Pharma Solutions

Measurement data monitoring system:
testo Saveris

Software:
testo Saveris CFR 4.6 SP1
testo Saveris CFR transport add-on

Instruction manual

Contents

1 About this document

- The instruction manual is an integral part of the testo Saveris measurement data monitoring system.
- Keep this documentation to hand so that you can refer to it when necessary.
- Please read this instruction manual through carefully and familiarize yourself with the product before putting it to use.
- Hand this instruction manual on to any subsequent users of the product.
- Pay particular attention to the safety instructions and warning advice in order to prevent injury and damage to the product.
- Please read this instruction manual through carefully and familiarize yourself with the product before putting it to use.

1.1 Symbols and writing standards

Display	Explanation
	Note: basic or further information.
1. ... 2. ...	Action: several steps, the sequence must be followed.
• …	List
> ...	Action: one step or optional step.
- ...	Result of an action.
✓ ...	Requirement
1 ... 2 ...	Position numbers for the clarification of the relationship between text and picture.
Menu	Elements of the instrument, the instrument display or the program interface.
[OK]	Control keys of the instrument or buttons of the program interface.
... | ...	Functions/paths within a menu.
"..."	Example entries

1.2 Warning notices

Always pay attention to any information marked with the following warning notices along with warning pictograms. Implement the specified precautionary measures!

⚠ DANGER

Life-threatening danger!

⚠ WARNING

Indicates possible serious injuries.

⚠ CAUTION

Indicates possible minor injuries.

ATTENTION

Indicates possible damage to equipment.

2 Safety and disposal

2.1 Safety

- Always operate the product properly, for its intended purpose and within the parameters specified in the technical data. Do not use any force.
- Never use the Saveris probes to measure on or near live parts.
- Only carry out maintenance and repair work on the components of the testo Saveris measurement data monitoring system that are described in the documentation. Follow the prescribed steps exactly when doing the work. Use only original spare parts from Testo.
- The use of the wireless module is subject to the regulations and stipulations of the respective country of use and, in each case, the module may only be used in countries for which a country certification has been granted. The user and every owner undertake to adhere to these regulations and prerequisites for use and acknowledge that the re-sale, export, import, etc. in particular in, to or from countries without wireless permits, is their responsibility.
- When selecting the mounting location, ensure that the permissible ambient and storage temperatures are adhered to.

At temperatures below 5°C, the (rechargeable) batteries will not charge; there is only a limited possibility of reliable system operation in this temperature range.

- Do not use the product if there are signs of damage to the housing.
- Do not commission the instrument if there are signs of damage on the housing.
- Dangers may also arise from objects being measured or the measuring environment. Always comply with the locally valid safety regulations when carrying out measurements.
- Do not store the product together with solvents.

2.2 Batteries

The batteries in the Saveris base, the Saveris Ethernet data loggers and the Saveris analog couplers are wearing parts which have to be replaced after approx. 2 years. If batteries are faulty, it is not possible to guarantee full operability of the GSM module. In the event of a power failure, data loss cannot be ruled out for all components. When a component's batteries are no longer fully functional, it triggers a **Defective battery** system alarm.

The batteries (order no. 0515 5021) should then be replaced immediately to ensure full functionality and data security.

3 Protecting the environment

- Dispose of faulty and spent batteries in accordance with the valid legal specifications.
- At the end of its useful life, deliver the product to the separate collection point for electric and electronic devices (observe local regulations) or return the product to Testo for disposal.
-  WEEE Reg. No. DE 75334352

4 Support

You can find up-to-date information on products, downloads and links to contact addresses for support queries on the Testo website at: www.testo.com.

5 Using the system

5.1 Fields of application

The testo Saveris measurement data monitoring system can be used anywhere where temperature and humidity-sensitive products are produced, stored or transported; for example in the food industry (cold rooms, deep freeze rooms and refrigerated/deep freeze transporters), in smaller food production companies, such as bakeries and butcher's shops, or in the pharmaceutical industry (temperature-controlled cabinets, storage and transportation of drugs).

But the testo Saveris measurement data monitoring system can also be used in other industries for monitoring IAQ in buildings, as well as for quality assurance in store rooms for products in every phase of production.

The testo Saveris measurement data monitoring system is only used to monitor readings, not to control and regulate them.

The Saveris base with the SMS module may not be operated in environments where, for example, use of a mobile phone is prohibited.

Mobile monitoring is only available for countries with appropriate radio authorization of 868 MHz.

5.2 How it works

5.2.1 Measurement data monitoring for monitoring in the stationary area

The testo Saveris measurement data monitoring system enables ambient or process data for temperature and humidity in closed areas (production plants, warehouses) to be measured and saved. The values measured by the probes in the system are transmitted to the Saveris base, either wirelessly or via cable (Ethernet), by data loggers, which are also used as a buffer memory for the measurement data, and the values are then saved in the base. A connected computer transfers the measurement data of the Saveris base to permanent archiving in a database.

5.2.2 Measurement data monitoring for transport monitoring with radio data loggers ("mobile monitoring")

The monitoring of ambient parameters during the transport of sensitive goods is done by radio data loggers which are fitted in the transport container (e.g. in a truck). If the transport container returns to the base, the readings recorded by the data logger are transmitted via extender (or also directly) to the Saveris base as soon as there is an adequate radio link. The Saveris cockpit unit can be used

in the truck for direct checking of readings. If radio data loggers are registered in mobile zones, all the radio data loggers are in one radio cell on the same channel. The Saveris extenders work as external antennas of the Saveris base with a spatial distribution. All of these radio data loggers are registered on the Saveris base.

5.2.3 Measurement data monitoring for transport monitoring with transport data loggers

For monitoring the transport of sensitive products, such as pharmaceuticals, food or electronics, transport data loggers are placed with the goods being transported. Depending on the type of transport data logger used, the recorded measurement data are either transmitted wirelessly (via Bluetooth® connection with testo 182) or via a USB interface (testo 184). The testo Saveris measurement data monitoring system allows data from transports and from stationary measurement data monitoring to be saved in the same database.

The testo Saveris CFR software and testo Saveris CFR transport add-on are prerequisites for measurement data monitoring with transport data loggers.

5.3 Exclusion of liability

The testo Saveris measurement data monitoring system was developed to consolidate a large amount of measurement data from spatially separated data loggers in the Saveris software, to document them without interruption and to provide alarms in the event of irregularities.

The design of the testo Saveris measurement data monitoring system is not intended for the purpose of undertaking control and regulation tasks. In particular, the alarms are not to be seen as so-called critical alarms which are able to avert dangers to life and limb or damage to property.

Liability on the part of Testo SE & Co. KGaA for damages from this type of application is excluded.

6 Product description

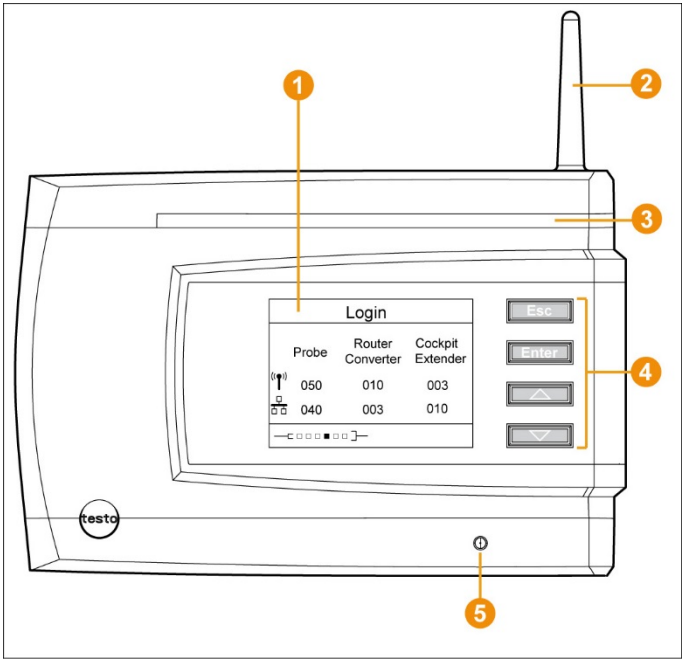
6.1 System overview

Component	Function
testo Saveris base	Readings are transmitted wirelessly or via an Ethernet connection to the Saveris base which then saves them. The data are then called up by a computer from the Saveris base and saved in a database.
Probes	Probes measure temperature, humidity and other parameters and supply their measurement data to data loggers. In the testo Saveris measurement data monitoring system, probes are either structurally integrated into the data loggers or can be mounted on these externally.
Radio data loggers for testo Saveris	Saveris radio data loggers record readings from probes and transmit these wirelessly via radio link.
Ethernet data loggers for testo Saveris	Saveris Ethernet data loggers record readings from probes and transmit these via Ethernet connection.
Transport data loggers for testo Saveris	Transport data loggers (**testo 182** and **testo 184**) are placed with sensitive goods that are being transported and record measurement data during transportation.
Wireless analog couplers Ethernet analog couplers and transmitters for testo Saveris	Saveris analog couplers enable the integration of additional measurement parameters into the testo Saveris measurement data monitoring system by incorporating all transmitters with standardized current/voltage interfaces. Transmitters record readings from data loggers and transmit these via an optional additional component (Ethernet module) by Ethernet connection.

Component	Function
testo Saveris router	The radio link can be improved or extended in poor structural conditions by using a Saveris router. Several Saveris routers are possible in the testo Saveris measurement data monitoring system. At the same time, the series connection of up to 3 routers (V 2.0 offers optimum flexibility in terms of wireless range.
testo Saveris converter	By connecting a Saveris converter to an Ethernet jack, the signal of a Saveris radio data logger can be converted into an Ethernet signal. This combines the flexible connection of the Saveris radio data logger with use of the existing Ethernet, even over long transmission paths.
testo Saveris extender	By connecting a Saveris extender to an Ethernet jack, the signal of a Saveris radio data logger, whether being used in a stationary or mobile mode, can be converted into an Ethernet signal. This combines the flexible connection of the Saveris radio data logger with use of the existing Ethernet, even over long transmission paths.
Gateway BT	BT Gateway for testo 182(“gateway” for short) is used for non-contact registration and readout of testo 182 via a Bluetooth® connection (BT). After the temperature data recorded by the testo 182 have been transmitted to the readout gateway, they are transferred to the Saveris database.
testo Saveris cockpit unit	The testo Saveris cockpit unit permits reading control of Saveris radio data loggers during transport operations. The testo Saveris cockpit unit enables drivers of the transport vehicles to keep an eye on the measurement data at all times and they are alerted if there are limit value violations.

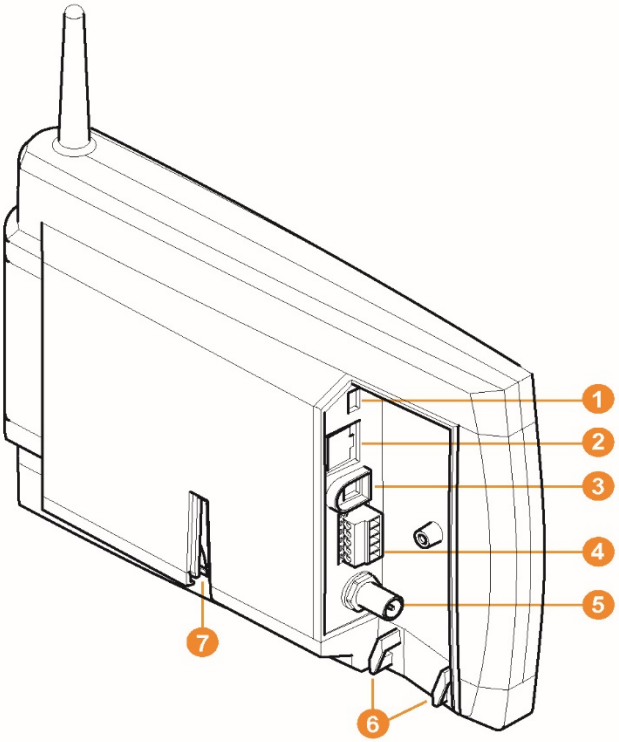
6.2 testo Saveris base

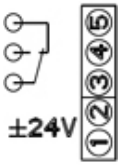
6.2.1 Front



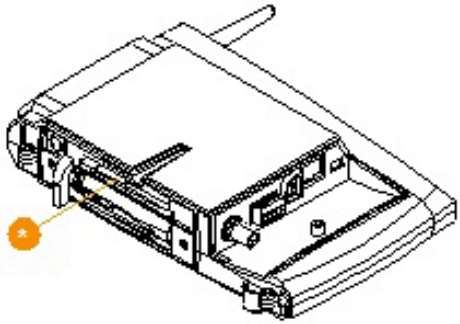
1	Display for the visualization of alarms and user guidance
2	Antenna
3	Warning LED
4	Keypad for operation of the Saveris base
5	LED for status display

6.2.2 Rear



1	USB cable connection
2	Network cable connection
3	Power supply connection via mains plug
4	Power supply connection via 24 V AC/DC and alarm relay 
5	Connection for external GSM antenna
6	Eyelets for strain relief
7	Guide for stand or wall bracket

6.2.3 Underside



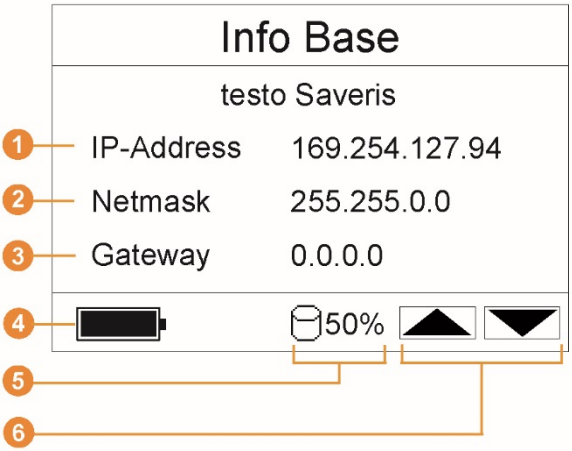
* Insertion slot for the SIM card

6.2.4 Control keys

Key	Explanation
[Esc]	Switches from the **Login** menu to the **Info System** menu. In the **Info Base** menu, briefly press [Esc] twice: shuts down the Saveris base press and hold down [Esc]: starts up the Saveris base
[Enter]	Starts the login status for the Saveris radio data loggers in the **Info System** menu.
[▲], [▼]	Navigation keys for changing the menus.

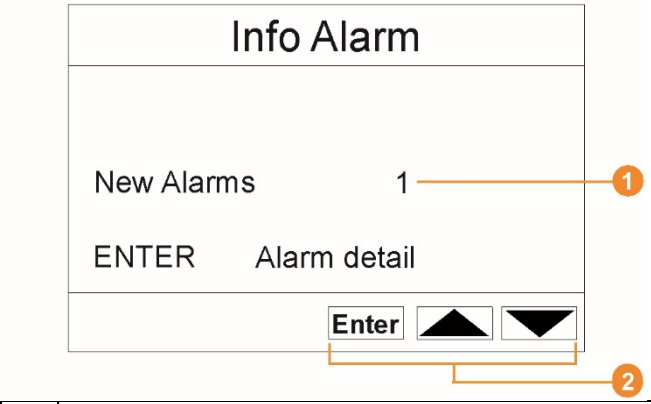
6.2.5 Displays

Info Base menu



1	**IP address** of the Saveris base The IP address is the unique identification number of the Saveris base within the network
2	**Netmask** which is saved in the Saveris base. The netmask is the basic address of the network which the Saveris base is integrated into.
3	**Gateway** which is saved in the Saveris base. A gateway is a transfer point between networks that work with different protocols or data formats. A "translation" into the other protocol or data format is then performed by the gateway in each case.
4	Indicator for interrupted power supply. Indicator flashes when the Saveris base is being operated by batteries and the power supply has been interrupted.
5	Indicator that there is free capacity in the Saveris base's data memory.
6	Keys that are assigned functions in this menu.

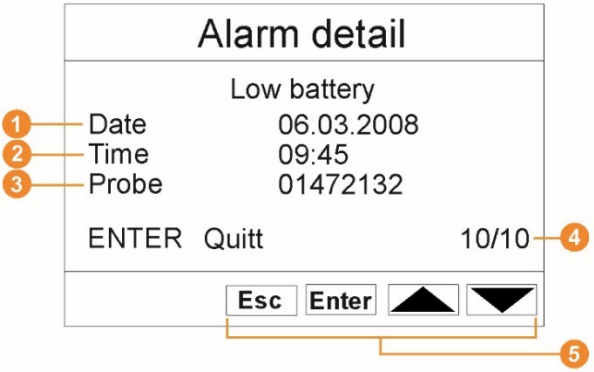
Info Alarm menu



1	Number of newly triggered alarms
2	Keys that are assigned functions in this menu.

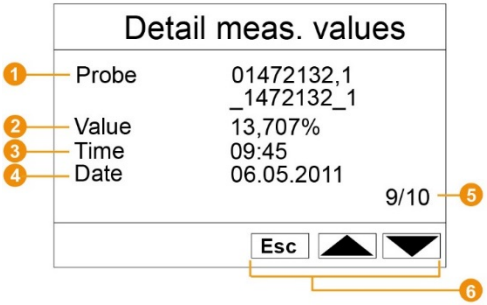
New alarms have to be checked and acknowledged at regular intervals. A large number (>100) of unacknowledged alarms will impair the system performance. The system automatically acknowledges unacknowledged alarms once these number 200 or more.

Alarm detail menu



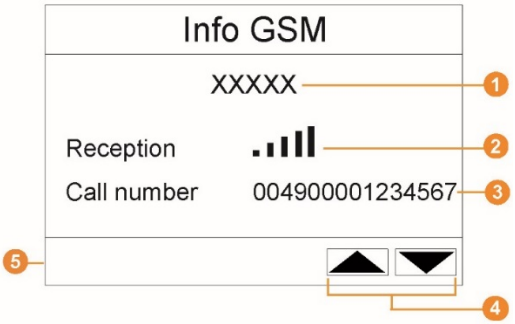
1	**Date** on which the alarm was triggered.
2	**Time** at which the alarm was triggered.
3	**Probe** for which the alarm was triggered.
4	Alarm number and total number of alarms.
5	Keys that are assigned functions in this menu.

Detail meas. values **menu**



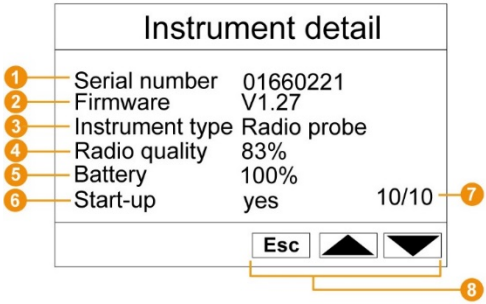
1	**Probe**: Radio data logger and channel for which the reading was transferred. The first number specifies the serial number with the channel and the second line the channel name in the system.
2	**Value**: Reading with associated unit.
3	**Time**: Time at which the reading was transferred.
4	**Date**: Date on which the reading was transferred.
5	Reading number and total number of readings.
6	Keys that are assigned functions in this menu.

Info GSM **menu**



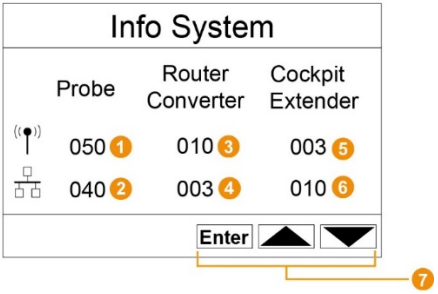
1	Name of network operator.
2	**Reception**: Display of the reception quality.
3	**Call number**: Telephone number which is saved on the SIM card.
4	Keys that are assigned functions in this menu.
5	Version number of the internal GSM module.

Instrument detail **menu**



1	**Serial number**: Serial number of the registered instrument.
2	**Firmware**: Firmware version of the registered instrument.
3	**Instrument type**: Type designation of the registered instrument.
4	**Radio quality**: Radio quality of the registered instrument (does not apply to Saveris Ethernet data loggers and Saveris extender).
5	**Battery**: Battery status of the instrument (does not apply to Saveris extender, Saveris converter and Saveris cockpit unit).
6	**Start-up**: Start-up indicates whether the instrument has been configured by the startup wizard.
7	Number of registered instruments.
8	Keys that are assigned functions in this menu.

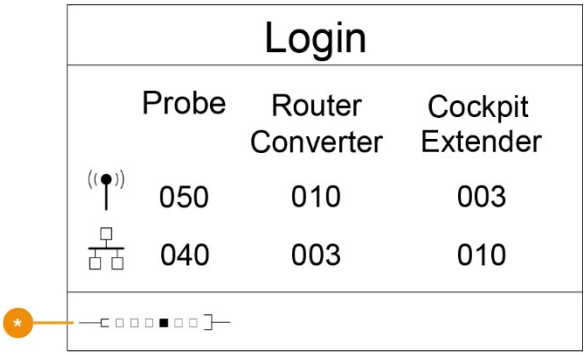
Info System **menu**



1	**Probe**: Number of registered Saveris radio data loggers.
2	**Probe**: Number of registered Saveris Ethernet data loggers.
3	**Router Converter**: Number of registered Saveris routers.

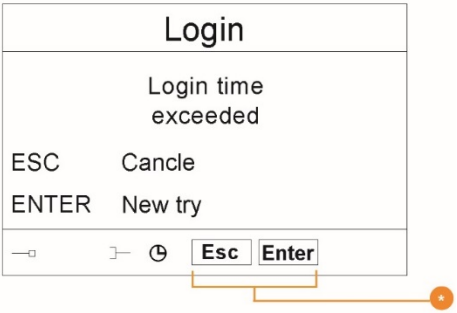
4	**Router Converter**: Number of registered Saveris converters.
5	**Cockpit Extender**: Number of registered Saveris cockpit units.
6	**Cockpit Extender**: Number of registered Saveris extenders.
7	Keys that are assigned functions in this menu.

Login 1/2 (Login) menu



*	Status display when registering data loggers.

Login 2/2 (Login) menu

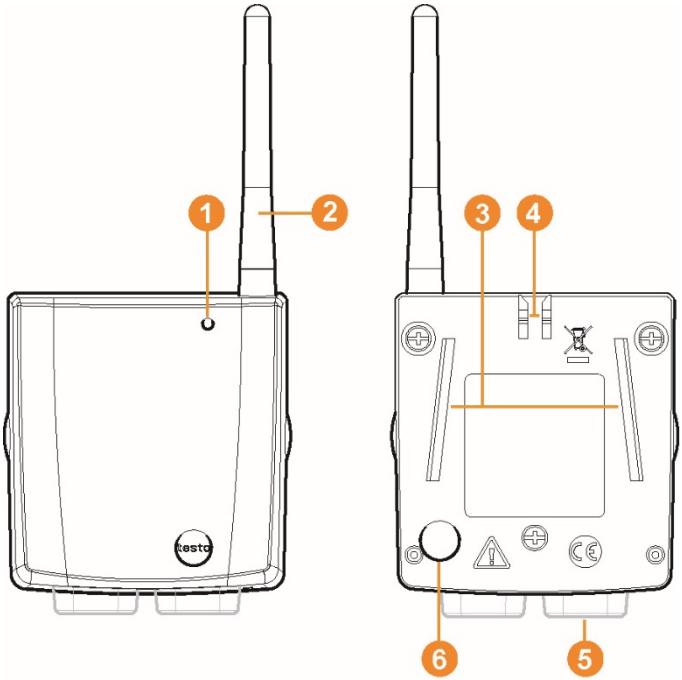


*	Keys that are assigned functions in this menu.
	Login time exceeded
	ESC Cancel
	ENTER New try

This display is shown if no registration signal has been received from a data logger within approx. 30 seconds.

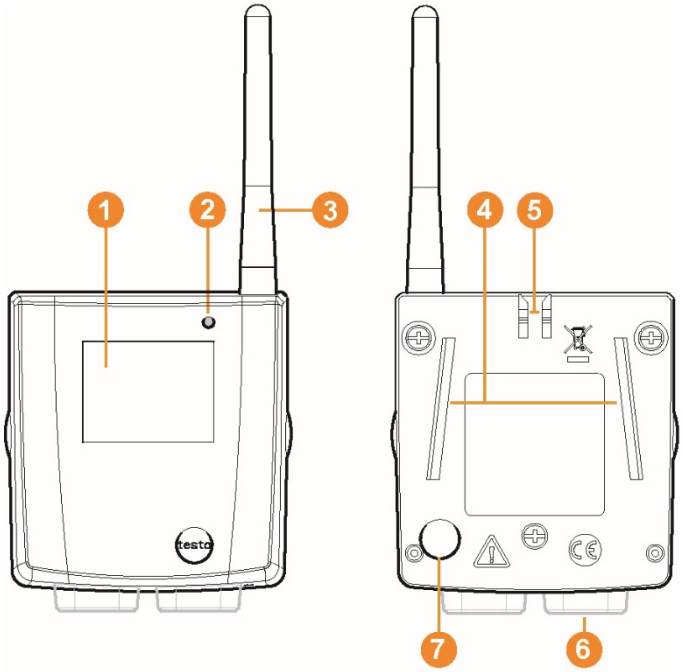
6.3 Radio data logger for testo Saveris

6.3.1 Saveris radio data logger without display



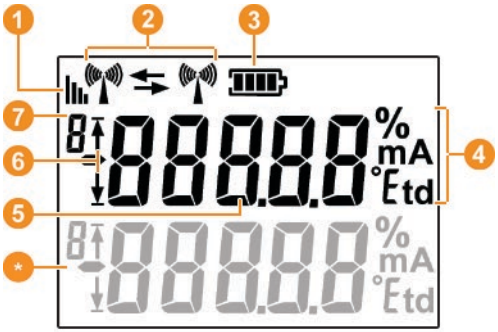
1	LED for status display.
2	Antenna for radio transmission of measurement data to the Saveris base.
3	Guide rails for the wall bracket.
4	Catch for the wall bracket.
5	Ports, depending on the type.
6	Connect key for registering the probe on the Saveris base and for a status request during operation.

6.3.2 Saveris radio data logger with display



1	Display for showing readings, battery and connection status, along with the field status of the radio link.
2	LED for status display.
3	Antenna for radio transmission of measurement data to the Saveris base.
4	Guide rails for the wall bracket.
5	Catch for the wall bracket.
6	Ports, depending on the type.
7	Connect key for registering the Saveris data logger on the Saveris base and for a status request during operation.

6.3.2.1 Displays



1	Quality of the radio link.
2	Indicator as to whether a communication with the Saveris base or a Saveris router or Saveris converter is being carried out.
3	Status of batteries.
4	Unit of the reading: - % for humidity measurement - mA for current measurement - °Ctd or °Ftd for dewpoint measurement.
5	Reading.
6	Indication as to whether the reading has overshot the upper (↑) limit value or undershot the lower (↓) limit value.
7	Number of the channel.
*	Display for a second sensor in the probe.

6.3.3 Saveris radio data logger LED status displays

Registering on the Saveris base

1 Hold down the connect key on the rear of the data logger until the LED begins to flash orange

Display	Explanation
Flashing orange	Attempt to establish the connection to the Saveris base.
Lit up green	Registration on the Saveris base was successful.
Lit up red	Registration on the Saveris base failed.

Status displays during operation

1 Briefly press the connect key on the rear of the data logger once and the LED shows the status of the connection to the Saveris base.

Display	Explanation
Flashing 3 x green	There is a very good connection to the Saveris base.
Flashing 2 x green	There is a good connection to the Saveris base.
Flashing 1 x green	There is a borderline connection to the Saveris base.
Flashing 3 x red	Registration on the Saveris base failed.

6.4 testo Saveris 2 H2

6.4.1 Short description

Saveris WLAN data logger for wireless LAN integration. The product version with order number 0572 2035 01 is compatible with testo Saveris, but not with the testo Saveris 2 data logger system.

6.4.2 Display and control elements

6.4.2.1 Overview

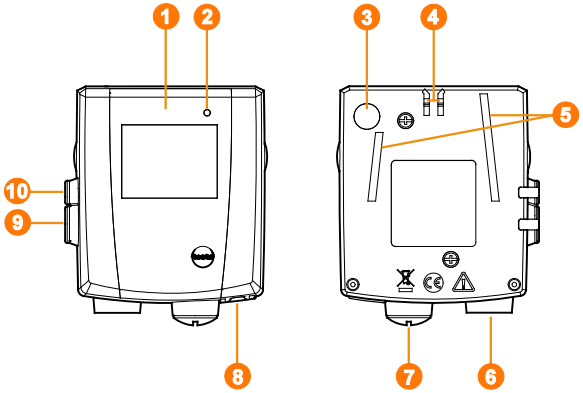
1 Display
2 Status LED:
- flashes red for an alarm,
- flashes green for communication
3 Control key, to start data transfer manually
4 Battery compartment (rear)
5 USB and probe ports (bottom, instrument-specific)

6.4.2.2 Display icons

Symbol	Description
	Battery capacity 75% to 100%
	Battery capacity 50% to 74%
	Battery capacity 25% to 49%
	Battery capacity 5% to 24%, icon flashes: Battery capacity < 5%
	External power supply (via USB port)
	WLAN signal strength 100%
	WLAN signal strength 75%
	WLAN signal strength 50%
	WLAN signal strength 25%
	There is a data connection to the Saveris base, icon flashes: data connection to testo Saveris is being established.

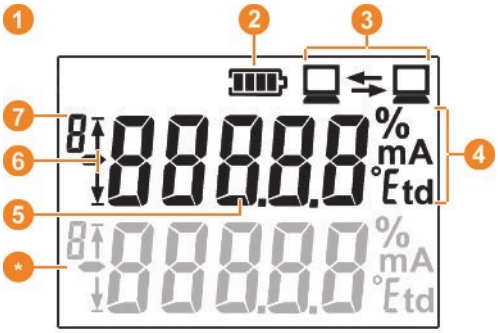
Symbol	Description
⚠	Alarm message
1	Measurement channel 1
2	Measurement channel 2
↑	Alarm status: upper limit value overshot
↓	Alarm status: lower limit value undershot

6.5 Ethernet data logger for testo Saveris



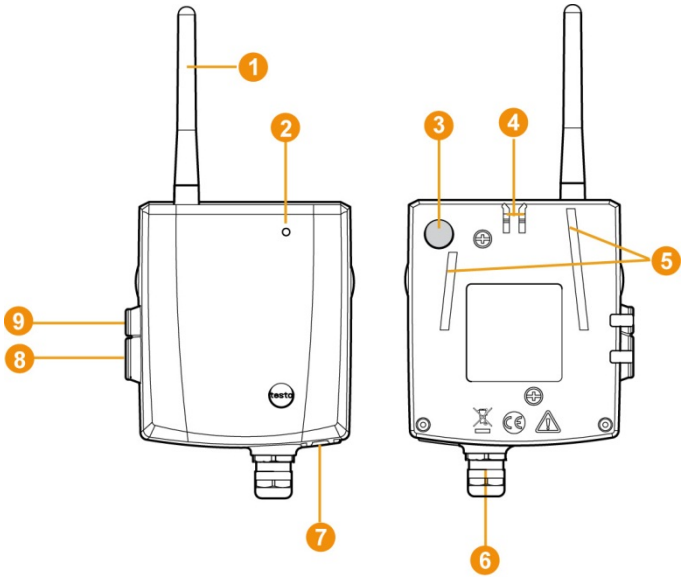
1	Display for showing readings and transmission information.
2	LED for status display.
3	Connect key.
4	Catch for the wall bracket.
5	Guide rails for the wall bracket.
6	Input for external probes.
7	Input for external 24 V AC/DC power supply, M1.6 x 1.5 cable coupling.
8	Input for Ethernet interface
9	Input for service interface
10	Input for power supply via mains unit.

Displays



1	-
2	Status of batteries
3	Indicator as to whether a communication with the Saveris base is being carried out.
4	Unit of the reading: - **%** for humidity measurement - **mA** for current measurement - **°Ctd** or **°Ftd** for dewpoint measurement.
5	Reading.
6	Indication as to whether the reading has overshot the upper (↑) limit value or undershot the lower (↓) limit value.
7	Number of the channel.
*	Display for a second sensor in the probe.

6.6 Saveris wireless analog coupler



1	Only with wireless analog coupler U1: antenna for sending the measurement data.
2	LED for status display.
3	Connect key for registering the wireless analog coupler on the Saveris base and for a status request during operation.
4	Catch for the wall bracket.
5	Guide rails for the wall bracket.
6	Input for external 24 V AC/DC power supply, M1.6 x 1.5 cable coupling.
7	Only with Saveris Ethernet analog coupler U1E: Input for connecting the network cable.
8	Input for service interface
9	Input for power supply via mains unit

6.7 Transport data logger

6.7.1 testo 182 – BT transport data logger

6.7.1.1 Use

- The instruction manual is an integral part of the instrument.
- Pay particular attention to the safety instructions and warning notices in order to prevent injuries and damage to the product.
- Keep this documentation on hand so that you can refer to it when necessary.
- Always use the complete original instruction manual.
- Ensure all users of the product throughly read this documentation.

Other Testo components are required for functions such as registration, readout, evaluation, inspection and analysis of the measurement data of the testo 182 described here. These are not included in this documentation, however they can be obtained from your Testo partner.

6.7.1.2 Intended purpose

- testo 182 is used to record and save measurement data in the course of monitoring the transportation of cold chain products.
- Configuration of testo 182 is customer-specific and is carried out during production at Testo. No subsequent modification of the configuration is possible.
- testo 182 is designed for single use only. Therefore it must not be used more than once.
- testo 182 with an expired use-by date must not be used.
- Operation is manual, with no additional auxiliary devices.
- testo 182 should be placed as close to the products as possible. However, the goods must not impair testo 182.
- When positioning testo 182, make sure that the surrounding goods do not press on the button of testo 182.
- testo 182 can only be used in conjunction with the associated hardware and software.
    - For applications in the regulated environment of the pharmaceutical industry, the registration and readout gateway (BT gateway; 0572 0223) and also the testo Saveris CFR software (0572 0185) are required, incl. Transport Add-on (0572 1860).
    - For applications in the food industry, the BT gateway for testo 182 and a Testo Cloud account are required.

6.8 Safety instructions

6.8.1.1 Description of the instrument

Scope of delivery

- testo 182 BT transport data logger (40 pcs per packaging unit)
- Optional: location sticker, location tape
- Short instructions

Configuration

testo 182 is supplied ex-works with a specific configuration, which is defined by the customer. This configuration cannot subsequently be changed. Configurable parameters are:

- Measuring cycle (1 min – 24 h)
- Upper and lower alarm threshold (within the measuring range -30 °C to +50 °C / -22 °F to +122 °F)
- Alarm behavior (immediate alarm in the event of a limit value violation or cumulative alarm after x limit value violations)
- Start delay (0 mins to 60 mins, a 15-minute delay is recommended based on the sensor's acclimatization time)
- Optional accessories: location tape and location sticker

6.8.1.2 Operating elements of the product

	Element		Element
1	Serial number/barcode (removable)	**2**	Start/Check key
3	LED (red)	**4**	LED (green)
5	Serial number/barcode (integrated)	**6**	Order number and configuration
7	Refer to instruction manual	**8**	Location tape

6.8.1.3 Using the product

Starting measuring process

In order to monitor cold chain drugs in the pharmaceutical environment, it is necessary to install a BT gateway for testo 182 as a registration gateway at the transmitter, and a BT gateway for testo 182 as a readout gateway at the receiver. You will find details on this in the instruction manual for the gateway.

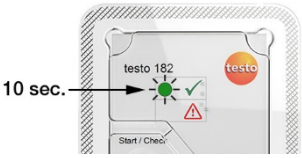
1 Press **Start/Check** for at least one second to start testo 182.

testo 182 must be within the wireless range of the registration gateway for the measurement start and synchronization

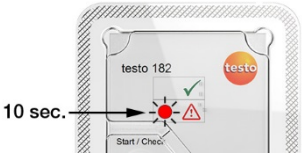
2 LED flashes alternately red and green: testo 182 is being registered.

3 LED flashes green: Registration successful.

- testo 182 begins (after start delay) to record readings



LED flashes red: Registration failed.



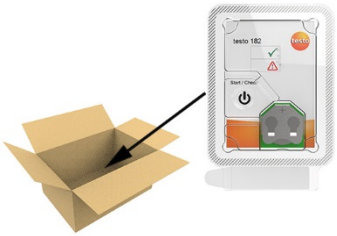
Each time the **Start/Check** button is pressed again, this produces a status display.

LED lights up green while the button is pressed: measurement data is within the limit values

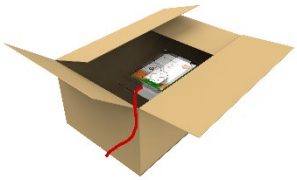
LED lights up red while the button is pressed: measurement data is outside the limit values.

4 Optional: stick barcode label onto the delivery note.

5 Enclose testo 182 with the shipment.



6 Optional: attach location tape to the outside of the packaging.



7 Optional: attach location sticker to the packaging so that it is clearly visible from the outside.

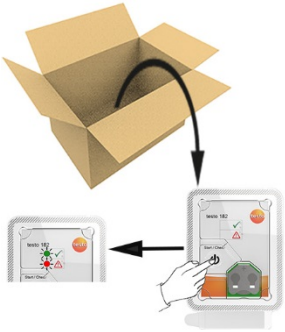
Completing the measuring process and reading out the testo 182

1 Completing the measurement process and reading out the testo 182
- LED lights up green:
limit values adhered to

- LED lights up red:
limit values violated

ATTENTION

If too much time elapses between removing the data logger and pressing the button, this can lead to a limit value violation due to a deviating ambient temperature.



2 Pressing the button establishes a connection to the BT gateway for testo 182. The measurement data is transmitted to the database via the gateway. The two LEDs flash alternately for the duration of the data transfer.

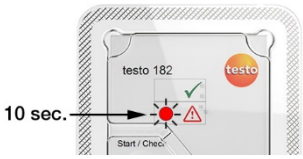
ATTENTION

If no connection can be established, the testo 182 spends 60 seconds attempting to set up the connection. If no data transfer can be carried out within this time, the testo 182 resumes its measurement. If this happens, please repeat the readout process.

If it is not possible to read out the testo 182, you can send it to your Testo Service to read. In this case, please send the start time of the testo 182 (date and time) in addition to the testo 182. Please clean the testo 182 before sending it to Testo.

3 Following successful data transfer, the LEDs flash red and green at one-second intervals, continuously.

If the connection for the data transfer is interrupted, the red LED flashes. testo 182 attempts to establish the connection again (step 2).



4 Any additional press of the button indicates whether the limit values were adhered to or violated.

5 Used testo 182 can be assembled in the box provided and returned to Testo. Please clean the testo 182 before assembling them in the box.

6 Dispose of the testo 182 properly.

LED status display

The following statuses are indicated via the LEDs:

Status LED	Cause
testo 182 flashes alternately red and green (only pharmaceutical applications).	testo 182 attempts to establish communication with the registration gateway and is then registered by this / testo 182 attempts to establish communication with the readout gateway and then transmits the data to this.
testo 182 flashes green for a duration of 10 sec. (only pharmaceutical applications)	testo 182 has been registered. The measurement starts.
testo 182 flashes red three times after attempting to communicate with the registration gateway (only pharmaceutical applications)	testo 182 could not be registered.
After being switched on, the testo 182 flashes green and red once (food applications).	Activation was successful.

Status LED	Cause
After being switched on, testo 182 flashes green at one-second intervals for a duration of 10 seconds (food applications).	System test was carried out successfully.
After being switched on, the testo 182 flashes red at one-second intervals for a total of 10 seconds (food applications).	An error occurred during the system test. Data logger must not be used!
The green LED lights up while the button is pressed.	testo 182 limit values have thus far been adhered to.
The red LED lights up while the button is pressed.	testo 182 limit values were violated.
Eco Logger flashes red three times 60 seconds after attempting to communicate with the readout gateway.	Communication with the readout gateway has failed. testo 182 will make another attempt to transfer its data when the button is pressed again.
Green and red LEDs flash simultaneously at one-second intervals after removal and pressing the **Start/Check** button.	The measurement data was transferred successfully.

Querying the status of the testo 182

The LEDs on testo 182 provide an indication as to whether the limit values were adhered to or violated. After a testo 182 is switched on, if the **Start/Check** button is pressed again, one of the two LEDs lights up while it is pressed.

- LED lights up green: the measurement data is within the limit values.
- LED lights up red: the limit values were violated. There is an alarm.

Even after the data transfer, you can check whether alarms were triggered over the measuring period by pressing the **Start/Check** button.

6.8.2 testo 184 - USB Transport data logger

6.8.2.1 Use

The testo 184 USB transport data loggers are used to save and read out individual readings and measurement series. They have been specifically designed for monitoring the transportation of products subject to cold chain requirements.

Temperature and humidity readings are saved throughout the entire duration of the measurement program.
Acceleration readings are monitored throughout the duration of the measurement program and saved when the set limit value is exceeded.

Data logger programming and measurement report output are implemented via PDF files, no software needs to be installed.

Product versions T1 and T2 are single-use data loggers with a time-limited service life.

Configuration and readout of the testo 184 G1 USB transport data logger are not possible with the testo Saveris CFR Software and its transport add-ons.

6.8.2.2 Exclusion of liability

USB data loggers are USB mass storage devices. Antivirus protection for USB mass storage device is not Testo's responsibility.

6.8.2.3 Status LEDs

To increase the battery life, the status LEDs are not permanently lit. They flash once every 5 seconds. The status LEDs are disabled in hibernation mode.

Alarm

Feature	LED colour
No alarm	Green
Alarm	Red

Battery

Feature	LED colour
Battery life > 10 days	Green
Battery life < 10 days	Red

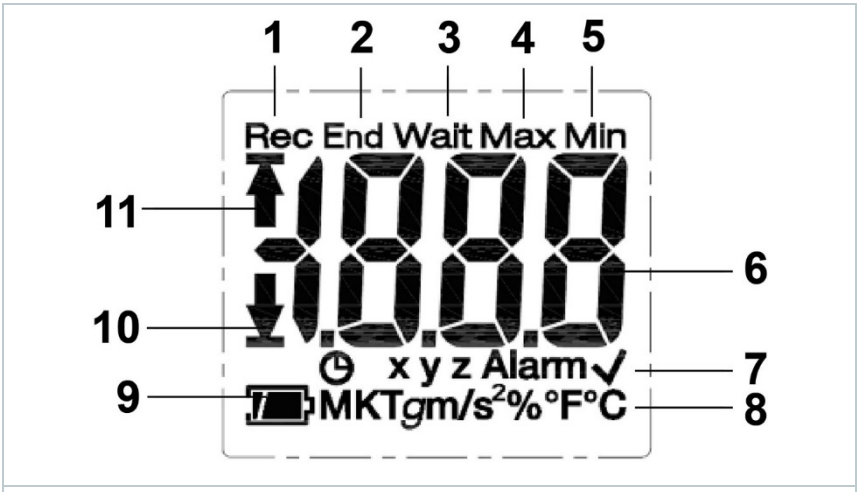
Mode

Feature	LED colour
WAIT mode (wait for program start)	Green and red
Rec mode (measurement program running)	Green

Feature	LED colour
End mode (measurement program finished)	Red

6.8.2.4 Display (LCD)

Not available for all product versions.



1	Measurement program running	**2**	Measurement program finished
3	Wait for start of measurement program	**4**	Highest saved reading
5	Lowest saved reading	**6**	Reading
7	Status information: ◷ start criterion date/time programmed/time mark, xyz measurement axes for acceleration measurement, Alarm set limit value(s) exceeded, ✓ set limit value(s) not exceeded	**8**	Units
9	Battery capacity: sufficient, part empty low (flashing) empty	**10**	Lower limit value has been exceeded
11	Upper limit value has been exceeded		

For technical reasons, the display speed of liquid crystal displays becomes slower at temperatures below 0°C (approx. 2 seconds at -10°C, approx. 6 seconds at -20°C). This has no influence on the measuring accuracy.

For technical reasons, battery performance decreases at lower temperatures. This has no influence on the measuring accuracy. We recommend the use of fully charged batteries in order to avoid a *reset* of the instrument at low temperatures.

6.8.2.5 Key functions

Commissioning

The data loggers are delivered in hibernation mode to prolong the battery life. In this mode, the status LEDs and the display are disabled.

> Press the **START** key or the **STOP** key.

\- **Wait** mode is activated.

START key

✓ **Wait** mode and start criterion Key Start programmed.

> Press **START** key for approx. 3 seconds to start the measurement program.

\- The measurement program starts: **Mode** status LED flashes green, **Rec** appears on the display.

✓ Product versions with display:

> Press **START** key to toggle between the displays.

Display sequence (max. display range per version, individual items of data are not displayed depending on the operating mode):

Display	T2	T3	H1
Current temperature reading (**°C / °F**)	x	x	x
Current average value **MKT** (Mean Kinetic Temperature)	x	x	x
Current relative humidity reading (**%**)	-	-	x
Current acceleration reading, X axis (**x, g**)	-	-	-
Current acceleration reading, Y axis (**y, g**)	-	-	-
Current acceleration reading, Z axis (**z, g**)	-	-	-
Maximum temperature reading (**Max, °C / °F**)	x	x	x

Display	T2	T3	H1
Minimum temperature reading (Min, °C / °F)	x	x	x
Maximum relative humidity reading (Max, %)	-	-	x
Minimum relative humidity reading (Min, %)	-	-	x
Maximum acceleration reading , X axis (Max, x, g)	-	-	-
Maximum acceleration reading, Y axis (Max, y, g)	-	-	-
Maximum acceleration reading, Z axis (Max, z, g)	-	-	-
Time mark ( )	x	x	x
Battery life in days ( )	x	x	x

STOP key

✓ Rec mode and stop criterion Key Stop programmed.

> Press STOP key for approx. 3 seconds to end the measurement program.

- The measurement program ends: Mode status LED flashes red, End appears on the display.

START + STOP key

The data loggers may be placed in hibernation mode to prolong the battery life. In this mode, the status LEDs and the display are disabled.

✓ WAIT or End mode.

> Press the START key and the STOP key simultaneously for approximately 3 seconds.

- Hibernation mode is activated.

6.8.2.6 Important information and definition of terms

- **Single-use data loggers** (versions T1 and T2): the data logger has a time-limited service life, which begins from the first time the program is started.
- **Start** and **stop setting**: the criteria for starting and stopping the program are defined in the configuration file.
  One of the criteria must be selected for starting the program. When selecting the criterion, a time delay can be entered (program starts x minutes after pressing the key).

Both criteria can also be selected for stopping the program. The criterion that occurs first stops the program.

- **Measuring interval**: the measuring interval defines the intervals at which readings are saved.
- **Time mark**: time marks can be set for documentation by pressing the **START** key for 3 seconds during the measurement, e.g. when responsibility is switched to another institution. A maximum of 10 time marks can be set. Setting a time mark resets the statistical values **Min, Max** and **MKT**.
- **Report time zone**: defines the time zone to which all time specifications in the measurement report refer. No possible time zone changes during the measurement are taken into account.

If the data logger was in **rSt** mode and could not be reconfigured, configuration via a copy of an XML file may result in the time & time zone not being correct.

- **Reset mode** (**rSt**): is triggered by an interruption to the power supply, e.g. during battery replacement. A reconfiguration of the data logger is required to resume operation. Data that have already been recorded will not be affected.
- **MKT** (Mean Kinetic Temperature): MKT is a single, calculated temperature. MKT may be considered as an isothermal storage temperature. It simulates the non-isothermal effects of temperature variations during storage.
- Calculation:

$$Tmkt = \frac{\Delta E/R}{-ln\frac{e^{-\Delta E/RT1} + e^{-\Delta E/RT1} + e^{-\Delta E/RTn}}{n}}$$

Tmkt = Mean Kinetic Temperature in degrees Kelvin

∆E = activation energy (standard value: 83.144 kJ/mol)

R = universal gas constant (0.0083144 kJ/mol)

T1 = average temperature in degrees Kelvin during the first time period

Tn = average temperature in degrees Kelvin during the nth time period

- **MKT activation energy**: the default activation energy is set at 83.144 kJ/mol, as recommended in USP <1160>. If other estimates are available as a result of studies that have been carried out, the activation energy can be customized.
- **Individual alarm**: an alarm is triggered when the set limit value is exceeded
- **Cumulative alarm** (only for temperature and humidity measurement): an alarm is not triggered when the set limit value is first exceeded, but only once the overall duration, during which limit values are exceeded, exceeds the set waiting period (allowed time).

- **Wall bracket** (version G1 scope of delivery): for the acceleration measurement, the data logger must be permanently connected to the object being monitored.
  To do this, mount the wall bracket using 2 screws or 2 cable ties and then push the data logger into the wall bracket.

6.8.2.7 Using the product

Creating testo 184 config templates

In order to create a template or a template library for your data logger with the **testo 184 configuration template editor** application, you need a **testo 184** data logger. Once they have been created, the templates can be executed on your data logger using the **testo 184 configuration template user**.

✓ **testo 184** must not be in **REC** mode.

1 Remove the protective cap of the USB interface from the **testo 184** and connect the instrument to the computer.

2 Start the **testo 184 configuration template editor** application.

Creating new template library

✓ **AWS S3 Bucket** has been set up and is accessible.

1 Select **[New]** to create a new template library.

Alternatively, you can edit an existing template and use it on the data logger. To do this, select the required template library in the selection list and click on **[Edit]**.

In order to delete a template library, select the required template library in the selection list and click on **[Delete template]**.

▸ After you have chosen whether you want to create a new template or edit one that already exists, a dialogue opens.

2 Enter start point and end point (sender and recipient) for the transport.

3 Click on **[Logger configuration]**.

▸ The **Limit values** tab of the **Instrument features** window opens.

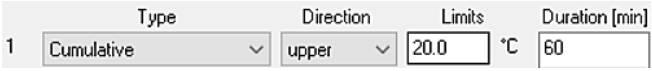
4 You can adjust the name of the measurement channel under **Temperature channel name**.

5 Choose **Type single** in the selection list to specify a single overshooting or undershooting of limit values.

> Choose **cumulative** if you wish to specify an overshooting or undershooting of limit values over a longer period of time as a limit.

6 In the selection list, choose **Direction upper** for an upper or **Direction lower** for a lower limit.

7 Enter the required limit value under **Limits**.
For cumulative overshooting or undershooting of limit values, enter the duration in minutes for which the value must be overshot or undershot in order to trigger a violation of limit value.
Example:



Type: Cumulative, Direction: upper, Limits: 20°C, Duration (min): 60
Explanation: If a temperature of 20°C is exceeded for more than one hour, a violation of limit value is displayed.

8 Further setting options:

Type Disabled	Disable a limit value
Enable MKT	Simulate temperature fluctuations over a specific period of time.
LEDs	Switch the data logger's LEDs for operation on or off.
LCD	Switch the transport data logger's LCD screen on or off
°C or **°F**	Select temperature unit
Start date/time selection list	Choose **Start date/time** selection list to define a specific time from which the data logger needs to start recording readings.
Key	If you wish to start the measurement via the data logger's start key, select **Key**. In order to delay the start after pressing the key, you can select the **[Delayed start]** field and enter the required delay time

PC	Select **PC** to start recording while the data logger is still connected to the PC. If **PC** is selected, you can start or stop the recording via **[Start]** and/or **[Stop]**. Click on **[Extended]** to adjust the activation energy and to enable or disable NFC communication and time marks.
Measuring cycle	Define cycle of measurements. Battery life reduces as the measuring cycle lowers
End	Enter end of recording.
Template name	Name and save the template that has been created so that it can be reused at any time.
Templates in this template library	View templates already created
Delete template	Delete selected template.

9 Click on **[Finish]** to save the changes or **[Cancel]** to reject the changes.

If a new library was created at the start, a new window opens.

- Select the name of the new template library. At the bottom of th window, you will see a list of existing template libraries.
- Confirm by clicking **[OK].**

Configuring testo 184 with config templates

✓ **testo 184** must not be in **REC** mode and **AWS S3 Bucket** with templates is accessible.

1 Remove the protective cap of the USB interface from the **testo 184** and connect the instrument to the computer.

2 Start the **testo 184 configuration template user** application.

3 Select the required template library and the specific template for this transport.

4 You can add the required name for the measurement data under **Enter title**.

5 Click on **[Program according to template]** to configure the data logger according to the selected template.

6 Complete configuration: click on **[OK]**.

If the data logger's measurement is already running before you configure it, this is now ended if you click on **[Cancel]**.

▸ Control light lights up green: the **testo 184** has been successfully configured.

7 End **testo 184 configuration template user** application: click on **[Close]**.

6.8.2.8 Measuring

Starting measurement

Depending on the configuration of the **testo 184**, the measurement program is started via one of the following criteria:

- Key start: hold down the **START** key for > 3 seconds.
- Time start: the measurement starts automatically once the configured time has been reached.

- **testo 184** switches to **Rec** mode, the **Mode** status LED flashes green.

- Start via PC: (Only accessible via **testo 184** template editor)

Setting time marks

While the measurement program is running (**Rec** mode), up to 10 time marks can be set. These are used to document the transfer of responsibility, for example.

> Hold down the **START** key for > 3 seconds.

- The number of set time marks is displayed for 3 seconds and ◷ flashes three times (instruments with display), Mode status LED flashes green/red three times.

Ending measurement

Depending on the configuration of the data logger, the measurement program is ended via one of the following criteria:

- Key stop: hold down the **STOP** key for > 3 seconds.
- Time stop: the measurement stops automatically once the configured time has been reached.

- **testo 184** switches to the **End** mode, the **Mode** status LED flashes red.

6.8.2.9 Reading out testo 184

✓ **AWS S3 Bucket** is accessible.

1. Remove the protective cap of the USB interface from the **testo 184** and connect the instrument to the computer.
2. Start the **testo 184 Saveris** application.

▸ The data logger's serial number is displayed, along with sender, recipient and carrier.

3. Display report as pdf file: click on **[Display report]**.
4. Save measurement data recording: click on **[Save in database]**.

▸ Control light lights up green: measurement data have been saved in the database.

5. End **testo 184 Saveris** application: click on **[Close]**.

6.8.2.10 Maintaining the product

Changing batteries

It is not possible to change the batteries for instrument types T1 and T2 (single-use data loggers).

Changing the batteries stops any measurement that is currently running. However, stored measurement data are preserved.

An interruption of the power supply leads to the **testo 184** data logger's time settings being reset. In order to reinstate the correct time setting, configuration must be carried out via the pdf file, the Comfort Software or by means of the **testo 184 configuration template user** application.

1. Read out stored data.
2. Place the data logger on its front.
3. Open the battery compartment on the rear of the data logger by turning anti-clockwise. Ideally, use a coin to do this.
4. Take empty batteries out of the battery compartment.
5. Insert new batteries (see **Technical data** for type required) into the instrument so that the positive terminal is visible.

Only use new branded batteries. If a partially exhausted battery is inserted, the capacity of the batteries will not be calculated correctly.

6. Place the battery compartment cover on the battery compartment and close it by turning clockwise. Ideally, use a coin to do this.
- The data logger is in reset mode, **rSt** lights up (instruments with display), status LEDs are disabled.
7. Reconfigure data logger.

Cleaning the instrument

ATTENTION

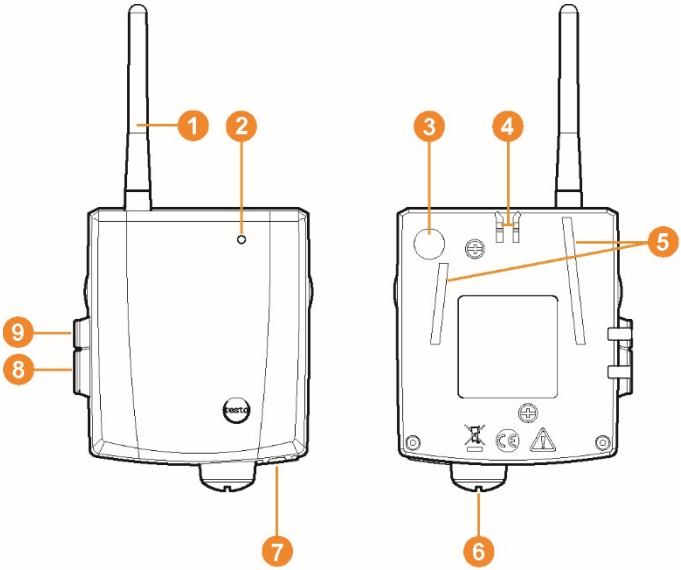
Sensor may be damaged!

> Make sure that no liquid gets inside the housing when cleaning.

> If the housing of the instrument is dirty, clean it with a damp cloth.

Do not use any aggressive cleaning agents or solvents! Mild household cleaning agents and soap suds may be used.

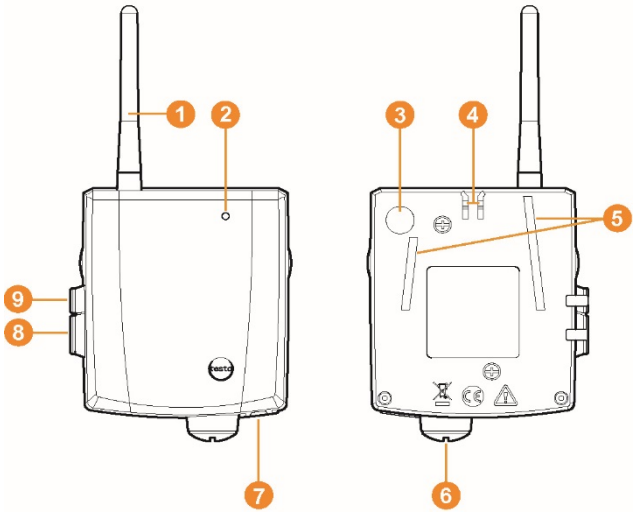
6.9 testo Saveris router



1	Antenna for radio transmission of the measurement data.
2	LED for status display.
3	Connect key for registering the Saveris router on the Saveris base and for a status request during operation.
4	Catch for the wall bracket.

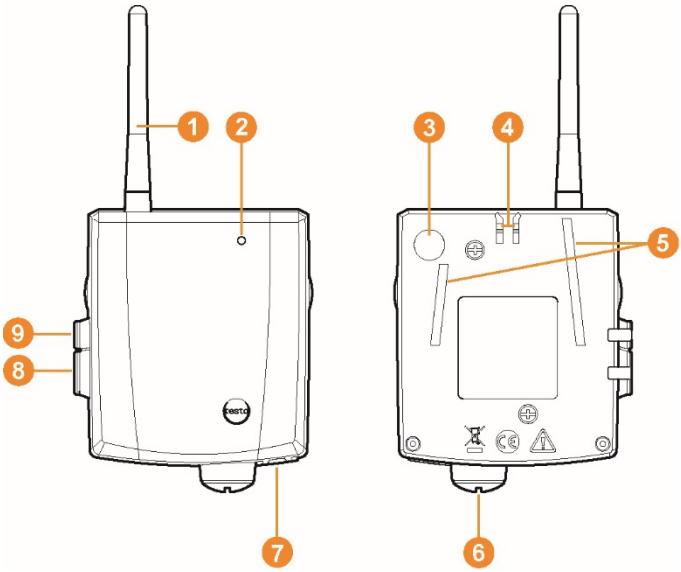
5	Guide rails for the wall bracket.
6	Input for external 24 V AC/DC power supply, M1.6 x 1.5 cable coupling.
7	-
8	Input for service interface.
9	Input for power supply via mains unit

6.10 testo Saveris converter



1	Antenna for radio transmission of the measurement data.
2	LED for status display.
3	Connect key for registering the Saveris router on the Saveris base and for a status request during operation.
4	Catch for the wall bracket.
5	Guide rails for the wall bracket.
6	Input for external 24 V AC/DC power supply, M1.6 x 1.5 cable coupling.
7	Input for connecting the network cable (optional power supply via PoE).
8	Input for service interface
9	Input for power supply via mains unit

6.11 testo Saveris extender[1]



1	Antenna for radio transmission of the measurement data.
2	LED for status display.
3	Connect key to query the status during operation.
4	Catch for the wall bracket.
5	Guide rails for the wall bracket.
6	Input for external 24 V AC/DC power supply, M1.6 x 1.5 cable coupling.
7	Input for connecting the network cable (optional power supply via PoE).
8	Input for service interface
9	Input for power supply via mains unit

[1] Component is only permitted for mobile monitoring in all countries with a radio frequency of 868 MHz. Saveris extender cannot be operated via VPN.

6.12 BT Gateway for testo 182

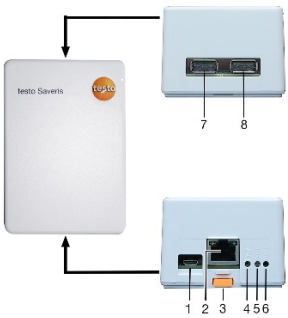
6.12.1 Use

Once they have been manufactured, drugs must be subject to temperature-controlled transportation. Strict adherence to temperature limits is essential in order to maintain the efficacy of the drugs. Testo has developed the testo 182 BT transport data logger (0572 2800) for reliable and cost-effective temperature monitoring of drugs.

The gateway for testo 182 (“gateway” for short) described here is used for non-contact registration and readout of the testo 182. During the configuration, you select whether it is to be a registration gateway or a readout gateway.

The temperature data recorded by the testo 182 is transferred to the Saveris database following transmission to the readout gateway, where it is analyzed, organized and archived together with other environmental data in compliance with the 21 CFR Part 11 specifications..

6.12.2 Instrument overview



	Element		Element
1	Micro USB (5VDC) mains adapter	**2**	Network connection and PoE supply
3	Snap lock for top-hat rail	**4**	LED status display for power supply
5	Reset key	**6**	Status LED
7	USB 2: USB port wireless stick	**8**	USB 1: USB port for RNDIS in configuration mode and wireless stick

6.12.3 LED status displays and key functions on the gateway

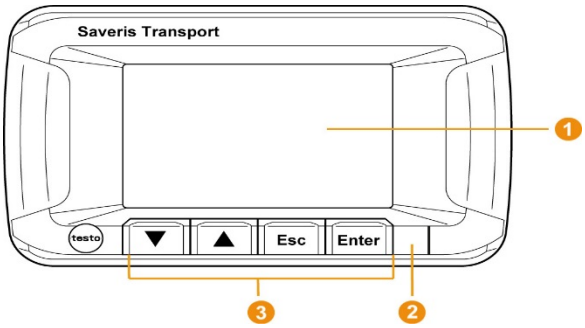
LED status display for power supply	Function
LED lights up solid green	Power supply established, gateway in operation
LED does not light up	Power supply interrupted

Status LED	Function
LED flashes blue at one-second intervals	Gateway is starting
LED flashes green at one-second intervals	Configuration mode active
LED lights up solid green	Standard operation
LED flashes green 10 times	Firmware update successfully completed
LED flashes red 5 times	Firmware update finished with an error
LED flashes green 5 times	Gateway reset to factory settings
LED lights up solid red	Communication error

Reset key	Function
Press key for approx. 5 sec.	Gateway is restarted
Press key for approx. 15 sec.	Gateway is restarted in configuration mode
Press key for at least 30 sec.	Gateway is reset (factory reset)

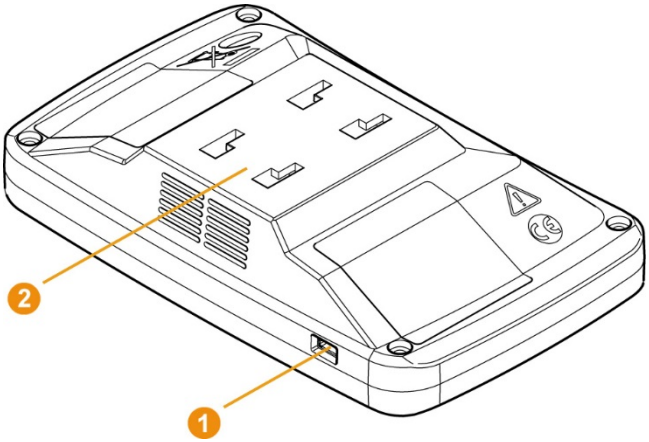
6.13 testo Saveris cockpit unit[2]

6.13.1 Front



1	Display for the visualization of alarms and user guidance
2	Warning LED and PC interface
3	Keypad for operating the Saveris cockpit unit

6.13.2 Rear



1	Mini USB cable connection
2	Guide for bracket

[2] Component is only permitted for mobile monitoring in all countries with a radio frequency of 868 MHz.

6.13.3 Control keys

Key	Explanation
[Enter]	Hold down **[Enter]** for 3 seconds: Switch on the Saveris cockpit unit. Starts the login status for the Saveris cockpit unit in the **Login** menu. Switch to the next menu level down. Confirm selected functions.
[Esc]	Saveris cockpit unit is not registered on the Saveris base: In the **Select language** menu, press **[Esc]** briefly once: Shut down the Saveris cockpit unit. Switch to the next menu level up. Saveris cockpit unit is registered on the Saveris base: Hold down **[Esc]** for 3 seconds: Shut down the Saveris cockpit unit.
[▲], **[▼]**	Navigation keys to switch menus or to select an option.

6.13.4 Displays

Icons

The following icons are displayed at the top right of all views

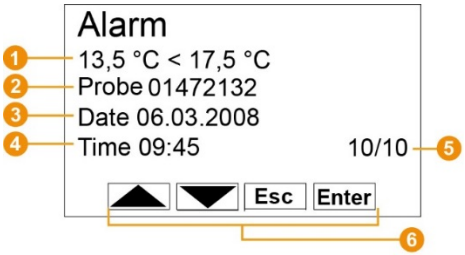
Display	Explanation
	Tour started.
	Data transfer is running between the following components: - Saveris cockpit unit and Saveris extender/Saveris base - Saveris data logger in the currently selected mobile zone and Saveris extender/Saveris base
!	Feedback informing the driver that a Saveris data logger of the selected tour contains measurement data that have not yet been transferred to the Saveris base. The symbol only appears after a second measuring cycle or 30 minutes.

Device settings menu

Sub-menus:

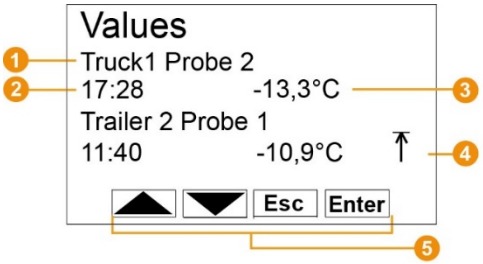
- Day/night settings
- Illumination
- Reading display settings
- Factory reset

Alarm menu



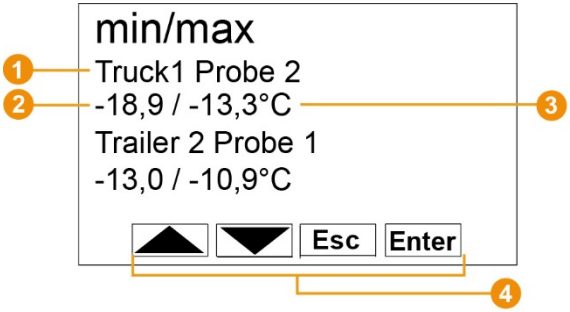
1	Description of why an alarm has been triggered.
2	**Channel name (Probe)**: Data logger which the alarm was triggered for.
3	**Date**: Date on which the alarm was triggered.
4	**Time**: Time at which the alarm was triggered.
5	Alarm number and total number of alarms.
6	Keys that are assigned functions in this menu.

Readings menu



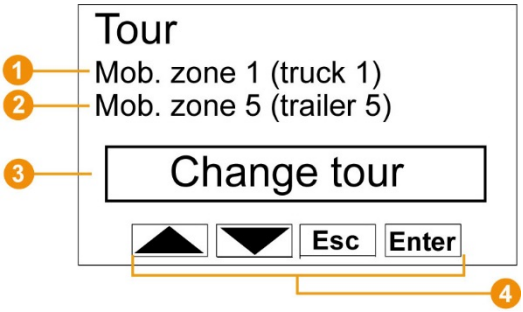
1	Data logger and associated mobile zone for which the reading was transferred.
2	Time at which the reading was transferred / date on which the reading was transferred (shown alternately in this row).
3	Reading with associated unit.
4	Indication of limit values being exceeded.
5	Keys that are assigned functions in this menu.

Min/Max menu



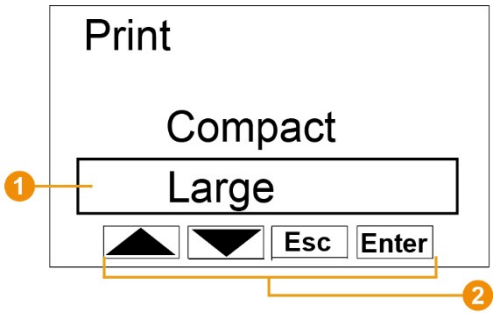
1	Data logger and associated mobile zone for which the reading was transferred.
2	Min. reading with associated unit.
3	Max. reading with associated unit
4	Keys that are assigned functions in this menu.

Tour settings (Tour)menu



1	Selection of the first mobile zone (with [▲], [▼]).
2	Selection of the second mobile zone (with [▲], [▼]).
3	Selection of the action: Change tour, Start tour, Stop tour (with [▲], [▼]).
4	Keys that are assigned functions in this menu.

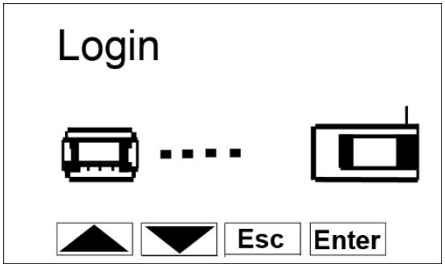
Print menu



1	Selection of the output type.
2	Keys that are assigned functions in this menu.

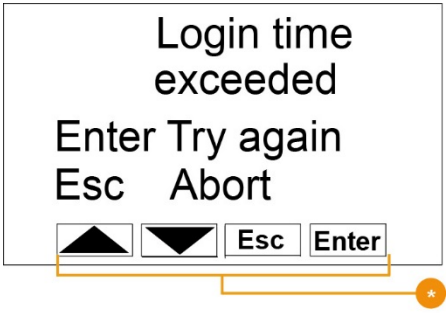
The print data can be sent via infrared to the Testo printer 0554 0549.

Login 1/2 menu



	Status display when the Saveris cockpit unit is registering on the Saveris base.

Login 2/2 menu



Login time exceeded

This display appears when the Saveris cockpit unit was unable to register on the Saveris base within approx. 30 seconds.

*	Keys that are assigned functions in this menu.
	Login time exceeded
	ESC Cancel
	ENTER New try

6.14 Use of the testo Saveris CFR software for the intended purpose

The **testo Saveris CFR software** serves the purpose of saving, reading out and analyzing individual readings and measurement series. The **testo Saveris CFR** version was specially developed to fulfil the requirements of the FDA regarding the electronic storage of data records in accordance with 21 CFR Part 11, when working in conjunction with data loggers.

Controlling user access has top priority:

this involves the **testo Saveris CFR Software** using the security mechanisms of the Windows® operating systems.

During the installation phase, a system administrator with special rights must set up the **testo Saveris CFR software** using the security settings of Windows. These include, above all, the assignment of users to local groups. The allocation of user IDs and passwords and of user rights and the regulation of document flow within the company must comply with the organizational guidelines as laid down.

The factory setting of the **testo Saveris CFR software** security settings complies with the requirements specified in 21 CFR Part 11.

It is to a large extent the responsibility of the operating organization to ensure that the appropriate access rights are made available to its users in individual cases. Testo is not responsible for the consequences arising from incorrect handling of the allocation of user rights at operating system or application program level.

In addition to special software, hardware which is adapted to this area is also required, i.e. the data loggers used must be equipped with password and serial number functions.

For each of these data loggers, there is a matching device driver that is specially adapted to the capabilities of the instrument hardware and its operation.

The data loggers are programmed with the **testo Saveris CFR software** and can then record measurements independently, the collected measurement data are then transferred to a PC via an interface.

The data are also read out using the **testo Saveris CFR software**, which activates the interfaces and provides all other functions.

The readings which are captured together with date/time are tabulated in a special 21 CFR Part 11 form; unmodified raw data and data that have been processed, for example for better comprehension, can be distinguished and appropriately marked.

21 CFR Part 11 places special requirements on the responsibility of the user / operating organization of the complete system, consisting of one or several PCs as well as the relevant data loggers.

The solution provided by Testo is to be seen here as a tool that contains all the necessary aids for implementation of a validated measurement system within the FDA regulations and for reliable management of the electronic data records that it generates.

Use for the intended purpose in this context above all means that a set of SOPs (standard operating procedures) is created for use of the data acquisition system, which ensures that the data loggers and the software **testo Saveris CFR software** are correctly handled.

These instructions must be adapted to the respective company and purpose of use and, together with the data loggers, they form the validated measuring system required by the FDA in 21 CFR Part 11 for the creation of electronic data records, authenticated, where required, by electronic signatures.

In particular, the user/operating organization is responsible for instruction and training of users; in this respect, Testo can only provide the necessary basic material in the form of the present instruction manual.

It is also the responsibility of the user/operating organization to ensure that the measurement data are available over the required storage period.

6.14.1 21 CFR Part 11 and terminology established there

What is 21 CFR Part 11?

Section 21 of the Code of Federal Regulations (CFR) is an area of the laws and regulations passed by the government of the United States of America in connection with the Food and Drug Administration (FDA).

In particular, Part 11 deals with "Electronic Records" and the use of "Electronic Signatures", i.e. with the handling of electronically stored data records and the required security measures associated with them.

What do these regulations concern?

All data that are included in GxP inspections and are permanently held on electronic data storage media. It therefore involves all files and data records that may be the subject of an FDA inspection.

It also involves all electronic signatures that, as computer generated authorizations, represent the legally binding equivalent of handwritten signatures.

Why are these regulations so important?

In the pharmaceutical industry, paper-based systems and handwritten signatures are increasingly being replaced by electronic systems and procedures. In order for these data records to have the same legally binding force with regard to the FDA as the previous paper-based organizations and processes, the requirements of 21 CFR Part 11 must be fulfilled.

These regulations stipulate that data records in the pharmaceutical industry may also be handled electronically and regulate the use of electronic signatures in the place of traditional, handwritten signatures.

All pharmaceutical companies which manage electronic signatures and electronic data records for their production processes, together with the associated obligation to provide proof, and which wish to sell their pharmaceutical products on the US market, must meet the requirements of 21 CFR Part 11.

During an inspection by the FDA, the fulfilment of these requirements is actively verified and failure to do so leads to corresponding blocking notices.

Who must fulfil these regulations?

All companies or manufacturers that market or intend to market their pharmaceutical products on the US market must fulfil these requirements. In other countries, these regulations have also already been acknowledged and are available and obligatory as a quality standard.

What are the possibilities, especially in the area of measuring technology and data acquisition?

Conformity with 21 CFR Part 11

- Compliance in this area means fulfilling requirements that are, above all, organizational but also technical.
- Fulfilling organizational requirements means that pharmaceutical companies create organizational structures and define, describe and document all processes in order to prove what protective measures are used by the respective company to comply with the regulations and how they are enforced.
- The core of such documentation consists of SOPs (standard operating procedures), which describe and regulate all processes in detail. These describe in detail how those responsible have to handle or use processes and systems in order to meet the stipulated requirements.
- Fulfilling technical requirements: The fulfilment of requirements at a technical level is based on the use of products that are specially manufactured for use in this area.
- This area includes the **testo Saveris CFR Software** described here in accordance with 21 CFR Part 11, along with the data loggers approved for this purpose.

Only the combination of suitable technical systems with the appropriate SOPs (standard operating procedures) tailored to the process in question guarantees comprehensive fulfilment of the FDA requirements for the manufacturers of pharmaceutical products.

However, this also means that the use of technically suitable products, such as the data loggers does not in itself completely fulfil the FDA requirements; this can only be achieved by integrating measuring technology in an organization established in compliance with 21 CFR Part 11, together with company-specific SOPs.

For Testo, providing suitable systems means: Wherever possible, we seek to meet the stipulated requirements at the technical level in order to reduce the number of SOPs needed within the company to a minimum in each case.

This is the objective of our system, but it is also the subject of this instruction manual, which is intended to help you to identify critical processes in data acquisition and archiving and makes recommendations as to where you can secure your position with regard to the FDA by means of additional SOPs.

The complete text of the regulation is available on the Internet at:

http://www.fda.gov.

The following just provides you with a short summary:

Part 11 - electronic records and electronic signatures deals with the criteria for enabling electronic data records and signatures to be regarded as equivalent to handwritten signatures and paper documents. This covers data records that are created, altered, maintained, archived and transmitted.

Such data records can be securely handled in so-called closed systems, i.e. in an environment to which only a controlled group of people has access. With the **testo Saveris CFR software**, access is controlled via the proven Windows security system (allocation of USER IDs, rights management, user for password management, user authentication). The authentication concept (user rights which enable or disable software functions) is determined by the IT administrator for three user levels in the **testo Saveris CFR software**.

The system used must be validated within its environment in order to ensure that accuracy, reliability and efficiency are guaranteed, invalid or changed data records should be identified and isolated in good time, either automatically or by suitable validation measures.

Further measures, described in paragraph 11.10, serve to protect established electronic data records against unauthorized access and modifications.

Besides the actual readings/data records, the database is also used to save so-called audit trails, which contain all marginal information that has accumulated since the commissioning of the system.

Every action of relevance for an electronic data record is recorded, together with a unique user ID and date/time.

Paragraph 11.10 draws particular attention to the obligation to keep all persons concerned in the creation, processing and archiving of electronic data records

up-to-date with regular training in order to ensure that these persons have the necessary knowledge to use the required systems and procedures reliably. With regard to the implementation of the technical requirements for the data loggers and the **testo Saveris CFR software**, reference will be repeatedly made, throughout this instruction manual, to the text of 21 CFR Part 11 in order to build understanding of how detailed functions are implemented in the context of 21 CFR Part 11.

6.14.2 Information for the administrator

One of the focal points of the 21 CFR Part 11 regulation deals with controlled system access. The background to this is the fact that so-called closed systems, i.e. clear, small system units, with only a few, very specially defined external interfaces and a defined group of authorized users, can be easily controlled via a small number of SOPs.

As, in practice, the responsibility for allocating user accounts and user rights lies in the hands of administrators who have far-reaching, cross-system rights, the following information is addressed to the administrator or the group of people authorized to integrate the **testo Saveris CFR software** into a validated process or a validated overall system.

The Testo installation program links the **testo Saveris CFR software** program with the access control mechanisms of the Windows® operating systems.

The installation program requires administrator rights.

During the installation of the program:

- local groups are created to link the **testo Saveris CFR software** with the NT security system: this involves 3 local groups being added in the system management, in addition to those already in existence:
  - Testo - Comsoft - Admins
  - Testo - Comsoft - Power Users
  - Testo - Comsoft - Users

  The local groups are only valid on the PC on which they were created and they are the key to concept for the access rights to the database.
- the **testo Saveris CFR software** is registered as source of event report entries (audit trail and event logs).

After the installation you must allocate individual users, who are to work with the program, to one of the above named groups.

The following procedure applies, especially for the installation or operation of the **testo Saveris CFR software** within a company network:

Server/domain

1. Create global user group(s) centrally in the Active Directory, e.g. "ComSoft Admin", "ComSoft Power Users" and "ComSoft Users").
2. Assign group members.

Workstation computer

3. Install **testo Saveris CFR software** (locally) on the workstation computer.
4. Include global group(s) as members in local Testo groups.

6.14.3 General information for users of the testo Saveris CFR software

The descriptions and sections of this instruction manual in particular refer to the requirements of 21 CFR Part 11.

If individual functions which are described in the instruction manual are not available to you for selection, you may not have the appropriate rights. In this case you should contact the administrator.

Pay attention to the following exceptions in terms of CFR operation:

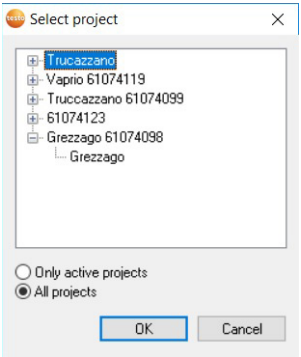
- The base is connected to the PC via an Ethernet cable. Connection via USB is not possible.
- Alarms cannot be acknowledged via the Saveris base, but only directly in the CFR software with the appropriate rights.
- Alarms cannot be acknowledged via SMS or email.

7 Using the product

7.1 Starting the Saveris software

1. Select **[Start]** | **All programs** | **Testo** | **Saveris**.

- The **Testo Saveris software** program window is opened with the **Select project** dialogue.



2. Select the

- **Only active project** option, if you need to open the data for an ongoing project
- **All projects** option, if you need to open the data for a finished project.

3. Select the project that is to be opened in the tree structure.
4. Confirm by clicking on **[OK]**.

- The **Testo Saveris software** program window is displayed with the selected data record in the foreground.

It can take a few minutes for the first readings to be displayed.

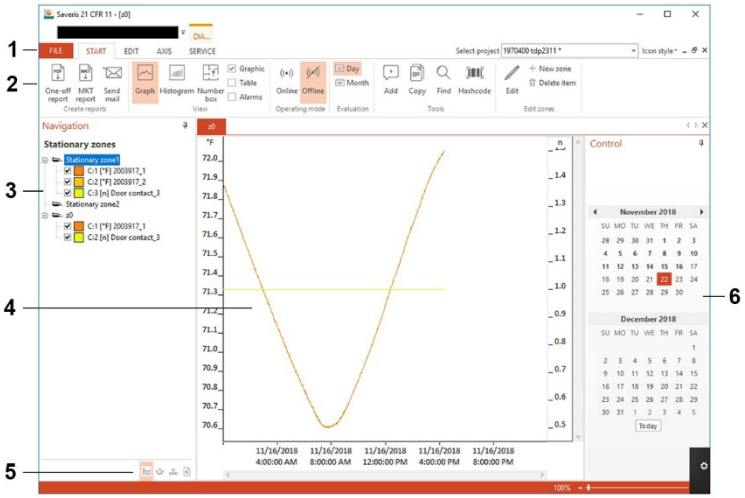
7.2 Use of testo Saveris software for monitoring in the stationary area

7.2.1 General

The following section deals with the functionality of the testo Saveris software which is relevant for measurement data monitoring in closed areas (production plants, warehouses).

7.2.2 User interface

In this section, you will find out how the user interface of the Saveris software is designed.



1	Menu bar	**4**	Display area The readings are represented in the display area as diagrams and tables, as well as the alarms received being listed. The data from several measurements series can be opened and you can switch between them via the tab
2	Menu functions	**5**	Navigation area

3	Data area The data area is used for measurement data management. You can create new groups of readings and copy the data from individual channels within the groups	**6**	Calendar and alarm acknowledgement In offline mode (see section 7.2.3.1 **Start** → **Start** | **Operating mode**), the calendar is displayed which allows fast navigation within the data records. Open data records in the display area by clicking on a certain day in the calendar or by marking a period of several days in the calendar with the mouse button held down. In the online mode, this area shows the alarm acknowledgement where you confirm the alarms received.

7.2.3 Menus and commands

In this section, you find out which menus and commands are available to you and what you can use these commands for.

7.2.3.1 Start

Start | Clipboard menu

Menu functions	Description
Copy	Copies the marked element onto the clipboard.

Start | Edit zones menu

Menu functions	Description
Edit zone	Changes the allocation of the channels to the marked zone.
New zone	Creates a new reading group.
Delete	Deletes the marked element.
Rename	Renames the marked zone.

Start | Create reports menu

Menu functions	Description
One-off report	Define report contents and create one-off report.

Menu functions	Description
MKT report	Generates a retrospective MKT (Mean Kinetic Temperature) calculation as a pdf report for the selected zone. Reporting period, channels and activation energy can be selected.

Start | Operating mode menu

Menu functions	Description
Online	The measurement is performed at the same time, meaning that the data are automatically updated. No time period can be selected using the calendar in the online mode.
Offline	The measurement is performed with a time delay, meaning that the data that are called up are not automatically updated. The data will not be called up by the base until you are actively working in the software, e.g. when changing the view or opening another group.

Start | Analysis menu

Menu functions	Description
Day	Shows the calendar for selecting the day, in order to call up the data for the corresponding day or for multiple days from the database.
Month	Shows the calendar for selecting the month, in order to call up the data of the corresponding month from the database.

Start | View menu

Menu functions	Description
Graphic	Shows the graphic display of the readings if the checkbox is activated.
Table	Shows the tabular display of the readings if the checkbox is activated.
Alarms	Shows the list of the triggered alarms if the checkbox is activated.

Menu functions	Description
Diagram	Option for the graphic display. The readings are shown as a diagram.
Histogram	Option for the graphic display. The current reading is shown as a column.
Monitor	Option for the graphic display. The readings are shown in fields that you can position freely on a wallpaper.

Start | **Notes** **menu**

Menu functions	Description
Insert	Adds a free comment text to a desired channel at a point in time that can be selected. The note can be seen in the **Graphic** view as a yellow icon and as a red triangle in the table cell in the **Table** view. The entered comment text appears when you move the mouse over it. The comment can be edited and deleted via the context menu.

Start | **Hash code** **menu**

Menu functions	Description
Hash code	Display hash values of the readings.

Start | **Search** menu

Menu functions	Description
Search	Opens a search window in the **Data** and **System** navigation areas where you can search through zones and channels using a text word search.

7.2.3.2 Edit

Edit in the diagram view

The **Edit** menu (diagram) is only displayed if the diagram has been activated by clicking on the window.

Edit | Tools menu (diagram)

Menu functions	Description
Zoom in	Draw a rectangle in the diagram window to zoom in on the area covered. This function can also be used during a measurement in online mode. However, this means the extract shown always displays the current value. When you click on **[Original size]**, the diagram is once again displayed in its full size.
Crosshairs	Crosshairs which can be used to follow the curve are shown by clicking on a point of a measurement curve. The date, time, reading number and reading are shown in the process.
Regression curve	Regression curves are an aid to enabling better evaluation of large, complex amounts of data. This involves "outliers" being suppressed and the actual course of the curve being reproduced using a theoretical, mathematical function. The regression curve is shown by clicking on a measurement curve. The regression coefficients are displayed in the status bar.
Limit values	Activate the checkbox to show the limit values in the diagram.

Edit | Font menu

Menu functions	Description
Font	Opens the selection list of available fonts.
Font size	Opens the selection list of available font sizes.

Edit | Curves menu (diagram)

Font	Opens the selection list of available fonts.
C:1, C:n	Legend for the diagram. Clicking on the entry of a curve opens the dialogue for the characteristics of the curve.

Edit in the table view

The **Edit** (table) menu is only displayed if the table has been activated by clicking on the window.

Edit | Formulae menu (table)

Menu functions	Description
New formula	Opens an input window for entering a new calculation formula.
Edit formula	Allows an existing formula to be edited.
Delete formula	Deletes an existing formula.

Edit | Tools menu (table)

Menu functions	Description
Mark	Marks data over a definable time period or definable rows (index range).
Drop marking	Drops the marking.
Add rows (minimum, maximum, mean value)	Inserts a row at the end of the table with the corresponding value for the whole table.  The min, max and mean values cannot be determined via a time period/index range defined in the table.
Compress	Compresses the table to definable intervals. Only the first and the last value are shown for the individual intervals. The other readings are hidden.
Drop compression	Drops the compression.

Edit | Font menu

Menu functions	Description
Font	Opens the selection list of available fonts.
Font size	Opens the selection list of available font sizes.

Edit | Search menu (table)

Menu functions	Description
Minimum	Shows the smallest reading of the selected channel within the table.
Maximum	Shows the largest reading of the selected channel within the table.

Edit in the monitor view

The **Edit** menu (monitor) is only displayed if the diagram window has been activated by clicking on the window.

Edit | Tools menu (monitor)

Menu functions	Description
Wallpaper	Opens the **Open** dialogue to select the wallpaper for the monitor. The following image formats can be added: .bmp, .jpg, .wmf, .ico and .gif.  The wallpaper must be stored locally on the PC.
Background colour	Opens the **Colour** dialogue to select the background colour for the number field.
Adjust | **Broadband**, **Formatfüllend**	Setting for adapting the wallpaper to the number field: • Broadband: the image size is adjusted to the width and/or height of the window and the image is centred in the window. The ratio of image height to image width is retained in this process. • Filling Frame: the image is expanded so that it fills the entire window.
Rearrange	Resets the arrangement of the number fields.

Menu functions	Description
Edit wallpaper	The wallpaper can be edited with Microsoft® Paint.
Delete wallpaper	Deletes the currently displayed wallpaper.

Edit | Forms menu (monitor)

Menu functions	Description
Insert	Insert arrows and text fields.
Delete	Deletes a selected element.
Colour	Colour setting for a selected element.
Undo	Resets the latest changes.

You can adjust the number fields as required using the right mouse button. You can thus show or hide their frames or their transparency, for example.

You can move the fields and change their size with the left mouse button.

7.2.3.3 Axes

Axes | Axes menu

This menu allows you to configure the value and time axis.

Axes | Value axis menu

Menu function	Description
Division	Input of upper and lower limits and division setting (finer/coarser).

Axes | Time axis menu

Menu function	Description
Division	Division setting (finer/coarser).

7.2.3.4 Template

Template | Template menu

Select a standard template in this menu into which the data that are to be saved or printed are integrated.

The templates differ in terms of the protocol header, that is in terms of the company logo, the address field or the specification of statistical values.

Template | Edit menu

Menu function	Description
Edit template	Enables the editing of an existing template.
Create new template	Enables the creation of a new template.

7.2.3.5 Service

Service | Service menu

This menu can be used to display the service data.

Menu function	Description
Display service data	Creates an *.html file with the service data. The software version number can be found under service data.

7.2.3.6 Select projects

The project data for all projects already created can be displayed using the selection menu without having to restart the software.

7.2.3.7 Style template

Selection of the colour scheme for the program window.

7.2.4 Analyzing measurement series

You can represent measurement series as a diagram or a table.

1. In the **Start | View** menu, mark the **Graphic** function if the data are to be displayed graphically and choose the form of display.
   - The measurement data can be shown as a **diagram**, **histogram** or **number field**.
   - Choose **Table** if the data are to be displayed in tabular form.

7.2.4.1 Diagram view

In this view, the readings are shown as line diagrams.

✓ In the **Start** | **View** menu, the **Diagram** command is activated. You now have to select the data record that you wish to display.

1 In the calendar, select the day or time period that needs to be evaluated.

2 In the tree structure of the data area, open the group that contains the data to be displayed.

▸ The data for the selected data is displayed.

2.1 If necessary, deactivate channels via the checkboxes for the display.

You can show or hide the gridlines for the corresponding axis by clicking on the time axis or the value axis.

Zooming in

Zoom in on a detail of the diagram, for example to check the behaviour of the readings within a specific time span.

1 Click on **Edit** | **Tools** | **Zoom in**.

2 In the diagram, press and hold the left mouse button to highlight the area that needs to be enlarged.

If you click on **[Original size]**, the whole diagram is shown again.

Information on a reading (crosshairs)

If you move the crosshairs along a curve, you will quickly get detailed information on the individual readings.

1 Click on **Edit** | **Tools** | **Crosshairs**.

2 In the diagram, click on the point for which the details need to be shown.

▸ A dialogue is displayed with the following information about the reading:

- date on which the reading was recorded,
- time at which the reading was recorded,

- number of the reading and
- reading.

You can move along the curve with the left mouse button pressed and held enabling you to see the detailed information for the readings.

To do this, it is not necessary to follow the course of the curve exactly; the crosshairs do this automatically when you move the mouse to the right or left.

Showing regression curve

Place a regression curve over the diagram to show the course that the measurement series tends to take.

1. Click on **Edit** | **Tools** | **Regression curve**.
2. Click on the reading curve for which the regression curve needs to be shown.

▸ The regression curve is shown and its regression coefficients are displayed in the status bar.

If you click on the curve again, the regression curve is once more hidden.

Characteristics of a curve

You can adapt the display of a measurement series to your requirements. So, you can for example change the line width of a curve or the representation of the limit values in the diagram.

1. Switch to the diagram view of the measurement series whose characteristics need to be displayed.
2. In the **Edit** | **Lines** menu, click on the entry of a curve whose characteristics need to be displayed.

▸ The **Characteristics of (curve name)** dialogue is opened.

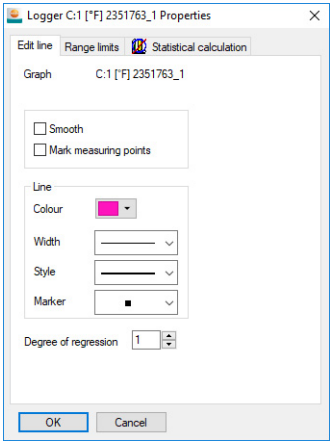
The following tabs are available in the dialogue:

- **Edit line** tab
- **Range limits** tab
- **Statistical computation** tab

Buttons of the dialogue

Button	Explanation
[OK]	Applies the changed settings. The dialogue is closed.
[Cancel]	Closes the dialogue without applying the changes.

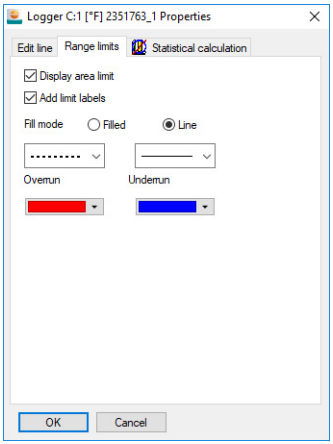
Edit line tab



Name	Explanation
Smooth	The measuring points are connected by an interpolated curve; that is, the plot-points on the curve between two measuring points are estimated mathematically.
Mark measuring points	The individual measurement points are represented by a symbol. The value shown exactly corresponds to the measured value only at these points. The measuring points are connected with straight lines during the measurement. When the measurement is paused, the curve can be smoothed.
Colour	Line colour of the curve.
Width	Line width of the curve.

Name	Explanation
Style	Line style of the curve.
Marker	Symbol for the measuring points.
Degree of regression	Possible values "0" to "7". "0" degree of regression corresponds to a pure mean value calculation, "1" degree to the linear trend, a higher value helps in the event of curves with several extreme values.

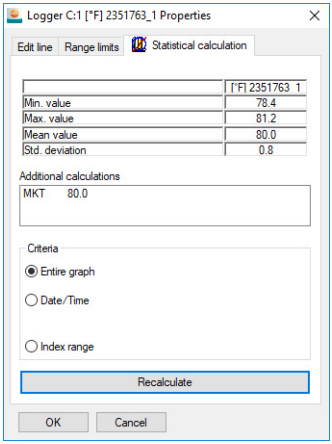
Range limits **tab**



Name	Explanation
Display range limits	Specification as to whether the limit values should be shown in the diagram.
Add limit labels	Specification as to whether the limit values should be labelled (**Upper**/**Lower limit value: name of curve**).
Area fill	Specification as to whether the areas outside the limit values should be marked by means of an area fill.
Selection list for area fill	Selection of the fill.
Line fill	Specification as to whether the limit values should be shown by horizontal lines.

Name	Explanation
Selection lists for line fill	Selection lists for line type and line thickness.
Overshot	Colour selection for filling the area above the upper limit value.
Undershot	Colour selection for filling the area below the lower limit value.

Statistical computation tab



Name	Explanation
Min. value	Smallest reading of the curve.
Max. value	Largest reading of the curve.
Mean value	Arithmetically-determined average reading.
Std. deviation	Measure of the scattering of the readings around the mean value.
Criteria	Setting display criteria: all, date/time and index range.
Recalculate	Recalculates the curve.

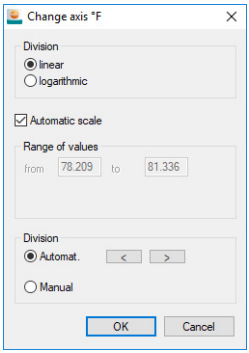
Settings for the axes in the diagram

Change the settings of the axes in the diagram to adapt the display to your requirements.

Settings for the value axis

1 Double click on the required value axis in the diagram or use the right mouse button.

▸ The **Change axis [Unit of the readings]** dialogue is displayed.

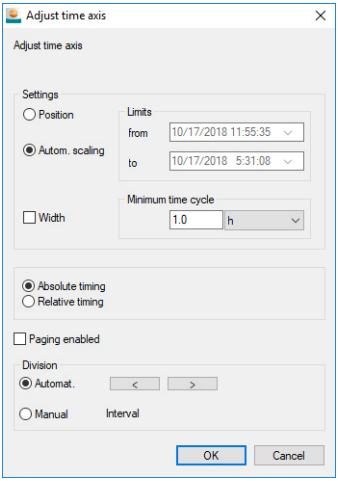


Name	Explanation
Division linear	Specification that the axes are divided in a linear manner.
Division logarithmic	Specification that the axes are divided logarithmically, meaning the division increments represent powers of ten.
[OK]	Applies the settings until other data are called up. The dialogue is closed.
[Cancel]	Closes the dialogue without applying any changes at all.
Automatic scale	Specification as to whether the program should perform scaling of the value axis.
Range of values from...to	Manual input of the value range when **Automatic scale** is disabled.
Division automat.	Specification that the program should perform the division of the axis.
Division manual	Specification that the division of the axis should be performed manually.
Grid [<], [>] (when automatic division is enabled)	By clicking on **[<]** or **[>]**, make the axis division larger or smaller.
Interval (when manual division is enabled)	Manual entry of the grid.

Settings for the time axis

1 With the right mouse button, click on the time axis in the diagram.

▸ The **Adjust time axis** dialogue is displayed.



Name	Explanation
[OK]	Applies the settings until other data are called up. The dialogue is closed.
[Cancel]	Closes the dialogue without applying any changes at all.
Position	Shows a freely-definable extract of the diagram.
Automatic scaling...	Shows the entire diagram in the window.
Extract	Shows a firmly defined extract that can be moved over the time axis.
Limits from…to (when **Position** view is enabled)	Limits for the **Position** view.
Minimum time cycle (when **Extract** view is enabled)	Specification of which time period should at least be shown.
Selection list for the unit (when **Extract** view is enabled)	Unit of the time axis in the minimum time cycle: **sec** (second) **min** (minute) **h** (hour) **d** (day).
Absolute	All times are the real times at which the readings were recorded.

Name	Explanation
Relative	Sets the starting time to 00:00; the time then runs relative to this starting point.
Paging enabled	The function associated with this is not available in the Small Business Edition.
Division automat.	Specification that the program should perform the division of the axis.
Division manual	Specification that the division of the axis should be performed manually.
Grid [<], **[>]** (when automatic division is enabled)	By clicking on **[<]** or **[>]**, make the axis division larger or smaller.
Interval (when manual division is enabled)	Manual entry of the grid.
Selection list for the unit (when manual division is enabled)	Unit of the time axis: **sec** (second) **min** (minute) **h** (hour) **d** (day).

7.2.4.2 Table view

The readings are listed in table form in this view.

✓ In the **Start** | **View** menu, the **Table** command is activated. You now have to select the data record that you wish to display.

1 In the calendar, select the day or time period that needs to be evaluated.

2 In the tree structure of the data range, open the zone that contains the data to be displayed.

▸ The table view of the selected data is displayed.

3 If necessary, deactivate channels via the checkboxes for the display.

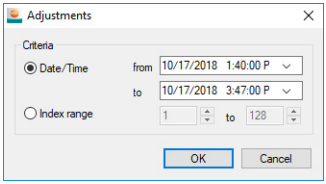
Marking readings

Mark specific readings, for example to perform a statistical computation for part of the measurement series.

The min, max and mean values cannot be determined via a time period/index range defined in the table.

1. Click on **Edit** | **Tools** | **Mark**.

▸ A dialogue for determining the criteria is displayed.



2. Select the **Date/time** option if the readings for a specific time period need to be marked.
   - ▸ The selection lists for determining the time period are enabled.
   - Select **Index range** if the readings in specific table rows need to be marked.
     ▸ The selection lists for determining the index range are enabled.
3. Determine time period or index range.
4. Click on **[OK]**.

▸ The dialogue is closed and the corresponding readings in the table are marked.

The selected readings can be copied and further edited using suitable software (e.g. with Microsoft® Excel®).

Dropping marking

1. Click on **Edit** | **Tools** | **Drop marking**.

▸ The marking of the readings is deleted.

Inserting extreme values or mean value into the table

Insert the minimum/maximum reading, along with the mean value over the whole table, at the end of the table.

1 Click on **Edit** | **Tools** | **Add rows** | **Minimum**, **Maximum** or **Mean value**.

▸ A row is added at the end of the table with the appropriate value over all the readings.

2 Repeat step 1 to insert another value into the table.

To remove a value from the table, click on the appropriate entry in the **Add rows** menu again.

Compressing tabular values

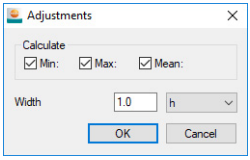
Compress the table to definable time intervals to make the table clearer when there are large amounts of data.

Only the first and the last value are shown for the individual intervals. The other readings are hidden.

In addition, the minimum, maximum and/or mean value can be shown for the respective time period.

1 Click on **Edit** | **Tools** | **Compress**.

▸ The dialogue for determining the options is opened.



2 Determine via the checkboxes whether the respective minimum reading (**Min**), maximum reading (**Max**) and/or mean value (**Mean**) needs to be calculated for the individual time spans.

At least one of these values must be activated to enable compression of the table to be carried out.

3 Enter the time span under **Extract** and determine its unit. Possible settings for the unit:

- **sec** (second)
- **min** (minute)
- **h** (hour)
- **d** (day).

4 Click on **[OK]**.

▸ The dialogue is closed and the table is shown in compressed format.

Determining largest reading

1 In the **Edit** | **Search** | **Maximum** menu, click on the curve for which the largest reading needs to be determined.

▸ The largest reading is displayed as marked in the table.

Adding Rows

1 In the **Edit** | **Tools** | **Add rows** menu, activate the selection that needs to be displayed in the extra rows.

▸ The additional rows are displayed in the table.

Compressing

Tabular values are displayed in compressed format. The limits for the compression range and the additional min, max and mean values are displayed.

1 Click in the **Edit** | **Tools** | **Compress** menu.

▸ A selection window is displayed.

2 Set calculation and extract and confirm with **OK**.

▸ The table display is reduced to the selected min, max and mean values and to the time period entered.

Dropping compression

Table compression is dropped again.

1 Click in the **Edit** | **Tools** | **Drop compression** menu.

▸ The table is again displayed with all the individual values.

Determining the smallest reading

1 In the **Edit** | **Search** | **Minimum** menu, click on the curve for which the smallest reading needs to be determined.

▸ The smallest reading is displayed as marked in the table.

7.2.4.3 Floorplan view

The readings are shown as number fields in this view. If you take advantage of the opportunity to insert a wallpaper, e.g. a floor plan of a building, you quickly achieve a spatial overview of the current ambient conditions.

✓ In the **Start** | **View** menu, the **Monitor** command is activated. You now have to select the data record that you wish to display.

1 In the calendar, select the day or time period that needs to be evaluated.

2 In the tree structure of the data range, open the zone that contains the data to be displayed.

▸ The monitor display for the selected data is shown.

3 If necessary, deactivate channels via the checkboxes for the display.

7.2.4.4 Histogram view

In this view, the readings are shown as a histogram, meaning the last reading of a channel is shown as a column

✓ In the **Start** | **View** menu, the **Histogram** command is activated. You now have to select the data record that you wish to display.

1 In the calendar, select the day or time period that needs to be evaluated.

2 In the tree structure of the data area, open the group that contains the data to be displayed.

▸ The histogram for the selected data is displayed.

3 If necessary, deactivate channels via the checkboxes for the display.

7.2.4.5 Archiving with automatic reports

A simple and reliable option for archiving your data is automatic reporting.

The reports are created by the software and saved on a daily, weekly or monthly basis at a specified location on the computer or a server; see also section 7.2.4.9 **Configuring automatic reports** for this.

The reports are saved as pdf files, so that they can easily be viewed or sent by email, without it being possible to change the data stock.

7.2.4.6 Generating an evaluation

You can print out measurement series or have reports on the data generated either automatically by the software at definable intervals or manually for the required time period.

7.2.4.7 Printing measurement data

Measurement data can be printed in diagram or table form.

1. Select the day or time period in the calendar for which the report needs to be created.

▸ The data for the day or time period are displayed as a diagram or table, depending on the setting.

2. In the **Start** | **View** menu
   - 2.1 Choose the **Diagram** command when the table view is activated, but the diagram view needs to be printed.
   - 2.2 Choose the **Table** command when the diagram view is activated, but the table view needs to be printed.
3. In the **Template** | **Template** menu, select the types of report header.

Via the **File** (Testo logo) | **Page view** command, open a preview of the report.

Use portrait format for printing a table, but landscape format is recommended for printing a diagram.

Specify the format via **File** | **Page setup...**

4. Select the **Print** command in the **File** menu.

▸ The **Print** dialogue is displayed for selection of the print options.

5. If necessary, change print options and click on **[OK]**.

▸ The report is printed.

7.2.4.8 Creating automatic reports

Use the **One-off report** function to generate 21 CFR 11-compliant printouts of any period of time.

1. Select **Stationary zones** main menu.
2. Mark required time period on the calendar.
3. In the **Start** tab under **Create reports**, click on **One-off report**.

▸ The pdf report contains:

- CFR-compliant cover sheet with hash code of the pdf report

- Graphic, measurement data table and alarms for the selected zone
- Audit trail of the time span specified in the calendar

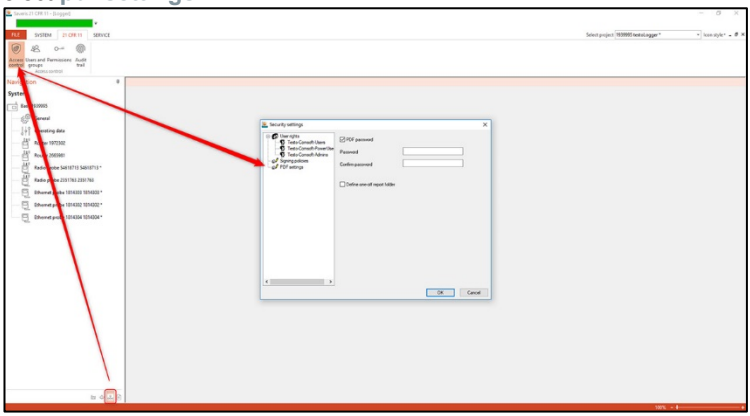
The pdf report can be saved as a pdf with a master password.

The master password is only requested when the report is opened with Adobe Acrobat. No request is made when opening with Adobe Reader.

✓ User is authorized for this.

1 In the **System** main menu, in the **CFR** tab, click the **Security settings** button.

2 Select **pdf settings**.

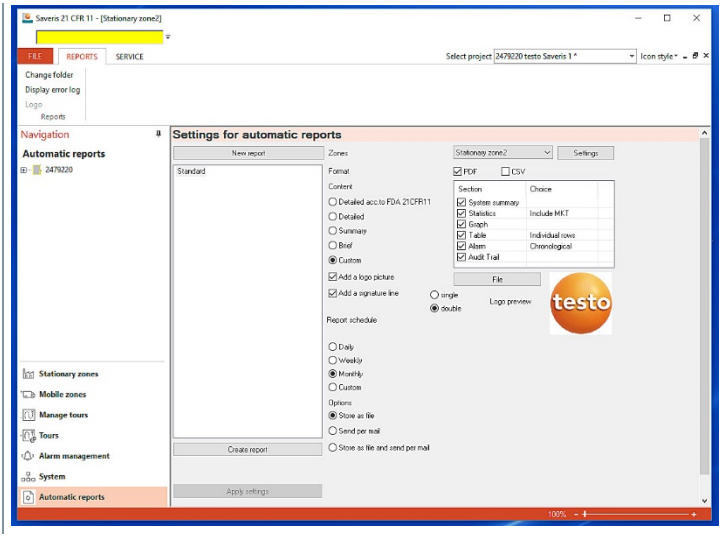


7.2.4.9 Configuring automatic reports

In the report settings, you can determine how automatic reporting should be done.

1 In the navigation area, click on **Automatic reports**.

▸ The **Settings for automatic reports** submenu is displayed in the data window.



Name	Explanation
[New report]	Adds a new reporting task to the list.
List of the reporting tasks	List of the created reporting tasks.
Zones	Selection list of the group for which the report needs to be generated.
Format	pdf, csv
Content group box	When the option is enabled, the corresponding data sheet is attached to the report - **Detailed acc. to FDA 21CFR11** - **Summary** - **Brief** - **Custom** - **Add a logo picture** - **Add a signature line**

Name	Explanation
Report schedule	Specify whether the report is to be generated **daily**, **weekly, monthly** or at a **custom** time.  **Daily**: The report is generated daily at 1 a.m. **Weekly**: The report is generated every Sunday at 1 a.m. **Monthly**: The report is generated on the last day of the month at 1 a.m. **Custom**: A future time period can be set (start date/time, end date/time) for which a report is to be generated on a one-off basis. The report is generated after the time period has elapsed.
[Options]	Specification as to how the report is to be used: **Store as file**, **Send by email**, **Store as file and send by email**.  **Store as file**: The report is saved on the PC. **Send by email**: The report is sent to one or more email addresses. **Store as file and send by email**: The report is saved on the PC and sent to one or more email addresses.
Recipient input field	Input field for one or more email addresses of the employees to whom the report is to be sent. When there are several email addresses, please use “;” as a separator.
Address book	Addresses can be selected from the address book.
Apply settings	Saves the report configurations that have been carried out.

The storage location for the reports was determined during the installation of the Saveris software.

The path specification is shown under the **Determine folder** field.

7.2.5 Managing zones (not possible for measurement data monitoring with transport data loggers)

Once you have familiarized yourself with the menus of the Saveris software, you can turn to creating zones, for example to separate the data loggers according to location. You could perhaps combine data loggers that are located in storerooms into one zone and data loggers that are located in refrigerated rooms into another.

Changing or deleting zones during operation will affect subsequent generation of pdf reports. As these changes also apply retrospectively, old zone configuration data are overwritten.

If a pdf report is generated retrospectively from the past, only the most recent zone configuration is used for reporting. Without a database backup, complete traceability of the changed or deleted zones cannot be guaranteed.

Data loggers are assigned to zones in the startup wizard. They can be changed later via **Start** | **Edit**.

You can assign a maximum of 4 data loggers to one mobile zone and monitor a maximum of 2 mobile zones simultaneously in one tour.

7.2.5.1 Creating zones

1 In the navigation area, click on **Stationary zones** or **Mobile zones**.

▸ The available zones are displayed in the data area.

2 In the **Start** | **Edit zones** menu, select the **New zone** command.

▸ The **New zone** dialogue is displayed.

3 If required, deactivate a channel which is not needed.

At least one channel must be activated.

In mobile zones, all channels of a probe must be assigned to the same zone.

4 In the **Name** field, enter the name of the new zone.

Assign names for the zones that are not longer than 15 characters.

5 Confirm entries with **[OK]**.

▸ The **New zone** dialogue is closed and the new zone is listed in the tree structure in the data area.

7.2.5.2 Changing zones

You can add channels to an existing zone. You can delete channels from a zone that you no longer require there. You can also change the name of the zone.

1 In the navigation area, click on **Stationary zones** or **Mobile zones**.

▸ The available zones are displayed in the data area.

2 In the tree structure of the data area, select the zone that needs to be changed.

3 In the **Start** | **Edit zones** menu, select the **Change zone** command.

▸ The **Change zone** window opens.

4 Click on the checkboxes in front of the channels that are to be added to the zone or deactivate them to remove the channel from the zone.

5 In the **Name** field, overwrite the zone name.

6 Confirm the input with **[OK]**.

7.2.5.3 Deleting zones

1 In the navigation area, click on **Stationary zones** or **Mobile zones**.

▸ The available zones are displayed in the data area.

2 In the tree structure, mark the zone that should be deleted.

3 In the **Start** | **Edit zones** menu, select the **Delete** command.

▸ After confirmation, the zone is deleted.

In the database, the zone is marked as deleted and disabled, but not deleted. A disabled zone is only visible in the time period in which it was active.

7.2.5.4 Assigning zones

You can limit zone access to certain users and user groups. Multiple selection is also possible.

Zones are visible to all users as standard.

✓ Users or user groups are created in the active directory.

1 In the navigation area click on **System**.

2 In the **System | Security** menu, select the **Authorizations** command.

▸ The **Authorizations** window opens.

3 Mark zone for which access needs to be limited.

4 Click on **[Search]**.

▸ The **Search** window opens where the users or user groups from the Active Directory are listed.

5 Mark users or user groups that should be given access to the selected zone.

6 Confirm the input with **[OK]**.

▸ The selected users are assigned to the relevant zone in the **Authorizations** window.

7 Click on **[OK]**.

7.2.6 Configuring alarms

Information on the alarm function

- The alarms occurring in the Saveris system are primarily used to notify the user in good time that problems have occurred which jeopardize the continuous availability of the data in the database. Generally, action is then required.

- Alarms indicate a one-off, but possibly also regular, malfunction. The aim must be to minimize the number of alarms that occur during operation and eliminate such alarms wherever possible. There may be a maximum of 200 outstanding unacknowledged alarms at any one time. An increasing number of unacknowledged alarms not only makes troubleshooting in serious cases more difficult, but also slows the system response during operation.

Alarms are configured in four steps:

5. Setting up Saveris base alarms
   The configuration of the system alarms allows you to determine the conditions under which the base triggers an alarm.
6. Set up alarm groups.
   The alarm groups allow you to determine for which probes and under what conditions an alarm is triggered for system alarms and for channel-related alarms.
7. Enter recipient.
   You must enter the recipients to be able to send alarm messages by SMS or email.
8. Define rules.
   The rules allow you to determine which employee should be notified if an alarm is triggered in a group and which employees receive a message if the alarm is not acknowledged.

Since the probes that monitor mobile units are not generally operated under target conditions (e.g. truck is not cooled during idle periods), limit values are only deemed to be relevant according to the tour blank. The Saveris base therefore only outputs system alarms for probes in mobile zones – violations of limit values are suppressed.

7.2.6.1 Setting up Saveris base alarms

No configuration changes are transferred to the probe/base until you have exited the **Alarm management** menu!
You should therefore exit the **Alarm management** menu after any changes.

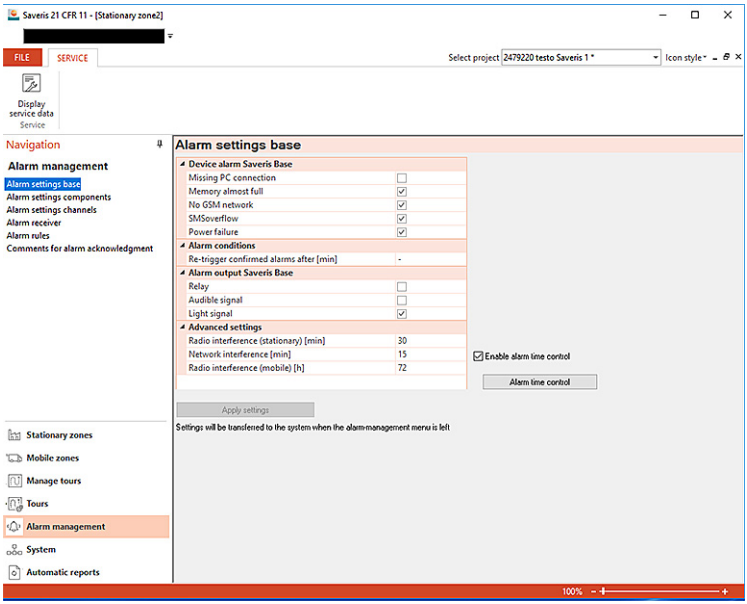
1 Click on **Alarm management** in the navigation area.

▸ The following submenus are displayed in the data area:
- **Alarm settings base**
- **Alarm settings component**
- **Alarm settings channel**
- **Alarm recipients**

- **Alarm rules**
- **Comments for acknowledging alarms**

2 Click on **Alarm settings base**.

The alarm settings for the base are shown in the display area.



Display	Explanation
Device alarm Saveris Base	Setting options for the Saveris base alarms No PC connection: no response from the PC. **Memory almost full:** alarm when the Saveris base memory overflows. **No GSM Network:** alarm when there is no GSM connection. **SMS overflow:** alarm when an error occurs in SMS transmission. **Power failure:** alarm when the base power supply fails.

Display	Explanation
Alarm conditions	Re-trigger confirmed alarms after [min]: re-triggers alarms that have already been acknowledged following a specified duration.
Alarm output Saveris Base	Relays Audible signal Light signal
Advanced settings	No radio signal (stationary) [min] No signal from network components [min] No radio signal (mobile) [h]
Apply settings	Saves the alarm settings.
Enable alarm time control	Activates the configured time control.
Alarm time control	Opens a window for configuring the time control.

3 Setting up Saveris base alarm settings.

4 Click on **Apply settings**.

5 Exit Alarm management menu.

▸ Alarm settings are transferred to the instruments.

7.2.6.2 Setting up time control

All alarms across the entire system are paused/activated via time control.

1 Click on **Enable time control**.

▸ The **Alarm time control** button is activated.

2 Click on **Alarm time control**.

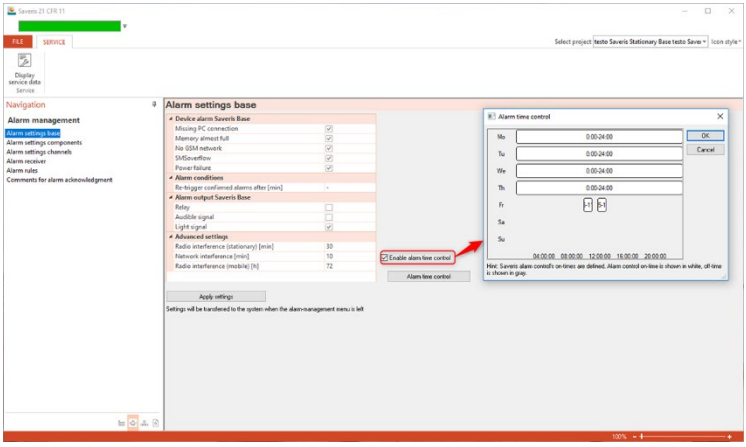
▸ An input window with a complete time control system is displayed. The time control is filled out from Monday to Sunday 0:00 – 24:00 ex-works.

3 Click on a time entry with the right mouse button and select **Delete**.

▸ The selected time entry is deleted.

4 Click on the blank time entry with the right mouse button and select **New**.

▶ An input window is displayed where you can enter the alarm ON times (from, to or all-day).



5 Click on **[OK]** to confirm the entry.

▶ The input window is closed and the modified times are displayed in the time control overview.

In order to create a second time entry for the same day, repeat step 4 and step 5.
Two time periods can be specified per day.

6 Confirm by clicking on **[OK]**.

▶ The input window is closed and the modifications to the time control are accepted.

7.2.6.3 Setting up alarm groups

Component alarms

No configuration changes are transferred to the Saveris radio data logger/Saveris base until you have exited the **Alarm management** menu!
You should therefore exit the **Alarm management** menu after any changes.

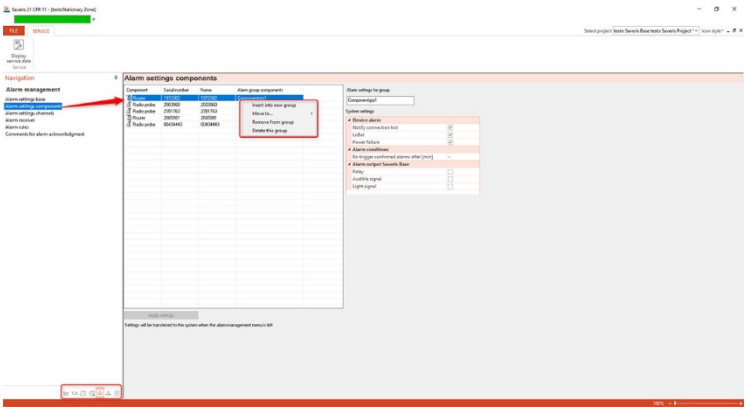
1 Click on **Alarm management** in the navigation area.

▸ The following submenus are displayed in the data area:

- **Alarm settings base**
- **Alarm settings component**
- **Alarm settings channel**
- **Alarm recipients**
- **Alarm rules**
- **Comments for acknowledging alarms**

2 Click on **Alarm settings component**.

▸ The alarm settings for data loggers are shown in the display area.



Display	Explanation
Insert into new group	Creates a new alarm group.
Move to…	Move component/channel to another alarm group.

Remove from group	Removes the component/channel from the specified alarm group.
Delete this group	Deletes the entire alarm group.
Alarm setting components	List of the available components and their affiliation to the selected alarm group.
Alarm settings for groups	Enter the group name.
System settings	System alarms: alarm activation for notification when there are connection problems, LoBat and power failure Alarm conditions: trigger acknowledged alarms after [min] Alarm output Saveris base: settings for relays, audible signal and light signal.
[Apply settings]	Saves the alarm settings of an alarm group.

Create new group

1. Right-click on component, then click on **Insert into new group**.
   - A new alarm group is created.
2. Overwrite the default names in **Group alarm settings**.

Move to…

1. Right-click on component, then click on **Move to ...**.
   - A selection of available alarm groups is displayed.
2. Click on required alarm group.
   - The component is assigned to the selected alarm group.

Remove from group

1. Right-click on component, then click on **[Remove from group]**.
   - The component is removed from the assigned alarm group.

Delete group

1 Right-click on component, then click on **[Delete this group]**.

▸ The assigned alarm group is deleted, all components that were assigned to this group are now without an alarm group.

Channel alarms

No configuration changes are transferred to the Saveris data logger/Saveris base until you have exited the **Alarm management** menu!
You should therefore exit the **Alarm management** menu after any changes.

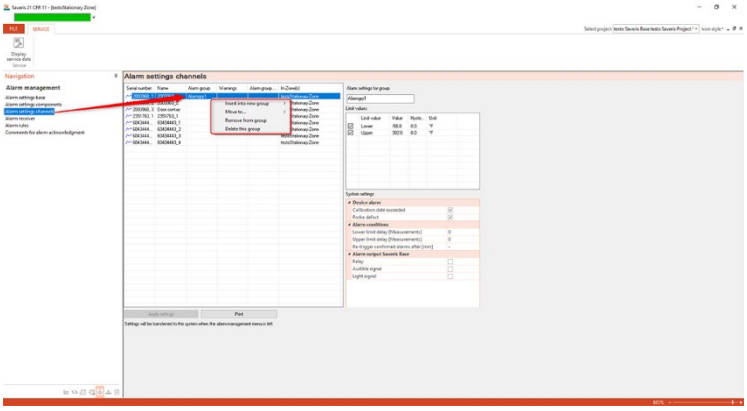
1 Click on **Alarm management** in the navigation area.

▸ The following submenus are displayed in the data area:

- **Alarm settings base**
- **Alarm settings component**
- **Alarm settings channel**
- **Alarm recipients**
- **Alarm rules**
- **Comments for acknowledging alarms**

2 Click on **Alarm settings channel**.

▸ The alarm settings for Saveris data loggers are shown in the display area.



Name	Description
Insert into new group	Creates a new alarm group, with a distinction between alarm, warning and trend alarm group.  A trend alarm is used to monitor temporal changes or the stability of measurement parameters. The change in the measurement parameter is determined over four measurement cycles and projected onto the change per hour. To this end, an alarm is useful unless the absolute value of the measurement parameter is supposed to be within specified limits, but rapid changes must be avoided.
[Move to]	Move component/channel to another alarm group.
Remove from group	Removes the component/channel from the specified alarm group.
Delete this group	Deletes the entire alarm group.
Alarm settings channels	List of the available channels and their affiliation to the selected alarm group.
Alarm settings for groups	Enter the group name.
System settings	Alarm conditions: settings for lower limit delay [measurements], upper limit delay [measurements] and trigger acknowledged alarms after [min] Alarm output Saveris base: settings for relays, audible signal and light signal.
[Apply settings]	Saves the alarm settings of an alarm group.

Name	Description
[Print]	Creates a file containing a summary of the alarm settings for Saveris probes and the Saveris base.

Create new group

1. Right-click on component, then click on **[Insert into new group]**.
   - A new alarm group is created.
2. Overwrite the default names in **Group alarm settings**.

Move to…

1. Right-click on component, then click on **[Move to …]**.
   - A selection of available alarm groups is displayed.
2. Click on required alarm group.
   - The component is assigned to the selected alarm group.

Remove from group

1. Right-click on component, then click on **[Remove from group]**.
   - The component is removed from the assigned alarm group.

Delete group

1. Right-click on component, then click on **[Delete this group]**.
   - The assigned alarm group is deleted, all components that were assigned to this group are now without an alarm group.

7.2.6.4 Creating recipient

No configuration changes are transferred to the Saveris data logger/Saveris base until you have exited the **Alarm management** menu!
You should therefore exit the **Alarm management** menu after any changes.

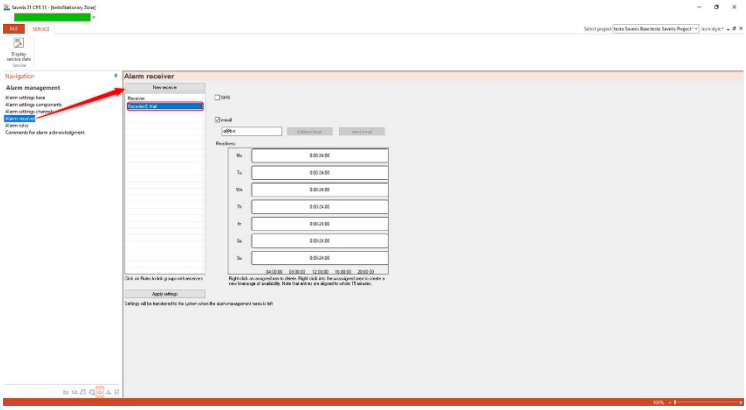
1. Click on **Alarm management** in the navigation area.

The following submenus are displayed in the data area:

- **Alarm settings base**
- **Alarm settings component**
- **Alarm settings channel**
- **Alarm recipients**
- **Alarm rules**
- **Comments for acknowledging alarms**

2 Click on **Alarm recipients**.

The recipient data are displayed in the display area.



Name	Description
[New recipient]	Creates a new entry in the recipient list.
Recipient list	List of possible recipients. The telephone number in the recipient list comes from commissioning. You can replace the number with a recipient name by clicking on the number with the right mouse button and choosing the **Rename** command.

Name	Description
SMS / email checkboxes	Specification as to whether the alarm message should be sent by SMS or email.
Input field for SMS function	Number to which the SMS should be sent.
Input field for email function	Recipient's email address.
Readiness	Overview of the recipient's availability times. Time entries are automatically rounded up/down to 1/4 hour. To change the availability time, you must delete the existing entry using the right mouse button and enter a new availability time.
[Apply settings]	Saves the alarm settings of an alarm group.

Create new recipient

1. Click on **[New recipient]**.

▸ A new entry with the same name is added to the recipient list.

If no recipient was defined with clear text beforehand, the telephone number is used here for the recipient name as an alternative.

2. Click on the new entry in the recipient list with the right mouse button and change the designation.

Recipient's mobile phone data (optional)

1. Activate the **SMS** checkbox when the recipient needs to be informed via SMS in the event of an alarm.

▸ The Input field for the telephone number is displayed.

2. Enter the corresponding numbers.

If an alarm chain is to be created from several recipients, the output targets (SMS or email) of the recipients must not be different within the respective alarm chain.

Entering recipient's email address (optional)

1 Activate the **Email** checkbox when the recipient needs to be informed via email in the event of an alarm.

▸ The Input field for the email address is displayed.

2 Enter the recipient's email address.

If an alarm chain is to be created from several recipients, the output targets (SMS or email) of the recipients must not be different within the respective alarm chain.

Transfer alarm settings

1 Exit "Alarm management" menu.

▸ Alarm settings are transferred to the instruments.

7.2.6.5 Creating alarm rule

No configuration changes are transferred to the Saveris probe/base until you have exited the **Alarm management** menu!
You should therefore exit the **Alarm management** menu after any changes.

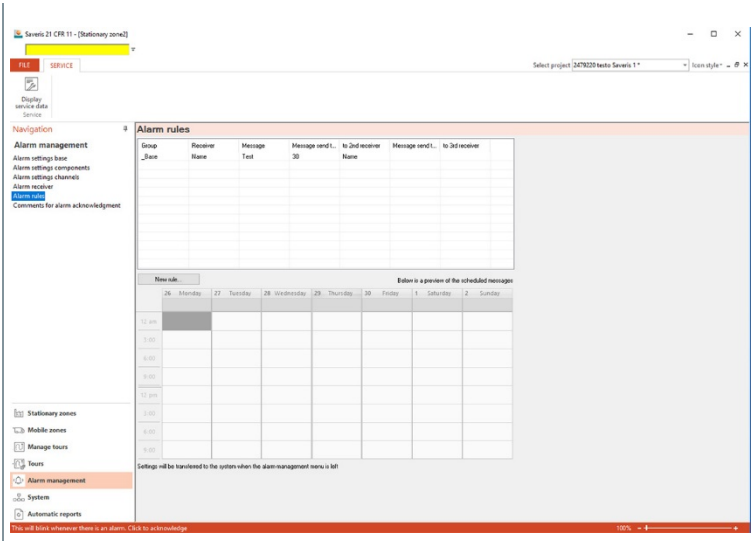
A prerequisite for creation of alarm rules is that the Saveris base alarm settings, the alarm groups of the Saveris probes and the recipients of the alarm messages have been entered.

1 Click on **Alarm management** in the navigation area.

▸ The following submenus are displayed in the data area:
- **Alarm settings base**
- **Alarm settings component**
- **Alarm settings channel**
- **Alarm recipients**
- **Alarm rules**
- **Comments for acknowledging alarms**

2 Click on **Alarm rules**.

▸ A list of the previously created alarm rules is shown in the display area.



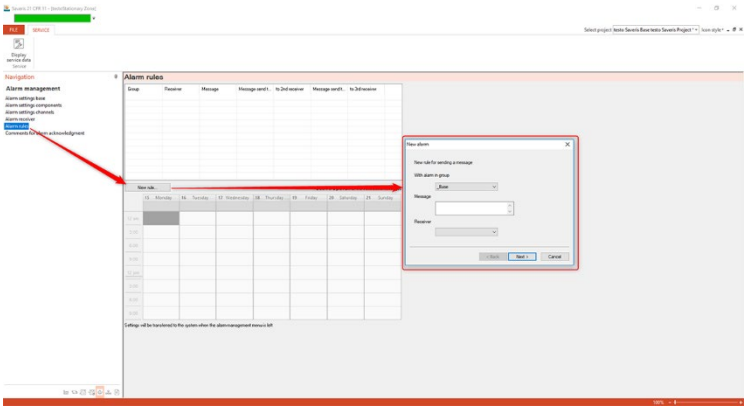
Name	Description
Group	Group for which the alarm rule applies.
Recipient	Recipient who is to receive the alarm message.
Message	Text of the alarm message.
Forward after	Time period after which the alarm message needs to be sent to another recipient if the first recipient does not acknowledge the alarm.
To 2nd recipient	Recipient who is to receive the forwarded alarm message if the first recipient does not acknowledge the alarm.
Forward after	Time period since the last dispatch after which the alarm message should be sent to another recipient if the alarm was not acknowledged. Recipient 3 receives alarm after (forwarding time from recipient 1 to 2 + forwarding time from recipient 2 to 3) minutes.

Name	Description
To 3rd recipient	Recipient who is to receive the forwarded alarm message if the alarm was not acknowledged.
[New rule…]	Starts the wizard for creating a new alarm rule.
Preview	Shows the configured scheduled messages.

Creating new rule

1 Click on **[New rule...]**.

▸ The wizard for creating a new rule is started.



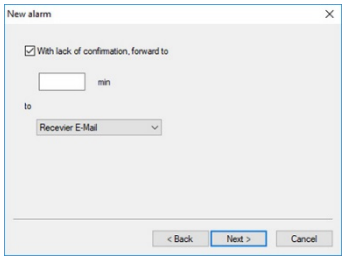
2 Specify group in the **With alarm in group** selection list for which the new alarm should apply.

3 Enter the alarm message text in the **Message** input field.

4 Determine the first recipient who is to receive the alarm message in the selection list of the same name.

5 Click on **[Next >]**.

- The dialogue for the forwarding function or for finishing the alarm rule is shown.



6 Either

6.1 click on **[Finish]**, when the alarm message does not need to be forwarded if the first recipient does not acknowledge the alarm **[Finish]** is only displayed if no forwarding is needed.

- The wizard is ended and the new rule is included in the list of alarm messages.

6.2 Or on the **With lack of acknowledgement, forward to** checkbox if the alarm message needs to be forwarded to another recipient.

- The **min** input field for specifying the time period after which the alarm message needs to be forwarded and the selection list for determining the next recipient is displayed.

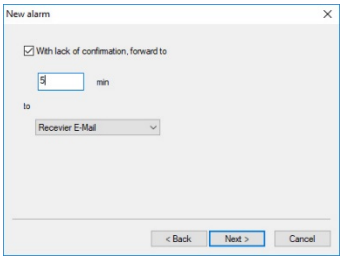
7 In the **min** field, enter the time period after which the alarm message needs to be forwarded. (Time between the alarm being received by recipient 1 and it being forwarded to recipient 2).

8 In the **to** selection list, specify the recipient who is to receive the alarm message.

The output targets (SMS or email) for recipient 1 and recipient 2 must not be different. For all recipients in an alarm chain, the same output target (all SMS or all email) must be set, otherwise the alarm chain will be interrupted.

9 Click on **[Next >]**.

▸ The dialogue for the forwarding function or for finishing the alarm rule is shown.



10 Either

10.1 click on **[Finish]**, when the alarm message does not need to be forwarded if the alarm is not acknowledged

▸ The wizard is ended and the new rule is included in the list of alarm messages.

10.2 Or on the **With lack of acknowledgement, forward to** checkbox if the alarm message needs to be forwarded to another recipient.

▸ The min input field for specifying the time period after which the alarm message needs to be forwarded and the selection list for determining the next recipient is displayed.

11 In the **min** field, enter the time period after which the alarm message needs to be forwarded. (Time between the alarm being sent to recipient 2 and it being forwarded to recipient 3).

12 In the **to** selection list, specify the recipient who is to receive the alarm message.

The output targets (SMS or email) for recipient 2 and recipient 3 must not be different. For all recipients in an alarm chain, the same output target (all SMS or all email) must be set, otherwise the alarm chain will be interrupted.

13 Click on **[Finish]**.

▸ The wizard is ended and the new rule is included in the list of alarm messages.

14 Exit "Alarm management" menu.

▸ Alarm settings are transferred to the instruments.

7.2.6.6 Alarm overview

In the alarm overview you will find a list of the groups with their specific alarm settings.

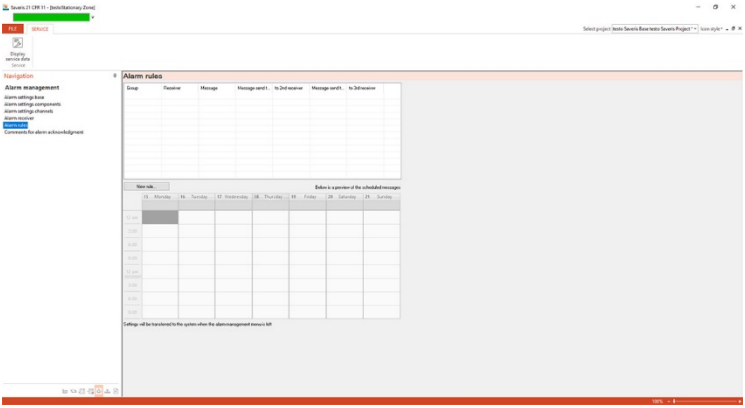
1 Click on **Alarm management** in the navigation area.

▸ The following submenus are displayed in the data area:

- **Alarm settings base**
- **Alarm settings component**
- **Alarm settings channel**
- **Alarm recipients**
- **Alarm rules**
- **Comments for acknowledging alarms**

2 Click on **Alarm rules**.

▸ The defined alarms are shown in the display area.



7.2.6.7 Comments for acknowledging alarms

You can create standardized acknowledgement comments, which are displayed in the acknowledgement window as a selection list.

1 Click on **Alarm management** in the navigation area.

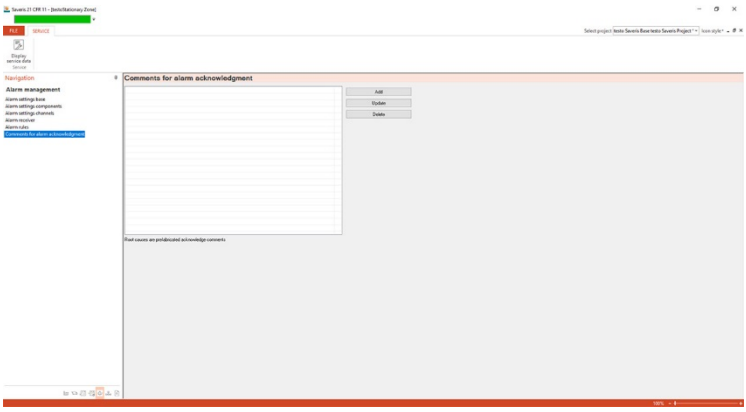
▸ The following submenus are displayed in the data area:

- **Alarm settings base**
- **Alarm settings component**
- **Alarm settings channel**

- Alarm recipients
- Alarm rules
- Comments for acknowledging alarms

2 Click on **Comments for acknowledging alarms**.

The defined acknowledgement comments are shown in the display area.



3 **[Add]**: Create acknowledgement comment.
[Update]: Edit existing acknowledgement comment.
[Delete]: Delete existing acknowledgement comment.

7.3 Use of testo Saveris CFR software for transport monitoring with radio data loggers (“mobile monitoring”)

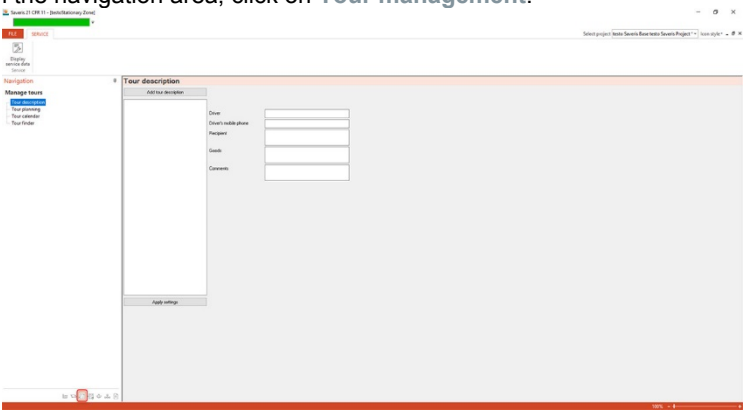
7.3.1 General

The following section deals with the relevant functionality of the testo Saveris software for measurement data monitoring in terms of transport monitoring using Saveris radio data loggers (“mobile monitoring”), see also section 5.2 **How it works**.

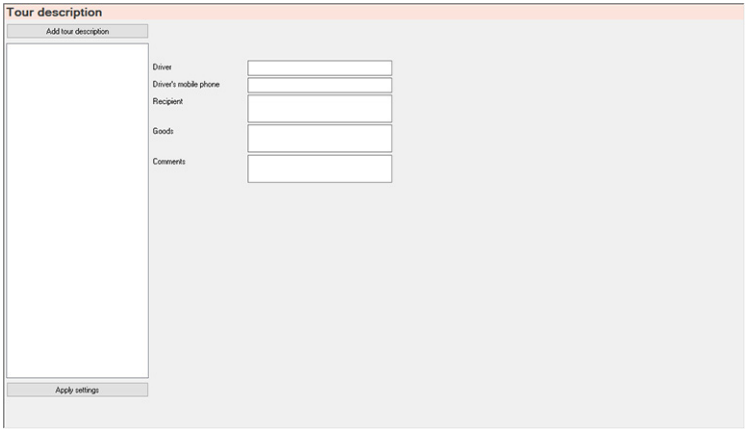
7.3.2 Setting up tours

7.3.2.1 Tour description

1 In the navigation area, click on **Tour management**.



▶ The **Tour description** dialogue is displayed in the data area.



2 Select **[New tour description]**.

3 Enter the name of the new tour description.

▶ The name appears in the tour calendar and in the Saveris cockpit unit.

4 Enter information.

5 Exit dialogue.

▸ Query appears asking whether information should be saved.

6 Click **[Yes]**.

▸ The tour description is saved and can be added to a tour during tour planning. The tour description is transferred to the Saveris cockpit unit and can be selected there.

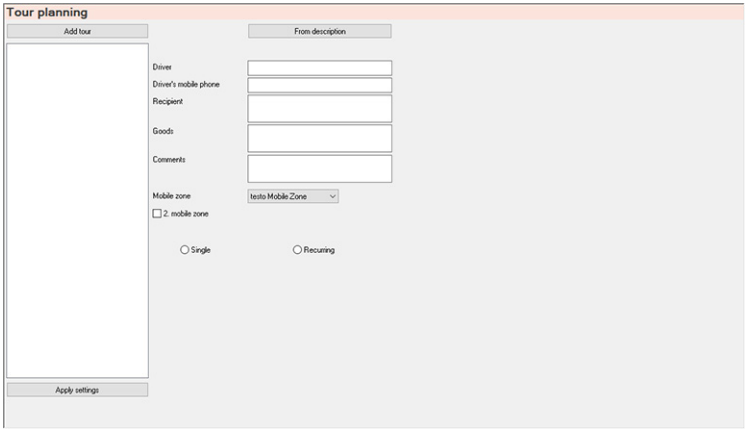
The Saveris cockpit unit can manage up to 100 tour descriptions.

7.3.2.2 Planning tours

This description only relates to tours that are planned for the future. The software is used to create a tour for this. This process is recommended if a Saveris cockpit unit is not used for tour entry.

1 In the navigation area, click on **Tour management**.

▸ The **Tour planning** dialogue is displayed in the data area.



2 Select **[Add tour description]**.

3 Enter the name of the new tour. The name appears in the tour calendar and in the Saveris cockpit unit.

4 Select mobile zones.

4.1 If required: add tour description.

5 Select time period during which the tour is to be carried out.

6 Exit dialogue.

▸ Query appears asking whether information should be saved.

7 Click **[Apply settings]**.

▸ The tour is saved and is displayed in the tour calendar as a planned tour.

Tours that have not yet taken place can only be changed in the **Tour management** navigation area.

7.3.2.3 Defining tours

This function is used to assign existing measurement data to tours at a later stage.

1 In the navigation area, click on **Mobile zone**.

2 Select **Tour definition**.

▸ The **Define tour** window is opened.

3 Define required tour. Via **[From tour description]** the additional information of an existing tour description can be included for this tour.

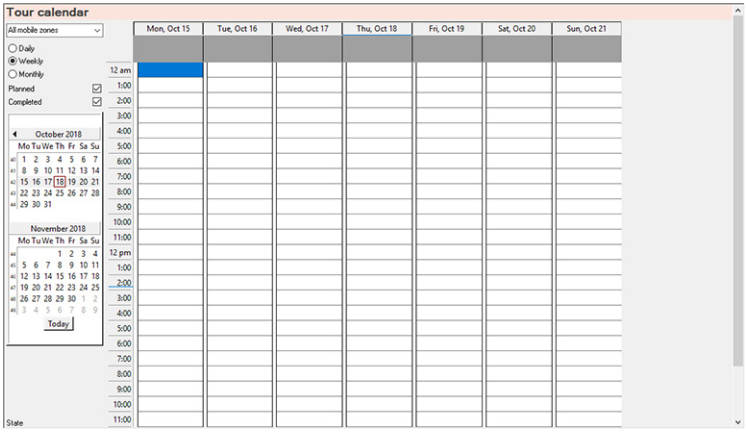
4 Confirm entries using **[Finish]**.

▸ Tour is saved and displayed in the tour calendar.

7.3.2.4 Displaying tours

1 In the navigation area, click on **Tour management**.

2 Select **Tour calendar**.

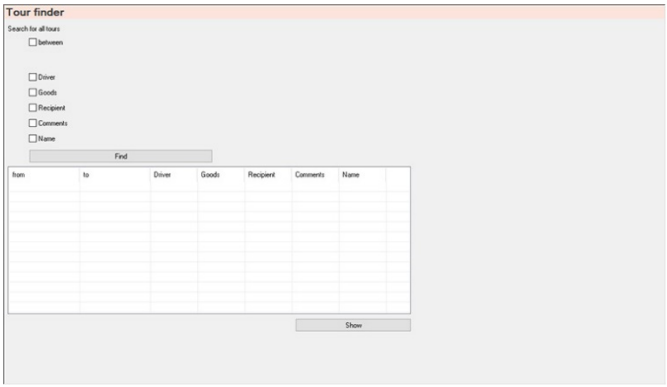


- Selection of the displayed mobile zone
- Adjustable filter options
- Calendar view
- Overview of the tours that have taken place and status of data transfer to the Saveris base:
  - Green: Data transfer complete
  - Yellow: Data transfer in progress
  - Red: Data transfer failed
- Planned tours are shown in white
- Tours that have taken place are shown in orange. Tour data can be displayed via the context menu in the **Tours** navigation area.

7.3.2.5 Searching for tours

1 In the navigation area, click on **Tour management**.

2 Select **Tour finder**.



3 Select or enter required search options.

When searching for tours within a time frame, the tour is considered as a whole. No result is shown if only one part of the tour is within the time frame specified in the search.

4 Click **[Find]**.

▸ Results are displayed.

5 Select required entry from the list of results.

6 Click **[Show]**.

▸ Selected tour data are displayed in the **Tour management** navigation area.

7.3.2.6 Changing tours

1 In the navigation area, click on **Tour management**.

2 Select **Change tour**.

▸ The **Define tour** window is opened.

3 Make required changes.

4 Click **[Next]** and **[Finish]**.

▸ Tour is changed.

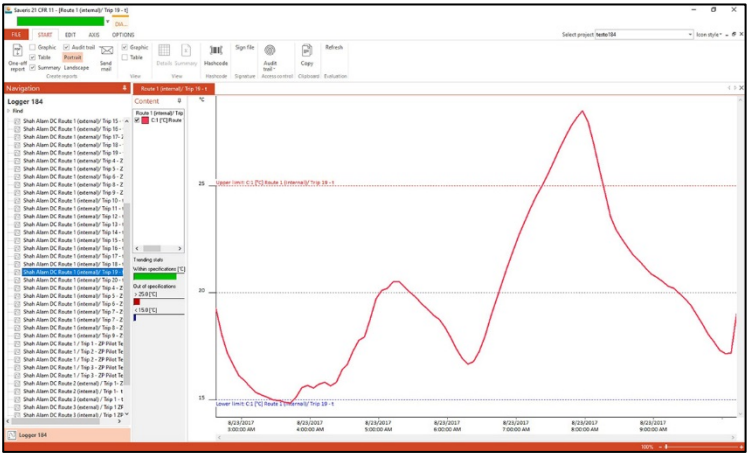
7.4 Use of testo Saveris CFR software for transport monitoring with transport data loggers

7.4.1 General

The following section deals with the relevant functionality of Saveris software for measurement data monitoring with respect to transport monitoring with transport data loggers.
The Saveris CFR software and Saveris CFR transport add-on are prerequisites for measurement data monitoring with transport data loggers.

7.4.2 User interface

In this section, you will find out how the user interface of the CFR viewer for data of the **testo 184 -** USB transport data logger and of the t.b.d. Is structured.



Menu bar

Menu	Explanation
	Setting options for the menu bar.
File	All the functions you require for opening, closing, saving and printing. The program can also be ended using this menu.

Menu	Explanation
Start	The contents of the menu bar include functions for the clipboard, evaluation, viewing in tables and diagrams and audit trail.
Edit	Functions for evaluating the diagrams or tables and setting options for the curves.
Axis	Setting options for the axes in the diagram view.
Options	Carry out system test, adjust font and display service data (e.g. software version number)

Navigation bar

Under navigation, you will see the transport routes and tours that have been created with the individual measurement data.
To search for a specific measurement data series, click on **[Search]**. Activate the check mark in front of the criterion which you would like to use for sorting.

7.4.3 Menus and commands

In this section, you find out which menus and commands are available to you and what you can use these commands for.

7.4.3.1 Start

Start | Clipboard menu

Menu function	Description
Copy	Copies the marked element onto the clipboard.

Start | Create reports menu

Menu function	Description
One-off report	Define report contents and create one-off report.
Send message	Define report contents and send report as an email.

Start | View menu

Menu function	Description
Graphic	Shows the graphic display of the readings if the checkbox is activated.
Table	Shows the tabular display of the readings if the checkbox is activated.

Menu function	Description
Individual values	Shows the table in individual values.
Overview	Shows statistical analysis of the measurement

Start | Hash code menu

Menu function	Description
Hash code	Display hash values of the readings.

Start | Signature menu

Menu function	Description
Sign file	Signature of the readings via PC user login

Start | System access controls menu

Menu function	Description
Audit trail	Display, save or export audit trail file.

Start | Analysis menu

Menu function	Description
Update	Database update.

7.4.3.2 Editing in the diagram view

The **Edit** menu (diagram) is only displayed if the diagram has been activated by clicking on the window.

Edit | Tools menu (diagram)

Menu function	Description
Edit style	Background, colour and style of the grid can be adjusted.
Zoom in	Draw a rectangle in the diagram window to zoom in on the area covered. This function can also be used during a measurement in online mode. However, this means the extract shown always displays the current value. When you click on **[Original size]**, the diagram is once again displayed in its full size.

Menu function	Description
Crosshairs	Crosshairs, which can be used to follow the curve, are shown by clicking on a point of a measurement curve. The date, time, reading number and reading are shown in the process.
Regression curve	Regression curves are an aid to enabling better evaluation of large, complex amounts of data. This involves "outliers" being suppressed and the actual course of the curve being reproduced using a theoretical, mathematical function. The regression curve is shown by clicking on a measurement curve. The regression coefficients are displayed in the status bar.
Limit values	Activate the checkbox to show the limit values in the diagram.

Edit | Curves menu (diagram)

Menu function	Description
C:1, C:n	Legend for the diagram. Clicking on the entry of a curve opens the dialogue for the characteristics of the curve.

7.4.3.3 Editing in the table view

The **Edit** (table) menu is only displayed if the table has been activated by clicking on the window.

Edit | Tools menu (table)

Menu function	Description
Mark	Marks data over a definable time period or definable rows (index range).
Drop marking	Drops the marking.

Menu function	Description
Add rows (minimum, maximum, mean value)	Inserts a row at the end of the table with the corresponding value for the whole table.  The min, max and mean values cannot be determined via a time period/index range defined in the table.
Compress	Compresses the table to definable intervals. Only the first and the last value are shown for the individual intervals. The other readings are hidden.
Drop compression	Drops the compression.

Edit | Search (table) menu

Menu function	Description
Minimum	Shows the smallest reading of the selected channel within the table.
Maximum	Shows the largest reading of the selected channel within the table.

7.4.3.4 Axes

This menu allows you to configure the value and time axis.

Axes | Value axis menu

Menu function	Description
Division	Input of upper and lower limits and division setting (finer/coarser).

Axes | Time axis menu

Menu function	Description
Division	Division setting (finer/coarser).

7.4.3.5 Options

Options | Management menu

Menu function	Description
System test	Test communication connections

Options | **Font** **menu**

Menu function	Description
Font	Choice of font and font size

Options | **Service** **menu**

Menu function	Description
Display service data	Creates an *.html file with the service data. The software version number can be found under service data.

7.4.4 Analyzing measurement series

7.4.4.1 Diagram view

In this view, the readings are shown as line diagrams.

✓ In the **Start** | **View** menu, the **Graphic** command is activated.

- On the left of the navigation bar, select the data record which you intend to display.
- Right clicking on a data sequence also enables this to be renamed, deleted or added to the current view, in order to compare the readings of two data sequences.
- You can show or hide the gridlines for the corresponding axis by clicking on the time axis or the value axis.
- If a second data sequence is added, you can select the time relationship of the data sequences in the graph by right clicking on the time axis of the diagram. Select **Relative** to superimpose the start of the relevant measurements, irrespective of the actual start time of the measurements.
- In the **Content** column, you can disable individual channels for the display, if necessary. The selection of channels allows you to see how many of the recorded readings are outside or within the specified limit values.

Zooming in

Zoom in on a detail of the diagram, for example to check the behaviour of the readings within a specific time span

1 Click on **Edit** | **Tools** | **Zoom in**.

2 In the diagram, press and hold the left mouse button to highlight the area that needs to be enlarged.

2.1 Alternatively, the diagram can be made larger or smaller via the zoom bar at the bottom on the right. Drag the bar to the left or right or click on **–** or **+** .

Clicking on the percentage next to the zoom bar displays the entire diagram again (100%).

Information on a reading (crosshairs)

If you move the crosshairs along a curve, you will quickly get detailed information on the individual readings.

1 Click on **Edit** | **Tools** | **Crosshairs**.

2 In the diagram, click on the point for which the details need to be shown.

▸ A dialogue is displayed with the following information about the reading:

- date on which the reading was recorded,
- time at which the reading was recorded,
- number of the reading and
- reading.

You can move along the curve with the left mouse button pressed and held enabling you to see the detailed information for the readings.

To do this, it is not necessary to follow the course of the curve exactly; the crosshairs do this automatically when you move the mouse to the right or left.

Showing regression curve

✓ Place a regression curve over the diagram to show the course that the measurement series tends to take.

1 Click on **Edit** | **Tools** | **Regression curve**.

2 Click on the reading curve for which the regression curve needs to be shown.

▸ The regression curve is shown and its regression coefficients are displayed in the status bar.

If you click on the curve again, the regression curve is once more hidden.

Characteristics of a curve

You can adapt the display of a measurement series to your requirements. So, you can for example change the line width of a curve or the representation of the limit values in the diagram.

1. Switch to the diagram view of the measurement series whose characteristics need to be displayed.
2. In the **Edit** | **Lines** menu, click on the entry of a curve whose characteristics need to be displayed.

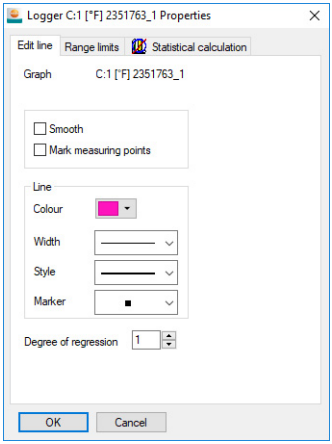
▸ The Characteristics of (curve name) dialogue is opened. The following tabs are available in the dialogue:

- **Edit line** tab
- **Range limits** tab
- **Statistical computation** tab

Buttons of the dialogue

Button	Explanation
[OK]	Applies the changed settings. The dialogue is closed.
[Cancel]	Closes the dialogue without applying the changes.

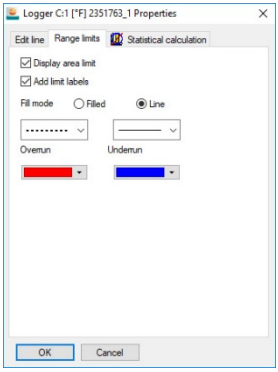
Edit line **tab**



Name	Explanation
Smooth	The measuring points are connected by an interpolated curve; that is, the plot-points on the curve between two measuring points are estimated mathematically.

Name	Explanation
Mark measuring points	The individual measurement points are represented by a symbol. The value shown exactly corresponds to the measured value only at these points. The measuring points are connected with straight lines during the measurement. When the measurement is paused, the curve can be smoothed.
Colour	Line colour of the curve.
Width	Line width of the curve.
Style	Line style of the curve.
Marker	Symbol for the measuring points.
Degree of regression	Possible values "0" to "7". "0" degree of regression corresponds to a pure mean value calculation, "1" degree to the linear trend, a higher value helps in the event of curves with several extreme values.

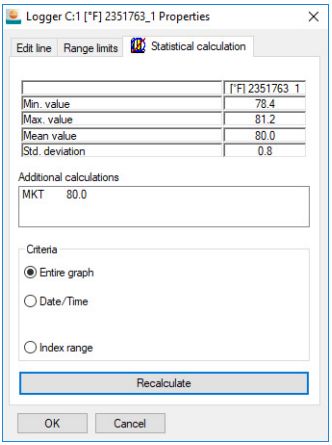
Range limit display tab



Name	Explanation
Display range limits	Specification as to whether the limit values should be shown in the diagram.

Name	Explanation
Add limit labels	Specification as to whether the limit values should be labelled (Upper/Lower limit value: name of curve).
Area fill	Specification as to whether the areas outside the limit values should be marked by means of an area fill.
Selection list for area fill	Selection of the fill.
Line fill	Specification as to whether the limit values should be shown by horizontal lines.
Selection lists for line fill	Selection lists for line type and line thickness.
Overshoot	Colour selection for filling the area above the upper limit value.
Undershoot	Colour selection for filling the area below the lower limit value.

Range limit display tab



Name	Explanation
Min. value	Smallest reading of the curve.
Max. value	Largest reading of the curve.
Mean value	Arithmetically-determined average reading.
Std. deviation	Measure of the scattering of the readings around the mean value.

Name	Explanation
Criteria	Setting display criteria: all, date/time and index range.
Recalculate	Recalculates the curve.

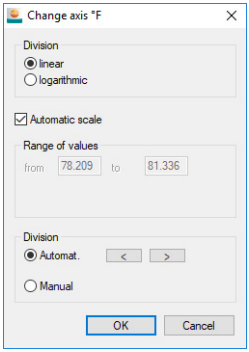
Settings for the axes in the diagram

Change the settings of the axes in the diagram to adapt the display to your requirements.

Settings for the value axis

1 Double click on the required value axis in the diagram or use the right mouse button.

▸ The **Set axis [unit of the readings]** dialogue is displayed.



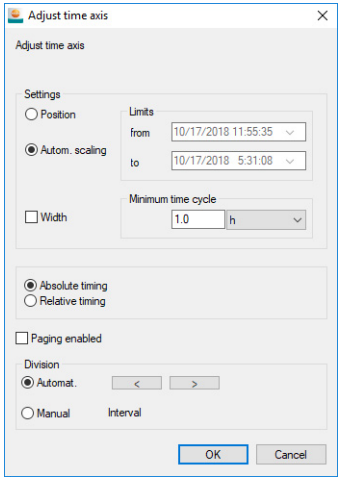
Name	Explanation
Division linear	Specification that the axes are divided in a linear manner.
Division logarithmic	Specification that the axes are divided logarithmically, meaning the division increments represent powers of ten.
[OK]	Applies the settings until other data are called up. The dialogue is closed.
[Cancel]	Closes the dialogue without applying any changes at all.
Automatic scale	Specification as to whether the program should perform scaling of the value axis.
Range of values from...to	Manual input of the value range when **Automatic scale** is disabled.
Division automat.	Specification that the program should perform the division of the axis.
Division manual	Specification that the division of the axis should be performed manually.

Name	Explanation
Grid [<], [>] (when automatic division is enabled)	By clicking on **[<]** or **[>]**, make the axis division larger or smaller.
Interval (when manual division is enabled)	Manual entry of the grid.

Settings for the time axis

1 With the right mouse button, click on the time axis in the diagram.

▸ The **Adjust time axis** dialogue is displayed.



Name	Explanation
[OK]	Applies the settings until other data are called up. The dialogue is closed.
[Cancel]	Closes the dialogue without applying any changes at all.
Position	Shows a freely-definable extract of the diagram.
Autom. scaling...	Shows the entire diagram in the window.
Extract	Shows a firmly defined extract that can be moved over the time axis.
Limits from ... to (when **Position** view is enabled)	Limits for the **Position** view.
Minimum time cycle (when **Extract** view is enabled)	Specification of which time period should at least be shown.

Name	Explanation
Selection list for the unit (when **Extract** is enabled)	Unit of the time axis in the minimum time cycle: • **sec** (second) • **min** (minute) • **h** (hour) • **d** (day).
Absolute timing	All times are the real times at which the readings were recorded.
Relative timing	Sets the starting time to 00:00; the time then runs relative to this starting point.
Paging enabled	The function associated with this is not available in the Small Business Edition.
Division automat.	Specification that the program should perform the division of the axis.
Division manual	Specification that the division of the axis should be performed manually.
Grid [<], [>] (when automatic division is enabled)	By clicking on [<] or [>], make the axis division larger or smaller.
Interval (when manual division is enabled)	Manual entry of the grid.
Selection list for the unit (when manual division is enabled)	Unit of the time axis: • **sec** (second) • **min** (minute) • **h** (hour) • **d** (day).

7.4.4.2 Table view

The readings are listed in table form in this view.

✓ In the **Start** | **View** menu, the **Table** command is activated. You now have to select the data record that you wish to display

1 In the calendar, select the day or time period that needs to be evaluated.

2 In the tree structure of the data range, open the zone that contains the data to be displayed.

▸ The table view of the selected data is displayed.

3 If necessary, deactivate channels via the checkboxes for the display.

Marking readings

Mark specific readings, for example to perform a statistical computation for part of the measurement series.

The min, max and mean values cannot be determined via a time period/index range defined in the table.

1 Click on **Edit** | **Tools** | **Mark**.

▸ A dialogue for determining the criteria is displayed.

2 Select the

2.1 **Date/time** option if the readings for a specific time period need to be marked.

▸ The selection lists for determining the time period are en

2.2 **Index range** option if the readings in specific table rows need to be marked.

▸ The selection lists for determining the index range are er

3 Determine time period or index range.

4 Click on **[OK]**.

▸ The dialogue is closed and the corresponding readings in the table are marked.

The selected readings can be copied and further edited using suitable software (e.g. with Microsoft® Excel®).

Dropping marking

1 Click on **Edit** | **Tools** | **Drop marking**.

▸ The marking of the readings is deleted.

Inserting extreme values or mean value into the table

Insert the minimum/maximum reading, along with the mean value over the whole table, at the end of the table.

1 Click on **Edit** | **Tools** | **Add rows** | **Minimum**, **Maximum** or **Mean value**.

▸ A row is added at the end of the table with the appropriate value over all the readings.

2 Repeat step 1 to insert another value into the table.

To remove a value from the table, click on the appropriate entry in the **Add rows** menu again.

Compressing tabular values

Compress the table to definable time intervals to make the table clearer when there are large amounts of data.

Only the first and the last value are shown for the individual intervals. The other readings are hidden.

In addition, the minimum, maximum and/or mean value can be shown for the respective time period.

1 Click on **Edit** | **Tools** | **Compress**.

▸ The dialogue for determining the options is opened.

2 Determine via the checkboxes whether the respective minimum reading (**Min**), maximum reading (**Max**) and/or mean value (**Mean**) needs to be calculated for the individual time spans.

At least one of these values must be activated to enable compression of the table to be carried out.

3 Enter the time span under **Extract** and determine its unit.

Possible settings for the unit:

- **sec** (second)
- **min** (minute)
- **h** (hour)
- **d** (day).

4 Click on **[OK]**.

▸ The dialogue is closed and the table is shown in compressed format.

Dropping compression

Table compression is dropped again.

1 Click in the **Edit** | **Tools** | **Drop compression** menu.

▸ The table is again displayed with all the individual values.

Determining largest reading

1 In the **Edit** | **Search** | **Maximum** menu, click on the curve for which the largest reading needs to be determined.

▸ The largest reading is displayed as marked in the table.

Adding Rows

1 In the **Edit** | **Tools** | **Add rows** menu, activate the selection that needs to be displayed in the extra rows.

▸ The additional rows are displayed in the table.

Compressing

Tabular values are displayed in compressed format. The limits for the compression range and the additional min, max and mean values are displayed.

1 Click in the **Edit** | **Tools** | **Compress** menu

▸ A selection window is displayed.

2 Set calculation and extract

3 Press **OK** to confirm.

▸ The table display is reduced to the selected min, max and mean values and to the time period entered.

Dropping compression

Table compression is dropped again.

1 Click in the **Edit** | **Tools** | **Drop compression** menu.

▸ The table is again displayed with all the individual values.

Determining the smallest reading

1. In the **Edit** | **Search** | **Minimum** menu, click on the curve for which the smallest reading needs to be determined.

▸ The smallest reading is displayed as marked in the table.

Adjusting time range

1. In the **Start** | **View** menu, activate the **Table** checkbox.
2. In the **Start** | **View** | **Overview** menu, activate the **Time range** checkbox and select the required start and end point.

▸ You will see the amended time range in the diagram.

Adjusting limit values

1. In the **Start** | **View** menu, activate the **Table** checkbox.
2. In the **Start** | **View** | **Overview** menu, activate the **Edit upper limit value** or **Edit lower limit value** checkbox and adjust the limit value as required.

▸ You will see the amended limit value in the diagram.

7.4.5 Signing measurement series

1. In the **Start** | **Signature** menu, select the **Sign file** command.
2. Log in using your PC user name and password.
3. Select the reason for the signature from the selection list.
4. Confirm your signature with **[OK]**.

7.4.6 Report creation

The **Start** | **Create report** menu enables you to create a one-off pdf report. You can specify what its contents are to be via the checkboxes.
Here you can also choose whether the report is to be created in portrait or landscape format.
With **[Send message]** you can send the report as an email. Specify the recipient and subject. After you have activated the attach pdf checkbox, you can choose the contents of this pdf report from the list. You can also attach a csv.
You can compose the text of the email in the lower text field.
Click on **[OK]** to send the email.

7.5 Enhanced functionality with testo Saveris CFR software

7.5.1 Electronic signature

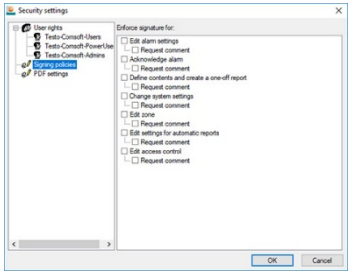
For certain user actions the system requests an electronic signature, which is also shown in the audit trail, together with specification of the reason for the signature.

Configuring electronic signatures:

1. In the **System** main menu, on the **21 CFR 11** tab, click on **Security settings**.

   ▸ The **Security settings** window is opened.

2. Under **Signing policies** select the user actions for which an electronic signature should be mandatory.



An electronic signature can be made mandatory for the following user actions:

- Acknowledging alarms
- Editing alarm settings
- Defining automatic reports
- Defining report contents and creating one-off reports
- Changing settings in the system area
- Editing security settings
- Changing name or content of a zone

The signature for a certain user action includes:

- Type of user definition (e.g. Alarm confirmed)
- Date and time
- Reason for the signature

The signature of a file comprises User ID, date, time and reason for the signature.

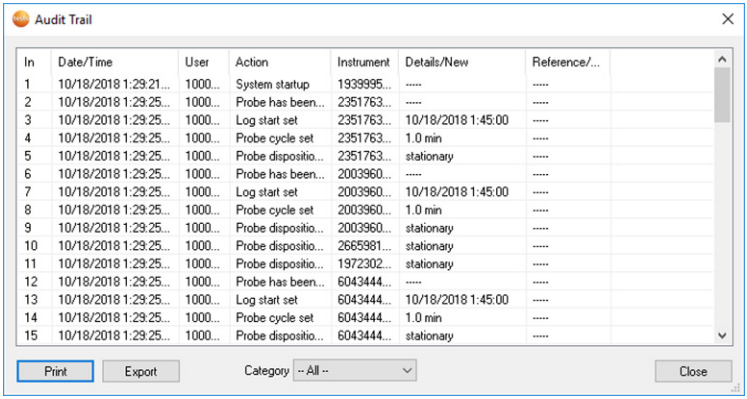
7.5.2 Audit trail

In addition to the restriction of authorized users, the possibility of granting differing rights and the safeguarding of stored reports by means of access limitations to the archiving area, audit trails constitute another major pillar for verifiably securing saved pdf reports.

The Saveris audit trail in particular captures entries that can be directly allocated to an electronic record.

Creating or saving electronic records and tracking any changes made to these data during the archiving period are relevant here.

The Saveris audit trail data are directly linked with the data file and inseparably connected to it. This ensures that, even when transferring data files from one system to another, the audit trail data are not lost and always remain fully available.



The Saveris audit trail records the following events:

- Alarm confirmed
- Alarm confirm failed
- Alarm group has been created
- Alarm group has been updated
- Alarm group has been removed
- Alarm group has been removed automatically
- Alarm processing has been resumed
- Alarm processing has been suspended
- Alarm recipient changed
- Alarm recipient deleted
- Alarm recipient created

- Alarm route changed
- Alarm route created
- Alarm route deleted
- Alarm schedule created
- Alarm schedule updated
- Alarm schedule created
- Alarm settings deleted
- Alarm schedule has been defined
- Alarm schedule has been disabled
- Alarm schedule has been enabled
- Automatic report definition created
- Automatic report definition updated
- Automatic report definition deleted
- Automatic report has been sent
- Automatic report has been created
- Certificate has been imported
- Channel upper/lower warning limit set
- Channel upper/lower limit set
- Channel name set
- Cockpit unit settings changed
- Custom time zone has been set
- Failed to pass an updated alarm configuration to the base
- Firmwareupdate
- Log renamed
- Log start set
- Note has been added
- Note has been updated
- Note has been deleted
- One-off report folder settings changed
- One-off report folder permission granted to
- pdf Password changed
- Probe cycle set
- Probe disposition is
- Probe has been added
- Probe has been removed

- Probe removal failed
- Probe replacement
- Probe settings changed
- Report creation has been cancelled
- Report has been created
- Right granted
- Right removed
- Router configuration
- Signed
- Sign report
- Signature enforced
- Signature not enforced
- System startup
- System has been stopped
- Time synced
- Tour created manually
- Tour description created
- Tour description updated
- Tour description deleted
- Tour planning created
- Tour planning updated
- Tour planning deleted
- Tour deleted
- Tour updated
- Unit has been changed
- User login
- User logout
- Web login using windows credentials
- Web login with basic authentication
- Web logout basic authentication
- Web logout using windows credentials
- Zone has been deleted
- Zone has been created
- Zone has been updated
- Zone renamed

- Zone settings have been updated

The Saveris audit trail contains the following information relating to the events mentioned:

- Index (sequential audit trail number)
- Date/time (when was a system change made?)
- User (who made the change?)
- Action (what was done/changed?)
- Instrument (specification of the serial number and channel of the Saveris component concerned)
- Details (what further details are there about the change/event)
- Reference

The Saveris audit trail can be filtered according to categories and exported and printed as an HTML file. Export and printing requires a browser that supports HTML.

In Client, you can view both the audit trail for stationary and mobile zones and data for transport. If you would like to view the audit trail for a measurement series of your transport data logger, you need to restart Saveris CFR Client and select the transport project at the beginning.

7.5.3 Saveris CFR user management

7.5.3.1 Access control at system level

Users and user groups

After the installation you must assign individual users, who are to work with the program, to one of the local groups: testo ComSoft Admin, testo ComSoft Power Users and testo ComSoft Users.

The following procedure applies especially for the installation or operation of the Saveris software within a company network:

Server/domain

1. Create global user group(s) centrally in the Active Directory, e.g. "Saveris Admin", "Saveris Power Users" and "Saveris Users".
2. Assign group members.

Workstation computer

1. Install Saveris software (locally) on the workstation computer.

2 Include global group(s) as members in the local testo Saveris group(s).

For a detailed description, please see the user manual for your Windows operating system.

Detailed assignment of individual rights is carried out in the Saveris CFR software and the rights specified there apply for all members of the respective user group.

Individual parameters

Here you can define the scope of the local security and set the necessary control parameters.

1 Under **Start / System control**, select the **Management** area and click on the **Local security guideline** icon there.

2 Carry out required settings for the following functions:

- Password guidelines
- Account lockout guidelines
- Account lockout threshold
- Monitoring guidelines
- User rights
- Security options

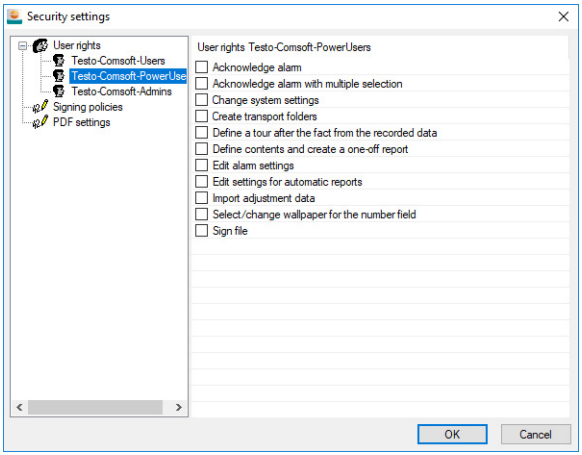
For a detailed description, please see the user manual for your Windows operating system.

The control mechanisms of Windows® Security are by definition effective in relation to the (system) session. A session listed in the audit trail is correctly terminated by logging out of the system. Log off as user after ending the Saveris application.

7.5.3.2 Granting user rights in testo Saveris CFR

Individual rights for user groups

A database administrator or member of the local Testo ComSoft Admins group can enable or disable individual functions or system possibilities for user groups previously set up at operating system level.

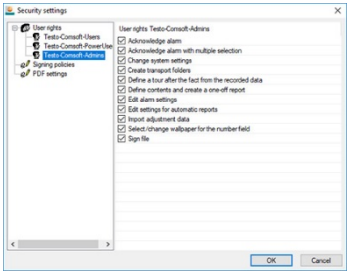


1 In the **System** main menu on the **21 CFR 11** tab, click the **Security settings** button.

2 The security settings window is opened.

Under local groups you can assign individual rights to the 3 user groups: Admins, Power Users and Users.

A list of individual rights appears under each group, which are each checked via a mouse click, thus making them accessible for the selected user group.



In detail, the following rights can be granted/denied:

- Acknowledging alarms
- Acknowledging alarms using multiple choice
- Changing alarm settings
- Defining automatic reports
- Defining report contents and creating one-off reports
- Signing files
- Changing settings in the system area
- Selecting/changing wallpaper
- Importing adjustment data
- Defining tours retrospectively from existing data records

8 Tips and assistance

8.1 Questions and answers

Question	Possible cause / solution
The Saveris converter does not transfer any data to the base.	The cable connection to the converter is faulty. • Remove the power supply and check whether the Ethernet cable is connected correctly. • Reconnect the power supply. The Saveris converter checks its configuration and if there is an error, it resets all values to the factory settings.
Saveris cockpit unit does not print.	The power supply to the Saveris cockpit unit has been interrupted. • Restore the power supply to the Saveris cockpit unit. • Restart printing.
Saveris cockpit unit printout is terminated.	The power supply to the Saveris cockpit unit has been interrupted. • Restore the power supply to the Saveris cockpit unit. • Restart printing.

8.2 Standard operating procedures (SOPs)

This section contains suggestions for instructions for the operation of Saveris in CFR-relevant environments.

- The customer must make sure that a back-up power supply is available for the PC which operates the Saveris CFR software .
- The customer must make sure that the password protection is active and that the password has only been disclosed to authorized persons.
- The customer must define an appropriate data backup cycle and ensure that suitable backup processes, backup media and backup environments for data, software and the required hardware are available.
- Before editing zones, the customer must back up the database. This is the only way that reports identical to previously generated reports for the same period can continue to be generated after zones are changed. Ideally, zones are only edited in the commissioning phase. The right to change zones should then be withdrawn.

- It is the customer's responsibility to set up operating system accounts and user groups properly and to assign the user accounts to suitable users.
- It is the customer's responsibility only to use the Saveris wizard for commissioning the system or a project or for servicing (e.g. probe calibration).
- It is the customer's responsibility to check and save the audit trail data.
- The customer must make sure that the password protection is active and that the password for the pdf documentation has only been disclosed to authorized persons.
- It is the customer's responsibility to create user profiles and to assign these users to the specified user groups (Testo ComSoft Admin, Testo Power Users, Testo Users).
- It is the customer's responsibility to ensure that only a Saveris software server is connected to the Saveris base.
- It is the customer's responsibility to protect the USB interfaces of the Saveris components.
- The customer must ensure the operating conditions of a closed system.
- It is the customer's responsibility to define appropriate processes and controls to ensure the correct synchronization of the system clock.
- It is the customer's responsibility to activate the password function for pdf reports and to define a Master password in the Saveris CFR software.
- It is the customer's responsibility only to disclose the master password for pdf reports to authorized personnel.
- It is the customer's responsibility to assign accounts and passwords unambiguously and uniquely to individuals.
- It is the customer's responsibility to assign suitable / appropriate access rights.
- It is the customer's responsibility to check the database capacity at regular intervals (once every three months) in the startup wizard, under the Projects tab and, if necessary, to take any follow-up measures that may be required if the database is full.
- It is the customer's responsibility to configure the project protection functions properly – e.g. a suitable storage location for pdf reports must be defined and be provided with appropriate security settings – and to ensure that employees immediately log off when they exit the system.
- It is the customer's responsibility to ensure strict compliance with the password discipline.
- It is the customer's responsibility to define suitable account processes and rules and to make sure that these are strictly complied with. The customer retains the control over Saveris CFR duplicates.

- It is the customer's responsibility to carry out user account management properly.
- It is the customer's responsibility to operate the system as a closed system and to check the Windows access options and the system event log thoroughly and in good time.
- It is the customer's responsibility to define suitable rules and processes for handling system abuse.

Testo Industrial Services offers system qualification services to support validation in customer specific applications. Training courses for IT managers are also provided.

8.3 Saveris base alarm messages

Alarm message	Possible cause / solution
L_CommUp L_CommApp	Error during USB or Ethernet initialization. - Disconnect all links to the Saveris base. - Reconnect all links. - Restart the Saveris base.
L_GSM L_GSMMenu	Error during GSM modem initialization. - Check the GSM module's rechargeable battery power. - Restart the base.
L_RF2010Server, L_RF2010IO- L_RF2010MemPool, L_RF2010StreamRip L_UDPRF2010	Error during radio module initialization. Option 1 - Check in the startup wizard whether the extreme SMS gateway is enabled. - Reboot the Saveris base. If there are problems, please contact our support team. - Option 2 - Restart the base. If the problem persists, please contact our support team.
L_UIPrio L_DispDrvUI,	Error loading the UI/display. Reboot the base. - Restart the Saveris base.
L_MemoryMgmt	Error loading memory management. - Please contact our support team.
L_AlarmCtrl L_AlarmCfg	Error loading the alarm controller. - Please contact our support team.
L_FileSysChk L_FileSys L_AccelFileSys	Error loading the mass storage device. - Please contact our support team.

Alarm message	Possible cause / solution
L_EventLog L_AlarmLog L_TourLog L_ErrorLog L_GsmStatLog	Error loading a log. - Please contact our support team.
L_RFTest2010	Error testing the radio module. - Please contact our support team.
L_BaseConf L_LowElement L_UppElement	Error loading basic functionality. - Please contact our support team.
L_Group L_TourCard	Error loading the basics for mobile zones. - Please contact our support team.

8.4 Alarm messages testo 184 - USB transport data logger

Alarm message	Possible cause / solution
E0x is displayed (instruments with display), all status LEDs are flashing red	An error has occurred. • **E01**: configuration failed / pdf file faulty. • **E02, E03, E04** or **E05**: sensor faulty. • **E06**: maximum number of time marks set, new time mark cannot be set.
---- is displayed (instruments with display)	• No reading available (after setting a time mark) • Reading invalid.
Hi is displayed (instruments with display)	Reading is above the measuring range.
Lo is displayed (instruments with display)	Reading is below the measuring range.
En is displayed (instruments with display)	Set time mark function is disabled.
Err is displayed (instruments with display)	Configuration not possible, e.g. because **Rec** mode is active.
Configuration via the pdf file is not possible	If you have used the Comfort Software 21 CFR Part 11 for the configuration, the configuration via the pdf file is disabled.
The size of the pdf configuration file is 0 kb or the file is damaged.	Copy the pdf file of another testo 184 or download the configuration file from the Testo website: http://www.testo.com/.

Alarm message	Possible cause / solution
Different time or time zone in the report	> The testo 184 has not been configured after a battery replacement. Repeat the configuration to restore the correct time settings. > Check whether the PC which was used for the configuration has the correct time settings.
Different time or time zone in the report	> The testo 184 has not been configured after a battery replacement. Repeat the configuration to restore the correct time settings. > Check whether the PC which was used for the configuration has the correct time settings.
No measurement protocol was created	> Please check whether the data logger is in record/end mode. > Please reconnect the data logger to the PC. > Please check whether there is enough free memory capacity available on the data logger.
The pdf configuration is not ready for use	> Please check whether the data logger is in record mode. > Please check whether the correct data logger mode is selected. > Please check whether the testo 184 data logger was configured via the Comfort Software 21 CFR Part 11. This prevents configuration via the pdf file.
There is no LCD.	Please check whether the LCD is disabled in the configuration.
There is no time mark display.	Please check whether the time mark display is disabled in the configuration.
There is no NFC.	Please check whether the NFC is disabled in the configuration.

Alarm message	Possible cause / solution
The humidity value measured is out of tolerance.	a Was t99 response time achieved? b Was the H1/G1 data logger stored for longer than 60 hours at a relative humidity of more than 80% without an airtight bag? c Was the H1/G1 data logger used for longer than 60 hours at a relative humidity of more than 80%? Solution for points b and c: > Store the instrument in a well-ventilated location for 12 hours at >30°C and a relative humidity of less than 20%. or > Store the instrument for 12 hours at 20°C to 30°C and a relative humidity of around 75%.

8.5 Accessories

Description	Order no.
Spare batteries for radio probes (4 x AA alkali manganese Mignon batteries)	0515 0414
Spare batteries for radio probes for operation below -10°C (Energizer L91 photo lithium)	0515 0572
Spare rechargeable battery for Saveris base, Ethernet probe and analog coupler	0515 5021
100-200 V DC mains unit; for Saveris base, router, converter, Ethernet probe	0554 1096
Mains unit (top-hat rail mounting) 90 to 240 VAC / 24 VDC (2.5 A)	0554 1749
Mains unit (desktop instrument) 90 to 240 VAC / 24 VDC (350 mA)	0554 1748
Programming adapter (from mini-DIN to USB) for base, Ethernet probe, converter and extender for the configuration of IP addresses and for the adjustment of the radio and Ethernet probes.	0440 6723
Antenna with magnetic foot with 3 m cable for base with GSM module	0554 0524
Antenna with magnetic foot (quad band) for Saveris base with GSM module	0554 0525
Alarm module (visual & acoustic), can be connected to alarm relay, Ø 700 x 164 mm, 24 V AC/DC / 320 mA, steady red light, continuous tone: buzzer approx. 2.4 kHz	0572 9999 ID no. 0699 6111/1

Description	Order no.
Saveris protective housing for protection from high-pressure cleaning and impacts, IP 69 K, suitable for radio probes T1/T1D/T2/T2D/Pt/PtD/H4D	0572 0200
Testo fast printer with wireless infrared interface, 1 roll of thermal paper and 4 Mignon batteries for printing out readings on Saveris cockpit unit	0554 0549
testo Saveris SBE, including USB cable for connection of the Saveris base to the computer	0572 0180
testo Saveris PROF, including USB cable for connection of the Saveris base to the computer	0572 0181
Saveris adjustment	0572 0183
Saveris CFR, including PC-base Ethernet connection cable	0572 0182
ISO temperature calibration certificate; temperature probe; calibration points -8°C; 0°C; +40°C; per channel/instrument (suitable for Saveris T1/T2)	0520 0171
ISO temperature calibration certificate; temperature probe; calibration points -18°C, 0°C, +60°C; per channel/instrument (not suitable for Saveris T1/T2)	0520 0151
DAkkS[3] temperature calibration certificate; temperature probe; calibration points -20°C, 0°C, +60°C; per channel/instrument	0520 0261
ISO humidity calibration certificate; humidity probe; calibration points 11.3% RH and 75.3% RH at +25°C; per channel/instrument	0520 0076
DAkkS humidity calibration certificate; humidity probe; calibration points 11.3% RH and 75.3% RH at +25°C; per channel/instrument	0520 0246

[3] Successor organization of the DKD (German calibration service)

Testo SE & Co. KGaA
Testo-Straße 1
79853 Lenzkirch
Germany
Tel.: +49 7653 681-0
Fax: +49 7653 681-7699
E-Mail: info@testo.de
www.testo.de

0970 2503 en 01 V04.6-SP1