IN LINE WITH THE FUTURE

EXCELLENT TABLET TESTING TECHNOLOGY IN RESEARCH AND PRODUCTION

By Kraemer & Ischi

IN LINE WITH THE FUTURE

EXCELLENT TABLET TESTING TECHNOLOGY IN RESEARCH AND PRODUCTION

Dear readers,

What makes a tablet testing system an excellent product?
Is it the systems quality? Its operating life? Professional advice? Or is it the impressive range of services?

It comes down to a combination of all these aspects, plus more than 30 years of experience in the industry that make our products so unique. Tablet testing technology by Kraemer & Ischi can be found wherever there is a need for the highest level of quality.

Kraemer & Ischi tablet testing systems can be found in research and production for ...

- pharmaceuticals
- food
- veterinary products
- oral hygiene
- electrical technology
- washing and dishwashing products
- pellets
- industrial press products

We deliver a made-to-measure solution to meet your specific requirements. This catalogue provides you with an overview of devices, services and fittings in the IPC.line for industrial production and LAB.line, our new product line for research and laboratory use.

Why Kraemer & Ischi?

+ Because we provide you with the right solution.
+ Because you benefit from more than 30 years of experience.
+ Because we support you 24/7, around the world.
+ Because you will always be one step ahead with us.
+ Because we always put quality first.

Contents

LAB.line

Compact, space-saving laboratory devices for identifying the physical properties of tablets and capsules efficiently

LABORATORY TESTING SYSTEMS

Semi and fully automatic testing devices
P-SERIES & MODULES 08

Manual testing devices
H-SERIES 10

Manual testing devices
T-SERIES 12

Abrasion and friability testers
AE 1 + 2 13

Semi-automatic disintegration tester
DISI-M 14

Automatic disintegration tester
DISI-A / TOUCH 15

IPC.line

Wear-resistant and reliable testing systems for in-process control

INDUSTRIAL TESTING SYSTEMS

Automatic testing system
UTS 4.1 18

Automatic testing system with active ingredient content measurement
UTS NIR 20

Automatic testing systems in protection class IP54 / IP65
UTS IP LR / IP65 22

Automatic testing system – hermetically sealed & washable
UTS IP65i 24

Automatic weighing systems
CIW 6.2 / CIW 6.3 26

OPTIONS

Touchscreen 28

Centering and measuring unit for oblong-shaped tablets
OZB / OZB IP 29

Feeder, sample collector and sorting diverter 30

ATS air conveyor systems 31

Sampling diverter 32

Measuring range for expansion 33

Transportation equipment 34

Options matrix/overview 35

Accessories

Accessories and software for the entire product line – laboratory & IPC

Dynamic calibration 38

Mechanical tablets 39

Calibration case 40

Software for tablet testing systems
TTS11 41

Quality control software
PH21 42

Quality documentation packages
QM PACKAGE 43

System validation
IQ - Installation qualification
OQ - Operational qualification
PQ - Performance qualification 44

Kraemer & Ischi

Two family companies providing excellent testing technology together 46

LAB.line

COMPACT, SPACE-SAVING LABORATORY DEVICES FOR IDENTIFYING THE PHYSICAL PROPERTIES OF TABLETS, CAPSULES, TABLET CORES, GRANULES ETC. EFFICIENTLY

LABORATORY TESTING SYSTEMS

Semi and fully automatic testing devices
P-SERIES & MODULES 08

Manual testing devices
H-SERIES 10

Manual testing devices
T-SERIES 12

Abrasion and friability testers
AE 1 + 2 13

Semi-automatic disintegration tester
DISI-M 14

Automatic disintegration tester
DISI-A / TOUCH 15

NEW

MEASURED PARAMETERS

- WEIGHT
- THICKNESS
- DIAMETER
- LENGTH
- HARDNESS
- WIDTH

STANDARD DEVICE

P-Series

Semi and fully automatic testing devices with modular extension levels

The versatile laboratory testing devices in the P-Series offer you the latest technology, space-saving design and maximum flexibility. Tailor the basic devices (P2-P5) to your needs at any time – thanks to the practical 'Plug & Play' extension module. This allows you to upgrade the semi-automatic basic devices to a fully-automatic testing system at any time.

The new LAB.line design also offers many practical advantages. It is very easy to clean thanks to generous radii, rounded edges and smooth surface.

Standard device & modules: a flexible master of transformation

MEASURED PARAMETERS

MODEL	WEIGHT	THICKNESS	LENGTH	HARDNESS	WIDTH
P2	●	●	—	—	—
P3	—	●	●	●	—
P4	●	●	●	●	—
P5	●	●	●	●	●

● Included

MODEL	L x W x H (mm)	Weight (kg)
P2 - P5	320 x 320 x 185	< 15

The P5 series sets new standards in laboratory testing technology. The P5 version automatically tests all five parameters. Using the BELT/ROTO system integrated into the hardness station, the tablets are accurately rotated by 90 degrees and positioned for width measurement. The BELT system is used for difficult shapes as it can position the tablets even more accurately.

ADVANTAGES

+ Modularly expandable
+ 'Plug & Play' modules
+ Sensor-supported menu navigation
+ Integrated 360° LED status display
+ Automatic positioning of tablets
+ Clean design

OPTIONS

- Load cells: 40 N, 400 N (standard), 800 N, 1600 N
- Modules: hood, feeder, separation, sample collector
- BELT system
- ROTO system

BELT system

ROTO-System (manual grooving plate) for easy tablet positioning in the P4 model

You can find more information on Lab.line products for research and laboratory use at

www.labline.info

NEW

STANDARD DEVICE

H-Series

Manual testing devices

The H-Series manual laboratory testing devices in the new LAB.line design combine the latest technology and usability. Rounded shapes, generous radii and smooth surfaces make them very easy to clean.

The integrated touchscreens are easy and intuitive to use: you can initiate a product change or obtain conclusive test results quickly in just a few clicks.

There is the option to extend the measuring range to 1600 N and to test and analyse even harder tablets and other press products. A thickness measurement station is integrated into the H4 version. Connect an external scale to the H5 version and test all five parameters.

MEASURED PARAMETERS

- HARDNESS
- LENGTH
- WIDTH
- THICKNESS
- DIAMETER
- EXTERNAL SCALE

ADVANTAGES

+ Clean design
+ Intuitive touchscreen operation
+ Measuring range (length) up to 60 mm
+ Measuring range (hardness) up to 1600 N as option

OPTIONS

- Load cells: 40 N, 400 N (standard), 800 N, 1600 N
- Base with two larger collection containers

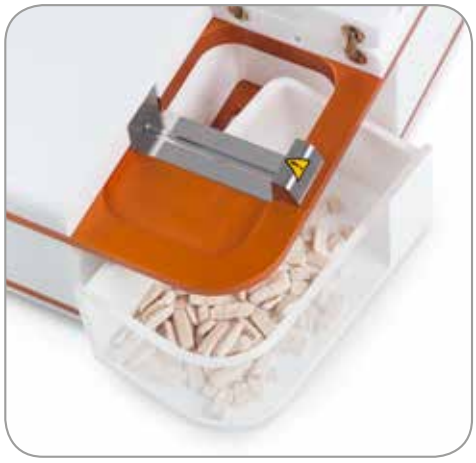
MODEL	L x W x H (mm)	Weight (kg)
H-SERIES	230 x 268 x 102	7

Compact, ergonomic, efficient

MEASURED PARAMETERS

MODEL	HARDNESS	LENGTH	WIDTH	THICKNESS	WEIGHT (external scale)
H3	●	●	●	—	—
H4	●	●	●	●	—
H5	●	●	●	●	○

○ Optional
● Included



Collection container for tested tablets

Basic version H5 with external balance

Interchangeable fixed jaw for different tablet shapes

Easy installation of the large collector

MEASURED PARAMETERS

- HARDNESS
- LENGTH
- WIDTH
- THICKNESS
- DIAMETER
- EXT. SCALE

ADVANTAGES

+ User-friendly seven-segment display with buttons
+ Quick and simple calibration
+ Small and robust

OPTIONS

· Load cells:
440 N, 400 N (standard)
· Manual thickness meter
· External scale

STANDARD DEVICE

T-Series

Simple manual testing device HC6.2

The T-Series represents traditional products, continuing to offer you our devices in their tried-and-tested design and technology.

The clear displays and buttons make them easy to use, allowing you to operate the device safely even when wearing gloves and protective clothing.

Measure the hardness, length and width using the standard device. Print your test results directly from an external printer by using the USB port. You can manage up to 99 products externally and load them via a USB memory stick. An integrated product memory is available as an option.

	MEASURED PARAMETERS				
MODEL	HARDNESS	LENGTH	WIDTH	THICKNESS	WEIGHT (external scale)
HC6.2	●	●	●	—	—
HC6.2 EXT	●	●	●	○	—
HC6.2 EXT +	●	●	●	○	○

○ Optional ● Included

MODEL	L x W x H (mm)	Weight (kg)
HC6.2 STANDARD VERSION	230 x 240 x 120	7

HC 6.2 with external thickness gauge and scale

STANDARD DEVICE

AE 1+2

Abrasion and friability testers

The abrasion and friability testing device consists of two test stations. If required, test drums can be equipped to test for wear due to rolling and falling or to test the abrasion of tablets, tablet cores, granules etc.

The tester meets all the latest requirements of the European & US Pharmacopoeia, GMP and GLP.

- Quick drum assembly
- User-friendly membrane keypad
- GMP-compliant stainless steel housing

MEASURED PARAMETERS

ABRASION

FRIABILITY

ADVANTAGES

+ Compact stainless steel housing
+ Quick drum assembly
+ Automatic emptying

OPTIONS

- Friability test drum
- Abrasion test drum

MODEL	L x W x H (mm)	Weight (kg)
AE 1	320 x 300 x 250	6.5
AE 2	320 x 430 x 250	7

Abrasion and friability testing device AE 2 with 2 test drums

MEASURED PARAMETERS

DISINTEGRATION TIME

ADVANTAGES

+ Magnetic coupling of the testing baskets
+ Available with up to four independent measuring stations
+ Stainless steel housing

OPTIONS

· Testing basket B for tablets from Ø 18 mm

STANDARD DEVICE

DISI-M

Semi-automatic disintegration tester with LCD display and individual timer

The DISI-M tablet disintegration tester offers user-friendliness in a tried-and-tested design. Opt for the manual DISI-M disintegration tester as a cost-effective alternative to the automatic DISI-A model. The DISI-M fulfils all EP/USP requirements.

The testing baskets can be attached and removed quickly thanks to the magnetic coupling. A few quick steps is all it takes to dismantle the testing baskets ready for cleaning.

As each station is powered separately, you can examine up to four different products at the same time. The softstart function ensures that the testing basket is immersed in a controlled manner.

MODEL	Stations (pieces)	L x W x H (mm)	Weight (kg)
DISI-1M	1	340 x 250 x 750	20
DISI-2M	2	475 x 250 x 750	30
DISI-3M	3	610 x 250 x 750	40
DISI-4M	4	750 x 250 x 750	50

Simple & practical: the testing baskets are magnetically coupled

Special testing basket for large tablets

The DISI-M disintegration tester is available with a choice of 1 to 4 measurement stations

STANDARD DEVICE

DISI-A / Touch

Automatic disintegration tester

With DISI-A, you control all operation and data analysis safely and easily via computer and PH21 software.

The system fulfils the requirements of FDA 21 CFR Part 11. All operation procedures are password-protected and monitored continuously by the system. All relevant procedures, for example amendments to master data, calibration and much more, are automatically recorded in the log book (audit trail).

The standalone variant DISI-A Touch is easy to operate using the integrated touchscreen. It is possible to upgrade to PC version at any time. The system fulfils all EP/USP requirements.

The device has 4GB of product memory. The standard printout of DISI-A Touch offers an overview of results in table form. You can export data via a USB stick.

MEASURED PARAMETERS

DISINTEGRATION TIME

ADVANTAGES

+ Touchscreen or computer operation
+ Magnet coupling of the testing baskets
+ Wireless signal transmission
+ Integrated temperature sensors in testing baskets

OPTIONS

- Testing basket B for tablets from Ø 18mm

	Stations (pieces)	L x W x H (mm)	Weight (kg)
DISI-1A / TOUCH	1	340 x 250 x 750	22
DISI-2A / TOUCH	2	475 x 250 x 750	32
DISI-3A / TOUCH	3	610 x 250 x 750	42
DISI-4A / TOUCH	4	750 x 250 x 750	52

Special testing basket for large tablets

The **DISI-A**, seen here with two measurement stations, is operated via the PH21 computer software

The **DISI-A Touch** is operated via the touchscreen

IPC.line

WEAR-RESISTANT AND RELIABLE TESTING SYSTEMS
FOR IN-PROCESS CONTROL

INDUSTRIAL TESTING SYSTEMS

Automatic testing system
UTS 4.1 18

Automatic testing system with active ingredient content measurement
UTS NIR 20

Automatic testing systems in protection class IP54 / IP65
UTS IP LR / IP65 22

Automatic testing system – hermetically sealed & washable
UTS IP65i 24

Automatic weighing systems
CIW 6.2 / CIW 6.3 26

OPTIONS

Touchscreen 28

Centering and measuring unit for oblong-shaped tablets OZB / OZB IP 29

Feeder, sample collector and sorting diverter 30

ATS air conveyor system 31

Sampling diverter 32

Measuring range extension 33

Transportation equipment 34

Options matrix / overview 35

MEASURED PARAMETERS

- WEIGHT
- THICKNESS
- DIAMETER
- HARDNESS
- LENGTH
- OPTIONAL: WIDTH

ADVANTAGES

+ Solid industrial construction
+ Reliable results
+ Universal application

OPTIONS

- PH21 software, compliant with 21 CFR Part 11
- Oblong Centering System (OZB)
- 12-, 24- or 48-station feeder
- Single air conveying system
- Double air conveying system
- Three-slot sorting diverter
- 12-, 24- or 48-station sample collector

STANDARD DEVICE

UTS 4.1

Automatic testing system

UTS 4.1 is a universal and fully-automatic tablet testing system developed for industrial applications. UTS 4.1 is a tried-and-tested model within a series of tablet testing systems proven over many years – developed in close cooperation with the pharmaceutical industry. UTS 4.1 enables round, oval, square and rectangular tablets as well as various special shapes to be tested. The tried-and-tested Oblong Centering System (OZB) can be integrated for difficult oblong tablets.

Use UTS 4.1 as a laboratory device or online monitoring device linked to a tablet press. The sampling process here can be triggered in the production machine or via our PH21 software.

MODEL	L x W x H (mm)	Weight (kg)
UTS 4.1	590 x 400 x 530	40

UTS4.1 tablet testing system, the no. 1 tablet tester

Option: Oblong Centering System (OZB)

Option: transportation casters, see page 34

BESTSELLER

UTS 4.1-12F

With 12-station feeder

UTS4.1-12F tablet testing system with 12-station feeder

BESTSELLER

UTS 4.1-S10

Dust-proof design

The UTS4.1-S10 dust-proof design ensures safe operation

BESTSELLER

UTS 4.1 Touch

With touchscreen operation

User-friendly, intuitive operation via touchscreen

CUSTOMER-SPECIFIC SOLUTIONS

UTS

Special solutions that suit your requirements are available on request. Below are some examples:

UTS	
S7	With special feeder for tablets up to Ø 25 mm
S8	For tablets up to Ø 50 mm
S9	For mini tablets
S16	With feeder via a conveyor belt and five-channel sorting diverter
S17	With two-channel sorting diverter
S20	With single tablet feeder

MEASURED PARAMETERS

- WEIGHT
- THICKNESS
- DIAMETER
- LENGTH
- HARDNESS
- ACTIVE INGREDIENT CONTENT

ADVANTAGES

+ Shorter release times
+ Programmable cycles during ongoing production
+ Qualitative and quantitative online analysis
+ Use in laboratory or production
+ Dust-proof

OPTIONS

· Windows software
· Single air conveying system
· Double air conveying system
· 24-station sample collector

STANDARD DEVICE

UTS NIR

IP54

Automatic testing system with active ingredient content measurement

The UTS NIR automatic tablet testing system combines measurement of the physical parameters weight, thickness, diameter and hardness with near-infrared spectroscopy (FT-NIR analysis) in order to identify a tablets active ingredient content.

UTS NIR is thus a fully automated online PAT tool which can be used in production or as an offline testing device in the laboratory.

In conjunction with a tablet press, the system allows you to monitor the production process continuously and transmit all measurement results directly to the tablet press, allowing a quick response if errors arise and ensuring an optimal production process.

The transmission FT NIR spectrometer NIRFlex N-500 by Büchi Labortechnik AG used also allows you to transfer applications safely from the laboratory device to the UTS NIR.

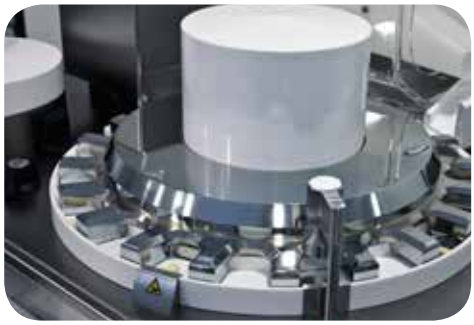
The accurate, patented two-jaw centering mechanism positions the test specimen accurate to ± 0.1 mm, guaranteeing very precise measurement results that are standard in the laboratory sector.

Its compact and space-saving construction make the UTS NIR suitable for all tablet processes carried out by conventional press manufacturers. Diverse sample collectors may be provided depending on the customers' requirements, allowing further analyses to be carried out in the laboratory.

All parts that need to be cleaned can be quickly and easily dismantled without tools.

The system conforms to the European & US Pharmacopoeia and is compliant with 21 CFR Part 11.

MODEL	L x W x H (mm)	Weight (kg)
UTS NIR	740 x 586 x 581	107



Robust measurement technology

Reliable tablet transfer

Precise tablet positioning (patent stamp)

Outward transfer of NIR test specimens

Compact UTS NIR system with hood and sorting diverter

In cooperation with:

BÜCHI SWITZERLAND

MEASURED PARAMETERS

- WEIGHT
- THICKNESS
- DIAMETER
- LENGTH
- HARDNESS

ADVANTAGES

+ Use in the laboratory as a standalone version
+ Dismantling of all parts that need to be cleaned without tools
+ Very easy and thorough cleaning of test area
+ Integrated test specimen adjustment

OPTIONS

- PH21 software
- 12-station feeder with single tablet mode
- Single air conveying system
- Double air conveying system
- 12-station sample collector

STANDARD DEVICE

UTS IP LR

IP54

Automatic testing systems with protection class IP54

The UTS IP LR is designed to enable the working space/test area to be thoroughly cleaned. The device is very easy to maintain as all parts can be completely dismantled for cleaning, without the use of tools.

In the feeder chute, the tablets are automatically dedusted, separated and transported to the test area. Here, a computing transport system is responsible for positioning the tablets on the measurement stations. This positioning method ahead of the hardness tester allows almost any shape of tablet to be optimally positioned for measuring the diameter and hardness. The stop bar, slider and transport segment can be optimally adapted to any product. These parts can be exchanged with very little effort when the product changes.

MODEL	L x W x H (mm)	Weight (kg)
UTS IP LR / IP65	590 x 560 x 540	40

CUSTOMER-SPECIFIC SOLUTION

UTS IP LR-S2	Designed with a 12-station feeder and sample collector Designed with a cyclone for air transport connection and bypass for single tablets

Patented radial transport rake

STANDARD DEVICE

UTS IP65

IP65

Automatic testing system with protection class IP65

The UTS IP65 is designed for operation in isolators or washing bays and is fitted with a pressure equalisation function. The UTS IP65 is largely identical to the UTS IP-LR, with the following differences:

- External operation (no operating display on the device)
- Encapsulated weighing equipment
- Wash down available

MODEL	L x W x H (mm)	Weight (kg)
UTS IP65	400 x 500 x 500	40

MEASURED PARAMETERS

- WEIGHT
- THICKNESS
- DIAMETER
- LENGTH
- HARDNESS

ADVANTAGES

+ Dismantling of all parts that need to be cleaned without tools
+ Very easy and thorough cleaning of test area
+ Integrated test specimen adjustment

OPTIONS

- PH21 software
- Single air conveying system
- Double air conveying system

Designed for isolators.
Connections via Triclamp DIN DN50.

Patented integrated distributor discs

MEASURED PARAMETERS

- WEIGHT
- THICKNESS
- DIAMETER
- LENGTH
- HARDNESS

ADVANTAGES

+ Single testing system with integrated washing nozzles
+ WIP system – wash in place
+ WOL system – wash offline
+ Integrated 360° LED status display
+ Hermetically-sealed system, OEB 5 class
+ Insulator is superfluous due to the sealed system

OPTIONS

- PH21 software
- Designed for single tablet feeder
- Hood with glove ports

STANDARD DEVICE

UTS IP65i

IP65

Automatic testing system – hermetically sealed & washable

The UTS IP65i system is an addition to washable tablet presses for WIP or WOL applications for processing medium and highly potent products.

As an addition to the existing dust-proof and easy-to-clean testing systems UTS4.1-S10 / UTS IP LR, the UTS IP65i is the first fully washable, universal testing system and is the only one of its kind in the world. The working space/testing area corresponds to the protection class IP65 and the cleaning process is conducted in a controlled manner.

The integrated failsafe system rules out any potential operating errors as early as the preparatory phase as well as during the washing process, thus ensuring error-free processes. For the washing programmes, user-defined parameters set the washing period per wash cycle, the number of wash cycles and the length of each individual washing phase.

The system can be used in the following applications:

- Online, controlled by tablet press
- Standalone with computer software
- Online with computer software

MODEL	L x W x H (mm)	Weight (kg)
UTS IP65i	570 x 570 x 755	80

Open structure for optimal cleaning results

Isolated working space

UTS IP65i: Compact,
space-saving design

MEASURED PARAMETERS

- WEIGHT
- THICKNESS

ADVANTAGES

+ Solid industrial construction
+ Quickly and reliable weighing
+ Use as a standalone or online version in the laboratory

OPTIONS

- PH21 software
- 12-, 24- or 48-station feeder
- Single air conveying system
- Double air conveying system
- Three-slot sorting diverter
- 12-station sample collector

STANDARD DEVICE

CIW 6.2 / 6.3

Automatic weighing systems

The CIW automatic weighing system allows you to weigh tablets, tablet cores, capsules and similar products during or after the production process.

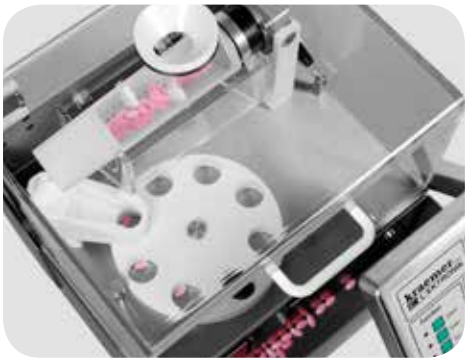
Based on the UTS tablet testing systems by Kraemer, the standard device also offers a tablet separating system and a special transport star in order to position the test specimen accurately on the integrated scale.

All parts that need to be cleaned can be quickly and easily dismantled without tools.

The CIW 6.3 model is largely identical to the CIW 6.2 model, but also contains a precise measurement device to determine the thickness.

- Laboratory device with PH21 computer software, compliant with 21 CFR Part 11.
- Online monitoring device, following a tablet press. Sampling here can be triggered by the production machine or via our PH21 software.

MODEL	L x W x H (mm)	Weight (kg)
CIW 6.2 / 6.3	480 x 480 x 480	30



Test specimens can be weighed quickly and accurately with the CIW automatic weighing system

BESTSELLER

CIW 6.x-12FS

With 12-station feeder

Automatic testing of multiple products

BESTSELLER

CIW 6.x-S10

Dust-proof design

Dust-proof test area

CUSTOMER-SPECIFIC SOLUTIONS

CIW

Special solutions that suit your requirements are available on request. Below are some examples:

S9	For mini tablets only
S9-12F	For mini tablets with 12-station feeder
S13	Direct feeder
S14	Three-channel sorting diverter at ejection point
S15	Five-channel sorting diverter at ejection point
S16	With conveyor feeder

ADVANTAGES

+ Simple and easy operation
+ Retrofitting to existing UTS 4.1 testing devices
+ Network print function
+ Extensive product memory

OPTION

Touchscreen

Easy operation without a computer

The touchscreen is an ideal addition to our tried-and-tested tablet testing systems. Switching is very easy, as the interface is modelled on the familiar appearance. The intuitive menu navigation offers many advantages:

- Record products with nominal values, batches, tolerance limits, test classes and test parameters
- Save measurement series (not compliant with 21 CFR Part 11)
- Print measurement results directly or archived printouts using the connected printer
- Create various calibration specifications, monitoring the intervals
- Print calibration and adjustment protocols
- Modify setup parameters easily and conveniently
- Track measured values in clear live diagrams
- Read system messages in plain text

MODEL	Screen
TOUCHSCREEN	7-inch

Intuitive touchscreen operation

OPTION

OZB / OZB IP

IP65

Centering and measuring unit for oblong-shaped tablets

The Oblong Centering Unit (OZB) is available as an optional module and can be retro-fitted to all testing systems from version 4 (UTS). The centering unit is installed above the hardness measuring station. Products with longer shapes, such as oblong tablets, are accurately positioned and guided without contact during the hardness test. Customer-specific centering jaws are available for unusual tablet shapes.

1. Centering function

The exact positioning and guidance gives you maximum reliability when measuring the hardness of oblong tablets. 'Multiple' centering is already integrated and only needs to be activated.

2. Width measurement (not for OZB IP)

The jaws of the OZB unit allow the tablet width to be automatically measured. In conjunction with the PH21 software or the touchscreen, the width can be defined as a fifth measured parameter. Alternatively, the OZB can be used instead of the thickness gauge to measure the tablets thickness. This special function resolves the problem for oblong tablets which are positioned on their side as the result of an unfavourable height/side ratio.

We have developed the OZB IP unit specifically for use in washable devices. It is used exclusively for positioning. The jaws are not clamped as they are in the standard OZB model, but are attached magnetically.

MEASURED PARAMETERS

WIDTH

ADVANTAGES

+ Reliable positioning
+ Width measurement

OPTIONS

· Customer-specific jaws

MODEL	L x W x H (mm)
OZB	50 x 70 x 85
OZB IP	108 x 74 x 133

Centering and width measurement

Oblong Centering Unit (OZB)

Oblong Centering Unit IP (OZB IP): especially for use in washable devices

ADVANTAGES

+ Time saving
+ Fill tested and sorted tablets
+ Available for almost any UTS and CIW device

OPTION

Feeder, sample collector and sorting diverter

Automated feeding and sorting of different batch samples

Feeder & sample collector

Do you have different products and not much time? Automate and accelerate the testing process! Using the sample feeder, the testing devices do the work for you – no need to start each test procedure individually. The additional sample collector enables undamaged tablets to be stored for measurement later. The sample feeder and sample collector are available in three sizes – with 12, 24 and 48 stations.

Sorting diverter

Good, bad, destroyed – immediately recognisable! With the three-channel sorting diverter, tablets are filled separately immediately after testing. This is very useful for analysing undamaged test specimens further in the laboratory.

Feeder for UTS and CIW devices

Sorting diverter based on the example CIW

Sample collector with transportation equipment based on the example CIW

OPTION

ATS air conveyor system

Fast transportation of tablets from the press to the testing system

In the ATS air conveying system, tablets are sampled directly on the press and transported to the corresponding testing device through a hose – even across large distances and to other rooms.

The tablet air conveying system is designed in a way that ensures tablets are transported gently, with little vibration or friction. In accordance with the Venturi principle, tablets are transported by means of air flow, via a special transport hose, to the collecting cyclone. Here, the tablets are gently slowed down and fall into the testing device separation process once the air has been switched off.

The air conveying system consists of a conveying valve and a collecting cyclone, connected by a hose.

MODEL	L x W x H (mm)
ATS AIR CONVEYOR SYSTEM	240 x 140 x 170/230

Range:
10 metre limit, up to 5 metres with 2 metre difference in height

ADVANTAGES

+ Time saving
+ Fast transportation

OPTIONS

- Single air conveying system for connection to simple tablet presses
- Double air conveying system for connection to double rotary tablet presses
- Dust extraction

Single air conveying system ATS-1

Double air conveying system ATS-2

ADVANTAGES

+ Retrofitting possible
+ For autonomous monitoring
+ Height adjustable

OPTION

Sampling diverter

For removing tablets on the press and feeding them to the testing system

Use the sampling diverter to monitor production autonomously on older tablet presses or those that are not fully automated. Sampling is controlled by PH21 software and is not linked to the press. However, it is possible to send a stop/off signal to the press or use a visual signal to indicate tests that violate set tolerances.

The sampling diverter is height-adjustable and is installed at the production machines outlet

OPTION

Measuring range extension

Exchangeable load cells for particularly hard or soft tablets

The measuring range extension for the hardness test station is used for particularly hard or soft tablets. For IPC.line testing devices, the load cells can be replaced at a later stage and adjusted to the new products. The matrix on page 35 shows which testing devices can be fitted with special load cells.

MEASURED PARAMETERS

HARDNESS

ADVANTAGES

+ Higher measuring accuracy
+ Subsequent addition possible

LOAD CELLS	Measuring range (N)
STANDARD	4 - 400
OPTION	4 - 40
OPTION	8 - 800
OPTION	16 - 1600

Standard and mini load cells

ADVANTAGES

+ Testing devices can be moved within the press room easily and with little effort
+ Ergonomic handling: no need to lift the equipment
+ Available for almost any UTS and CIW device

OPTION

Transportation equipment

For greater mobility in production

Practical stainless steel transportation equipment with four casters – two lockable and two rotatable.

The testing systems are quick and easy to assemble, allowing simple transportation. The weight of the solid, industrial constructions should not be underestimated. If the testing devices are mounted on casters, they must not be lifted when being moved within the press room or between press rooms. The transportation equipment ensures greater industrial safety and speeds up processes in the workplace.

Transportation equipment for UTS 4.1 with 4 casters

Transportation equipment for CIW 6.2 with 2 casters

Options at a glance

There are numerous extensions available to allow you to adjust your testing system at any time. Find the right option for your application.

MODELS	UTS 4.1	UTS NIR	UTS IP LR	UTS IP65	UTS IP65i	CIW 6.2	CIW 6.3
Touchscreen	○						
OZB	○						
Sample feeder	○		○			○	○
Sample collector	○	○	○			○	○
Sorting diverter	○					○	○
ATS air conveying system	○					○	○
Sampling diverter	○					○	○
Load cell 40 N	○						
Load cell 400 N	●	●	●	●	●		
Load cell 800 N	○						
Transportation equipment	○	●	○		●	○	○

○ Optional

● Included in the standard version

Accessories

ACCESSORIES AND SOFTWARE
FOR THE ENTIRE PRODUCT RANGE – LAB.line & IPC.line

Dynamic calibration	38
Mechanical tablet	39
Calibration case	40
Software for tablet testing systems **TTS11**	41
Quality control software **PH21**	42
Quality documentation packages **QM PACKAGE**	43
System validation **IQ** - Installation qualification **OQ** - Operational qualification **PQ** - Performance qualification	44

MEASURED PARAMETERS

HARDNESS

ADVANTAGES

+ Comprehensive calibration
+ No calibration weights required

ACCESSORIES

Dynamic calibration

Dynamic adjustment and calibration

Each of our tablet testing devices contains the standard accessories for calibration with weights and gauge blocks. The consistency and linearity of the load cells in the testing devices is demonstrable and outstanding.

Up to 40 kg of weights would have to be used in order to ensure comprehensive calibration. This would be impractical and risky. We recommend dynamic calibration for a comprehensive calibration process.

The "Dynamic Calibration Package" consists of:

- a certified external load cell
- a software package for the testing device and a display unit for the dynamic calibration

During the dynamic calibration process, the hardness measuring station approaches the predefined number of measuring points dynamically. The software records the measurement results of the testing device and compares them with the reference load cell. A calibration protocol can be printed out at the end.

ACCESSORIES	L x W x H (mm)
DYNAMIC CALIBRATION PACKAGE	152 x 90 x 34

For dynamic calibration, the load cell is inserted into the hardness test station of the tablet testing system.

ACCESSORIES

Mechanical tablet

Testing device for daily function control

The mechanical tablet is a small testing device that allows you to conduct quick and easy function control on the hardness measuring station at any time. Each unit is tested and certified by the manufacturer. The certificate is included.

The testing device is actuated approx. 20 times in the hardness measuring station and the average value of the last 10 measurements is determined by the operator.

Please note: The function test with the mechanical tablet does not replace calibration!

MEASURED PARAMETERS

HARDNESS

ADVANTAGES

+ Quick control
+ Simple operation
+ Stainless steel design

ACCESSORIES	L x W x H (mm)	Available designs (N)			
MECHANICAL TABLET	24 x 24 x 70	50	100	150	200

Function test with the mechanical tablet

ADVANTAGES

+ Complete range of accessories, packed compactly into one case
+ Space-saving and convenient

OPTIONS

- Gauge block 5 mm for standard OZB (Oblong Centering Unit)
- Gauge block 3 mm for OZB with narrow jaws
- Weight 2 kg for 50 N load cell
- Weight 10 kg for 1000 N load cell (not included in case)

ACCESSORIES

Calibration case

Case with weights, gauge blocks and tools

This handy case contains everything you need to calibrate your devices. The case is included in the scope of delivery with purchase of an automatic testing system. It can also be bought separately for other testing devices.

- Calibration plate to ensure weights are applied reliably
- Weight 5 kg
- Weight 50 g
- Gauge block 20 mm
- Gauge block 10 mm
- Allen key 4
- Allen key 2.5

ACCESSORIES	L x W x H (mm)
CALIBRATION CASE	270 x 100 x 250

SOFTWARE

TTS11 software

Software for tablet testing systems

The high-performance TTS11 software is the perfect instrument for continuously controlling and monitoring your entire production processes.

The most important performance features at a glance:

- For Windows and Linux platforms (cross-platforming possible)
- SQL database standard: Frontbase (adjustment to other databases possible)
- Compliant with 21 CFR Part 11
- Integrated audit trail, regulated access control and access management, documented change control
- Integrated adjustment and calibration function and monitoring
- Archive manager for managing and issuing completed tests
- Network-compatible
- IPC quality controls
- Automatic identification of test machine by software system
- Evaluation manager with a diverse range of options for evaluating measurement results, product, batches, containers, single test
- Selection of evaluation parameters and variable limit values
- Batch management
- Test carried out in accordance with DAB/USP or company specification
- Alarm function and management for documenting incidents during the test
- Conversion functions for different measurement units
- Tolerance bands relative or absolute

OPTIONAL

- Software also available as a version for evaluation only
- Monitored, read-only database access via ODCB interface
- Connection to central data management (such as plant control station), integrated transfer of master data, transfer of test parameters etc.
- E-documents, test protocols and evaluations as PDF file, authorisation with electronic signature

Monitor and manage your devices and production processes with the high-performance TS11 software

ADVANTAGES

+ Advanced functionality
+ Modularly expandable
+ Compliant with 21 CFR Part 11

SOFTWARE

PH21 software

For all testing devices and quality assurance

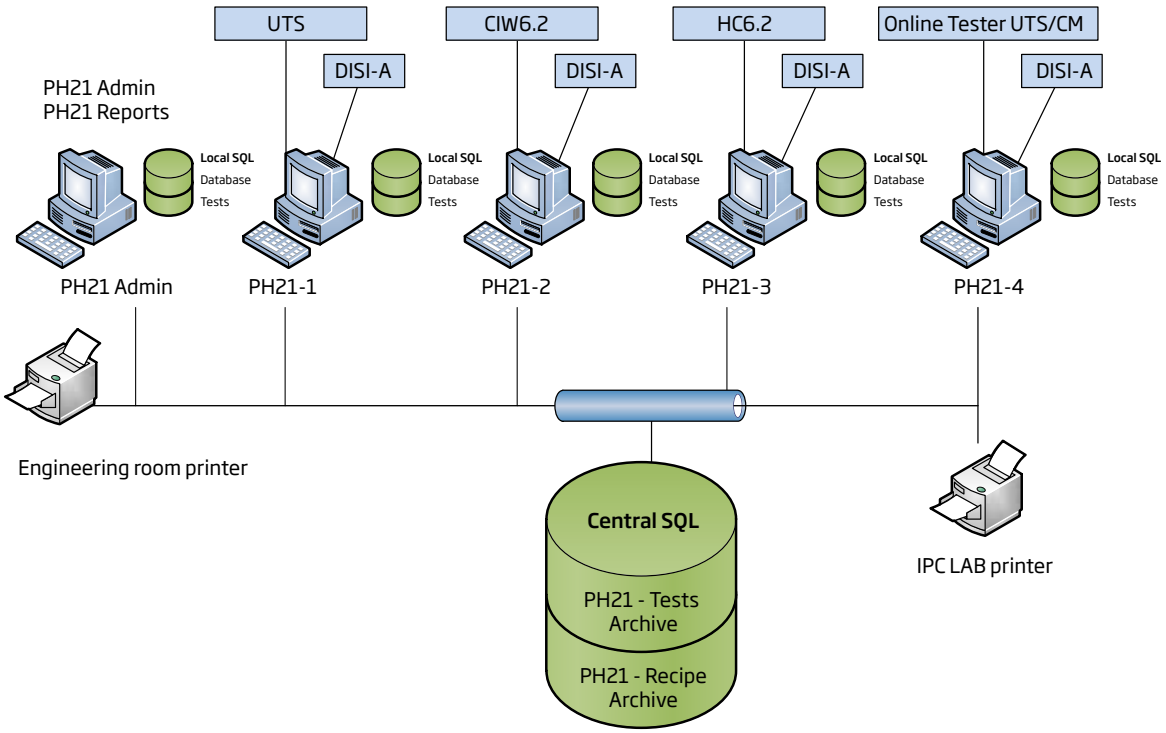
The PH21 pharmaceutical quality assurance system enables you to control and evaluate your tablet testers, disintegration testers and weighing machines centrally. Once it is stored in the central product database, you can use product-specific data for all tests on the connected devices.

The PH21 system supports the connection of up to 32 external pharmaceutical testing devices. Such devices include Kraemer Elektronik's well-known UTS tablet testing systems, tablet hardness testers and disintegration testers, as well as weighing machines for in-process control.

For larger applications, the PH21 system can be installed and operated as a client-server application. The entire software is 100% compliant with FDA 21 CFR Part 11 and allows you to use a wide scope of evaluation options for completed tests. Automatic backups in the background guarantee failsafe in-process control.

Numerous interfaces are available for communication and data exchange with external software applications.

Networking example:



SOFTWARE ACCESSORIES

QM package

Quality documentation package

Enhance your PH21 software! Use the QM package for computer system validation on site or to document product quality. The QM package is available as an option.

ADVANTAGES

+ Complete documentation
+ Documented quality
+ Efficient system validation

The QM package contains tests for all components in the PH21 software:

- The PH21 main menu
- Automatic testing system applications
- Automatic disintegration time/ testing device applications
- Other external testing device applications such as: hardness testers, laboratory scales, callipers, manually entered values,...
- Other applications, such as: online data transfer, barcode operation, LIMS integration...

Each test contains:

- inspection instructions
- printed PDF reference reports
- audit records

SERVICE

System validation IQ / OQ / PQ

Are you prepared for TQM and audits?

Device qualification as part of quality management or validation is an unavoidable requirement at many companies when it comes to selecting suppliers.

In addition to the final test protocol and the adjustment and calibration protocol, which is delivered together with all testing devices as standard, Kraemer & Ischi issues IQ/OQ documents on request. We offer IQ/OQ documentation to support the customer's IQ/OQ.

If you intend to use our services for a PQ, please contact us early on.

IQ – Installation qualification

Installation qualification (IQ) is documented proof that testing devices have been supplied and installed in line with the requirements prescribed in the design qualification and legal safety regulations. The documentation for installation qualification consists of an IQ test plan and IQ report.

The scope of the installation qualification:

- Inventory of the components delivered and check of the order documents
- Conformity check of the manufacturer's documentation (nameplate, delivery note)
- Assembly test and review of correct installation on the basis of the layout plan (if required)

OQ – Operational qualification

Operational qualification (OQ) is a test process that evaluates whether the testing device functions correctly. During the operational qualification, all points specified in the test plan are checked and documented in writing. In some circumstances (otherwise only common for performance qualification (PQ)), checks according to OQ can only be conducted with customer products.

Operational qualification must be passed for a testing device to be approved. Operational qualification can only be carried out once installation qualification has been passed. The documentation for operational qualification consists of an OQ test plan and OQ report.

Operational qualification involves identifying and monitoring the following quality-related alarm, control and switch functions:

- Initialisation of the testing device
- Weight – adjustment and calibration
- Thickness – adjustment and calibration
- Hardness/breaking strength – adjustment and calibration
- Diameter– adjustment and calibration
- Length and width – adjustment and calibration
- OZB – adjustment and calibration
- Adjustment and calibration protocol
- Product setup
- Verification of test results
- Documented proof that operating personnel have been trained

PQ – Performance qualification

Performance qualification (PQ) is a key part of validation of the entire production process over a certain period of time and for a specific product. It proves and documents that testing devices work within the specified limit values. The testing devices are not examined separately, but always as part of the entire process. Although PQ generally includes the OQ tests under process conditions, it is essential that a detailed test plan is drawn up on the basis of a thorough process description before the beginning of the validation process.

Performance qualification comprises:

- Documentation under process conditions, outlining that the testing device or the entire process with the product results in the expected, defined results
- The scope of the PQ can result from the operator's specifications or normative and legal requirements
- Documentation of the process and results in the qualification report
- Validation through multiple repetition, reproduction of processes (often three times in pharmaceutical/medical technology)

Two family companies providing excellent testing technology together

Kraemer Elektronik GmbH

Röntgenstraße 68 - 72
64291 Darmstadt
Germany

T. +49 6151 · 935936
www.kraemer-elektronik.com
info@kraemer-elektronik.com

KRAEMER ELEKTRONIK – FROM AERONAUTICAL TO MEASUREMENT TECHNOLOGY

Our love of technology is what drives us. Since being founded by Norbert Kraemer in 1978, Kraemer Elektronik has been developing sophisticated and high-precision measurement systems for industrial production and the development of new products. Kraemer measurement systems first catered to the food and aerospace industries before expanding into the chemical and pharmaceutical industry, always ensuring the highest quality in production. We have been developing tablet testing devices since 1978, followed by tablet hardness testing devices from 1983.

Following the early death of Norbert Kraemer, Thilo Kraemer took over the reins of the company and has continued its success as the sole registered owner since 2006. Influenced by his father's

Charles Ischi AG

Langfeldstrasse 26
CH-4528 Zuchwil
Switzerland

Tel. +41 32 621 · 49 23
www.ischi.ch
info@ischi.ch

IN THE CENTRE OF SWITZERLAND. IN THE HEART OF EUROPE. WITH CONNECTIONS AROUND THE WORLD.

"Charles Ischi Pharma-Prüftechnik" began in 1992 as a single company whose aim was to acquire customers from the local pharmaceutical industry in Switzerland. The company was soon able to develop its own sales network throughout Europe and in the Middle East. Charles Ischi, the owner and Managing Director, converted it into a joint stock corporation in 2000.

Today, Charles Ischi AG operates successfully in the international market as the general representative of Kraemer Elektronik GmbH. The excellent teamwork between the two companies ensures that the joint development and implementation of numerous customer-specific projects works so well.

inventive talent and pioneering spirit, Thilo Kraemer's leadership has seen many product innovations, while proven technologies are constantly further developed. Today, the Kraemer product portfolio ranges from manual testers to fully-automatic testing systems. In the LAB.line range, you will find both tried-and-tested and state-of-the-art measurement and testing technology especially for the laboratory. The IPC.line represents robust measurement systems specifically for use in harsh industrial environments.

Thanks to long-standing partnerships with OEM partners, national sales organisations and Charles Ischi AG, the international sales and service network, Kraemer systems are in constant operation in many industries and laboratories around the world, creating ever-better products.

Thilo Kraemer, Managing Director

The sales and service network is being expanded all the time. Around 45 representative offices are currently active all over the world. Connections around the globe emanate from the company's headquarters in Zuchwil, in the central Swiss canton of Solothurn – in the heart of Europe. It is from here that Charles Ischi AG coordinates the global sales network and maintains contact with both long-standing and new customers – even at a personal level.

"Our strong client relationships play a huge part in our success," explains company founder and Managing Director Charles Ischi.

Thanks to the very good access to the European transport network and close proximity to Basel and Zurich airports, our employees from the Sales & Service divisions can be on site quickly, anywhere in the world.

Charles Ischi, Managing Director

P-Series

The New Stars of the LAB.line

The P-Series sets new standards for laboratory tablet testing technology

Kraemer and Ischi, specialists for pharmaceutical testing equipment are launching new products: The P-Series are the innovative stars of the new LAB.line product range specifically for Laboratories.

The compact, space-saving testers determine the physical composition of tablets. Thanks to a modular construction, the standard basis version (P2-P5) can be upgraded with additional modules into a fully integrated automated testing line.

The new design of the LAB.line testers also offers numerous practical advantages. Cleaning is easy due to the rounded corners and smooth surfaces.

Modular. Precise. High quality.
The right solution for every application.

With the P5 version all 5 parameters are checked automatically:

HARDNESS | WEIGHT | THICKNESS | LENGTH | WIDTH

More information:

www.labline.info

6133 - EN

IN LINE WITH THE FUTURE

You will find information on Lab.line products
for Research & Laboratory under:

www.labline.info

Manufacturer

kraemer ELEKTRONIK Pharmaprüfsysteme

Kraemer Elektronik GmbH

Röntgenstraße 68 - 72
64291 Darmstadt
Germany

T. +49 6151 · 935936
www.kraemer-elektronik.com
info@kraemer-elektronik.com

International sales

Charles Ischi AG
TESTING TECHNOLOGY

Charles Ischi AG

Langfeldstrasse 26
CH-4528 Zuchwil
Switzerland

T. +41 32 621 · 49 23
www.ischi.ch
info@ischi.ch

Local representative