Q-Doc Quality Documentation Software

sotax
Solutions for Pharmaceutical Testing

The SOTAX Q-Doc Quality Documentation Software for automated control, reporting and data management for the in-process control measurements of tablets

- Electronic reporting and data management for the R&D, Quality Control and Production laboratories
- Record Batch and Lot measurements to include weights, thickness, hardness, disintegration, friability and powder flow results
- 21 CFR Part 11 compliant software with network and LIMS connections
- Automated control of the SOTAX family of hardness testers, disintegration, friability and powder flow testers

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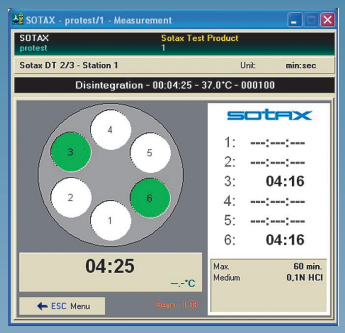
Q-Doc Quality Documentation Software



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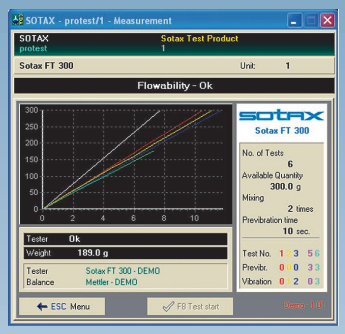

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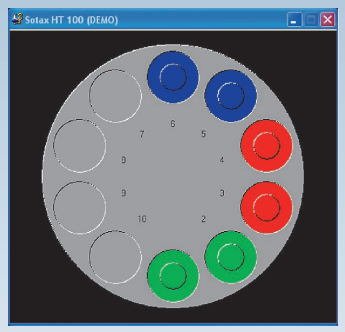

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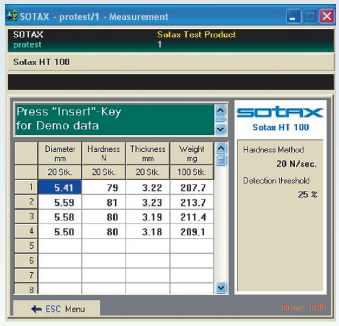

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Q-Doc software is the quality documentation package for SOTAX physical test equipment including the following:

- Disintegration Tester SOTAX DT 2 / DT 3
- Flowability Tester SOTAX FT 300
- Hardness Tester SOTAX HT 1
- Hardness Tester SOTAX HT 10
- Hardness Tester SOTAX HT 100
- Balance (Mettler)

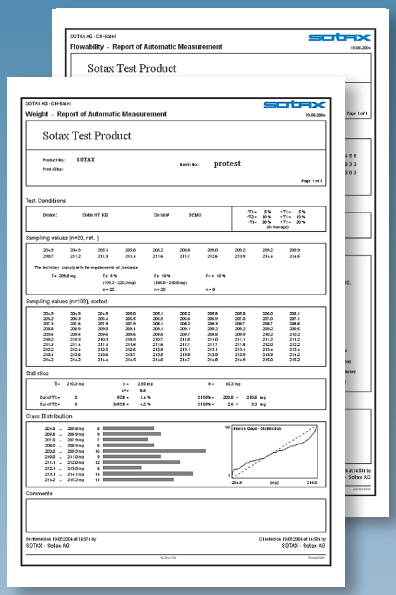
Main features

- Designed for Microsoft Windows 2000/XP/Vista
- User-friendly, users see menus and dialogs for their hardware respective of device configuration and user rights
- LIM System:
  - Data acquisition from different instruments
  - Calculate data for preset product specifications
  - Decision for product specifications
  - Simple pass / fail of batch
  - Archive
  - Reports of each specification and batch
- Network environments, e.g.:
  - Single system with one or more devices
  - Two PC's each connected with one or more devices
  - Server solutions can be tailored to your specific requirements
- Graphic view of devices with real time status (see pictures)
- Data from different devices can be collected simultaneously
- Data export to Excel
- Delayed start function
- Automated decision in principle, using electronic signature for confirmation
- Different search functions allow the status of every batch in every product to be seen
- Help system for administrators and users
- Context-based online help system
- Currently available in English or German language

Benefits

- Easy and unique menu-driven software handling
- Increased productivity through full automation
- Anytime information of product and batch status
- Support for customers validation including user requirements' specification, risk analysis, installation and operating qualification

1 SOTAX DT 2 data acquisition | 2 SOTAX FT 300 data acquisition | 3 SOTAX HT 100 positioning | 4 SOTAX HT 100 data acquisition



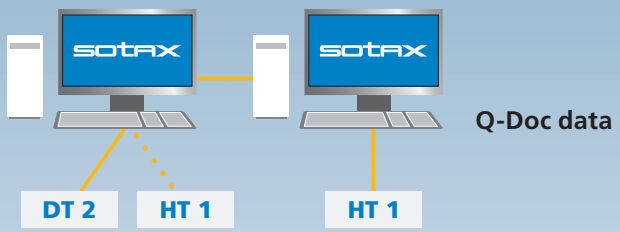
Analysis reports of flowability (FT 300) and weight (HT 100)

Report

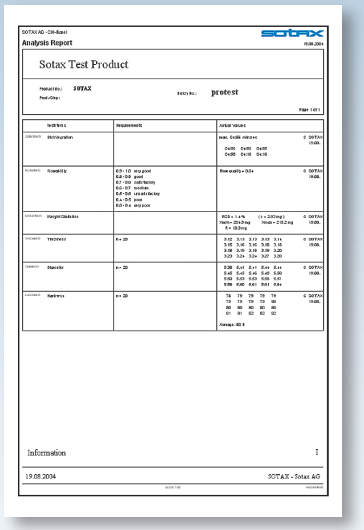
- Reports for measurement analysis
- Reports for different methods of one product
- Includes requirement, raw data and results
- Signed reports cannot be edited
- Restore every time from data base
- Your company logo can be inserted into the report

Environments

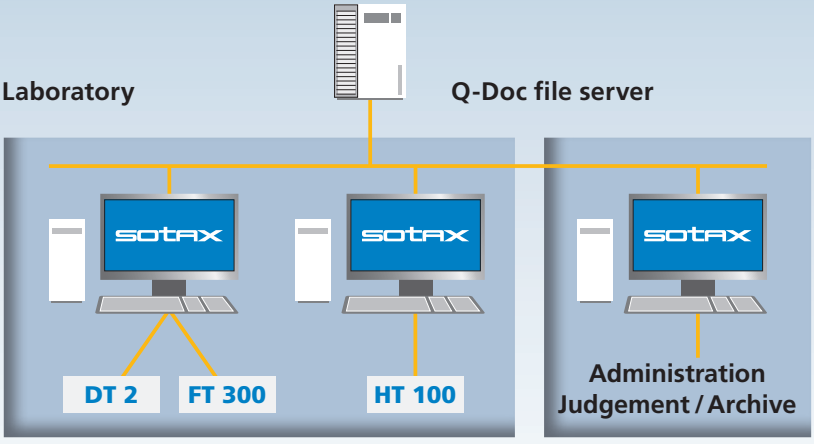
Single system:
Data acquisition of one or more devices. Data and the results are stored in the analysis report.



Two PC's connected:
Simultaneous data acquisition from both PC's. Data is stored in one PC.



Master report of different product specifications (test items) of one batch: This report includes the different test items (e.g. disintegration, flowability, weight, height, hardness etc.) with the results.



Server-based:
Each user has different rights for each different device. This can be tailored to customers' requirements.

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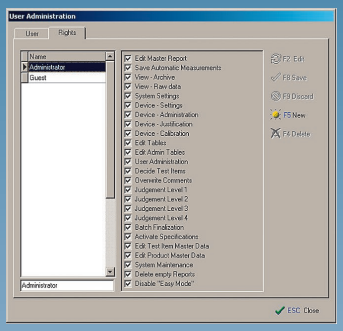
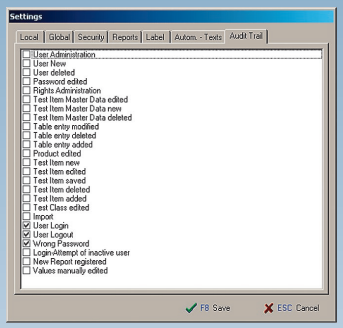
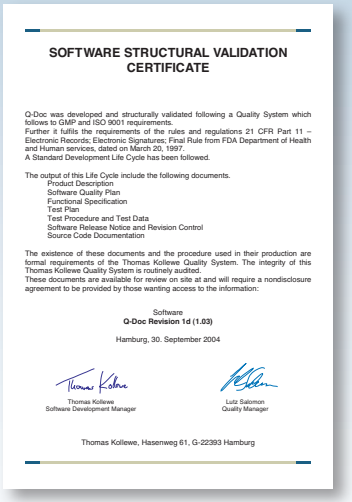


User rights



Audit trail level



SOFTWARE STRUCTURAL VALIDATION CERTIFICATE

Q-Doc was developed and structurally validated following a Quality System which follows to GMP and ISO 9001 requirements.
Further it fulfils the requirements of the rules and regulations 21 CFR Part 11 – Electronic Records; Electronic Signatures; Final Rule from FDA Department of Health and Human services, dated on March 20, 1997.
A Standard Development Life Cycle has been followed.

The output of this Life Cycle include the following documents.
Product Description
Software Quality Plan
Functional Specification
Test Plan
Test Procedure and Test Data
Software Release Notice and Revision Control
Source Code Documentation

The existence of these documents and the procedure used in their production are formal requirements of the Thomas Kollewe Quality System. The integrity of this Thomas Kollewe Quality System is routinely audited.
These documents are available for review on site at and will require a nondisclosure agreement to be provided by those wanting access to the information:

Software
Q-Doc Revision 1d (1.03)

Hamburg, 30. September 2004

Thomas Kollewe
Software Development Manager

Lutz Salomon
Quality Manager

Thomas Kollewe, Hasenweg 61, G-22393 Hamburg

Software structural validation certificate

Q-Doc validation

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21 CFR Part 11 compliance

Complies to the rules and regulations of 21 CFR Part 11 – Electronic Records; Electronic Signatures; Final Rule from FDA Department of Health and Human services, dated on March 20, 1997.

- Fully 21 CFR Part 11 compliant
- High security through closed system with password access and different assignable user rights. Periodic password changes and deactivation after failed log-in
- Raw data is stored and can be recalled for verification at any time, original methods saved and method changes are recorded as a new version with time/date stamps
- Complete audit trail for access, tests and master data
- Electronic signature required for judgement and administrative tools

Minimum hardware and software requirements

Pentium III, 450 MHz
64 MB RAM
Screen resolution 1024 x 768
2 GB hard disk space
Operating system Microsoft NT/2000/XP/Vista Terminal Server

Z500-3204/09

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