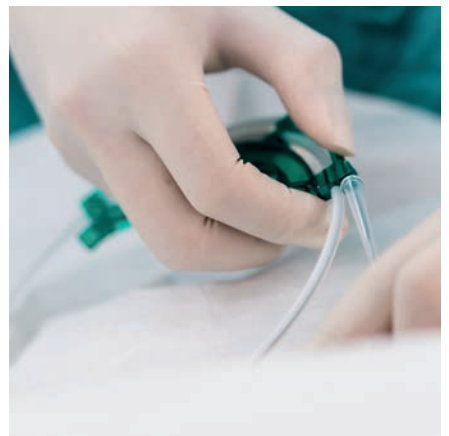
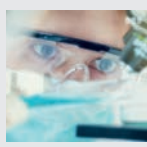


Testing Machines and Testing Systems for the Medical and Pharmaceutical Industry





1 The ZwickRoell Group

Contents	Page
1.1 Passion and expertise	3
1.2 Trusted partner for the medical and pharmaceutical industries	4

2 Therapy Systems

2.1 Tests on injection systems	6
2.2 Tests on injection pens	8
2.3 Fully automated tests on injection systems	9
2.4 Tests on syringes	9

3 Catheters and Stents

3.1 Tests on catheters	12
3.2 Tests on stents	14

4 Biomechanics

4.1 Tests on hip implants	15
4.2 Tests on spinal column implants	16
4.3 Tests on knee implants, osteosynthesis implants and screws	20

5 Dental Industry

5.1 Tests on dental implants	18
5.2 Tests on dental ceramics	19

6 Latex, Rubber and Silicone Products

6.1 Tests on contact lenses	20
6.2 Tests on condoms	20
6.3 Tests on rubber gloves	20

7 Textile Medical Products and Instruments

7.1 Testing textile medical products	21
7.2 Testing surgical instruments	22

8 Medical and Pharmaceutical Packaging

8.1 Tests on blister packs	23
8.2 Additional tests on packaging	24

9 Biomaterials and Clinical Research

9.1 Tests on biomaterials	26
9.2 Tests on bone materials	28

10 Products and Services

10.1 Testing machines for quasi-static applications	28
10.2 Testing machines for dynamic applications	29
10.3 Automation	30
10.4 Testing in biophysical environment	29
10.5. testXpert III testing software	32
10.6 Assistance with validation of testing systems	36
10.7 Daily Check device	38
10.8 Retrofitting for testing machines	38
10.9 Overview of ZwickRoell services	39

1 The ZwickRoell Group

1.1 ZwickRoell—Passion and expertise

Our company philosophy is founded on a passionate commitment to our customers. We work hard to ensure customer satisfaction by having over a third of our employees engaged in service and support.

As a family-owned company with a tradition stretching back 160 years, we place great value on honesty and fairness. Over the years an ethos of close collaboration based on mutual trust between our partners, suppliers and customers has evolved, something that we all value highly.



Fig.1. Reliable test results with machine and software solutions from ZwickRoell

The basis of a successful partnership: innovative employees, innovative products



Always at your service

Over 1000 people are employed at our headquarters in Ulm, Germany. Many of them have been with us for years—decades even. Their knowledge, ability and commitment are what lies behind the worldwide success of the ZwickRoell Group.

We are present in over 50 countries around the world.

The right solutions

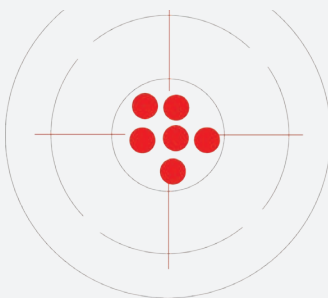
Whether for static materials testing or the various forms of fatigue testing—we have the right solutions. We offer products for hardness testing as well as instruments for impact testing and for melt index determination.

And for that rare occasion when we don't have a solution that fits, our experts will find one—from the smallest customization to a fully automated testing system or a test bench for special purposes.

1.3 ZwickRoell—a trusted partner for the medical and pharmaceutical industries

Reliable test results in R&D, quality control and production

Accurate and reliable test results are an important foundation in all development stages of automobiles and components. Testing solutions from ZwickRoell deliver accurate, repeatable, reproducible and traceable test results.



Quality management

The various statutory requirements, including the Medical Device Regulation (MDR), or regulations such as FDA 21 CFR Part 11, are implemented in full by ZwickRoell. For manufacturers and institutes our testing instruments facilitate implementation of standard-based requirements in the testing process as a whole.



Connectivity and digitization—let us help lead you into the future

Smart products and networking are here to stay in the medical and pharmaceutical industries. ZwickRoell supplies flexible, innovative testing solutions, the product of close collaboration with research and industry.



A trusted partner for the medical and pharmaceutical industries for over 40 years

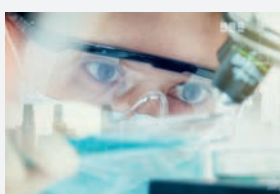
We have been supplying testing systems to the medical engineering and pharmaceutical industries since the 1970s. Through our intelligent solutions we have gained the confidence of international manufacturers, research institutes and certification bodies.





Intelligent testing solutions—the right product for every application

ZwickRoell's wide range of testing systems features modular design, enabling optimum adaptation to testing requirements. We provide varied testing solutions, from standard-based tests to materials testing machines for a variety of testing situations to complex, fully automated testing systems. All ZwickRoell testing systems are synonymous with reliable test results, simple operation and a high level of availability.



From therapy systems to medical research—testing solutions for all segments

As well as testing systems for the fundamental challenges associated with materials technology we provide comprehensive testing solutions for all relevant medical and pharmaceutical segments: therapy systems, catheters/stents, biomechanics, dentistry, latex/rubber, textile medical products/instruments, packaging and medical research.

Worldwide network of experts

We provide support for our customers in every country in which medical and pharmaceutical products are manufactured. Our skilled employees undergo systematic training to ensure our customers around the world receive optimum consultation and support.





2 Therapy Systems

2.1 Tests on injection systems

Injection systems include items such as syringes, needles, autoinjectors and injection pens with fixed and variable dosing. ISO 11608-1 describes the basic requirements for injection systems.

2.1.1 Tests on autoinjectors (ISO 11608-5)

An autoinjector is a medical device for administering liquid medications and is therefore subject to stringent quality checks.

The correct injection at the right dosage is critical in achieving a successful outcome to medication therapy, leading pharmaceutical manufacturers to strive for a high level of automation in

the handling of autoinjectors. The patient needs only to remove the safety cap, position the injector and start the injection by pressing a button.

The subsequent injection process is completely automated. However, this means that all relevant autoinjector functions must be checked before production batches are released on to the market. The checks are performed to ISO 11608-5.

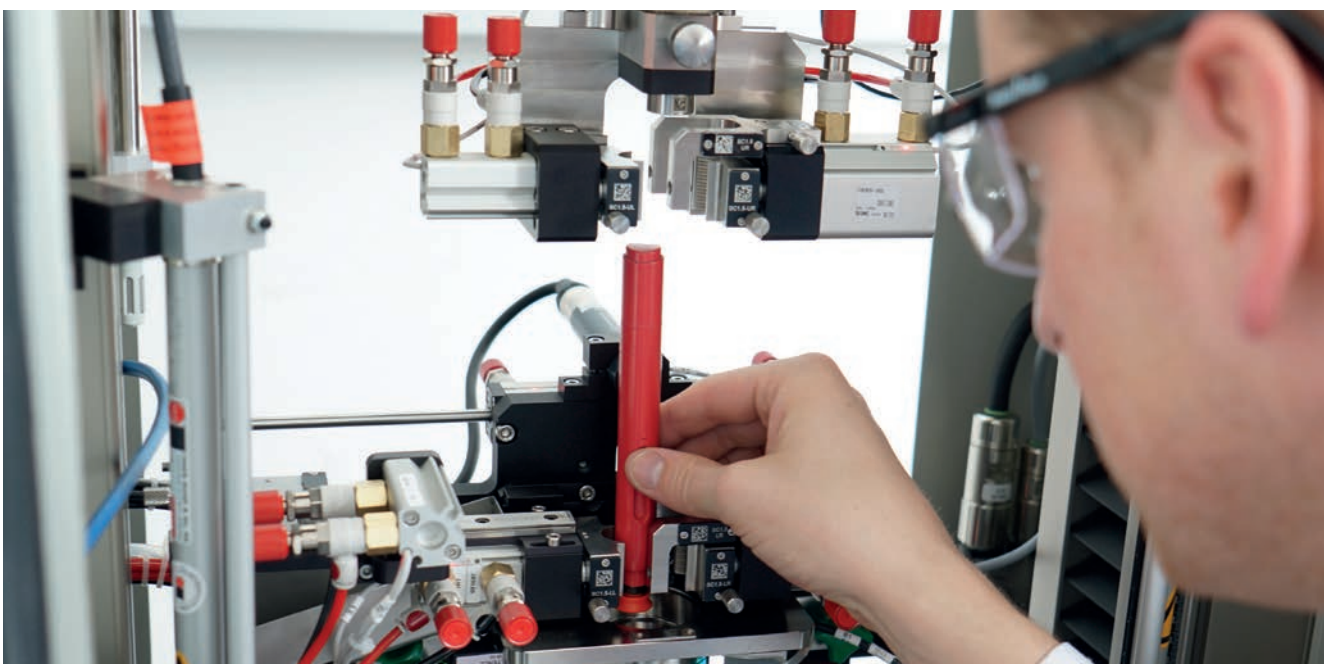


Fig. 1. Automated testing system for autoinjectors

Testing systems for this are available from ZwickRoell, enabling automated testing as follows:

- Safety cap removal force/torque
- Autoinjector actuation force and displacement
- Injection time measurement
- Measurement of expelled volume of medication (including last drops) via integrated high-resolution balance
- Effective needle length at injection
- Safety function of needle guard

The semi-automatic test has the advantage that all tests can be carried out on a single specimen without fixture alterations. The testing system can be upgraded for additional tests whenever required, enabling it to cater for different market requirements or product developments; in addition the click sounds made by autoinjectors at the start and end of the injection can be recorded using an optional microphone (audible feedback).

Other options include active tracking of the plunger and a retractable needle; an HD camera can additionally be integrated to record fluid expulsion. These recordings can then be stored traceably with the test results. The machine can also optionally be equipped with monitoring systems to comply with the requirements of EN ISO 13849. Control and evaluation of these additional functions and of the complete test sequence is via ZwickRoell's testXpert III testing software.

2.1.2 Simulation and characterization of spring forces and syringe glide forces

Spring forces have a critical bearing on the success of injections using

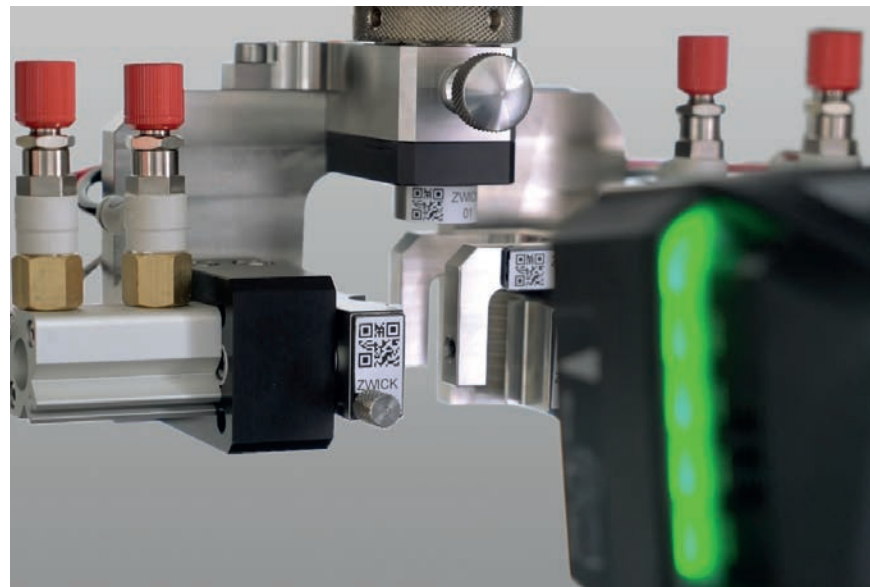


Fig. 1. Available from ZwickRoell are various options for minimizing the risk of confusion (barcode scanners for specimen grips, poka-yoke jaw system).

an autoinjector. They must therefore be measured accurately and the syringe systems used must be subjected to different spring loads. This can be done using force-controlled simulation of a spring curve in a ZwickRoell materials testing machine. These tests can be used at an early stage in the development of an autoinjector and in prospective aging tests. A single testing actuator with travel speeds of up to 0.5 m/s is generally used, along with the very fast testControl II electronics.

2.1.2.2 Tests on injection pens (ISO 11608-1)

During insulin therapy the insulin is usually injected subcutaneously using pre-filled syringes or insulin pens. These pens resemble a ball-point pen and contain insulin cartridges. Single-use pens are disposed of when the cartridges have all been used, whereas multi-use pens can be re-used with new cartridges. The standard used in quality

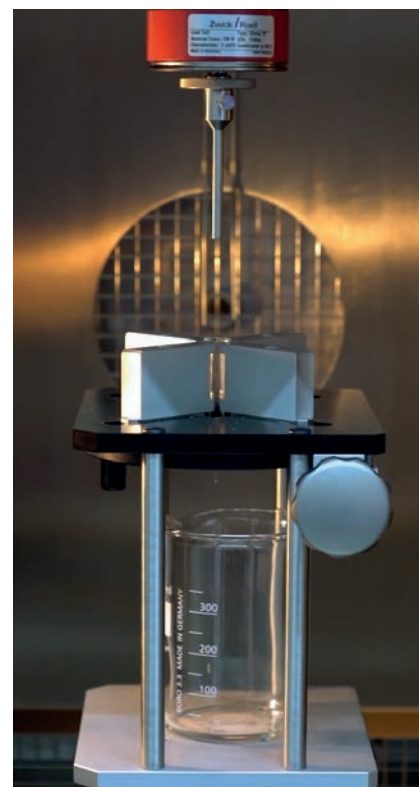
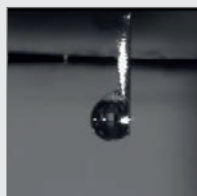


Fig. 1. Simulation of spring forces and syringe glide forces

Testing autoinjectors: overview

Injection time measurement, effective needle length, volume of medication ejected, identification of last drops



Click-detection via microphone during injection
Needle tip error analysis using HD camera



Other test steps/features

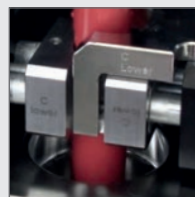
- Mistake-proofing (poka-yoke)
- Integration of barcode reader
- Specimen identification
- Measurement of ambient humidity / temperature
- Color recognition actuating button



Safety cap removal force/torque



Determination of needle shield removal force



Autoinjector activation force and travel



assurance tests on insulin pens and cartridges is ISO 11608 Parts 1 and 3.

A testing system with additional torsion drive is required for these tests; this allows the various pen functions such as dose pre-setting, actuation force, stroke and actual dose to be measured in a continuous sequence. Pen needles can also be tested to ISO 11608-2 using a system of this type. As well as dose accuracy, needle unscrewing torque is measured.

During testing of filled pens, dose accuracy is tested to ISO 11608-1

using an integrated high-resolution balance. Further automation of the test can be achieved by using a pattern-recognition camera for the dosing field setting. Manufacturers can also test pens not filled with medication. As well as forces/moments, plunger rod advance is measured with high accuracy.

2.3 Fully automated tests on injection systems

Reliable test results are a basic requirement when testing medical products. Extensive automation improves test-result reproducibility, minimizes operator influence and

simplifies validation using measurement system analysis (MSA Gauge R&R) studies. In addition to the automated test sequence, the roboTest R handling system provides automatic specimen feed.

2.4 Tests on syringes

Syringes have a wide range of application and come in correspondingly numerous forms. ZwickRoell has a large variety of standardized test devices.

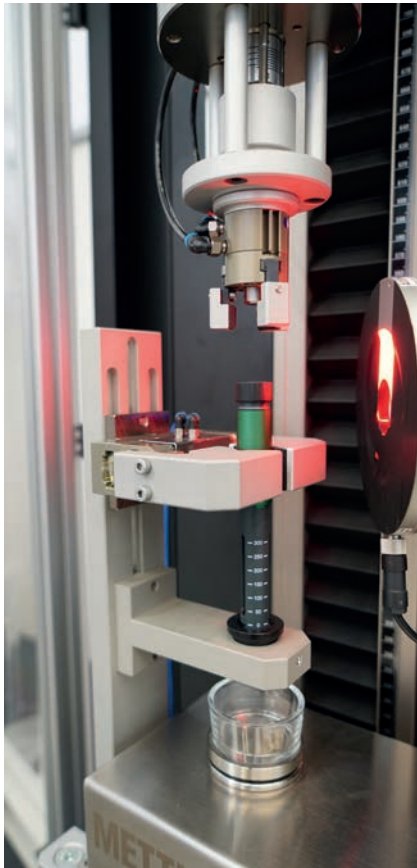


Fig. 1. Testing system for injection pens

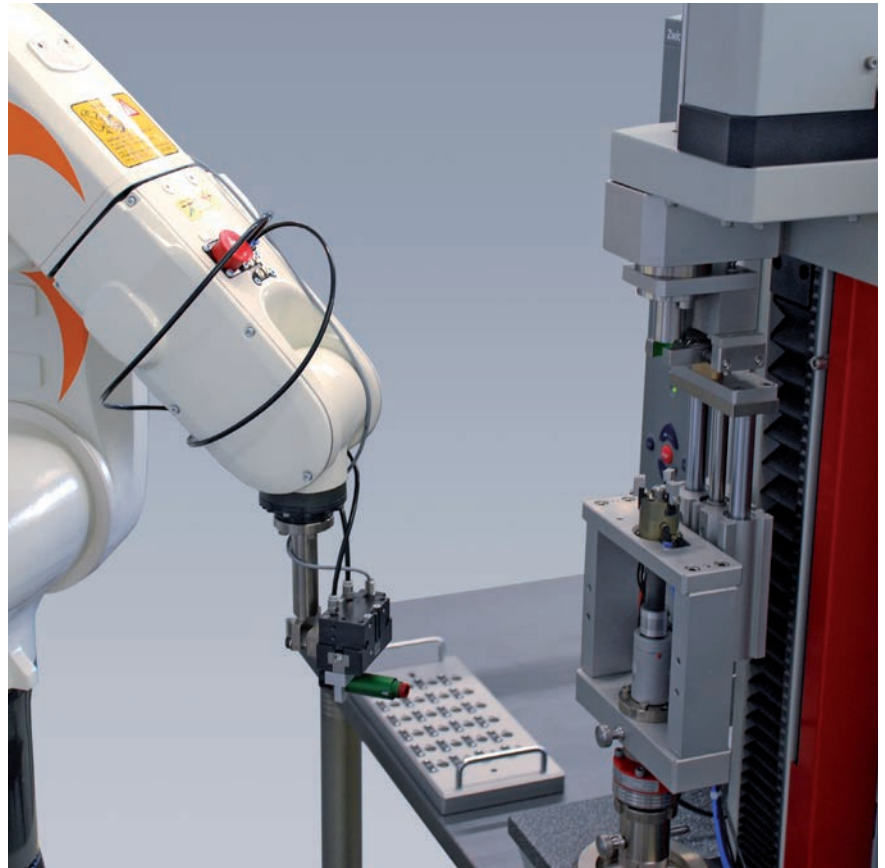


Fig. 2. Fully automatic testing system for insulin pens

2.4.1 Test on finished syringes as per ISO 11040 Parts 4 and 8

ISO 11040 covers pre-filled syringes. Parts 4 (Glass barrels for injectables and sterilized sub-assembled syringes ready for filling) and 8 (Requirements and test methods for finished pre-filled syringes) describe ten mechanical tests. ZwickRoell has a complete portfolio of products to satisfy the requirements of ISO 11040-4 and 11040-8. The variable test devices are suitable for a wide range of syringe types and geometries.

Some tests require a testing machine with additional torsion drive. The universal test device for syringes can also be used for tests on cartridges by means of suitable adapters. Torsion and leakage tests are described in ISO 80369.

Test on finished syringes as per ISO 11040 Parts 4 and 8



Overview of tests

- C1. Flange breaking resistance
- C2. Luer cone breaking resistance
- E. Glide-force test to evaluate syringe lubrication
- F. Needle penetration test
- G1. Needle pull-out force
- G2. Closure system liquid leakage test
- G3. Luer lock adapter collar pull-off force
- G4. Luer lock adapter collar torque resistance
- G5. Luer lock rigid tip cap unscrewing torque
- G6. Pull-off force of tip cap or needle shield

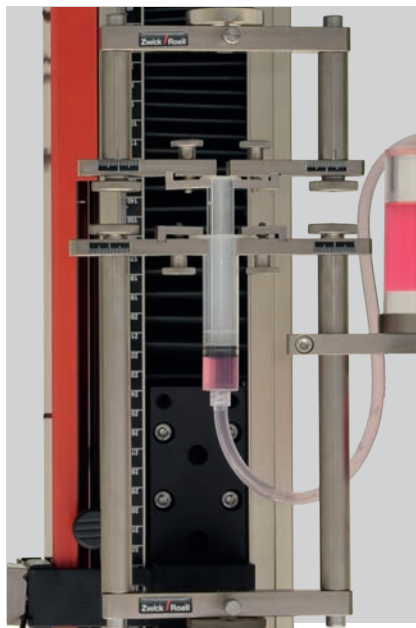


Fig. 1. Determination of piston operating force (ISO 7886-1)

2.4.2 Piston operating force, EN ISO 7886-1

Device for determination of the piston operating force for sterile single-use syringes as per EN ISO 7886-1.

2.4.3 Serial and parallel tests on syringe systems

If it is necessary to test a large number of syringes in a short time a materials testing machine with a carousel can be used. A large number of specimens can be fed to the machine via a magazine and tested one after the other. Operator influence on the test is reduced, resulting in greater stability in MSA/ Gauge R&R studies.

Another application concerns for example syringes used in syringe pumps. In this case the syringe plungers are depressed over a



2.4.4 Luer/luer lock connections (ISO 80369 Parts 7 and 20)

For quality control of these components a materials testing machine with superimposed torsion drive is used. Luer or luer lock connections are tested for stability in various tests as per ISO 80369 Parts 7 and 20 (formerly ISO 594-1 and ISO 594-2). The superimposed axial/torsion drive of a zwickiLine torsion materials testing machine enables



Fig. 3. Testing luer lock connections

The resistance to breakage of injection needles is determined in a two-point flexure test as per EN ISO 9626 (Annex D). In the test the needle is held at one end and the free end is bent through a defined angle. For the stiffness test on the needle (cannula) tubing as per EN ISO 9626 (Annex C) a three-point flexure test kit is used.

Fig. 4. Flexure test on needles



3 Catheters and Stents

3.1 Tests on catheters

3.1.1 Testing cardiovascular and urological catheters

Catheters are medical devices in the highest risk category and are subject to strict quality requirements. Suitable testing systems are available from ZwickRoell.

3.1.2 Horizontal test on catheter systems

Development work on catheter and guidewire systems includes attempts to reduce the coefficient of friction and the breakaway force. ZwickRoell's horizontal AllroundLine testing machine enables determination of shear forces in a simulated catheter insertion with very high accuracy. The frictional behavior of the catheter is measured by pushing it through an artificial artery, known as the "tortuous path". The test is carried out in a horizontal orientation in order to simulate the physiological status of the patient during the surgical intervention.

The horizontal AllroundLine testing machine features sufficient room both above and below the main test axis for multiple 3D models for dry testing or for tests in a temperature-controlled medium bath. Tests with or against the liquid flow are also possible.

3.1.3 Glidability tests on catheters

The frictional behavior of cardiovascular and urological catheters must be tested when they are wet. For this, the catheter is removed from a temperature-controlled water bath and drawn through jaws which close with a defined gripping force.

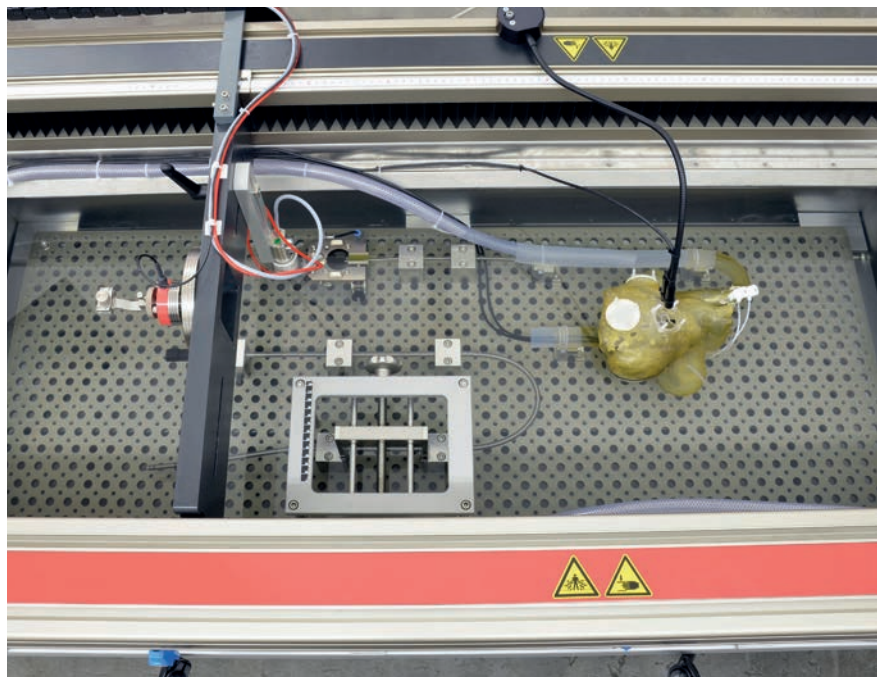


Fig. 1. Horizontal testing machine for catheters and guidewires

These jaws can be opened and closed automatically to enable repeated cyclic testing. In addition, the jaws can be changed quickly to provide different and/or undamaged sliding surfaces for the tests.

3.1.4 Tensile tests on catheter systems

To determine the insertion and connecting forces of catheter tube systems in accordance with ISO 10555-1 the system must be subjected to tensile loading up to failure. A wide variety of connecting diameters are required for this. The specimen grips possess a rotating self-locking disc with various opening widths, allowing a wide range of connectors to be tested.

Pneumatic specimen grips for maximum tensile forces up to 1 kN are suitable for reproducible gripping of the opposing end of the catheter.

The grips are closed by means of a foot pedal, leaving both hands free for inserting the specimen. The closing force is steplessly adjustable via a pneumatic control unit, while the low overall height of the specimen grips allows optimum use to be made of the test area of the materials testing machine. ZwickRoell also has a comprehensive range of jaws available for widely differing applications.

3.1.5 Flexure tests on guidewires, catheters, and medical tubes

The two-point flexure test kit for determination of the kink resistance of guidewires is designed for loads up to 50 N. Grip-to-grip separation is steplessly adjustable and the kit includes a dial gauge for displaying grip-to-grip separation from 0 to 55 mm, with an accuracy of 0.1 mm.

Specimen clamping is in the vertical plane, with the bending angle (max. 90°) generated via the kit's rotating clamping unit.

An additional flexure test kit for testing the flexure characteristics of stiff medical tubes (catheters etc.) and guidewires consists of a flexure table and two holding-down clamps for gripping specimens. Differing specimen diameters are accommodated by variously-shaped holding-down clamps (straight and prismatic), which are easily exchanged. The kit is designed for a maximum compression force of 50 N.

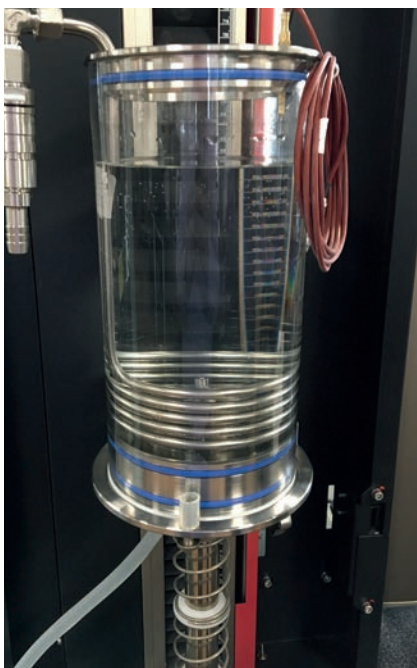


Fig. 1. Glidability test



Fig. 2. Tensile test on catheter systems

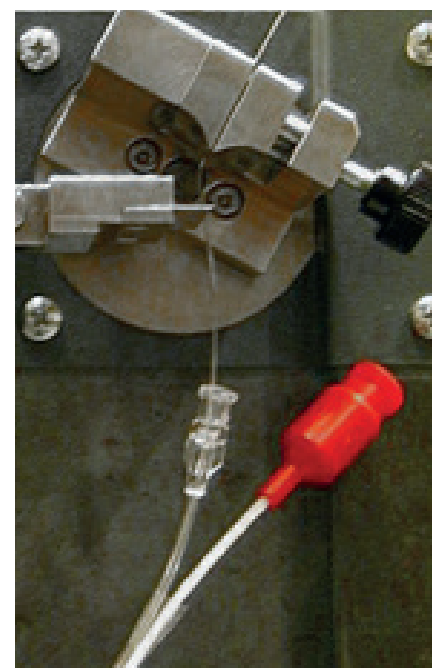


Fig. 3. Flexure test on catheters

3.2 Tests on stents

Stents are subject to heavy loads on insertion and while in place in blood vessels or ureters. The stents must be tested under these loads beforehand.

3.2.1 Radial compression test on stents

Together with obtaining accurate material characteristic values, determination of radial compression strength is the most important test for stents. They must exert a radial force which is sufficient to ensure that the stent remains fixed in the previously narrowed location and to prevent renewed constriction of the blood vessels. ASTM F3067 describes the radial compression testing of balloon-expandable and self-expanding stents.

Available from ZwickRoell is a testing solution featuring a zwickiLine materials testing machine equipped with a 37 °C chamber to simulate tests at body temperature.

Radial force is measured using Blockwise radial compression test fixtures specifically designed for testing stents and available in various diameters and lengths. They simulate the pressure exerted on the stent by the artery, together with the restoring force, by means of segmentally arranged wedge jaws which generate a uniform surface pressure. The stent is inserted, compressed radially to a minimum target diameter, then unloaded.

3.2.2 Non-contact strain measurement on wires and stent struts

To simulate stent systems, detailed material characteristic values are required. Along with tests on the entire system, components such as single wires and stent struts are often tested. This includes tensile strength and strain at break, as well as determination of minimum yield strength. This defines the force at which a material under single-axis tensile load demonstrates no permanent deformation. More efficient and above all more accurate is strain measurement using an extensometer. The probability of error is much smaller since measurement takes place directly on the specimen and therefore outside the force flow.



Fig. 1. Radial compression tests on stents

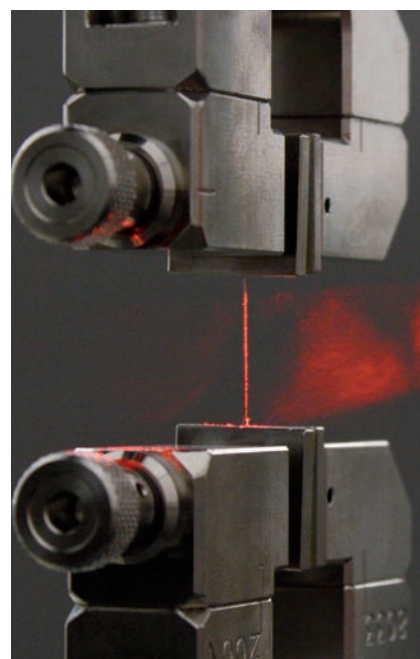


Fig. 2. Tensile test on stent strut



4 Biomechanics

4.1 Tests on hip implants

The hip joint is the articulation of the pelvis with the femur. Disease may necessitate replacement of part or all of the hip joint with an implant.

4.1.1 Fatigue tests on hip endoprotheses to ISO 7206 and ASTM F2068

The ZwickRoell HC Compact servo-hydraulic and LTM electro-dynamic testing machines can be used to simulate dynamic loadings on a hip prosthesis stem in accordance with the relevant standards: ISO 7206-4, ISO 7206-6, ISO 7206-8 and ASTM F2068. The mechanical general requirements defined in the standard, including the orientation of the hip endoprosthesis to the test load, the embedding height and the load-application angle, can be fulfilled exactly by means of the appropriate ZwickRoell embedding device. The tests can be performed under physiological ambient conditions (e.g. temperature-controlled saline solution) using the ZwickRoell temperature-conditioning bath.

4.1.2 Testing the anchoring of a hip endoprosthesis and other components

Hip endoprotheses can be anchored in the femur with or without the use of bone cement. The strength of the fastening in the bone must be tested. For this an endoprosthesis is anchored in natural or artificial bone. Cyclic loading is used to enable measurement of forces and of any micro-movements (via movement sensors) between prosthesis and bone. Artificial hip joints

must withstand both compressive and torsion loadings. The optimum materials and alloys are determined by testing in a materials testing machine with superimposed axial and torsional loadings.

4.2 Tests on spinal implants

4.2.1 Tests on spinal implants

ASTM F1717 describes static and dynamic tests on spinal implant constructs in a vertebrectomy model. A spinal implant, generally con-



Fig. 1. Fatigue test on hip prosthesis

sisting of a rod and screw system, is tested under static and dynamic loading. The implants are mounted on a test block made of ultra high molecular weight polyethylene (UHMWPE) material. The use of simulated vertebral bodies improves test reproducibility compared to those using human preparations.

In addition to purely axial tensile, compression or flexure tests, a pure or combined torsional load can be applied to spinal systems in accordance with standards including ASTM F1717, ASTM F2706 and ISO 12189.

These tests can optionally be performed under physiological (in vivo) conditions (e.g. temperature-controlled saline solution) using the ZwickRoell temperature-controlled bath. Also available from ZwickRoell is the SAFD (Statistical Analysis of Fatigue Data) program. This technical/scientific software enables prac-

tical statistical evaluation of tests in the high-cycle fatigue and long-life fatigue ranges.

4.2.2 Tests on spinal implants to ASTM F2077

ASTM F2077 describes a series of different quasi-static and oscillating tests to enable mechanical comparison of intervertebral body fusion devices. These include shear, compression and torsion tests, which provide a simplified in-vivo simulation of the loads imposed on spinal implants.

The spinal implant is loaded between two plastic (oscillating test) or metal (quasi-static test) blocks. These are matched to the external contour of the vertebral body. The fixtures required for testing to ASTM F2077, together with the corresponding interfaces, are available from ZwickRoell as a basis for the system.

ZwickRoell can design individual blocks for customers on request, on provision of the relevant data.

All tests can also optionally be performed under physiological (in-vivo) conditions using the ZwickRoell temperature-controlled bath at $37\text{ °C} \pm 2\text{ °C}$.

4.2.3 Torsion test on spinal implants to ASTM F2077 and ASTM F1717

As a result of comminuted fractures of a vertebral body or tumors in the area of the spinal column it may be necessary to replace a vertebral body with an implant. These vertebral body implants are tested by carrying out quasi-static and oscillating torsion tests in accordance with ASTM F2077 and ASTM F1717.

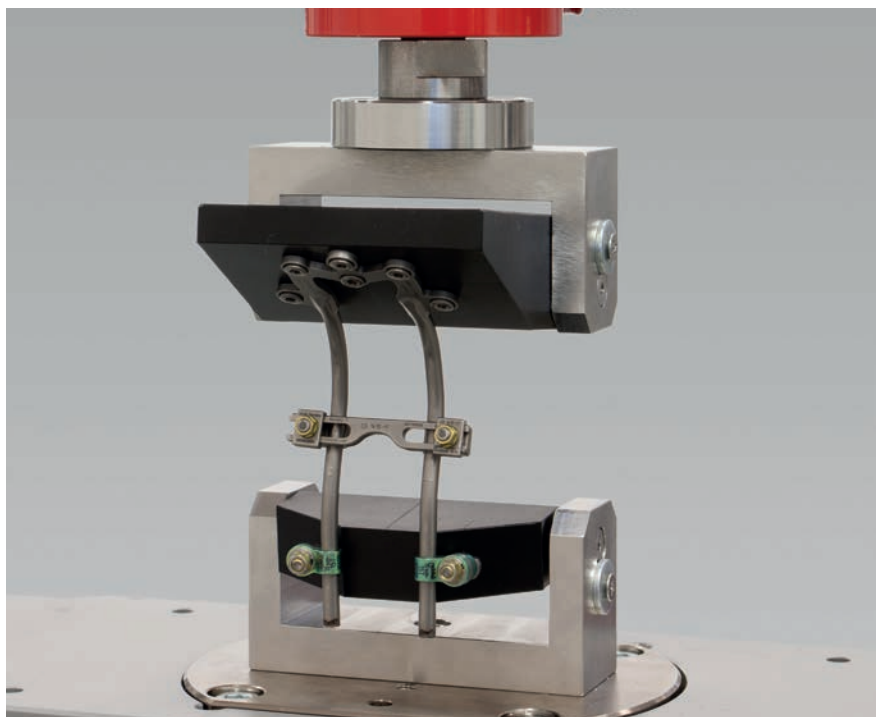


Fig. 1. Fatigue test on spinal implant



Fig. 2. Torsion test on vertebral body implant

4.3 Tests on knee implants, osteosynthesis implants and screws

4.3.1. Fatigue tests on tibial trays of artificial knee-joints to ASTM F1800 and ISO 14879

As the knee is required to withstand heavy compressive and movement loading when in place, tibial trays for artificial knee-joints are for example tested for up to 10 million cycles. The fatigue test to ASTM F1800 and ISO 14879 is performed under pulsating compressive loading applied to one end of the tibial tray. Operation is extremely easy. One half of the tibial tray is gripped in a clamping device and additionally secured with, for example, bone cement. The unsupported half of the tibial tray is subjected to physiologically representative loads applied via a defined compression die.

4.3.2 Flexure test on bone plates to ASTM F382 and ISO 9585

Tests with the test kit for bone plates and fixation devices enable mechanical tests to ASTM F382 and ISO 9585 for quality control or for research and development purposes. The static and dynamic

strength of bone plates are tested in 3-point and 4-point flexure tests; the flexure test kit consists of two anvils in parallel alignment, with fixed mountings. It is also possible to test bone pins to ASTM F1264 using a similar test arrangement.

4.3.3 Tests on bone screws to ASTM F543 and ISO 6475

The standards describe four mechanical tests on bone screws (including torsional strength, insertion and removal torque, pull-out strength and self-tapping performance).

A zwickiLine torsion materials testing machine is used, enabling a constant preload to be applied to the bone screws and a superimposed torsional motion introduced. In addition to the test fixtures, ZwickRoell also offers the associated embedding devices.

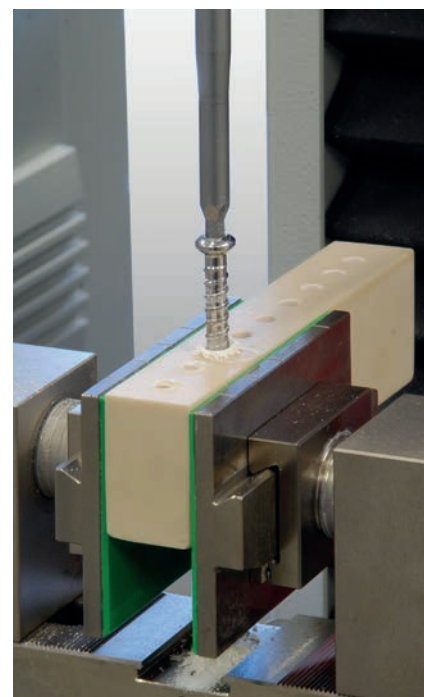


Fig. 3. Test on bone screws



Fig. 1. Fatigue test on tibial tray



Fig. 2. Flexure test on bone plates



5 Dental Industry

5.1 Tests on dental implants

5.1.1 Fatigue test on dental implants to ISO 14801

Dental implants are used to replace teeth. The implant is embedded in the bone, acting as the root of the missing tooth. The test device for dental implants (chewing simulator) applies an oscillating/pulsating compressive load as specified in ISO 14801.

This test enables a comparison of dental implants of different designs or sizes.

Flexible adjustment (between 0° and 50°) of the angle of the implant axis to the test axis, together with a quick-adjust 30° setting, allow this device to be used for testing dental implant systems with and without angled connectors. Embedding the dental implants in a pot allows differences in thread designs to be compensated for and implant lever ratios to be adjusted. The pot plus implant is fixed in the test device with the aid of a clamping device.

The test device is used in conjunction with a ZwickRoell LTM electro-

dynamic testing machine. The tests can optionally be performed under physiological (in vivo) conditions using the ZwickRoell temperature-controlled bath. For practical statistical evaluations of fatigue tests in the finite life range (high cycle fatigue) and in the transitional range to fatigue strength (long life fatigue), ZwickRoell offers the tech-

nical-scientific program SAFD (Statistical Analysis of Fatigue Data).

5.1.2 Test on dental products under physiological conditions

For tests on teeth, dentures, and filling materials, ZwickRoell offers a test stand based on the HCT 10 servo-hydraulic testing machine,



Fig. 1. Fatigue test on dental implants

which enables a dynamic load with axial force up to 10 kN and a torque of up to 100 Nm.

In this test up to five specimens are placed in a water bath at the same time and are loaded at a testing frequency of up to 25 Hz axially, torsionally or with a transverse motion via an intermediate test piece. The forces are recorded by a load cell between the actuator piston and test die, or by 3-component load cells below the water bath.

5.2 Tests on dental ceramics

5.2.1 Flexure tests on ceramics to EN 843-1 and ISO 6872

A special test device for flexure tests on ceramics to EN 843-1, specimen shapes A and B, and ISO 6872 is available from ZwickRoell. The basis of the device is a guide frame in which the flexure tables and dies required for the flexure test are installed.

The linear guide contained in the guide frame ensures exact alignment between the flexure table and the die. This simplifies removing and re-installing the device by eliminating the need for complete re-alignment. The anvils offer the degree of motion required by the test standards, ensuring that specimen is loaded in the most ideal way possible. A suitable measuring transducer is optionally available for determination of the flexural elasticity modulus.

5.2.2 Hardness test on dental ceramics

Dental ceramics used as filling materials or as restorative materials must, in addition to health and visual considerations, satisfy requirements regarding strength, wear and durability. Strength properties can for example be verified by means of hardness testing. Due to limited reflectivity, optical hardness testing as per Vickers can only be employed to a limited extent.

However the instrumented indentation test, based on measurement of indentation depth, has proved very effective.

Other mechanical characteristics in addition to hardness can be derived from the test sequence as a whole; for example creep or creep relaxation of the dental material can also be measured.



Fig. 1. Chewing simulator



Fig. 2. 4-point flexure test on dental ceramics



Fig. 3. Hardness test on dental ceramics



6 Latex, Rubber and Silicone Products

6.1 Tests on contact lenses

Manufacturers of hydrogels and finished contact lenses must test certain elastic characteristics of the material. To simulate the repeated application and removal of lenses, the break resistance of the dry and moist material, as well as the structure of the material at deflection, must be tested.

ZwickRoell offers a temperature-controlled bath with special submersible pneumatic grips for testing contact lenses. The values determined are Young's modulus, strain up to break, and tensile strength.

Since the forces measured here are very small, the buoyancy components of the specimen grips suspended in the bath must be compensated for in the testing software.

6.2 Tensile test on condoms

zwickiLine table-top testing machines are ideal for determining the tear strength and strain at tear of condoms. The pulleys are arranged horizontally and mounted at one end only. One of the pulleys is driven via a toothed belt proportionally to the crosshead movement, allowing the condom specimen to be loaded uniformly over its entire circumference.

6.3. Tensile test on rubber gloves to ISO 11193-1/2, ISO 37

Methods used to guarantee the required operational reliability include mechanical tests. Tear-strength tests are performed on gloves with and without a seam, as well as on artificially aged gloves.

The test is performed in accordance with ISO 37. Three dumbbell-shaped specimens are punched out of the palm, back and cuff of the sample glove, parallel to the longitudinal axis. Embossed areas should be avoided.

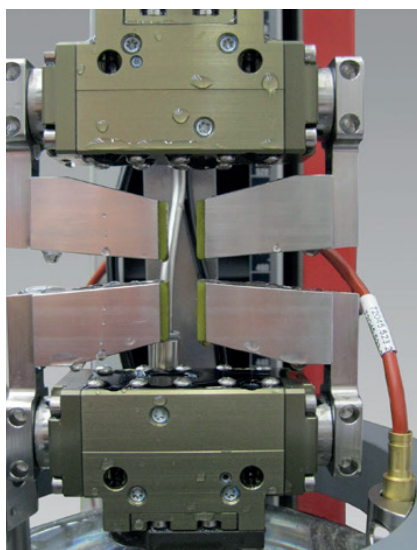


Fig. 1. Test on contact lenses

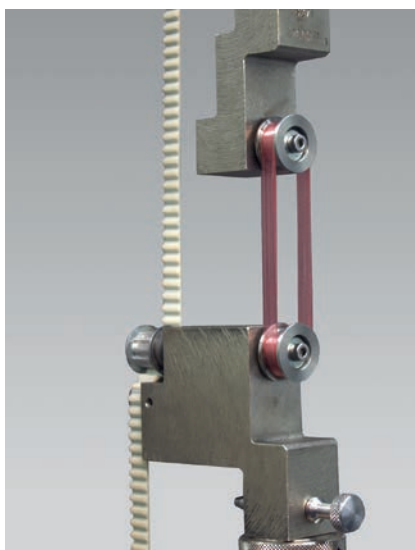


Fig. 2. Tensile test on condoms



7 Textile Medical Products and Instruments

7.1 Testing textile medical products

Textiles are used for numerous medical applications, including dressing and treating wounds, a wide variety of suture materials, textile-based implant structures (e.g. hernia net implants) and surgical drapes and clothing. Materials used include natural and synthetic fibers, together with breathable films and material combinations. The many different products and materials

employed in this area call for a wide range of materials tests and function tests.

7.1.1 Unrolling test for gauze bandages

To avoid the problem of individual fibers of gauze bandages "catching" on the winding below and preventing reliable unrolling, it is necessary to determine the force required to unwind the bandages from a roll. For this, a ZwickRoell materials testing machine with a nominal force 10 kN is used, together with a motor-driven unrolling unit.

The sequence is controlled by a specially adapted program from ZwickRoell's testXpert III testing software. This test fixture can also be used for pull-off tests on plaster (band-aid) strips.

7.1.2 Measuring the peel adhesion force of wound dressings

EN 1939 describes the method for measuring the adhesive force of self-adhesive tapes. To measure the adhesive force of wound dressings or other self-adhesive medical products the specimen is pulled off a metal plate during the test. This can be performed at various angles.

However, the forces measured in this way are twenty times greater than those arising when the dressing is used on skin. Manufacturers of adhesive products therefore test adhesive force on natural skin, in order also to be able to detect any sensation of pain by the patient, together with any skin irritation which may occur.



Fig. 1. Unrolling test on gauze bandages

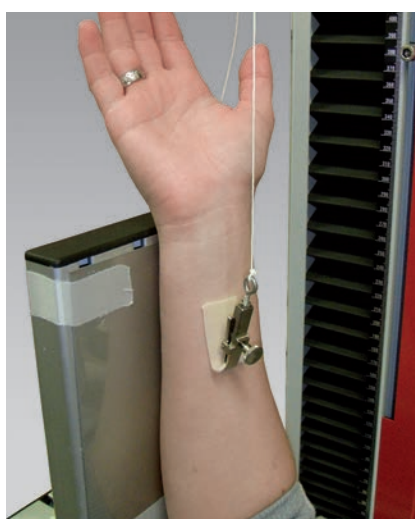


Fig. 2. Measuring adhesive force

7.1.3 Tests on surgical suture materials and needle/thread combinations

Methods used for characterization of surgical suture materials include tensile tests. During the test the monofilament, multifilament and braided yarn structures used must be securely clamped. A wide range of ZwickRoell specimen grips are available for this. It is also necessary to verify by means of additional tensile tests that the thread is held securely in the needle.

7.4.1 Testing surgical textiles for prevention of infection

Reusable or single-use textiles for surgical masks and gowns and drapes are intended to ensure infection prevention for doctors and patients in both inpatient and outpatient contexts.

Products for use in this area are subject to certification and in-production quality checks before being released on to the market. A central component of EN 13795 is the test methods for measuring product characteristics such as the tear strength of surgical textiles in both dry and wet states. Tensile tests applying transverse and longitudinal strain to individual materials or seams are used to simulate the loadings and strains imposed on textiles in use.

7.1.5 Testing medical non-wovens

The tests performed on medical non-wovens are as varied as their range of use. One important test is the tensile test on strip specimens (EN 29073-3 / ISO 9073-3 / ASTM D5035).

The measured value determined is the maximum tensile force, including the average value per direction of removal.

7.2 Testing surgical instruments

Surgical instruments may be divided into holding, grasping, and cutting instruments, as well as into suture instruments, optics, and combined instruments. ZwickRoell's wide product range, with its modular design concept, allows for the construction of many different test arrangements for use on components and finished goods, for example determining characteristics of a cutting edge or measuring wear resistance.



Fig. 1. Tensile test on medical textiles



Fig. 2. Penetration test for a bone drill



Fig. 3. Compression test on sagittal saw blade



8 Medical and Pharmaceutical Packaging

8.1 Tests on blister packs

8.1.1 Peel tests on peel and blister packs

This device is suitable for testing the seam seal of peel-off packaging by peeling off the lid or sealing-material of dimensionally stable or rigid packaging. The tensile strength of the adhesive bond between the film

and the plastic blisters is measured. A variable gripping unit is used to retain the blister packaging. During the test, up to 90 % of the lid is peeled off.

The screw clamp has a maximum opening width of 2 mm and is suitable for gripping forces up to 300 N.

8.1.2 Testing seamed seal strength

A tensile test is performed on 15mm-wide strips at a peel angle of 90°. The seal must display a defined strength, depending on the purpose for which the packing material is used. The strips can be cut using foil-cutters, parallel blades or scissors.

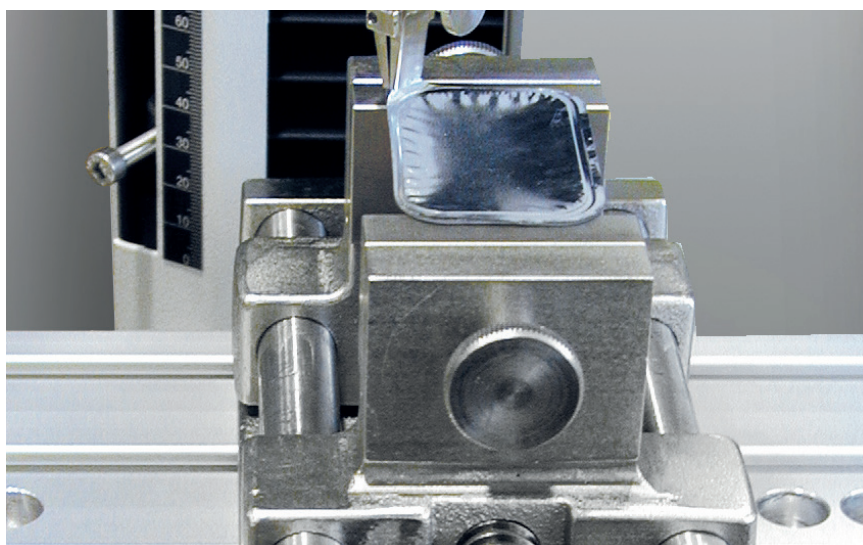


Fig. 1. Peel test on peel pack



Fig. 2. Testing seamed-seal strength

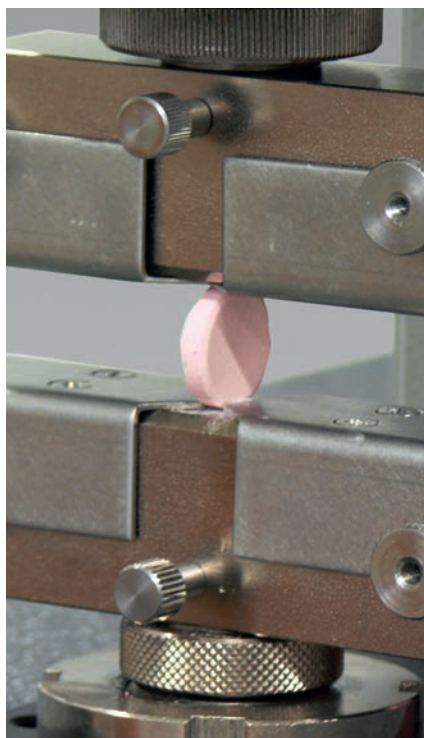


Fig. 1. Compression test on pill/tablet

8.1.3 Push-out test on blister packs

This device is suitable for testing the push-out force of blister contents such as pills and other medical products. Pushed-out remains fall out of the pack via the ejection chute in the compression platen. Specimen alignment is facilitated by a laser pointer which focuses on the die position above the specimen before the push-out test. The rustproof compression die is designed for a maximum force of 30 N.

8.1.4 Compression test on pills and tablets

The test kit includes identical upper and lower specimen grips. The tablet is placed on the test surface and held by the lateral, compression spring-loaded clamping sheet. The compression test kit is available in various versions.

8.2 Other tests

8.2.1 Determination of the residual seal force (RSF) of vials

The residual seal force (RSF) is the force with which the rubber stopper between the flanged cap and the neck of the vial is braced. This force measurement provides an indirect indication of the present security of the vial closure. However, these measurements must be correlated with established tests that examine the seal integrity of the stopper.

For testing the residual seal force of flanged caps, ZwickRoell recommends a device with inserts and compression dies of various sizes. Measuring the preload force of the rubber stopper on an aluminum flanged cap indicates the seal integrity of the vial closure. Modular design allows the various inserts to be changed quickly and easily.

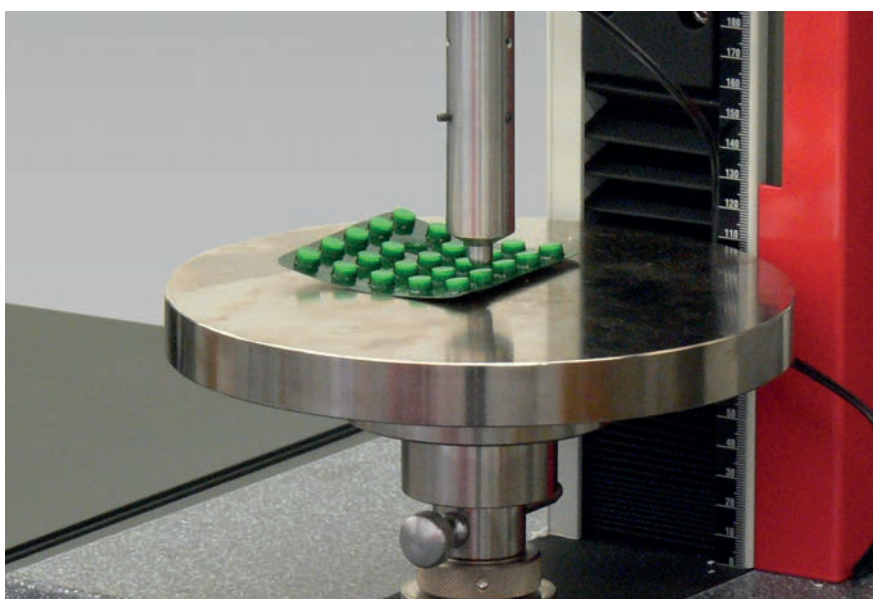


Fig. 2. Push-out test on blister packs



Fig. 3. Determination of residual seal force (RSF)

8.2.2 Push and turn test on screw caps

This test determines the superimposed compression/torsional forces for opening and closing childproof containers or pharmaceutical packaging. A zwickiLine tabletop testing machine of Fmax 2.5 kN and an additional torsion drive of 5 Nm torque are used for this.

The two test axes can be used for independent or combined axial/torsion tests as required, the package being opened via a rotary movement with superimposed axial loading. Important parameters are the required opening torque and the correct operation of the childproof mechanism.

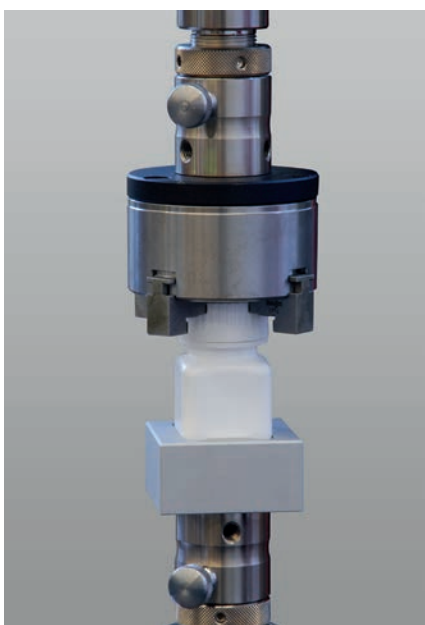


Fig. 1. Push and turn test on screw cap

8.2.3 Determination of the breakaway torque of syringe tip caps

Torque is applied to tip caps on single-use medical syringes to determine their breakaway torque. The syringe barrel is gripped firmly in a holding fixture. The tip cap is held in a positive-fitting fixture with toothed pulley and belt, while the end of the cap rests in an end-support. To prevent transverse frictional forces the holding fixture and support bearing are mounted on a common precision slide carriage. During the test the positive-fitting tip cap holder is rotated 180° by testing machine travel. This ensures that the tip cap is fully twisted off.

For torsion tests on eye-dropper bottles the specimen is rotated by the crosshead travel via gearing. The integrated torsion transducer records the torque for the complete rotation.



Fig. 2. Determination of tip cap breakaway force

8.2.4 Compression tests on cardboard packaging

The procedure used for the box crush test (BCT) varies according to the standard and material. One or more packages are loaded up to failure, enabling the maximum stacking height to be determined.

Determination of inherent stiffness: this test provides information for the packaging manufacturing process. The package is loaded with a defined force on closing (lid/closure attachment) and must withstand this process without becoming damaged.



Fig. 3. Box crush test on medication packaging



9 Biomaterials and Clinical Research

9.1 Tests on biomaterials

9.1.1 Biaxial test on biomaterials

To enable adequate modeling the biomechanical behavior of soft biological tissues and its underlying structure must first be accurately determined. As biological tissues found in the body are continuously exposed to multi-axial loads,

research into this area calls for a testing machine capable of applying multi-axial loads to the tissue specimen. The biaxial testing machine incorporates four linear drives which are controlled independently of each other via position, force or strain. Force measurement is via (water-proof) load cells, two of each in the X and Y directions. There are also four electronic measurement and control units plus a fluid-bath for optimum temperature conditioning of the sample.

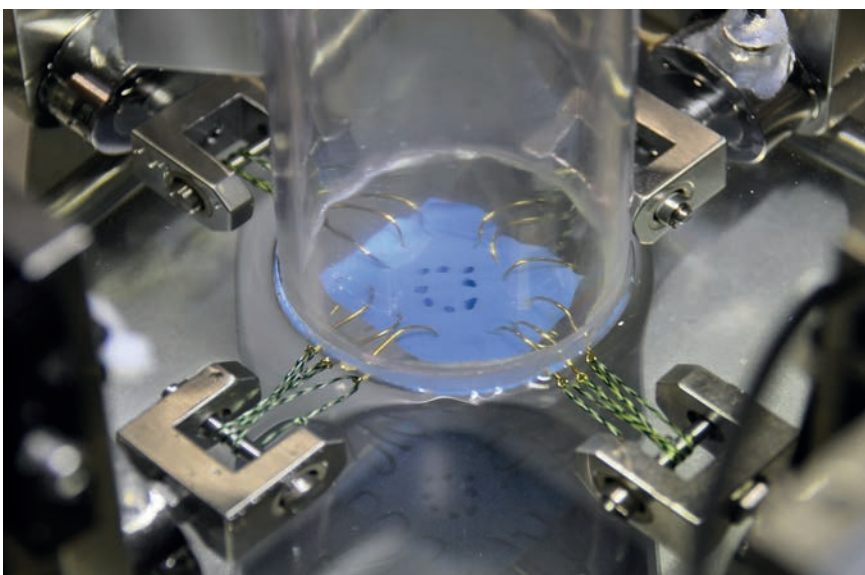


Fig. 1. Biaxial test on biomaterials in fluid bath

9.1.2 Triaxial test on biomaterials and tissues

To enable determination of the shear properties of soft biological (orthotropic) tissue a testing system for triaxial applications has been developed. The testing machine consists of two main components: an upper platform designed to move vertically (in the z-direction) and a lower platform designed to move in the horizontal plane in two directions perpendicular to each other (x and y-directions).

During the test the tissue specimen is attached to the upper and lower platforms using a thin coating of super glue and immersed in a temperature-conditioned physiological solution. The lower platform moves relative to the horizontally fixed upper platform, causing the specimen to shear.

The forces occurring in the three orthogonal directions (x, y and z) can be measured simultaneously with a special load cell mounted on the upper platform.

9.1.3. Triaxial test on tissue using torsion

The testing machine for cardiovascular tissues allows an axial force (strain), an internal pressure (inflation) and a rotational movement (torsion) to be applied to the tissue. The tissues under test are located in a bath containing a physiological solution. Symmetrically moving crossheads ensure that the center of the specimen always remains in the same horizontal position.

Due to the sensitivity of the structures being tested, strain must be measured without affecting the specimen. Measurement is performed using a combination of laserXtens and videoXtens non-contact measuring systems.



Fig. 1. Triaxial test on tissue using torsion

9.2 Tests on bones

Load test on human femur with strain gauges applied

The test is used to establish to what extent an implanted endoprosthesis stiffens the bone, thereby producing what is referred to as a stress-shielding effect. For this a human femur is placed in a testing machine; the horizontal orientation with microbead cushions is designed to eliminate transverse forces.

The femur head is then loaded axially. Strain gauges adhered to the surface of the bone enable comparison of the surface stress on the femur before and after implantation of the prosthesis.



Fig. 2. Load test on human femur

9.2.2 Flexure test on sheep bones

A 3-point flexure test on sheep bones is designed to determine flexural strength after fracture healing. For this a bone healed after break is fixed at its ends in supports and the load is applied using a table-top testing machine. The specimen grips are designed so that rotation of the bone by defined angular degrees is possible, allowing the flexural strength of the entire circumference of the bone to be determined.

The characteristic values obtained in this way are used in an FEM simulation of the healing behavior of bone fractures.

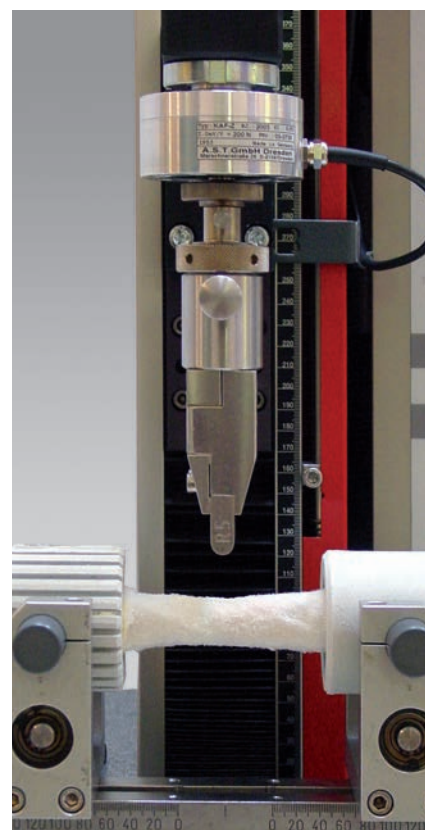


Fig. 3. Flexure test on sheep bones

10 Products and Services

10.1 Testing machines for quasi-static applications

zwickiLine

Included in our testing machines rated up to 5 kN is the single-column zwickiLine, which offers a powerful, flexible testing solution for a wide range of materials and components. This materials testing machine is equally ideal for research and development and for routine quality assurance testing. The wide range of equipment options allows zwickiLine to be used for testing both materials and a variety of components.

AllroundLine

AllroundLine is suitable for applications in all fields. A proven operating concept combined with flexible, modular load-frame design guarantees an optimum solution for demanding testing applications. It is equally ideal for quality-control testing or as part of research projects. Development and manufacture of AllroundLine, including all mechanical, electronic and software components, together with the comprehensive range of accessories, takes place at ZwickRoell's production facility in Germany, enabling optimum matching of all items. These materials testing machines are available in a force range from 5 kN to 250 kN.

Torsion drives

Torsion drives from 2 Nm to 2,000 Nm are available for torsion tests on materials or components. ZwickRoell supplies a variety of testing machines to cater for different requirements, including varied installation options.

These torsion drives were developed as a modular system, making them suitable for retrofitting also. A Master Test Program for multiple test axes plus a graphical sequence editor for four test axes are available in the testXpert III testing software. For pure torsion tests there are the TorsionLine testing machines with horizontal testing axis and optional weight loading unit.



Testing machines: zwickiLine and zwickiLine with torsion drive

AllroundLine testing machine

10.2 Testing machines for dynamic applications

Electromechanical testing actuator

These all-purpose electro-mechanical testing actuators are suitable for tensile and compression applications and can be integrated into testing devices in various configurations. Areas of use range from materials and component testing to testing finished end-products.

They also enable testing of production steps (e.g. assembling/joining, force-fitting and assembly) and are suitable for long-stroke cyclic fatigue strength tests.

LTM electrodynamic testing machine

Electrodynamic testing machines are used to determine material and component fatigue-strength in the fatigue life and fatigue limit ranges.

The oil-free drive technology, combined with ease of installation, makes them ideal for use in medical engineering, as well as for research and training. Typical examples include tests on hip joints, knee implants and dental implants.

The LTM dynamic testing machine range is currently available with forces of ± 1 to ± 10 kN and a piston stroke of 60 mm.

HC Compact servo-hydraulic testing machine

The HC Compact servo-hydraulic testing machine comprises a hydraulic power-pack, test frame and testing actuator and is suitable for tests on materials and components under quasi-static and dynamic loading. The HC Compact is a complete testing system and extremely space-saving, as the low-noise power pack forms the base support for the test frame. With a testing actuator mounted in the upper cross-head and a hard-chromed T-slotted platform, the testing machine is suitable for static and dynamic tests of all types up to ± 25 kN, including flexure tests, tests on components and biomedical tests.



Electromechanical testing actuator

LTM electrodynamic testing machine

HC Compact servo-hydraulic testing machine

10.3 Automation

Various forms of test automation for the medical engineering and pharmaceutical industries are available from ZwickRoell. Key advantages and features are listed below.

- The elimination of operator influence (hand temperature/moisture, off-center or angled specimen insertion etc.) results in high test-result reproducibility.
- Qualified laboratory staff are relieved of routine activities, leaving them available for more complex tasks.

- The machine can be used during idle times (lunch breaks and night shifts), increasing utilization and enabling “faster” results.
- The testing system reduces the testing costs per specimen and pays for itself very quickly.
- The system enables secure, reliable documentation and statistical long-term monitoring

The levels of automation range from multiple tests within a single testing machine to full automation with robotic specimen feeding system.



Fig. 3. Semi-automatic test on syringes



Fig. 1. Multiple tests on autoinjectors



Fig. 2. Testing system with fully automated specimen feed

10.4 Testing in biophysical environment

Testing in liquid media

In the field of biomaterials, research is carried out into the mechanical properties of both regenerative and artificial materials. To reflect the physiological conditions of the body, mechanical tests should be performed in a temperature-controlled fluid-bath.

Stents made of Nitinol are also tested in a temperature-controlled medium, as the material displays different characteristics at 37 °C from those at room temperature

Temperature-controlled bath for medical testing applications

- Suitable for static and servo-hydraulic testing machines.
- For applications in media such as saline solutions, ethyl alcohol, blood etc.



Fig. 1. Fluid bath with temperature control unit

- Container (Duran glass) can be moved axially to enable clamping of the specimen outside the liquid medium.
- Various test fixtures or specimen grips can be connected to the mounting stud located inside the bath. ZwickRoell has a large range of submersible specimen grips.
- Optional temperature control unit for installation in temperature-controlled bath. Temperature range: room temperature to 80 °C. Temperature control on the specimen via sensor probe.

Horizontal testing machine with water baths for tests on catheters etc.

- Determination of friction coefficients of catheters, guidewires and other minimally invasive instruments (flexible endoscopes)
- Testing catheter insertability in 3D models
- Performing horizontal tests including in temperature-controlled medium

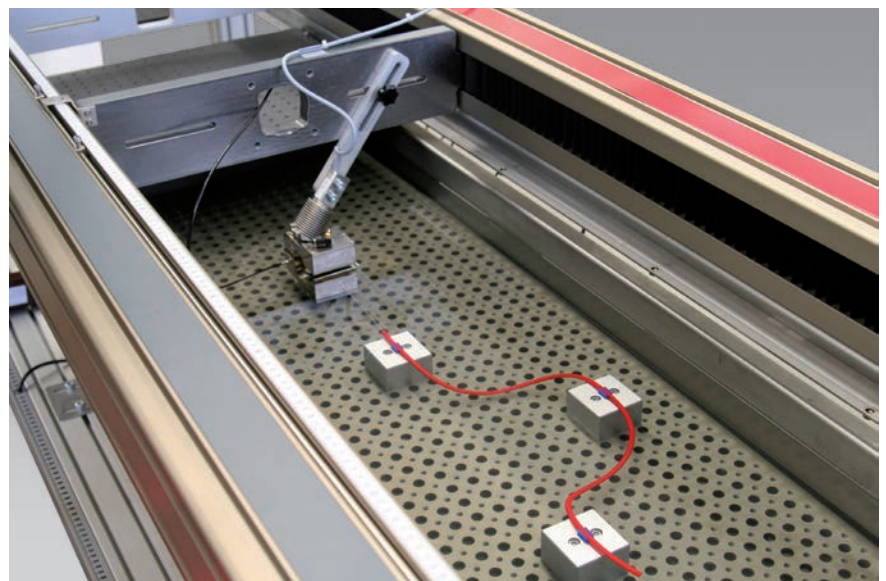


Fig. 2. Horizontal testing machine with fluid bath

Testing at temperature

ZwickRoell's 37 °C temperature chambers enable testing at controlled temperatures (e.g. up to 37 °C). Relative humidity in the temperature chamber can also optionally be controlled, from ambient humidity to 90 % relative humidity.



Fig. 3. Temperature chamber installed in a materials testing machine



Fig. 1. Workflow based on working processes: administrator's view, with full functionality - www.testXpert.de

10.5 testXpert III testing software

Intuitive and workflow-based from the very start!

testXpert III is the result of close collaboration with users in materials testing and the experience gained from over 30,000 successful testXpert installations. With its intuitive, structured operation, testXpert III is easy to use right from the start. Informative icons and clear visual linking of related items assist the user, while reducing mouse movement and clicks.

A workflow based on your lab processes

The software guides you through the various stages of a test, from preparing and running the test to analyzing results.

- Set up testing system—configure all machine-related settings for your testing application.
- Configure test—set all test-related parameters, such as selecting results with the intelligent wizard.
- Run test—experience fast and easy navigation through the entire test sequence.

View results—verify all test data, also in secure mode.

Intelligent user management allows you to define user roles or import user roles direct from Windows accounts via LDAP. The user can focus on the task at hand right from the start and avoid input errors. testXpert III is workflow-based throughout, keeping training time to a minimum and enabling efficient, reliable testing.

System Configuration Builder — a unique software concept

System Configuration Builder allows you to preset and save all relevant testing system and safety settings such as crosshead position, fixture separation or sensor configuration

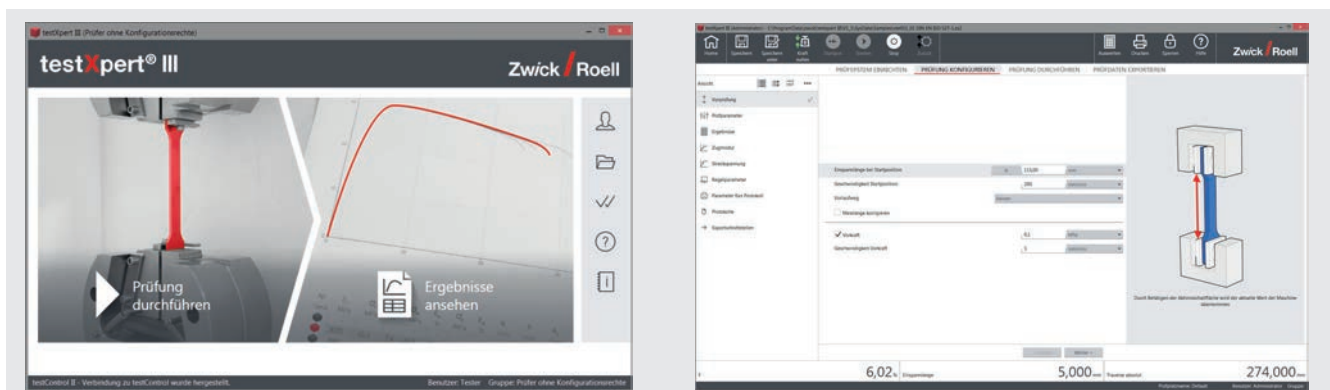


Fig. 2. View optimized for the tester (left); intelligent wizard for test configuration (right)

in a freely definable system configuration. The saved system configuration checks the connected sensors. The test can only be started if the parameters match the preset requirements, ensuring exactly repeatable test conditions.

Reliable importing & exporting
testXpert III can communicate directly with any IT system. All test-related data is imported quickly and directly from ERP systems, databases or external devices. Data can easily be exported to all your usual evaluation/analysis platforms.

Standard-compliant testing
testXpert III offers over 600 prepared Standard Test Programs, preconfigured to test standard requirements and with integrated results tables and statistics. You can begin standard-compliant testing immediately, testXpert III will take care of the rest!

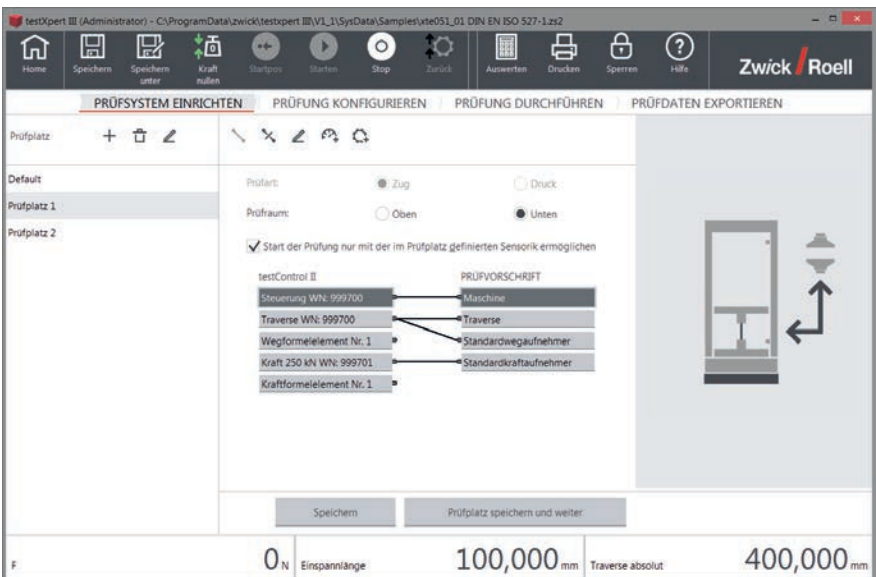


Fig. 1. Saved test configurations can be recreated following a change of test arrangement, allowing tests to be performed using identical settings.

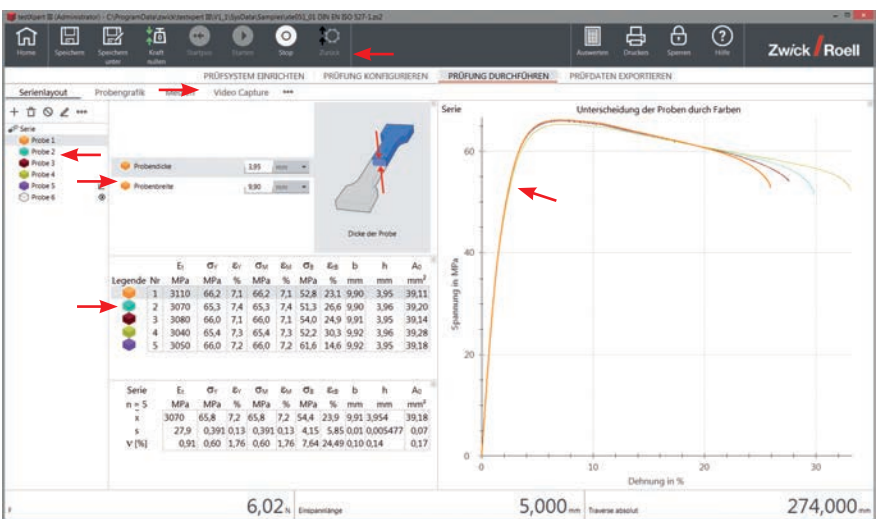


Fig. 2. Structured workflow with clear visual association of related content

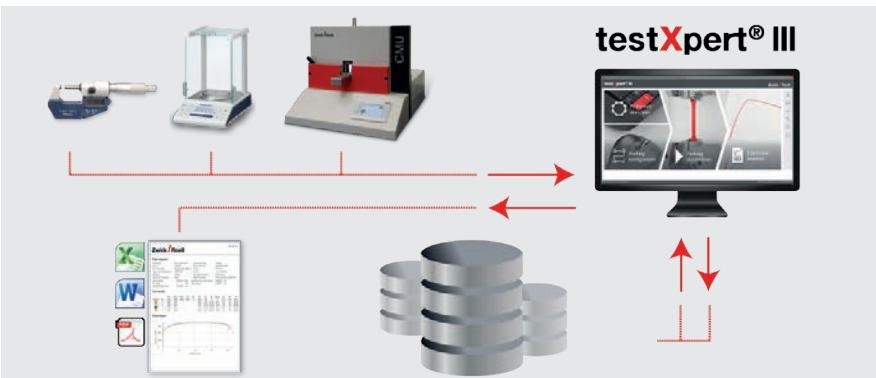


Fig. 3. Simple, reliable interfaces for sharing test results

Traceable, tamper-proof test results in accordance with FDA 21 CFR Part 11

Ever-increasing demands are placed on software used in the medical and pharmaceutical industries to document the traceability of completed actions.

testXpert III's Traceability option enables logging of actions and changes before, during and after the test, making test results and documentation traceable and safeguarding them against tampering.

Integrated User Management and functions such as Electronic Records or Electronic Signature ensure that test results are safeguarded against tampering at all times, fulfilling the FDA requirements in 21 CFR Part 11 together with the organizational measures and procedure instructions of the individual company concerned.

To complement this ZwickRoell also provides a Qualification Service package (DQ/IQ/OQ) for validation support. testXpert III logs all test and system-related actions and settings and is always able to answer the question

"When does who do what, why and who is responsible?"

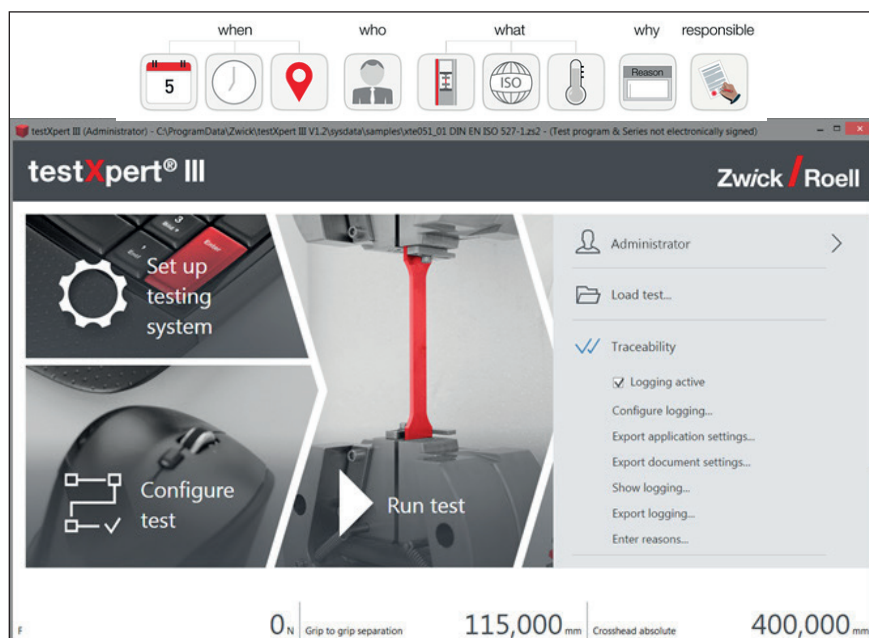


Fig. 1. Expanded traceability in accordance with FDA 21 CFR Part 11

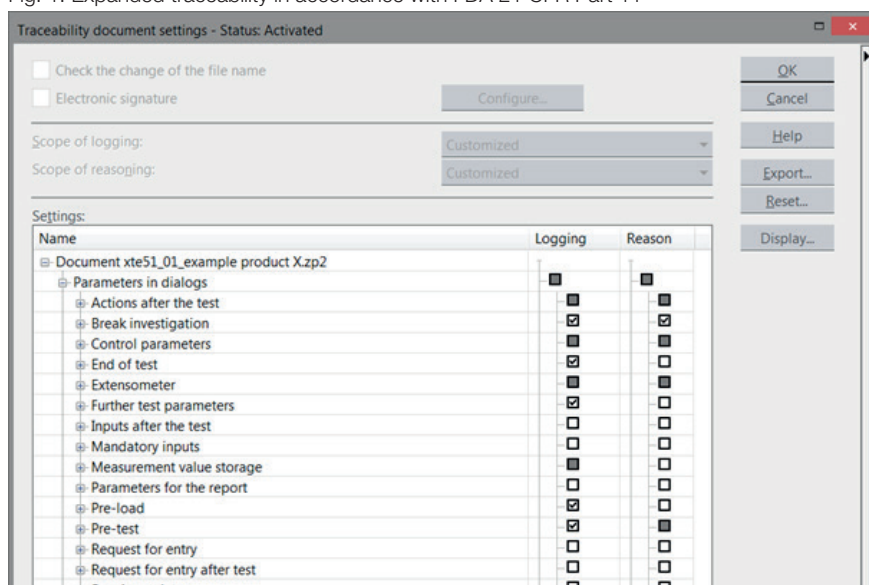


Fig. 2. Configuration dialog box for the settings of the traceability

Electronic Records

The Electronic Records function enables complete, tamper-proof documentation of all actions and changes performed in testXpert III. The user defines the level at which actions must be logged and if necessary explained in accordance with the user's regulatory requirements

(e.g. changes to a test-relevant parameter such as test speed). This data is stored in the audit trail.

The logging entries are stored (automatically and according to type) in the system audit trail or in the relevant test program/test series. The data is stored in binary form and cannot be changed via

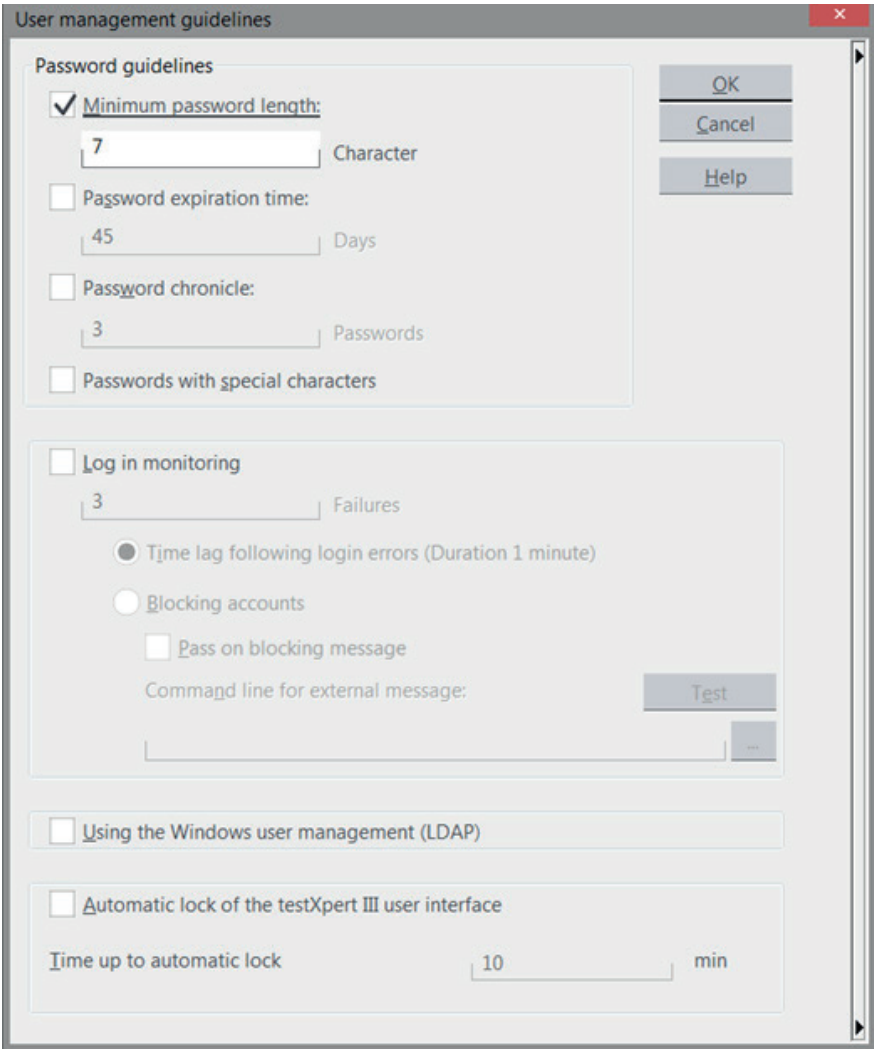
Windows standard programs. In addition testXpert III performs CRC checks to ensure the system is tamper-proof. Output can be generated in "readable" form (HTML / PDF) in testXpert III at any time.

Logged data is archived in encrypted form. Optional reasons/explanations are automatically added to the relevant log entry (with both old and amended values). A free remark can be inserted into the audit trail via a menu item.

Electronic Signature

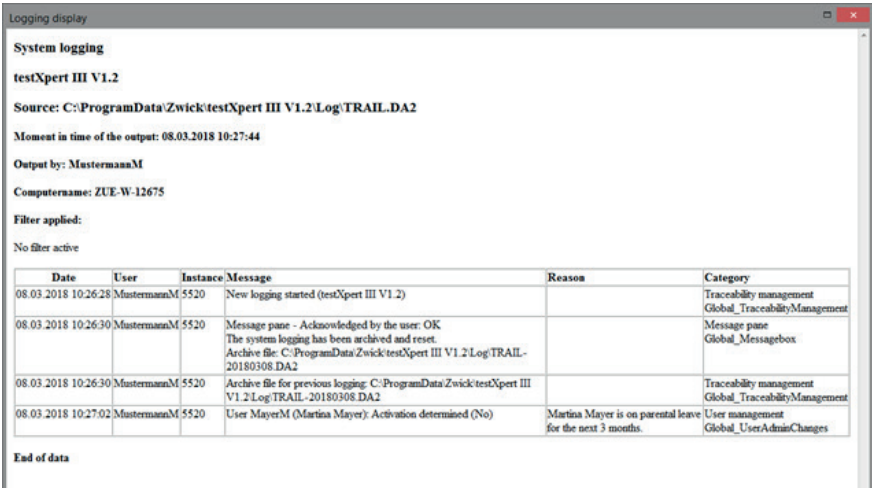
The Electronic Signature function also provides a reliable safeguard against unwanted changes to the test program/test series, while enabling documented assumption of responsibility combined with a change to paperless documentation.

The signature on the test log can be replaced by a digital signature for the test program/test series by entering user name and password in the testing software. It is also possible to specify how many signatures are required and who is authorized to sign. Once in signed status the test program and test series are safeguarded against unauthorized changes.



The dialog box titled "User management guidelines" contains several sections. The "Password guidelines" section has checkboxes for "Minimum password length:" (checked, 7 Character), "Password expiration time:" (unchecked, 45 Days), "Password chronicle:" (unchecked, 3 Passwords), and "Passwords with special characters" (unchecked). Below this is a "Log in monitoring" section with a checkbox (unchecked, 3 Failures), radio buttons for "Time lag following login errors (Duration 1 minute)" (selected) and "Blocking accounts" (unchecked), and a "Pass on blocking message" checkbox (unchecked). A "Command line for external message:" field with a "Test" button is also present. At the bottom, there are checkboxes for "Using the Windows user management (LDAP)" (unchecked) and "Automatic lock of the testXpert III user interface" (unchecked), with a "Time up to automatic lock" field set to 10 min.

Fig. 1. Configuration of user management guidelines



The "Logging display" window shows system logging for testXpert III V1.2. It includes metadata like source, time, output by, and computername. A table of log entries follows, with columns for Date, User, Instance, Message, Reason, and Category. The log ends with "End of data".

Date	User	Instance	Message	Reason	Category
08.03.2018 10:26:28	MustermannM	5520	New logging started (testXpert III V1.2)		Traceability management Global_TraceabilityManagement
08.03.2018 10:26:30	MustermannM	5520	Message pane - Acknowledged by the user: OK The system logging has been archived and reset. Archive file: C:\ProgramData\Zwick\testXpert III V1.2\Log\TRAIL-20180308.DA2		Message pane Global_Messagebox
08.03.2018 10:26:30	MustermannM	5520	Archive file for previous logging: C:\ProgramData\Zwick\testXpert III V1.2\Log\TRAIL-20180308.DA2		Traceability management Global_TraceabilityManagement
08.03.2018 10:27:02	MustermannM	5520	User MayerM (Martina Mayer): Activation determined (No)	Martina Mayer is on parental leave for the next 3 months.	User management Global_UserAdminChanges

Fig. 2. Display of system logging - complete, without filters

10.6 Support for validation of ZwickRoell testing systems

Statutory requirements and guidelines

Extremely high demands are placed on quality assurance in the medical and pharmaceutical industries. National and international laws and directives require that all processes and computer-controlled systems directly related to product manufacture must be subject to validation.

Observance of these guidelines is verified in an audit. This results in a need for appropriate documentation and supervision of all activities in order to minimize risks and guarantee patient safety.

Responsibility for validation lies with the regulated undertaking

The regulated undertaking (operator) must establish guidelines and procedures to satisfy the legal requirements.

Good Automated Manufacturing Practice (GAMP) can be applied here as a globally recognized code of practice for validation. It describes the tasks and duties of the supplier and the end user, together with the validation process.

A significant element of validation is the technical inspection of individual systems and devices. This section is designated Qualification.

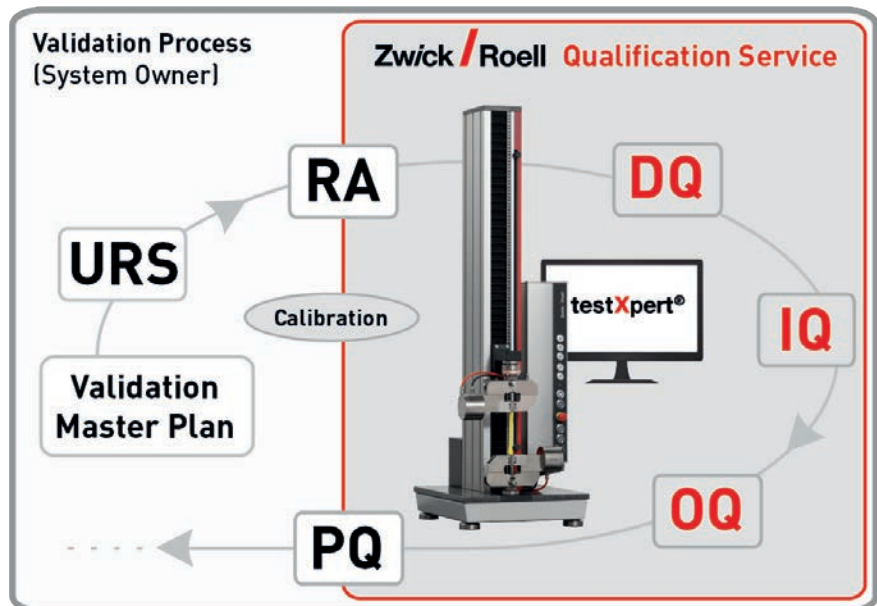


Fig. 1. Sequence of validation process

Process of qualification by ZwickRoell

- Generation of User Requirements Specifications (URS)
- Generation of Risk Analysis (RA) based on URS. The RA serves as a Traceability Matrix
- Designs specified in the User Requirements (URS) are reviewed in the Design Specification (DS).
- Verification of correct supply, installation and documentation of the system within the scope of Installation Qualification (IQ)
- Verification that the machine and software can perform their basic operations correctly during Operational Qualification (OQ)

Qualification Service for new and existing testing systems

ZwickRoell qualification documents are brought together in a basic package covering the basic equipment of the testing system.

Since 2015 regulated undertakings have been required to produce User Requirements Specifications (URS) (EU GMP Annex 15).

We therefore provide support in the form of a URS specifically tailored to our testing systems.

The individual User Requirements are transferred to the Risk Analysis and assessed there for relevance to GMP and occupational health and safety. All requirements classified as relevant to GMP and occupational health and safety are channeled into the Design and Test documents and are reviewed during Qualification.

Traceability is ensured throughout, from the User Requirements Specification to the RA to the Design and Test documents.

Modular qualification solutions

In addition to the basic package, ZwickRoell can also provide semi-individual/individual and periodic qualification. In the case of semi-individual qualification the basic documentation can be expanded to include your additional requirements. Individual qualification can be based on either the basic documentation or your User Requirements Specification (URS).

The basic package contains comprehensive documentation consisting of URS, RA, DS, IQ and OQ. All documents will be made available to you for checking and authorization before Qualification takes place.

Qualification will be performed on-site at your premises by specially trained ZwickRoell service technicians.

Wide-ranging benefits of the ZwickRoell Qualification Service

Cost and time savings

No tying-up of your resources in preparing and implementing qualification. Bottom-up document structure enables rapid project implementation.

Expert consultation

ZwickRoell possesses the expertise required to provide competent advice on the required scope of the qualification.

Know-how

Experienced, specially trained service technicians carry out the qualification step by step following commissioning and calibration at your premises.

Qualification of a ZwickRoell testing system which has already been installed is also possible.

Experience

The content of the documents is based on years of experience in the qualification of testing machines. The documents are continually updated to conform with new rules and new insights derived from the market.

ZwickRoell has performed several hundred successful qualifications—both nationally and internationally.

Flexibility

The scope of the qualification can be expanded on the basis of the basic documentation. We will also be happy to produce a completely individually tailored qualification based on your User Requirements Specifications (URS).

Quality

ZwickRoell is EN ISO/IEC 17025 accredited and can provide calibration of testing systems in addition to qualification on a "one-stop" basis.



Fig. 1. ZwickRoell service technician carrying out qualification at a customer's premises

10.7 Daily Check device

The Daily Check device is used for regular checks on load cells up to 500 N by means of comparison values which have been measured following recalibration / adjustment.

Advantages and features

- Use with any required number of machines—easy to install and remove
- Detection of systematic errors in compression and tensile directions in load cell (Xforce load cells feature symmetrical design)
- Performing checks between periodic calibrations ensures that the load cell is free of systematic errors.
- The results of the daily check are recorded in a testXpert report.



Fig. 1. Daily Check device

10.8 Retrofitting for testing machines

Every year over 3,500 customers upgrade their testing machines using proven ZwickRoell products:

- Load cells—sensitive and robust with the highest accuracy class
- Specimen grips and test fixtures Modular design enables easy and flexible retrofitting



Fig. 2. Xforce load cells

- Extensometers—maximum measuring precision, measurement in compliance with ISO 9513
- Safety for operator and machine, with retrofitting of safety technology (e.g. safety doors) to existing testing systems
- testXpert III—stay up to date at all times; testing software updates and upgrades ensure you always have the latest functions
- Temperature chambers and medium containers

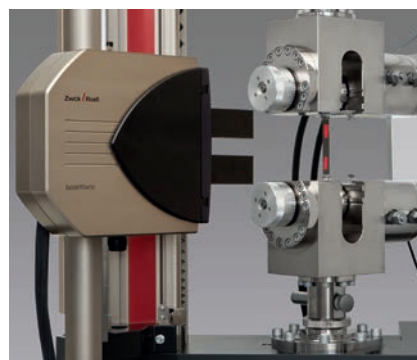


Fig. 4. Extensometers can be retrofitted as and when required



Fig. 3. Various specimen grips and test fixtures for biomechanics tests

10.9 Overview of ZwickRoell services

Customers can depend on ZwickRoell for consultation and support in implementing a wide range of testing requirements. Our involvement doesn't end there; a range of tailored services is available through the entire life-cycle of a testing system.

We assist our customers with their testing activities and requirements, helping them to achieve their goals.

Whatever the need, whether testing new materials, relocating the testing system, extending the service life of testing machines, avoiding downtime or re-training employees—ZwickRoell's wide-ranging service portfolio contains solutions for all requirements.

10.9.1 Training courses in the ZwickRoell Academy

The ZwickRoell Academy offers an interesting, modular training program—we will turn you and your employees into testing specialists!

Our portfolio ranges from courses on testXpert testing software to applications courses, from efficient metals, plastics, extrusion and hardness testing to courses tailored to your organization's individual needs—including directly at your premises.

9.9.2 Laboratory for materials and components testing

For companies with a testing requirement but no suitable testing option, ZwickRoell's laboratory for materials and component testing is ready to provide expert assistance.

With the latest technology and testing machines, we guarantee fast, standard-compliant testing. Natu-



Fig. 2. Modular training programs for beginners and advanced students

rally we can also perform tests in accordance with factory standards.

It makes no difference whether just a single test is involved or an entire test series.

We can also assist in the event of capacity bottlenecks or perform cross-validation tests.

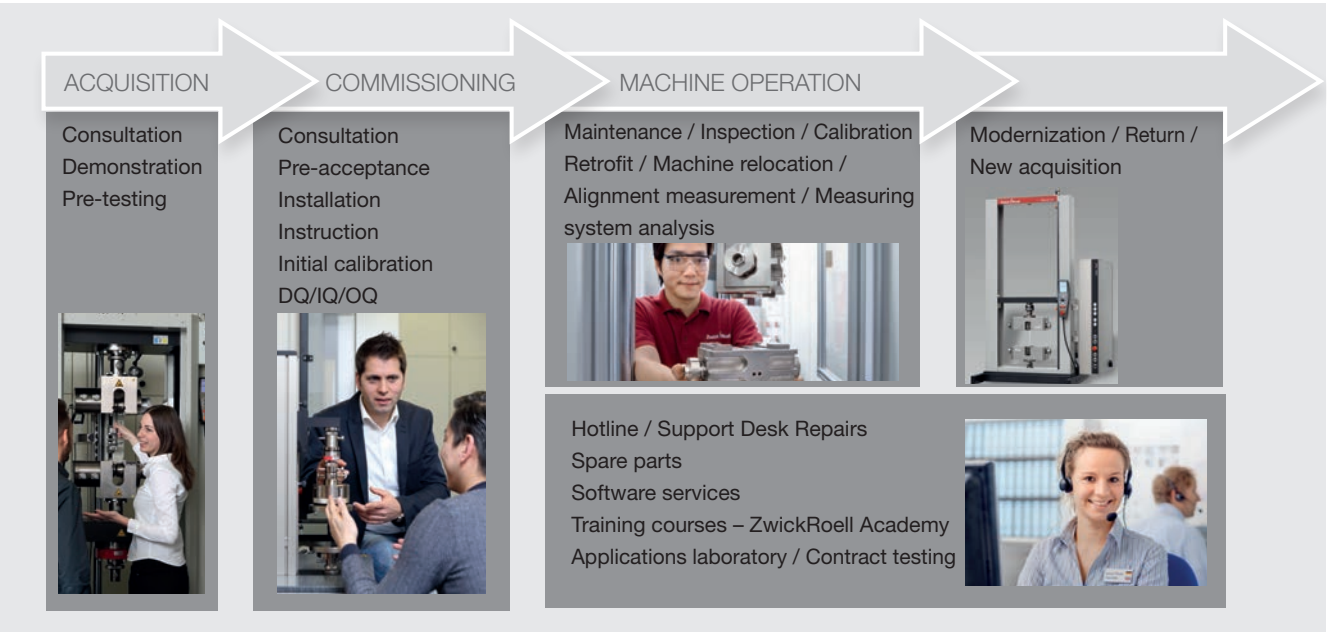


Fig. 1. ZwickRoell provides continuous support throughout the entire life-cycle of materials testing systems.

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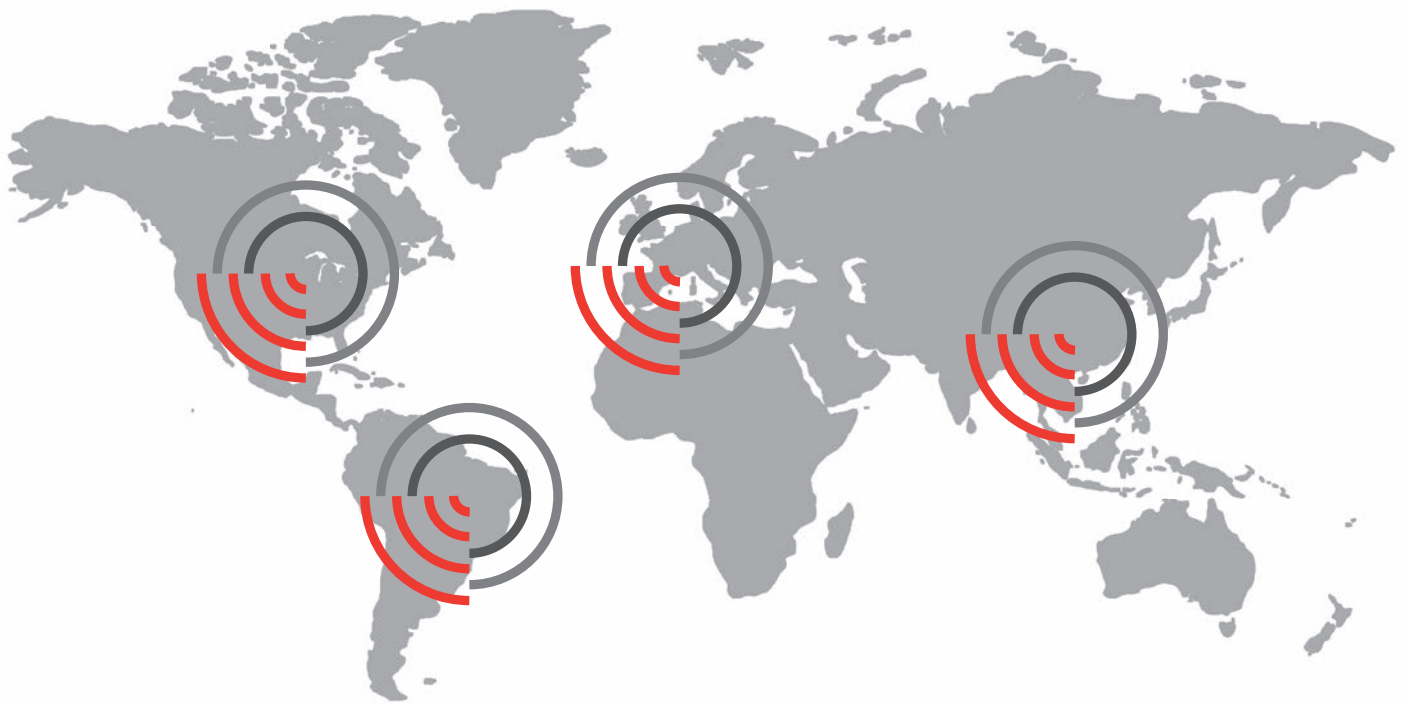
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