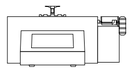
Physical Testing

Hardness

MT50

p. 5

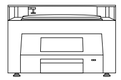


Robust manual hardness tester with Dr. Schleuniger® measuring technology for fast and precise recording of up to 5 parameters. Simple operation with EasyTouch™ and optimized test sequences for different requirements.

Hardness

ST50

p. 17

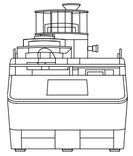


Smart, Smarter, SmartTest. Semi-automatic tablet testing system with SmartAlign™ for reliable alignment of various tablet shapes. 5 parameters with integrated weighing module and Dr. Schleuniger® measuring technology.

Hardness

AT50

p. 29

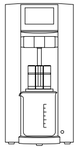


Robust tablet testing system for fully automated measuring of 5 physical parameters. Operate stand-alone on your lab bench to load multiple batches or integrate online with your tablet press for automated IPC.

Disintegration

DT50

p. 47

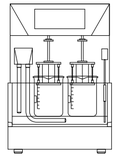


Bathless disintegration tester with 1 – 4 stations for automated detection of the disintegration time per sample. Shortest warm-up times with induction heating and continuous temperature measurement of the test medium.

Disintegration

DT2

p. 59



Disintegration tester with 2 independent test stations for manual protocolling of the disintegration time (individual or per test run). Printout of test reports.

Friability

FT2

p. 69

Friability tester with 1 – 2 drums and integrated 10 ° tilting function according to USP <1216>. Suitable for connecting a laboratory balance. Printed test reports or electronic data management with q-doc® software.

Tapped Density

TD1

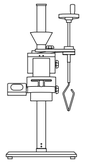
p. 79

Standardized determination of the tapped density of powder and granules according to USP, Ph. Eur., ASTM, and DIN EN ISO requirements. Suitable for connecting a laboratory balance. Printout of test reports or electronic data acquisition.

Flowability

PF1

p. 89

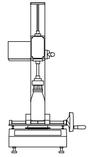


Standardized characterization of powders, granules and other bulk materials according to Pharmacopoeia (USP, Ph. Eur.). Powder flow through an orifice with funnel or cylinder, as well as determination of the angle of repose.

Cap Torque

TM200

p. 99



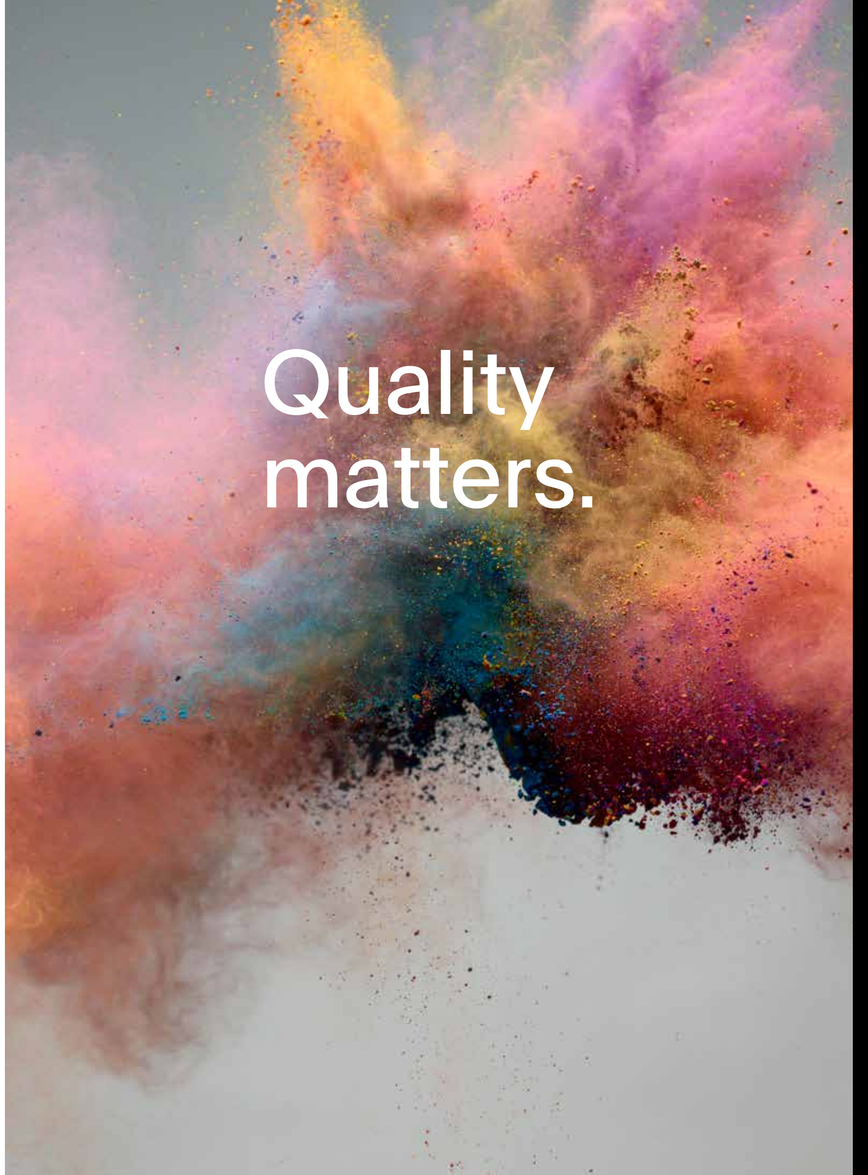
Tester for manual or motorized inspection of the cap torque of various screw caps incl. child-proof caps. Printout of test reports or electronic data acquisition.

Data Management

q-doc®

p. 109

More than "just" data integrity. Automated data collection and evaluation of all batch tests. Standardized drivers for over 30 test devices, central database, LDAP integration, and flexible configuration according to individual SOPs.



Weight

Thickness

Width

Diameter / Length

Hardness

Disintegration

Friability

Tapped Density

Flowability

Cap Torque

Data Management

Hardness

Tablet hardness – sometimes also referred to as tablet breaking force (USP <1217>) or resistance to crushing strength (Ph. Eur. 2.9.8) – measures the mechanical integrity of a tablet. SOTAX hardness testers with precision Dr. Schleuniger® measuring technology, standard-setting user friendliness, and robust Swiss quality components guarantee highest accuracy and test results you can rely on. Since 1972, reliable testing of virtually all tablet shapes from round to oval, convex oblong, and special shapes has made our systems the preferred choice of leading Pharmaceutical companies in R&D, QC, and IPC all over the world.

MT 50

Robust and easy to use, the MT50 is the ideal choice for manual testing – from multi-parameter analysis to “hardness only” tests of all types of shapes, sizes, and materials.

Manual Tablet Hardness Tester

MT50 — It doesn’t get any easier.

sotax.com/MT50

- 5 parameters
- Simple operation
- Robust and precise up to 800 N
- Dr. Schleuniger® technology
- Electronic data management

FastTest™ thickness station for efficient multi-parameter measuring

Intuitive icon-based EasyTouch™ control with user administration

SmartWay™ networking and data management with q-doc®

Configurable test reports and various printer interfaces including export of test results to USB flash drive

Width / Length (Diameter) / Hardness station with optimized jaw movements for highest precision and short cycle times

Recording of weight measurements from external analytical balance

SmartProtect™

Exchangeable tongues for easy tablet orientation

Debris collection bin

All sizes, shapes, and materials.

Your application?

The MT50 is designed for testing almost anything. From pharmaceutical dosage forms to catalysts, pellets, extruded materials, and more. Robust Dr. Schleuniger® technology paired with powerful state-of-the-art electronics provide for highly accurate and repeatable hardness results up to 800 N. Low breaking forces (< 10 N) associated with small and brittle test samples are precisely measured using a special “sensitive mode”.

100 % flexible.

The highly accessible test area accepts all types of shapes, sizes, and materials. Optimized jaw movements provide short cycle times, while quick-change tongues allow for simple tablet handling by the operator. Clip-on jaws further extend the MT50 testing capabilities for 3-point bending strength tests or other testing methods.

Quick-change tongue with groove for easy alignment of convex shapes

Extended jaw for testing large objects up to 65 mm

Quick-change tongue with flat surface

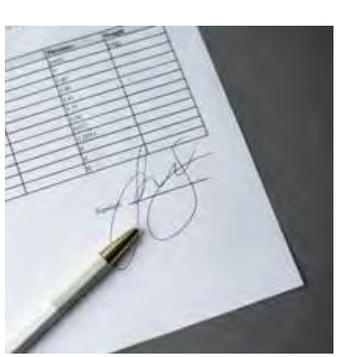
Clip-on jaws for 3-point bending strength test

Fast, Faster, FastTest™

Simply the fastest way to perform a series of measurements. Equipped with an integrated thickness gauge, the MT50 becomes a true multi-purpose testing system that accumulates weight, thickness, width, length / diameter, and hardness results in a single test protocol. With little practice, operators can execute multi-parameter runs quicker and easier than with any other manual tester on the market.

EasyTouch™

Available in your local language, the MT50 user interface is all about easy operation. Operators simply select a product and press “START” – ensuring that tests are always performed according to predefined methods. Additionally, simple quick-tests can be performed anytime. Different access levels make sure that settings or product specifications can only be modified by authorized personnel.

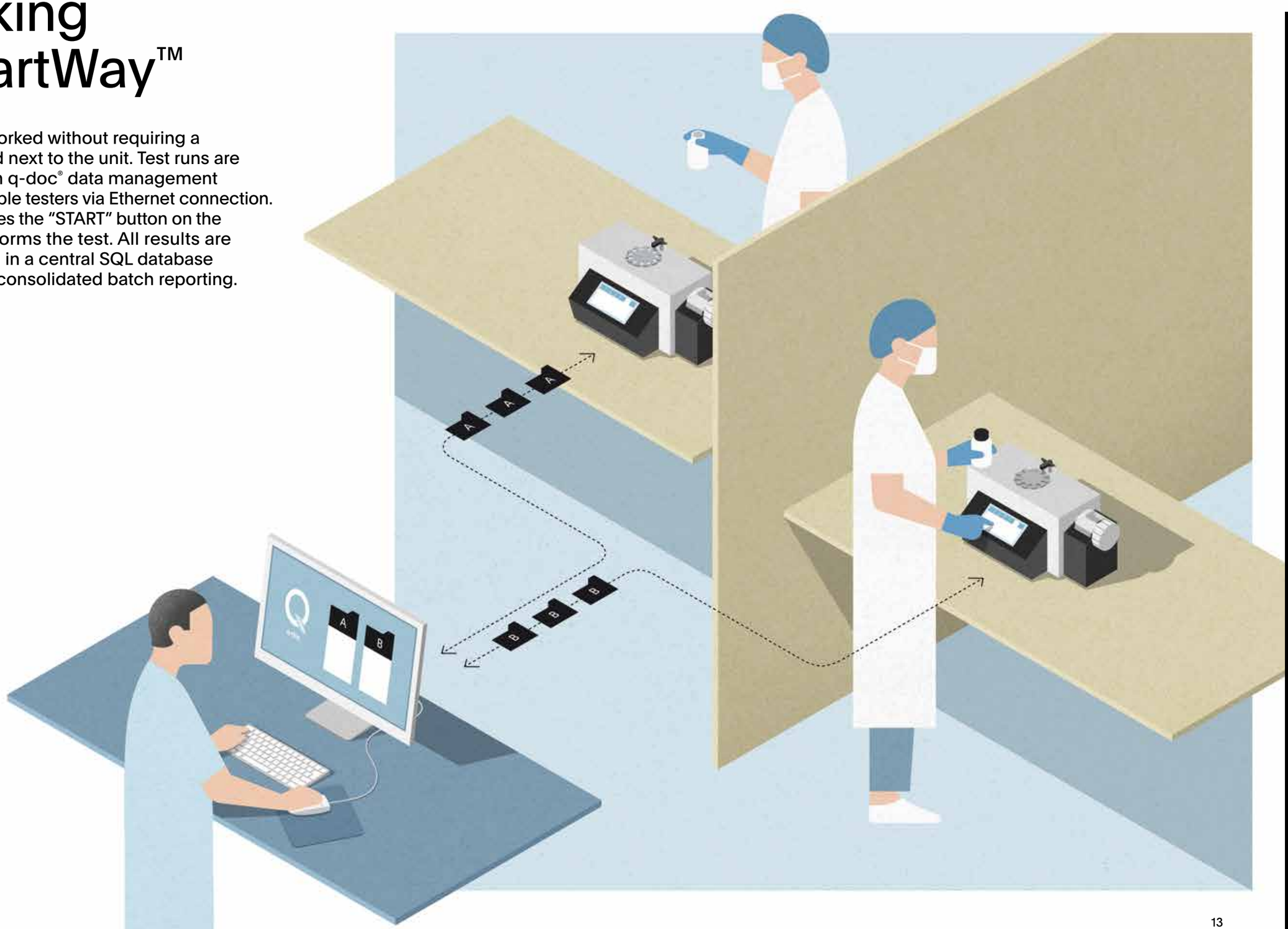


Reporting.

A test protocol is automatically generated and printed at the end of each test. Results for all tested parameters including statistical analysis are presented in a clearly structured format.
If pre-programmed products have been used, the printout includes all specifications and indicates whether limit violations (T1 / T2 / PL) have occurred. Report templates can be easily configured to individual requirements – from comprehensive test protocols to very basic reporting needs.

Networking the SmartWay™

The MT50 can be networked without requiring a computer to be located next to the unit. Test runs are automatically sent from q-doc® data management software to one or multiple testers via Ethernet connection. The operator only presses the “START” button on the MT50 display and performs the test. All results are automatically recorded in a central SQL database for full traceability and consolidated batch reporting.



Make life easier.

Daily functional check?

Quickly check the hardness station of your MT50 before starting daily tasks. Sometimes referred to as “mechanical tablet”, the function checking device FCD™ is calibrated to simulate the breaking of a tablet at a defined force. Simply place the FCD™ in the MT50 test area and start the automated checking routine. If required, a report including “pass / fail” evaluation can be printed on completion.

DQD™ dynamic qualification.

Using a fully traceable and certified high-precision load cell, the entire hardness range can be qualified using the DQD™ qualification tool. A fully automated routine allows to adjust and verify the complete measuring range on multiple points without requiring static reference weights.
Ask your local sales and service partner for more information on available SOTAX Premium Services.

MT50 Technical Specifications

Weight (Mass)	External balance	Mettler Toledo® / Sartorius®
	Units of measure	mg / g
	Resolution	1.0 mg / 0.1 mg / 0.01 mg
Thickness	Units of measure	mm / inch
	Resolution	0.01 mm
	Measuring range	2 – 25 mm
	Repeatability	± 0.03 mm
Width / Length (Diameter)	Units of measure	mm / inch
	Resolution	0.01 mm
	Measuring range	2 – 35 mm / optional: up to 65 mm
	Repeatability	± 0.03 mm
Hardness	Units of measure	N / Kp / Sc / UDF
	Measuring range	2 – 800 N
	Repeatability	± 1 N
	Dr. Schleuniger® S-beam load cell	99.98 % linearity, over entire measuring range
	Calibration (Adjustment / Verification)	Static: with reference weights; dynamic: with DQD™
Measuring principle	Constant speed	0.05 – 5 mm/s, programmable
	Linear force increase	10 – 200 N/s, programmable
Printer	PostScript® 3 (PS3)	Ethernet, USB
	Epson® 40col.	RS-232 serial
Interfaces		Ethernet, 2 × USB, 3 × RS-232 serial
Power supply		100 – 240 V / 50 – 60 Hz
CE Conformity	The MT50 fully complies with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

		Standard	Easy
Configuration	Weight (Mass), with external balance	○	–
	Thickness, with integrated FastTest™	○	○
	Width	○	–
	Length (Diameter)	○	○
	Hardness	●	●
EasyTouch™	Program capacity	100 products	–
	User administration	●	●
	Xport™ option (export on USB flash drive)	○	–
Data Management	q-doc® software, with SmartWay™ networking	○	–
Weight	(without packaging)	10 kg (22 lbs)	
Dimensions	Width	404 mm (15.9 inch); with 65 mm option: 434 mm (17.1 inch)	
	Depth	288 mm (11.4 inch)	
	Height	177 mm (7.0 inch); with FastTest™: 207 mm (8.2 inch)	

● included / required
○ optional

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Hardness
Semi-Automatic

ST 50

Fast, efficient, and precise – the ST50 sets new standards for testing 5 physical parameters. Operators simply insert samples, press “START”, and let the instrument do the rest.

Semi-Automatic Tablet Testing System

Hardness
Semi-Automatic

reddot award 2014
winner

ST50 — Smart. Smarter. SmartTest.

sotax.com/ST50

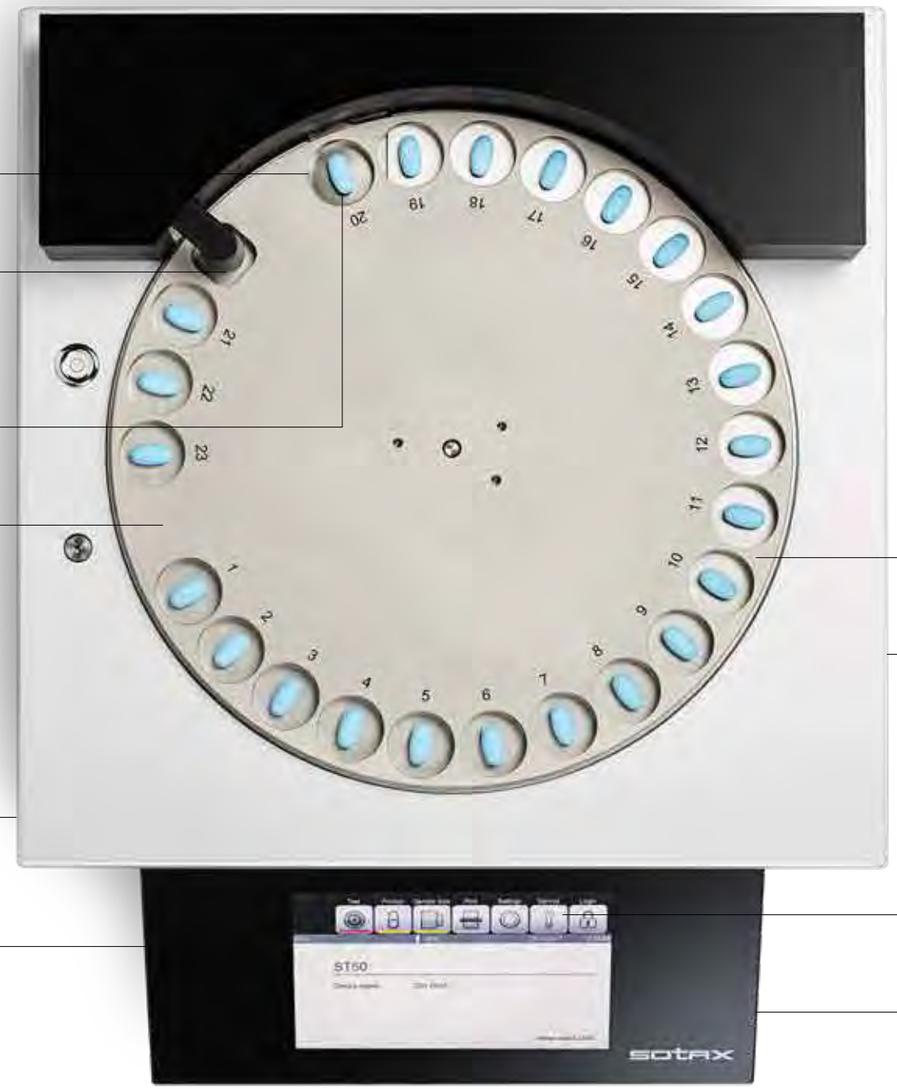
5 parameters

Tablet orientation with SmartAlign™

Video monitoring

Fast and precise up to 800 N

Electronic data management



Width / Length (Diameter) / Hardness station with SmartAlign™

Thickness station with highly accurate linear sensing technology

Video monitoring for full traceability and simplified OOS investigations

Integrated weighing module or external analytical balance

High-precision calibration with static SmartCal™ weights or dynamic qualification with DQD™

Configurable test reports and various printer interfaces including export of test results to USB flash drive

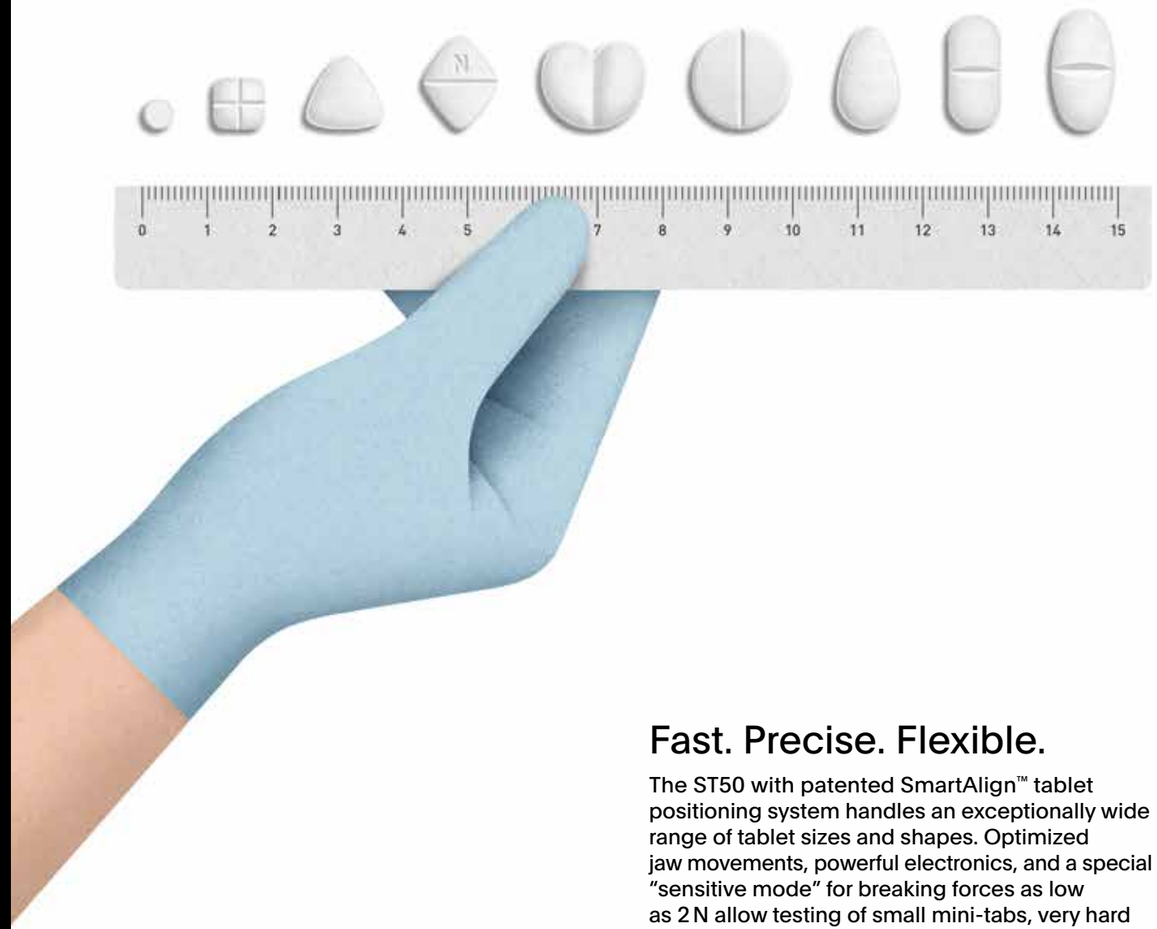
23-position carousel (quick-change without any tools)

Anti-static safety cover

Intuitive icon-based EasyTouch™ control with user administration

SmartWay™ networking and data management with q-doc®

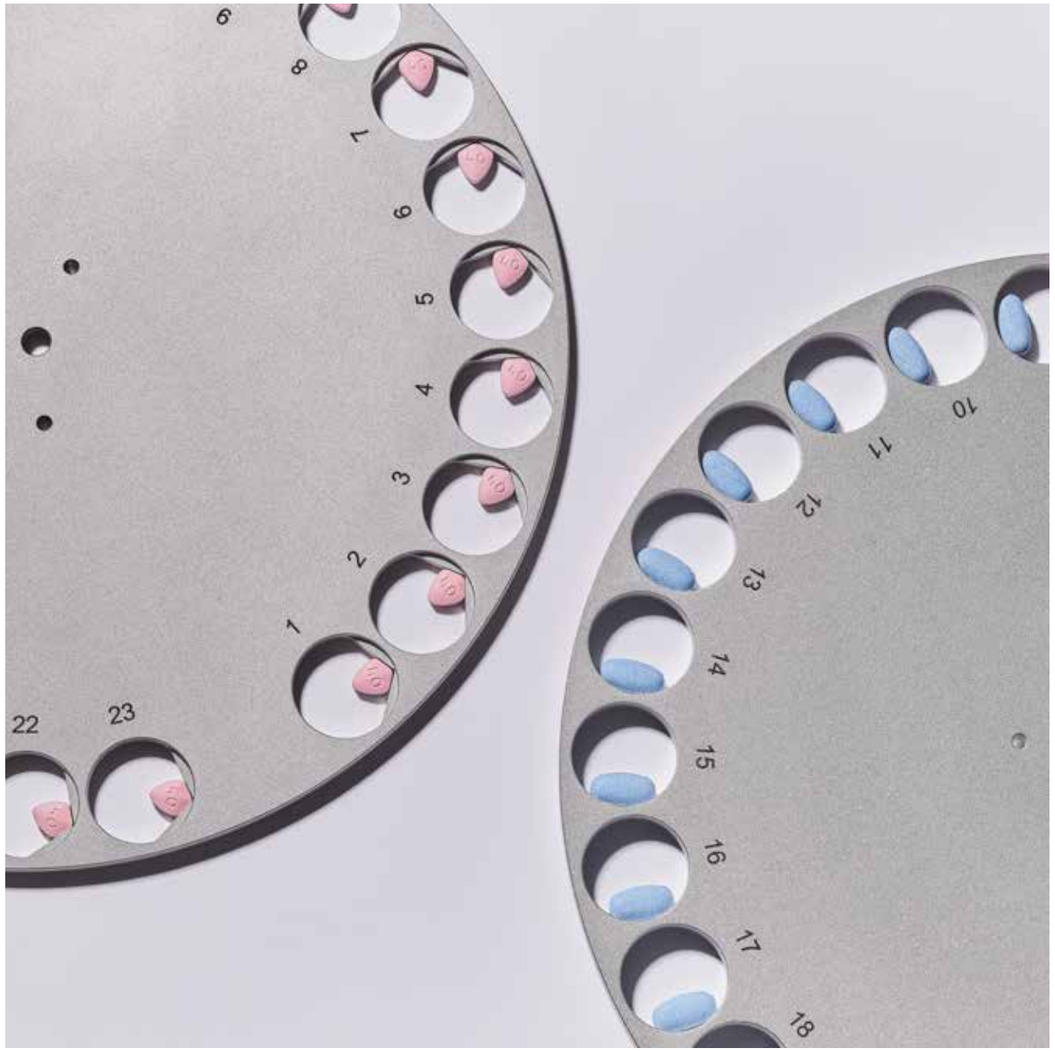
Reliable tablet orientation with Smart Align™



Fast. Precise. Flexible.

The ST50 with patented SmartAlign™ tablet positioning system handles an exceptionally wide range of tablet sizes and shapes. Optimized jaw movements, powerful electronics, and a special “sensitive mode” for breaking forces as low as 2 N allow testing of small mini-tabs, very hard tablets up to 800 N, and even large effervescent tablets up to 25 mm diameter – all on the same unit.

Hardness
Semi-Automatic



Special applications.

Proven to master even the most unusual shapes, the ST50 can be fitted with a custom carousel specifically designed for your application. Change-over only takes seconds and doesn’t require any tools. Because settings are stored individually for each product and method, the correct custom parameters are automatically loaded when starting a test run.

Video monitoring.

The ST50 can be optionally fitted with video monitoring to automatically record the tablet position during width, length / diameter, and hardness measuring. Video clips are created for each sample – marked with tablet ID# and time stamp for easy retrieval in case of OOS investigations. In R&D, it provides great observation possibilities for better understanding of breaking characteristics.

Intuitive and user-friendly with EasyTouch™

Simple.

Intuitive icon-based navigation and logical menu structures with intelligent operator assistance ensure fast test setup, short training times, and error-free data entry. Although available in more than 15 different languages, the visual EasyTouch™ experience is almost language independent.
To prevent unauthorized access, the ST50 features a complete user administration.

Prevent mistakes.

Whenever a test is performed, all required product and method parameters are automatically loaded – ensuring that test conditions comply with your specifications. Because key test parameters such as nominal values, tolerances, and even the hardness measuring principle may differ from product to product, the EasyTouch™ manages all settings individually per product.

Reporting.

The ST50 offers two configurable templates for your test protocols – from comprehensive reports to very basic reporting needs. At the end of each run, a test protocol is automatically printed. Alternatively, results can be exported to a USB flash drive or stored electronically in a central SQL database for consolidated batch reporting with q-doc® data management.

SmartWay™ —
Send test runs to the ST50.

Managing your testing processes including all method specifications and test results from multiple instruments has never been easier. With SmartWay™ networking, you don't even need a computer next to your tester(s). Supervisors send test runs to be performed directly to one or multiple instruments using q-doc® data management. All operators have to do is to insert tablets and press the "START" button on the ST50 touch screen.

Calibration — Simply precise.

Static qualification with a single SmartCal™ reference weight that can be applied in multiple positions

Static qualification with SmartCal™

The patented SmartCal™ system uses a single certified reference weight in multiple positions to change the force applied on the ST50 load cell. A menu-guided qualification routine allows for high-precision adjustment and verification with different loads applied. Calibration does not require any (partial) disassembly of the tester or stacking of several reference weights.

Dynamic qualification of the entire hardness range without requiring static reference weights

DQD™ dynamic qualification.

Using a fully traceable and certified high-precision load cell, the entire hardness range can be qualified using the DQD™ qualification tool. A fully automated routine allows to adjust and verify the complete measuring range on multiple points without requiring static reference weights. Ask your local sales and service partner for more information on available SOTAX Premium Services.

ST50 Technical Specifications

Weight (Mass)	Integrated weighing module	Sartorius®
	Units of measure	mg / g
	Resolution	0.1 mg
	Measuring range	up to 60 g
	Repeatability (typically)	0.15 mg
	Linearity deviation (typically)	± 0.2 mg
	External balance	Mettler Toledo® / Sartorius®
	Resolution	1.0 mg / 0.1 mg / 0.01 mg
Thickness	Units of measure	mm / inch
	Resolution	0.01 mm
	Measuring range	2 – 15 mm
	Repeatability	± 0.03 mm
Width / Length (Diameter)	Units of measure	mm / inch
	Resolution	0.01 mm
	Measuring range	2 – 25 mm
	Repeatability	± 0.03 mm
Hardness	Units of measure	N / Kp / Sc / UDF
	Measuring range	2 – 800 N
	Repeatability	± 1 N
	Dr. Schleuniger® S-beam load cell	99.98 % linearity, over entire measuring range
	Calibration (Adjustment / Verification)	Static: with SmartCal™ weights; dynamic: with DQD™
Measuring principle	Constant speed	0.05 – 5 mm/s, programmable
	Linear force increase	10 – 200 N/s, programmable
Printer	PostScript® 3 (PS3)	Ethernet, USB
	Epson® 40col.	RS-232 serial
Interfaces		Ethernet, 2 × USB, 3 × RS-232 serial
Power supply		100 – 240 V / 50 – 60 Hz
CE Conformity	The ST50 fully complies with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

		WTDH	TDH+
Configuration	Weight (Mass)	Integrated	External
	Thickness	●	●
	Width	●	●
	Length (Diameter)	●	●
	Hardness	●	●
Safety cover	(anti-static)	●	○
EasyTouch™	Program capacity	100 products	100 products
	User administration	●	●
	Xport™ option (export on USB flash drive)	○	○
Data Management	q-doc® software, with SmartWay™ networking	○	○
	Video monitoring	○	○
Weight	(without packaging)	32 kg (71 lbs)	30 kg (67 lbs)
Dimensions	Width	395 mm (15.6 inch)	395 mm (15.6 inch)
	Depth	505 mm (19.9 inch)	505 mm (19.9 inch)
	Height	260 mm (10.3 inch)	256 mm (10.1 inch)

● included / required
○ optional

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Hardness
Automatic

AT 50

The AT50 sets new standards for highly efficient testing of multiple batches in the lab – or fully integrated online testing with your tablet press. Robust and fast with reliable precision.

Automatic Tablet Testing System

AT50 — One for All.

sotax.com/AT50

For all your tablets

Fast testing of 5 parameters

Small footprint

Online with your tablet press

Benchtop in R&D, QC, and IPC labs

Universal high-speed separator for reliable feeding of all shapes and sizes

Short cycle times with minimal distances between stations

Weight measuring station with fast “weight only” mode

Linear feeder prevents convex tablet shapes from rolling

High visibility and very easy cleaning of entire test area

Capsuled Width / Length (Diameter) / Hardness measuring station

Reliable orientation of all tablet shapes with AutoAlign™ and SmartAlign™

Thickness measuring with integrated TouchControl™ sensor

Networking with q-doc® data management or online integration with your tablet press

For all your products.

Convex | Oblong | Oval | Almond | Hexagon | Round | Triangle

All tablets.
All environments.

Reliable positioning of samples for repeatable results is at the very heart of the AT50. Knowing that some tablet shapes pose different automation challenges for separation, transport, and correct alignment, our engineers combined proven features with new innovations. The result is an extremely flexible, robust, and fast automatic testing system. The AT50 simply handles all your tablets – including difficult-to-orient oblongs, oval tablets, and even unconventional convex or flat shapes.

Make testing continuous.

Up to 10 different products can be loaded concurrently using an integrated magazine feeder. Once started, the AT50 executes complete sequences of test runs without requiring any change-over. You can even make your testing continuous by adding new sample sets to empty magazines anytime.

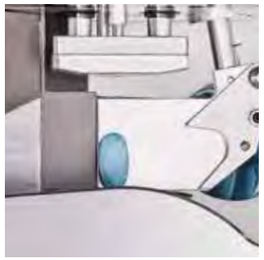
Short cycle times.

Universal separator.

The self-adjusting high-speed feeder reliably separates all sizes and shapes – from very small samples to large effervescent tablets.

SmartAlign™

A flap with tilting mechanism reliably positions all standard shapes and unconventional dosage forms such as hexagonal tablets.



AutoAlign™

Two counter-rotating rollers accurately align even the most convex shapes for width / length (diameter) / hardness measuring.

Trouble-free weighing.

Tablets are automatically centered on the vibration-resistant weighing platform. Fragments or double tablets are immediately discharged.

Highly accurate thickness.

A linear feed track ensures that tablets always arrive on their convex side for correct thickness measuring. An integrated TouchControl™ sensor prevents compression during measuring.

For the lab.

SmartAdd™ — Keep on running.

Short cycle times and multi-batch handling make the AT50 a true workhorse for your laboratory. Receive a new lot from production for urgent testing or a new stability timepoint comes into the lab? No problem, the SmartAdd™ magazine feeder allows flexible interaction and avoids downtime.

Compact — Minimum bench space.

Compact and robust, the AT50 has a small footprint and fits on a standard laboratory bench. The open test area ensures that measuring processes remain fully visible at all times and that operators can easily perform routine cleaning of the stations.

Load up to 10 different products

Continuous testing

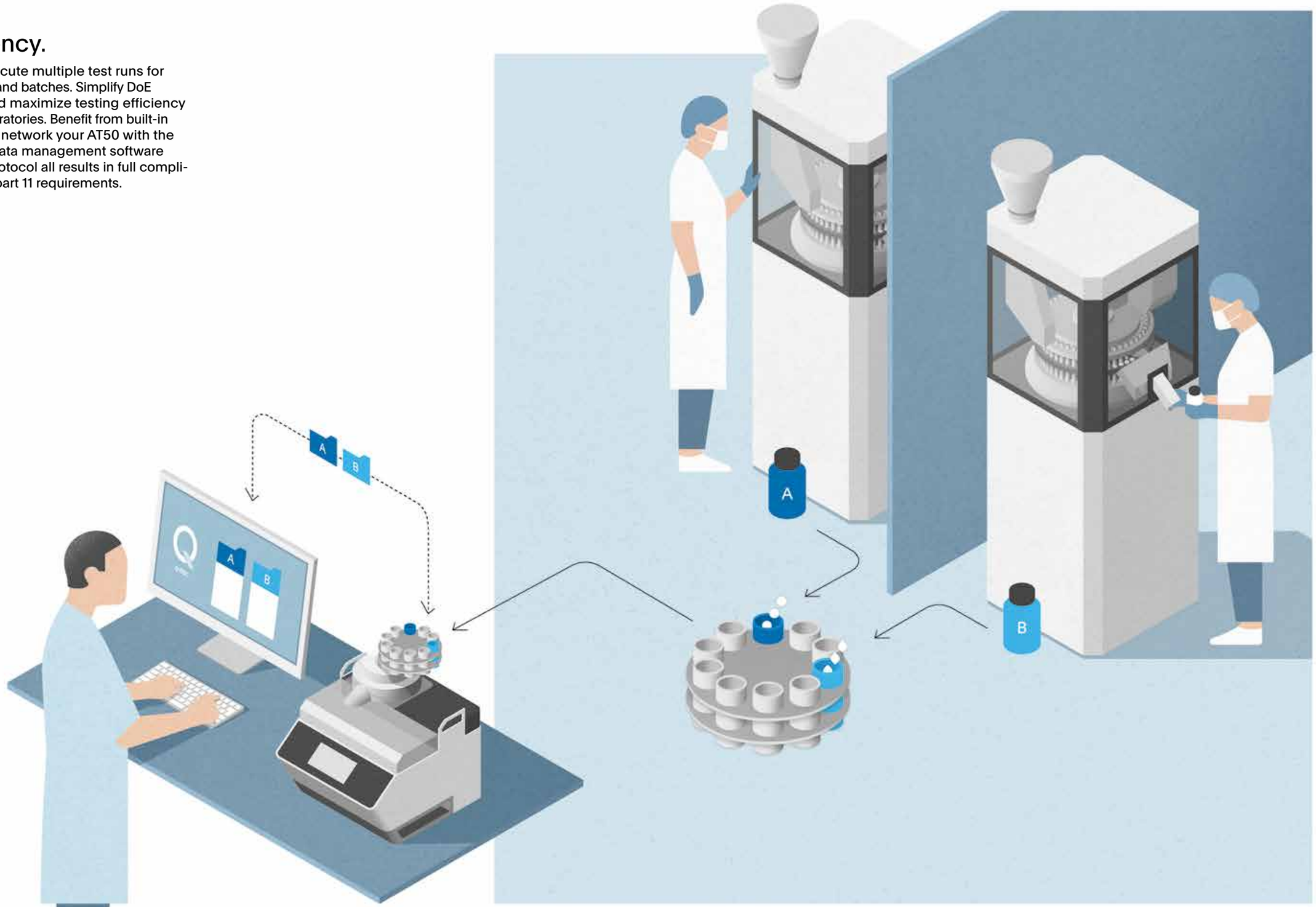
Add new sample sets anytime

No change-over

Excellent visibility of all processes

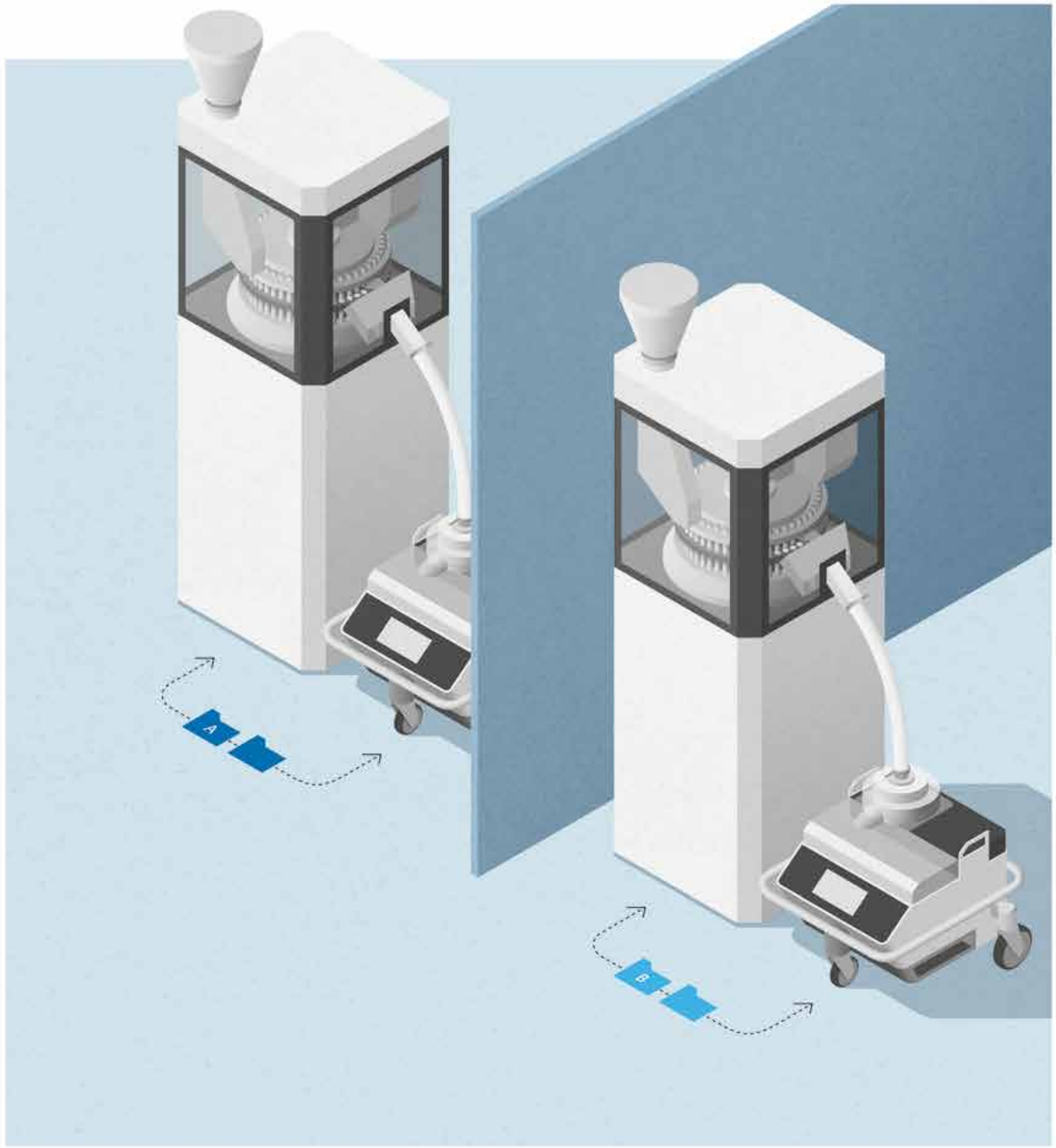
Lab efficiency.

Automatically execute multiple test runs for different products and batches. Simplify DoE studies in R&D and maximize testing efficiency in QC and IPC laboratories. Benefit from built-in data integrity and network your AT50 with the powerful q-doc® data management software to automatically protocol all results in full compliance with 21 CFR part 11 requirements.



For your tablet press.

Designed for demanding environments such as compression rooms, the AT50 can be connected online with your tablet press for 100 % unattended in-process control (IPC). Tablet samples are automatically diverted and tested in regular time intervals – without any operator required. Based on measured results, the tablet press self-adjusts compression parameters if needed.



Sample collection.

Collect samples at regular time intervals for future reference or for further testing in the lab. Tested, non-broken tablets are automatically diverted into individual bins. Different collection modes for double-sided presses and bulk collection are readily available.

No dust inside the tester.

Prevent dust from entering the AT50 using our unique DustX™ brake cyclone. Diverted samples are gently decelerated as they arrive at the tester and dust is completely removed. Ideal for both single and double-sided tablet presses with venturi system.

AT50 Technical Specifications

Weight (Mass)	Integrated weighing module	Mettler Toledo®
	Units of measure	mg / g
	Resolution	0.1 mg
	Measuring range	up to 60 g
	Repeatability (typically)	0.15 mg
	Linearity deviation (typically)	0.3 mg
Thickness	Units of measure	mm / inch
	Resolution	0.01 mm
	Measuring range	2 – 20 mm
	Repeatability	± 0.03 mm
Width / Length (Diameter)	Units of measure	mm / inch
	Resolution	0.01 mm
	Measuring range	2 – 25 mm
	Repeatability	± 0.03 mm
Hardness	Units of measure	N / Kp / Sc
	Measuring range	2 – 800 N
	Repeatability	± 1 N
	Dr. Schleuniger® S-beam load cell	99.98 % linearity, over entire measuring range
	Calibration (Adjustment / Verification)	Static: with reference weights; dynamic: with DQD™
Measuring principle	Constant speed	0.05 – 5 mm/s, programmable
	Linear force increase	10 – 200 N/s, programmable
Power supply		100 – 240 V / 50 – 60 Hz
CE Conformity	The AT50 fully complies with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

		Stand-alone	Online
Configuration	10-magazine feeder, with SmartAdd™	○	–
	DustX™ brake cyclone	–	○
	Sample collector, with 10 collection bins	–	○
	Integrated wheels	–	●
	Integrated feet	●	–
Tablet alignment	SmartAlign™ with flap	●	●
	AutoAlign™ with rollers	○	○
Controller	q-doc® data management software	●	○
	Tablet press *	–	●
Ingress protection	(against dust and water)	IP52	IP52
Weight	(without packaging)	70.5 kg (156 lbs)	76 kg (168 lbs)
Dimensions	Width	450 mm (17.8 inch)	580 mm (22.8 inch)
	Depth	600 mm (23.7 inch)	730 mm (28.7 inch)
	Height	475 mm (18.7 inch)	527 mm (20.8 inch)

* Different communication protocols available for various tablet press models

● included / required
○ optional

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Disintegration

Disintegration testing determines whether tablets or capsules disintegrate within a defined period of time when placed in a liquid medium. Compliant design according to current Pharmacopeia (USP <701>, USP <2040>, Ph. Eur. 2.9.1) and robust Swiss quality components provide a reproducible and standardized method of ensuring that complete disintegration has taken place. Innovative automated end-point detection and recording of individual disintegration times per sample allow unattended testing without manual observation by operators.

Disintegration
Automatic

DT 50

The bathless DT50 revolutionizes disintegration testing.
Easy to operate with automatic test start, induction heating system, and 100 % unattended end-point detection.

Automatic Disintegration Tester

DT50 — Bathless. Better. Beautiful.

sotax.com/DT50

User-friendly touch screen operation

Fully compliant wireless self-centering baskets

Automatic test start when target temperature has been reached

100 % unattended end-point detection for each tablet

Continuous monitoring of medium temperature

Bathless induction heating for very short heating times

Master Station

Modular additional stations

Client Station

Preheating of media for seamless pH-changes

Media Preparation Station

100 % unattended end-point detection

Bathless

Automatic test start

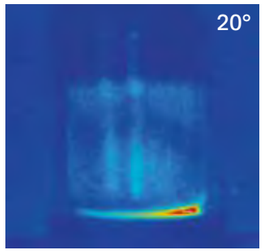
Permanent medium temperature monitoring

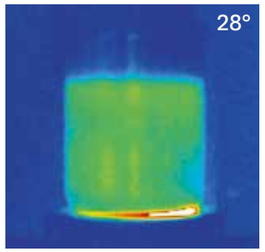
Electronic data management

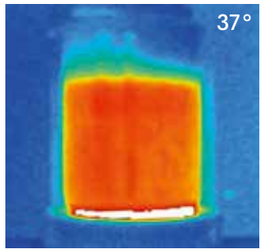
Innovative design.

Temperature under control.

Fast bathless induction heating reduces unproductive waiting times to an absolute minimum and ensures very homogeneous temperature distribution inside the beaker. Medium temperature is permanently monitored. Once the target temperature has been reached, the test starts automatically – and continuous temperature readings are taken for reporting purposes.





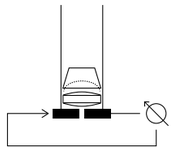


End-point detection. 100 % unattended.

How does it work?

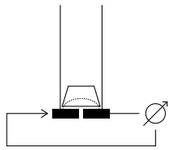
The unique split-sieve technology automatically detects whether a tablet has completely disintegrated. Each disc features pins, that connect the opposite outer sides. As soon as a test object has completely disintegrated, the opposing pins bridge the split sieve – and the time since test start is recorded.

Tablet intact



Split sieve parts do not connect

Tablet disintegrated



Contact through pins in disc

Flexible configurations.

Extend your DT50 to a disintegration system with up to four independent testing stations – plus one Media Preparation Station. Retrofit is simple with a standard Ethernet connection. The modular design ensures that the system layout remains flexible and can be changed anytime if needed.

Easy handling.

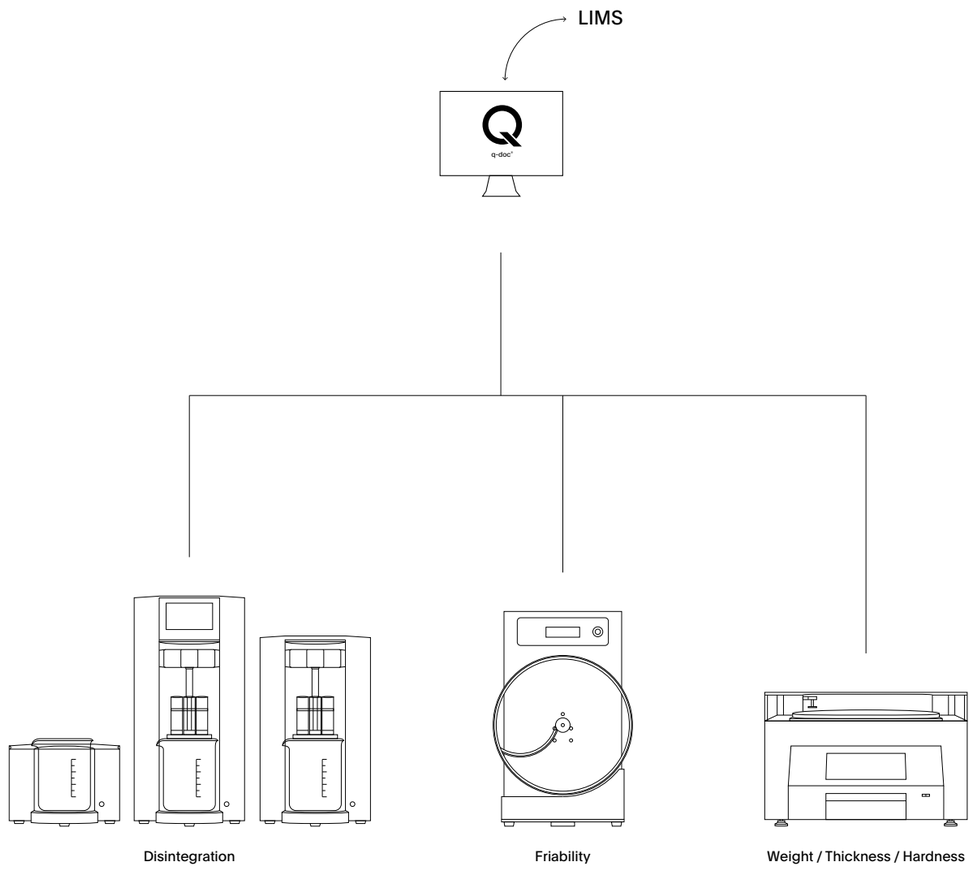
From test setup to cleaning – the DT50 has been optimized for fast and ergonomic handling. The wireless baskets with self-centering magnetic coupling can be exchanged within seconds. Upon completion of each test, a report with recorded disintegration times per tablet, statistics, and temperature protocol is automatically printed.

Maximum Configuration with 1 × Master Station, 3 × Client Station, and 1 × Media Preparation Station

Manage your data.

The DT50 integrates seamlessly with q-doc® data management software. Each station is controlled individually. To make testing of large tablets and re-tests according to USP <701> as easy as possible, results from multiple stations can be combined into a single test protocol. For efficient batch analysis, q-doc® automatically consolidates all testing data into one clearly structured batch report.

Example:
q-doc® network with DT50



DT50 Technical Specifications

Stations		1 – 4 independent test stations
End-point detection	Technology	Split sieves, discs with detection pins
	Automatic detection mode, per sample	●
	Manual detection mode, per sample	●
	Manual detection mode, all samples	●
Basket types (Apparatus A)	6-tube basket, 10 mesh, automatic	○
	6-tube basket, 10 mesh, manual	○
Basket types (Apparatus B)	3-tube basket, 10 mesh, automatic	○
	3-tube basket, 10 mesh, manual	○
Other basket types	6-tube basket, 18 mesh, automatic	○
	6-tube basket, 31 mesh, automatic	○
	Single tube basket, 10 mesh, manual	○
Accessories	Capsules support, for 6-tube basket	○
	Disc remover tool	○
Strokes per minute	Frequency (setting according to USP / Ph. Eur.)	30
	Frequency (setting according to JP)	31
	Accuracy	± 1
Stroke height	Height	55 mm
	Accuracy	± 2 mm
Temperature	Range	25 – 40 °C, programmable
	Temperature control	IR sensor, per station
	Measuring accuracy	± 0.2 °C
User interface*	Program capacity	100 products / methods
	User access restriction	●
Printer*	PostScript® 3 (PS3)	Ethernet
	Epson® 40col.	RS-232 serial
Data Management*	q-doc® software, with full control of stations	○
CE Conformity	The DT50 fully complies with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

		Master	Client	Media Preparation
Max. # stations	(per system)	1	3	1
Interfaces	Ethernet	●	●	–
	RS-232 serial	●	–	●
Power supply	100 – 240 V / 50 – 60 Hz	●	●	●
Power consumption		50 Watt / 3A	50 Watt / 3A	50 Watt / 3A
Weight	(without packaging)	8 kg (18 lbs)	7 kg (16 lbs)	3 kg (7 lbs)
Dimensions	Width	225 mm (8.9 inch)	225 mm (8.9 inch)	225 mm (8.9 inch)
	Depth	200 mm (7.9 inch)	200 mm (7.9 inch)	200 mm (7.9 inch)
	Height	460 mm (18.1 inch)	380 mm (14.9 inch)	155 mm (6.1 inch)

* applies to DT50 system (Client station control via Master station)

● included / required
○ optional

Technical specifications are subject to change without prior notice. Products illustrated in this brochure may include options or modifications not fitted as standard. No liability for errors and omissions.

DT 2

Manual Disintegration Tester

Record and report disintegration times individually per sample or as a completed set. Two independent stations with reliable temperature control.

DT2 — Advanced Simplicity.

sotax.com/DT2

Method programming and alarm signal for pH change

Recording of individual disintegration times per sample or of a complete set

Powerful integrated heating system with sensor

Fully compliant manual baskets with unique quick-lock mechanism to prevent horizontal movement

Printing of test protocols

Temperature probe can be attached to a basket for medium temperature monitoring

Two independent stations

- Independent stations
- Recording of individual end-points
- Different test run modes
- Precise temperature control
- Printing of test protocols

Change-over.

Changing baskets is fast and easy. The unique quick-lock mechanism allows to quickly attach prepared basket assemblies and prevents horizontal movement during tests – ensuring repeatable test conditions. Automated basket lift-in / out and audible alarm signals further add to the user-friendliness of the DT2.

Temperature.

An integrated heating system with dual-sensor ensures precise temperature control of the test medium. A built-in sensor continuously monitors the circulating water temperature and an additional external probe can be mounted on the basket to monitor the medium temperature during the test.

Protocol as needed.

The DT2 allows to record and report disintegration times in different test modes. End-points can be protocolled individually per sample – or alternatively the operator simply checks whether all samples have disintegrated within the specified run time. If baskets are lifted out during a test for visual checking, the “test hold time” is automatically recorded.

Printed report.

Operators can conveniently print a report at the end of each test documenting disintegration time(s) and test conditions. Depending on how the test has been performed, the test report will show individual disintegration times per tablet / capsule or total run time for a set of samples.

DT2 Technical Specifications

Stations		2 independent stations
End-point detection	Manual detection mode, per sample	●
	Manual detection mode, all samples	●
Baskets (Apparatus A / B)	6-tube basket, 10 mesh, manual	○
	3-tube basket, 10 mesh, manual	○
Strokes per minute	Frequency	30
	Accuracy	±1
Stroke height	Height	55 mm
	Accuracy	±2 mm
Temperature	Range	25 – 40 °C, programmable
	Temperature control	Dual control, built-in sensor / external sensor
	Measuring accuracy	±0.2 °C
Bath capacity		5.5 liter
User interface	Program capacity	10 methods
Printer	Epson® 40col.	IEEE 1284 parallel
Interfaces		IEEE 1284 parallel
Power supply		100 – 240 V / 50 – 60 Hz
Power consumption		1‘100 VA
Weight	(without packaging)	24 kg (53 lbs)
Dimensions	Width	380 mm (14.9 inch)
	Depth	410 mm (16.2 inch)
	Height	560 mm (22.1 inch)
CE Conformity	The DT2 fully complies with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

● included / required
○ optional

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Friability

Friability describes the mass reduction of a solid dosage form such as compressed, uncoated tablets occurring when subjected to mechanical strain during handling such as tumbling, vibration, or rubbing in a blister packaging. According to USP <1216> and Ph. Eur. 2.9.7, a maximum mean weight loss of not more than one percent (1 %) is considered acceptable for most products. Effervescent tablets and chewable tablets may have different specifications for friability. Measurement of tablet friability supplements other physical strength measurements such as abrasion tests and tablet hardness measuring (breaking force determination).

FT 2

Single or dual drum tester with calculation of percent friability / weight loss. Print test protocols and connect your external analytical balance.

Friability and Abrasion Tester

FT2 — Single or dual drum testing.

sotax.com/FT2

- 1 – 2 drums
- Connect analytical balance
- Print test protocols
- Password protection
- Electronic data management

Calculation of percent friability / weight loss and printing of test protocols

Perform two friability / abrasion tests simultaneously

Programmable rotational speed / time

Menu-guided qualification procedure with printed report

Integrated 10° tilting mechanism as per USP

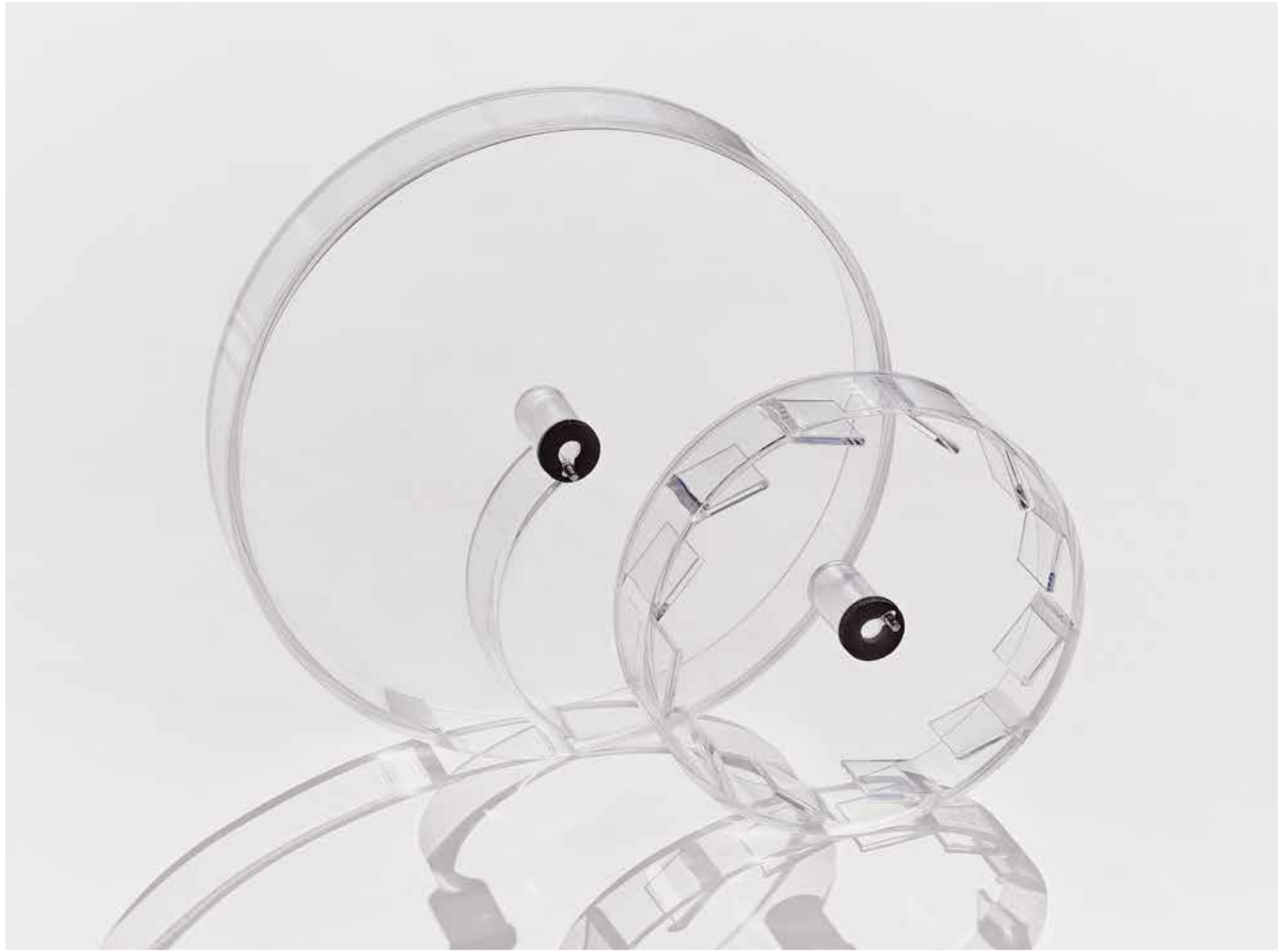
Collection tray for each drum

User-friendly SingleButton™ navigation

Networking and data management with q-doc®

Recording of weight readings from external analytical balance

Ease of regulatory compliance.



Prevent errors.

Manual tasks typically associated with the recording of weight measurements or report creation can be virtually eliminated by connecting a standard laboratory balance. If desired, operators can start tests using a predefined USP / Ph. Eur. method – ensuring that tests are performed according to specifications.

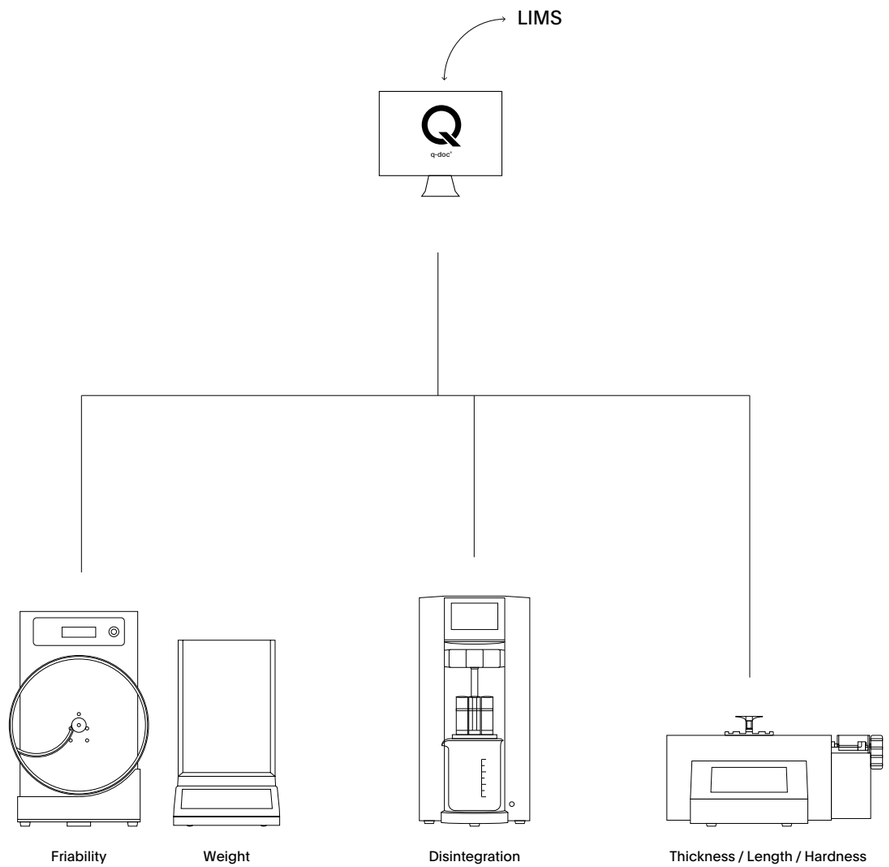
Robust design.

The FT2 features a maintenance-free drive that guarantees gentle starting and stopping motions. A quick-lock system prevents any slippage. Whether operated in single or dual configuration, friability drums don't have to be removed to insert tablets. On completion of a test run, samples are automatically discharged into separate collection trays.

Protocol your test results.

Test protocols including weight loss and percent friability calculations can be conveniently printed directly from the tester. Additionally, the qualification procedure is fully menu-guided including a printed report. If needed, the FT2 can also be integrated with q-doc® data management for consolidated batch reporting of various tests performed on different instruments.

Example:
q-doc® network with FT2



FT2 Technical Specifications

Number of drums		1 – 2
Drum types	Friability drum, anti-static	○
	Abrasion drum, anti-static	○
Test modes	USP <1216>	●
	Ph. Eur. 2.9.7	●
	User-defined	●
Rotation	Speed	20 – 100 rpm, programmable
	Accuracy	±1 rpm
Test modes	Time	●
	Revolution count	●
10° tilting function		●
Balance connection	Mettler Toledo® / Acculab®	●
User interface	Password protection	●
Printer	LAN printer / Epson® 40col.	Ethernet / RS-232 parallel
Data Management	q-doc® software, for data collection	○
Interfaces		Ethernet, 2 × RS-232 serial
Power supply		100 – 240 V / 50 – 60 Hz
Weight	(without packaging)	8 kg (17.7 lbs)
Dimensions	Width	305 mm (12 inch)
	Depth	280 mm (11 inch)
	Height	475 mm (18.7 inch)
CE Conformity	The FT2 fully complies with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

● included / required
○ optional

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Tapped Density

Tapped density of powders or granulates is an increased bulk density attained after mechanically tapping a cylinder containing the sample. SOTAX tapped density testers combine Method 1 and Method 2 with different stroke heights (drop) as described in United States Pharmacopeia (USP <616>) and European Pharmacopoeia (Ph. Eur. 2.9.34) in one compact unit. Comparison of the bulk and tapped densities with Compressibility Index and Hausner Ratio indicate the ability of the powder to flow and settle.

TD 1

Compact tester that combines two USP / Ph. Eur. methods in one instrument. Print test protocols and connect your external analytical balance for automated data transfer.

Tapped Density Tester

TD1 — Compact. Versatile. Compliant.

sotax.com/TD1

Suitable for different cylinder sizes / volumes

Quick-change between different stroke heights for USP / Ph. Eur. methods 1 and 2

Menu-guided qualification procedure with printed report

Test protocols including Tapped Density, Compressibility Index, and Hausner Ratio

Networking and data management with q-doc®

User-friendly SingleButton™ navigation

Recording of weight readings from external analytical balance

Two test methods in one instrument

USP, Ph. Eur., ASTM, and DIN EN ISO compliant

Print test protocols

Password protection

Small footprint

Simply versatile.

The TD1 combines two USP / Ph. Eur. test methods with different stroke heights into one compact single station instrument. Its unique quick-change holder accepts various cylinder sizes – making it the ideal tester for both routine and research tasks. Starting test sequences is fast and easy with SingleButton™ navigation.

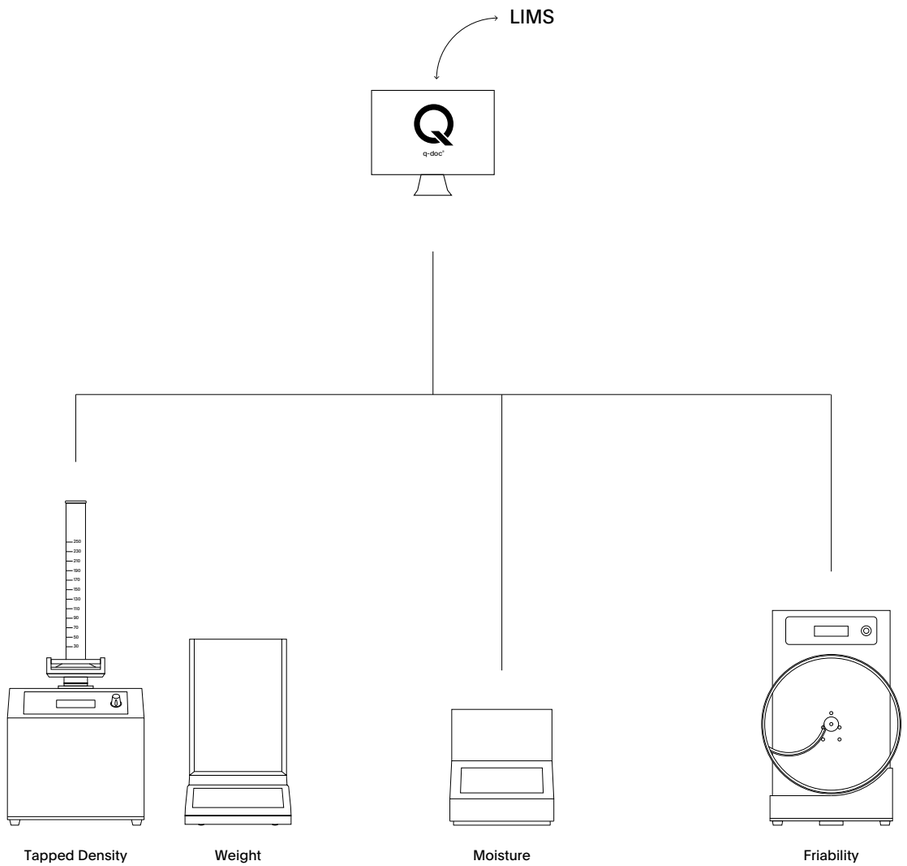
100 % compliance.

Robust in design, the TD1 fully complies with all applicable norms and standards for tapped density testing of powders – including Pharmacopeia, ASTM, and DIN EN ISO. Qualification intervals can be set as required by your internal procedures. To ensure standardized execution, the qualification routine is fully menu-guided.

Report results as needed.

To document testing sequences, the TD1 features built-in reporting capabilities. Test protocols with automatic calculation of Tapped Density, Compressibility Index, and Hausner Ratio can be printed on completion of a test. If needed, the TD1 can also be integrated with q-doc® data management for consolidated batch reporting of various tests performed on different instruments.

Example:
q-doc® network with TD1



TD1 Technical Specifications

Number of stations		1
Test methods	USP <616> / Ph. Eur. 2.9.34, Method 1	●
	USP <616> / Ph. Eur. 2.9.34, Method 2	●
	ASTM B 527	●
	DIN EN ISO 787-11	●
	DIN EN ISO 3953	●
	User-defined	●
Strokes per minute	Method 1	300
	Method 2	250
	User-defined	50 – 300, programmable
Stroke height	Method 1	14 mm, ± 2 mm
	Method 2	3 mm, ± 0.2 mm
Cylinder types	Glass cylinder, 250 mL volume	●
	Glass cylinder, 100 mL volume	●
	Glass cylinder, 25 mL volume	○
	Glass cylinder, 10 mL volume	○
Balance connection	Mettler Toledo® / Acculab®	●
User interface	Password protection	●
Printer	LAN printer / Epson® 40col.	Ethernet / RS-232 serial
Data Management	q-doc® software, for data collection	○
Interfaces		Ethernet, 2 × RS-232 serial
Noise emission	without optional noise reduction cabinet	78 dB (A)
	with optional noise reduction cabinet	58 dB (A)
Power supply		100 – 240 V / 50 – 60 Hz
Weight	(without packaging)	9 kg (19.8 lbs)
Dimensions	Width	230 mm (9.1 inch)
	Depth	300 mm (11.8 inch)
	Height (without glass cylinder)	270 mm (10.6 inch)
CE Conformity	The TD1 fully complies with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

● included / required
○ optional

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Flowability

Characterizing the flow properties of powders and granulates with standardized test methods is essential in pharmaceutical manufacturing. Different “Angle of Repose” and “Flow through an Orifice” type tests are described in Pharmacopeia (USP <1174> and Ph. Eur. 2.9.36). As typically no single test method can adequately characterize the flow properties of pharmaceutical powders, the SOTAX flowability tester combines three standardized testing methods in one robust and versatile unit.

PF 1

Modular tester for standardized powder flow characterization using three different methods according to USP <1174> / Ph. Eur. 2.9.36.

Powder and Granulate Flowability Tester

PF1 — Three in One.

sotax.com/PF1

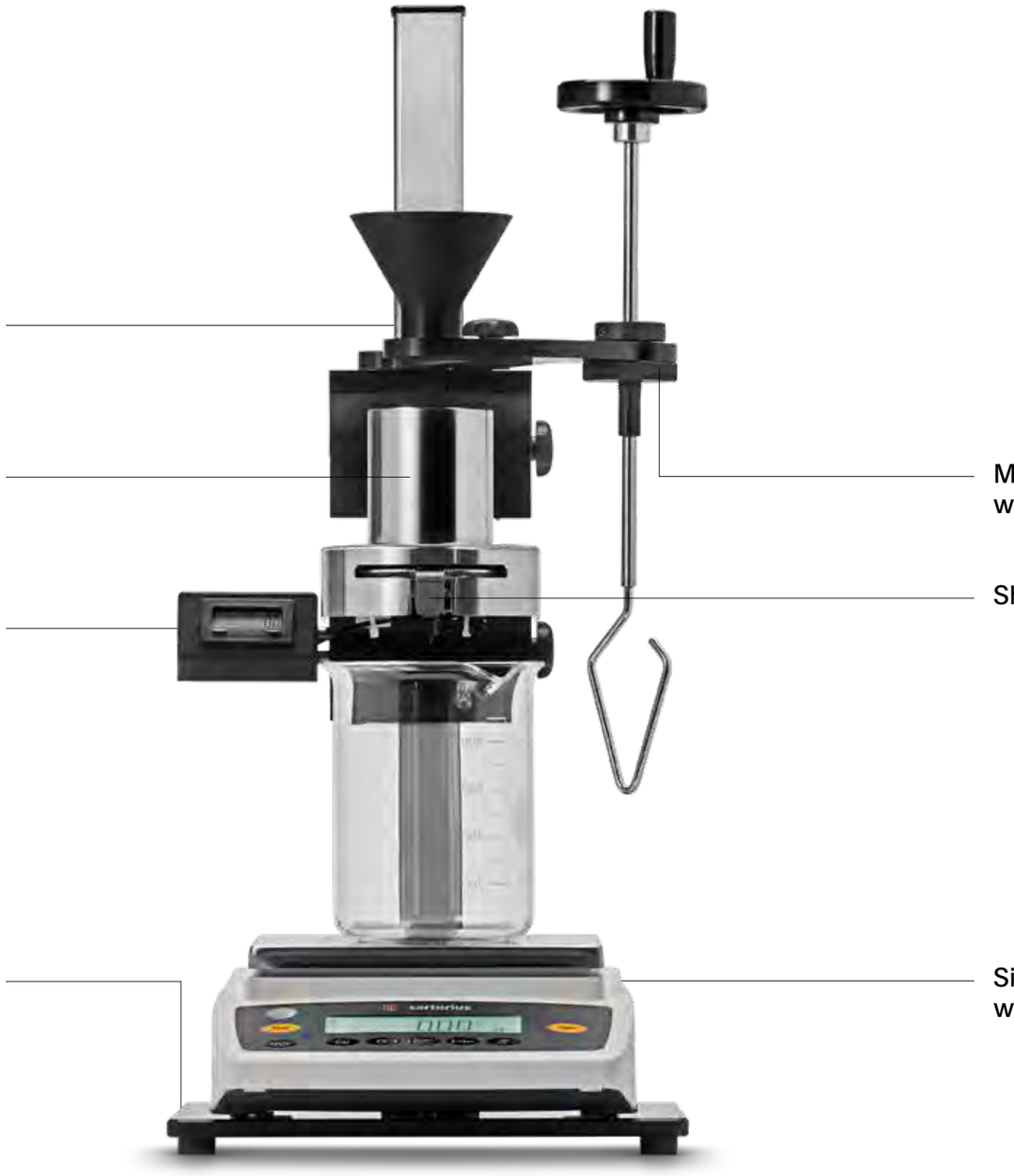
- 3 different test setups
- Flow through an orifice with funnel or cylinder
- Mass per time or volume per time
- Angle of repose
- Timer and balance

Robust stand with two easily height-adjustable arms

“Flow through an orifice” type tests with cylinder or funnel

Integrated timer starts and stops automatically when opening / closing the shutter

The base readily accepts an additional platform for standardized measuring of cone height for “angle of repose” tests



Multi-purpose pivot arm for test setup with stirrer and filling funnel

Shutter to open / close the orifice

Simplified “mass per time” measuring with laboratory balance

Angle of repose.

Evaluate flow properties of solids based on the shape of the cone. By measuring the cone height on a standardized platform, the angle of repose can be easily calculated to classify the powder (e.g. according to Carr). To create a symmetrical cone, the height of the orifice through which the powder passes can be fixed or varied as the pile forms.

PF1 with funnel

Flow through an orifice.

Using the cylinder setup is ideal to determine the flow rate of “powder moving over powder”. This method eliminates the effect of the container material on test results. Discs with different orifices allow for variation of the flow-through opening diameter. To simulate the flow of powder moving along the wall of a container or hopper in a production situation, a funnel in the form of a truncated cone is also available.

PF1 with cylinder

Configurations.

The PF1 can be configured to perform three different types of powder flow tests – and allows to vary test conditions in a repeatable way. When equipped with an analytical balance, the flow rate can be measured continuously to detect momentary flow rate variations.

Angle of repose

Flow through an orifice — with funnel

Flow through an orifice — with cylinder

PF1 Technical Specifications

Pharmacopeia		USP <1174>, EP 2.9.36
Test methods	Flow through an orifice, with funnel	●
	Flow through an orifice, with cylinder	●
	Angle of repose	●
Weight	(without packaging)	20 kg (44.1 lbs)
Dimensions	Width	267 mm (10.5 inch)
	Depth	356 mm (14 inch)
	Height	608 mm (23.9 inch)

	Flow through an orifice, with cylinder	Flow through an orifice, with funnel	Angle of repose*
Stand, with base plate	●	●	●
Multi-purpose pivot arm, height-adjustable	●	●	●
Filling funnel, for pivot arm	●	●	●
Stirrer, for pivot arm	–	○	–
Flow-through arm, height-adjustable	●	●	●
Timer	●	●	●
Funnel, incl. 3 different nozzles	–	●	○
Cylinder, incl. set of 20 discs	●	–	○
Laboratory balance	○	○	–
Glass beaker, 1'000 mL	○	○	–
Platform, incl. collection tray	–	–	●
Digital height gauge	–	–	●

* requires either cylinder or funnel

● included / required
○ optional

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Cap Torque

Child-resistant packaging or C-R packaging has special closures designed to reduce the risk of children ingesting dangerous items. This is often accomplished by the use of a special safety cap. It is required by regulation for prescription drugs, over-the-counter medications, pesticides, and household chemicals. Cap torque testing is performed for both conventional closures and child-resistant bottle caps. In case of liquids, the lower torque limit is considered the minimum pressure of the cap to avoid any leak of the product. The higher torque limit is the maximum force the customer can apply to open or close the product's cap.

TM 200

Proven tester for repeatable measuring of opening and closing force of bottle caps including child-resistant closures and pump caps. Universal or customized adapters for different style closures.

Cap Torque Tester

TM200 — Simple. Universal. Repeatable.

sotax.com/TM200

Motorized drive unit MDU2 for repeatable open and close movements

Quick-change cap adapters, universal or custom-made to the specific shape of a cap

Universal self-centering bottle holder

Networking and data management with q-doc®

Setting of downward force for child-resistant bottle caps

Suited for small bottles to large jugs

Print test protocols and calibration reports

Calibration with traceable reference weights

- Child-resistant closures
- Open and close torque
- Repeatable motorized movements
- Calibration with traceable weights
- Electronic data management

Universal.

The TM200 is specifically designed to precisely measure the opening and closing torque of bottle caps. Its universal holder accommodates anything from small bottles to large jugs. A high-precision load cell located in the main unit continuously measures the force throughout the testing process.

Molded cap adapter –
tailored to individual cap shape

Repeatable.

A motorized drive unit eliminates inconsistencies that would otherwise occur with manual twisting of bottle caps. Caps can be automatically opened and closed with constant and repeatable velocity. For testing child-resistant caps, a defined downward force is exerted on the cap under test.

Cap adapters.

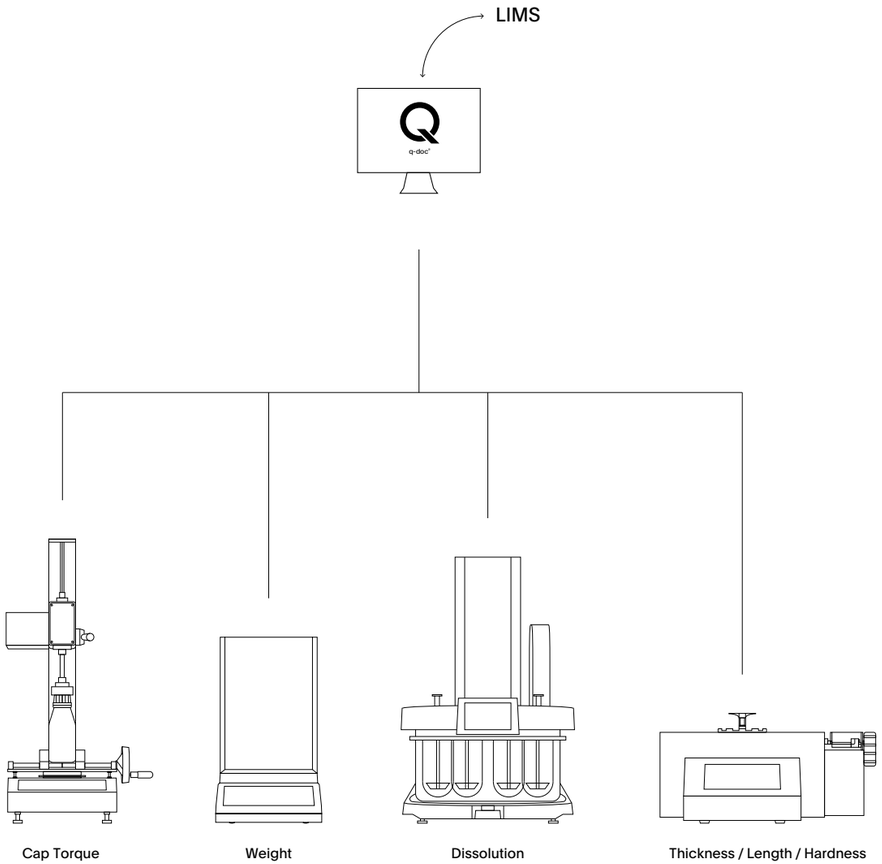
Molded cap adapters that are custom-made to the specific shape of a cap eliminate additional pressure typically caused by clamping or other cap fixtures. Alternatively, universal membrane cap adapters can be utilized for caps with a flat top – minimizing the necessary number of adapters.

Universal membrane adapter –
for caps with a flat top

Manage your test data.

The TM200 allows programming of up to 10 different products. For each test, up to 100 measurements can be protocolled and reported by connecting a printer. Alternatively, the TM200 can be connected with q-doc® software for electronic data collection and consolidated batch reporting from multiple instruments in different departments.

Example:
q-doc® network with TM200



TM200 Technical Specifications

Test modes	Open	●
	Close	●
	Open & Close	●
Torque range		0 – 452 Ncm (0 – 40 lbin)
Unit of measure		Ncm, Nm, kgcm, lbin, lboz
Bottle dimensions	Diameter range	20 – 220 mm
	Max. bottle height *	330 mm
Motorized drive unit	MDU2	○
Cap adapter *	Molded cap adapter, for bottle caps (custom)	○
	Molded cap adapter, for pump caps (custom)	○
	Universal membrane cap adapter, Ø small	○
	Universal membrane cap adapter, Ø medium	○
	Universal membrane cap adapter, Ø large	○
User interface	Program capacity	10
Printer	Epson® 40col.	RS-232 serial
Data Management	q-doc® software, for data collection	○
Interfaces		2 × RS-232 serial
CE Conformity	The TM200 and MDU2 fully comply with all CE and EMC equipment guidelines relative to mechanical and electrical safety and electromagnetic compatibility.	

		TM200	MDU2 drive unit
Power supply		100 – 240 V / 50 – 60 Hz	100 – 240 V / 50 – 60 Hz
Weight	(without packaging)	11.5 kg (25.4 lbs)	20.5 kg (45.2 lbs)
Dimensions	Width	285 mm (11.2 inch)	260 mm (10.2 inch)
	Depth	295 mm (11.6 inch)	395 mm (15.6 inch)
	Height	190 mm (7.5 inch)	795 mm (31.3 inch)

* with motorized drive unit MDU2

● included / required
○ optional

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Data Management

Data management addresses different aspects of data collection, analysis, approval & evaluation, and reporting. Ensuring regulatory compliance and potential efficiency gains are the two main drivers for most software and data management projects at pharmaceutical companies today. From single workstations to multiple networked instruments, SOTAX software solutions improve your data collection, analysis, approval, and reporting processes – while helping your organization to comply with current FDA data integrity guidelines and 21 CFR part 11 regulations on electronic record keeping.

Data
Management

q-doc®

Take control of your data with q-doc® software. Built-in compliance and efficient recording, protocolling, and analysis of test data from more than 35 different instrument types.

Data Management Software

All your data in one place.

Take full control of your data and manage all your methods, results, and users with q-doc®. Use the same method on different systems, consolidate data from multiple test runs in a single report, and avoid redundant management of users and their passwords. From electronic signatures, audit trail, and advanced user management to LDAP integration, batch comparison, and LIMS import / export functions – the q-doc® framework is designed for implementation of an efficient, fully 21 CFR Part 11 compliant system.

sotax.com/q-doc

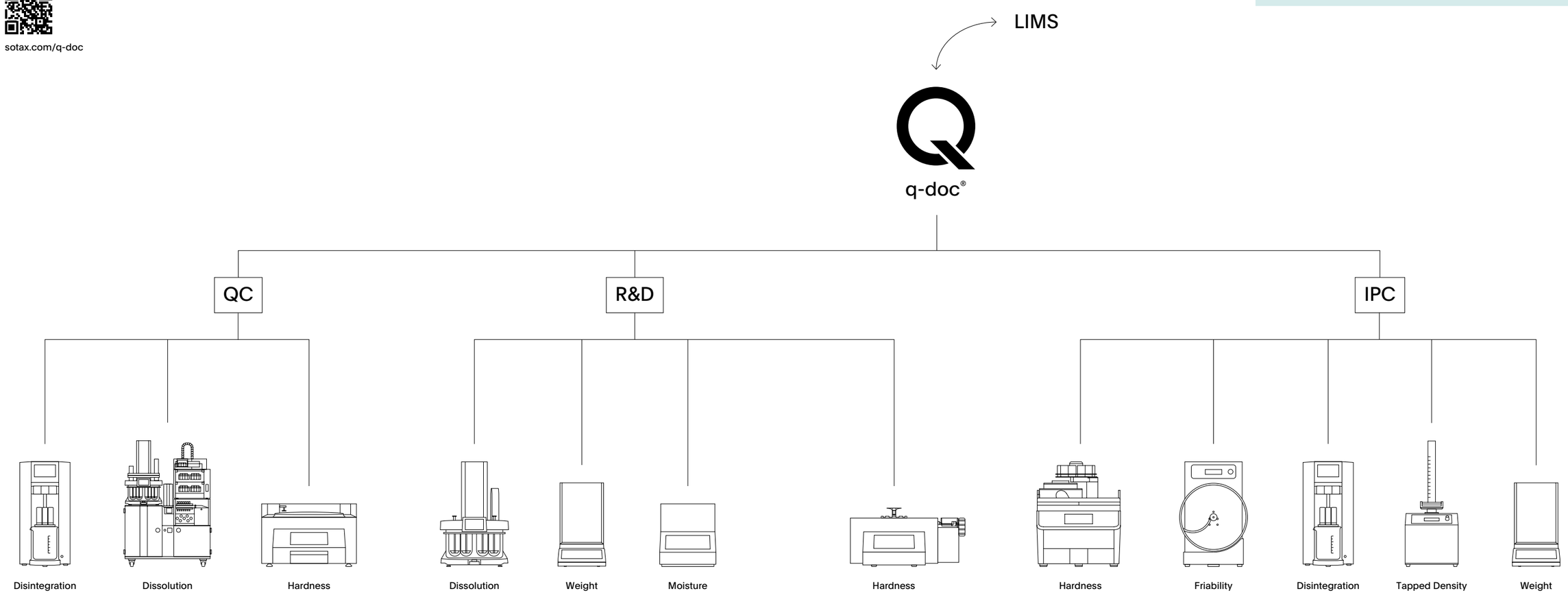
One solution for all instruments

Networking

21 CFR part 11

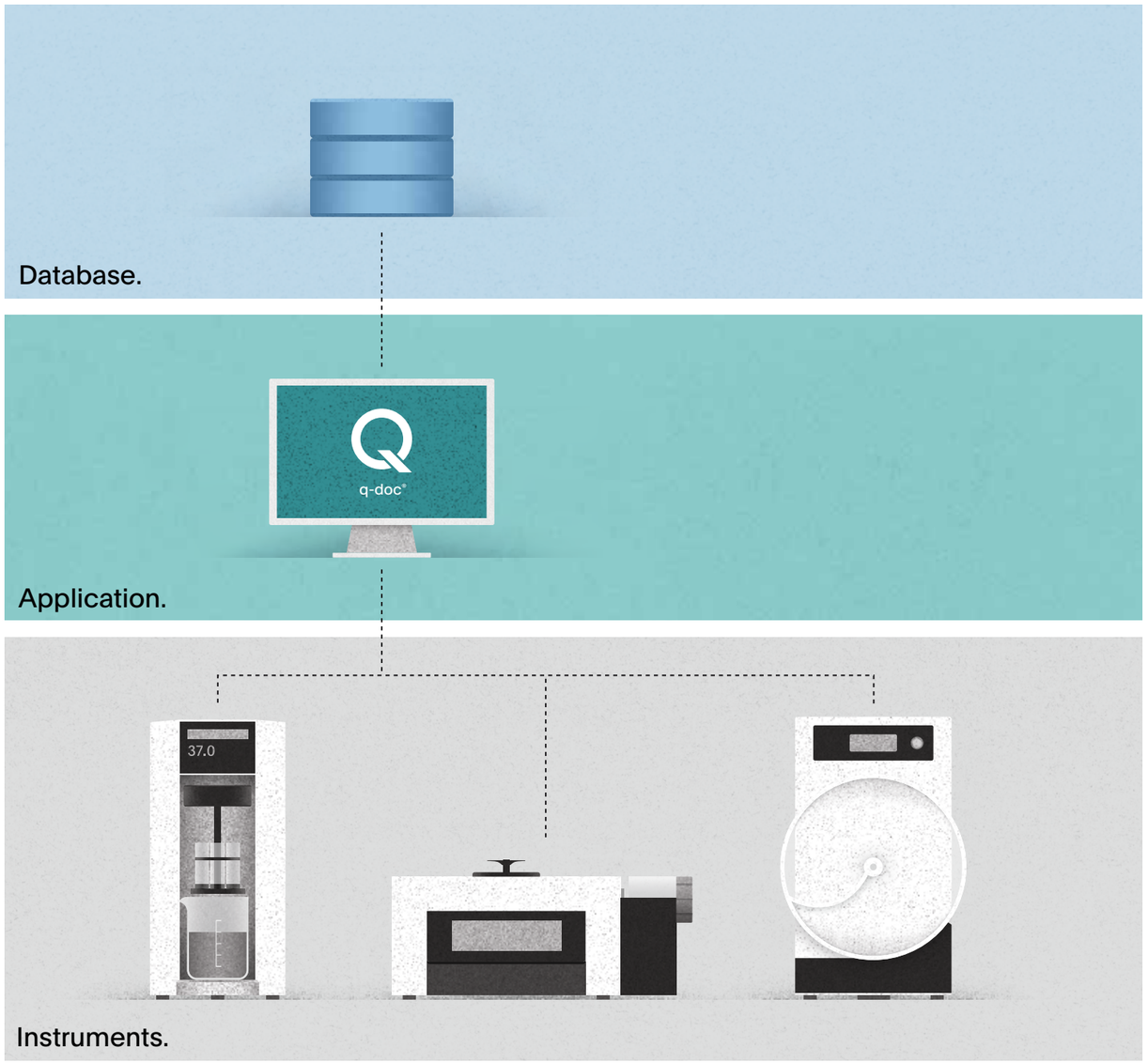
Consolidated batch reporting

Data integrity



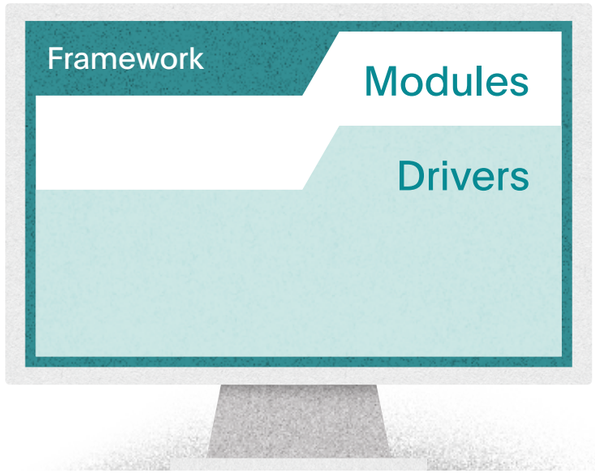
Framework.
Modules. Drivers.

Example: q-doc® single workstation with three connected instruments



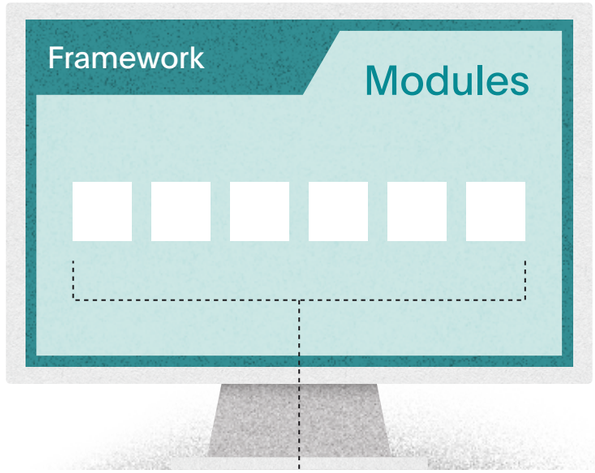
Framework —
All key functions.

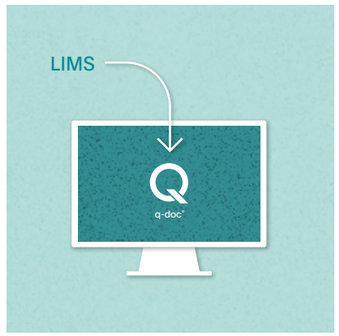
Whether installed on a single PC or on multiple networked computers, the q-doc® framework with central SQL database is designed for both stand-alone and networked operation alike.
It includes all basic functions to collect, record, analyze, evaluate, report, and manage test data in full compliance with 21 CFR part 11 requirements.
To simplify daily processes, login with chip ID, barcode printing, and touchscreen-supported operation are standard.



Modules —
Extend as needed.

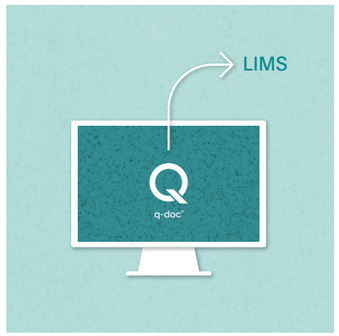
Modules further extend the q-doc® framework with import / export functions, LDAP integration for simplified user administration by IT administrators, data trending and batch comparison to analyze results over a period of time, data evaluation including re-test procedures according to pre-defined USP and Ph. Eur. specifications, and other data management possibilities to simplify operation in large interdisciplinary networks.





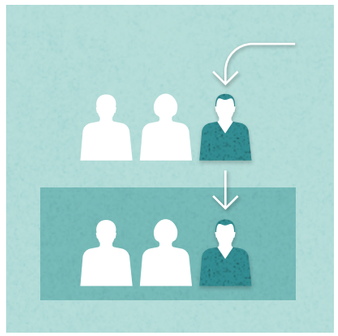
Job Import

Automate daily routine tasks such as registration of new batch numbers or creation of new test runs – and avoid common mistakes caused by manual transcription of complex data strings. The powerful import module allows to automatically transfer information directly from your LIMS, MES, or ERP system to q-doc® without any operator action required.



LIMS Export

How do you want to evaluate your test results? The LIMS export module allows to automatically transfer individual results, test run statistics, and complete batch records to third party systems. Whether you would like to export evaluated test runs (checked & judged) or simply transfer recorded results – the automated process can be flexibly adapted to your needs.

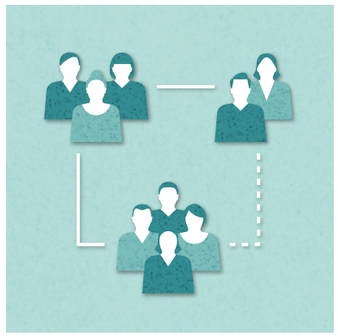


LDAP Integration

Ensure that your company's password policy is "automatically" followed without creating any additional workload. Avoid redundant local user management and directly integrate q-doc® with user groups in your company's Active Directory (AD). No need to remember multiple passwords anymore – operators can simply use their current Windows® password.

Data Trending

No need to export your test results to perform batch comparisons. Use the seamlessly integrated q-doc® data trending module to analyze individual results from all test runs within a batch – or compare multiple batch records over a defined period of time. In IPC, the module allows to view data in real-time on a separate monitor to quickly identify trends.



Workgroups

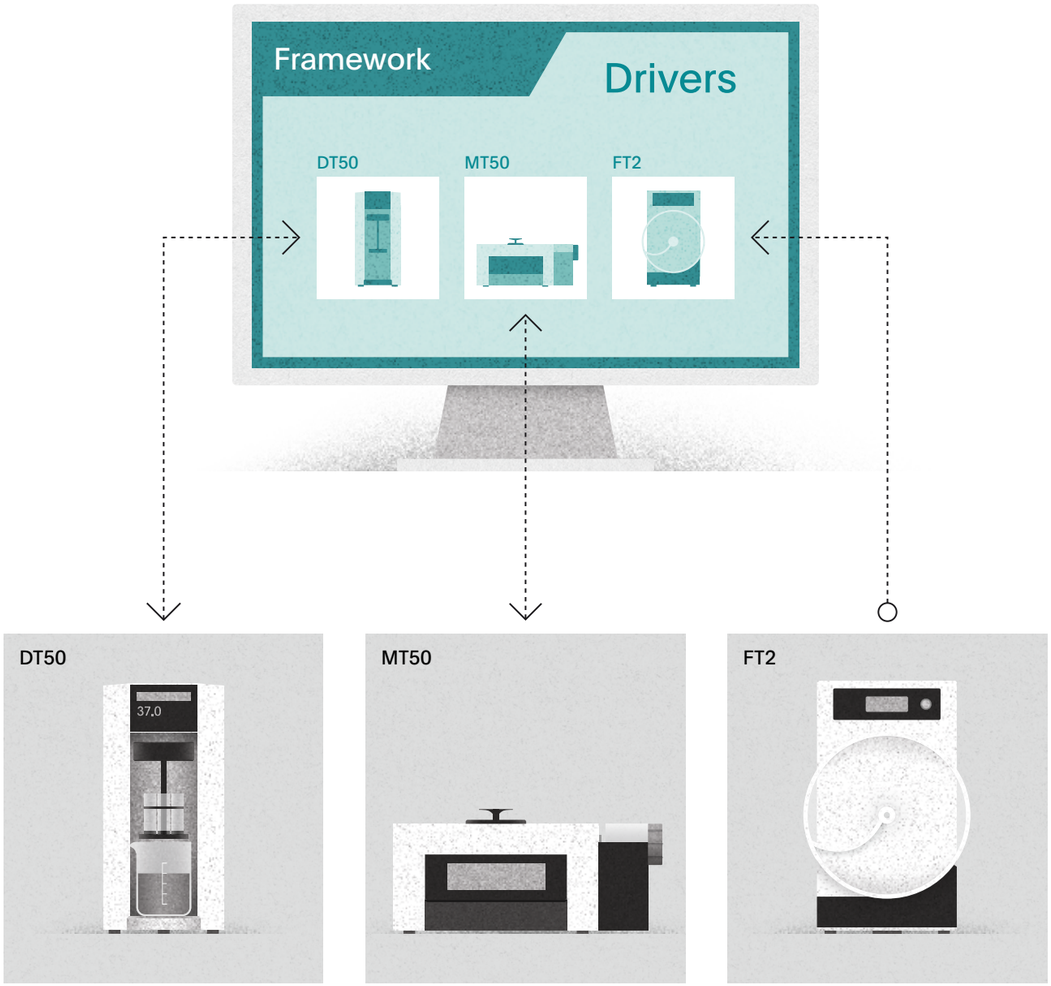
Limit what operators can see on "their" networked q-doc® workstation. Particularly useful for large installations with multiple PCs, the workgroups module allows to flexibly restrict usage by product, batch, or PC – independently from general user rights. People within a workgroup only see the jobs, batches, and tests relevant for their tasks at hand.

Extended Evaluation

- Pass / Fail evaluation and automated re-test procedure <USP 701> and Ph. Eur. 2.9.1
- Evaluate content uniformity based on weight variation <USP 905>
- Calculate tensile strength <USP 1217>
- Pass / Fail evaluation based on Uniformity of Mass according to Ph. Eur. 2.9.5

Drivers —
Connect your instruments.

Record weight measurements from your balances, connect different physical and dissolution testing systems, and seamlessly protocol everything in one place. Standard q-doc® drivers for more than 35 different instrument types and system configurations are readily available for establishing a highly efficient data management system in R&D, QC, and IPC departments.



Instrument		Weight (Mass)	Thickness	Width	Diameter / Length	Hardness	Disintegration	Friability	Tapped Density	Flowability	Moisture	Cap Torque	Dissolution
	Physical Testing												
AT50	Automatic tablet testing system	●	●	●	●	●							
AT4	Automatic tablet testing system	●	●		●	●							
HT100	Automatic tablet testing system	●	●	●	●	●							
ST50	Semi-automatic tablet testing system	●	●	●	●	●							
HT10	Semi-automatic tablet testing system	●	●	●	●	●							
MT50	Manual tablet hardness tester	●	●	●	●	●							
HT1	Manual tablet hardness tester	●	●	●	●	●							
8M	Manual tablet hardness tester	●	●		●	●							
6D	Manual tablet hardness tester				●	●							
DT50	Automatic disintegration tester (1 – 4 stations)						●						
DISI	Automatic disintegration tester (1 – 4 stations)						●						
DT2	Manual disintegration tester (2 stations)						○						
FT2	Friability tester (1 – 2 drums)							●					
TD1	Tapped density tester								●				
FT300	Flowability tester									●			
PF1	Powder and granulate flow tester									○			
TM200	Cap torque tester											●	
Balance	Mettler Toledo® (different models)	●											
Balance	Sartorius® (different models)	●											
Gauge	Mitutoyo® (different models)		●	●	●								
Gauge	Preisser® (different models)		●	●	●								
HR83	Mettler Toledo® moisture analyzer										●		
HX204	Mettler Toledo® moisture analyzer										●		
HS153	Mettler Toledo® moisture analyzer										●		
HB43	Mettler Toledo® moisture analyzer										●		
	Dissolution Testing												
ATF Xtend™	Fully automated dissolution testing system *												●
ATS Xtend™	Semi-automated dissolution testing system *												●
AT Xtend™	Manual dissolution tester												●

* different configurations

● standard q-doc® driver available
○ manual input

Data integrity. Built-in.

From version control to advanced user access right management and a human readable audit trail – q-doc® fulfills all requirements for implementation of a fully 21 CFR part 11 compliant system. Modular documentation packages for qualification / computer system validation ensure ease of regulatory compliance and are proven to be accepted by local authorities all over the world.

No modification of original records
Measurement data (“raw data”) is automatically stored in an SQL database and cannot be edited or deleted.

Audit trail
All relevant user interactions and changes are documented. In case of investigations, entries can be easily searched, filtered, printed, and exported.

Version control
Full traceability of product and method modifications with automatic version control including configurable release procedure with electronic signature.

Electronic signature
q-doc® can be configured to explicitly require an electronic signature to complete critical actions like making changes to method data.

User access restriction
User groups and their access rights can be defined and configured to ensure that only authorized persons can perform certain tasks.

Password security
Even without LDAP integration, q-doc® allows to define several password security rules according to your company policy.

Auto-locking
If there is no user action performed within a configurable time period, q-doc® will automatically lock the application.

q-doc® — Installation requirements

Operating system (OS)	Microsoft®	Windows® 7 / 10, Windows® Server 2008 R2 / 2012 / 2012 R2 / 2016
	System	32 bit, 64 bit
Hardware	RAM	min. 4 GB, better 8 GB
	CPU	min. 2 GHz, better Dual core / Quad core
	Free disc space	min. 20 GB
	Display resolution	1920 × 1080
	Mouse	●
	Keyboard	●
	Communication ports	Depending on connected instruments / systems
Database	MS-SQL® (Express or full version)	2008 R2, 2012, 2014, 2016

● required

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Services

Friendly and competent customer service is key to retaining you as a satisfied customer. Based on this basic premise, our service engineers and sales & service partners assist you throughout the life cycle of your instrumentation – wherever and whenever you need us. Since its foundation in 1973, SOTAX has continuously extended the range of available services and has become a preferred partner of leading pharmaceutical companies worldwide.

Services

From application support to qualification services and on-site assistance – SOTAX service is ready to go the extra mile. Wherever and whenever you need us.

Global Customer Services

Physical Testing Services.

Your Application — Checked.

Send us tablet samples and SOTAX physical testing specialists will assess possibilities for automating your tests. Whether you would like to perform a general feasibility check or need assistance in finding optimum process parameters – our experts are proven to find solutions for even the most unusual tablets shapes and special applications.

Your Questions — Answered.

Our SOTAX support teams in Europe, North America, and Asia find solutions to your technical problems, help in troubleshooting, and coordinate activities with field service if needed. Friendly, uncomplicated support by experienced professionals and product specialists whenever you require assistance.

Your Project — Managed.

Larger installations and networked solutions require planning and coordination. Many projects fail simply due to inadequate preparation and a lack of resources. From URS to implementation in managed phases, qualification, and training – our project managers help your organization to actively address the various challenges on the road ahead.

Your Problems — Prevented.

Extend the life time of your equipment with SOTAX preventive maintenance programs. Avoid costly machine downtime and keep performance high. Our certified service engineers inspect your instruments in regular intervals, exchange critical parts before failure occurs, and execute routine maintenance according to standardized checklists.

Your People — Trained.

Getting the most out of your equipment requires trained and qualified operators, supervisors, and administrators. Standardized training modules allow targeted knowledge transfer – tailored to the different functions within your organization. From performing tests to method programming, user administration, system setting, and reporting of results.

Your Instruments — Compliant.

From first installation to qualification and regular calibration – SOTAX on-site services give you ease of regulatory compliance throughout the life cycle of your instruments. Standardized execution and documentation by certified service engineers ensure results that are accepted by regulatory authorities all over the world.

Analytical Services.

From method development to stability studies and commercial batch release in a US-FDA-inspected, certified Pharmaceutical Establishment with GMP-compliant quality system – our analytical services are a one-stop solution for Pharmaceutical companies. Based on decades of experience and unique application knowhow, our team of experts will find a solution for your specific challenge.

R&D Services

- API screening and characterization
- Feasibility studies
- Method development
- Method automation
- Method validation and re-validation
- Method transfer

Routine Analytical Services (GMP)

- QC analysis
- Stability studies
- Clinical and commercial batch release

Support Services

- Troubleshooting and investigations
- Training
- Consulting
- Audits

Instrument Services.

Friendly and competent local service is the cornerstone of our business. A global network of service engineers and certified SOTAX partners assists you throughout the life cycle of your instrumentation – from on-site installation, qualification, and training, to preventive maintenance, regular re-qualification, and uncomplicated troubleshooting support in case of problems.

Compliance Services

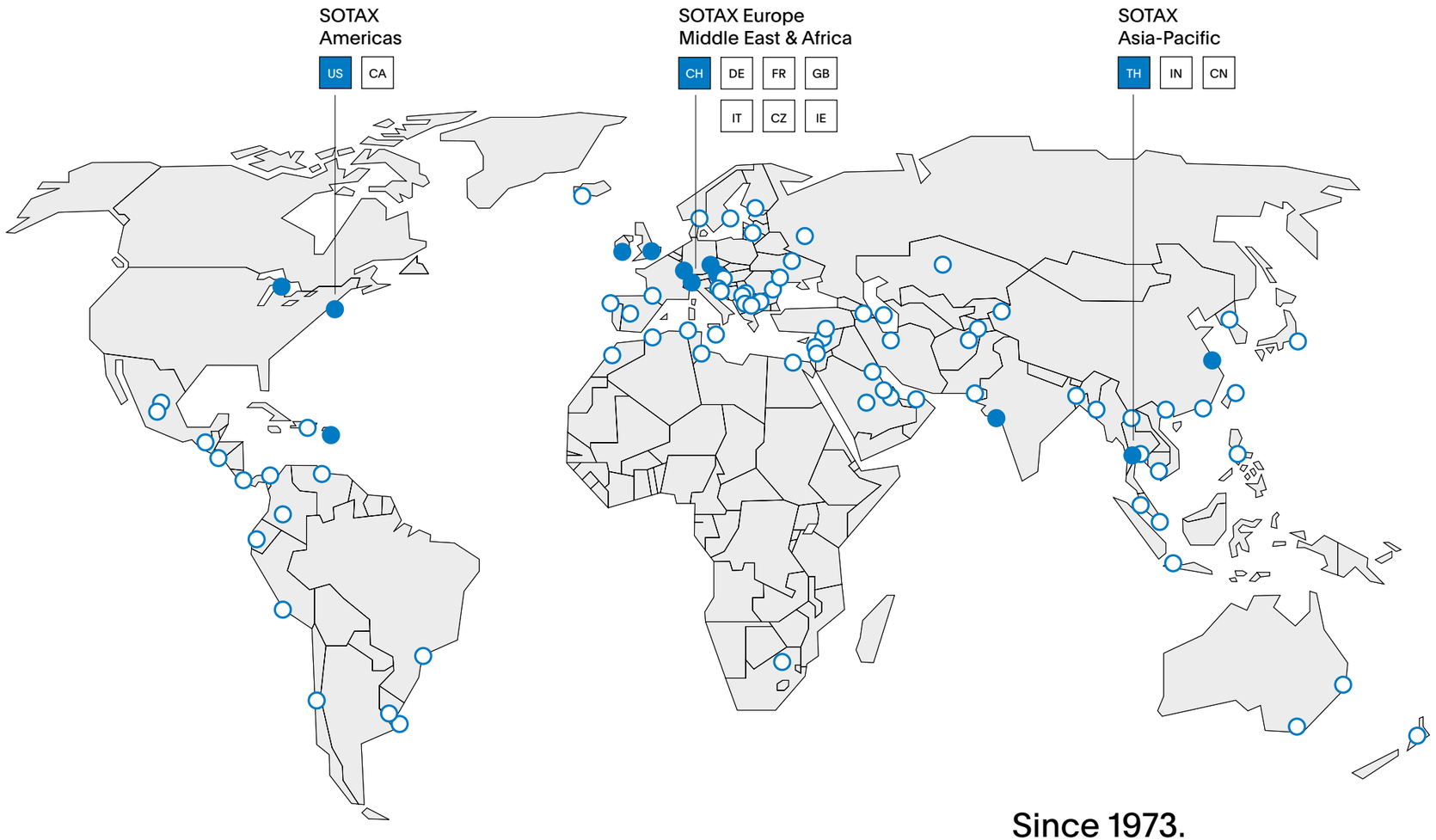
- Installation
- Qualification (IQ / OQ / PQ)
- PVT / ASTM
- Routine calibration and qualification
- Computer system validation (CSV)

Support Services

- Training
- Preventive maintenance
- Troubleshooting
- Repair
- Project management
- FAT / SAT
- LIMS integration
- Relocation services

sotax.com/services

We are there for you. Worldwide.



- SOTAX
- SOTAX Sales and Services Partner

Global network of trained and certified service engineers

Local presence in 90 countries

SOTAX companies in 12 countries

Largest service organization in our industry

Since 1973.

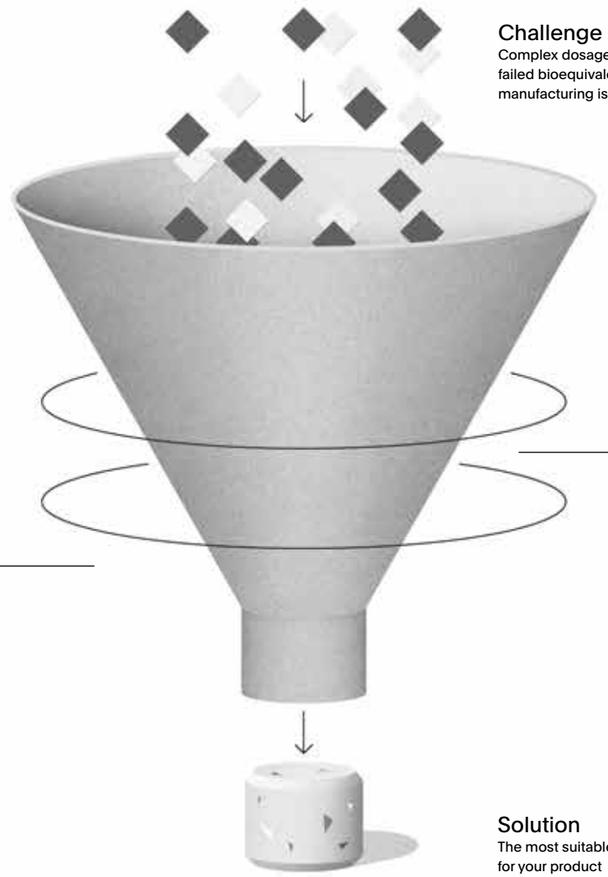
SOTAX is built on services. Deeply rooted in more than 45 years of experience, we are specialists in what we do. Whether you need assistance with method transfer, require application support, or are looking for friendly, competent, and cost-effective qualification of your installed base – we are there for you. Throughout the life cycle of your products. Wherever you are.

sotax.com/worldwide

For Experts.
By Experts.

SOTAX offers unique specialist knowhow in close cooperation with SPS Pharma Services. Set in an independent cGMP-compliant and FDA-inspected facility, a team of scientists, analysts, and lab assistants helps companies worldwide in overcoming the various challenges associated with release testing of pharmaceutical dosage forms.

SPS Pharma Services



Challenge
Complex dosage form, failed bioequivalence study, manufacturing issue

Know-how
Formulation properties, methods, analytics, instrumentation capabilities

Equipment
Dissolution
(USP 1 / 2 / 3 / 4 / 5 / 6 / 7)

Content testing
(uniformity, assay)

Automated platforms

Physical testing

Solution
The most suitable method for your product

SOTAX Customer Services

		Analytical Services	Instrument Services
R&D Services	API screening & characterization	●	–
	Feasibility studies	●	–
	Method development	●	–
	Method automation	●	–
	Method validation & re-validation	●	–
	Method transfer	●	–
Routine Analytical Services (GMP)	QC analysis	●	–
	Stability studies	●	–
	Clinical & Commercial batch release	●	–
Compliance Services	Installation	–	●
	Installation qualification (IQ)	–	●
	Operational qualification (OQ)	–	●
	Performance qualification (PQ)	–	●
	PVT / ASTM	–	●
	Computer system validation (CSV)	–	●
	Routine calibration	–	●
	Routine re-qualification	–	●
Support Services	Training (for different target groups)	●	●
	Acceptance tests (FAT / SAT)	–	●
	Project management	–	●
	Preventive maintenance	–	●
	Troubleshooting & investigations	●	●
	Repair	–	●
	Consulting	●	●
	LIMS integration	–	●
	Audits	●	–
	Relocation services	–	●

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SOTAX Group

SOTAX Group

Reliable automation of simple laborious steps and finding innovative solutions for your testing problems has been our mission since 1973. From the world’s first flow-through dissolution tester to self-cleaning systems, patented tablet alignment, and user-friendly data management – SOTAX engineers specialize in making testing easier, faster, and more precise for you.

Knowing that there is more to a solution than innovative technology, we are proud to have the largest field service organization in our industry. Our global team of application experts, product specialists, and service engineers are looking forward to supporting you whenever you need it.

Whether you need help with an application problem or would like to learn more about possible efficiency gains in dissolution testing, physical testing, or automated sample preparation – SOTAX is your one-stop solution.

Product segments.

Data Management

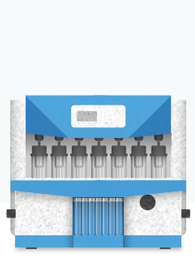
Dissolution Testing

USP 1 / 2 / 5 / 6

- Manual
- Semi-Automated
- Fully Automated

USP 4

- Manual
- Semi-Automated



Automated Sample Preparation

Physical Testing

Hardness	Disintegration
Friability	Tapped Density
Flowability	Cap Torque
PAT	

Customer Services

Analytical Services

R&D Services	Routine Analytical Services (GMP)	Support Services

GMP CERTIFIED FDA

Instrument Services

Compliance Services	Support Services

Driving Innovation. Milestones.

Foundation
SOTAX in Switzerland
(1973)

Flow-Through
Method
Integration in USP
(1991)

Foundation
SOTAX in USA
(1996)

Foundation
SPS Pharma Services
(2005)

Product Line
Content Testing
(2006)

Foundation
SOTAX in India
(2011)

Fully Automated Systems
ATF and AT50
(2018)

Acquisition
Labserv and GNA Analytical
(2019)

Product Line
Flow-Through Dissolution Tester
(1978)

Fully Automated Dissolution Tester
AT 700
(1993)

Product Line
Tablet Hardness Tester
(2002)

Acquisition
Zymark Automation
(2008)

Acquisition
Dr. Schleuniger® Pharmatron
(2013)

Product Line
Xtend™ Dissolution
(2014)

SOTAX Worldwide.

Europe

Switzerland (HQ Europe)
Aesch / Basel
P Tech Support +41 61 487 5460
P Office +41 61 487 5454
info@sotax.com

Czech Republic
Prague
P Tech Support +41 61 487 5460
P Office +420 246 039 260
sotaxcz@sotax.com

France
Saint-Louis
P Tech Support +41 61 487 5460
P Office +33 3 8970 0846
info@sotax.com

Germany
Lörrach
P Tech Support +41 61 487 5460
P Office +49 7621 16 5635
info@sotax.com

Great Britain
Foston / Derbyshire
P Tech Support +41 61 487 5460
P Office +44 20 8349 6947
sotaxgb@sotax.com

Italy
Milan
P Tech Support +41 61 487 5460
P Office +39 02 8363 2641
sotaxitalia@sotax.com

Ireland
Longford
P Office +353 43 334 7779
contact@labserv.ie

Americas

USA (HQ Americas)
Westborough, MA
P Tech Support +1 508 544 4040
P Office +1 508 417 1112
sotaxusa@sotax.com

Canada
Westborough, MA
P Tech Support +1 508 544 4040
P Office +1 508 417 1112
sotaxcanada@sotax.com

Asia-Pacific

Thailand (HQ Asia-Pacific)
Bangkok
P Tech Support +91 99 202 11 211
P Office +66 26 42 68 62
sotaxasia@sotax.com

China
Shanghai
P Tech Support +41 61 487 5460
P Office +8621-6135 6268, ext. 205
sotaxchina@sotax.com

India
Mumbai
P Tech Support +91 99 202 11 211
P Office +91 22 4295 0191
sotaxindia@sotax.com

sotax.com

MB20038EN_01

sotax.com