



Committing to the future

On The Safe Side

21 CFR Part 11 compliant measurement data monitoring automated with **testo Saveris™**.



testo Saveris™ System overview

The testo Saveris monitoring system saves time thanks to automated measurement and offers centralised documentation as well as an alarm function. It guarantees the safety of your measurement data in production processes, during the storage of pharmaceutical products and in clean room air conditioning.

1 testo Saveris base

Reliable measurement data monitoring due to:

- Connection of up to 150 Saveris wireless probes
- Flexible system design of wireless probes and Ethernet probes in one system

Easy to use thanks to:

- Fast overview of system components, measurement data and alarms

Secure data due to:

- LED alarm/ audible/ relay/ texting optional
- Storage and alarm even if PC is not running
- Built-in emergency rechargeable battery guarantees safety of data if there is loss of power
- Long-term memory ensures data safety and independence from PC

2 testo Saveris CFR software

Reliable measurement data monitoring on account of:

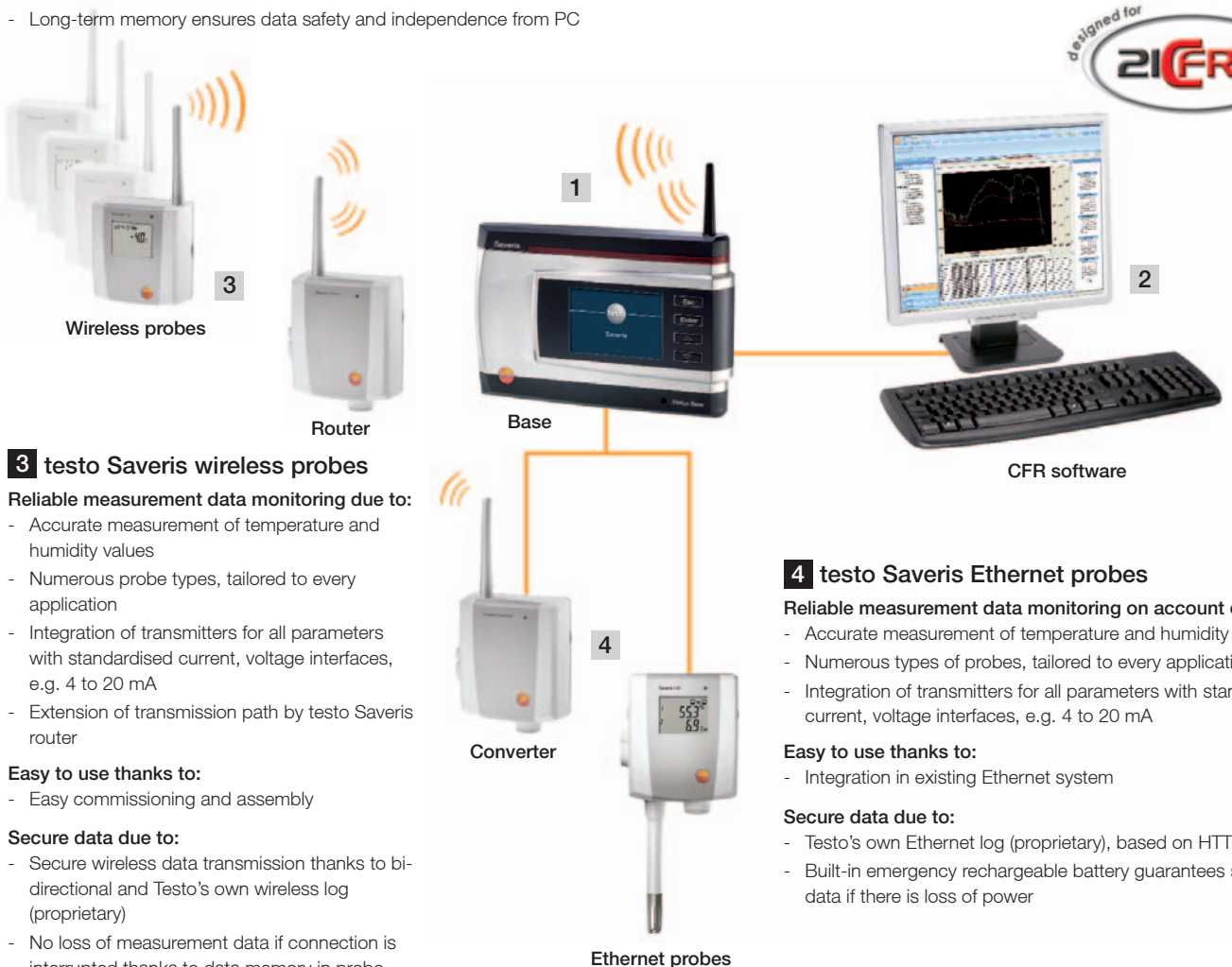
- Centralised documentation of all measurement data
- Network enabled software: server software, any number of client/viewer work stations within a network

Easy to use thanks to:

- Graph / Table / Alarm overview
- Easy calendar management

Secure data due to:

- Validation enabled software
- Alarm by email



3 testo Saveris wireless probes

Reliable measurement data monitoring due to:

- Accurate measurement of temperature and humidity values
- Numerous probe types, tailored to every application
- Integration of transmitters for all parameters with standardised current, voltage interfaces, e.g. 4 to 20 mA
- Extension of transmission path by testo Saveris router

Easy to use thanks to:

- Easy commissioning and assembly

Secure data due to:

- Secure wireless data transmission thanks to bi-directional and Testo's own wireless log (proprietary)
- No loss of measurement data if connection is interrupted thanks to data memory in probe

4 testo Saveris Ethernet probes

Reliable measurement data monitoring on account of:

- Accurate measurement of temperature and humidity values
- Numerous types of probes, tailored to every application
- Integration of transmitters for all parameters with standardised current, voltage interfaces, e.g. 4 to 20 mA

Easy to use thanks to:

- Integration in existing Ethernet system

Secure data due to:

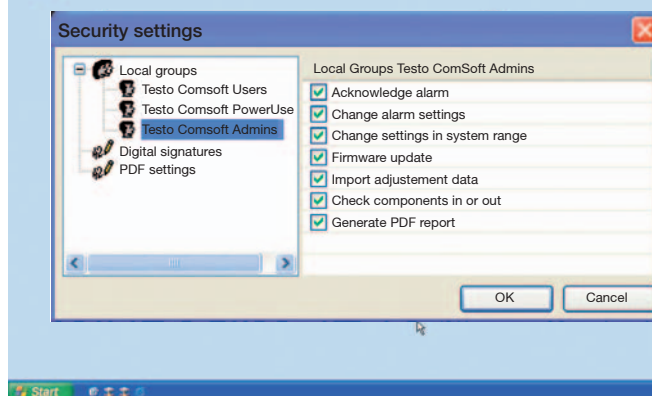
- Testo's own Ethernet log (proprietary), based on HTTP log
- Built-in emergency rechargeable battery guarantees safety of data if there is loss of power

Additional benefit:
Wireless probes in Ethernet systems can be integrated through the testo Saveris converter

testo Saveris™ Validation enabled software

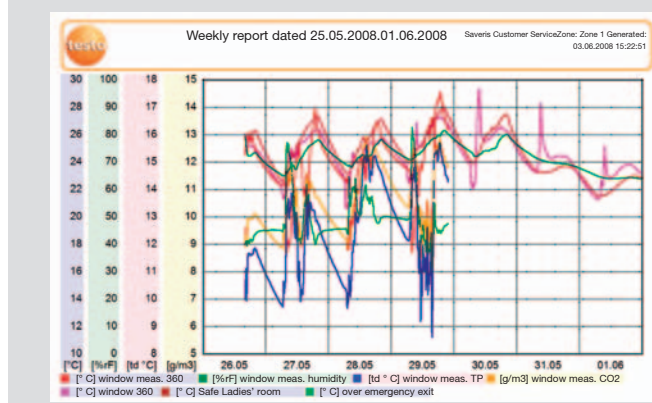
1 Highest data security

- Complete integration of access concept in tried-and-tested Windows security system (e.g. user and password management)
- Authorisation concept: Allocation of rights through administrator for three user levels
- Testo's own log (proprietary) with wireless and Ethernet communication
- CFR compliant data management with database whose checksum has been verified
- Use of checksums to guarantee correct and secure data transmission/übertragung
- Automatic daily backup and manual backup of database files möglich



2 Tamper-proof PDF reports

- Automated 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



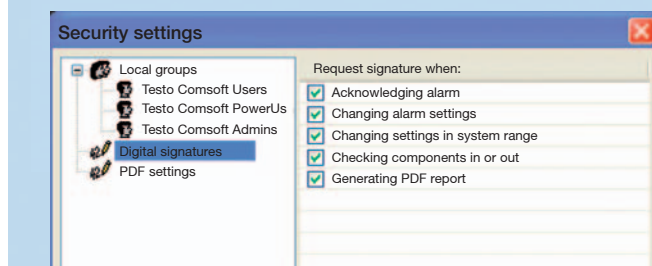
3 Traceability of user activities

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

Index	Date/Time	User	Activity	Instrument	Details	Reference
1	10.07.2009 11:19:32	Administrator	Time synced	1508003	1	10.07.2009 11:19:32
2	10.07.2009 11:20:59	Administrator	System startup	1508003		
3	10.07.2009 11:21:03	Administrator	Probe has been added	1705083		
4	10.07.2009 11:21:03	Administrator	Log start set	1705083	10.07.2009 11:22:00	
5	10.07.2009 11:21:03	Administrator	Probe cycle set	1705083	1.0 min	
6	10.07.2009 11:21:03	Administrator	Probe has been added	1472045		
7	10.07.2009 11:21:03	Administrator	Log start set	1472045	10.07.2009 11:22:00	
8	10.07.2009 11:21:03	Administrator	Probe cycle set	1472045	1.0 min	
9	10.07.2009 11:21:03	Administrator	Probe has been added	1472150		
10	10.07.2009 11:21:03	Administrator	Log start set	1472150	10.07.2009 11:22:00	
11	10.07.2009 11:21:03	Administrator	Probe cycle set	1472150	1.0 min	
12	10.07.2009 11:21:03	Administrator	Probe has been added	1526334		
13	10.07.2009 11:21:03	Administrator	Log start set	1526334	10.07.2009 11:22:00	
14	10.07.2009 11:21:03	Administrator	Probe cycle set	1526334	1.0 min	
15	10.07.2009 11:21:10	Administrator	Channel name set	1705083	1705083_1	°C
16	10.07.2009 11:21:10	Administrator	Channel lower limit set	1705083	-50.00	
17	10.07.2009 11:21:10	Administrator	Channel upper warning limit set	1705083	-50.00	

4 Electronic signatures

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



Documentation and service for testo Saveris 21 CFR Part 11

Included in the software package for testo Saveris CFR software

Independent certificate by Fraunhofer IESE Institute

Approved 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. It was approved in accordance with the GAMP Special Interest Group: Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures.

Documents to support your validation

1. Individual customised templates for risk analysis
2. Individual applicable templates for
 - validation master plan
 - validation specifications

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



Services for CFR software

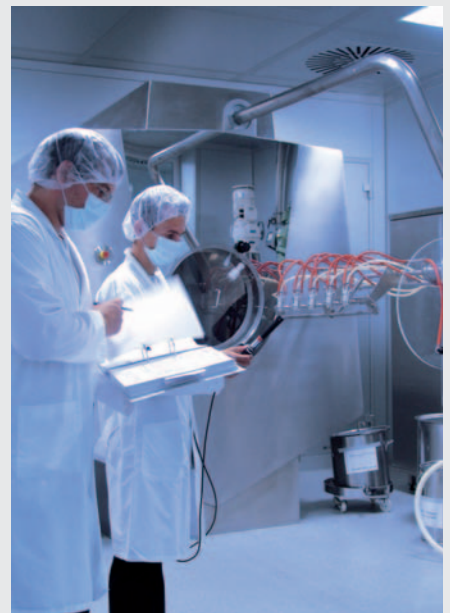
Testo offers full services for calibration and validation / qualification

Calibration and adjustment:

- Adjustment software using which customer's own calibrations / adjustments are possible (password protection, historical traceability of adjustment data in testo Saveris CFR software)
- Storage of calibration date in probe, reminder to calibrate by text or email
- Calibration service in laboratory and on site in numerous countries. To find out more contact your nearest Testo, testo industrial services or Testo partner in your country.

Validation / Qualification:

- Testo Industrial Services (TIS) (a subsidiary of Testo) offers you customised validation and qualification concepts for the testo Saveris system:
- DQ, IQ, OQ, PQ (qualification)
 - Mapping (for optimum determination of probe location)
 - Custom-made risk analyses in accordance with GAMP5
 - Documentation in customer or Testo format



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

www.testo.de/saveris

Find out more about the testo Saveris measurement data monitoring system on the Internet.

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