

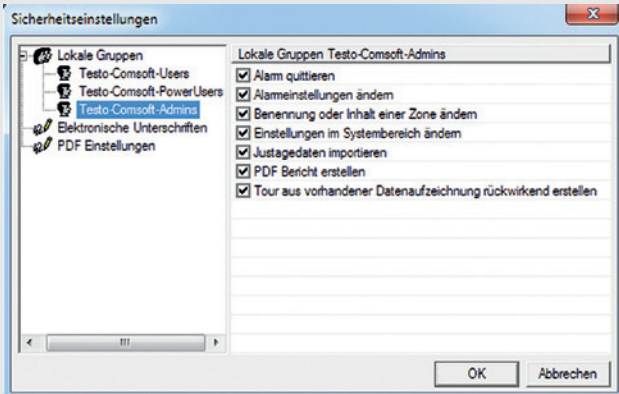


Validatable 21 CFR Part 11 software for testo Saveris.

Maximum data security thanks to CFR-compliant data storage.

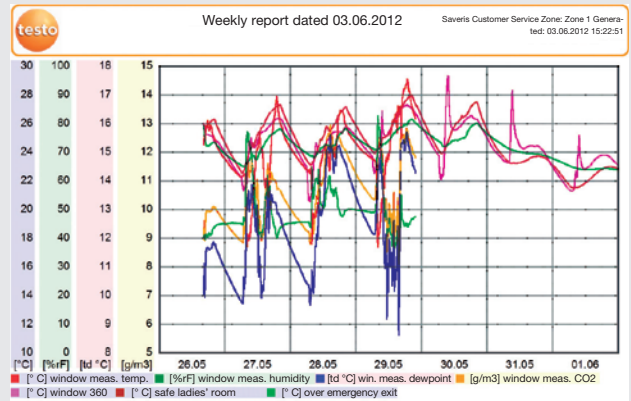
Validatable testo Saveris software

Maximum data security



- Complete integration of access concept in tried-and-tested Windows security system (e.g. user and password management)
- Authorisation concept: allocation of rights by administrator for three user levels
- Testo's own protocol (proprietary) with wireless and Ethernet communication
- CFR-compliant data storage with checksum-verified database
- Use of checksums to guarantee correct and secure data transmission
- Automatic daily backup and manual backup of database files possible

Tamper-proof PDF reports



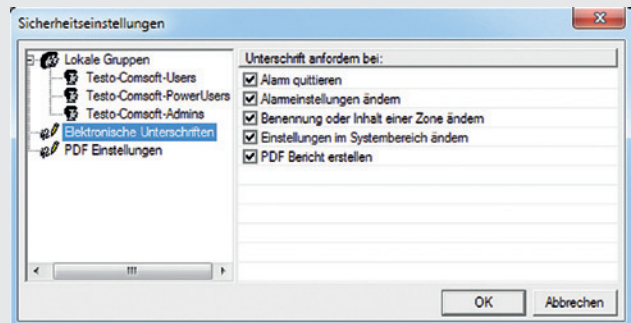
- Automatic PDF reports (daily/weekly/monthly)
- Manual creation of PDF reports for user-defined time, secured with master password
- 21 CFR Part 11 compliant printouts
- Identification code for clear allocation of PDF reports

Traceability of user activities

In.	Datum/Zeit	Benutzer	Aktion	Gerät	Details	Bezug
1	27.09.2012 10:08:23	sn	System startup	2303351	---	---
2	27.09.2012 10:08:27	sn	Probe has been added	1994820	---	---
3	27.09.2012 10:08:27	sn	Log start set	1994820	27.09.2012 10:13:00	---
4	27.09.2012 10:08:27	sn	Probe cycle set	1994820	1.0 min	---
5	27.09.2012 10:08:27	sn	Probe disposition is	1994820	mobile	---
6	27.09.2012 10:08:27	sn	Probe has been added	2003957	---	---
7	27.09.2012 10:08:27	sn	Log start set	2003957	27.09.2012 10:13:00	---
8	27.09.2012 10:08:27	sn	Probe cycle set	2003957	1.0 min	---
9	27.09.2012 10:08:27	sn	Probe disposition is	2003957	stationary	---
10	27.09.2012 10:08:27	sn	Probe has been added	2351779	---	---
11	27.09.2012 10:08:27	sn	Log start set	2351779	27.09.2012 10:13:00	---
12	27.09.2012 10:08:27	sn	Probe cycle set	2351779	1.0 min	---
13	27.09.2012 10:08:27	sn	Probe disposition is	2351779	stationary	---
14	27.09.2012 10:08:27	sn	Probe has been added	1997630	---	---
15	27.09.2012 10:08:27	sn	Log start set	1997630	27.09.2012 10:13:00	---
16	27.09.2012 10:08:27	sn	Probe cycle set	1997630	1.0 min	---
17	27.09.2012 10:08:27	sn	Probe disposition is	1997630	mobile	---
18	27.09.2012 10:08:32	sn	Channel name set	1994820_1	1994820_1	°C
19	27.09.2012 10:08:32	sn	Channel name set	1994820_1	1994820_1	°C

- Audit trail for traceability of user activities in the system
- Audit trail documents time, user name, activity carried out, Saveris components and details about the activity carried out

Electronic signatures



- Electronic signatures with information about the reason for the signature, e.g. to change configuration
- An electronic signature can be made mandatory for defined user activities

Documentation and services related to testo Saveris 21 CFR Part 11

Included in the testo Saveris CFR software package:

Independent certificate by Fraunhofer IESE Institute

Tested measurement data monitoring system with certificate: the Fraunhofer Institute for Experimental Software Engineering confirms that the testo Saveris measurement data monitoring system meets 21 CFR Part 11 requirements. Testing took place in accordance with the evaluation guidelines of the GAMP Special Interest Group: Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures.



Documents to support your validation

These documents support you in the validation of the testo Saveris system based on GAMP5:

1. Customisable templates for risk analysis
2. Individually usable templates for
 - validation master plan
 - validation specifications

Services related to the testo Saveris CFR software

Testo offers full services for calibration and qualification/validation

Calibration and adjustment:

- Adjustment software using the customer's own calibrations/adjustments are possible (password protection, historical traceability of the adjustment data in the testo Saveris CFR software)
- Storage of calibration date in the probe, calibration reminder via SMS or e-mail
- Calibration service in laboratories and on site in numerous countries. To find out more, contact your nearest Testo branch, Testo Industrial Services or Testo partner in your country.

Qualification/validation:

The Testo subsidiary Testo Industrial Services (TIS) offers you customised qualification and validation concepts for testo Saveris:

- DQ, IQ, OQ, PQ (qualification)
- Mapping (for optimum determination of probe location)
- Customised risk analyses in accordance with GAMP5
- Documentation either in customer or Testo format

Overview: qualification and validation packages

Premium:

The "Premium" package offers you fully comprehensive GAMP5 validation, which can include your specific requirements for implementing risk analysis, after which you can skip directly to productive use. The modular and detailed risk analysis process (FMEA) and coherent validation documentation (uninterrupted serial numbering of the requirements, risks and measures) facilitates not only traceability but also the evaluation of future system alterations, quickly and securely.

Comfort:

The "Comfort" package also offers you a risk-based model. In this case, however, the design documentation as well as the proof of suitable peripheral conditions (IT environment and suitability/SOP training for staff) is your responsibility. Adaptation to specific requirements is not included, as the risk estimate is provided in a standard document.

Basic:

If you require only a technical configuration and function test of the monitoring system with GxP-compliant documentation, you will find the right solution in our "Basic" package. You can then integrate the package into your own CS validation.

More information at: www.testo-industrial-services.com