PROVEN SAFETY AND QUALITY – FROM DESIGN TO PRODUCTION

Medical device manufacturing

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

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KISTLER
measure. analyze. innovate.

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Kistler – your partner for medical device manufacturing

The market sets high requirements for manufacturers of medical devices as well as plant and machinery manufacturers operating in environments where medtech equipment and pharmaceutical goods are produced. They have to comply with large numbers of national and international standards, directives and guidelines in order to guarantee a product's safety and quality.

This is why process monitoring plays an increasingly important part in quality assurance on automated and semi-automated production lines in these industrial sectors.

We offer you efficient support with making your manufacturing and assembly processes more reliable and transparent, so you can boost the quality of your products throughout the production chain – and that includes quality assurance. We focus equal attention on product traceability and on reducing the cost and effort of documentation.

In compliance with FDA and MDR requirements for the of medical devices, Kistler offers support and solutions that meet the very highest technical standards:

- Modular process monitoring systems in the ComoNeo and maXYmos product families, tailored to your specific needs
- maXYmos TL ML, the world's first FDA- and MDR-compliant process monitoring system
- A complete solution for electromechanical NC joining systems (servo press)
- Miniaturized pressure, force and torque sensors for every application

Our application-specific know-how and proven solutions will help you to combine consistent quality and maximum safety with cost-effective operation.

We are 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 manufacture – from the design concept, product development and qualification phases all the way through to final release.

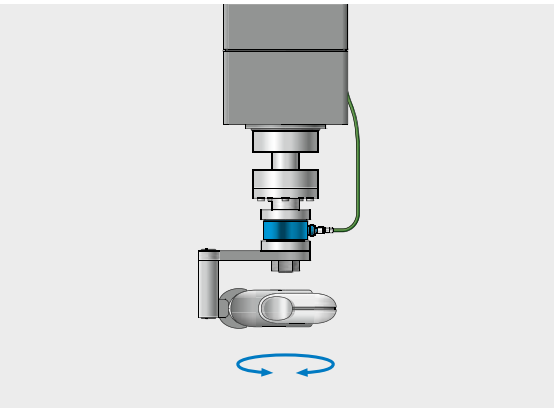
Compliance with national and international standards and regulations is the essential and fundamental requirement for the manufacture of products in the medical technology sector.

Good Manufacturing Practice (GMP)

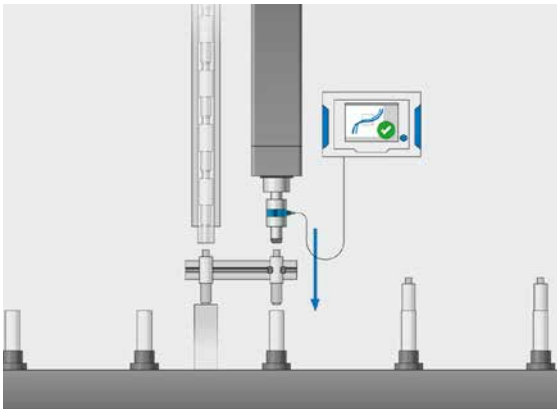
Regulatory requirements/standards:
FDA 21 CFR part 11
EU GMP Annex 11: Computerized Systems

Exactly the right solution – tailored to your needs

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.



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



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

Practical example 1: disc inhaler
In disc inhalers, the mouthpiece is closed with a protective cap that only sits correctly if it was placed in position with a specified torque during production. This process can be monitored and recorded thanks to sensors and systems from Kistler. The benefits: significantly improved process reliability and product quality.

Practical example 2: insulin pen
Insulin pens pose two production challenges: several plastic parts have to be manufactured with very low tolerances and then these parts must be joined to the expensive capsule of the active substance and the triggering mechanism to create a functioning device. This is why all the pen's functionally relevant parts are tested as early in the process as possible. As well as guaranteeing uninterrupted quality testing for large quantities, technology from Kistler reduces scrap. The benefits: significantly lower costs and end-to-end documentation of the production processes.

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

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

1 Design > 2 Development > 3 Qualification > 4 Production

- IQ (installation qualification)
- OQ (operational qualification)
- PPQ (process performance qualification)

Sensors, systems and service from Kistler – your professional provider of solutions across all phases of the process

Compliance with regulatory requirements, safe processes and reliable product quality – we support you from design through to production

Our high-precision customized solutions are the result of many years of partnership and collaboration with various customers in the medtech and pharmaceutical industries. As industry experts, we will help you meet the demanding requirements for the strictly regulated medtech market – from design through to production.

Continuous process monitoring and control based on piezoelectric measurement technology is a proven, effective method of attaining your high quality targets.

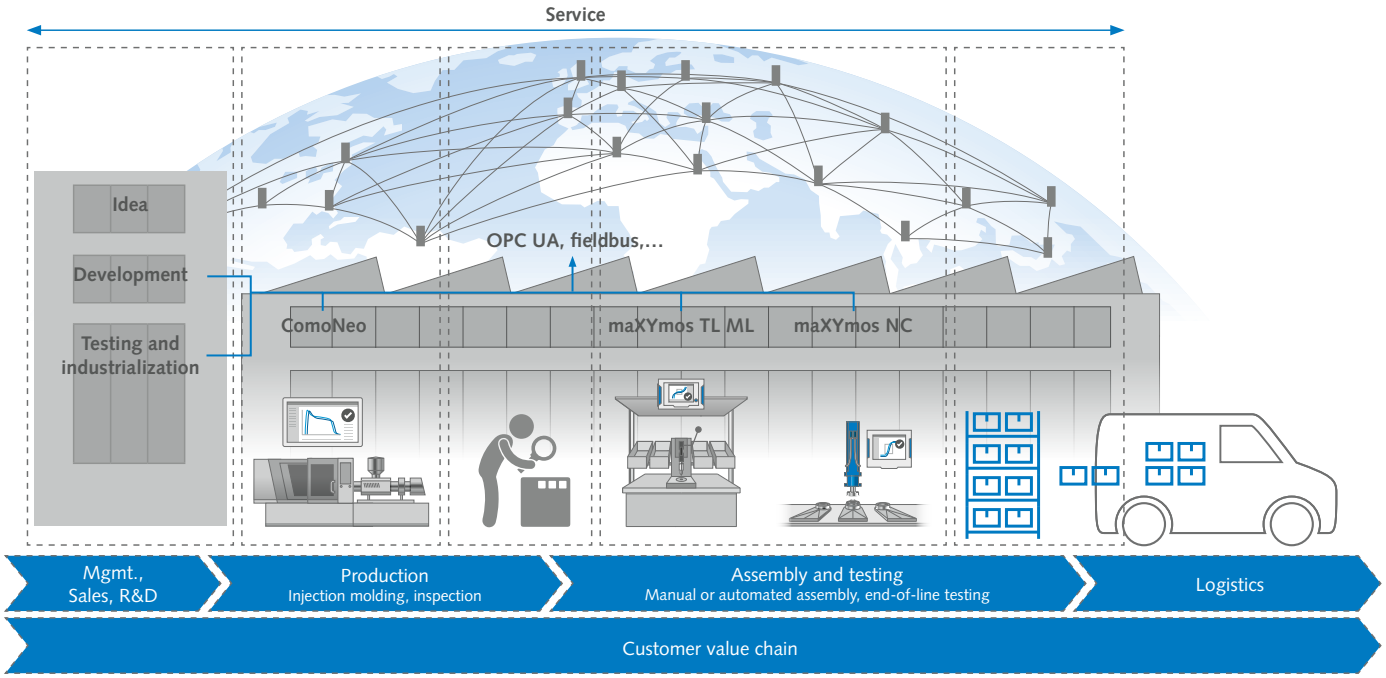
Take advantage of our technological know-how and our industry expertise!
We are thoroughly familiar with the complex process that medical devices undergo.

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

4 Production
When you deploy our systems, you can guarantee that your processes are reliable and stable – and full traceability of your products is ensured.



Boost value – from primary shaping to final release

Injection molding processes, assembly and joining systems, and product testing (including quality assurance): throughout the value chain, generate more added value by combining smart, modular process monitoring systems and miniaturized pressure, force and torque sensors.

Production
In manufacturing processes for parts made from plastic, 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. What makes this possible? The ComoNeo monitoring and control system, based on piezoelectric cavity pressure sensor technology.

Assembly
In processes where various components are assembled to produce a medical device, sensors are deployed – as appropriate to each application area – to ensure that the product is assembled correctly. Quality assurance is based on process monitoring with our maXYmos TL ML and maXYmos NC systems.

Product testing
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, our sensors can test the spring force of the triggering mechanism to prevent incorrect dosage of the medication.

Documentation and data storage
The values measured and process data obtained in the preceding steps are processed as appropriate and made available to the customer. Quality-relevant data – in either raw or processed form – can be transferred via a direct, tamper-proof connection to the customer's database for storage.

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 the plant. This minimizes costly machine downtime and also eliminates the possible requirement for revalidation of production processes after the sensors have been calibrated.

All your benefits:
- Zero-defect production
- Maximum process transparency and reliability
- Automatic data backup and documentation
- Compliance with all standards and regulations
- Optimized process efficiency
- Reduced quality costs
- Productivity boost
- Rapid amortization (ROI)

Production – reliable quality for injection molding of complex parts

Do you have your sights set on the zero-defect mark for your injection molding production? The most reliable method of achieving this goal is process-integrated monitoring and control based on cavity pressure measurement.

Cavity pressure provides a direct criterion to determine part quality in the production of plastic components. Due to cavity pressure measurement, scrap is detected as early as possible and processes can be gradually optimized to achieve constant product quality.

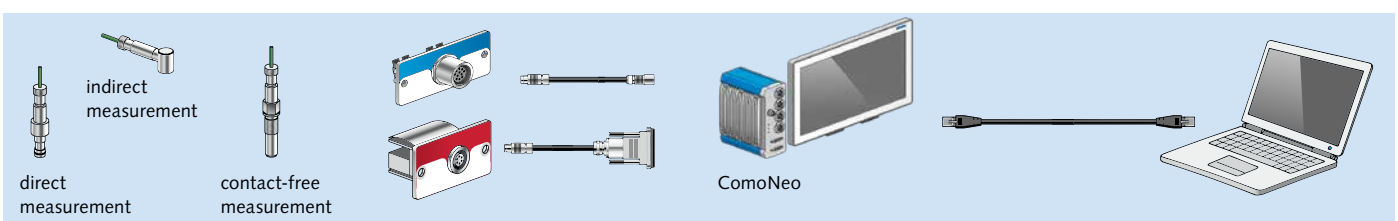
ComoNeo process monitoring system
ComoNeo records all conditions in the mold during the injection molding process. Special functions enable the analysis, optimization, monitoring and documentation of the injection molding process and are suitable and reliable tools for the various phases of qualification and validation up to production. The integrated user management and automatic recording of user activities offer the greatest possible process security and transparency.

Benefits of ComoNeo and cavity pressure sensors from Kistler:
- Monitoring of up to 32 pressure signals and 16 temperature signals in real time
- Extensive portfolio of high-precision pressure and temperature sensors to equip a varied range of molds
- High-performance products for universal use

Visit our website for comprehensive product details:

Source: Riegler GmbH & Co. KG

Application-specific features of ComoNeo:
- ComoNeoPREDICT:
  Online prediction functionality based on DoEs
- ComoNeoMERGE:
  Process monitoring functionality for multi-component injection molding
- ComoNeoLDAP:
  Automatic management of policies and users (User Management)
- ComoNeoLOG:
  Computer generated and time stamped electronic record of all user activities (Audit Trail)
- ComoNeoCONNECT:
  Data transfer via OPC UA



Assembly and product testing – why our maXYmos systems are the right choice for process monitoring

The process monitoring systems in our maXYmos family offer you options for FDA- and MDR-compliant process monitoring of assembly and joining operations in automated and semi-automated production plants, and also for manual workstations.

maXYmos systems visualize the process profiles and also offer an extensive range of interfaces for connecting sensors. Force, pressure, acceleration and torque are direct criteria for determining the quality of production in the medical device industry.

Integrated directly into the production line, these systems use measurement curves to monitor, evaluate, control and document the quality of an individual manufacturing step, a component or the entire product in real time. In accordance with the tolerances defined and specified in the qualification and process validation phases, the system decides whether each workpiece is good or bad.

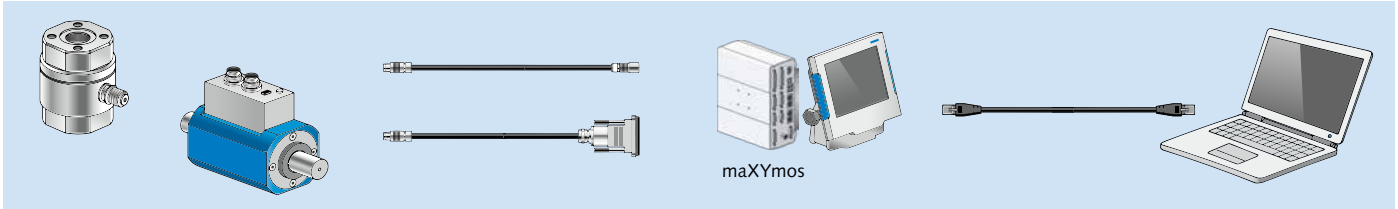
Your key benefit?
Time-to-market for your medical devices is significantly reduced – because 100 percent testing of individual production steps makes your validation processes far faster. And in some cases, the obligation to validate the monitored production process can be eliminated altogether!

General features of maXYmos:
- Designed for especially small measurement ranges for force-displacement monitoring in production and product testing (e.g. pressure testing, spring testing or end-of-line testing).
- Can be integrated into any existing production line
- Compatible with electromechanical, hydraulic and pneumatic production systems
- OPC UA capability

Visit our website for comprehensive product details:

Source: Riegler GmbH & Co. KG

Application-specific features of maXYmos TL ML
- Integrated user management
- Audit trail:
  - Recording and monitoring of all changes to testing processes, with time and user indexing for end-to-end traceability of each individual product for download and backup
  - Storage in write-protected files
- Security:
  - Optional blocking of ports for secure integration into the customer's data structure
- Complete documentation: for Installation Qualification (IQ) and Operational Qualification (OQ) based on prepared checklists
- Integrated printer drivers for hard copy documentation of test records



Assembly and product testing – complete system for electromechanical joining with press-fit

Do you want to take advantage of the possibilities for standard-compliant process monitoring of assembly using electromechanical joining systems (servo presses)? Or are you planning to switch from pneumatic and hydraulic systems?

We offer you a comfortable solution to achieve these goals: a complete system comprising our maXYmos NC process monitoring system and the NCFT joining module.

maXYmos NC controls, monitors, evaluates and documents force-displacement curves for joining and press-fit processes, exclusively in conjunction with NC joining modules and the IndraDrive servo amplifier that is included in the system.

Our NCFT 2157B joining module features a linear axis with an integrated piezoelectric force sensor in the ram and integrated control.

Now there is no need to search for the right components and install them. Even "novices" can easily manage parameterization thanks to this coordinated system.

Servo presses – maximum energy efficiency
Servo presses attain energy savings of up to 90 percent as compared to pneumatic and hydraulic systems* – so your operating costs (TCO) are cut and your CO_2 emissions are significantly lower. And that means you are also helping to protect the climate!

* Study by the University of Kassel (2012)

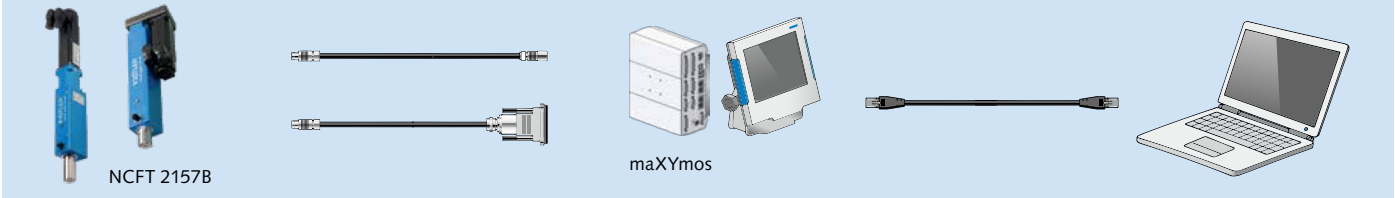
Application-specific features of maXYmos – optional:
- Integrated user management
- Audit trail
- For more, see maXYmos TL ML

Visit our website for comprehensive product details:

Source: Riegler GmbH & Co. KG

Benefits of our electromechanical NCFT joining modules:
- Suitable for clean room use
- Measurement range from 0.05 kN to 1.5 kN
- Telemetry ensures utmost measurement accuracy
- High overload protection for sensors
- Excellent dynamics with up to 400 mm/s for very short cycle times
- Integrated switching between two measurement ranges
- Two versions:
  – Straight design with 100 mm stroke
  – Angled design with 250 mm stroke

Measure | Connect | Monitor and control | Document and analyze


NCFT 2157B

maXYmos

Our service: from the original idea through to series production

No matter which application area your medical device is intended for, Kistler supplies solutions precisely tailored to your objectives – solutions that deliver enhanced process.

Source: Riegler GmbH & Co. KG

Services
Our services support you from the original product idea through to series production.

- Our sensor positioning service assists you with correct sensor installation, helping you to determine meaningful quality gates
- Application training for sensors and process monitoring systems
- Process investigations and tests on site at customer's premises, or on our own test systems
- Support with installing sensors and commissioning (IQ) including connection to third-party systems, e.g. via fieldbus or OPC UA
- Support with mold validation to determine process limits (OQ)
- Compliance with QM system requirements
- Reducing the risk of incorrect use -> reliable and stable processes
- Advice on data analysis and data models
- Calibration of sensors and measuring chains directly on the plant, or at Kistler's calibration laboratory with traceability to ISO 17025 (depending on the application case)

Management of test and measurement equipment
Many customers need support to clarify questions and take decisions on calibrating and managing their equipment:

- Why is calibration necessary?
- How often should equipment be calibrated / how are the intervals defined?
- Should we calibrate individual sensors or measuring chains?
- Traceable calibrations or service calibrations?

Kistler will be glad to advise you, and we will assist you with setting up a management system for your test and measurement equipment to make sure that you are audit-proof. Contact us – our experts are standing by to help you!

In-situ calibrations
To meet customers' special requirements and in cases where the measurement setup cannot be dismantled (as happens in medtech applications), we will perform in-situ calibrations at your premises.

An in-situ calibration may also be required for regulatory reasons, or because of the need to minimize downtimes caused by time-consuming disassembly procedures.

Would you like to learn more about our applications? Explore now:

www.kistler.com/applications

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