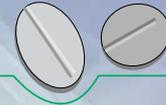


Product Catalogue 2013

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Abrasion and Friability Test Unit

Abriebs- und Friabilitäts-Testgerät



The Abrasion and Friability Test Unit is equipped with two test stations. Alternative test drums can be mounted for executing roll- and fall friability tests or for abrasion tests on tablets, capsules, granules, etc.

- Quick release nut for drum installation
- GMP-conform stainless steel housing
- Operator friendly foil key pad



Das Abriebs- und Friabilitäts-Testgerät verfügt über zwei Teststationen. Wahlweise können Testtrommeln für den Test auf Roll- und Fallverschleiss oder für den Test auf Abrieb von Tabletten, Drageekernen, Granulaten etc. bestückt werden.

- Schnellverschluss für Testtrommeln
- GMP-konformes Gehäuse in Edelstahl
- Bedienerfreundliche Folientastatur

ISCHI AE-1

Operating modes:

Preset time:

A preset time from 1 minute to 23 hours and 59 minutes is entered via the keypad and remains visible on the LC-display while running together with the time still left to run. The unit switches off automatically when the test period has elapsed.

Preset number of revolutions:

The total number of revolutions (up to 999'999) is entered via the keypad and remains visible on the LC-display while running together with the number of revolutions still left to run. The unit switches off automatically when the correct number of revolutions has been executed.

Set rotational speed:

The speed of rotation is set via the keypad to be between 10 and 99 rpm.

Further features:

- Stainless steel housing
- Electronics built using modern SMD-technology
- Simple operation via LC-display and numeric keypad
- Interface RS232C
- Dimensions: 320 x 420 x 250mm
- Weight: 7kg
- Mains voltage: 230V / 115V
- Mains frequency: 50Hz / 60Hz
- Power consumption: 30W

Available Test Drums:



Friability Test Drum
Friabilitäts-Testtrommel

Betriebsarten:

Zeitvorwahl:

Die Zeitvorwahl von 1 Minute bis 23 Stunden 59 Minuten wird auf der Tastatur eingegeben, bleibt auf der LC-Anzeige im Betrieb sichtbar und zusätzlich wird die verbleibende Testzeit angezeigt. Nach Ablauf der eingestellten Testzeit schaltet das Gerät automatisch ab.

Gesamtumdrehungsvorwahl:

Die Gesamtumdrehungsanzahl (bis 999'999 Umdrehungen) wird auf der Tastatur eingegeben, bleibt auf der LC-Anzeige im Betrieb sichtbar und zusätzlich werden die verbleibenden Umdrehungen angezeigt. Sobald die vorgewählte Anzahl der Umdrehungen erreicht ist, schaltet das Gerät automatisch ab.

Drehzahleinstellung:

Die Drehzahl von 10 bis 99 Umdreh./Min. wird auf der Tastatur eingegeben.

Weitere Merkmale:

- Gehäuse aus rostfreiem Stahl
- Elektronik in modernster SMD-Technik
- Einfache Handhabung mittels LC-Anzeige und numerischer Tastatur
- Schnittstelle RS232C
- Dimensionen: 320 x 420 x 250mm
- Gewicht: 7kg
- Netzspannung: 230V / 115V
- Netzfrequenz: 50Hz / 60Hz
- Leistungsaufnahme: 30W

Erhältliche Testtrommeln:



Abrasion Test Drum
Abrieb-Testtrommel

Equipment for quality and in-process control

Regardless, whether it concerns a single standalone tester or testing systems for the automatic in-process control during the manufacturing process: we can serve you with a complete product range and fulfill nearly all your requirements in this sector.

High quality materials, precise assemblies and professional software provide a package which you can rely on.

Geräte für die Qualitäts- und Inprozesskontrolle

Egal, ob es um ein Einzelgerät oder um die Integration von Testern in Produktionsstrecken geht, wir können mit unserer umfangreichen Produktpalette nahezu alle Anforderungen erfüllen.

Hochwertige Materialien, präzise Verarbeitung und ausgefeilte Software machen unsere Geräte zu Testgeräten, auf die Sie sich absolut verlassen können.

Charles Ischi AG Pharma Prüftechnik

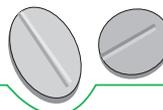
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Charles Ischi AG

TESTING



TECHNOLOGY

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**PRODUCTS FOR QUALITY AND
 IN-PROCESS CONTROL IN THE
 PHARMACEUTICAL INDUSTRY**



Tablet Hardness Tester HC6.2

With new Additional Test and Operational Options:
 Stand-alone with printer
 Product memory for up to 99 products
 PC-Software PH21

HARDNESS DIAMETER WEIGHT THICKNESS FRIABILITY SOFTWARE

Outstanding Features.

Compact Design.

The **HC6.2** Tablett Hardness Tester, product by Kraemer Elektronik GmbH, Germany, provides latest technology in a compact and user friendly easy to use design.

Easy to operate.

Keep it simple! The operation of the **HC6.2** is very quick and easy to operate.

All functions for the operation of the Tablet Hardness Tester are done through the standardized operating and display panel.

Precise and reliable.

The **HC6.2** Tablet Hardness Tester guarantees a maximum of reliability and precision. It is driven by a precise stepper motor, providing compatible test results compared to the well known Automatic Tablet Testing Systems UTS and Check-master models.

Easy to calibrate.

Calibrate your tester in two minutes and in three easy steps:

1. Open the security lock and slide display panel to the back.
2. Set the mini-load cell to the vertical position.
3. Start adjustment procedure.

The calibration can be done by the classical 5 kg weight method or by the optional **Dynamic Calibration Device**.



Static Calibration



Dynamic Calibration with certified load cell

Calibration Set of weights and gauges as well as Qualification Documents IQ/OQ available as an option.

Multiple Options.

Option 1 Basic Tester with Printer.

The basic model measures hardness and diameter, and allows the connection of a deskjet printer via USB-port. The optional memory for 99 products allows the external administration of product specifications and upload via USB memory stick.

Option 2 Tester, Micrometer, Balance, Printer.

An extension module is available which allows the installation of a thickness gauge and the connection of a balance (Sartorius or Mettler), which can be used as well for friability testing.



Up to five parameters may be printed on one report: Hardness, Diameter, Weight, Thickness and Friability.

Option 3 Tester, Micrometer, Balance, PC, Printer

Option 3 allows the data acquisition and evaluation by our PH21 software.



The software is fully 21CFR Part11 compatible, available with MS-Access or MS-SQL-Server Database and offers connectivity to data management systems.

Technical data HC6.2

Measuring principle:	Electronic load cell with strain gauges.
Measuring range:	0.5-50N, 4-400N, 8-800N
Accuracy:	± 0.1N (50N), ± 1N (400N), ± 2N (800N)
Units:	N, Kp, Sc
Force increase:	250 N/sec
Work cycle of pressure jaw:	0.35 mm/sec
Tablet diameter:	2.00 - 30.00 mm
Interface:	2x USB Master, 1x USB Slave, 1x RJ45 Ethernet, Option: 2x RS232 for balance and thickness gauge
Power supply:	100 - 240 VAC, 50 / 60 Hz
Dimensions:	230 x 240 x 120 (W x D x H mm)
With option thickness:	290 x 240 x 200 mm

Net weight:	7 kg (Tester only)
Printer	Common Printers with USB Interface (HP Deskjet)

Any Questions?

For more information, worldwide references and technical data of the Tablet Testing System please see the Internet at:

www.ischi.ch



Charles Ischi AG
TESTING TECHNOLOGY
Certified ISO 9001:2000

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**PRODUCTS FOR QUALITY AND
 IN-PROCESS CONTROL IN THE
 PHARMACEUTICAL INDUSTRY**



As many other quality products from Kraemer Elektronik, the Kraemer **CIW6.2** weighing system has been developed in close cooperation with the pharmaceutical industry.

Designed as an important and economical extension for capsule and tablets production, it excels through the following features:



The modular and flexible concept of the tester allows perfect applications in the laboratory and in production:

- Laboratory tester system with PC-Software PH21, fully 21 CFR Part 11 compliant.
- Online-Production Survey system in connection with a tablet press or capsule filling machine, where sampling may be controlled by the tablet press or our PH21 PC-Software.



- Fully automatic operation
The **CIW6.2** weighs your test samples fully automatically with no need to monitor the production process at any time.
- Reliable weighing
Our weighing systems check weighing of your capsules, tablets and other solid dosage forms administered can be omitted in future.
- Easy maintenance and cleaning
Tool free disassembly of all relevant parts makes for easier cleaning of the machine.

Tablets may be fed to the tester by:

- 12-Station Feeder
- Direct feeding via sampling gate by gravity
- Single / Double Air Transport System

For test sample collection and storage the following options are available:

- 3-way diverter for sorting tablets by quality
- 12-station collector unit

The optional transport device allows easy handling of the unit in the production area.

Technical data CIW6.2

Precision scale:	Sartorius WZ64S
Weighing unit:	Selectable: 1 mg or 0.5 mg
Power supply:	100 - 240 V, 50/60 Hz
Fuses:	2 fuses of 1 A each
Switching outputs:	Two 24 V outputs for diverter or air conveyor control
Interface:	RS232 for PC connection
Dimensions:	48 x 48 x 48 (W x D x H cm)
Weight:	30 kg

Any Questions?

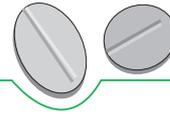
For more information, worldwide references and technical data of the Weighing System please see the Internet at: www.ischi.ch

We are always at your disposal for any further questions you might have and would be glad to advise you concerning individual modifications and applications.

Please contact us.
We are looking forward to it!

Charles Ischi AG
TESTING TECHNOLOGY
Certified ISO 9001:2000





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PRODUCTS FOR QUALITY AND IN-PROCESS CONTROL IN THE PHARMACEUTICAL INDUSTRY



The Kraemer CIW6.3 Weighing System is a further development of our high quality weighing systems. It has been expanded with a precise thickness measurement station.

As important and for all as an economical addition to the capsule and tablet production it is equipped with all the relevant performance features:

- **Fully automatic functionality**

The CIW6.3 undertakes the weighing and thickness measurement of your samples completely automatic. Your production can thus remain for the most part completely unsupervised.

- **Reliable weighing**

Our weighing system works with absolute precision. This makes a further time consuming manual re-weighing of your capsules, tablets or other administration forms unnecessary.

• **Precise thickness measurement**

By means of a thickness tester with magnet sensor technique the CIW6.3 weighing system measures your samples quickly and reliably.

- The machine works primarily only with a computer; for example with our PH21 Software. Your weighing results can be worked and archived in a database. For service work (Adjustment, Calibration and Validation) a manual test without computer can be performed.

• **Comfortably outfitted**

Various model versions of the CIW6.3 weighing system are available for your selection. With an ATS air transport system as well as a 12 station feeder and/or collector all your possibilities stand open.

- Tool free disassembly of all the cleaning relevant parts make for easy cleaning of the machine.

The standard delivery includes:

- Patented KRAEMER separating feeder
- Automatic tablet transportation
- Integrated precision scale Sartorius WZ64S
- Operating- and display panel
- Interface RS 232 for data output / communication
- Calibration set

Options:

- Kraemer ATS Air transport system for automatic sampling
- 12 station feeder for laboratory use
- 12 station collector unit
- other, special collector units are available on request

Any Questions?

For more information, worldwide references and technical data of the Weighing System please see the Internet at: www.ischi.ch

We are always at your disposal for any further questions you might have and would be glad to advise you concerning individual modifications and applications.

Technical data CIW6.3

Precision scale:	Sartorius WZ64S
Weighing unit	Selectable: 1mg, 0.5mg or 0.1mg (adjustable) 10mg to 50g
Weighing range	+/- 1mg, stable environment
Weighing accuracy	+/- 2mg, unstable environment
Drive	Stepper motor
Measurement principle	Magnet sensor
Measurement unit	mm or inch
Measurement range	1-17 mm
Measurement accuracy	+/- 0.05 mm
Power supply	100 – 240 V, 50/60 Hz
Fusing	2 fuses of 1 A each
Switching outputs Interface	Two 24 V outputs for diverter or air transport control Parallel
Dimensions	printer interface, RS232 for PC connection
Weight	48x48x48cm
	30kg

Charles Ischi AG
TESTING TECHNOLOGY
Certified ISO 9001:2000





Charles Ischi AG

TESTING



TECHNOLOGY

DISI-A

AUTOMATIC TABLET

DISINTEGRATION

TESTER

**High
accuracy**

**Precise
measuring**

**Reliable
Results**

*DISI-A :
The DISI-A model is operated via PC with the
well known PH21 Software for Data Acquisition,
Storage of Data Results and Analysis.*



The Automatic Tablet Disintegration DISI-A combines a proven design with new innovative concepts of data acquisition and data analysis.

More than 20 years of experience in the field of Pharmaceutical electronic and software applications have influenced the DISI-A's unique design and features.

It is available in two versions:

DISI-A TOUCH

The model DISI-A TOUCH incorporates a Touch-Screen Display with a large product memory and does not require a PC. Test reports may be printed after each test to a locally connected USB printer. This model can also be upgraded to a PC-Version.



The manufacturer's quality standards have been audited and acknowledged by several major pharmaceutical companies.

- **precise**
- **reliable**
- **innovative**
- **easy operation**

The basket reciprocation mechanism

The baskets move vertically by stepping motors running in micro step mode. This allows the baskets to move smoothly in and out of the media and ensures strictly sinusoidal motion. Also, with multiple station testers the up and down movements are exactly identical in time and speed.

The temperature control

The water bath is heated by a thermostatic temperature control unit. This provides quick and reliable heating and will keep the temperature of the immersion fluid within close limits. Each basket is equipped with its own temperature sensor. The temperatures will be recorded continually and any variation outside the limits will raise an alarm and abort the test.

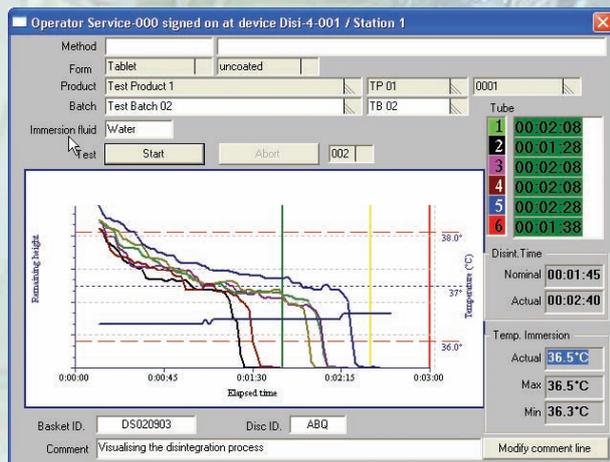
System operation

DISI-A TOUCH without PC-Software

The DISI-A TOUCH model is operated via an Integrated Touch-Screen Display, therefore does not require a PC. A compatible printer (PCL3 to PCL5e) may be connected directly to the Tester via USB port. This solution provides the most advanced technology for automatic tablet/capsule disintegration testing, without the use of a PC. An upgrade to the PC-Version is possible any time later.

DISI-A with PC-Software PH21

All the DISI-A operations are performed via the PC's Windows based operating interface. Thanks to the very well-known Windows operating environment the user will become familiar in a very short period of time.



The system corresponds to the latest requirements of FDA 21CFR11. All operations are password protected. A flexible access management scheme allows tailoring the access control to any customer specific requirements. All relevant operations will be logged into a protected event logbook (audit trail).

Continuous indication of the current tablet height. The operator will be informed immediately about unsuccessful tests, if for example not all tablets disintegrate in the expected time.



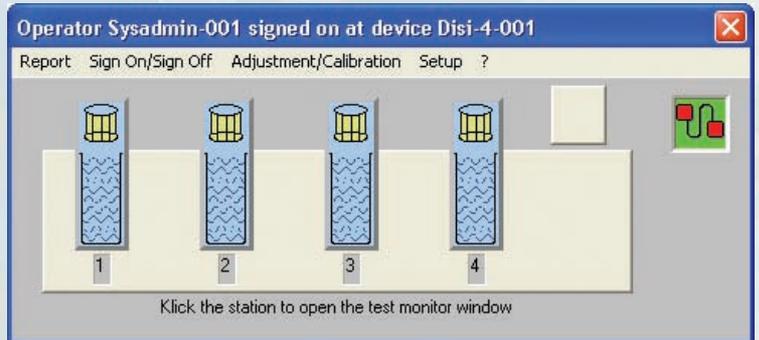
Data analysis

DISI-A

The data analysis concept is based on the successful PH21 production control Software. All data points are stored and may be traced back to the batch and test number. Tabular and/or graphical reports may be printed for single tests and whole batches. It is also possible to print out summary statistics of several batches.

DISI-A TOUCH

The DISI-A TOUCH model does not locally store test results, therefore does not fall under the rule of 21CFR11. This makes the qualification of the instrument a lot easier! However, an option for data export into CSV or TXT file is available, for further analysis of data in a PC, if required. The standard test printout of the DISI-A-TOUCH provides a tabular test report.



Adjustment/calibration

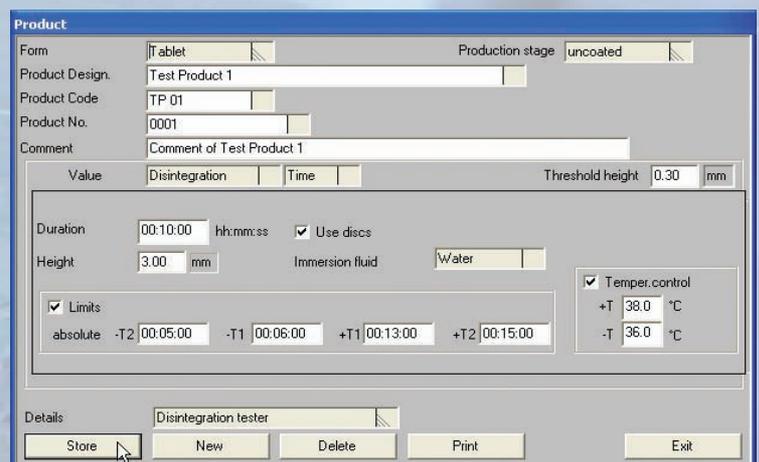
The DISI Tester incorporates a surprisingly easy, system guided self-adjusting facility. All adjustments are done electronically. Re-adjustment can be done at any time by clicking the respective button from the adjustment/calibration window. Adjustment and calibration are computer-assisted and the date of the next calibration will be monitored by the software. A warning will be released when the preset calibration interval has been exceeded.

Validation and support

IQ/OQ qualification documents are available for all models. Additional quality packages such as internal documentation, audits and on-site validation support are available on request. Introductory and extended training events are also provided. The software license includes free phone, fax and e-mail support.

Integration into the PH21 System

The DISI disintegration tester application is a cornerstone of the PH21 production control system. Other test equipment like the Kraemer UTS tablet testing system for weight, thickness, diameter and hardness and Kraemer CIW tablet weight checkers can be connected via the DIN-Measurement bus. The PH21 software also provides the possibility to interface with LIMS and MES production control systems.





Principle of measurement

When tests are performed using discs, the heights of the tablets will be sensed whenever the basket moves upward. The decrease of the tablet's heights will be sent to the connected PC and displayed graphically and in real time on the PC's monitor. If the use of discs is not permitted by the monograph, the operator will be prompted to enter the disintegration results manually.

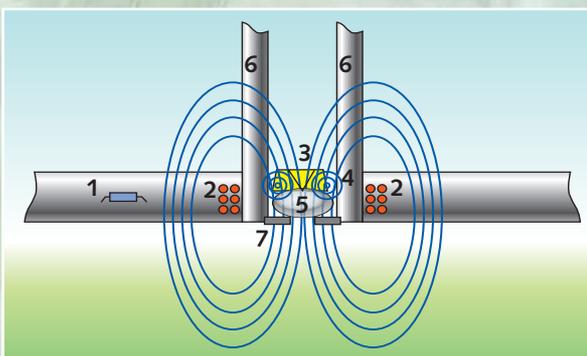
The patented principle of measurement is the attenuation of an electromagnetic field when moving a short-circuited coil through this field. The electromagnetic fields are produced by six coils located in the basket's lower plate. The electromagnetic circuits for signal conditioning are also hermetically sealed into this base plate. A tiny copper ring is moulded into each of the six discs. This ring will attenuate the electromagnetic flux when the disc moves up or down.

Energy supply and signal coupling between the basket assembly and the tester's frame is done electromagnetically. This will prevent all contact problems caused by corrosion or contamination found with many traditional designs.



The basket assembly is extremely robust. It may even be fully submerged into an ultrasonic cleaning bath. The magnetic coupling of the basket reciprocation mechanism makes it easy and safe to use.

- 1: lower basket plate with integrated transmitter coils and electric switching circuit
- 2: transmitter coil, molded into basket plate
- 3: disc
- 4: conduction ring, molded in disc
- 5: test object (tablet)
- 6: tube
- 7: sieve



Technical data for DISI-A and DISI-A Touch

DIMENSIONS, WEIGHTS	DISI-1A	DISI-2A	DISI-3A	DISI-4A
Width	335mm	470mm	605mm	740mm
Depth	250mm	250mm	250mm	250mm
Height	720mm	720mm	720mm	720mm

Weight dry	22kg	32kg	42kg	52kg
Weight filled	28kg	41kg	54kg	67kg
Volume of waterbath	6 l	9 l	12 l	15 l
Volume of beaker	1000ml	1000ml	1000ml	1000ml

MAINS SUPPLY	DISI-1A	DISI-2A	DISI-3A	DISI-4A
Mains voltage	100-240V	100-240V	100-240V	100-240V
Mains frequency	47-63Hz	47-63Hz	47-63Hz	47-63Hz
Power consumption	50W	75W	100W	125W
Fuse	2AT	2AT	2AT	2AT

THERMOSTAT	DISI-1A	DISI-2A	DISI-3A	DISI-4A
Mains voltage	230V / 115V			
Mains frequency	50Hz / 60Hz			
Power consumption	2,1KW / 1,1KW			

INTERFACES

COM1	RS232	Point to point for single system
	Sub-D 9 channel	PH21-protocol / DIN 66348/2
COM2	RS232	Connection for TOUCH-SCREEN PANEL

ENVIRONMENTAL CONDITIONS

Environment temperature	18-27°C
Max. temperature of testbasket	40°C
Max. temperature of water bath	40°C
Relative humidity	20-80% not condensed

ACQUISITION OF MEASURED VALUE Identification of disintegration

Principle of measurement	electromagnetic
Acquisition area	0-10mm
Time resolution (= lifting cycle)	2s
Accuracy	+/- 0.2mm

ACQUISITION OF TEMPERATURE

Measurement range	0-40°C
Temperature resolution	0,1°C
Accuracy	+/- 0,2°C in the range 35-39 °C

RECIPROCATING MECHANISM

Speed	30 strokes/min +/- 0,1
Stroke	55mm

Compliance:

The tester DISI-A and DISI-A TOUCH series are fully compliant with the european and american pharmacopoeia PH-EUR and USP.



Certified ISO 9001:2008

Equipment for quality and in-process control

Regardless, whether it concerns a single standalone tester or testing systems for the automatic in-process control during the manufacturing process: we can serve you with a complete product range and fulfill your requirements in this sector.

High quality materials, precise assemblies and professional software provide a package which you can rely on.

Consulting

Sales

Installation

Service

Training

We support you in your planning, offer our expertise and experience, in order to provide the right and best solution for your application.

But also after the sale of a system, you are not left alone. Installation and service is one of our main competencies. The training we provide gives you the confidence that each of your employees can properly operate the equipment.

We are only satisfied when you are satisfied.

For more information please contact:

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Charles Ischi AG

PHARMA



PRÜFTECHNIK



DISI-M

SEMIAUTOMATIC TABLET

DISINTEGRATION

TESTER

Low cost

High precision



The series of DISI-M Tablet Disintegration Tester combines a proven design with new innovative concepts of technology and user friendliness. DISI-M has been developed in conjunction with the automatic Tablet Disintegration Tester DISI and provides an economic solution at a high quality standard.

More than 10 years of experience in the field of pharmaceutical electronic and software applications have influenced the DISI's unique design. The system is designed according to the USP and EP standards for disintegration testing and is available with 1,2,3 or 4 individual test stations.

- **precise**
- **reliable**
- **innovative**
- **easy to use**





System operation

All DISI-M operations are performed via the front panel machine operating interface. Thanks to the very easy operating environment the user will become familiar with the system in a very short period of time.

The basket assembly is extremely robust and may be easily removed through a quick release attachment. For cleaning the baskets may be fully submerged into an ultrasonic cleaning bath.

The basket reciprocation mechanism

The baskets move vertically by stepping motors running in micro step mode. This allows the baskets to move smoothly in and out of the media and ensures strictly sinusoidal motion. Also, with multiple station testers the up and down movements are exactly identical in time and speed.

The temperature control

The water bath is heated by a thermostatic temperature control unit. This provides quick and reliable heating and will keep the temperature of the immersion fluid within close limits. The thermostat is easily removable for bath cleaning and servicing and provides as an "external" unit more safety and reliability.

Validation and support

IQ / OQ documents are available as well as on-site support for installation and validation.

Summary

Disintegration tester with LCD-Display, individual timer and automatic drive in and out of the media.

- The system is fully compatible to the EP / USP
- Baskets are easy removable
- Quick and easy basket disassembly for cleaning
- Precision microstep linear drive of each test station
- Accurate speed and uniformity of movement
- Softstart feature for basket entering the medium
- Rigid stainless steel housing
- Thermostat with digital display



Standard delivery includes:

- Tester unit
- Plexyglass water bath
- Thermostat 25-40°C
- Test vessels
- Baskets with disks
- Power cable
- Operating manual



Technical Data

DIMENSIONS, WEIGHTS	DISI-1M	DISI-2M	DISI-3M	DISI-4M
Width	340mm	475mm	610mm	750mm
Depth	250mm	250mm	250mm	250mm
Height	750mm	750mm	750mm	750mm

Weight dry	20kg	30kg	40kg	50kg
Weight filled	26kg	39kg	52kg	65kg
Volume of waterbath	6l	9l	12l	15l
Volume of beaker	1000ml	1000ml	1000ml	1000ml

MAINS SUPPLY	DISI-1M	DISI-2M	DISI-3M	DISI-4M
Mains voltage	100-240V	100-240V	100-240V	100-240V
Mains frequency	47-63Hz	47-63Hz	47-63Hz	47-63Hz
Power consumption	50W	75W	100W	125W
Fuse	1AT	1AT	2AT	2AT

THERMOSTAT

Mains voltage	230V / 115V
Mains frequency	50Hz / 60Hz
Power consumption	2,1KW / 1,1KW

INTERFACES

Display RS232 Port Serial interface for display

ENVIRONMENTAL CONDITIONS

Environment temperature	18-27°C
Max. temperature of water bath	40°C
Relative humidity	20-80% not condensed

RECIPROCATING MECHANISM

Speed	30 strokes/min	+- 0,1
Stroke		55mm

Equipment for quality and in-process control

Regardless, whether it concerns a single standalone tester or testing systems for the automatic in-process control during the manufacturing process: we can serve you with a complete product range and fulfill nearly all your requirements in this sector.

High quality materials, precise assemblies and professional software provide a package which you can rely on.

Consulting

Sales

Installation

Service

Training

We support you in your planning, offer our expertise and experience, in order to provide the right and best solution for your application.

But also after the sale of a system, you are not left alone. Installation and service is one of our main competencies. The training we provide gives you the confidence that each of your employees can properly operate the equipment.

We are only satisfied when you are satisfied.

For more information please contact:

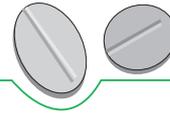
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PRODUCTS FOR QUALITY AND IN-PROCESS CONTROL IN THE PHARMACEUTICAL INDUSTRY



The universal, fully automatic Tablet Testing System **UTS4.1** was developed on the basis of the already long proven and perfected test systems for tablets in close cooperation with the pharmaceutical industry.

The tablet samples are measured and tested precisely for Weight, Thickness, Diameter and Hardness (Break force).

Round, oval, square and rectangular shapes can be tested without problem. For difficult oval shaped tablets the proven OZB Oblong Centering System can be adapted, this option is also retrofittable.

The simple and direct feed by means of the patented Kraemer Elektronik Feeder chute improves the measuring accuracy and reliability.

Unnecessary abrasion and contamination of the test stations is avoided through specially developed cleaning and de-dusting devices.

The test stations are automatically cleaned fully and efficiently after each tablet test.



OBLONG CENTERING DEVICE OZB



ONLINE-TESTER UTS4.1-ATS1



ONLINE-TESTER UTS4.1-ATS2

The modular and flexible concept of the tester allows perfect applications in the laboratory and in production:

- Laboratory tester system with PC-Software PH21, fully 21 CFR Part 11 compliant.
- Online-Production Survey system in connection with tablet presses. Tablet sampling may be controlled by the tablet press or by the PH21 PC-Software.

Tablets may be fed to the tester by:

- Direct feeding by gravity
- 12-Station Feeder
- Single Air Transport System, for connection to single-sided tablet presses
- Double Air Transport System, for connection to double-sided tablet presses

For test sample collection and storage the following options are available:

- Reject bin for all tablets
- 3-way diverter for sorting tablets by quality
- 12-station collector unit for the storage of representative sample throughout the batch

Functions:

- For use as standalone or online application
- Operation in lab or production with full automatic process monitoring
- Display for all 4 measurement values with Online display
- Adjustment and calibration functions
- Configuration program for customer specific applications
- RS232 / RS485 computer interface
- 24V switched outputs for sample pull, air transport and alarms
- In and outputs for control and integration of external equipment

Technical data UTS4.1

Scale: Precision weighing cell Sartorius WZ64S
Weight unit: 1 mg / 0,5 mg / 0,1 mg (adjustable)
Weighing range: 10 mg to 50 g
Weighing accuracy: ± 1 mg in stable environment
 ± 2 mg in unstable environment

Thickness tester:

Drive: Stepper motor
Measurement principal: Linear potentiometer
Measuring unit: mm or inch
Measuring range: 1-17 mm
Measuring accuracy: ± 0,05 mm

Hardness tester:

Drive: Stepper motor
Force measurement: Load Measurement Cell (LMZ)
Measurement principal: Pressure Load Cell (DMS)
Force unit: N, Kp or Sc
Measuring range: 4-400 N (800 N or 50 N Optional)

Measuring accuracy DMS:

±1N (by 800 N ±2 N; 50 N ± 0,1N)

Measuring accuracy Electronics/Mechanics:

±1N (by 800 N ±2 N; 50 N ± 0,1N)

Measuring accuracy total:

±2N (by 800 N ±4 N; 50 N ± 0,2N)

Force increase DMS: 250 N/sec.

Work cycle Pressure jaw: 0,35 mm/sec.

Fast forward travel: 8,5-17 mm/sec.selectable

Backward travel: 8,5-17 mm/sec.selectable

Diameter tester:

Drive: Stepper motor
Measurement principal: Stepper motor
Measuring unit: mm or inch
Measuring range: 3-18 mm (3-30 mm manual)
Measuring accuracy: ± 0,1 mm

Measurements: 59 x 40 x 53 (W x D x H cm)

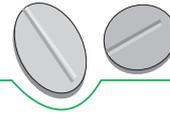
Weight: 40 kg (without Magazine feeder or Collector)

Power requirements: 100-240 V, 50 Hz/60 Hz

These versions conform to the current recognized machine safety standards. All rights reserved for technical changes.

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TESTING



TECHNOLOGY

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PRODUCTS FOR QUALITY AND IN-
PROCESS CONTROL IN THE
PHARMACEUTICAL INDUSTRY



SOFTWARE

NIR

HARDNESS

DIAMETER

THICKNESS

WEIGHT

The universal, fully automatic Tablet Testing System **UTS4.1** was developed on the basis of the already long proven and perfected test systems for tablets in close cooperation with the pharmaceutical industry.

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Round, oval, square and rectangular shapes can be tested without problem. For difficult oval shaped tablets the proven OZB Oblong Centering System can be adapted, this option is also retrofittable.

The simple and direct feed by means of the patented Kraemer Elektronik Feeder chute improves the measuring accuracy and reliability.

Unnecessary abrasion and contamination of the test stations is avoided through specially developed cleaning and de-dusting devices.

The test stations are automatically cleaned fully and efficiently after each tablet test.

The modular and flexible concept of the tester allows perfect applications in the laboratory and in production:

- Laboratory tester system with PC-Software PH21, fully 21 CFR Part 11 compliant.
- Online-Production Survey system in connection with tablet presses. Tablet sampling may be controlled by the tablet press or by the PH21 PC-Software.

Tablets may be fed to the tester by:

- Direct feeding by gravity
- 12-Station Feeder (see front page)
- Single Air Transport System, for connection to single-sided tablet presses
- Double Air Transport System, for connection to double-sided tablet presses

For test sample collection and storage the following options are available:

- Reject bin for all tablets
- 3-way diverter for sorting tablets by quality
- 12-station collector unit for the storage of representative sample throughout the batch



OBLONG CENTERING DEVICE OZB



ONLINE-TESTER UTS4.1-ATS1



ONLINE-TESTER UTS4.1-ATS2

Functions:

- For use as standalone or online application
- Operation in lab or production with full automatic process monitoring
- Display for all 4 measurement values with Online display
- Adjustment and calibration functions
- Configuration program for customer specific applications
- RS232 / RS485 computer interface
- 24V switched outputs for sample pull, air transport and alarms
- In and outputs for control and integration of external equipment

Technical data UTS4.1

Scale: Precision weighing cell Sartorius WZ64S
Weight unit: 1mg / 0,5 mg / 0,1 mg (adjustable)
Weighing range: 10 mg to 50 g
Weighing accuracy: ± 1 mg in stable environment
 ± 2 mg in unstable environment

Thickness tester:

Drive: Stepper motor
Measurement principal: Linear potentiometer
Measuring unit: mm or inch
Measuring range: 1-17 mm
Measuring accuracy: ± 0,05 mm

Hardness tester:

Drive: Stepper motor
Force measurement: Load Measurement Cell (LMZ)
Measurement principal: Pressure Load Cell (DMS)
Force unit: N, Kp or Sc
Measuring range: 4-400 N (800 N or 50 N Optional)

Measuring accuracy DMS:

±1N (by 800 N ±2 N; 50 N ± 0,1N)

Measuring accuracy Electronics/Mechanics:

±1N (by 800 N ±2 N; 50 N ± 0,1N)

Measuring accuracy total:

±2 N (by 800 N ±4 N; 50 N ± 0,2N)

Force increase DMS: 250 N/sec.

Work cycle Pressure jaw: 0,35 mm/sec.

Fast forward travel: 8,5-17 mm/sec.selectable

Backward travel: 8,5-17 mm/sec.selectable

Diameter tester:

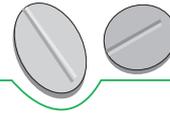
Drive: Stepper motor
Measurement principal: Stepper motor
Measuring unit: mm or inch
Measuring range: 3-18 mm (3-30 mm manual)
Measuring accuracy: ± 0,1 mm

Measurements: 59 x 40 x 53 (W x D x H cm)

Weight: 40 kg (without Magazine feeder or Collector)

Power requirements: 100-240 V, 50 Hz/60 Hz

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PRODUCTS FOR QUALITY AND IN-PROCESS CONTROL IN THE PHARMACEUTICAL INDUSTRY



It is an ideal instrument to test low quantities, for example in a tableting booth next to the tablet press. The operator loads the tablets manually, but the measurements are then taken automatically.

Designed as an important and economical extension for capsule and tablet production, it excels through the following features:

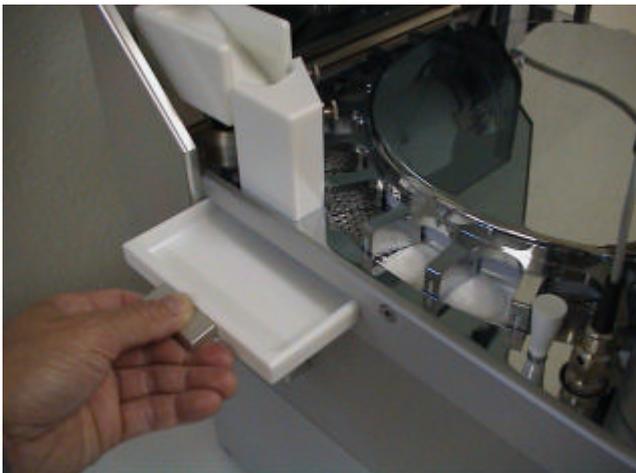
- **Automatic operation**
- **Precise and reliable measurement**
- **Modular and flexible**
- **Easy to service**

Automatic operation

Up to 20 tablets or capsules may be manually fed into the transport starwheel.

Then the test can be started from the PC software and all tablets are being measured fully automatically.

The simple and reliable transport starwheel positions and moves the products to the measuring stations for weight, thickness, diameter and hardness.



An additional dedusting section keeps the product and the tester clean.

Remaining dust and debris are collected in a special dust container.

For special shaped and unstable oblong tablets an optional tablet measurement and centering unit (OZB) is available.

It is installed above the hardness tester unit and provides a maximum of security and reliability when testing special shaped tablets on hardness.



The above described features guarantee a maximum of reliability for the automatic operation of the system with different shapes and sizes of tablets and capsules.

Precise and reliable weighing

The system incorporates the highly precise Sartorius weigh cell. It's small structural shape allows a complete integration into the system, providing a better protection against influences from outside as for example air draft or vibration.

Modular and flexible

The modular system allows the use of the system in production and in the laboratory. Different feeder, collector units and a transport device is available as a later upgrade.

Example of transport device in combination with a special, dust-tight version of UTS:



Any configuration changes and add-on options are configurable through the user-friendly front display.

Easy to service

All functions for the scale such as adjustment, calibration and configuration are available through the tester front display. Because of the ideal integration of the scale into the system (closed surface of the side wall with entrance to the scale through a service flap), a simple cleaning procedure is guaranteed.

For service work, the scale can be removed from the system through the side wall quickly and with little effort. It may be placed besides the tester with the electrical connections remaining in place.

The standard delivery includes:

- Automatic tablet transportation
- Operating- and display panel
- Calibration set
- Integrated precision scale Sartorius WZ64S
- Interface RS 232 for data output / communication

Options:

- Patented KRAEMER separating feeder
- Transport device
- 12 station collector unit
- Special parts for up to 25mm
- Data Acquisition and Analysis Software for Windows-PC, fully 21CFR Part11 compatible.
- Kraemer ATS Air transport system for automatic sampling
- 12 station feeder for laboratory use
- Special feed parts for 2mm Minitabs on request
- OZB Oblong Measurement and Centering Unit
- Qualification Documents (IQ/OQ)
- QM-Packages for software validation

Technical data

Scale:

Precision scale	Sartorius WZ64S
Weight unit	mg, 0.5mg or 0.1mg adjustable
Weighing range	10mg to 50g
Reproducibility	<=+/- 0.0001g
Linearity	<=+/- 0.0001g

Thickness tester:

Drive	Stepper motor Linear
Measurement principle	Potentiometer mm or inch
Measuring unit	Measuring range
range	Measuring accuracy
	1-17mm
	+/- 0.05 mm

Hardness tester:

Drive	Stepper motor
Force measurement principle	Load measurement cell (LMZ) Pressure load cell (DMS)
Measuring unit	N, Kp or Sc
Measuring range	4-400N (800N or 50N optional) +/-1N
accuracy DMS	Force increase of (800N +/-2N, 50N +/-0.1N) 250N/sec
DMS Test speed of pressure jaw	0.35mm/sec
Travel speed of pressure jaw	8.5-17mm/sec adjustable
Return travel speed	8.5-17mm/sec adjustable

Diameter tester:

Drive	Stepper motor
Measurement principle	Stepper motor
Measuring unit	mm or inch
Measuring range	3-30mm
Measuring range oblong length	5-20mm
Measuring accuracy	+/- 0.05mm

Calibration/validation	Menu-controlled via software or local display 100 – 240
Power supply Interface	V, 50/60 Hz
Dimensions Weight	Hardware COM1 RS232C for PC, option RS485
	53x66x54cm
	50kg

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The Kraemer UTS-IP65i is a new further development of our high quality range of automatic tablet testing systems and provides a professional solution for the production of medium and high potent drugs.

In addition to our existing dust-tight (UTS4.1-S10) and easy to clean (UTS-IP-LR) systems, the **UTS-IP65i** represents the first fully washable, universal and automatic Tablet Testing System in the world.

The system may be used in the following applications:

- in conjunction with a tablet press
- stand-alone with PC-software
- online with PC-software

Features

Washable tablet testing system for measuring weight, thickness, diameter, hardness.

Protection: IP67-68 in working area, main housing area IP63.
Pressure decay test: > 3 min. (typical results around 20-30 minutes)

Including patented KRAEMER separating feeder.
Standard measuring range for weight 10mg-50g, thickness 1-17 mm, diameter 3-30mm, hardness 4-350N.
Integrated precision scale Sartorius WZ64S.
Operating and display panel for all four parameters, including calibration and validation features.

Integrated spray nozzles:

- 3x Rotating spray nozzle on base plate.
- 1x Rotating spray nozzle on top cover center section.
- 1x Spray nozzle in tablet inlet feeder chute

Cleaning media connection:

- Tri-Clamp DIN DN50 water outlet.
- Tri-Clamp DIN DN20 water inlet

Tablet infeed and outfeed with Tri Clamp DIN DN50.
Integrated wash program for moving motors during wash cycle.
Dust protected connectors for power and communication.
RS232 /RS485 interface for computer.
Interface for software under Windows.
In-and outputs for control and implementation of external devices.
Incl. CE conformity based on norms for machines EG-Ri. 2006/42/EC.

Washing the Tester

A possible wash concept after production of high potent drugs is to seal and disconnect the tester from the tablet press and move it to a washing area. Furthermore, the UTS-IP65i includes a special wash program which can be configured by the user (see description below).

Example of a washing concept and procedure after a production batch run:

Preparation of the Tester:

- Shut off the electrical power supply
- disconnect the electrical power supply cable and communication cable on the unit
- heat seal and cut the tablet inlet connection
- heat seal and cut the tablet outlet connection
- remove any excess of layflat tubing on the outlet connection by heat sealing and cutting
- wheel the unit to the wash area
- connect the drain hose and open drain valve
- connect the compressed air connection
- connect the water hose and open water valve
- reconnect power to the UTS-IP65i
- start the washing process

New fail safe system:

The latest version of UTS-IP65i includes an integrated fail safe system, which prevents any operating errors during the wash preparation and operation.



Wash program:

The user may setup the wash program in the tester setup with 4 parameters, defining the time for the washing cycle and how often the cycle should run. There are 4 washing phases:

Phase 1: In the first phase the feeder chute opens to the star wheel to clean the chute.

Phase 2: In the second phase the feeder chute turns around, the star wheel is also moving. The transport path, the star wheel and the feeder chute is cleaned.

Phase 3: In the third phase the advance mechanism and the thickness gauge move forward and back for careful cleaning.

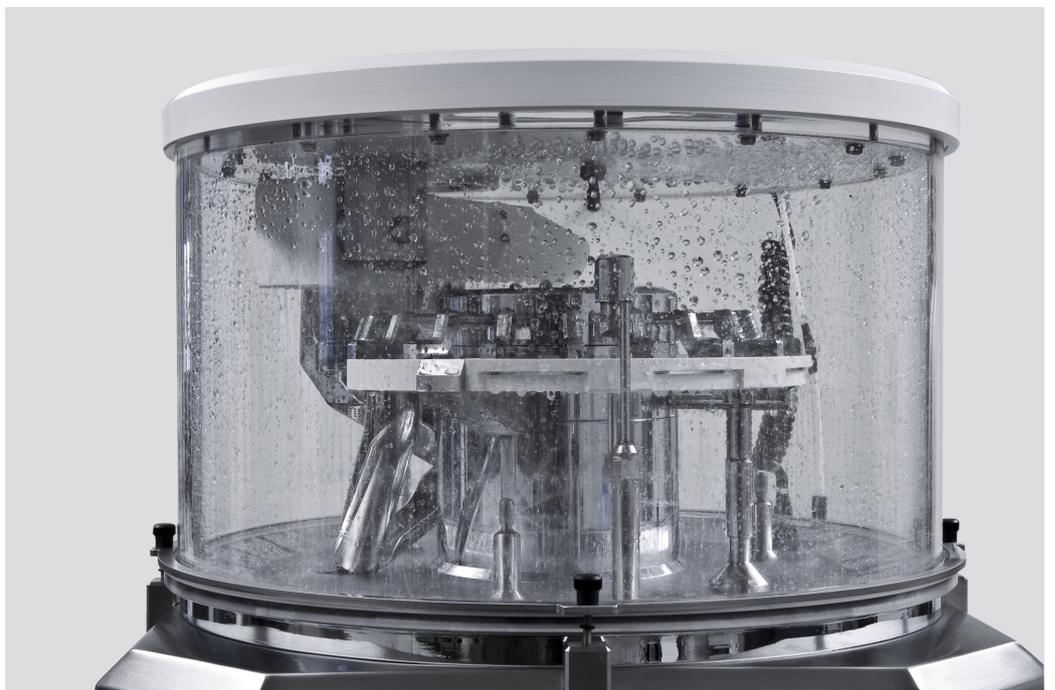
Phase 4: In the last phase only the star wheel turns around. In this phase the water is pushed out of the transport path.

The washing process may be started and stopped through the local operating display located on the top of the tester.

Testing Area



Wash Cycle



SOFTWARE

NIR

HARDNESS

DIAMETER

THICKNESS

WEIGHT

Technical data UTS-IP65i

Scale: Precision scale Sartorius WZ64S
 Weight unit: 1 mg, 0,5 mg or 0,1 mg adjustable
 Weighing range: 10 mg to 50 g
 Weighing accuracy: +/- 1 mg stable environment
 +/- 2 mg unstable environment

Thickness tester:
 Drive: Stepper Motor
 Measurement principle: Linear potentiometer
 Measuring unit: mm or inch
 Measuring range: 1-17 mm
 Measuring accuracy: +/- 0,05 mm

Hardness tester:
 Drive: Stepper motor
 Force measurement: Load measurement cell (LMZ)
 Measurement principle: Pressure load cell (DMS)
 Measuring unit: N, Kp or SC
 Measuring range: 4-400N (LMZ 500N standard)
 0,4-40N (LMZ 50N optional)
 Measuring accuracy DMS +/-1N

Diameter tester:
 Drive: Stepper motor
 Measurement principle: Stepper motor
 Measuring unit: mm or inch
 Measuring range round: 3-20mm
 Measuring range oblong length: 3-25mm
 Measuring accuracy: +/-0,1mm

Weight: 80 kg

Utilities:

Equipment: Kraemer UTS-IP65i
Power requirements: 100-240V, 50Hz/60Hz
Compressed air: 6.5 bar
Water supply for wash cycle: 5 bar / 30l/min

For more information please make contact with our local representative or directly with us: www.ischi.ch



Charles Ischi AG
 TESTING TECHNOLOGY
 Certified ISO 9001:2000

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TESTING

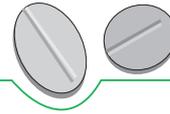


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TESTING



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SOFTWARE

NIR

HARDNESS

DIAMETER

THICKNESS

WEIGHT

The UTS-IP-LR is so designed that the complete work-room can be cleaned.

All parts of the UTS-IP-LR that need to be removed for washing can be dismantled complete without tools and afterwards re-assembled. This ensures a higher service friendliness.

Tablets of any form can be fed by hand or through various transport systems into the patented Feeder chute.



In the Feeder chute the tablets are automatically dedusted and transported one at a time to the test stations.

Through the new positioning method in front of the hardness tester it is possible to optimally position almost every tablet for a diameter and hardness measurement.

The tablet stop, the pusher and the transport segment can be adapted optimally for a product.

These parts can be exchanged with a few flicks of the wrist for a product changeover.



Overview of advantages

- Standalone system for the Laboratory
- Fully automatic testing of the four parameters: Weight, Thickness, Diameter and Hardness
- All outer edges are smooth and easy to clean
- Protection classification IP65
- RS232/RS485 interface for Computer
- Tool free disassembly of all relevant parts for cleaning
- Press communication possible
- Data connection of Combox to machine over bus system
- Separate Combox with two 24V switched outputs for Diverter or Air transport control, Integrated power supply and Display
- Interface for software under Windows
- Expandable with TTS11 21 CRF Part 11 compliant software
- Sample collector with 2 containers

Technical data UTS-IP-LR:

Scale: Precision weighing cell
Sartorius WZ64S

Weight unit: 1 mg / 0,5 mg / 0,1 mg (adjustable)

Weighing range: 10 mg to 50 g

Weighing accuracy: ± 1 mg stable environment
 ± 2 mg unstable environment

Thickness tester:

Drive: Stepper motor

Measurement principal: Magnet sensor

Measuring unit: mm or inch

Measuring range: 1-17 mm

Measuring accuracy: $\pm 0,05$ mm

Hardness tester:

Drive: Stepper motor

Force measurement: Load Measurement Cell (LMZ)

Measurement principal: Pressure Load Cell (DMS)

Force unit: N, Kp or Sc

Measuring range: 4-400 N
(800 N or 50 N Optional)

Measuring accuracy DMS: ± 1 N (by 800 N ± 2 N,
by 50 N $\pm 0,1$ N)

Measuring accuracy of the electronics and mechanics: ± 1 N (by 800 N ± 2 N,
by 50 N $\pm 0,1$ N)

Measuring accuracy total: ± 2 N (by 800 N ± 4 N,
by 50 N $\pm 0,2$ N)

Force increase DMS: 250 N/sec.

Work cycle Pressure jaw: 0,35 mm/sec.

Fast forward speed
Pressure jaw: 8,5-17 mm/sec. selectable

Rearwards speed
Pressure jaw: 8,5-17 mm/sec. selectable

Diameter tester:

Drive: Stepper motor

Measurement principal: Stepper motor

Measuring unit: mm or inch

Measuring range: 3-18 mm, 3-30 mm (manual)

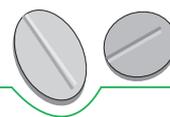
Measuring range
Oblong length: 5-20 mm

Measuring accuracy: $\pm 0,1$ mm

Weight: 40 kg (only UTS-IP-LR,
without feed systems)

Measurements: 59 x 56 x 54 (B x T x H cm)

Power requirements: 100-240 V , 50 Hz/60 Hz



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SOFTWARE

NIR

HARDNESS

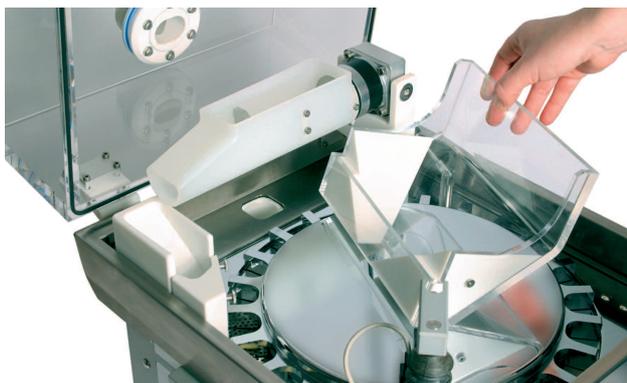
DIAMETER

THICKNESS

WEIGHT

The universal, fully automatic Tablet Testing System The Tablet Testing System **UTS4.1-S10** as dust-proof version was developed on the basis of the already long proven and perfected test systems for tablets in close cooperation with the pharmaceutical industry.

The samples are measured and tested precisely for Weight, Thickness, Diameter and Break force. Round, oval, square and rectangular forms can be tested without problem. For special product forms the proven Star wheel transport system can be adapted quickly and easily.



The simple and direct feed by means of the patented Kraemer Elektronik Feeder chute improves the measuring accuracy and reliability. Unnecessary abrasion and contamination of the test stations is avoided through specially developed cleaning and de-dusting devices.



The test stations are automatically cleaned fully and efficiently after each tablet.

The trash containers front and back can be removed and sealed dust-proof.

Through the modular and flexible concept the machine can be used as a:

- Laboratory machine with PC software; for example our TTS11 software CFR 21 Part 11 conform.
- Evaluation and monitoring machine connected to a production machine (Tablet press), where the choice can be made from where the sample pull is to be started; from the production machine as well as the test system itself; for example our **TTS11** software CFR 21 Part 11 conform.

Functions:

- For use as table or stand model
- Operation in lab or production with full automatic process monitoring
- Display for all 4 measurement values with Online display
- Adjustment and calibration functions
- Configuration program for customer specific applications
- RS232/RS485 computer interface
- 24 V switched outputs for sample pull, air transport and alarms
- In and outputs for control and integration of external equipment

Technical data UTS4.1-S10

Scale: Precision weighing cell Sartorius WZ64S
 Weight unit: 1 mg / 0,5 mg / 0,1 mg (adjustable)
 Weighing range: 10 mg to 50 g
 Weighing accuracy: ± 1 mg in stable environment
 ± 2 mg in unstable environment

Thickness tester:

Drive: Stepper motor
 Measurement principal: Linear potentiometer
 Measuring unit: mm or inch
 Measuring range: 1-17 mm
 Measuring accuracy: $\pm 0,05$ mm

Hardness tester:

Drive: Stepper motor
 Force measurement: Load Measurement Cell (LMZ)
 Measurement principal: Pressure Load Cell (DMS)
 Force unit: N, Kp or Sc
 Measuring range: 4-400 N
 (800 N or 50 N Optional)

Measuring accuracy DMS:

± 1 N (by 800 N ± 2 N, by 50 N $\pm 0,1$ N)

Measuring accuracy Electronics/Mechanics:

± 1 N (by 800N ± 2 N, by 50 N $\pm 0,1$ N)

Measuring accuracy total:

± 2 N (by 800 N ± 4 N, by 50 N $\pm 0,2$ N)

Force increase DMS: 250 N/sec.

Work cycle Pressure jaw: 0,35 mm/sec.

Fast forward travel Pressure jaw:

8,5-17 mm/sec. selectable

Rearwards travel Pressure jaw:

8,5-17 mm/sec. selectable

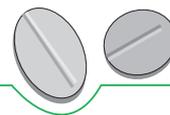
Diameter tester:

Drive: Stepper motor
 Measurement principal: Stepper motor
 Measuring unit: mm or inch
 Measuring range: 3-18 mm (3-30 mm manual)
 Measuring accuracy: $\pm 0,1$ mm

Measurements: 59 x 49 x 50 (W x D x H cm)

Weight: 40 kg

Power requirements: 100-240 V, 50 Hz/60 Hz



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**PRODUCTS FOR QUALITY AND
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SOFTWARE

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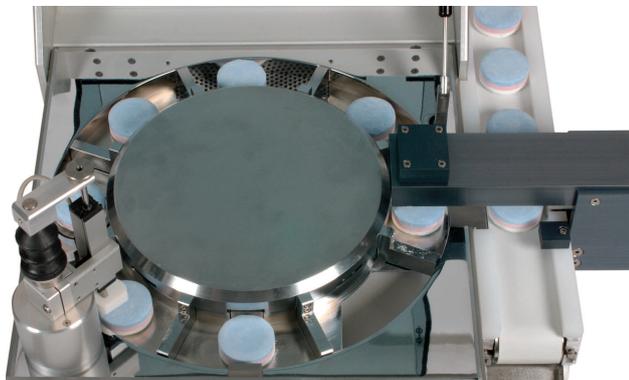
WEIGHT

Tablet Testing System UTS4.1-S8

Especially designed for the testing of large pharmaceutical products such as effervescent tablets, veterinary products, but also for detergent products for washing and dishwashing machines.

The Tablet Testing System **UTS4.1-S8** was developed on the basis of the well known and successful range of Tablet Testing Systems used for many years by the pharmaceutical industry.

This new machine was especially designed for testing large pharmaceutical products such as effervescent tablets or veterinary products and also detergent products for washing machines and dishwashers.



The products are precisely tested for weight, thickness, diameter and hardness (break force). The **UTS4.1-S8** reliably handles round, oval, square and rectangular products. For peculiar shaped products the proven starwheel transport system can be adapted quickly and easily. The system concept allows for easy integration into production or packaging lines.

The feeding of products is done by means of a flexible



transport band. In this way the products are fed and correctly orientated providing precise measuring and test results.

The simple and direct feed to the Kraemer starwheel transport system improves the measuring accuracy and reliability. Unnecessary abrasion and contamination of the test and measuring stations is avoided by specially developed de-dusting and cleaning features. The test stations are fully automatic and efficiently cleaned after each tablet.

The tablet testing system can be connected to a production machine via the built-in interfaces; or can be controlled using one of our computer software packages:

- DOS software
- TTS software
- TTS11 software CFR 21 Part 11 conform

Functions:

- For use as table or stand model
- Operation in lab or production with full automatic process monitoring
- Display for all 4 measurement values with Online display
- Adjustment and calibration functions
- Configuration program for customer specific applications
- RS232/RS485 computer interface
- 24 V switched outputs for sample pull, air transport and alarms
- In and outputs for control and integration of external equipment

Technical data UTS4.1-S8

Scale: Precision weighing cell Sartorius WZ64S
 Weight unit: 1 mg / 0,5 mg / 0,1 mg (adjustable)
 Weighing range: 10 mg to 50 g
 Weighing accuracy: ± 1 mg in stable environment
 ± 2 mg in unstable environment

Thickness tester:

Drive: Stepper motor
 Measurement principal: Linear potentiometer
 Measuring unit: mm or inch
 Measuring range: 1-27 mm
 Measuring accuracy: $\pm 0,05$ mm

Hardness tester:

Drive: Stepper motor
 Force measurement: Load Measurement Cell (LMZ)
 Measurement principal: Pressure Load Cell (DMS)
 Force unit: N, Kp or Sc
 Measuring range: 4-400 N
 (800 N or 50 N Optional)

Measuring accuracy DMS:

± 1 N (by 800 N ± 2 N, by 50 N $\pm 0,1$ N)

Measuring accuracy Electronics/Mechanics:

± 1 N (by 800N ± 2 N, by 50 N $\pm 0,1$ N)

Measuring accuracy total:

± 2 N (by 800 N ± 4 N, by 50 N $\pm 0,2$ N)

Force increase DMS: 250 N/sec.

Work cycle Pressure jaw: 0,35 mm/sec.

Fast forward travel Pressure jaw:

8,5-17 mm/sec. selectable

Rearwards travel Pressure jaw:

8,5-17 mm/sec. selectable

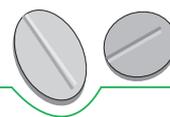
Diameter tester:

Drive: Stepper motor
 Measurement principal: Stepper motor
 Measuring unit: mm or inch
 Measuring range: 3-50 mm
 Measuring accuracy: $\pm 0,1$ mm

Measurements: 59 x 56 x 54 (W x D x H cm)

Weight: 42 kg

Power requirements: 100-240 V, 50 Hz/60 Hz



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PRODUCTS FOR QUALITY AND IN- PROCESS CONTROL IN THE PHARMACEUTICAL INDUSTRY



The Kraemer Universal Tablet Testing System UTS4.1 with Touch Screen Option...

...helps you navigate easily and effortlessly through the calibration- & adjustment procedure via a state-of-the-art Touch Screen display.

...is a very user-friendly product that enables you to print reports at any time onto a connected USB-printer.

Through this Touch Screen display, you have many options available right at your fingertips:

- Set-up parameters
- Administer a product catalogue with unlimited storage of products
- Start tests with product data or direct tests without product data
- Customise your settings and reports

The UTS Touch Screen Option can be connected to any online tester with a tablet press or with existing PH21 Software.

A UTS with a standard display panel can be upgraded with a Touch Screen at any time. The Touch Screen can be retrofitted to any existing units.

FEATURES OF THE UTS WITH TOUCH SCREEN

Adjustment / Calibration	Easy & user-friendly menu guided procedure via display
Tests	Tests with product data or direct tests without product data
Set-up of parameters	Direct access to parameter set-up via display with complete information and description of each parameter
Product capturing	Administration of product catalogue, unlimited storage of products
Reports	Different report options, can be customised; Can be viewed on display or printed
Calibration protocol	Calibration report can be printed at any time
Archiving of tests	Possible
Print-outs	USB-printer supported
Languages	Currently: German & English. Additional languages on request
Suitable for:	Online testers with tablet press; Testers with PH21 Software; Upgrade of standard display panel for extended functionality; For retrofit of existing units
Not suitable for:	Does not replace PH21 Software; Not suitable for high volume laboratory testing; CFR21 Part11 compliant testing
Facts, Benefits & Advantages	User-friendly Extended stand-alone function Compact state-of-the-art design Easy & fast access of parameters All tests can be printed via a USB printer



Touch Screen Menu

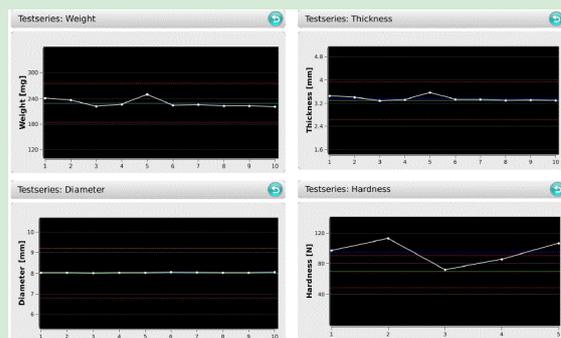


Diagram reports

Different Menu Options

Step 1: Product Selection

Here, a product is selected and confirmed with OK.

Step 2: Enter batchnumber

Subsequently, an optional batch number can be entered that is then printed on the protocol.

Step 3: Number of measures

Subsequently, the number of tablets to be tested is selected for each measurement station. After confirmation with OK the tester starts the test.

At conclusion of the test, if activated, a protocol is printed and then the report opened (see 6.2).

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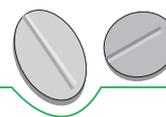
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**PRODUCTS FOR QUALITY AND
IN-PROCESS CONTROL IN THE
PHARMACEUTICAL INDUSTRY**



PH21 Software System

THE Pharmaceutical Software Production Control System for Solid Dosage Forms

The PH21 Software System can support multiple tester applications for Weight, Thickness, Diameter, Hardness, Disintegration & Friability through a centralised database.

Through this convenient centralisation, the parameters only have to be input once.

Tablet tests for a particular batch can be performed on any available tester. The results will be added to the centralised batch record.

Functions such as Auto-Archive automatically save batch data onto an SQL database server and therefore guarantee robustness and reliability of the system.

A separate external reporting tool provides fast access to batch data archives, which proves very useful during Audits, since past batches can be accessed directly, without having to be restored first.

This comprehensive state-of-the-art software in this field is fully compliant with FDA CFR21 Part 11.

PH21 Data Acquisition and Analysis Software

Functionality

The PH21 system offers complete functionality for application in the laboratory and in production.

The full version of the PH21 software includes features for production such as:

- features for online-testing directly at the tablet press
- online-quality control charts
- automatic data export functions
- multi-tester applications for weight, thickness, diameter, hardness, disintegration, friability
- ODT online data transfer options for multi-tester applications, where product and test data may be managed from a central admin system.
- maintain a product library with unlimited number of product specifications
- perform tests of different shapes and sizes of tablets
- create reports of individual tests, group of tests, complete batches and multi-batch reports (annual reports)
- provide menu-guided adjustment and calibration procedures, including reports and calibration interval control.

Scalability

The PH21 system may be used to operate a single tablet tester in a conventional laboratory environment, or the PH21 system can drive multiple devices in a real-time in-process control application.

Robustness & Reliability

The PH21 system is designed for quality and in-process control in the laboratory as well as for production lights-out operation. Automatic sampling, testing and generating of test protocols, including online quality control charts with SPC-functions (Statistical Process Control) makes it the state of the art software in this field. All significant events are logged and may be analysed at a later time.

Features like the Auto-Archive function allow to save batch data fully automatically onto an SQL database server, where the data is backed up and saved. The Software automatically keeps a copy of any product before a change to a product parameter is made, so each and every change to product records can be traced back to the very first creation of this record. Even deleted product records can be retrieved at any time. This guarantees the robustness and reliability of the whole system.

Security

Every button may be assigned an access restriction level. Every user group has its individual access restriction, a numerical value from zero (no access restriction/super user) to nine (maximum access restriction/low priority user). This access control scheme can be tailored to any customer's security requirements. The system is being delivered pre-configured as a standard version, ready to use.

Compliance

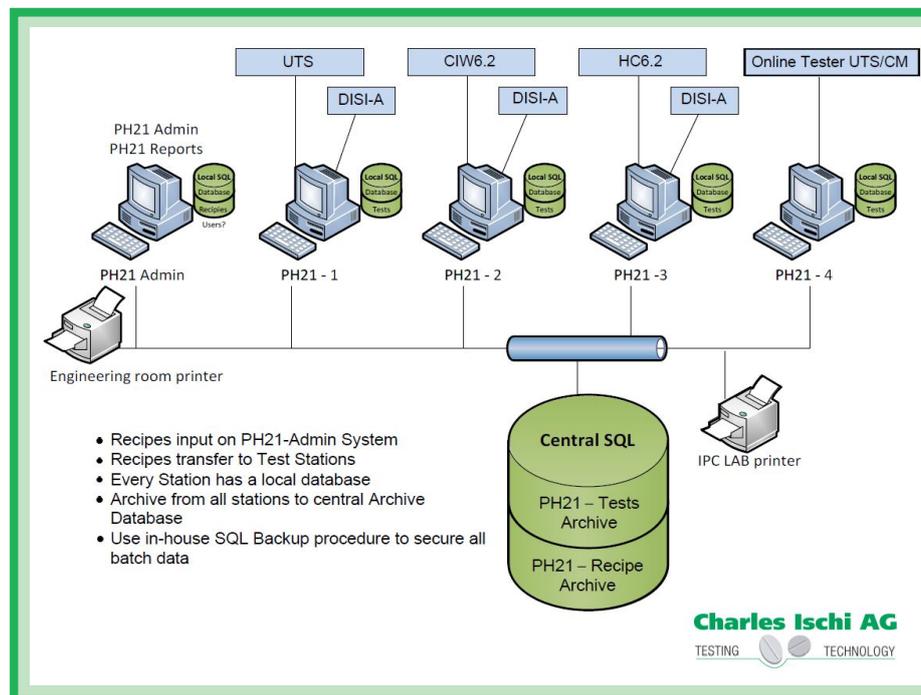
Beginning with the system design, special care has been taken to ensure correct operation of the system. Each new version is only being released after passing the internal testing / verification and validation procedure. The PH21 software fully complies with FDA regulation 21 CFR Part11 and the European Regulations for software applications in GMP-critical environments within the pharmaceutical industry.

External Reporting Tool

A separate reporting tool has been developed to provide fast access to batch data archives. This special software package is very useful during Audits, when asked to provide test data from certain batches from years back. Since the reporting tool accesses the batch archives directly, it is not necessary to first restore batches. Fast and direct access is proven through this tool.

There is also a light version of PH21 software available that offers reduced functionality for operation of a single laboratory tester such as a UTS4.1, a CIW6.2 or an HC6.2.

Since 1993, the software has been installed and validated successfully throughout the pharmaceutical industry worldwide.



Any Questions

For more information, visit our website: www.ischi.ch

We are always at your disposal for any further questions you might have and would be glad to support you in the realization of an efficient test and batch data management system for your company.

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Certified ISO 9001:2000





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Products for our Swiss Customers:

Charles Ischi AG is the official distributor for Switzerland for the Belgium manufacturer PHARMA TECHNOLOGY.

PHARMA TECHNOLOGY designs and manufactures a wide range of **High Tech Tablet Deduster, Metal Check & Loading Systems** for tablets and capsules.

The latest generation of Tablet-/Capsule Dedusting Technology:

PharmaFlex



PFC750 Dust Tight



Modulare Segment
Technology



WIP-Version

Standard Tablet Dedusters / Combi units in stainless steel:



DV500



Combi 500



Combi + 500

For more information, please visit our website:

www.ischi.ch