testo Comfort Software CFR 4

Instruction manual



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2 Specifications

2.1. Intended purpose

The testo Comfort Software CFR 4 serves the purpose of saving, reading out and analysing individual readings and measurement series. The CFR version was especially developed to fulfil the requirements of the FDA regarding the storage of data in accordance with 21 CFR Part 11, when working in conjunction with data-loggers.

The regulation of user access has top priority:

The software testo Comfort Software CFR 4 thereby uses the security mechanisms of the Windows® operating systems.

During the installation phase a system administrator with special rights must set up the software testo Comfort Software CFR 4 using the security settings of Windows. These include, above all, the allocation of the users to the local groups. The allocation of the user IDs and passwords and of user rights and the regulation of document flow within the company must comply with the organisational guidelines as laid down.

The factory setting of the software testo Comfort Software CFR 4 with respect to security complies with the requirements set forth in 21 CFR Part 11.

It lies largely within the responsibility of the operating organisation to ensure that the appropriate access rights are made available to its individual users. Testo is not responsible for the consequences at operating system or application program level of errors in the allocation of user rights.

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

The following Testo instrument families have been appoved for use in 21 CFR Part 11 environments in connection with testo Comfort Software CFR 4: testo 175, testo 176, testo 177, testo 184.

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

The data loggers are programmed with the testo Comfort Software CFR 4 and can then record measurements independently, the collected measurement data are then transferred to a PC via a serial interface.

The data are also read out using the testo Comfort Software CFR 4, which activates the interfaces and makes all other functions available.

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The captured data, together with date and time, are tabulated in a special 21 CFR Part 11 form; unmodified original 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 organisation of the complete system, consisting of one or several PCs as well as the relevant data loggers.

In this sense, the solution made available by Testo is to be seen as a tool that contains all the necessary aids for implementing a validated measuring system within the FDA regulations and for managing the electronic records that it generates.

Intended use in this context means, above all, that a set of SOPs (standard operating procedures) is drawn up for the use of the data acquisition system, which ensure that the data logger and the software testo Comfort Software CFR 4 is operated correctly (See also Standard operating procedures (SOPs), page **20.).**

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

In particular, the user/operating organisation is responsible for instruction and training of operators; 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 organisation to ensure that the measurement data are available during the required procedural period.



The instruction manual only relates to CFR-specific software functions. To find out how the software works, please refer to the separate instruction manual for testo Comfort Software Professional 4.

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2.2. 21 CFR Part 11 and terminology used

What is 21 CFR Part 11?

Section 21 of the Code of Federal Regulations (CFR) is a part 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 and the required security measures.

What is affected by these regulations?

All data that are included in GxP inspections and are permanently held on electronic data storage media. Thus all files and data that may be included in an FDA inspection are affected.

Also affected are all electronic signatures that, as computer generated authorisations, represent the legally binding equivalent of handwritten signatures.

Why are these regulations so important?

In the pharmaceutical industry, paper-based systems are increasingly being replaced by electronic systems and procedures. In order for these data records to be recognised by the FDA as authentic and legally binding in the same way as the former paper-based organisations and processes, the requirements of 21 CFR Part 11 must be fulfilled.

These regulations provide 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 who wish to sell their products on the US market and who manage electronic data records and electronic signatures in their production processes together with the associated accountability 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 fulfil them leads to corresponding blocking notes.

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Who must fulfil these regulations?

All companies or manufacturers that market or intend to market their pharmaceutical products in the USA must fulfil these requirements. Also in other countries these regulations have been acknowledged, are available and obligatory as quality standard.

What are the possibilities, especially in the area of measuring techniques and data capture?

Conformity with 21 CFR Part 11

- fulfilling the requirements in this area means, above all, fulfilling organisational but are also partly technical requirements.
- Fulfilling organisational requirements means that pharmaceutical companies will set up organisational structures and define, describe and document all processes in order to demonstrate what protective measures are used by the company in order 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 the responsible persons are to carry out processes and use systems in order to achieve the required results.

*See also Standard operating procedures (SOPs), page **20.***

- Fulfilling technical requirements: The fulfilment of technical requirements is based on the use of products that are especially manufactured for use in this area.
- This area also includes the software testo Comfort Software CFR 4 in accordance with 21 CFR Part 11 described hereunder with the data loggers approved for this purpose.

Only the combination of suitable technical systems with the appropriate SOPs (standard operating procedures) matched to the process in question guarantees proper 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 fulfil the FDA requirements, this can only be achieved by integrating measuring technology in an organisation established in compliance with 21 CFR Part 11, together with company-specific SOPs.

Providing suitable system measn for Testo: Wherever possible, we seek to meet the requirements at the technical level in order to reduce the number of SOPs needed within the company to a minimum.

This is the task of our system and also the subject of this instruction manual which should help you to identify critical processes in data capture and archiving and makes recommendations on how you

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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 is a short summary:

Part 11 – electronic records and electronic signatures deals with the criteria for regarding electronic datasets and signatures as equivalent to paper documents with handwritten signatures. 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 persons has access. With the software testo Comfort Software CFR 4 the access control takes place via the well established Windows security system (allocation of USER-ID´s, rights management, user for password management, user authentication). The authentication concept (user rights for enabling or disabling software functions) is determined by the IT administrator for three user levels in the software testo Comfort Software CFR 4.

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

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

Besides the actual readings/datasets the database is also used to safe so-called Audit Trails, which contain all boundary information that has accumulated since the commissioning of the system.

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

Paragraph 11.10 draws special 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 correctly. With regard to the implementation of the technical requirements in the data loggers and the software testo Comfort Software CFR 4 reference will be repeatedly made, throughout this instruction manual, to the text of 21 CFR Part 11 in order to show how various individual functions are implemented as defined in 21 CFR Part 11.

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3 First steps

3.1. System requirements

Operating system

The software can be run on the following 32-bit and 64-bit operating systems:

- Windows® 10
- Windows® 11
- Others: on request

Computer

The computer must meet the requirements of the corresponding operating system. The following requirements must additionally be fulfilled:

- Interface USB 2.0 or higher
- Internet Explorer 9.0 or higher

Date and time settings will be automatically accepted by the PC. The administrator must make sure that the system time is regularly compared with a reliable time source and adjusted, if necessary, to ensure authenticity of the measurement data.

3.2. 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, precisely defined external interfaces and a defined group of authorised users, can be easily controlled with a small number of SOPs.

As, in practice, the responsibility for allocating user accounts and user rights lies in the hands of administrators with far reaching and inter-system rights, the following information is addressed to the administrator or the group of people authorised to integrate the software testo Comfort Software CFR 4 in a validated process or a validated overall system.

The Testo installation program links the program testo Comfort Software CFR 4 with the access control mechanisms of the Windows® operating systems.

The installation program requires administrator rights.

During the installation of the program:

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- local groups are created to link the software testo Comfort Software CFR 4 with the NT security system: here 3 local groups are added to the system management, in addition to the already existing groups:

  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 the database concept.
- the software testo Comfort Software CFR 4 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 software testo Comfort Software CFR 4 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

3. Install the software testo Comfort Software CFR 4 on the workstation (locally).
4. Include the global group(s) as a member in the local Testo-ComSoft group(s).

See User regulation on testo Comfort Software CFR 4 level, page **13.**

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4 First steps

4.1. Running the installation

Please observe the following notes before the installation:

Administrator rights are required for the installation of the program.

Parallel operation of testo Comfort Software CFR 4 and testo Comfort Software Professional 4/ testo Comfort Software Basic 5 on one PC is not possible.
Therefore please do not install the testo Comfort Software CFR 4 on a PC that already contains testo Comfort Software Basic 5 or testo Comfort Software Professional 4.
Use another PC for the installation of the testo Comfort Software CFR 4.

If you run a software update please note:

- that you can only update from testo Comfort Software Professional 4 to testo Comfort Software CFR 4 (not from testo Comfort Software Basic 5 to testo Comfort Software CFR 4).
- When updating from testo Comfort Software Professional 4 to testo Comfort Software CFR 4 the feature **Audit Trail** is not available for running projects. We therefore recommend to quit all active projects and set up new projects after an update. This ensures that all functions of the CFR-software will be available.

Installation testo Comfort Software CFR 4

✓ Older versions of a testo Comfort Software have been deinstalled.

1. Insert CD-ROM in the drive

- After a short while the installation program will start automatically.

  > If not: Double-click on **Setup.exe** in the corresponding directory on the CD-ROM.

The pre-set path for saving is **Own files** of the user. This is determined by the MFC class library, the Windows® version and the set-up data at operating system level (it is not recommended to attempt to make changes here).

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Only users who are administrators or members of the above named groups can start the program testo Comfort Software CFR 4, whereby it is the responsibility of the system administrator to ensure that each password is only used once, i.e. two users should not work with the same password.

Remember, also, that changes to the security parameters affect the whole system and influence other applications.

After successful installation

After the installation the testo Comfort Software CFR 4 must be started once by the administrator, so that possibly needed settings can be made.

After this the user accounts are assigned to the ComSoft user groups (testo-omsoft-Admin, testo-Comsoft-Power-User and testo-Comsoft-User).

Finally you can change the standard settings for the rights within the testo Comfort Software CFR 4-application for the 3 user groups.

5 Using the product

5.1. Access regulation at system level

5.1.1. Users and user groups

After the installation you must assign the individual users, who are to work with the program, to a local group Testo - Comsoft - Admins, Testo - Comsoft - Power Users and Testo - Comsoft - Users.

The following procedure applies especially for the installation or operation of the testo Comfort Software CFR 4 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

3. Install testo Comfort Software CFR 4 on the workstation (locally).

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4. Include the global group(s) as a member in the local Testo-ComSoft group(s).

For a detailed description, see the User Manual for your Windows operating system.

The detailed assignment of the individual rights takes place in the testo Comfort Software CFR 4, the rights specified thereunder apply for all members of the respective user group.

5.1.2. Individual parameters

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

Under **Start / System control** select the area **Administration** and click on the icon **Local security guideline.**

Make the desired settings for the following functions:

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

For a detailed description, see the User Manual for your Windows operating system.



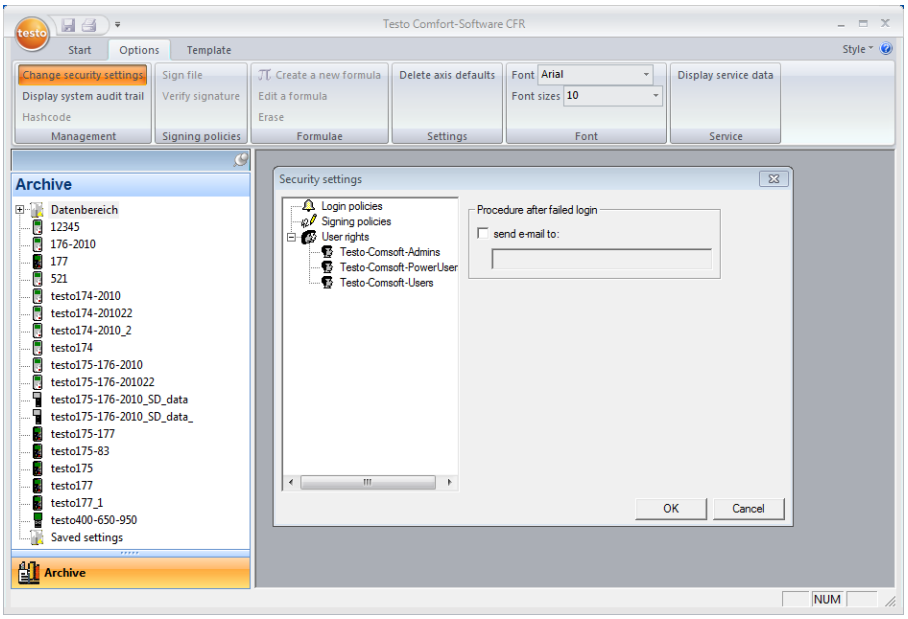
The control mechanisms of Windows®-Security are effective by definition in relation to the (system) session. The correct termination of a session listed in the Audit Trail takes place with a system lockout. Log off as user after quitting the testo Comfort Software CFR 4 application.

5.2. User regulation on testo Comfort Software CFR 4 level

5.2.1. Individual rights for user groups

An 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 on operating system level.

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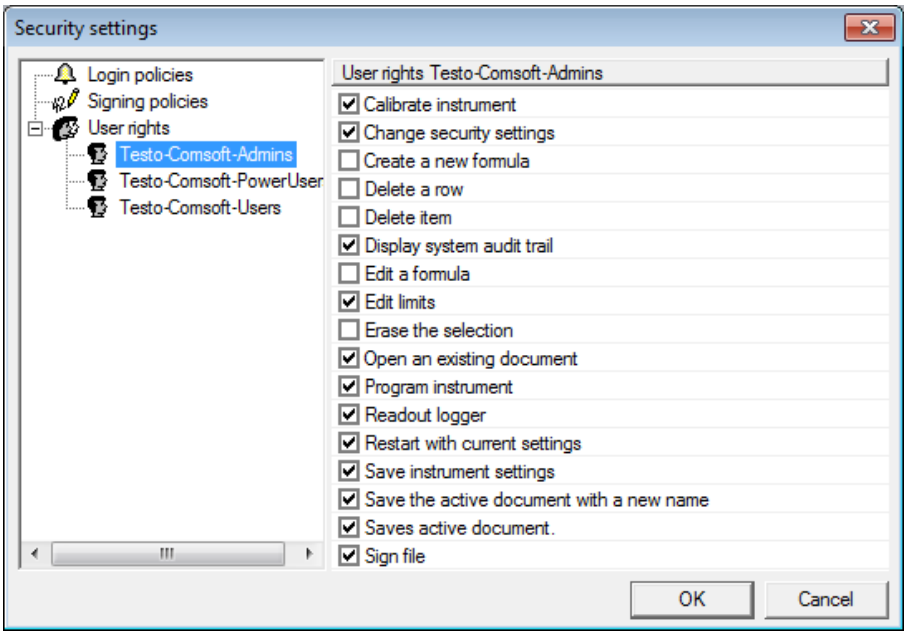


> On the tab **Options** click on the button **Change security settings**.

- The window **Security settings** is opened:

  Under **Local groups** you can assign individual rights to the 3 user groups: Admins, Power User and User.

  A list of individual features, which will each be ticked by a mouse click and thus be accessible by the selected user group, appears under each group.



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

Changed settings will only become effective after a restart.

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- Show Audit Trail
- Open file
- Sign file
- Adjust instrument
- Restart instrument
- Program instrument
- Save instrument settings
- Read out instrument memory
- Change limiting value settings
- Delete marked element
- Delete marking. Delete formula
- Create new formula

i	By enabling this function you can manipulate the original measurement data. In the most simplest of cases this means shifting an existing temperature curve by a freely selectable offset. However, such calculated channels are in any case additional, i.e. the associated measured data can only be hidden, but not replaced by calculated data.

- Change security settings

i	By standard only the ComSoft Admins group has write access to the access control data. If required access to the following directory must be enabled: <CSIDL_COMMON_APPDATA>\testo\comfort software

- Saves the active document under e new name
- Remove table lines
- Change existing formula

Under **e-mail messages** you may additionally specify an e-mail address, which will automatically be notified if the login fails because of faulty login information.

5.3. General notes for the testo Comfort Software CFR 4 user

The descriptions and chapters of operating instructions in particular refer to the requirements of 21 CFR Part 11.

The standard functions and the general operation of the software is still described in the operating instructions for testo Comfort Software Professional 4 .

Should individual functions, which are described in the operating instructions for testo Comfort Software Professional 4, not be

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available for selection, you may not have the appropriate access rights. In this case you should contact your administrator.

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5.4. CFR-specific functions

5.4.1. Electronic signature

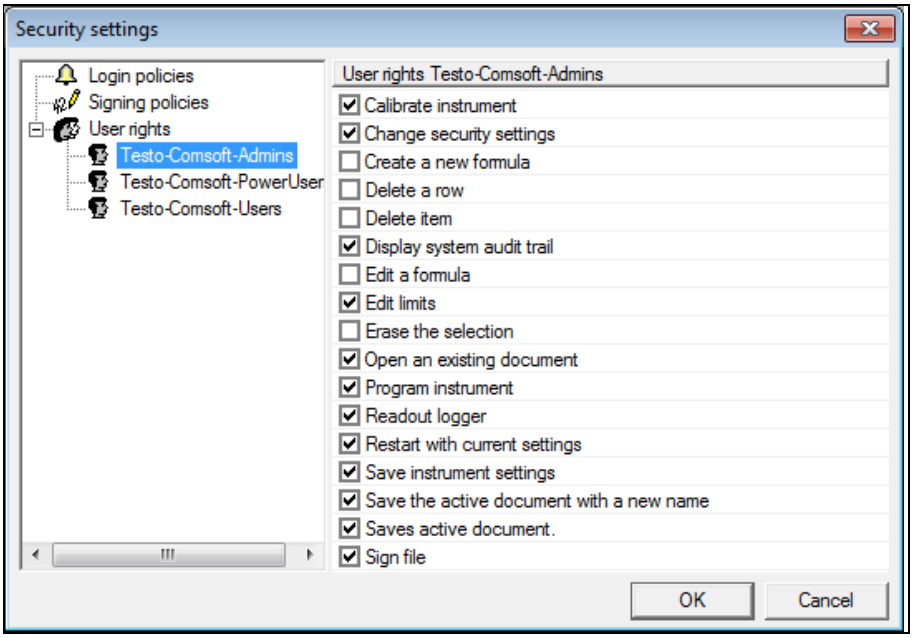
For certain user actions the system demands an electronic signature, which is also shown in the Audit Trail together with the reason for demanding the signature.

Configuring the electronic signature:

1. On the tab **Options** click on **Change security settings**.

- The window **Security settings** is opened:

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



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

- Enforce a signature when saving a file

5.4.2. Manual creation of PDF reports

Printouts of any chosen time period that comply with 21 CFR 11 can be created using the **Create report folder** function.

> Click on **testo symbol > Create report folder**.

The PDF report contains:

- CFR-compliant cover sheet with hash code of the PDF report
- Graphic, measurement data table and alarms of the selected zone
- Audit trail of the time span specified in the calendar

Multiple data loggers can be combined in one report.

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5.4.3. File audit trail

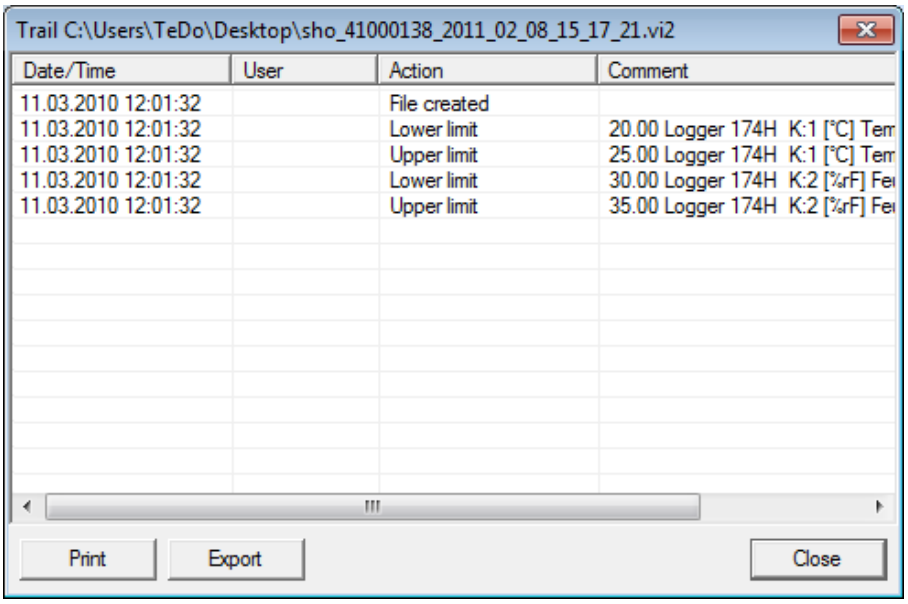
Besides the restriction of authorized users, the possibility of granting different rights and the safeguarding of stored reports by means of access limitations to the archiving area, the file audit trails are another major pillar for verifiably securing saved files.

The file audit trail captures entries that can be directly allocated to an electronic record.

These include the creation or saving of electronic records and any changes made to these data during the archiving period. Access right changes are also documented.

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

1. Open file for which the file Audit Trail should be displayed.
2. Click on **testo symbol** | **Display Audit Trail File**.



Audit Trail records the following events:

- Create document
- Document saved again after change
- Document signed, if necessary, existing signature replaced
- Lower limit initialised
- Upper limit initialised
- New formula created
- Unit changed
- Additional column inserted with converted unit

In Audit Trail the following information to the above mentioned events is additionally saved:

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- Date/time (when has a system change been made?)
- User (who has made the change?)
- Event (what has been done/changed?)
- Description (specification of serial number and channel of the affected component. Which details are available for the change/event)

The file audit trail can be exported and printed as an HTML file. Export and printing requires a HTML supporting browser.

5.4.4. System-Audit-Trail

> Choose **Options** | **Show System Audit Trail**.

The time marks identifying the corresponding actions originate from the system time, which is taken on directly. If you working across time zones you must assure a suitable world-time relation by applying corresponding standard operating procedures (SOP).

The system audit trail is stored in the computer's event log. The Windows event log is under the control of the system owner. The system owner must ensure that sufficient storage space is available to meet data storage requirements.

Another option is to create regular backup copies (e.g. on paper).

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6 Tips and assistance

6.1. Standard operating procedures (SOPs)

This chapter contains suggestions for instructions for the operation of data loggers in CFR-relevant environments.

- The customer must make sure that a back-up power supply is available for the PC which operates the software testo Comfort Software CFR 4.
- 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.
- The directories with the data from Testo measuring systems should be archived regularly via data backup.
- 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.
- An audit trail is only created the first time a series of measurements is saved.
- Electronic signatures are lost if the file is not saved after this.
- 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 logger configuration 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, Power User, User).
- It is the customer's responsibility to protect the USB interfaces of the data loggers.
- 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 assign accounts and passwords unambiguously and uniquely to individual persons.

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- It is the customer's responsibility to assign suitable / appropriate access rights.
- It is the customer's responsibility to correctly configure the project protection functions and to make sure that employees will 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 regulations and to make sure that these are strictly complied with. The customer retains the control over Comfort Software CFR duplicates.
- It is the customer's responsibility to execute the user account management correctly.
- It is the customer's responsibility to operate the connected system as a closed system and to check the Windows access options and the system event log thoroughly and at regular intervals.
- It is the customer's responsibility to define suitable regulations and processes to handle cases of system abuse.
- It is the customer's responsibility to do an installation qualification of the system.
- It is the customer’s responsibility to do an operation qualification of the system.

Testo Industrial Services offers system qualification services to support the validation of customer specific applications. We also offer training courses for responsible IT-personnel.

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