testo 190 CFR software

Instruction manual
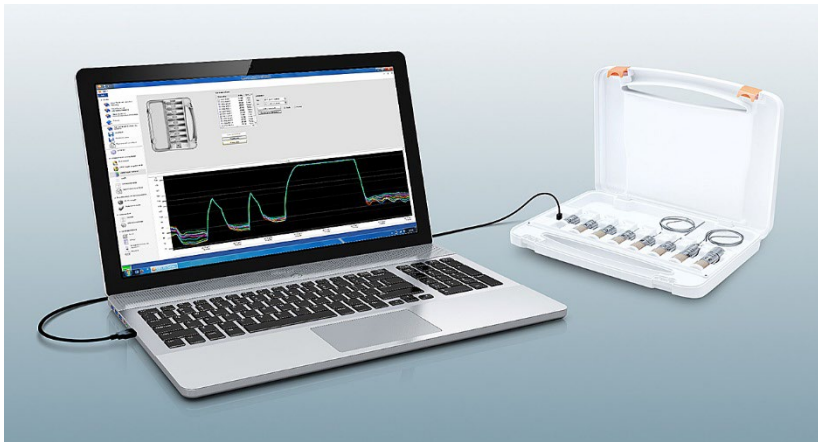
Contents

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1 Safety and disposal

1.1 About this document

- The instruction manual is an integral part of the instrument.

- Keep this documentation to hand so that you can refer to it when necessary.

- Always use the complete original instruction manual.

- 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.

> **i** Knowledge of Windows® operating systems is required to work with the software.

1.2 Symbols

Display	Explanation
i	Note: basic or further information
1 2 …	Action: several steps, the sequence must be followed
>	Action: one step or optional step
▶	Result of an action
✓	Requirement
Menu	Elements of the program interface
[OK]	Buttons of the program interface

2 Specifications

2.1 Intended purpose

The testo 190 CFR software is used for programming, reading out and evaluating testo 190 data loggers. The testo 190 CFR software was 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 data loggers are programmed with the testo 190 CFR software via the programming and readout unit, and they then measure independently. Once the measurement has been carried out, the measurement data collected is stored temporarily in the internal memory of the data logger. The measurement data is then transferred to the PC via USB cable using the programming and readout unit.

Issuing the electronic signature releases the measurement data for further processing steps following the readout process in the testo 190 CFR software. Calculations can then be carried out and acceptance criteria defined, enabling you to determine whether the measurement was successful at a glance. The measurement data can be examined very closely using various data analysis options. The prepared measurement data can be presented clearly and in full in a report.

2.2 System requirements

Operating system

The software was designed for the following 32 and 64 bit operating systems:

- Windows® 7 (except HOME Edition)
- Windows® 8 Pro, Windows® 8 Enterprise
- Windows® 8.1
- Windows® 10

Hardware

To ensure smooth communication between the programming and readout unit and the PC software, the following requirements must also be met:

- Interface USB 2.0 or higher
- Internet Explorer 9 or higher

For reporting, date and time settings are automatically transferred from 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 the authenticity of the measurement data.

2.3 Date/time settings

For reporting, date and time settings are automatically transferred from 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 the authenticity of the measurement data.

Within Windows, the IT administrator has the rights to set up the date and time settings to meet the needs of each user. The date and time settings should be backed up to the PC once they are configured by the IT administrator.

Windows time settings

The testo 190 CFR software has an interface to the Windows time setting on the PC. The time information can be displayed in the reports as hh:mm:ss or AM/PM.

Windows date settings

The testo 190 CFR software has an interface to the Windows date settings on the PC. The date is displayed in the reports for GMP purposes. The display depends on the date settings on the PC.

3 First steps

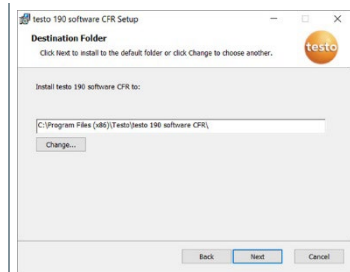## 3.1 Running the installation

i	To install the PC software, you need administrator rights for the PC you are using.

1 Insert the installation CD for the testo 190 CFR software in your computer.

2 Double-click to open the file Setup.

▶ The setup window opens.

3 Follow the setup instructions.

4 If necessary, change the destination folder in which the software is to be saved.

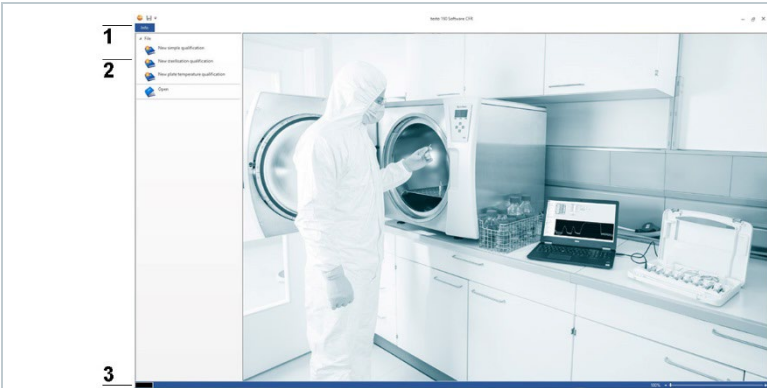# 4 Using the testo 190 CFR software

4.1 Start screen

The start screen of the testo 190 CFR software appears automatically once the software program is opened. From here, the system settings can be adjusted, the status display can be read and process templates can be selected.

1	System settings	2	Process templates
3	Status display		

4.2 "Info" system settings

The system settings can be found under the Info tab. In the system settings, you can make settings for Permissions and also Users and groups. You can also view the File audit trail and System audit trail.
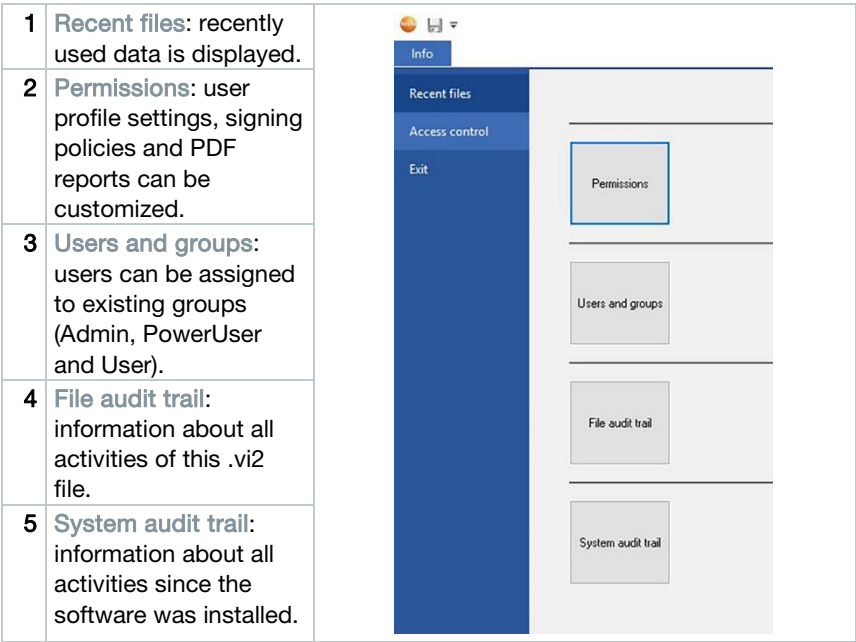
1	Recent files: recently used data is displayed.	
2	Permissions: user profile settings, signing policies and PDF reports can be customized.	
3	Users and groups: users can be assigned to existing groups (Admin, PowerUser and User).	
4	File audit trail: information about all activities of this .vi2 file.	
5	System audit trail: information about all activities since the software was installed.	

> ℹ️ To get back to the start screen from the Info system settings, click the Info field again. The field is located in the top left corner of the screen.

4.2.1 Permissions

> \> Click on Permissions in the left menu bar.

> ▶ Within the Permissions window, there are three types of configurable permissions: User rights, Signing policies and PDF settings.

> ℹ️ System Windows domain administrator rights are required in order to configure permission settings. Users who are assigned as admins within the software do not have access to the permissions folder unless they are also Windows administrators.

4.2.1.1 User rights

The three user types Admin, PowerUser and User are provided. Here in User rights, you can make settings specifying which operations can be carried out by the user types.

1 | Click on Info.

2 | Click on Permissions in the left menu bar.

3 | Click on the Permissions button.

4 | Click on User rights.

> ▶ In different categories (File, Instrument, Report), you can select which operations the groups are authorized to carry out.

User rights - File

Within User rights - File, an administrator can select specific file permissions for the three user groups. When the file permissions are selected, users can open new Sterilisation qualifications and New plate temperature qualification. Users can also be given the rights to Save and Save as within the software.

User rights - Instrument

Within User rights - Instrument, an administrator can select specific instrument permissions for the three user groups. When these are selected, users can

Program instrument, Read instrument, die Compile log results and Edit calibration data.

User rights - Report

Within User rights - Report, an administrator can select specific report permissions for the three user groups. When these are selected, within the software users can Edit templates, Create reports and Sign files.

4.2.1.2 Signing policies

Under Signing policies, you can define when an electronic signature is additionally required for saving or creating reports. The prompt for an electronic signature after reading out and finalizing the established readings cannot be changed.

1 Click on Info.

2 Click on Permissions in the left menu bar.

3 Click on the Permissions button.

4 Click on Signing policies.

> According to **21 CFR Part 11**, an electronic signature is required for defined processes. The electronic signature consists of your personal Windows login data (user name and password).

4.2.1.3 PDF settings

Under PDF settings, you can define whether the PDFs are to be protected by a password, have a specified storage location or should be write-protected.

1 Click on Info.

2 Click on Permissions in the left menu bar.

3 Click on the Permissions button.

4 Click on PDF settings.

> Reports not protected by a password are saved in accordance with the PDF/A-1b document standard. This prohibits the user of passwords.

ℹ️ Within the PDF settings, the IT administrator can configure a file path to automatically save reports in defined file folders. The selected file folder must be protected by your IT administrator.

4.2.2 Users and groups

Under Users and groups, you can assign users to the three existing local groups Admin, PowerUser and User. To define permissions for the three local groups, see the section Setting permissions.

1 | Click on Info.

2 | Click on Permissions in the left menu bar.

3 | Click on the Users and groups button.

4.2.2.1 Add user

ℹ️ You can directly manage users and groups and add users to groups without opening the testo 190 CFR software. To do this, open the Windows search function and enter the command "lusrmgr.msc" and follow the steps below.

1 | Click on Groups.

2 | Double-click one of the three defined groups (Testo-Comsoft-Admin, Testo-Comsoft-PowerUser and Testo-Comsoft-User).

▶ | Another window opens.

3 | Click on Add.

▶ | A new user can be added.

4 | Enter your Windows user name as an additional object name.

5 | Click on Check name.

6 | Click on OK.

7 | Click on Apply.

▶ The process is closed.

8 Click on OK.

9 Close window.

4.2.2.2 Removing users

ℹ️ You can directly manage users and groups and remove users from groups without opening the testo 190 CFR software. To do this, open the Windows search function and enter the command "lusrmgr.msc" and follow the steps below.

1 Click on Groups.

2 Double-click one of the three defined groups (Testo-Comsoft-Admin, Testo-Comsoft-PowerUser and Testo-Comsoft-User).

▶ Another window opens.

3 Click on an already added user.

4 Click on Remove.

▶ The user is removed.

5 Click on Apply.

▶ The process is closed.

6 Click on OK.

7 Close window.

4.2.3 File audit trail

The File audit trail file captures the entries, which can be directly allocated to an electronic record. These include the creation or saving of electronic records and any changes made to this data during the archiving period.

1 Click on Info.

2 | Click on Permissions in the left menu bar.

3 | Click on the File audit trail button.

> [i] To display a file audit trail, a file must be opened within the software. The storage location of the file audit trail folder must be protected by an IT administrator.

> [i] To print out an audit trail, click on Print. A document is automatically created and printed out. The audit trail file can also be exported. If you export this file, the action will not be removed or deleted from this electronic data record or data file.

4.2.4 System audit trail

Data such as adding or removing permissions and changes to temperature/pressure units of the system audit trail is directly linked to the files and intrinsically connected to them. This ensures that the audit trail data is not lost and always remains fully available, even when transferring files from one system to another.

1 | Click on Info.

2 | Click on Permissions in the left menu bar.

3 | Click on the System audit trail button.

▸ | Under System audit trail, the audit trail actions of the testo 190 CFR software system are listed.

> [i] To print out an audit trail, click on Print. A document is automatically created and printed out. The audit trail file can also be exported. If you export this file, the action will not be removed or deleted from this electronic data record or data file.

> [i] The storage location of the system audit trail file must be protected by an IT administrator. Windows events, such as adding or removing users within local user groups, are tracked by the Windows Event Viewer.
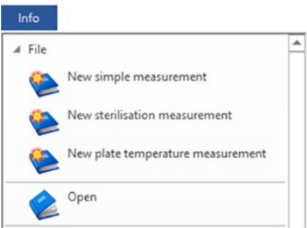
4.3 Status display

The status display informs you whether the programming and readout unit is successfully connected to the PC.

1	Status display lights up green: the programming and readout unit is successfully connected to the software.	
2	Status display lights up black: the programming and readout unit is not connected to the software.	

4.4 Process templates

The process templates provide you with templates for intuitive and user-friendly programming, reading and evaluation of the testo 190 data loggers. There are templates for Simple qualification, New sterilisation qualification and New plate temperature qualification. Saved .vi2 files can also be opened.

1	Start measurement process: click to open the appropriate/required process template.	
2	Open: click to open existing .vi2 files in the software.	

4.5 Contents of the process templates

The contents open automatically once you have clicked on a process template. You can now click on the icons step by step to complete the process. The contents of the process templates depend on the selected process and can therefore vary in terms of their scope.

Element	Designation
⚙	Units
💾	Save
💾	Save as
📄	Export to Excel
🔋	Battery check
📗	Programming of loggers
🗄	Readout of loggers
∿	Chart
▦	Raw data view
🛡	Calculations
✅	Acceptance criteria
📗	Test results
▦	Statistics
✅	Content
📋	System
👆	Adjust meas. point positions
📄	Create report

4.5.1 Units

Set the units of temperature and pressure that you need.

> **i** The programming and readout unit does not need to be connected in order to set the units.

1 | Click on one of the three process templates.

2 | Click on Units.

3 | Select units for temperature and pressure.

▶ | The defined temperature and pressure units are automatically saved.

> **i** Once the data loggers have been read, the units for the current file can no longer be changed.

> **i** Changes to the temperature and pressure units are recorded within the System audit trail.
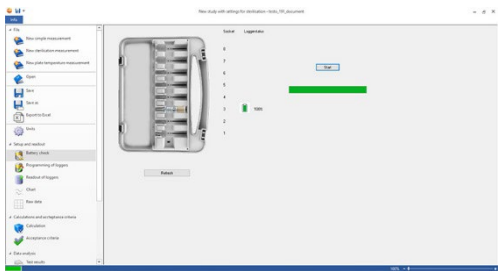
4.5.2 Battery check

Under Battery check, you can quickly and easily determine the battery status of the data loggers placed in the programming and readout unit.

✓ For a battery check to be carried out, the programming and readout unit must be connected to the PC via the USB cable supplied, and the data loggers placed in it.

✓ Make sure you have used the correct distance adapters.

ℹ️ For the testo 190 T1, testo 190 T2 and testo 190 T3 data loggers, you need the long distance adapter. For the testo 190 T4 data logger, you need a short distance adapter. The testo 190 P1 data logger does not require a distance adapter.

1	The data loggers positioned there are displayed.	
2	Start: start of battery status measurement.	
3	Battery check: check the battery status of the data loggers.	
4	Refresh: click on "Refresh" if the arrangement of the data loggers in the diagram above does not match the arrangement of the data loggers in the programming and readout unit	

ℹ️ During the battery check, existing measurement data from previous and current files is deleted for all data loggers placed in the readout unit.

4.5.3 Programming of loggers

Under Programming of loggers, you can prepare the data loggers for a measurement. You can define start and stop conditions and manage calibration data.

Element	Designation
❌	Data logger could not be programmed.
✔	Data logger successfully programmed.
⚙	Data loggers can now be programmed.
🔋	Battery needs replacing.
🔋	Battery will soon need replacing.
🔋	Battery is working properly.
🔄	Data logger has reached its maximum service life. Replace data logger.
🔁	Battery has been replaced.

1 | Place the data loggers in the programming and readout unit and connect this to the PC using the USB cable supplied.

▸ | The data loggers positioned in the programming and readout unit appear in the software and display the symbols (wheel with red arrow) and battery status.

2 | Click on Programming for the required socket.

▸ | The data logger in this socket can be programmed

ℹ The socket, data logger type, serial number and version number appear on the top right of the screen.

3 | Define the start conditions, the cycle and the stop conditions.

Start conditions:
Here you can choose between a measurement start as a function of date/time, a temperature or pressure overrange as well as a temperature or pressure underrange.
Cycle:
The cycle can be defined from one second (00:00:01) up to 24 hours (23:59:59).

Stop conditions:
Here you can choose between a measurement stop as a function of date/time, the defined number of readings or the maximum memory size.

4 | Click on Apply current.

▶ | The settings for this data logger will be applied.

If you want to program all data loggers located in the programming and readout unit with these settings, click on Apply to all.

ℹ️ If programming was successful, the symbol ✔ appears and the settings appear in the box at bottom left with the heading List of loggers already programmed for this measurement.

ℹ️ If the battery status is 🔋, the battery needs replacing. To change the battery, please refer to the instruction manual for the testo 190 data logger for temperature and pressure.
Interruption of the supply voltage is detected by the software and a query to reset the battery hour counter is started. Important: Start condition must be at least 3 minutes in the future.

4.5.3.1 Name data logger

You have the option of naming each data logger individually.

1 | Click on Programming for the required data logger.

▶ | Logger name opens.

2 | Enter the required name.

ℹ️ Input is limited to 20 characters.
Invalid characters: / \ : !

3 | Click on Apply current.

ℹ️ You can enter the name directly for all data loggers which are in the readout unit. If you then click on Apply to all, the setting is applied as defined by you.

▶ The process is completed.

4.5.3.2 Managing calibration data

You can program the calibration data on the data loggers. The calibration data must be carried out individually for each data logger in the programming and readout unit.

ℹ️ The calibration data is saved on the data logger and can be appended to the report.

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1 Click on Settings for the required socket.

2 Click on Calibration data.

3 Enter the Certificate ID, Calibration date and Next calibration.

Calibration settings		×
Probe	6142 0482 1	OK
Certificate ID		Cancel
Calibration date	1/ 1/2016	
Next calibration	1/ 1/2016	
☐ Activate reminder		

ℹ️ You can activate a reminder by ticking Activate reminder. The reminder is implemented in the software.

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4 Click on Apply current.

▶ The process is closed.

4.5.4 Readout of loggers

Under Readout of loggers, you can read the data loggers used and prepare them for the upcoming evaluation. In addition, the required time range can be defined precisely to the second.

Element	Designation
🔲	Data from a different study.
👓	Data logger ready for readout.
👓	Data logger readout was successful.

1 Place the data loggers in the programming and readout unit and connect this to the PC using the USB cable supplied.

<table>
<tr><td colspan="2">⚠ CAUTION</td></tr>
</table>

Risk of burns!
Hot data loggers!

- Allow the data loggers to cool down to at least 50 °C.

▸ The data loggers positioned in the programming and readout unit appear in the software and display the battery status.
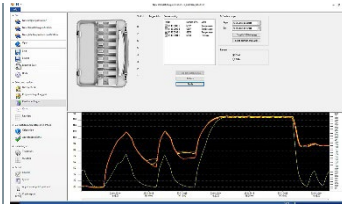
2 Click on Read out logger memory.

▸ The data loggers placed in the programming and readout unit are read.

ⓘ If readout is successful, the data loggers appear in the Current readings list.

3 Put a check mark next to the data loggers that you need for the subsequent evaluation.

4 Define the time period for the subsequent evaluation.

ⓘ Set the points for the Chart or Table to see the selected time range.

5 Click on Finish.

▸ The measurement data established for the subsequent evaluations is recorded.

ⓘ With the electronic signature and the justification for the signature, the user confirms that the established readings are complete. Following this process, the readings cannot be changed.

4.5.4.1 Selecting the data loggers and the time range

To limit the subsequent evaluation to the readings that are actually required, here you can define the required data loggers and the required time range.

1	Place a check mark to determine whether data loggers are used for the subsequent evaluation or not.
2	The start and end will be defined for the required time range.

4.5.5 Chart

The chart appears automatically once you have read the data loggers. Here you can quickly and easily analyze the determined readings using crosshairs or a zoom function. Time markers or simple notes can also be inserted here.
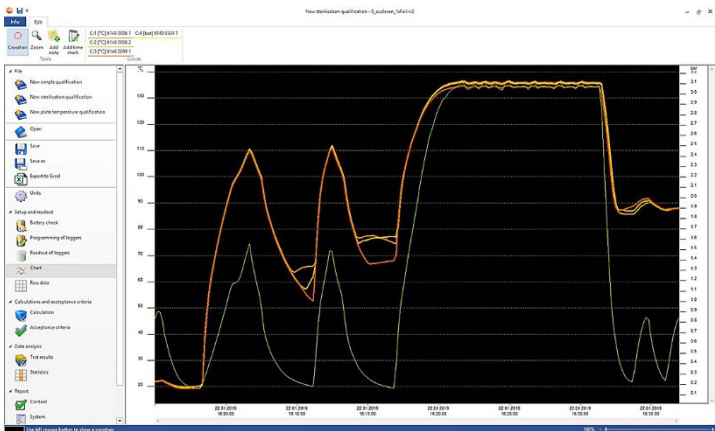
Tools, axes configuration, formula and curves are available for analyzing the measurement curves:

Tools:

- Crosshair ○ : The crosshairs are used for displaying individual measuring points. Enable function: Hold the left mouse button down and drag the mouse over the required area of the curve. The values of the curve at that point are shown in a small separate display window.

- Zoom 🔍 : Enable function: Hold the left mouse button down and drag over the required time period of the curve. An enlarged view of this section is displayed. To return to 100% visibility within the graph, the user can click

on the percentage symbol (%) on the right-hand side below the chart. The user can also increase or decrease the visibility by clicking on the (-) and (+) symbols on the right-hand side below the chart.

- Add note : Opens an input window -> input note -> OK. The input window is closed, a speech bubble is displayed in the curve, which can be dragged to the required position using the crosshairs selection function.

- Add time mark : Opens an input window -> input comments -> OK. The input window is closed, a green line is displayed in the curve. Right-click on the whole line to remove or edit the time marker. To move the time marker manually, click on the time marker in the chart with the left mouse button and keep it pressed. Position the time marker at the required place and release the mouse button.

> ℹ️ Notes can be edited or deleted by right-clicking on the speech bubble. Time markers can be edited or deleted by right-clicking on the line.

> ℹ️ The inserted time markers can be used to manually determine the holding phases. Alternatively, you can mark and label important areas on the chart.

Axes configuration:

- Temperature axis: automatically opens another window. Remove the check mark for Automatic scale in order to customize the range of values. The division of the range of values can also be changed from automatic to manual. This allows you to customize the scaling. To complete the process, click on OK.

- Pressure axis: automatically opens another window. Remove the check mark for Automatic scale in order to customize the range of values. The division of the range of values can also be changed from automatic to manual. This allows you to customize the scaling. To complete the process, click on OK.

- Time axis: automatically opens another window. Click on Position to display an individual time range on the chart. The division of the range of values can also be changed from automatic to manual. This allows you to customize the scaling. To complete the process, click on OK.

Formula:

- Measurement data: the temperature and pressure measurement data for the measurement is displayed.

- Saturated steam pressure: the measured and calculated pressure value is displayed on the chart and can be compared.

- **Lethality**: the lethality values of the data loggers are displayed.

> **i** In order to display the Saturated steam pressure or Lethality curves on the chart, the calculations must first be selected as described in the subsequent section 4.5.8.1.

Curves:

- The display of the curves can be modified in terms of colour, width, style and marker in the toolbar under Curves. This is done by clicking on the measuring point in the toolbar.

4.5.6 Raw data view

The raw data view shows you the readings determined for the data loggers used. In this overview, you can view all the determined readings.
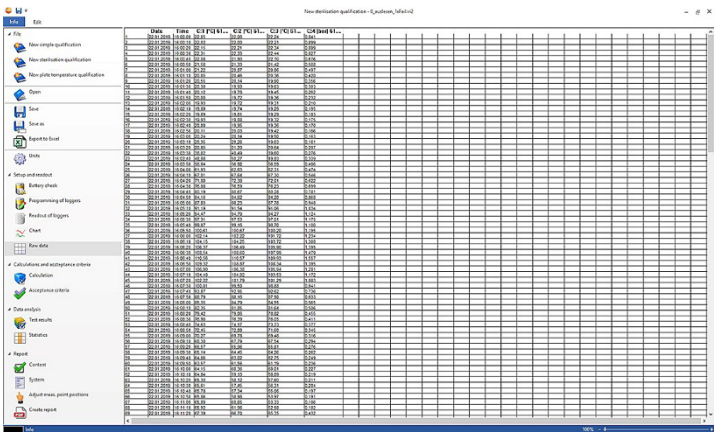
4.5.7 Export to Excel

> **i** Since tampering cannot be ruled out when exporting measurement data to Microsoft Excel or other systems, we recommend evaluating the measurement data completely in the testo 190 CFR software. Once the Excel file has been exported, the .csv data can no longer be uploaded to the testo 190 CFR software. The original electronic raw data is stored in the .vi2 file.

1 | Click on Export to Excel.

▷ The measurement data is saved in a .csv file and can subsequently be further processed.

4.5.8 New sterilisation qualification

4.5.8.1 Calculations

The testo 190 CFR software enables calculation of the holding phase, the lethality and the saturated steam quality.

1	Calculations: required calculations can be selected.
2	The calculation basis for determining the holding phase can be defined. Check the box for Determine holding phase and select the required calculation basis.
3	Parameters for calculating the lethality can be defined. Check the box for Add lethality calculation and define the required parameters.
4	The calculation basis for determining the saturated steam pressure test can be defined. Check the box for Calculation of saturated steam pressure and select the required calculation basis.

Holding phase

There are three options available for calculating the holding phase:

- **Automatically from all probes**: The holding phase is the longest period of time in which all data loggers achieve values above the specified sterilisation temperature.

> ℹ️ To carry out automatic computation of the holding phase, a temperature set point must be entered manually in the field to the right.

- **Automatically from a single probe**: The holding phase is the longest period of time in which the selected data logger reports values above the specified sterilisation temperature.

- **Manually by timemark**: Time marks set in the chart can be selected as the start and end time of the holding phase.

> **i** Insert at least two time marks in the chart and position them at the required times. These time marks are automatically displayed in the chart. In Calculations, you can then select the time marks that were set.

Lethality calculation

For the lethality calculation, we provide you with predefined parameters. Nevertheless, you can apply individual settings to the lethality calculation.

- **Temperature reference**: The temperature reference for calculating the lethality depends on the process being performed. When carrying out heating processes at a temperature > 100 °C, use the temperature reference of 121.1 °C. If the heating process is carried out at a temperature of < 100 °C, the reference value depends on the product.

- **Minimum temperature**: Only values where the measured temperature is above the minimum temperature are taken into account for the lethality calculation. Here you can define the temperature at which the lethality calculation starts.

- **Z-value**: The Z-value for calculating the lethality depends on the germ present in the product. This value can be found in the package information leaflet for the biological indicators used and is usually <=10. If you do not use biological indicators, the default value "10" is recommended for calculating the lethality rate.

- **D-value**: In the software, the D-value is not required for calculating the lethality. Here you can define whether the calculated lethality rate is output in "D".

Saturated steam pressure test

There are three options for calculating the saturated steam quality:

- **Temperature mean**: The calculation of the saturated steam pressure is based on the mean temperature of all loggers.

- **From a single meas. point**: The calculation of the saturated steam pressure is based on the temperature values of the specified logger.

- **Coldspot**: The calculation of the saturated steam pressure is based on the coldest temperature value of all loggers at each time point.

4.5.8.2 Acceptance criteria

The following acceptance criteria for the sterilisation measurement are available and can be defined:
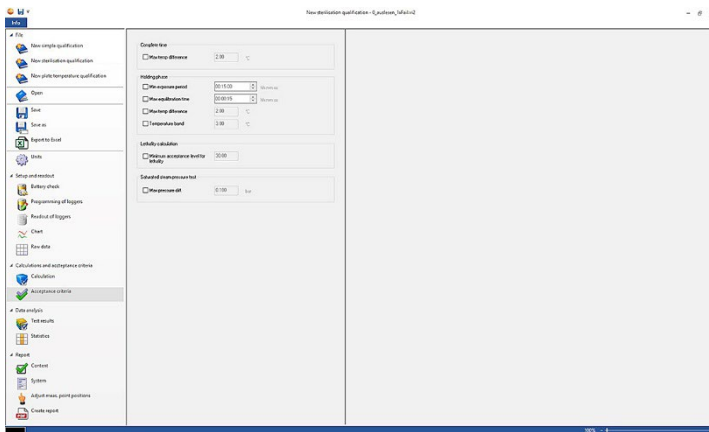
Complete time

- **Max temp difference**: Verifies that at no time (over the complete measuring time) does the difference of temperature between the lowest and highest measuring point exceed the defined limit.

Holding phase

- **Min. warm-up phase**: Verifies that the minimum warm-up phase is observed.

- **Min exposure period**: Verifies that the holding phase covers at least the defined duration.

- **Max equilibration time**: Verifies that all loggers achieve the sterilisation temperature at the defined time. This enables a distinction to be made between automatic (reference measurement point is the first data logger to reach the sterilisation temperature) or specify reference point (reference measurement point is the data logger selected).

- **Max temp difference**: Verifies that at no time (during the holding phase) does the temperature difference between the data logger with the lowest measured temperature and the data logger with the highest measured temperature exceed the defined limit.

- **Temperature band**: Verifies that all measured temperature values are within a temperature band. The band starts at the process temperature and its width is defined here.

- **Min. cooling phase**: Verifies that the minimum cooling phase is observed.

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Lethality calculation

- **Minimum acceptance level for lethality**: Verifies that all loggers achieve the defined lethality.

Saturated steam pressure test

- **Max pressure diff.**: Verifies that the difference between the calculated saturated steam pressure and the measured pressure (averaged over the holding phase) does not exceed the defined limit.

4.5.9 New plate temperature qualification

4.5.9.1 Calculations

The testo 190 CFR software enables both automatic calculation and manual definition and determination of the hold time.
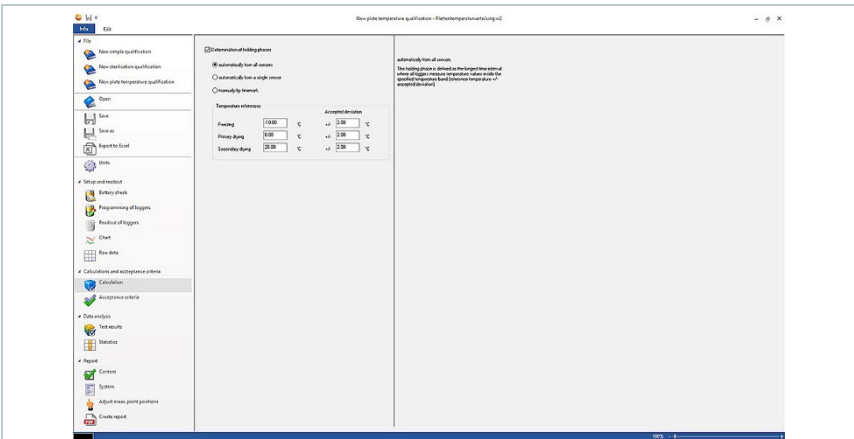
1	Calculations: required calculations can be selected.
2	The calculation basis for determining the holding phase can be defined. To do this, tick Determine holding phase and select the required calculation basis.
3	Temperature references of the holding phases can be defined.
4	Accepted deviations can be defined.

Hold time

To calculate the hold time, you can choose between three options:

- **Automatically from all probes**: The holding phase is defined as the longest time interval where all loggers measure temperature values inside the specified temperature band (reference temperature +/- accepted deviation).

> To carry out automatic computation of holding phases, the temperature references and the associated deviation must be entered manually in the empty fields.

- **Automatically from a single probe**: The holding phase is defined as the longest time interval where the specified logger measures temperature values inside the specified temperature band (reference temperature +/- accepted deviation).

- **Manually by timemark**: The beginning and end of the holding phases can be set to time marks that are previously defined in the chart.

> Insert time marks in the chart and position them at the required times. These time marks are automatically displayed in the chart. In Calculations, you can then select the time marks that were set.

4.5.9.2 Acceptance criteria

The following acceptance criteria for the new plate temperature qualification are available and can be defined:
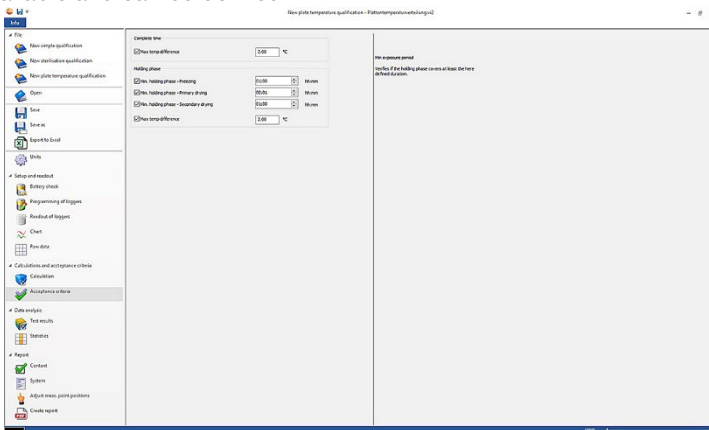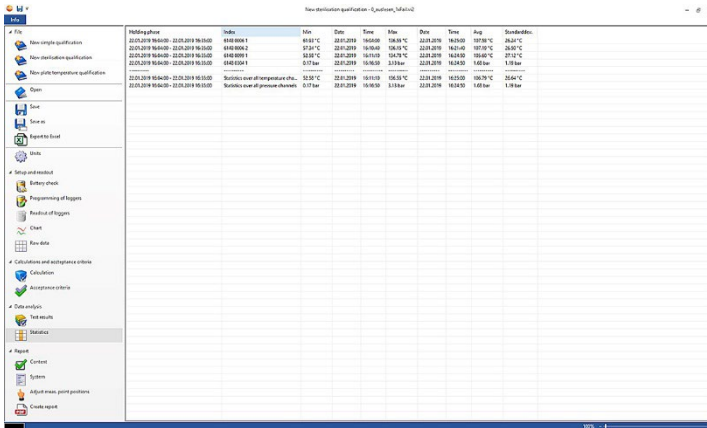
Complete time

- **Max temp difference**: Verifies that at no time (over the complete measuring time) does the difference of temperature between the lowest and highest measuring point exceed the defined limit.

Holding phases

- **Min exposure period**: Verifies that the holding phase covers at least the defined duration.

- **Min exposure period for freezing**: Verifies that the holding phase covers at least the defined duration in the freezing phase.

- **Min exposure period for primary drying**: Verifies that the holding phase covers at least the defined duration in the primary drying phase.

- **Min exposure period for secondary drying**: Verifies that the holding phase covers at least the defined duration in the secondary drying phase.

- **Max temp difference**: Verifies that at no time (during the holding phase) does the difference of temperature between the lowest and highest measuring point exceed the defined limit.

4.5.10 Test results

The Test results offer a quick overview, so that you can determine whether the previously defined acceptance criteria have been fulfilled.

- Test results: quick identification of whether the acceptance criteria have been fulfilled.

- Acceptance criterion fulfilled: ☑

- Acceptance criterion not fulfilled: ☒

- Edit test criteria: definitions of acceptance criteria can be adapted.

4.5.11 Statistics

The Statistics section offers an overview of the readings determined for individual data loggers and of all the data loggers used.

The Statistics section provides information on the following data in the holding phase:

- Minimum reading

- Maximum reading

- Difference between maximum and minimum

- Avg

- Standard deviation

- Lethality rate (if selected in **Calculations**)
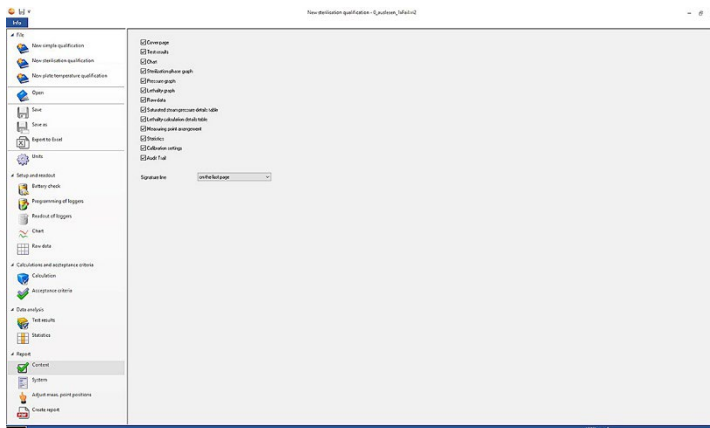
- Statistics over all channels

> If the warm-up and cooling phases were previously selected and defined in the acceptance criteria, data from these two phases can also be taken from the statistics.

4.5.12 Content

The content of the report can be defined by enabling or disabling the contents.

> The last defined report content is automatically applied to future reports.

- • **Content**: report content can be defined.

- • Define contents by applying the respective check mark.

- • **Signature line**: define the position of the signature fields in the report.

- • **Cover page**: the cover page of the report contains the information added in the System section.

- • **Test results**: the test results contain the information that was previously listed in the software under the item Test results.

- • **Chart**: a chart showing the entire measurement process is displayed here. Time markers and notes that have been inserted previously are also shown here.

- • **Sterilization phase graph**: the graph of the calculated or defined holding phase is output here. Time markers and notes that have been inserted previously are also shown here.

- • **Pressure graph**: the graph of the measured and calculated pressure values is shown here.

- • **Lethality graph**: a graph of the individual lethality rates is shown here. The accepted minimum lethality rate is also inserted in this graph.

- • **Raw data**: here the readings are displayed in tabular form.

- • **Saturated steam pressure details table**: in this table, the calculated pressure values for the temperature data loggers are shown in tabular form and with indication of time and date.

- • **Lethality calculation details table**: in this table, the lethality rates are shown in tabular form and with indication of time and date.

- • **Measuring point arrangement**: the exact placement of the data loggers during a measurement in a system can be found here.

- **Statistics**: the maximum reading, minimum reading as well as the mean value and standard deviation within the hold phases are displayed here. The lethality rate for the data loggers is also displayed. The statistics provide information about the values of each data logger individually, as well as about all temperature or pressure data loggers.

- **Calibration data**: the calibration status of the data loggers used can be found here.

- **Audit Trail**: the file audit trail is displayed here.

4.5.13 System

In the System section, any important information which should appear on a cover page of the report can be added. The fields Report title, Title and Entry are provided for you to fill out.

1 | Click in the empty field under Report title.

2 | Fill in the required report title.

3 | Click in the empty field under Title.

4 | Fill in the required title.

5 | Click in the empty field under Entry.

6 | Fill in the appropriate entry.

> **i** More information can be added to the cover page by clicking on the green plus sign. New fields for Title and Entry will appear. To remove the information entered, click on the red cross symbol.
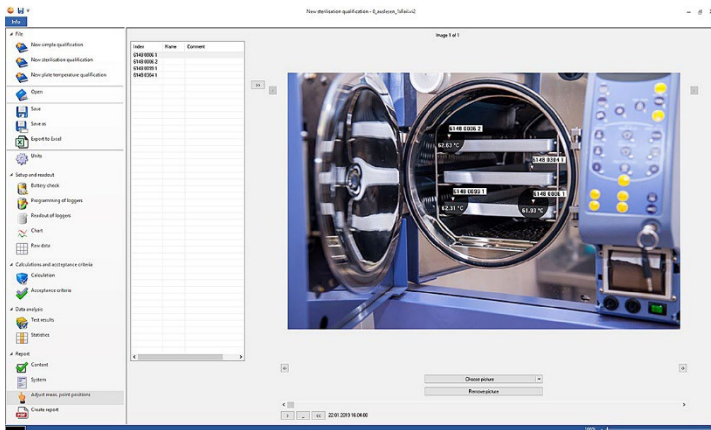
7 | Save template.

> **i** The system section can be saved as a template and is then automatically loaded in the event of new measurements.

4.5.14 Adjust meas. point positions

To add image documentation to the report, measuring points can be inserted into images here. The data loggers used can be individually named and the measuring point can be described in more detail.

- **Adjust meas. point positions**: images can be attached to the report, the data loggers used can be individually named and the position during the measurement can be described.

    1 | Click on Choose picture.

    ▶ | The selected image is added to the evaluation.

    > To add more images, click on Choose picture again.

    2 | Click on Remove picture.

    ▶ | The selected image is deleted.

Up to 20 images can be attached to a report. Press [<] or [>] to scroll between the images. The order of the images can be changed by pressing [<] or [>].

4.5.14.1 Name and describe measuring point, insert measuring point into image or remove

The serial number of the data logger can be assigned a Name and a Comment description. The name then appears in addition to the serial number in tables and graphs of the report. The name can contain a maximum of 6 characters. The used data loggers (measuring points) can be inserted into an appended image. Thus the measuring point can be accurately tracked.

Index	Name	Comment	
6148 0006 1			
6148 0006 2			
6148 0099 1			
6148 0304 1			

1	Name measuring point (use the mouse to click in the Name field)
2	Describe measuring point (use the mouse to click in the Comment field)
3	In one click, insert the measuring point with grey background into the image.

> To position the measuring point at the correct place in the image, click on the tip of the arrow of the inserted measuring point, and move the measuring point while holding down the mouse button.
>
> Right-click on the measuring point to remove the measuring point again.

4.5.15 Create report

✓ All the content required for the report must be selected.

1 Click on Report at the bottom of the left menu bar.

2 Save report in the predefined folder, see PDF settings section.

▶ Report is automatically created and opened.

> Depending on the defined report content, the duration of the report creation varies. Do not interrupt the saving process.

5 Creating templates

In order to simplify the editing of the processes, you can create templates. You can customize the scope of the template. You can create a suitable template consisting of Calculations, Acceptance criteria and System sections.

> **i** An established connection to the programming and readout unit is not required.

1 | Open the PC software

2 | Select one of the three process templates.

▶ | The selected process template opens.

3 | Click on Calculations in the left menu bar.

▶ | Calculations section opens.

4 | Define the required calculations.

5 | Click on Acceptance criteria in the left menu bar.

▶ | Acceptance criteria section opens.

6 | Define required acceptance criteria.

7 | Click on Content in the left menu bar

▶ | Content section opens.

8 | Define required report content.

9 | Click on System in the left menu bar.

▶ | System section opens.

10 | Define contents for the cover page of the report.

11 | Click on Save as in the left menu bar.

▶ The created template is saved.

ℹ To open a created template, click on Open in the left menu bar after opening the PC software program.

6 Data backup and recovery

It is the responsibility of the IT administrator to set up backup and recovery procedures for the testo 190 CFR software. The file audit trail and system audit trail(s) can be backed up by certain applications within Windows. The file audit trail can be restored by opening the file(s) within the testo 190 CFR software. The system audit trail can also be backed up and restored in the testo 190 CFR software.