Zwick / Roell

Testing Systems

Testing Machines and Systems for the Medical Industry

FP 740 2.0909

Intelligent Testing

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This brochure provides an overview of instruments, machines, systems and services available from Zwick Roell AG for testing products from the medical technology and pharmaceutical industries and their use in R&D, production, quality assurance and control, and in testing institutes and training centers.

The brochure therefore shows only part of Zwick Roell AG's comprehensive overall range.

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1 Zwick Roell AG – Over a Century of Experience in Materials Testing

Mechanical testing is one of the oldest forms of materials testing. Da Vinci and Galileo were already turning their attention to bending strain and the elastic properties of materials in the 15th and 16th centuries. Time brought new insights, culminating in the appearance of the first testing machines in 18th-century France.

Roell & Korthaus have been involved in materials testing since 1920, while Zwick began building machines and instruments for mechanical materials testing in 1937. Many years earlier, in 1876, Professor Seger had established a chemical laboratory providing scientific advice on a commercial basis to the stone industry. During the 20th century this evolved into the present-day concern Toni Technik, leading specialists in the field of construction materials testing systems.

These companies have comprised the Zwick Roell Group since 1992. July 2001 saw the group become a corporation under the name of Zwick Roell AG, incorporating Zwick, Toni Technik and Indentec Ltd. Between them these companies provide a comprehensive materials, construction materials and function testing program – from manually operated hardness testing instruments to complex systems for process-parallel applications. Acmel Labo, the French manufacturer of laboratory instruments for the cement, lime and plaster industry, has been part of the group since May 2002.

Zwick Roell AG's expertise in sensor technology for load and extension measurement was enhanced and consolidated by the acquisition of German company GTM in 2007 and Messphysik of Austria in 2006.

Zwick's years of accumulated experience are reinforced by a policy of maintaining regular contact with our many customers. This provides a solid platform from which the company supplies a wide range of products – from economical standard machines to customized versions for specialized testing situations. State-of-the-art engineering, powerful electronics and application-orientated software are the keynote of these modern, versatile, highly intelligent testing machines and systems.

Zwick Roell AG is far more than just a manufacturer, however. As long ago as 1994 the company received DIN EN ISO 9001 certification - a guarantee of consistently high product and service quality. In addition, accredited calibration laboratories allow companies in the Group to inspect and calibrate test equipment and provide internationally recognized certification.

Fig 1: Zwick Roell AG and Zwick GmbH & Co. KG: Administration Building, Ulm, Germany

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2 Zwick – The Specialist for Medical Testing Solutions

Medical engineering has joined materials testing in the metals and plastics industries in becoming an increasingly significant part of Zwick's activities. In the last four years alone the number of orders received from this field has doubled. Safety requirements occupy an even more prominent position in medical technology than in most other industries, simply because the products have a direct influence on human beings. To meet these requirements, quality testing naturally includes development, production and packaging of medical products, paying due attention to legal requirements and relevant standards; most importantly, it must also minimize the risk for patients and users.

No Matter what Segment of Medical Technology – Zwick has the Solution

Zwick already has more than 20 years experience of testing medical products and can offer a comprehensive product range and wide-ranging expertise in static and fatigue testing. This is the result of a multitude of successful projects and continuous development and enhancement of new and innovative products, backed by collaboration with universities, associations and industry.

Mechanical testing in research, development, production, packaging and quality assurance also benefits from this collaboration; working with industry and research institutes, Zwick develops customized solutions for a wide range of segments. A flexible, modular range of machines, specimen grips, accessories and software simplifies finding the optimum equipment, while Zwick's comprehensive service portfolio allows the special needs of medical engineering and pharmaceuticals to be catered for.

Customized Solutions for Maximum Flexibility

Zwick provides solutions tailored to the requirements of customers from the medical technology and pharmaceutical industries. The majority of materials testing machines installed in this sector are customized designs; test fixtures in particular must be adapted on an individual basis to suit the product in question. The wide degree of freedom offered by *testXpert*® II software is of great value in meeting varying testing requirements and Zwick provides suitable software functions and detailed documentation to facilitate validation in this heavily regulated sector.

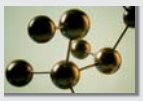
At universities and other educational institutes throughout the world, Zwick supports ground-breaking research with tailor-made solutions. In addition to serving in testing and research laboratories in education and industry, Zwick materials testing machines can also be found integrated into production lines for in-process checks. Our testing instruments and systems can also be combined with automatic specimen feeders, their modular design allowing them to be expanded and adapted to new situations as required.

Zwick is a member of numerous associations, bodies and networks and is continually adding to its fund of experience by sharing and exchanging information with various committees and collaborators.

Overview of Segments

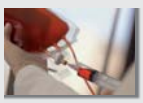
Packaging:
various materials, shapes and types of closure/seal, sterile/non-sterile

Latex, rubber and silicone products:
condoms, gloves



Clinical research:
materials, implants, artificial, human and animal tissues

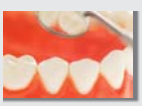
Biomaterials:
implants based on body's own or artificial materials (tissue engineering)



Therapy systems:
containers and tubing for liquids, catheters, hypodermics, injection pens, cannulae and injection needles

Instruments:
scissors, knives, forceps clamps, drills, surgical needles, endoscopes

Medical textiles:
wound dressings, plasters bandages, suture materials, surgical textiles, clothing



Dental industry:
metals, ceramics, plastics and combinations, filling materials, implants, prostheses

Biomechanics and orthopaedics:
prostheses/implants, trauma products (pins, screws, plates), stents

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2.1 Medical Packaging

Products from the medical technology and pharmaceutical industries must be securely packed and also ensure product safety over a longer storage period. Packaging is manufactured from a wide variety of materials, in various geometric forms and may be equipped with special functions.

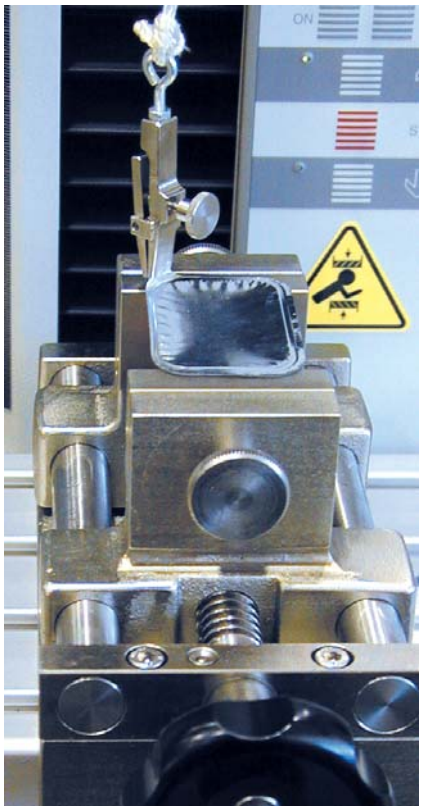

Fig. 1: Peel device for peel packs

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 channel in the compression platen. Specimen alignment is facilitated by a laser pointer which illuminates the die position above the specimen before the push-out test.

The spherical laser-pointer die can also be used for positioning specimens from other push-out tests. The compression die is designed for a maximum force of 30 N.

Peel Test on Peel and Blister Packs

This device is suitable for testing the seal edge of peel-off packaging by peeling off the lid or sealing material of dimensionally stable or rigid packaging media, e.g. individual blister packs for contact lenses. It possesses a support block with a holding-down device and screw clamp designed to retain the film in position. During the test, up to 90 % of the lid is pulled off. The screw clamp has a maximum opening width of 2 mm and is suitable for gripping forces up to 300 N.

Fig. 2: Testing device with laser positioning for push-out test

Toolbox

The “Toolbox” contains elements which can be combined in various ways for function-testing components. A T-slot base platform attached directly to the base crosshead forms the basic workplate, on which, for example, the T-slot supplementary platform can be mounted via brackets or pivoted joints. Further combinations of the holding-down device, various fixed and movable vises, the peel device, the linear displacement unit, the clamp set and an adapter plate are possible.

The compression die and the quick-release chuck are attached to the upper connection. All tools can be flexibly combined or linked in a variety of ways thanks to their versatile, modular design, allowing a wide range of geometrically differing components to be supported, held and positioned securely.

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Special Non-destructive Compression-test Kit for Medical Injection Vials

For testing the residual seal force of flanged caps, Zwick recommends a device with inserts and compression dies of various sizes. Measuring the pre-load force of the rubber stopper on an aluminium flanged cap provides an indication of the security of the vial closure. Modular design allows the various inserts to be changed quickly and easily; a protective screen is necessary for safety purposes, as glass breakage may occur during this test.

Fig. 1: zwicki-Line materials testing machine with residual seal force testing device

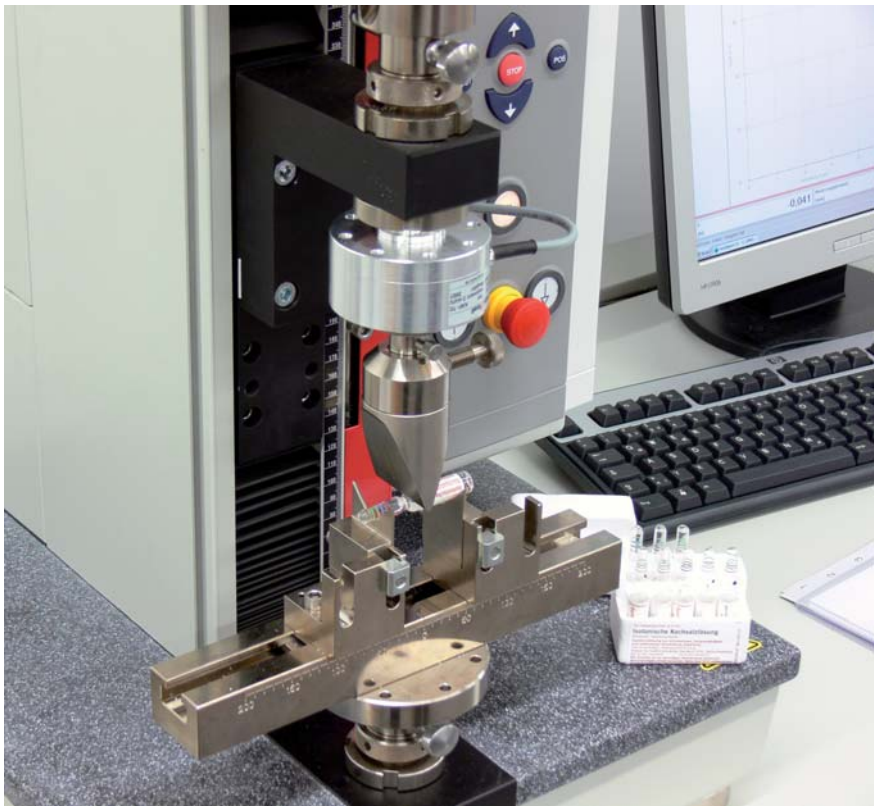

Fig. 2: Flexure test kit for testing snap-off ampoules

3-point Flexure Test on Snap-off Ampoules with Break Point

The universal 3-point flexure test kit allows break points and break forces on ampoules of various sizes to be tested, the ampoule geometry being accommodated via shims and a movable anvil. The kit is designed for a nominal force of 500 N and a protective screen is recommended for this test, as glass breakage may occur.

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Compression Test on Cardboard Packaging

Compression tests have various purposes, two of which are described below.

- Determining stacking behavior: there are various procedures for this test according to standard and material. Individual or multiple packages are loaded until failure, allowing the maximum stacking height to be calculated.

- Determining inherent rigidity: this test provides information for the packaging manufacturing process, as it is loaded with a defined force on closing (lid attachment) and must survive this procedure undamaged.

Fig. 2: Compression test on cardboard packaging

Tear Test

Standards ISO 34-1, ISO 6383-1, EN 495-2 and DIN 53363 relate to tear tests on plastic foils. The test simulates the behaviour of packaging foils when the package is opened.

When opening a plastic bag, the initial tearing strength should be approximately as much as the remaining tearing strength. If the maximum force at initial tearing is too high, the danger exists that the plastic bag will suddenly tear open completely and the contents will spill out. The ideal behaviour is not easy to adjust because the tear resistance (as well as the tensile strength), is very direction dependent with stretched foils.

Push & Turn Test on Screw Caps

Test to determine the superimposed compression / torsional forces on opening and closing of childproof containers or pharmaceutical packaging. For this a zwicki-Line tabletop testing machine of Fmax 2.5 kN and an additional torsion drive of 5 Nm torque are used. 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 a superimposed axial loading. Important parameters are the opening torque required and the functioning of the childproof mechanism.

Fig. 1: zwicki-Line Torsion for push & turn tests on pharmaceutical packaging

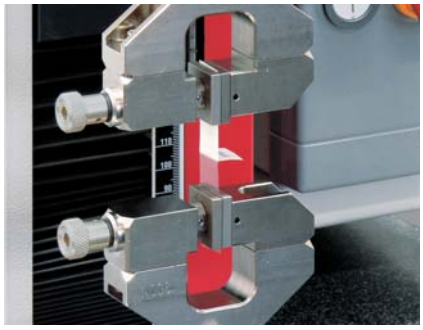

Fig. 3: Testing sealed seam strength

Fig. 4: Tear growth test on plastic film

Testing Sealed-seam Strength

Seamed seal strength of seals made of flexible packaging materials is determined to DIN 55529 and packaging materials and systems for medical products for sterilization are tested to DIN EN 868ff.

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2.2 Therapy Systems

During treatment of a patient various products are used to carry fluids to or away from the body. Minimum-invasion instruments such as catheter systems may also be inserted into the body.

2-point Flexure Test Kit for Hypodermic Needles, Medical Tubes and Guidewires

A kit for testing the flexure characteristics (e.g. buckling strength) of stiff medical tubes (catheters etc.), guide wires and hypodermic needles also with luer lock. Equipment includes a flexure table and two holding-down clamps for hypodermic needles, luer lock, guide wire or stiff medical tube. Differing specimen diameters are catered for by differently-shaped holding-down clamps (straight and prism-shaped) which are easily exchanged. The kit is designed for a maximum compression force of 50 N.

Fig. 1: 2-point flexure test kit for testing hypodermic needles

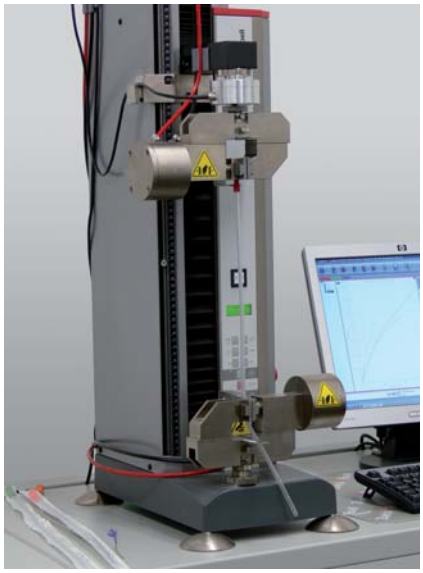

Fig. 2: Tensile test on catheter connections

2-point Flexure Test Kit for Catheter System Guide Wires

A 2-point flexure test kit for determining the kink resistance of guide wires, designed for forces up to 50 N. Grip-to-grip separation is infinitely adjustable and the kit includes a dial gage 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 rotating clamping unit.

Testing Catheter Connections

Pneumatic specimen grips for maximum tensile forces up to 1 kN are suitable for determining the insertion and connecting forces of catheter tube systems and can also be used for testing flat specimens made of metal, plastics, paper or foils. These single-actuator grips are closed by means of a foot pedal, leaving both hands free for fixing the specimen, while the closing force is infinitely adjustable via a pneumatic control unit. The low height of the specimen grips allows optimum use to be made of the test area of the materials testing machine and Zwick has available a comprehensive range of jaws for widely differing applications.

Device for Testing Dental Syringe Cartridges

This device enables tests to DIN EN ISO 11499 on dental syringe cartridges for local anesthesia to be performed and is used to determine the force required to move the plunger in the cartridge. It can also be used for additional tests, e.g. testing leakage on syringe cartridges. The test fixture has a clamping device with prism jaws, a compression die and drain hole in the lower part of the test arrangement, while a protective container provides shielding from slivers and acts as a fluid collector.

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Testing Luer-lock Connections

With catheter connections, as used with infusion needles, it is important that connections between individual components can be made simply and reliably. These tests can be performed with (for example) a Zwick Z020 testing machine with 500 Nm torsion testing device attached. It is important that compression load, torque and indentor cone are standardized.

Fig. 2: Testing luer-lock connections

Test Device with Fluid Reservoir for Determining Plunger Actuation Force

This device was developed to determine the forces required to actuate the plunger of sterile single-use hypodermic syringes (with contents as appropriate) in tests to DIN EN ISO 7886-1 and reproduces working conditions, i.e. filling and discharging of fluid. It consists of an upper and a lower clamping device for holding the syringes plus a height-adjustable fluid reservoir with connecting tube. The device can be easily dismantled for cleaning.

Fig. 4: Determining hypodermic plunger actuation force

Testing Device for Determining Penetration Force and Advancement Force of Cannulae

This test device has been designed especially for determining penetration force and advancement force of cannulae and hypodermic needles up to 200 N following LAB 530. For this the force/distance during the various phases of the injection is recorded. The upper clamping fixture can also hold hypodermic syringes with needles and auto-injectors with a specimen diameter of 5 – 10 mm or 12 – 18 mm. The device also has a lower retainer for the penetration material (usually foil) with various inserts, ensuring centering of different types and sizes of needle.

8-axis Device with Holding Fixture, for Testing Frictional Forces on Hypodermic Syringes

This device comprises an AllroundLine table-top testing machine expanded to 8 test axes to hold 8 load cells. It is equally suitable for use in the laboratory or for in-process monitoring and is used for testing the various frictional forces between syringe plunger and cylinder, or the sealing rings in syringe cylinders. The syringe holder has acrylic sleeves for syringes of different sizes, plus two containers for catching expelled liquids. This device can also be used for testing frictional forces on cylindrical ampoules.

Fig. 1: Foil retainer for penetration force measurement

Fig. 3: Device for simultaneous testing of up to 8 hypodermics

Variable Alignment of Zwick Materials Testing Machines

Zwick materials testing machines can also be used in a horizontal position for testing different therapy systems.

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Discharging Testing Device for Dosimeters and Syringe Cartridges

This height-adjustable clamping device was designed for testing dosimeters and syringe cartridges and is used to determine discharging forces and volumes. Scales for measuring expelled volumes are positioned in front of the testing machine and are shielded from external influences by an acrylic housing with removable cover, ensuring reproducible measurement. Carrier sleeves for glass cartridges are available as accessories. The device is designed for compression tests up to 100 N and can also be combined with a robotic specimen feed system, which thanks to its modular design can be expanded and adapted as required to accommodate a wide variety of testing situations.

Fig. 1: Discharging device for testing insulin pens

Automatic Testing of Injection Pens

Zwick's test device for automated testing of injection pens (e.g. insulin pens) is based on a zwicki-Line Z0.5 TN table-top testing machine with additional torsion drive, allowing the various operations of the pen to be tested using a single device. In this way the dosage setting, release force, stroke and the dose dispensed are all measured in one continuous process. The test device can be combined with a robotic specimen feed system and the test methods using either or both axes can be combined as required.

Fig. 2: zwicki-Line materials testing machine with integrated torsion drive for automatic testing of injection pens

Horizontal Test on Catheter Systems

Catheters, guidewires and other minimum invasion instruments pass through three distinct phases to follow a tortuous path through an artificial aorta. The various catheter forces can be measured in each of these phases – insertion into the artery in the inguinal region, straightforward progress along the artery and tracking artery curvatures of more than 90°.

- Initial insertion force of catheter
- Advancement force
- Flexibility of catheter tip with curvature greater than 90°
- Physiological environment through use of temperature-controlled water-bath using various media (pH value).

Development work on these catheter and guide wire systems includes attempts to reduce the co-efficient of friction and the breakaway torque. The horizontal Allround-Line testing machine offered by Zwick enables determination of shear forces in a simulated catheter insertion with very high accuracy. The test is carried out in a horizontal orientation in order to simulate the physiological status of the patient during the surgical intervention.

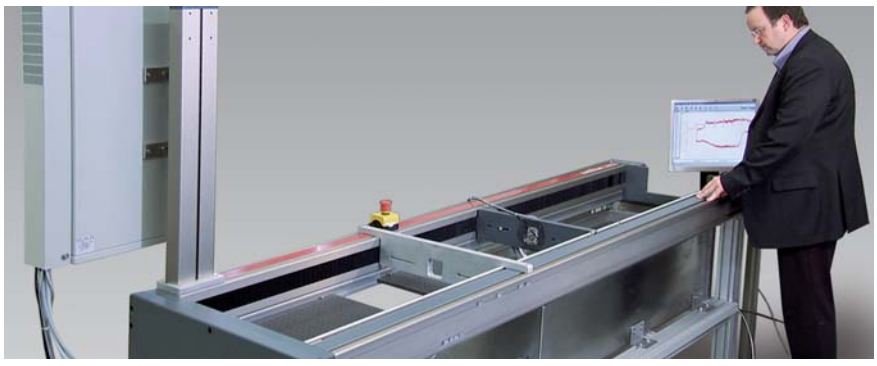

Fig. 3: Horizontal testing machine with integrated bath for catheter testing

2.3 Surgical Instruments

Medical / surgical instruments are found in a wide variety of materials or combinations with widely differing geometrical forms and can combine many different functions in one instrument.

Hardness Test

To test the hardness of metals or components used in surgical instruments, hardness testing methods to Rockwell, Brinell and Vickers (Knoop) or the modern instrumented indentation method (Martens hardness) are used.

Fig. 1: Device for compression tests on sagittal saw blades

Tensile Test on Metals and Metal Alloys

High-grade steel, high-tensile steel and titanium alloys are tested on a daily basis in incoming inspection or in materials laboratories of medical concerns by means of the classical tensile test. To determine the strength and deformation behavior of metals or components they are subjected to tensile, flexural and compression loadings. The requirements for this are specified in various standards, including ISO 6892, EN 10002, JIS Z 2241, ASTM A 370, and ASTM E8. Zwick supplies appropriate testing machines, extensometers (mechanical and optical), specimen grips, accessories and Master Test Programs with parameters already pre-defined to the specifications of the relevant standards for virtually all testing requirements.

Compression Test on Sagittal Saw Blade

The cutting precision and flexural strength of sagittal saw blades have a significant influence on operation outcomes. Function testing these saw blades involves simulation of handling by the surgeon. The complete saw plus blade is clamped in the testing machine, the saw is started and the blade is run against the bone substitute material. Pressing force and depth of cut are measured, to provide tolerance values for correct use; calculated characteristic values, such as stiffness, provide information regarding load influences which will bend or damage the saw blade.

For a further test of saw blade flexure strength, installation of a 3-point flexure test kit from the Zwick accessory range is quick and straightforward. These tests allow the cutting characteristics and precision of different saw tooth geometries to be investigated.

Bone Drill Penetration Test

Today's bone drills face exacting requirements with regard to cutting edge characteristics, contact force required, chemical resistance and avoiding bone heating. This test device is used to determine contact force, penetration force and torque required for a bone drill. Depending on the area of use and the bone quality involved, dental drills, cortical drills, oral surgery drills etc. are screwed into the appropriate material – dentine, bone or substitutes – using a specified feed pressure and torque.

The test allows overlaid measurement of torque and compression force. Zwick's comprehensive testing machine concept additionally provides flexure fatigue resistance testing via a 3-point flexure test kit plus hardness testing of the basic material.

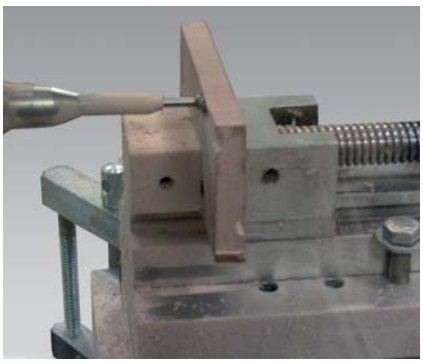

Fig. 2: Penetration test on bone drill

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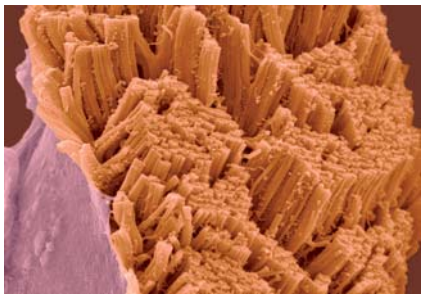
2.4 Biomaterials



With increasing life expectancy and greater demands by our society for unrestricted quality of life into advanced old age, the specialized area of regenerative and artificial organ and tissue replacement (tissue engineering) is assuming increasing importance. The mechanical properties of regenerative and artificial materials are one of the areas of research in the field of biomaterials.

Biaxial Test on Artificial Tissues

The mediX0.1 biaxial testing machine is designed for mechanical testing of natural and artificial tissues. Biaxial testing is often necessary to characterize the anisotropic properties of elastic tissues. With uniaxial tests mechanical properties can change during the test due to the potential for fibers to straighten along the measurement axis.

Fig. 1: mediX0.1 biaxial materials testing machine with laserXtens

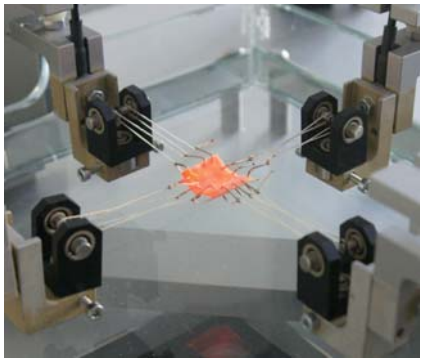


Fig. 2: Specimen grips for biomaterials in bath

The clamping system must be arranged so that the tissue is held securely during the test without being damaged. Unrestricted lateral movements must be possible in order to ensure homogeneous specimen deformation under biaxial loading, while the strain measurement device must on no account cause damage to the specimen and must be able to record strain in all loading directions.

Principal Features

- 4 high-resolution linear drives (stroke 50 mm), which can be position, load or strain-controlled completely independently of each other.
- Load measurement via four load cells (two load cells in X and Y-directions respectively) with a maximum test load of 100 N.
- Strain control and/or center-point control are via the non-contact laserXtens, which requires no markings on the specimen.
- Vibration-damped, movable table.
- Height-adjustable bath (for saline solution or other fluids) with optional heating.
- Force signal resolution: 0.6 mN.
- Travel measurement resolution: 0.1 µm.
- Maximum speed: 2000 mm/min

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Tensile Test on Artificial Tissue in Temperature-controlled Environment

Rapidly absorbable materials such as those increasingly used today in traumatology, surgery and wound-healing change their material properties progressively on contact with media such as blood, water or saline solution. This must be controllable so that absorbable biomaterials can be used in a targeted way. It is important during manufacture and development to be aware of the change in rigidity, tensile strength and proof stress (yield point) and where necessary to adjust it.

A temperature-controlled fluid bath has been added to Zwick's biomechanics accessory range, making it possible to simulate an in-vivo environment for tests on tissues. Suitable submersible accessories for specimen fixing are also available.

Principal Features

- Z2.5TN table-top testing machine, Fmax 2.5 kN.
- Test speed: 0.001 - 1000 mm/min.
- Temperature-controlled bath with separate heating circuit.
- Pre-conditioning of specimen in temperature-controlled bath available.
- Optionally available: videoXtens or submersible clip-on extensometer and various submersible specimen grips.

Fig. 1: zwicki-Line with temperature-controlled fluid bath and videoXtens (bath lowered for specimen change)

Fig. 2: Integration of a temperature chamber into the test arrangement

Testing Scaffolds for Bone Replacement

Research into biomaterials requires the test environment to correspond to actual conditions as far as possible. For this reason testing in this field is preferably carried out in fluid baths or complete incubators.

In this application, cells from bone marrow are applied to a carrier material and cultivated in a liquid nutrient under cyclic mechanical stimulation. For this an ambient temperature of 37 °C, 100% humidity and cyclic loading (using Zwick testing actuator) under very low forces are necessary.

The load is applied to the specimen via a die integrated into the incubator from above and the specimens immersed in the liquid nutrient are flushed with CO2 or N2 to adjust the pH value. Extensions lie between 30 and 100 µm.

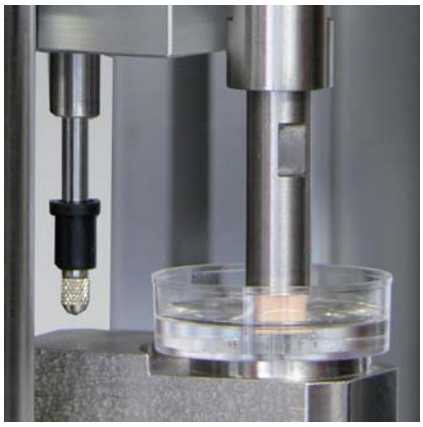

Fig. 3: Compression test on bone replacement material

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2.5 Biomechanics

Biomechanics is concerned with the functions and structures of the musco-skeletal system and movements of biological systems. Medical products to be tested are prostheses, osteosynthetic implants, trauma products and orthopedic implants.

Testing Anchoring of a Hip Endoprosthesis

Hip endoprostheses can be anchored in the femur with or without the use of bone cement. In addition to fatigue tests on the prosthesis itself, the strength of the fastening in the bone must also be tested. For this an endoprosthesis is anchored in natural or artificial bone, the load axis is adjusted by means of a clamping fixture and the entire test device is clamped in an Allround-Line Z020 testing machine. During the cyclic loading, loads can be measured, together with any micro-movements (via movement sensors) between prosthesis and bone

Fig. 2: Specimen grips for tests on endoprostheses

Function-testing Stirrup Prostheses

Stapes prostheses are used in Ear, Nose and Throat (ENT) therapy as a replacement for the stirrup, the prosthesis forming a direct connection between hammer and inner ear. The ball-joint allows optimum matching during the operation. To ensure functional integrity, the joint force must only move in a specified area. The prosthesis is only 5 mm in length and has a diameter of 0.5 mm. Using the zwicki-Line Z0.5 table-top testing machine, this force can be determined without damage occurring to the specimen.

Torsion-testing Screws in Bone Replacement Material

Here a bone screw is screwed into bone replacement material by means of a torsion drive. The relevant parameters here are the torque required in conjunction with the applied compression force.

The testing machine used is a zwicki-Line Torsion (5 kN nominal force, 20 Nm torsion drive).

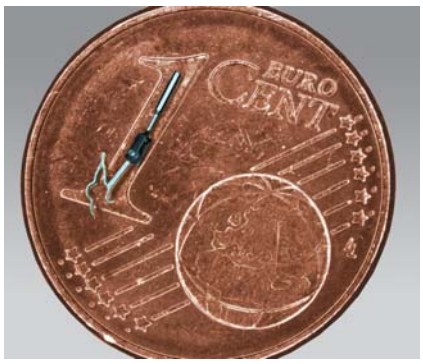

Fig. 1: Titanium stapes prosthesis (Heinz Kurz GmbH Medical Technology)

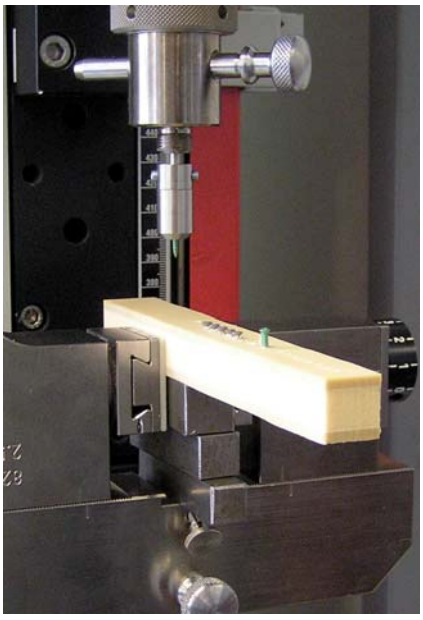

Fig. 3: zwicki-Line Torsion for penetration tests of bone screws

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Fatigue Testing on Spinal Implants

In spinal surgery, stabilization of the spine is achieved via a movable (disc prosthesis) or fixed (cage) intervertebral disc replacement. In addition, a stiffening operation using screws and rods, or the replacement of an entire vertebral body with a vertebral body replacement implant can be employed for stabilization.

All spinal implants have one thing in common – they must withstand all dynamic loads over many years.

Tests of this kind can be performed with the LTM1000 linear drive testing machine or with the Amsler HC-T servo-hydraulic testing machine with additional torsion components. In this way, for example, ISO 12189, ASTM F 2077, ASTM F 2347 or the FDA Guidance specifications, which describe dynamic compression, shear or torsion tests, can be implemented in compliance with standards.

Fig. 1: LTM1000 with spinal implant

Torsion Test on Artificial Ball-joints

Artificial hip-joints must withstand both compressive loads and torsion loads.

To determine the optimum materials and alloys, these are tested with a special testing unit consisting of a 20 kN capacity Zwick materials testing machine plus a 500 Nm torsion drive.

The artificial hip-joint (here made of metal) is rotated on a support unit (torsion loading) and at the same time compression loading is applied.

Fig. 2: Torsion test on artificial hip-joints

Fatigue Test on Hip-joint Prostheses

The Zwick Amsler HC Compact servo-hydraulic testing machine is 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 F 2068. Use of the appropriate embedding device enables the mechanical conditions specified in the standard, such as the orientation of the hip-joint prosthesis to the test load or the embedding height, together with the angle of load application, to be defined exactly.

To test the durability of the stem, dynamic loading on the hip-joint prosthesis during walking, with loosening already present, is simulated; by contrast, the neck region of the prosthesis, which is clinically well anchored, is subjected to alternating loading. The Zwick software also allows operator-friendly Locati tests to be performed.

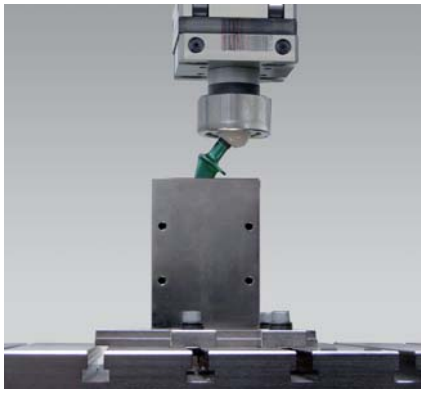


Fig. 3: Test device for holding hip-joint prostheses

Zwick / Roell

Fatigue Test on Lower Leg Prosthesis

A HC series servo-hydraulic testing machine is used for fatigue-testing prosthesis stems. The test arrangement shows a component from a leg prosthesis under continuous axial loading. The frequencies used are 10 Hz, similar to the fatigue test, and can be increased if a faster pace is to be simulated.

Principal Features

- Servo-hydraulic HC 10 for dynamic testing up to Fmax 10 kN
- Testing frequencies up to 100 Hz
- Extremely stiff and fatigue-resistant design
- Servo-hydraulic testing machine for tensile, compression and flexure tests
- Suitable for continuous, static, pulsating and alternating loading in quasi-static and dynamic tests
- Piston stroke 400 mm with end-position damping
- Customized holders for leg prostheses
- T-slot table
- HydroWin measurement and control electronics
- *testXpert*® and Workshop user programs

Advantages and Benefits for the Customer

- Simple, reliable operation via proven software-controller combination
- Universal clamping options via T-slot table and easy fixture change
- Extremely stiff, robust design intended for continuous loading at nominal force
- Tailor-made solutions are no problem thanks to a wide range of options

Fig. 1: Test device for lower-leg prostheses

Fig. 2: Test device for stents

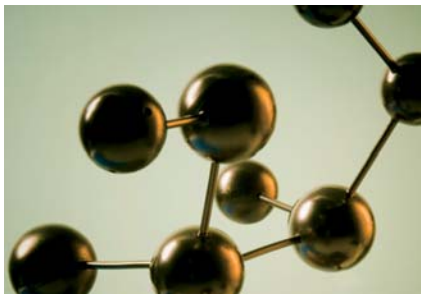
Fig. 3: Nitinol stent

Simultaneous Fatigue Tests on 30 Stents

To investigate the durability of stents a fixture has been developed which allows up to 30 stents to be accommodated simultaneously. This fixture, with an electric torsion drive (1 Nm), is used in combination with an HC 10 servo-hydraulic testing machine (10 kN) and allows both separate and superimposed loading of the stents with compression and torsion (5 Hz at ± 60°). The gripped area of the stents can also be provided with a fluid bath to enable testing under physiological conditions.

Zwick / Roell

2.6 Clinical Research



The field of clinical research involves mostly basic research into human, animal and substitute materials. Characteristic values are determined which provide information on the healing process after operations or when new medical devices or technologies are used.

Load Test on Human Femur with Strain Gages Applied

The test is used to establish to what extent an implanted endoprosthesis stiffens the bone, thereby causing a stress protection effect of the bone. For this a human femur is placed in a Zwick Allround-Line Z020 combined with a bearing, intended to eliminate transverse forces. The femur head is then loaded axially. Strain gages adhered to the surface of the bone enable comparison of the surface stress on the femur before and after implantation of the prosthesis.

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 or cast at its ends in supports and the load is applied using a zwicki-Line Z0.5 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 area of the bone to be determined. The characteristic values obtained in this way are used in an FEM simulation of the healing behavior of the bone fracture.

Fig. 1: Femur with strain gages applied

Fig. 2: Femur with implanted endoprosthesis and with strain gages applied

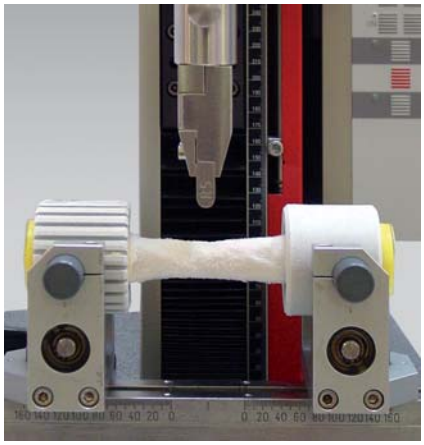


Fig. 3: 3-point flexure test kit for tests on sheep bones

Expandability of Zwick Materials Testing Machines

- Standard Zwick connecting elements for easy exchange of specimen grips or test devices
- Zwick Toolbox with combinable elements for function-testing components, with T-slot platform, fixed and movable vises and clamp set.
- Tests under temperature and media influence possible
- Up to ten digital or analog high-resolution inputs for synchronous data acquisition
- Integration of external measuring systems
- *testXpert*® II All-In-Suite offers a comprehensive range of software: all Master and Standard Test Programs, Graphical Sequence Editor plus all options.

2.7 Textile Medical Products

Textile medical products include elastic textiles for compression therapy, rigid systems such as plaster casts, products for treating wounds, surgical textiles (clothing for medical personnel and drapes for patients) and surgical suture materials.

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 Zwick materials testing machine of 10 kN capacity is used, together with a motor-driven unrolling unit. The sequence is controlled by a specially adapted program from Zwick's testXpert testing software.

Fig. 3: Unrolling test for gauze bandages

Fig. 1: Peel test on wound dressings

Fig. 2: Determining adhesive forces of wound dressings

Measuring Adhesive Force of Wound Dressings

DIN EN 1939 describes how the adhesive force of adhesive tapes is determined. 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 with the combination of skin and dressing! 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 depending on the used adhesive component.

Zwick / Roell

Testing Non-wovens used in the Medical Field

These materials are often used as wound dressings and as a component part of dressing materials, as an alcohol swab for preparing injections or in physiotherapeutic applications; they are a component part of patient and instrument drapes in the operating theater and used as a cover for dental tampons.

The investigations carried out on this material are as varied as the range of applications of the end products. One important test in this field is the tensile test on strip specimens (EN 29073-3 / ISO 9073-3 / ASTM D 5035).

Measured value is maximum tensile force. The coefficient of variation for the results is calculated. Other important test methods include absorption capacity (EN ISO 9073-6) and strike-through time for liquids (EN ISO 9073-8). A zwicki or ProLine (Z005) testing machine is typically used for these tests.

Fig. 5: Tensile test on non-wovens

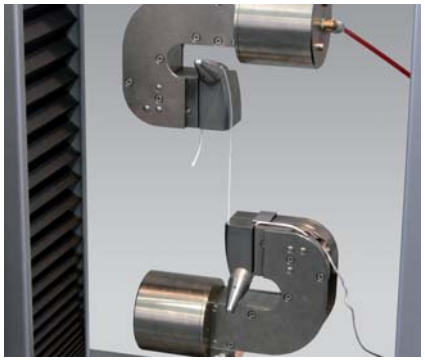


Fig. 1: Specimen grips for yarns

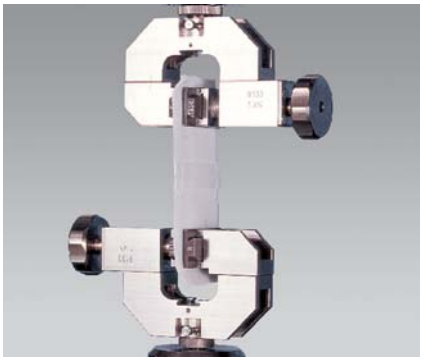


Fig. 3: Testing seam slippage resistance

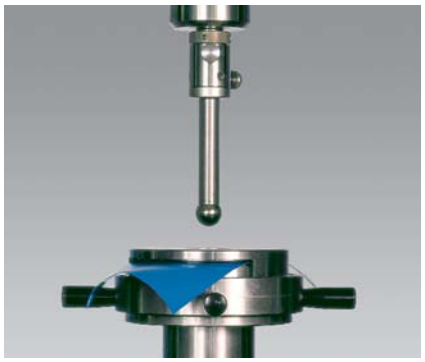


Fig. 2: Testing burst strength

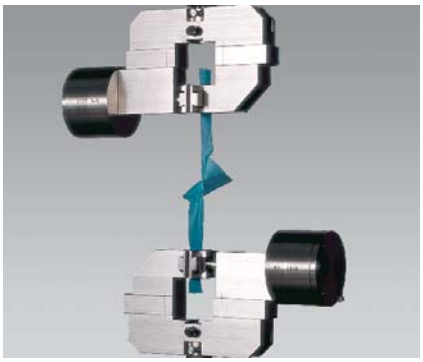


Fig. 4: Tear-growth test

Testing Surgical Textiles

A further aspect of medical textiles concerns infection prevention in both out-patient and in-patient areas. Reusable or single-use textiles for surgical masks and operating theater gowns and drapes are intended to ensure infection prevention for doctors and patients.

Standards EN 13795 and EN 14863 provide manufacturers with guidelines and common reference requirements to be met by surgical textiles.

2.8 Silicone Products

Many medical products are made of latex, rubber or silicone, the elastic properties of these materials being useful in this field, while their non-toxicity especially that of natural latex, plays an important role in medicine and hygiene in excluding germs.

Tensile Test on Rubber Gloves

Single-use medical gloves provide protection in operations, examinations and caring activities. The most important requirement is preventing the entry of air, fluids and micro-organisms. Manufacture involves immersing molds in solutions of natural rubber or latex mixtures. The number of immersion and drying processes is repeated until the required thickness is achieved, after which the gloves are vulcanized in curing ovens.

So that they do not tear when being pulled on in use, the gloves must display sufficiently elastic behavior.

Examples of stresses to which they are subjected include hooking on or holding pointed or sharp tools, foreign bodies or instruments. Methods used to guarantee the required operational reliability, include the following mechanical tests.

Tear-strength tests are performed on gloves with and without a seam, as well as on artificially aged gloves. zwicki-Line or ProLine testing machines are also used for this and testing takes place to ISO 37 and ASTM D412. Three shouldered test bars are punched out of the palm, back and cuff of the random sample glove, parallel to the longitudinal axis and avoiding structured areas.

Fig. 1: Tensile test on rubber raw material

Tensile Test on Condoms

zwicki-Line table-top testing machines are suitable for determining the tear strength and strain at tear of condoms. The required force measurement range as specified in the standard lies between 0 - 200 N and the load cell suitable for this has a nominal force of 200 N (measuring range from 2 N in Class 1 to DIN EN 10002-2). The crosshead speed is 500±50 mm/min.

Flanged rollers, arranged horizontally and mounted at one end only, are used to hold the specimens. One of these rollers is driven via a toothed belt proportionally to the crosshead movement, loading the condom specimen uniformly over its entire circumference. If the rollers were fixed or not driven, frictional forces would act in addition to the tensile force and the specimen could be unacceptably loaded and predamaged.

A thickness-measuring device can be connected via the serial port of the PC, so that these measured values are automatically input into the test as well.

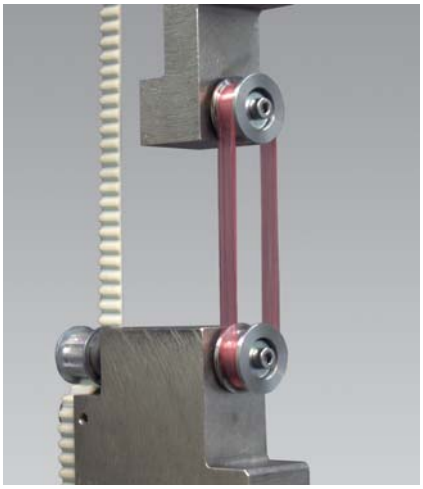


Fig. 2: Roller specimen grips for testing condom material

2.9 Dental Industry

Materials (ceramics and metals), composite materials and adhesive bonds used in the dental industry, together with dental prosthesis systems, are tested for their hardness, strength and fatigue limit.

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.

Visual requirements can be catered for by replicating the light effects of natural mineral dental enamel, including opalescence, fluorescence, transparency, through layers of color of varying intensity.

Strength properties can, for example, be verified by means of hardness testing. Due to limited reflectivity, the optical hardness testing method to Vickers can only be employed to a restricted degree.

However the instrumented indentation test, based on measurement of indentation depth, has proved very effective, as other mechanical characteristics in addition to hardness can be derived from the entire test sequence, for example allowing creep or relaxation of the dental material to be measured.

4-point Flexure Test Kit for Tests on Ceramics

- Die and lower bending table for 4-point flexure tests for tests on dental ceramics to ISO 6872 and on advanced technical ceramics to EN 843-1 Specimen Shape A
- Die and bending table each consist of 2 hardened anvils with rollers with adjustable span
- All rollers can be rotated, with swiveling or fixed mountings as required (lockable via pins)
- Can also be used as 3-point flexure test kit via simple modification

Fig. 1: 4-point flexure specimen gripping unit for dental ceramics

Fig. 2: Fully automatic Zwick/ZHU2.5/Z2.5 universal hardness testing machine with motorized displacement unit

Fatigue Test on Dental Materials

(Chewing simulator)

For tests on teeth, dental prostheses and filling materials a test stand based on the HCT-10 servo-hydraulic testing machine has been developed which enables dynamic loading with an axial force up to 10 kN and torque up to 100 Nm. Up to 5 specimens can be in a water-bath at the same time and are loaded with a testing frequency of up to 25 Hz axially, torsionally or with a transverse movement via an adaptable test piece. The forces are recorded by a load cell placed between actuator piston and die or via 3-component load cells underneath the water-bath.

Fig. 3: Dental specimens

Fig. 4: Test kit for dental implants (Dental Clinic, University of Ulm)

Zwick / Roell

3 Zwick Modular System for Individual Testing Requirements

Static Testing Machines


Material testing machines


Biaxial testing machines


Torsion testing machines


Materials testing machines with linear drive

Dynamic and Fatigue Testing Machines


Servo-hydraulic testing machines


Vibrophores


Pendulum impact testers


Materials testing machines with linear drive

Testing Instruments


Hardness testers


Vicat testers


Extrusion plastometers

Testing Software / Measurement an Control Electronics

testXpert® II

+ *testXpert*® II Medical option


testControl

Load Cells, Specimen Grips and Extensometers


Load cells


Specimen grips


Contact measuring systems


Non-contact measuring systems


Temperature chambers


High-temperature furnaces


Specimen preparation


Automation

Individual Testing Solutions

Zwick / Roell

3.1 Quasi-Static Materials Testing: Products and Services

Materials Testing Machines

Applications
Materials testing machines are used to determine the strength and deformation behavior of specimens and components, mostly under tensile, compression and flexure loading. Shear and torsion loads are also used. These testing machines feature long travel, wide test-speed ranges and interchangeable sensors and tools, allowing testing of specimens and components with widely differing forms and dimensions, made from various materials and materials combinations and with correspondingly different characteristics.

Basic Concept
Zwick has three series of quasistatic materials testing machines, differing in design, equipment, performance characteristics and expandability. This allows us to provide the most suitable machine for every budget.

Fig 1: The zwicki line is available in three different heights

- The zwicki-Line consists of high-quality, compact machines. These portable, easy-to-use single-column load-frames have been specially designed for mechanical testing with low test loads of 0.5 to 5 kN.
- The ProLine was developed to satisfy the demand for cost-effective testing machines for function- testing components and standard tests on materials. The 'Pure Portfolio' accessory range for the ProLine ensures an attractively priced system and short delivery times. Test loads are from 5 kN to 100 kN.
- The Allround-Line provides the solution to challenging testing situations and fulfils the most exacting requirements. It can be equipped or upgraded via a comprehensive accessory range and used with special sensors and multi-channel measuring technology.

Load Frames
Our standard production load frames are rated for loads up to 2000 kN. We design and manufacture special versions for specific applications, e.g. for higher rated loads or horizontally aligned load frames for testing in the component installation position.

Fig 2: ProLine Z050TN with CE conforming protective screen

zwicki-Line Single-column Model
This load frame is based on a highly bend-resistant aluminum extrusion, which was developed especially for the zwicki-Line. The workspace is freely accessible from three directions, making the zwicki-Line also suitable for small component testing and for use as a hardness tester. This modular system's low weight and compact base make it easily portable – and it will fit on any laboratory table.

ProLine Single and Double-column Table-top Machines
ProLine load frames incorporate two round steel columns, providing precise crosshead guidance, while the integrated spindle and guide protection guarantee reliable operation in industrial applications or when testing splintering materials.

Zwick / Roell

Allround-Line Table-top and Floor-standing Testing Machines
The table-top testing machines are equipped with two columns made of patented extruded aluminum. They are light and highly bend-resistant and combine the functions of spindle guide and spindle protection. T-slots on the outer sides allow simple mounting of accessories such as fixtures or safety guards, unrestricted by the moving crosshead.

All table-top testing machines can be fitted with stands to bring the workspace to the optimum height for the application or operator. This allows, for example, comfortable seated operation with plenty of legroom, making the system well suited to wheelchair users also.

Fig 1: Allround-Line floor-standing machine Z100

Hard-chrome plated guide columns and a precision ball screw with play-free spindle nuts guarantee a high level of precision for the floor-standing machines. Various crosshead configurations are available, providing either an upper or lower test area – or both. All load frames with electromechanical drives can optionally be equipped with a second test area. Benefits include rapid change to a different type of test without having to reconfigure the entire machine.

Drives for Quasi-static Test Situations

Electromechanical Drives
All electromechanical drives incorporate play-free, low-wear ball screws and digitally controlled drives and are used with load frames rated for test loads up to 2000 kN. Combined with the digital measurement and control system, they offer the following advantages:

- Extremely wide, infinitely variable speed-range
- Very low speed-settings possible (from about 0.5 µm/min)
- Highly precise, exactly reproducible positioning and speeds

The ProLine and zwicki-Line testing machines are fitted with DC motors. All other testing machines have especially low-inertia brushless three-phase AC motors.

Hydraulic Drives
This drive is located centrally to the fixed crosshead, making the test area below easily accessible. A servo or proportional valve regulates the oil flow between the hydraulic unit and differential cylinder. The oil pad in the upper pressure chamber eliminates the familiar problem of plunger pistons “jumping” when a specimen breaks. For high test loads in particular, the hydraulic drive is an extremely cost-effective solution.

Hybrid Drives
These patented drives combine the advantages of the electromechanical drive (high precision) with those of the hydraulic drive (high forces). As a result, even long-stroke cylinders designed for very high loads can be moved and positioned very precisely. This approach allows two parallel mounted cylinders coupled to the moving crosshead to be traversed with precise synchronism and regardless of their respective loadings. They follow, accurately and virtually without hesitation, the position parameters set by an electromechanical pilot drive. Special features of this drive:

- Long travel range (no adjustment of fixed crosshead necessary
- Relatively low load-frame height

Zwick / Roell

Biaxial Materials Testing Machines

The mediX0.1 biaxial testing machine is designed for testing natural and artificial elastic tissues. Biaxial testing is often necessary to characterize the anisotropic properties of elastic tissues. During uniaxial tests there is a possibility of fibers straightening along the measurement axis, causing the mechanical characteristics of the specimen to change. A clamping system is therefore required which holds the tissue securely during the test without damaging it.

Unrestricted lateral movements should be possible in order to ensure homogeneous specimen deformation under biaxial loading, while the strain measurement device must on no account cause damage to the specimen and must be able to record strain in all loading directions.

mediX0.1 has four high-resolution linear drives (stroke 50 mm) which can be position, load or strain-controlled completely independently of each other. Load measurement takes place via four load cells (two load cells each in X and Y directions) with a maximum test load of 100 N.

Strain control and center-point control is via a laserXtens extensometer, which requires no gage marks on the specimen.

Fig. 1: mediX0.1 biaxial materials testing machine with integrated laserXtens. Inset.: Specimen grips for biaxial tests on biomaterials

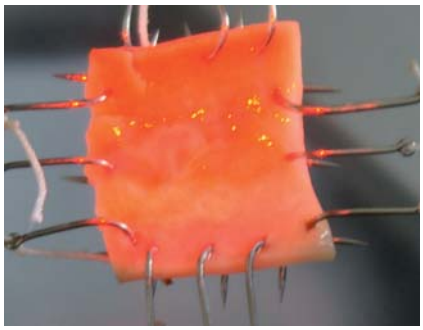


Fig. 2: Strain measurement with laserXtens (laser-speckle principle)

Possible Applications

- Planar mechanical test
- Uniaxial, equibiaxial, non-uniform loading
- Determination of mechanical properties of elastic tissues.

Equipment

- Vibration-damped, movable table
- Laser-speckle extensometer
- Height-adjustable fluid bath (for saline solution etc.)
- Optional: temperature control unit.

Specifications

Force measurement range per load cell: +/- 100 N
Force signal resolution: 0.6 mN
Travel: 50 mm
Displacement measurement resolution: 0.1 µm
Maximum speed: 2000 mm/min.

Zwick / Roell

Drive Axes as Individual and Expansion Solutions

Additional Zwick drive axes can be used as a flexible individual or expansion solution for materials testing machines. Combining several drive axes is also possible.

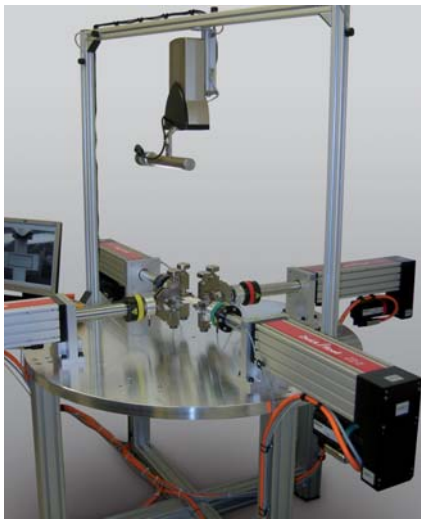


Fig. 1: Biaxial tensile testing with four electromechanical servo testing actuators

Electromechanical Servo Testing Actuator

Zwick's full range of electromechanical servo testing actuators combine versatility in use and high travel accuracy with high test speeds. They require no special hydraulic equipment or power packs, are a cost-effective solution for quasi-static and cyclic component testing and are compatible with *testControl* and *testXpert*®.

They can be used in many different situations, being available in a load range from 1 – 30 kN, with stroke from 200 – 400 mm. Their speed range is between 26 and 500 mm/s.

Pneumatic Testing Actuator

Zwick pneumatic testing actuators complete the drive systems for fatigue tests on components. Their low installation cost makes them a cost-effective alternative for simple tests.

Torsion Drives

Torsion drives from 2 Nm to 2000 Nm are available for the various materials testing machines for tests on components or materials which include torsion loading in addition to tensile/compression loading.

The torsion drives were developed as a modular system and can therefore also be retrofitted. In addition to a *testXpert*® II Master Test Program for multiple test axes, a graphical sequence editor for four test axes is also available.

For pure torsion tests there are the TorsionLine testing machines, which cover a torque range from 20 to 2000 Nm.

Fig. 2: Electromechanical servo testing actuator with external fixation of fractures

Fig. 3: zwicki-Line with torsion drive

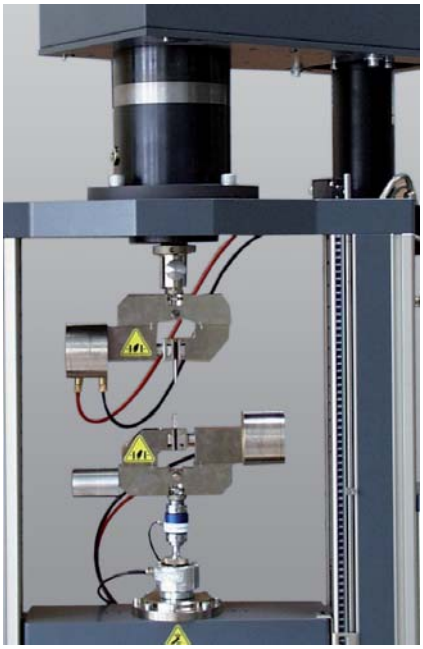


Fig. 4: Allround-Line with torsion drive

Zwick / Roell

Hardness Testing

ZHU/zwicki-Line Universal Hardness Testing Machine

Based on the zwicki-Line, the ZHU/Z2.5 universal hardness testing machine can, in addition to the classic Rockwell, Vickers, Knoop, Brinell and ball indentation hardness testing methods, be used for the innovative instrumented indentation test for determining hardness plus additional materials parameters of metallic materials (so-called Martens hardness, DIN EN ISO 14577). Install the patented hardness measuring head (resolution 0.02 µm) with integrated digital depth and load measurement system in a zwicki-Line materials testing machine with modified drive, add state-of-the-art *testControl* measurement and control electronics and *testXpert*® intelligent testing software and the result is an ideally balanced high-precision measuring system.

The ZHU/zwicki-Line can be upgraded to a fully automatic unit with motorized linear displacement unit controlled via *testXpert*®, eliminating potential operator errors.

Vickers Hardness Testers

The range of Vickers hardness testers covers various load ranges with differing levels of operator convenience, allowing the right instrument to be selected for every application.

Fig. 1: Zwick/ZHU2.5/Z2.5 fully automatic universal hardness testing machine with motorized displacement unit

Zwick/ZHV1 and ZHV2 Micro-Vickers Hardness Testers

Zwick micro-Vickers hardness testers cover the load range from HV0.01 to HV2 and support the following standards:

- Vickers (HV) to DIN EN ISO 6507, ASTM E 92
- Knoop (HK) to DIN EN ISO 4545, ASTM E 384.

For both load ranges there is a choice of operating concept:

ZHV-m (manual) – measuring is performed manually by the operator, using a microscope. The automatic turret allows one-button control when changing between lens and indenter, while the automatic test sequence and predetermined time frame eliminate operator influence during hold time.

ZHV-s (semi-automatic) / ZHV-a (fully automatic) – both feature completely automatic operation to the user's specifications. The semi-automatic version differs in having manual indentation focusing against motorized auto-focusing. Motorized load-change, automatic indentation measuring, automatically controlled turret (via *testXpert*®) for exchanging indenter and lens positions, motorized cross-table and fully automatic test sequences – uses include hardness profile tests with multiple sequences.

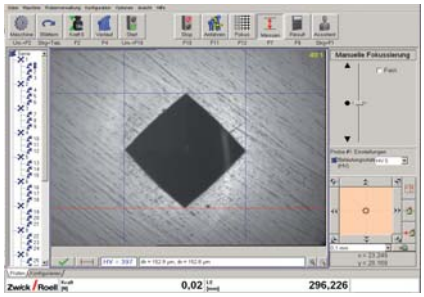


Fig. 2: Indentation cone after Vickers hardness test

Zwick / Roell

3.2 Fatigue and Impact Testing: Products and Services

Fatigue Testing Machines

Servo-hydraulic Testing Machines

Servo-hydraulic testing machines are universally applicable for materials and component testing under pulsating or alternating load, with periodic or random signals. Quasi-static and continuous loading are also easily achieved.

Special Features

- Precisely aligned load frames featuring extremely high stiffness
- Hydrostatic bearings, making the actuators virtually frictionless – and also wear-free
- LVDT extensometer with high resolution and linearity integrated centrally in the actuator rod
- Precision strain-gage load-cell for mounting on actuator rod or fixing to crosshead as required
- Wide range of hydraulic power packs
- Comprehensive range of accessories (specimen grips, extensometers, temperature chambers etc.)

Specifications

Model	HC
• Type/version	table
• Load frame	
nominal force [kN]	10 – 25
• Test stroke [mm]	100/250
• Specimen length [mm]	100 – 700
• Hydraulic power pack	
System pressure [bar]	210/280
Feed rate [l/min]	9 – 30
• Motor nominal power [kW]	5 – 20

Fig 1: Servo-hydraulic testing machine Amsler HCT 10/100

Amsler HC-compact

The Amsler HC-compact servohydraulic testing machine consists of a hydraulic power pack, test frame and test actuator and is suitable for materials and component testing under static and oscillating loads.

Advantages

- Space-saving design with integrated hydraulic power pack
- Whisper-quiet power pack allowing installation without additional noise protection measures in virtually any laboratory
- Testing actuator mounted in top crosshead permitting easy set-up for flexure and component testing
- T-slot platform hard-chromed for tests with corrosive media, e.g. saline solutions
- Seal-free testing actuator with hydrostatic bearings, guaranteeing significantly longer maintenance-free operation than with any other design.

Amsler HCT and HBT Tensile and Compression/Torsion Testing Machines

The servo-hydraulic testing machines in the Amsler HCT and HBT series are used to test the behavior of materials and components under combined tensile and compression/torsion loading. The tests can be performed with pulsating, cycling and static loading.

Fig 2: Servo-hydraulic testing machine Amsler HC-compact

Zwick / Roell

LTM1000 Materials Testing Machine with Linear Drive

Developed for quasi-static and fatigue tests on materials and components, Zwick's testing machine with linear drive is used in industries which place maximum demands on technology and cost-effectiveness, such as medical engineering (e.g. implants, dentistry), electrical engineering (e.g. switches and PCBs) and micromechanics (e.g. miniature components). It is also ideal for materials development, for example for testing miniature specimens, and with the addition of suitable attachments can be employed for environmental simulations in temperature chambers and baths.

The linear drive allows high-precision testing with excellent dynamic response in a wide range of applications. This low-maintenance machine features compact, space-saving design and a very low noise level and can quickly be put into operation. All it requires is an electricity supply – no need for water, oil or compressed air.

Advantages

- Piston stroke measurement directly adjacent to the specimen eliminates the need for separate extensometers in many applications
- Space-saving, low-noise design
- No additional fluids such as pneumatics, water or oil required
- Static tests can also be performed easily using *testXpert*® II universal testing software.

Features

- Long stroke for fatigue and static testing over a wide range of applications
- Precision, low-wear bearings on actuator
- High-resolution displacement transducer adjacent to specimen
- Easy quick adjustment of test area via separate crosshead
- Intelligent cooling system with automatic control
- Proven Zwick testControl electronics
- Intelligent *testXpert*® II testing software for simple, intuitive operation

Specifications

Model	LTM1000
• Stroke [mm]	70 (Amplitude ± 35)
• Continuous force (static) [N]	± 800
• Peak force (dynamic) [N]	± 1000
• Frequency [Hz]	10
• Weight [kg]	approx. 120 (electronics not included)
• Electrical supply requirements [V / kVA]	1x230 / 1.6

Fig. 1: LTM1000 materials testing machine with linear drive

Fig. 2: Testing a spinal implant

Zwick / Roell

4. System Components

4.1 *testXpert*® II – Intelligent and Protected from Manipulation

testXpert® has set a standard for intelligent materials testing software. Using *testXpert*® II allows you to reap the benefits of more than 80 years' experience of materials testing and over 15,000 successful installations worldwide. During development Zwick works on the principle that it is better to check everything at least twice, using multiple-stage tests to guarantee uniformly high testing software quality. The focus is on producing secure software with reliable result determination and maximum dependability.

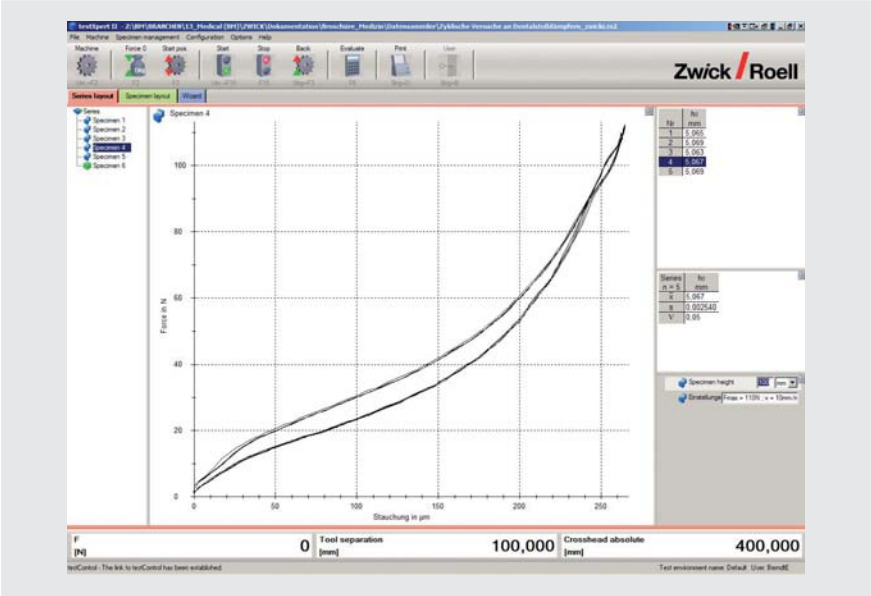


Fig. 2: Compression test on dental shock absorbers

Comprehensive User Management

Do you wish users only to carry out functions from a specified range of tasks? Or would you like to make their work easier by hiding unneeded functions in the menu bar? *testXpert*® II's powerful user management, which is already contained in the Basic Program, enables you to do so.

Choose from default user groups or define your own; you can authorize or disable individual menu items, standard actions (e.g. printing reports) or Test Programs. In this way you avoid input errors and prevent manipulation. In addition, user management allows password guidelines to be defined individually.

Test Programs/Free Sequence Programming

testXpert® II already contains prepared Standard Test Programs for a multitude of international test standards. For the medical and pharmaceutical industries Zwick has a specially designed Master Industry Package for medical technology, which in addition to Master Test Programs for cyclic tests and tear growth tests also contains the 'Expanded Traceability' option. Additionally, Zwick offers customized Test Programs which are created according to customers' specifications and/or factory standards. Through extensive testing we can guarantee that all Standard Modules will be compatible with earlier versions within the *testXpert*® II product range. In research in particular, it is often necessary to be able to program the test sequence freely. In the *testXpert*® II Graphical Sequence Editor you have an extremely comprehensive tool; simply program the test sequence you require, using straightforward function blocks on a graphic interface.

Fig. 1: User Management and digital logging

Zwick / Roell

Expanded Traceability as per FDA

testXpert® II generally records all actions during the test in order to make your results traceable. The 'Expanded Traceability' option is available especially for medical engineering and the pharmaceutical industry. This function provides all the tools required to fulfill, in combination with organizational procedures, the essential requirements stipulated by the FDA in 21 CFR Part 11 ('electronic records'). Your administrator stipulates what is recorded and for which actions and events the user must enter explanations. Afterwards all relevant actions, events and changes to important data are recorded and archived in secure binary format.

Together with User Management this function gives your administrator the necessary tools to regulate access to the testing machine and test data clearly and definitively.

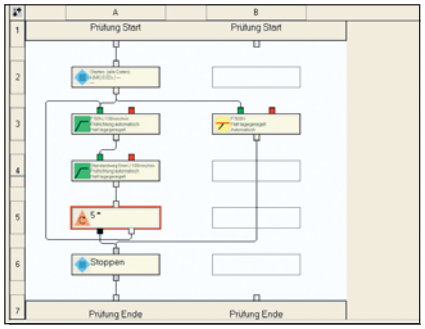


Fig. 1: Programming example *testXpert*® II Graphical Sequence Editor

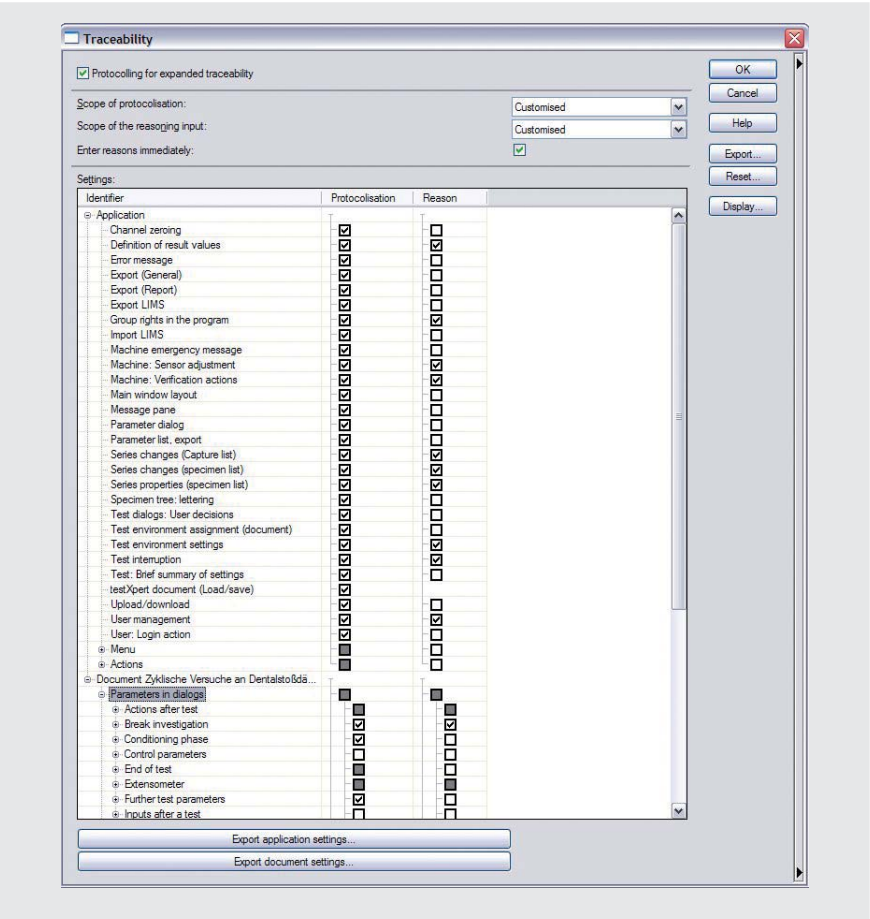


Fig. 2: Expanded traceability in *testXpert*® II

Synchronized Video Recording

A test can be recorded with an ordinary video camera, the video images subsequently being synchronized with the test data from the testing machine. The video can be played back in *testXpert*® II, while the test data synchronized to the video images is highlighted in a special graph.

Comprehensive Export Interfaces

All data from *testXpert*® II can be transferred extremely easily via standardized interfaces to all current Windows formats and other application formats (MS Excel, Access, Word, LabView, SAP, Oracle, ASCII). As a further option the integrated Online Language Swapping enables the test report to be produced in other languages without difficulty.

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4.2 Zwick *testControl* Measurement and Control Electronics

Measurement and control electronics are an essential component of any testing machine. Their design and features determine which drive can be operated, which measuring system connected and which functions controlled.

Zwick's powerful *testControl* measurement and control electronics have up to 10 digital or analog high-resolution inputs available for time-synchronous data acquisition. Any commonly used analog or digital signal can be connected to these standard interfaces. All signals are processed in real time and transmitted to the PC in high resolution at 500 Hz.

Many medical applications require additional measurement signals as well as the usual channels such as force and elongation. *testControl* offers the flexibility demanded of measuring systems in such applications, whether for applying additional strain gages to a specimen or simultaneously measuring temperature. In addition to these direct interfaces to *testControl*, external measurement systems such as the HBM MGCplus can be linked.

This gives the further option of quarter, half or full-bridge measurement of resistances, pressures, temperatures, accelerations, and single strain gages etc.

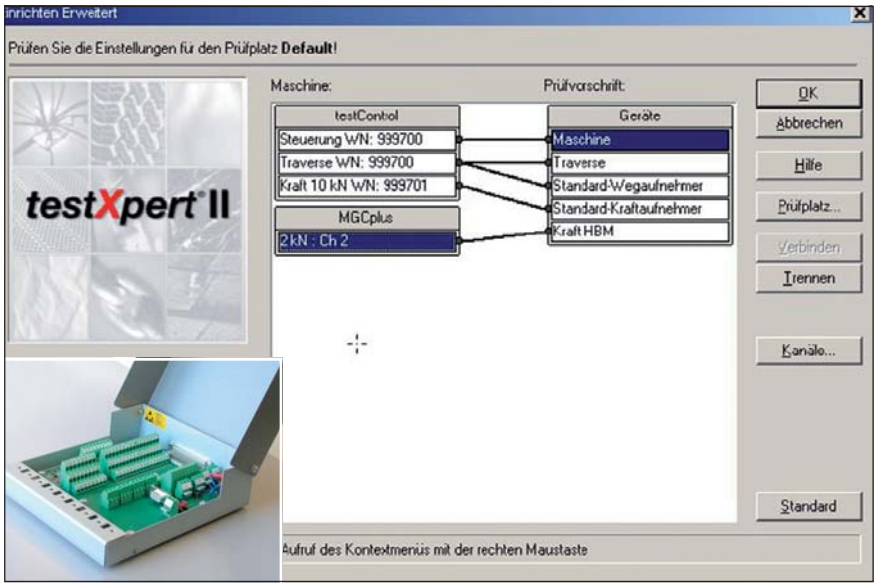

Fig 1: Full integration of a HBM MGCplus in *testXpert*® II
Small picture: Digital I/O box, additional with two output channels

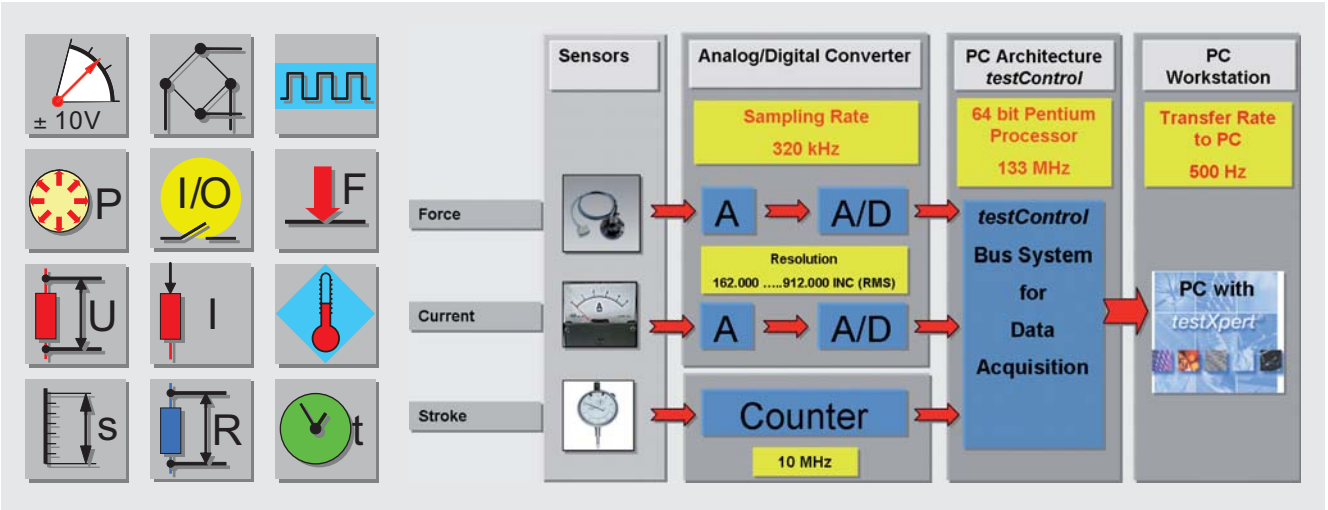

Fig 2: Analog and digital signals can be connected to *testXpert*® and *testcontrol*

Zwick / Roell

4.3 Zwick Extensometers

Measuring elongation and/or strain places extremely high demands on a modern testing system. For many years Zwick has been leading the field in developing digital extensometers for a wide range of applications.

Today Zwick has the most comprehensive range of analog and digital extensometers, both contact and non-contact. In 1998 Zwick had developed and introduced the worlds first digital clip-on extensometer. In 2004 the portfolio of extensometers was extended with the optiXtens and multiXtens.

2007 saw the unveiling of laserXtens, offering high-resolution (down to 0.15 µm), contact-free elongation measurement without the need to attach gage marks to the specimen. This system makes completely new applications possible, such as the testing of small specimens with gage lengths down to 1.5 mm. This technology and heritage allows Zwick to provide the optimum extensometer for every application.

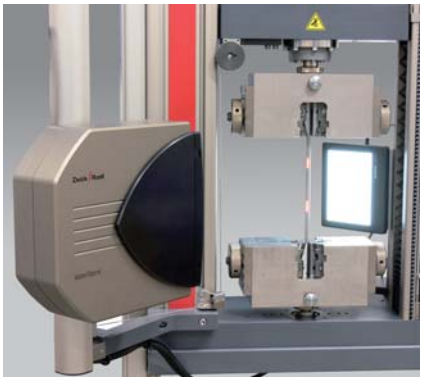

Fig 3: laserXtens with round specimen

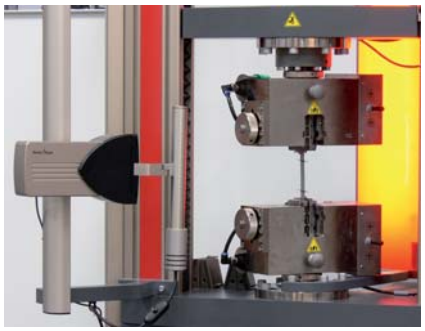

Fig 1: videoXtens

Fig 2: multiXtens

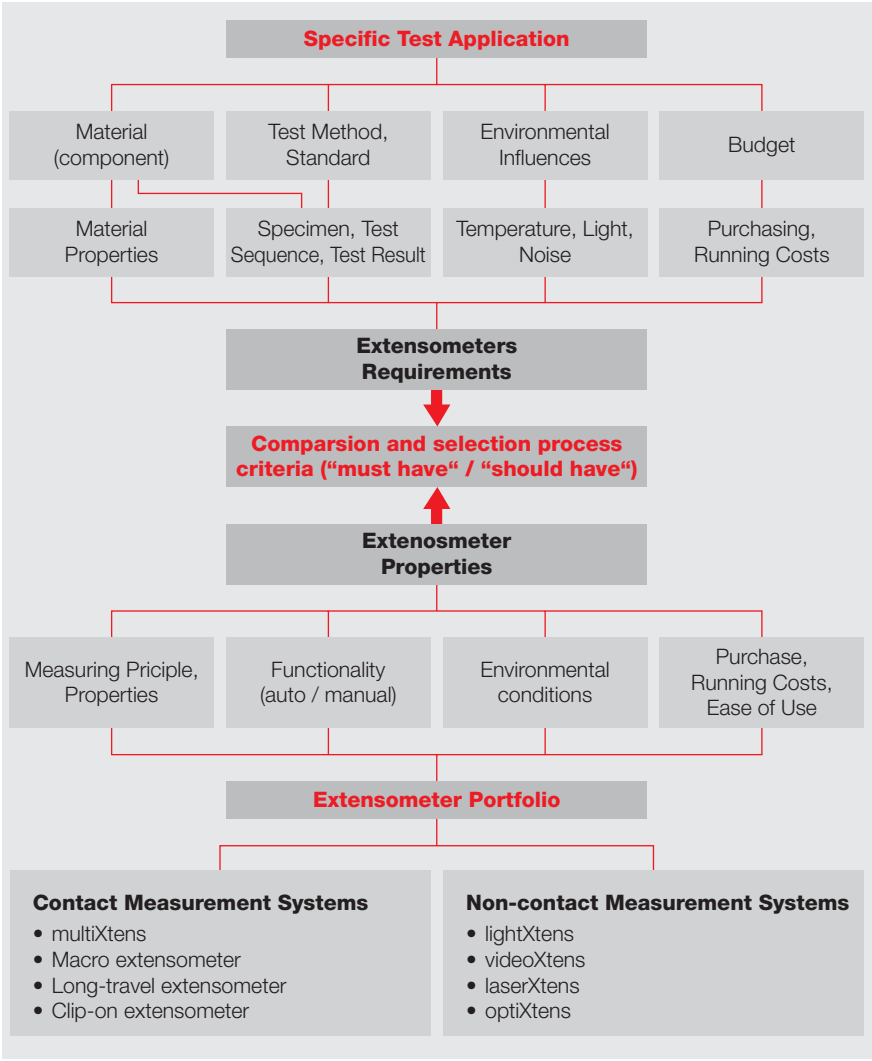

Fig 4: Selection process of extensometers

4.4 Zwick Specimen Grips

Zwick's comprehensive range of specimen grips of various designs and for differing test load ranges and test temperatures covers a wide field of application. The specific application range of a specimen grip is largely determined by its operating principle and maximum permitted test load; for tests in a temperature or climatic chamber the temperature range in which it can be used is also of significance.

Zwick develops customized specimen grips for the medical industry which are exactly verfied to the customer's specimen.

Load Transfer between Specimen and Grips

With most specimens the test load can only be transmitted indirectly i.e. by friction. This means that the frictional force between the specimen ends and the jaws of the specimen grips must always be greater than the test load. The gripping forces (perpendicular to the test load) required for this are generated externally (e.g. by pneumatic pressure) or derived mechanically from the test load (self-tightening specimen grips).

Fig 1: Pneumatic grips

Gripping Force

Specimen grips with externally generated gripping force apply the set force level throughout the test. Especially with thick or soft specimens, however, specimen material can flow out of the grips under the influence of the test load, reducing the specimen thickness. With hydraulic and pneumatic specimen grips the gripping force remains constant, because the pressure generator supplies more pressurized oil or compressed air. The gripping force of screw grips decreases to some extent depending on the stiffness and resilience of the grips.

Gripping Surface

Frictional force depends on both the magnitude of the gripping force and the coefficients of friction of the contact surfaces. For this reason interchangeable jaws or jaw inserts with various types of gripping surfaces (differing shape, surface structure, material etc.) are provided for many specimen grips.

Clamping Travel and Opening Width

Specimen grips with external gripping force generation have long clamping travel and thus also a large opening width, leaving a larger free area for convenient specimen insertion, even with thick specimens, and eliminating the need for exchangeable jaws for different specimen thicknesses.

4.5 Load Cells

Load cells are available for accurate measurements starting from 0.02 N. In combination with *testControl* digital measurement electronics they offer the following advantages:

- Measurement accuracy: Class 1 (1 % of measured value) from 0.2 to 100 % of nominal force and Class 0.5 (0.5 % of measured value) from 1 to 100 % of nominal force
- Resistant to parasitic influences (bending moments etc.)
- High flexural strength limit and torsional strength limit against break
- Zero point and characteristic value temperature compensation over the entire measurement range up to overload
- Very high effective measured value resolution and measurement frequency in combination with *testControl*
- General overload protection through *testXpert*® II; mechanical protection also available for load cells with low nominal force
- Automatic sensor identification system

Fig 2: Load cell Xforce; design: multiple strain-gage

4.6 Testing under Physiological Conditions

Test 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, the mechanical test 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 Tests

- Suitable for static and servo-hydraulic testing machines
- For applications in media such as saline solution, ethyl alcohol, blood etc.
- Container (Duran glass) can be moved axially to enable clamping of the specimen outside the liquid medium

Fig. 1: Media container with temperature control unit

- Various test fixtures or specimen grips can be connected /attached to the internally located mounting studs - Zwick has a large range of submersible specimen grips
- Quick dismantling for easy cleaning; disinfection also possible in autoclave at up to 120 °C
- Optional temperature control unit for installation in temperature-controlled bath: heat exchanger with separate heating circuit, heating power 2 kW, temperature range: Room temperature to 80 °C. Temperature control on the specimen via sensor arms; includes separate container for pre-conditioning specimen.

Horizontal Water-bath for Tests on Catheters etc.

- Determining friction coefficients of catheters, guide wires and other minimum invasion instruments (flexible endoscopes)
- Testing insertability of catheters into 3D models
- Performing horizontal tests, also in temperature controlled medium (can be heated from 30 - 80 °C)

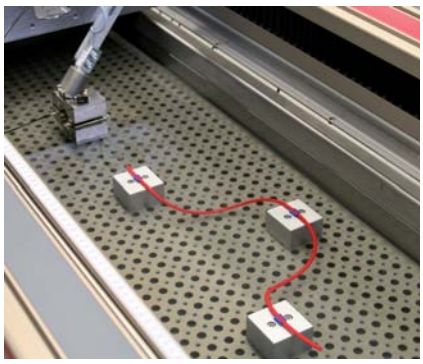

Fig. 2: Horizontal testing machine with fluid bath

Testing under Temperature Influence

Many materials change their mechanical properties quite significantly according to the ambient temperature. For testing applications at elevated or low temperatures Zwick supplies various versions for quasi-static and servo-hydraulic testing machines. The temperature chambers are also suitable for retrofitting existing machines and applications.

Fig. 3: Temperature chamber integrated into materials testing machine

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7 Zwick Services

Applications Test Laboratory and Contract Testing

In the last few years Zwick's applications laboratory has become competence-center of materals testing with active scientific exchange.

Functions:
- Demonstrations and pre-testing
- Performing and evaluating tests on customers' behalf

Services:
- Use of full Zwick portfolio
- Design and adaptation of specific testing devices
- Documentation and interpretation of component failure
- Access to expert knowledge of highly experienced staff
- Evaluation and documentation of tests
- Fast testing service to international standards, works standards and special regulations
- Advice on products, testing methods and test performance

Laboratory for Fatigue and Impact Testing

- Determining S-N curves for fatigue strength measurement of bonds, structures, and weld seams
- Fatigue test investigations under multi-axial load
- Fatigue strength investigations under in-service loadings
  - single and multi-stage testing
  - testing under temperature (-60 °C to +1200 °C)
  - connecting rod testing under simulated engine conditions
  - corrosive media on request
- Determining cyclic material behavior (LCF)
- Determining fracture mechanical characteristic values
- Performing tests under impact test force
- Application of measuring methods to obtain the relevant mechanical values (crack propagation, crack detection, local strains, temperature sequence etc.) for specimens and components

Laboratory for Quasi-Static Applications

- Tensile, compression, flexure and torsion testing
- Testing under temperature (-40 °C to +200 °C)
- Testing in high temperature range (+200 °C to +900 °C)
- Determining impact strength
- Hardness testing
- Melt index testing
- Component testing
- Viscosity testing
- Fracture mechanics testing

Fig 1: Zwick fatigue and impact testing laboratory

Fig 2: Zwick laboratory for quasi-static applications

5.2 Support for Validation of Zwick Testing Systems

Legal Requirements and Directives

Very high demands are placed on the quality and reliability of products used in medical engineering. Quality assurance is therefore an essential item in national and international laws and directives, for example the German Medicine Act (AMG) relating to the manufacture of medicines in Germany; the Code of Federal Regulations (CFR), which forms the legal basis of the US Food and Drugs Administration (FDA); the GMP (Good Manufacturing Practice) code of practice with its adjuncts, the PIC (Pharmaceutical Inspection Convention) and the relevant standards of ISO 9000ff.

These laws, directives and guidelines require that all processes, systems and activities directly or indirectly related to product manufacture must be suitably regulated monitored and supervised. These regulatory requirements also apply to computerized systems consisting of hardware and software. The documented verification is summarized under the umbrella term validation.

Definition of Validation and Responsibility

Through validation, documented verification is generated to demonstrate that methods, processes, materials and (computerized) systems consistently lead to the expected results and conform to the principles of Good Manufacturing Practice and fulfill the pre-determined specifications. The responsibility for validation lies with the company subject to regulation, which must establish guidelines and procedures to fulfill the legal requirements. Good Automated Manufacturing Practice (GAMP) serves here as a code of practice for validation recognized worldwide. It describes the tasks and duties of the supplier and the end user together with the validation process.

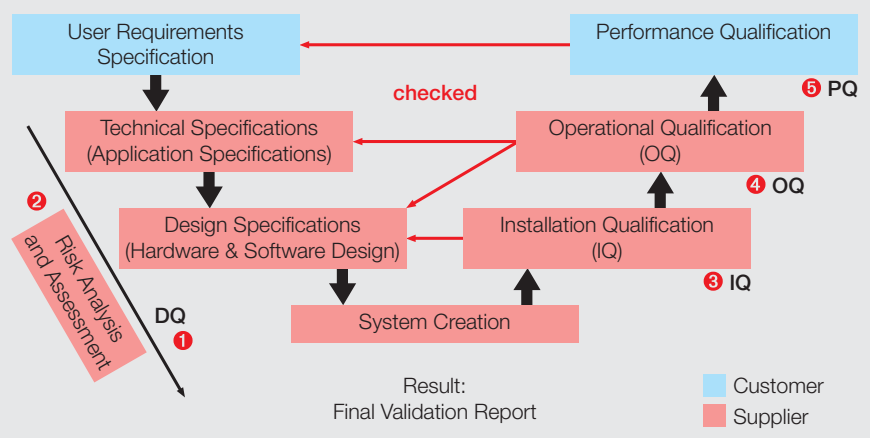

Fig. 1: Sequence of validation process

Qualification – a Component Part of Validation

A significant element of validation is the technical inspection of individual plant and instruments/devices. This part is described as Qualification and contains all steps from the planning phase with new plant (performance/technical specifications; design qualification) through the correct delivery and installation of the plant (Installation Qualification), checking for correct operation (Operational Qualification) and inspecting the measuring sensors present (calibration); to the inspection of reproducibility of specified sequences or parameters (Performance Qualification).

❶ Design Qualification (DQ) Performance and Technical Specifications

The design qualification as first step of qualification stipulates the functional and operational specifications of a plant or a system. Even at this early stage it must be verified that these specifications conform to the regulatory requirements.

❷ Risk Analysis and Assessment

Risk analysis is an important instrument of qualification. Potential risks are assessed regarding their probability of occurrence, together with their consequences for system owners and patients. Risk analysis is the basis for the description of IQ and OQ test cases.

❸ Installation Qualification (IQ)

Installation Qualification documents that the plant or system corresponds to the specifications of the Design Qualification and has been correctly delivered and installed.

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❹ Operational Qualification (OQ)

In the scope of Operational Qualification the operation of the plant or system is checked. The inspection takes place on the basis of suitable test cases, for which the test items and corresponding acceptance criteria are defined and specified in advance.

❺ Performance Qualification (PQ)

Performance Qualification takes place following successful performance of Operational Qualification and involves checking whether a plant or system also actually achieves the defined performance parameters under real production conditions. These tests are repeated at regular intervals.

Zwick Qualification Services

Zwick supports its customers in the DQ, IQ and OQ steps in the form of comprehensive and individual qualification documentation, and in performing qualification on-site. For PQ, Zwick provides assistance with suitable options for testing defined performance parameters.

Qualification Documentation from Zwick

Documentation is individually adapted and produced to suit the equipment of the testing system. Regulatory requirements are observed during creation of the documentation. All documents are to be authorized in advance.

Fig. 1: Zwick service technician implementing Qualification (IQ/OQ) at the customer's premises

Performing Qualification on-site

Experienced service technicians carry out the qualification at the customer's premises on the basis of the qualification documentation produced.

The individual test items are performed and each IQ or OQ test subsequently signed by qualifier and system owner.

The results of IQ and OQ are summarized in the IQ and OQ Plan and Report and all deviations found during IQ and OQ are documented, assessed as critical or non-critical and measures to eliminate them are evolved.

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5.3 Service and Support

SupportDesk

For further advice or assistance, such as technical or software support, the Zwick SupportDesk is in many cases a better option than an on-site visit. Our experienced staff will use their wide-ranging technical knowledge to provide you with an answer speedily and effectively.

Worldwide Service

Customer satisfaction has the highest priority at Zwick Roell A.G. Local service organizations in over 50 countries ensure optimum utilization and maximum availability of your testing systems.

Servicing

Zwick Service helps you reduce downtime significantly through regular servicing of your testing machines.

The condition of the machine is recorded at the service and necessary repairs are carried out and wear parts replaced immediately, where possible. The service engineer will also advise on preventive and/or precautionary measures.

Repair

If, despite careful servicing and maintenance a fault develops in a testing machine, an engineer from the large Zwick Service Network team will be with you in the shortest possible time. Many spare parts can be dispatched within 24 hours.

Calibration

Zwick's calibration service is accredited by DKD[1)], UKAS[2)], COFRAC[3)] and A2LA[4)] to DIN EN ISO/IEC 17025 for on-site calibration of materials testing machines.

The reference measuring equipment used is regularly recalibrated. Depending on the customer's requirements, either a works calibration (Zwick calibration certificate), ISO calibration (Zwick certificate with documentation showing measuring equipment supervision to ISO9001) or DKD calibration (DKD certificate) is performed.

If necessary, the testing machines and associated sensors will be adjusted during calibration.

[1)] DKD: Deutscher Kalibrier-Dienst
[2)] UKAS: United Kingdom Accreditation Service
[3)] COFRAC: Comité Français d´Accréditation
[4)] A2LA: American Association for Laboratory Accredition

Software Upgrade/Update

An update gives you access to the ongoing development of *testXpert*® software and opens the door to an expanded range of functions. Changes to testing standards are also incorporated into the latest versions.

Upgrading from an old DOS operating system to the latest Windows equivalent provides a secure, reliable route to the new technology. Upgrade from *testXpert*® to *testXpert*® II and enjoy access to all the latest *testXpert*® developments, with their many benefits for everyday use.

Retrofit/Modernization

Converting the old into new – ZwickService specialists professionally perform the modernization of your existing materials testing machine, regardless of the original manufacturer. This allows the latest digital control technology and software automation to enhance the performance of your testing system at the fraction of the cost of a new system.

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