



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.

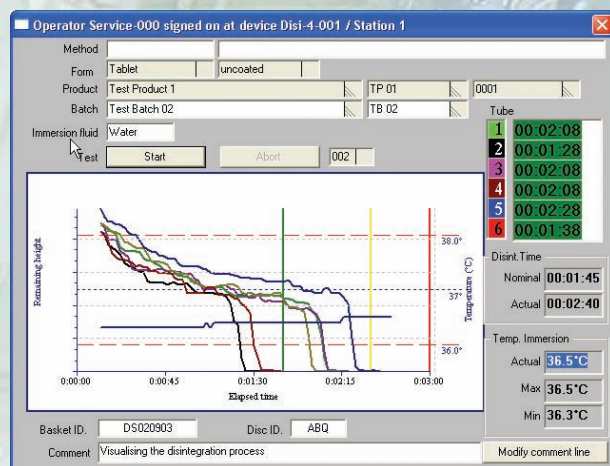
System operation

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.



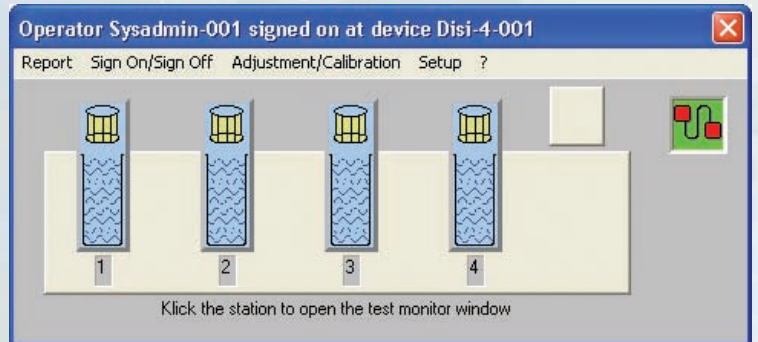
Data analysis

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

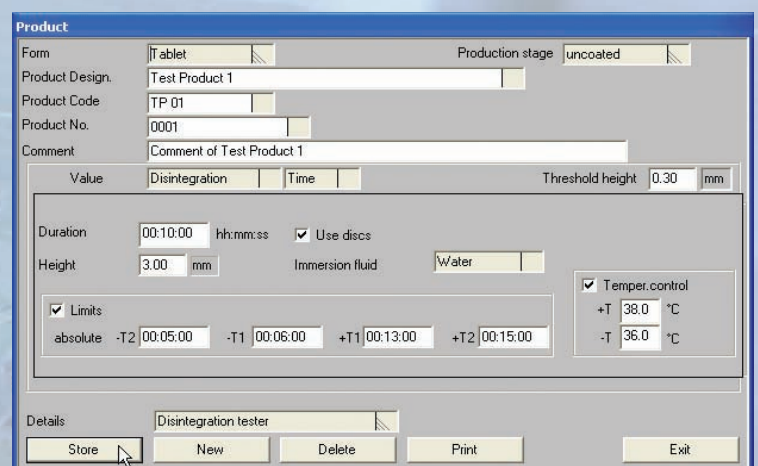
The DISI Tester incorporates a surprisingly easy, system guided self-adjusting facility. All adjustments are done electronically. Re-adjustment can be done at any time by clicking the respective button from the adjustment/calibration window. Adjustment and calibration are computer-assisted and the date 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.

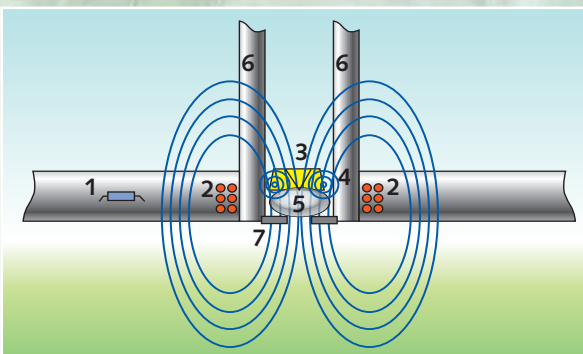
The patented principle of measurement is the attenuation of an electromagnetic field when moving a short-circuited coil through this field. The electromagnetic fields are produced by six coils located in the basket's lower plate. The electromagnetic circuits for signal conditioning are also hermetically 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

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.

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