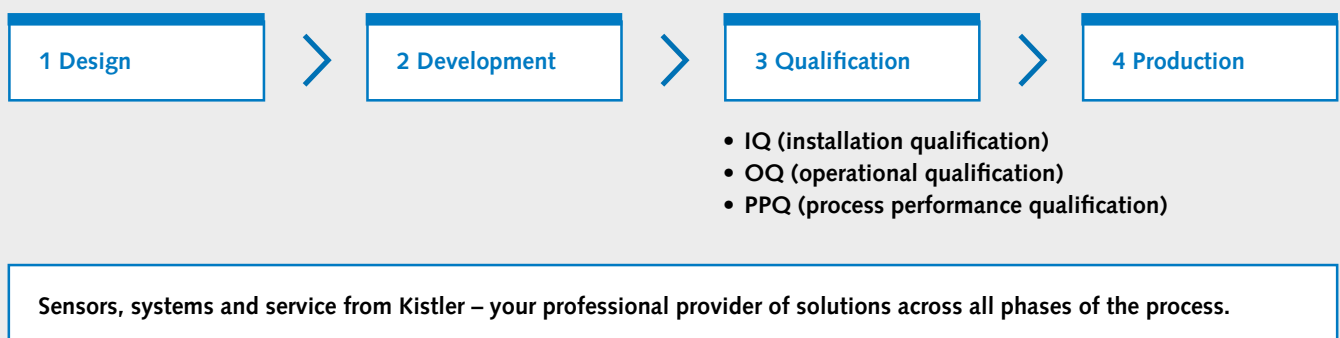
We offer you support to ensure that the sensors you need are installed correctly, and we also assist you with calibration and material certifications.

#### 3 Qualification

Vast amounts of time are often needed to determine the process limits, including the related documentation. With the help of our systems, you can significantly reduce the time you spend on this phase.

#### 4 Production

When you use our systems, you can guarantee that your processes are reliable and stable as well as full traceability of your products is ensured.



# Take advantage of our technological know-how and our expertise!

## Maximum quality in the production of plastic medical devices



### ComoNeo process monitoring system

Our ComoNeo system is used for automatic process monitoring and analysis. The focus here is on automated separation of scrap parts on the basis of cavity pressure data. The goal: zero-defect production.

- Monitoring process stability
- Automated detection of process deviations, including notifications to the user
- Transparent process control and production monitoring during qualification (OQ and PQ)
- OPC-UA communication to transfer part-specific process data to external databases for documentation purposes
- Integrated DoE interface for simpler determination of process limits, including documentation
- Analysis and correlation of process data with part-specific characteristics (Stata QC)
- Assistance systems for process monitoring and process restart

### Cavity pressure sensors

Cavity pressure provides a direct criterion to determine part quality in the production of plastic components. In addition to machine data, cavity pressure plays a key part in transparent process monitoring. To achieve this objective, Kistler offers you an extensive range of high-precision pressure sensors.

### Services

During the design phase, our sensor positioning service assists you with correct sensor installation, helping to you determine meaningful key process values.

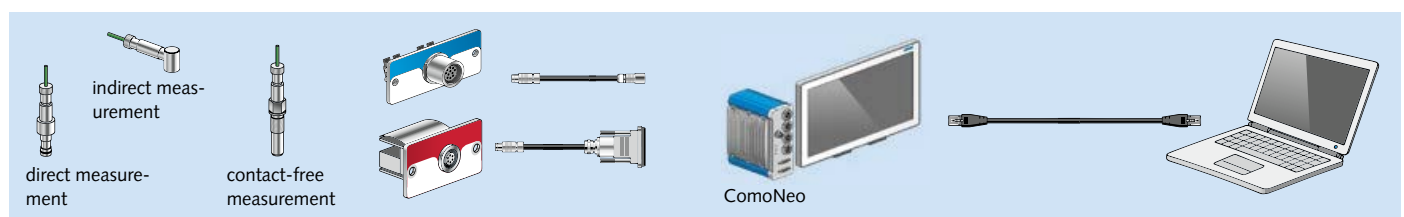
- Sensor and ComoNeo application trainings
- Sensor installation support and ComoNeo commissioning (IQ)
- Sampling support to determine process limits (OQ)
- Compliance with the QM system requirements
- Kistler's service products reduce risk of an incorrect use and guarantee reliable and stable processes

Measure

Connect

Monitor and control

Document and analyze





# 100% transparency in medical device production and testing



## Sensors

Force, pressure, acceleration and torque represent direct criteria for determining the production quality of medical devices, during manufacture and in testing processes. In addition to the machine data, these measurands play a key part in transparent process monitoring. To achieve this objective, Kistler offers you an extensive range of high-precision sensors.

## maXYmos process monitoring system

Our maXYmos system is used for automated monitoring and analysis of processes, in keeping with Industry 4.0 requirements. The focus here is on automated segregation of scrap parts, based on pressure, force and torque – always with the goal of zero-defect production in mind.

- Monitoring process stability
- Automated detection of process deviations, including notifications to the user
- Transparent process control and production monitoring during qualification (OQ and PQ)
- Fieldbus communication to transfer part-specific process data to external databases for documentation purposes
- Static process analysis of data with part-specific attributes

## Services

During the design phase, our sensor positioning service assists you with correct sensor installation, helping to you determine meaningful quality gates.

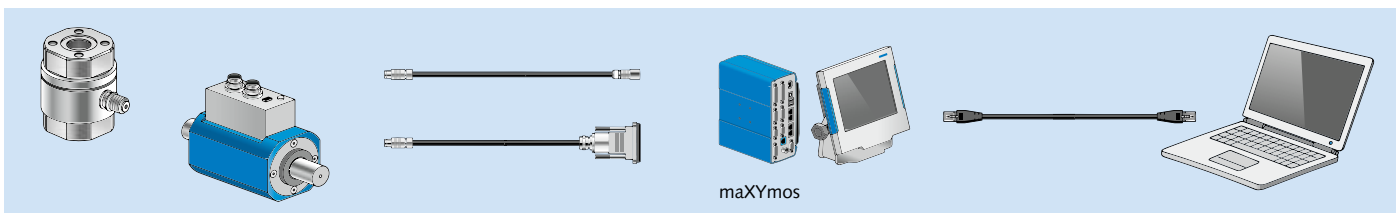
- Sensor and maXYmos application trainings
- Sensor installation support and maXYmos commissioning (IQ)
- Sampling support to determine process limits (OQ)
- Compliance with the QM system requirements
- Kistler's service products reduce risk of an incorrect use and guarantee reliable and stable processes
- Calibration of sensors and measuring chains directly on the plant, or at Kistler's calibration laboratory (with full traceability)

Measure

Connect

Monitor and control

Document and analyze



Find out more about our applications:  
[www.kistler.com/applications](http://www.kistler.com/applications)

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