



The SOTAX HT 10 Automated Tablet Testing System for fast, accurate and trouble-free measurements of all tablet shapes and sizes.

- ▶ **Automated testing** of the three essential physical parameters (thickness, diameter/length, and hardness) of up to 23 tablets
- ▶ Equipped with the **Auto Alignment™** device (patented), even the most difficult of tablet shapes are automatically aligned correctly to prevent erroneous hardness measurements
- ▶ **Two hardness measurements principles** "Constant Speed" or "Constant Force" with a measuring range of up to 500 or 1000 N can be applied to match existing hardness testers in the market
- ▶ Meets the USP chapter 1217 requirements: **three points calibration and tablet orientation**

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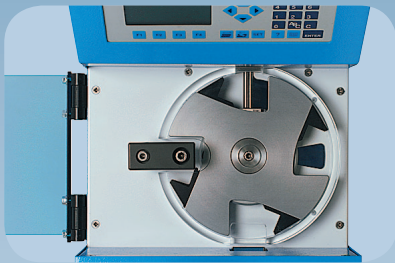




1

23-chamber feeder

- ▶ Twenty-three chambers, each chamber holding one sample, is easy to load, easy to remove and easy to clean.
- ▶ The feeder moves to transport the samples into the testing transporter.



2

Transporter

- ▶ The four-station transporter feeds the tablet clockwise through each test station.
- ▶ The Auto Alignment™ device (patented) on the hardness testing station guarantees that all common forms are correctly positioned.
- ▶ Special brushes mounted on the transport head, clean tablet debris from the feed path and the test jaw. Broken tablets are swept into the waste container as the transporter rotates.



3

Thickness measuring system

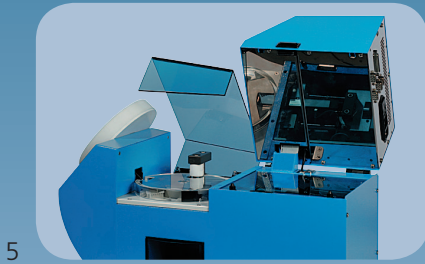
- ▶ Calibrated precision potentiometric displacement sensors measure thickness.
- ▶ The measuring plate is supported for easy adjustment and ensures that it remains parallel to the test platform.
- ▶ Automatic zeroing of the thickness measuring system after each test run.



4

Hardness measuring station

- ▶ The Auto Alignment™ (patented) ensures automatic and rapid alignment of all common forms at exactly 90 degrees to the test jaw before testing.
- ▶ Automated cleaning device that protects the hardness station from tablet residues.
- ▶ The measuring plate is supported for easy adjustment and ensures that it remains parallel to the test platform.
- ▶ Choice of measurement by "Constant Speed" or by "Constant Force". The jaw speed movement and the linear increase of force can be adjusted.
- ▶ These techniques compare and reproduce results of all common hardness testers.



5

Unique housing

- ▶ The unique housing allows opening of the internal control box and the main cover of the four-station transporter, enabling easy access to the testing station for calibration and cleaning without user adjustments.



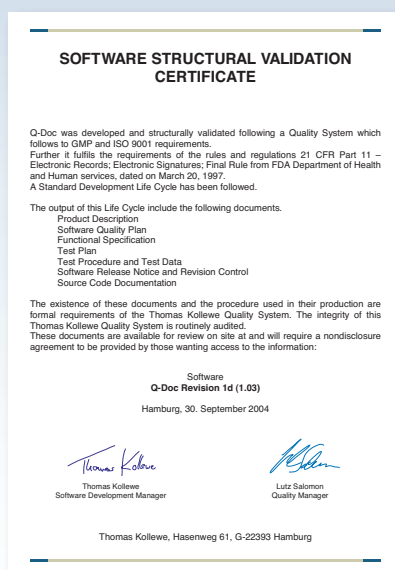
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Calibration

- ▶ For ease of calibration, the thickness and diameter station uses certificated gauge blocks.
- ▶ The hardness measuring station is calibrated easily (with a certified weight) by opening the housing. Adjustment and calibration of the HT 10 is guided and performed through the internal firmware.

Q-Doc hardness tester software

- ▶ Q-Doc is a powerful software package for Windows 2000/XP/Vista, allowing the storage of methods and test results for weight, thickness, diameter or length and hardness.
- ▶ A modern and user-friendly interface allows ease of operation and a high level of data security. Q-Doc software is fully 21 CFR Part 11 compliant. Periodic password change and user log-out after failed log-on is selectable.
- ▶ The easy mode system allows users fast and simple software handling. High level security is guaranteed by a closed system with password and different assignable user rights.
- ▶ Complete audit trail of access, test, method and hardware change.
- ▶ Q-Doc is available with LIMS capabilities and can be networked.



Test report

- ▶ The reported test results can be printed out, stored in the database, validated and/or sent to a network secure location.

Hardware configuration

Pentium IV
256 MB RAM
CD-ROM drive
Min. 800 x 600 resolution, 1024 x 768 recommended



Technical data

Measurement Principles	Constant Speed, Constant Force
Range	0.05 – 2.5 mm/sec 10 – 99 N/sec
Measurement Range	
Hardness Accuracy	5 – 500 (+/-1 N) 500 – 1000 N (+/-2 N)
Diameter/Length Accuracy	0.00 – 30.00 mm (0.00 – 1.2 in) +/-0.05 mm
Thickness Accuracy	0.00 – 18.00 mm (0.00 – 0.72 in) +/-0.05 mm
Power	230 V/50 Hz or 110 V/60 Hz
Width/depth/height	250/537/355 mm (10/21.48/14.2 in)
Weight	Approx. 18 kg (40 lb)

Order information

Part #	Description
8900-01	SOTAX HT 10 500 N
8900-02	SOTAX HT 10 1000 N
9276	Set for manual weight calibration (weight stone not included)
	Weight:
W005-0090	5 kg (11.03 lb)
W005-0100	10 kg (22.06 lb)
W005-0110	20 kg (44.13 lb)
	Gauge:
W005-0200	b. 5 mm (0.20 in)
W005-0270	b. 10 mm (0.39 in)
W005-0220	b. 20 mm (0.79 in)

Description

- ▶ The SOTAX HT 10 automatically measures tablet thickness, diameter or length and hardness for up to 23 samples (e.g. tablets, dragées, oblongs, effervescent tablets or similar drug delivery systems). A balance can be connected if tablet weight is required.
- ▶ The unique Auto Alignment™ device (patented) aligns samples correctly, preventing erroneous hardness measurements.
- ▶ The measurement principles are easily switched between “Constant Speed” and “Constant Force”.
- ▶ The HT 10 can be used as a standalone unit connected to a printer or controlled by the Q-Doc Software.
- ▶ The SOTAX HT 10 is an economical and indispensable tool for the in-process measurements required in production or quality control and research & development laboratories of pharmaceutical companies.

Features

- ▶ The SOTAX HT 10 is equipped with the unique Auto Alignment™ device (patented) instantly aligns the sample to the correct measurement position for hardness testing.
- ▶ The hardness can be measured in a range from 5–500 N as standard. The measurement principle of tablet hardness can be changed from “Constant Speed” (where the test jaw is moved at a constant speed adjustable from 0.05–2.5 mm/sec) to “Constant Force” (where the test jaw increases force linearly adjustable from 10–99 N/sec). This feature is easily selected before each test and can be used to compare and reproduce results for all common hardness testers available on the market as well as an excellent research tool.
- ▶ The SOTAX HT 10 is manufactured from high quality materials. The housing is made of galvanized, powder-coated sheet steel. No regular maintenance is needed.

Optional accessories

- ▶ Set for manual weight calibration
- ▶ Gauge blocks incl. certificate
- ▶ Weight stones incl. certificate
- ▶ Q-Doc Quality Documentation Software
- ▶ Balance (Mettler, Sartorius or Precisa)

Validation and qualification

- ▶ The SOTAX range of Hardness Testers meets and exceeds all pharmacopoeial requirements.
- ▶ The appropriate qualification documents (IQ/OQ) can be supplied with each system. Q-Doc software is delivered with IQ documents and all validation certificates. When required, system and software installation, validation and training can be carried out by a certified SOTAX service engineer or one of its agents located worldwide.