Miele

(DE) Benutzerhandbuch | (DK) Brugerhåndbogen | (EN) User manual | (ES) Este Manual | (FR) Manuel d´utilisation | (FIN) Kayttäjän oppaassa
(IT) Manuale dell‘ utente | (NL) Gebruikshandleiding | (NO) Brukerhåndboken | (PT) Manual do utilizador | (SE) Användarhandboken

Segosoft®

Miele Edition

Process Documentation

CE 0123

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1 Important Information for Users

Responsibilities:

The head / operator of the facility is responsible for traceable documentation of instrument preparation. This person decides how records are kept and how much is recorded. The settings in SegoSoft® [1] are standardised and the operator must set and adjust these to meet the needs and requirements of the facility. Only when used in this way can SegoSoft afford protection from legal liability risks.

Purpose

The Segosoft program is designed to prevent disease and infection by monitoring and supporting the preparation process of invasive and non-invasive medical devices.

Process validation:

Process validation is explicitly required in QM systems (DIN EN ISO 9001, DIN EN ISO 13485, GMP, DIN EN ISO 15189), in the guidelines of the German Medical Association (RiliBÄK) and in the German Medical Devices Operator Ordinance (MPBetreibV). It includes preparation of documentary confirmation that a process will always create a result or product which conforms to the set requirements.
As part of the legally stipulated process validation the following qualifications are specified for SegoSoft:

Installation Qualification (IQ),
Design Qualification (DQ),
Operational Qualification (OQ),
Performance Qualification (PQ),
Maintenance Qualification (MQ).

Comcotec can provide assistance creating those documents.

Reference to standards, directives and ordinances in their respective valid versions.

Professional competence of personnel

Under the terms of section 2 of health and safety regulations in health services [§ 2 UVV "Gesundheitsdienst" (VBG 103)], only persons
with professional training in health or
who are trained and supervised by a technically competent person
should be appointed to perform disinfection duties.
Persons who have the appropriate training and experience to detect
(infection) hazards and can take action to avert them are considered technically competent.
Disinfection tasks include planning the work as well as
conducting it.
For example, the technical competency required for planning disinfection tasks
can be expected:

– in the hospital, e.g. hospital hygienist, doctor with hygienist duties or specialist hygienist,
– doctors in public health,
– in medical practices, veterinary practices, practice manager. The technical qualifications required for performing disinfections can, for example,
be expected with:
– certified disinfection technicians,
– trained hygiene technicians,

1) SegoSoft is a registered trademark of Comcotec Messtechnik GmbH

Device drivers

Selecting the **right** device driver is a key factor for trouble-free and correct recording of process data by SegoSoft. The user is required to input the exact information for the device manufacturer and device type when setting up the device.

Release dialogue users:

Only persons who because of their training and occupation have the necessary specialist knowledge (qualified person) may be appointed.

Security functions:

The release decision made by a user is documented in the SegoAssurance module of the SegoSoft process documentation, where a PDF document that records the release by the user is generated and saved with a digital signature. This process uses the certificate assigned specifically to the user. The release decision by the user can be checked with Adobe Reader by comparing the data of the certificate with certificate data generated by SegoAssurance.

The most important security features of the SegoAssurance module are the

1. creation of a unique user certificate based on ITU-T Standard X.509 Version 3
2. documentation of the release decision with an advanced electronic signature

Intended use:

SegoSoft is a modern process documentation system for medical and laboratory applications that is independent of device manufacturers. All relevant parameters and data from cleaning, disinfection and sterilisation are recorded in a seamless documentation trail.
The purpose of process documentation is the collection and administration of data sent to the system by external devices, referred to as end devices. The primary goal here is to ensure the highest level of data security and an easily navigated archive of the collected data.
SegoSoft is designed for fully automatic documentation of the automatic processing mechanism. The operator is legally covered by the use of the prescribed SegoSoft version (e.g.: FDA user).

SegoSoft is not intended for optimising processes or process parameters of the attached medical devices.
Every change to processes or process parameters requires a new validation of the complete process.

Maintanance Qualifikation

Contains the documentary confirmation of regular main-tenance. Description of all the necessary cle-aning, maintenance and servicing measures.

Validity of digital signatures:

The coding algorithms must be renewed every two years to eliminate as far as possible the risk of the signed data failing to comply with legal requirements. If you have any questions, please contact our support staff. Use our Service Card and enjoy a range of services (telephone support, free product updates and free update of the digital signature).

Overview of functions

The software is used with the process of preparation of medical devices.It includes the following major functions:

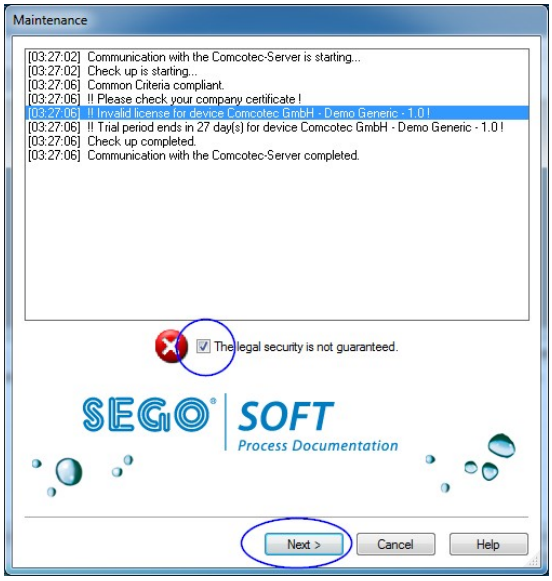
- Fully automatic documentation of the automatic preparation process by recording data (e.g. temperature, pressure, contact pressure) from device

interfaces (washer disinfectors (WD), sterilisers) and converting the data into a format that the user of the software can read,

- Consideration of the validation values of the respective instruments by taking the calibration is taken into account within the scope of a software validation (The validation of the reprocessing process by the user is required by MPBetreibV §8 prescribed by law)
- Confirmation that the data imported via the interface actually originate from the connected device,
- Calculation of various preparation parameters, such as A0 value, saturated steam temperature,
- Display of chart showing overlapping curves of actual and setpoint values,
- Optimisation of the preparation process of the connected medical devices with the above functions.
- Visualisation and documentation of the preparation process in real time.
- View of process for the release decision during preparation,
- Calculation of an expiry date for the sterile instruments according to the the setting of the reprocessing staff (default setting: 180 days)
- Labelling of sterile stored instruments with expiry date, batch number and sterilisation programme name.
- Legal confirmation recorded by electronic signature. Menu-controlled operation and archiving of relevant data after assessment and release by the technician, including confirmation of identity.
- Long-term archiving of documents with prevention of unauthorised changes.

Verification window

The verification window opens automatically opened immediately after starting SegoSoft. The user receives information on the security status of the practice and user certificates and the activation status of the preparation devices.



For example, if the digital signature has expired, **“Contact your software support! ”** appears in the verification window

By selecting the checkbox **“The legal security is not guaranteed”** the user confirms that the information has been read.

If, despite the warning **“The legal security is not guaranteed.”** other recordings are started, the process data will continue to be recorded. However, the data can no longer be released in accordance with legal

requirements.

To ensure the legal security of the process data the encryption algorithms of the digital signature must be renewed.
Please **“Contact your software support!”**

Maintenance information:

The head / operator of the facility is responsible for the maintenance information for the various preparation devices in SegoSoft. The maintenance intervals specified by the manufacturer must be observed.

Styles in the SegoSoft user manual:

Menu commands are printed in bold separated by “/”. For example “**File/Open**“ refers to the Open command in the File menu.
The contents of a dialogue window are also printed in bold. E.g.: “**Select a file name in the list and click OK**“.
Keys are printed in block letters, e.g.: “ENTER”. Key combinations such as ALT+F mean that the F and ALT keys must be pressed simultaneously.

CE mark

This product has a CE mark in accordance with the requirements of Directive 93/42/EEC (Medical Device Directive). With this label Comcotec Messtechnik GmbH declares that the labelled product meets the basic requirements of the Medical Device Directive and that this is monitored under the number 0123 by the specified certification office.

2 System requirements

SegoSoft is designed to run on standard personal computers. The specified configurations have been tested on a number of different systems.

The current system requirements can be viewed at:

https://www.segosoft.info

The system performance for SegoSoft should exceed the recommended minimum depending on the number and type of connected devices. This will ensure trouble-free operation.

2.1 Network

A functional network is required to record a medical device on he network. Consult your IT person to clarify the current status of the network.

3 User interface

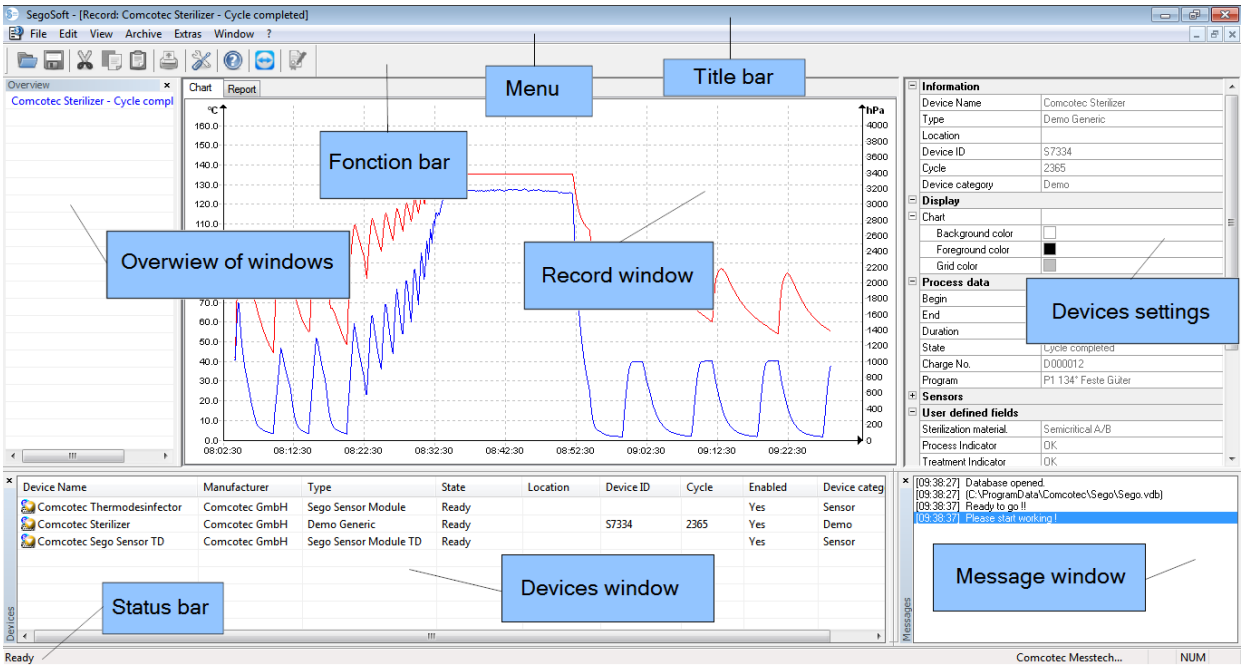
SegoSoft operates in a similar fashion to standard Windows programs with a standard Windows interface.

Title bar

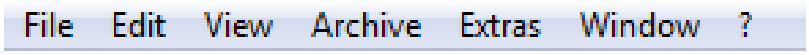
The top row of all programs shows the title of the program, e.g. “**SegoSoft**“, the current status of the sterilisation or disinfection process, e.g. “**SegoSoft** [**Record**

- **Recording - Pretreatment**]”, and the location of the program. For example, if the window for records

in the archive is open to its maximum size, the title bar shows “**SegoSoft** [**Records**]”.

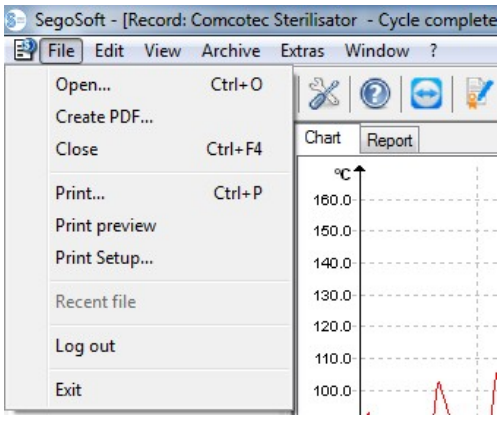


3.1 The menu



The menu commands are sorted by functional groups. As soon as a separate window is opened to run a menu command, additional commands for further processing appear e.g. “**Archive/Records**“, the command “**Window**“ also appears.

3.1.1 “File“ menu:



“**File/Open**“
Previously saved records can be opened in a dialogue window.

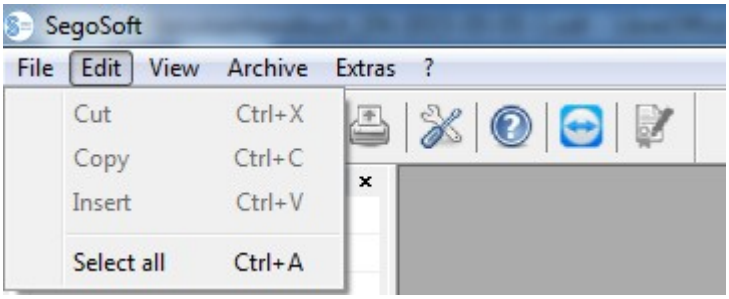
“**File/Print Setup**“
The connected printer can be set up in a dialogue window.
Settings for printing out to paper can be selected here specifically for SegoSoft.

The selected printer settings are listed in the device settings window of the specific preparation device in the **Output/Printer** folder.

“**File/Recent File**“
When SegoSoft is used for the first time, this command is greyed-out; at all other times a list of the recently opened files is displayed.

“**File/Log out**“
The user identified by password (password and user name prompt) can log out with this command. The user status is shown in the status bar (bottom right).

This command closes SegoSoft.



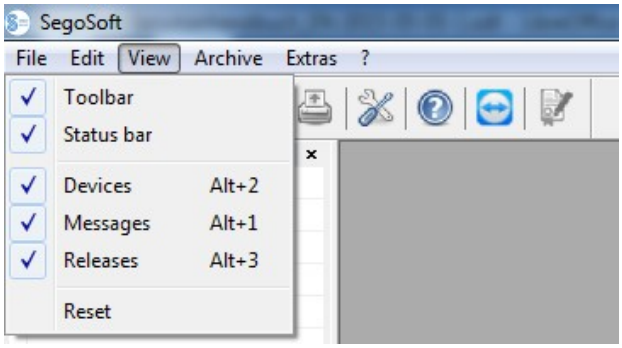
3.1.2 “Edit“ menu:

The commands “**Edit/Cut**“, “**Edit/Copy**“, “**Edit/Paste**“ are available depending on the connected device type (e.g. steriliser). Additional functions such as “**Edit/Graph”**, “**Edit/Record**“ and “**Edit/Select all**“ are also available depending on the main window**.**

“**Edit/Select all**“
All contents of the open window are selected.
The available **edit menu commands** can also be opened by selecting the device (e.g. steriliser) in the device window with the right mouse button and using the context menu.

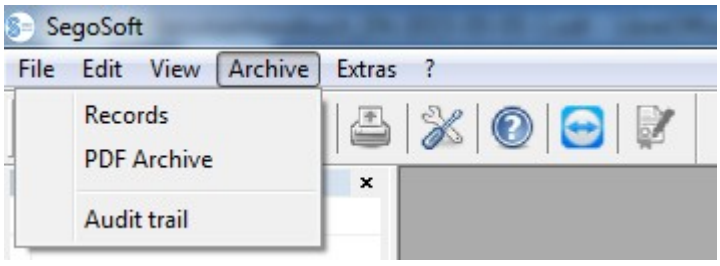
“**Edit/Record**“
In this menu a completed record of a device can be released, a record of a sealing device can be closed or the record can be checked for changes.

3.1.3 “View“ menu:

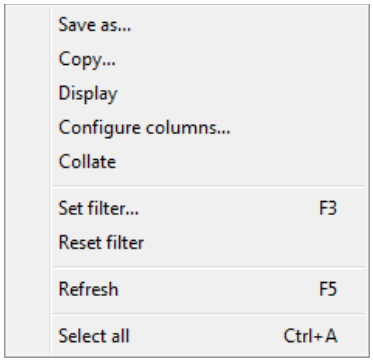


The default setting for the screen display of SegoSoft is set to show all available views. The screen views can be activated or deactivated by selection with the mouse. The reset function can be used to reset the view settings to the default settings.

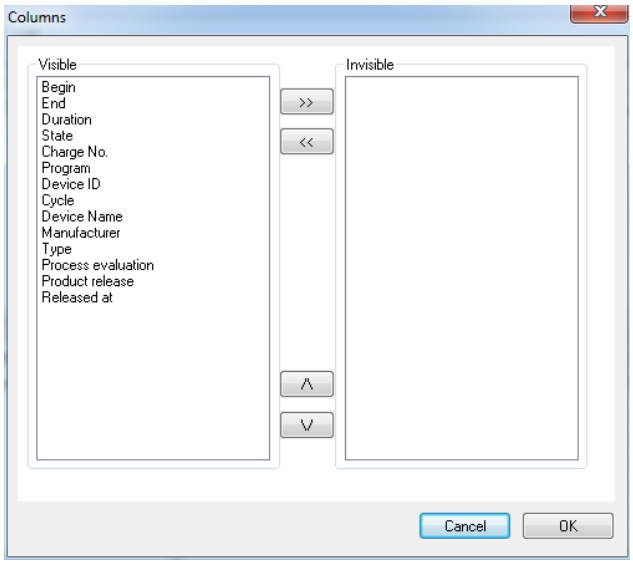
3.1.4 “Archive“ menu:



“**Archive/Records**“
A separate window **[Records]** is opened showing the process data records of all connected devices in table form.
(Start, End, Duration, Status, Batch no., Program, Manufacturer number, Cycle counter, Device name, Company, Type, Process evaluation, Product release, Released by, Released on)
Context menu selected by right mouse button in the records window

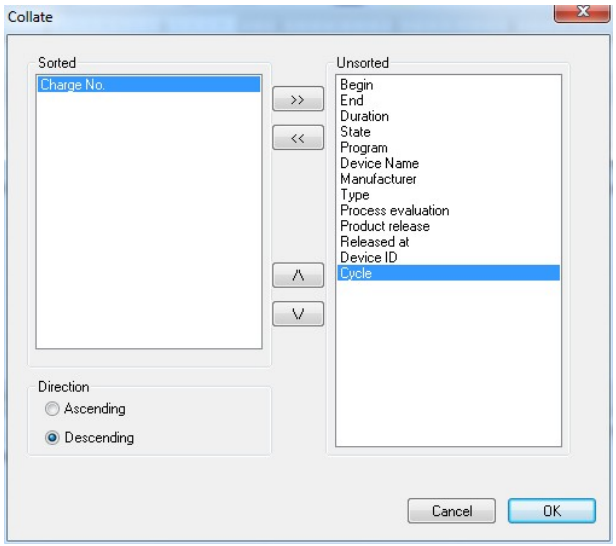


*"**Edit/Records/Configure columns**" or context menu with right mouse button "**Configure columns**"*



A separate window **[Columns]** opens. The table header for the process-data records in the separate window **[Records]** can be changed with the buttons. The order of the preset criteria (Start, End, Duration, Status, Batch no., Program, Manufacturer number, Cycle counter, Device name, Company, Type, Process evaluation, Product release, Released by, Released on) and the selection criteria entered by the user can be changed and displayed or hidden.

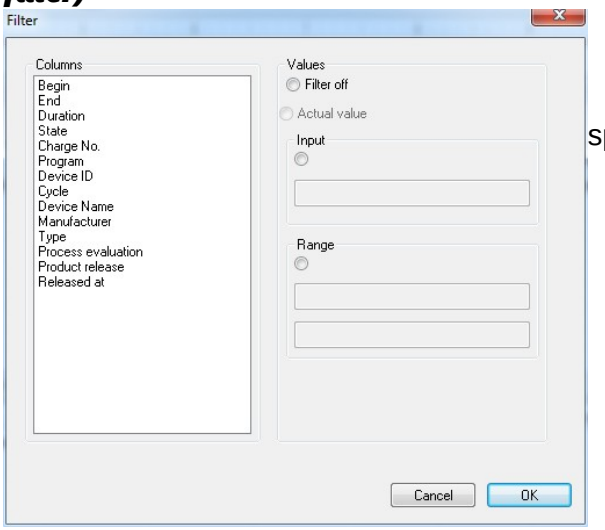
*"**Edit/Records/Records/Collate**" or context menu with right mouse button "**Collate**"*



A separate window **[Collate]** opens. The criteria for the table in the separate window **[Records]** can be sorted in ascending or descending order with the buttons.

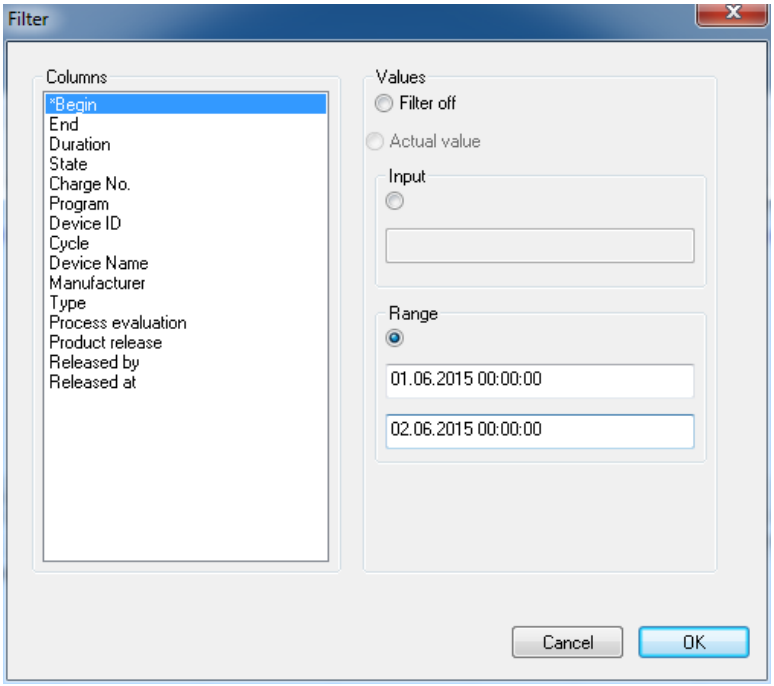
The sort function can also be set by clicking the required sort criterion with the mouse in the table header in the separate window **[Records]**.

***"Edit/Records/Search (Set filter)**" or context menu with right mouse button "**Search (set filter)**"*



A separate window **[Filter]** opens. A special search in the records can be started with the criteria in the process-data table displayed in the "**Columns**" field.

Several criteria can be applied to the search.



For example, if the search is for process data of a device with a known **Manufacturer number** within a specific **period** that were **released by a specific person**, the following filters are set.

"Manufacturer number" - activate input - enter manufacturer number,
"Released by" - activate input - Enter name of person who released it,
"Start" - activate range – enter searched time interval from to (DD.MM.YYYY hh:mm:ss)

The filters are marked with an asterisk in the "**Columns**" field.

The displayed entries of the remaining process-data table correspond to the inputs of the defined filters. When the "**Edit/Records/Search (Set filter)**" search function is opened again, the separate window **[Filter]** opens with the entries of the set filter. This allows the user to check which search has been started. New filters for the search can also be inserted.

*"**Edit/Records/Records/Reset filter**" or context menu with right mouse button "**Reset filter**"*
The entries of the set filter are deleted and the complete process-data table is displayed again.

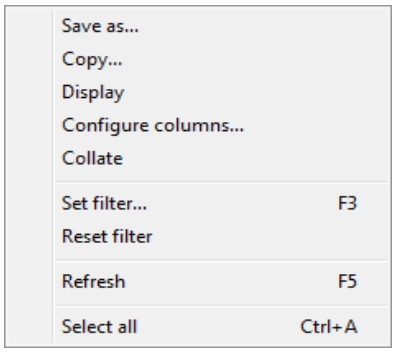
*"**Edit/Records/Records/Label printing**" or context menu with right mouse button "**Label printing**"*

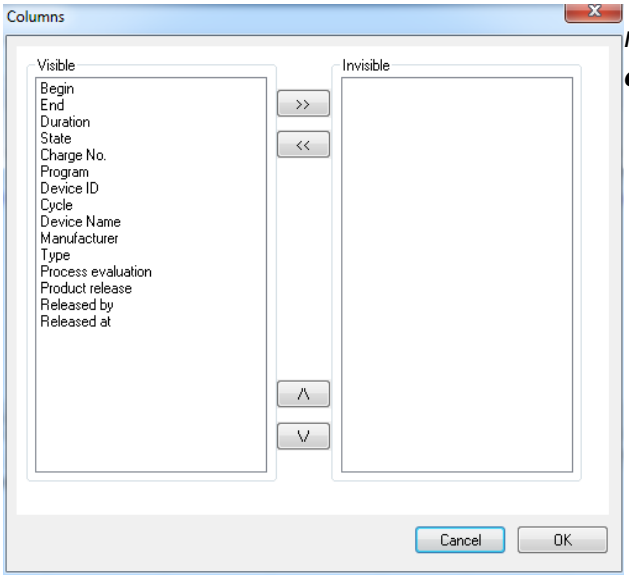
The prior marking of a released record with a positive product release is followed by printout or reprint of a label, if the technical requirements have been met.

*"**Edit/Records/Refresh**" or context menu with right mouse button **"Refresh"***
The view of the separate window **[Records]** is refreshed.
This function is also called by pressing F5.

"**Archive/PDF Archive**"
A separate window **[PDF Archive]** is opened showing the process data records of all connected devices in PDF format.(Start, End, Duration, Status, Batch no., Program, Manufacturer number, Cycle counter, Device name, Company, Type, Process evaluation, Product release, Released by, Released on). The number of criteria in the process-data table depends on the prior configuration of the columns.

Context menu selected by right mouse button in the PDF Archive window

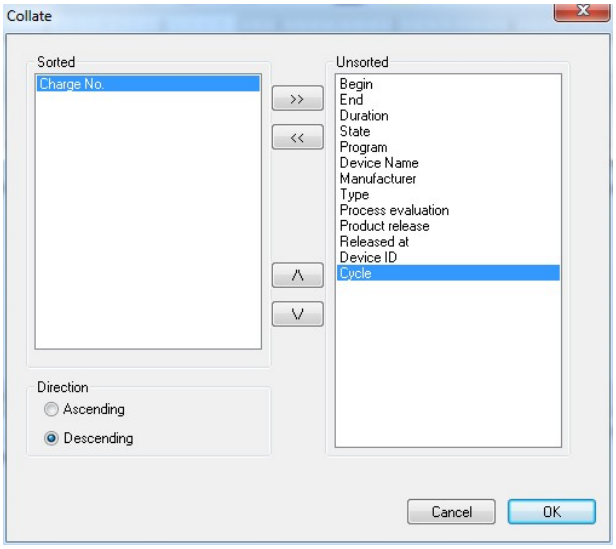




*"**Edit/PDF/Configure columns**" or context menu with right mouse button "**Configure columns**"*

A separate window **[Columns]** opens. The table header for the process-data records in the separate window **[PDF Archive]** can be changed with the buttons. The order of the preset criteria (Start, End, Duration, Status, Batch no., Program, Manufacturer number, Cycle counter, Device name, Company, Type, Process evaluation,Product release, Released by, Released on) and the criteria entered by the user can be changed and displayed or hidden.

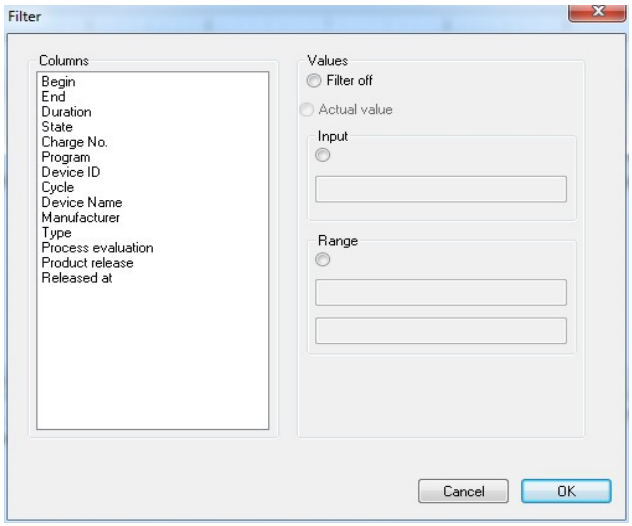
*"**Edit/PDF/Collate**" or context menu with right mouse button "**Collate**"*



A separate window **[Collate]** opens. The criteria for the table in the separate window **[PDF Archive]** can be sorted in ascending or descending order with the buttons. The number of sort criteria in the process-data table depends on the prior configuration of the columns.

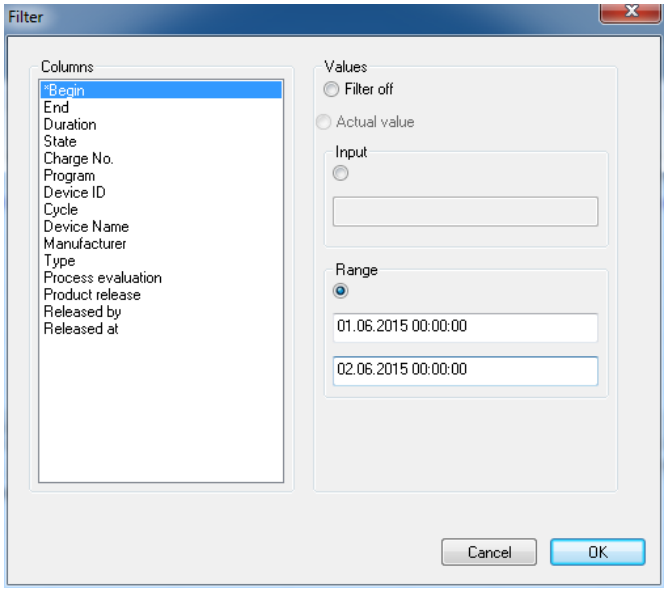
The sort function can also be set by clicking the required sort criterion with the mouse in the table header in the **[PDF Archive]** window.

***"Edit/PDF/Search (Set filter)**" or context menu with right mouse button "**Search (set filter)**"*



A separate window **[Filter]** opens. A special search in the records of the PDF archive can be started with the criteria in the process-data table displayed in the "**Columns**" field.

Several criteria can be applied to the search.



For example, if the search is for process data of a device with a known **Manufacturer number** within a specific **period** that were **released by a specific person**, the following filters are set.

“Manufacturer number” - activate input - enter manufacturer number,
“Released by” - activate input - Enter name of person who released it,
“Start” - activate range – enter searched time interval from to (DD.MM.YYYY hh:mm:ss)

The filters are marked with an asterisk in the “**Columns**“ field.

The displayed entries of the remaining process-data table correspond to the inputs of the defined filters. When the “**Edit/PDF/Search (Set filter)**” search function is opened again, a separate window **[Filter]** opens with the entries of the set filter. This allows the user to check which search has been started. New filters for the search can also be inserted.

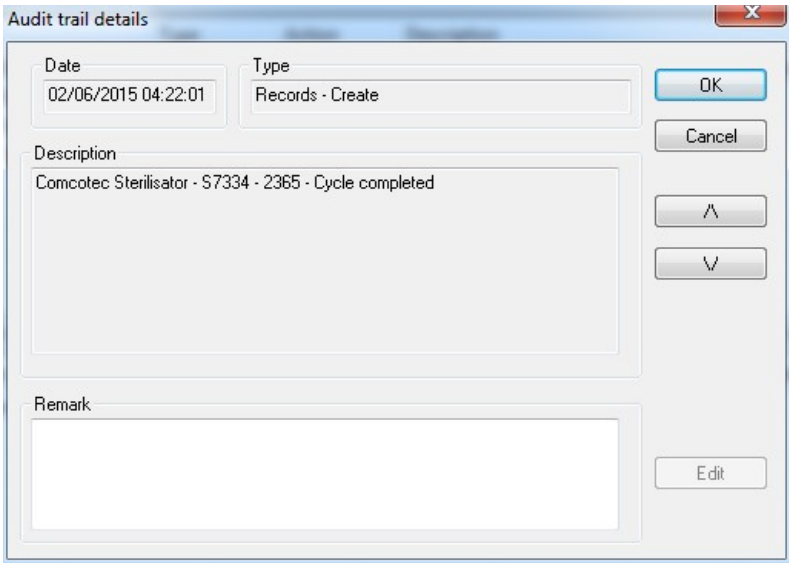
*“**Edit/PDF/Reset filter**“ or context menu with right mouse button “**Reset filter**“*
The entries of the set filter are deleted and the complete process-data table of the PDF archive is displayed again.

*“**Edit/PDF/Label printing**“ or context menu with right mouse button “**Label printing**“*
The prior marking of a released record with a positive product release is followed by printout or reprint of a label, if the technical requirements have been met.

*“**Edit/PDF/Refresh**“ or context menu with right mouse button “**Refresh**“*
The view of the separate window **[PDF]** is refreshed.
This function is also called by pressing F5.

“**Archive/Audit trail**“
A separate **[Audit trail]** window is opened with a protocol of all completed and interrupted processes in table form (secured to prevent manipulation). (Date, Type, Action, Description, User, Remark).

*“**Edit/Audit trail/Remarks**“*
Precondition for activating the command: The user must have the corresponding group rights, must be logged in and must have selected an entry in the list. An **“Audit details“** dialogue window shows the “**Remarks**“ field, in which additional information can be recorded.



3.1.5 Context menu “Devices“ (with the right mouse button in the devices window):

“**Connect**“

Precondition for activating the command: The device listed in the devices window (e.g. steriliser) must be marked. The device (e.g. steriliser) is connected to SegoSoft. The connection status to SegoSoft is shown in the devices window in the details view (“**Devices/Details**“).

“**Disconnect**“
Precondition for activating the command: The device in the devices window (e.g. steriliser) that is to be disconnected from SegoSoft must be marked.
The marked device (e.g. steriliser) will be disconnected from SegoSoft. The connection status to SegoSoft is shown in the devices window in the details view (“**Details**“).

“**Sorting**“
The devices listed in the devices window can be sorted alphabetically in a submenu by the following criteria. (Device name, Company, Type, Status und Location). An arrow is shown in the selected column description. Click on the arrow to sort in the reverse order (Z-A).

The sort function can also be set to the require sort type by clicking in the devices window with the mouse.

“**Archive**“
Precondition for activating the command: A device in the devices window (e.g. steriliser) must be marked.

“**Archive/Records**“: A separate window **[Records]** is opened showing the process data records of the marked device in table form.

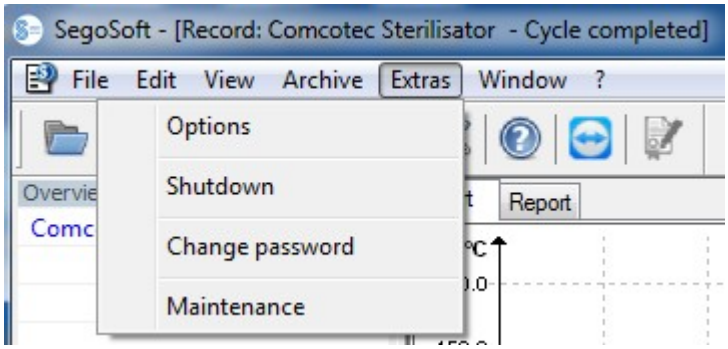
“**Archive/PDF**“ A separate window **[PDF Archive]** is opened showing the process data records of the marked device in PDF format.

“**Devices/Details**“

The specified devices are listed in the devices window by the following items: (Device name, Company, Type, Status, Location, Manufacturer number, Cycle count, Activated).

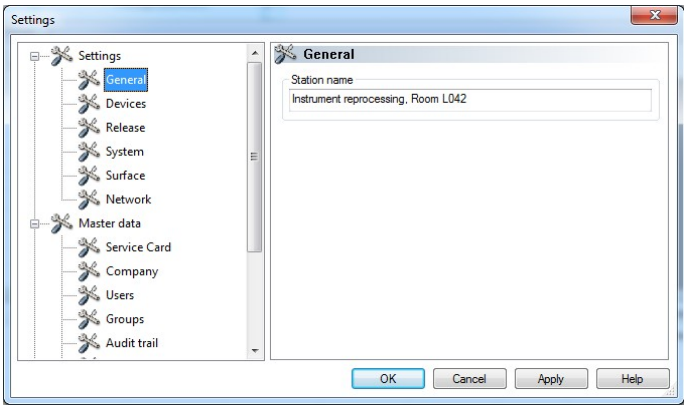
"**Devices/Large icons**"
The specified devices are listed as icons in the devices window.

3.1.6 "Tools" menu:

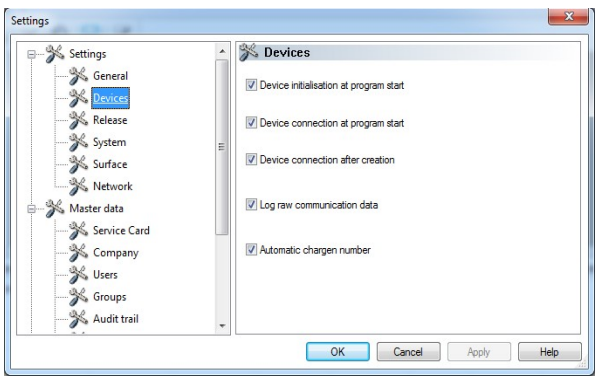


"**Tools/Settings**"
A separate window **[Settings]** opens. With the corresponding group rights the "**General**", "**Devices**", "**Release**" , "**System**", "**Interface**" and "**Network**" functions can be edited.

General:
The station name appears in the title bar.



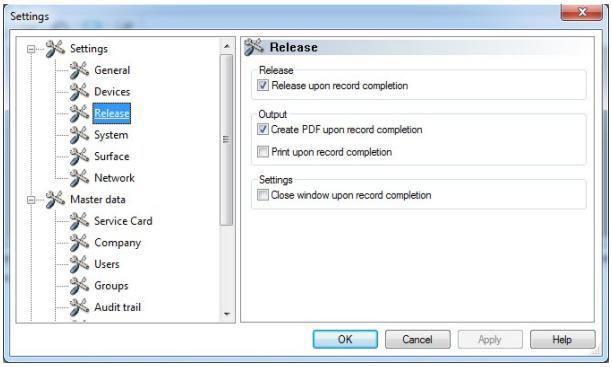
Devices:



Automatic settings by SegoSoft.
We recommend using the settings shown.

The head / operator of the facility is responsible for deactivation of the release (release upon completion of record).

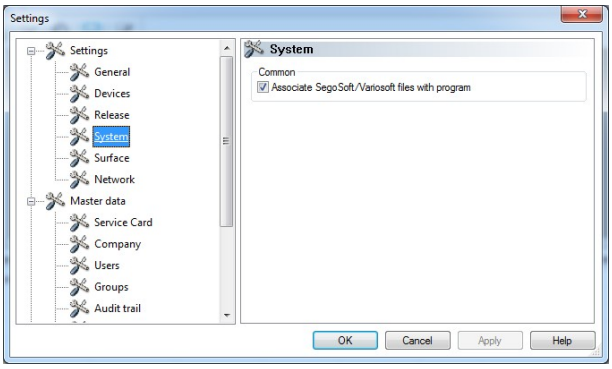
Release:



We recommend that you use the "**Release on completion of record**" setting. On completion of the preparation program the screen automatically displays the release dialogue window. This releases the device almost immediately.

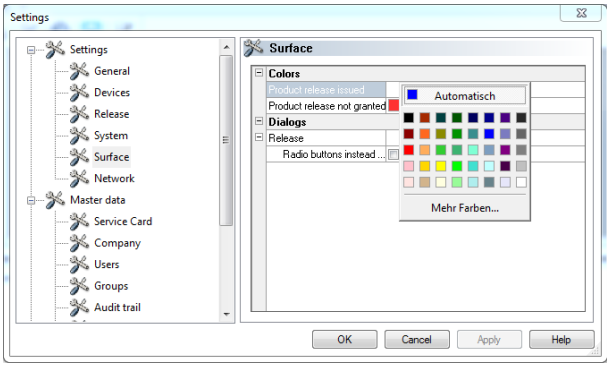
For long-term archiving the setting "**Create PDF upon completion of record**" is recommended.

System:



SegoSoft files on the computer are opened automatically in the SegoSoft program by double-clicking the left mouse button. We recommend that you use the "**Link SegoSoft/Variosoft files with the program**" setting.

Interface:



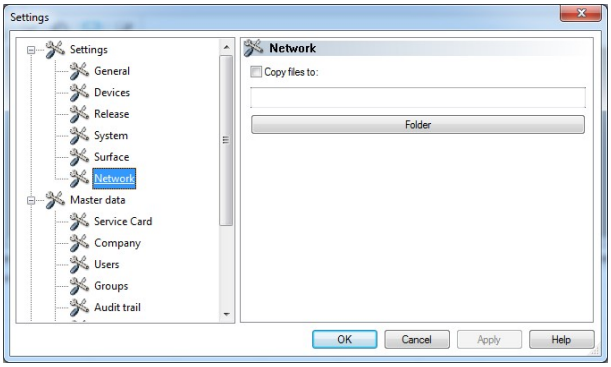
In the "**Interface**" the colours for the "**Product release issued**" and "**Product release not granted**" entries are selected.

Colour selection: Left click on the coloured box to open a separate selection window.

The process-data table in the archive (records and PDF) are blue if product release is issued and red if release is not granted.

The "**Release issued**" and "**Release not granted**" text in the release dialogue is also correspondingly coloured.

Network:



An automatic backup of the files generated by SegoSoft is created via the "**Network**" tab. The file backup can be on a server (recommended) or on an external storage medium. The condition for this is that the field "**Copy files to**" is marked and the location for the backup copy is set up via the directory.

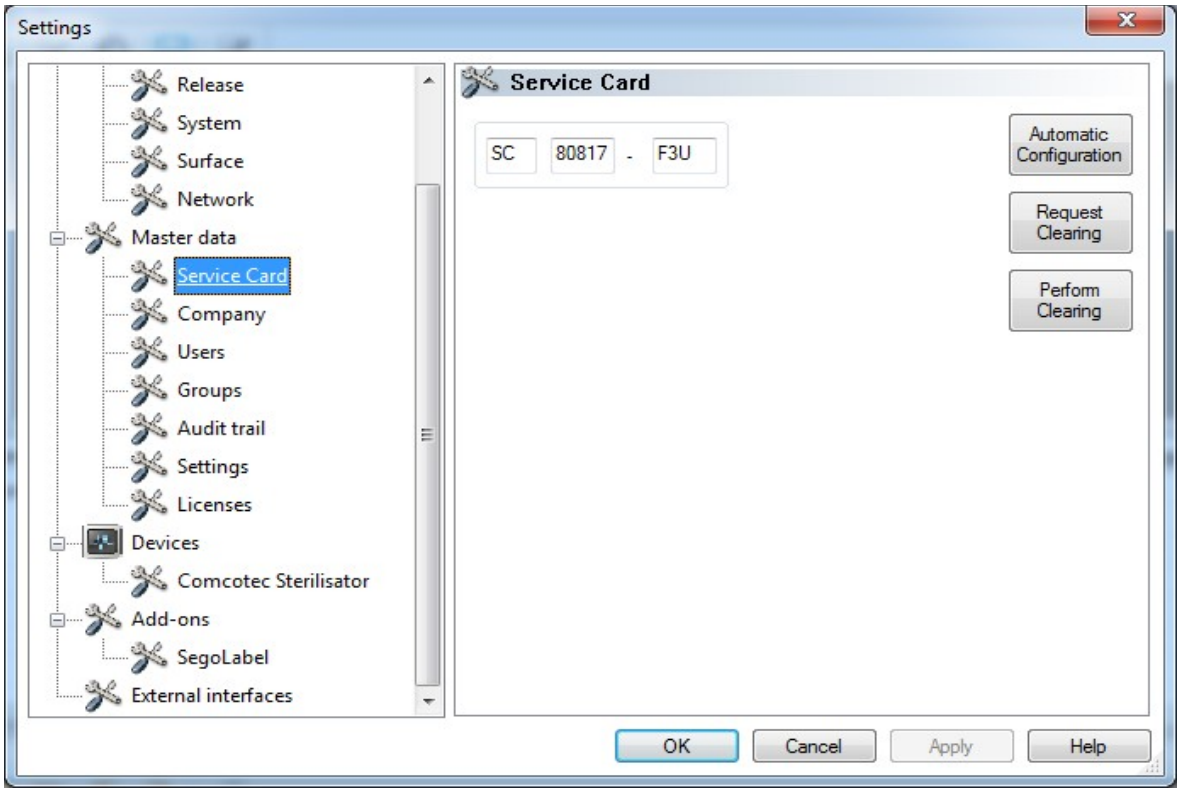
If the network is temporarily interrupted during the backup process, SegoSoft backs up the newly generated files by a regular prompt after the network connection has been restored.

"**Master data**"

In the **Master data** tree structure the "**Service card**", "**Company data**", "**Users**", "**Groups**", "**Audit trail**", "**Settings**" and "**Licences**" items can be opened. Changes can also be made subject to the corresponding group rights.

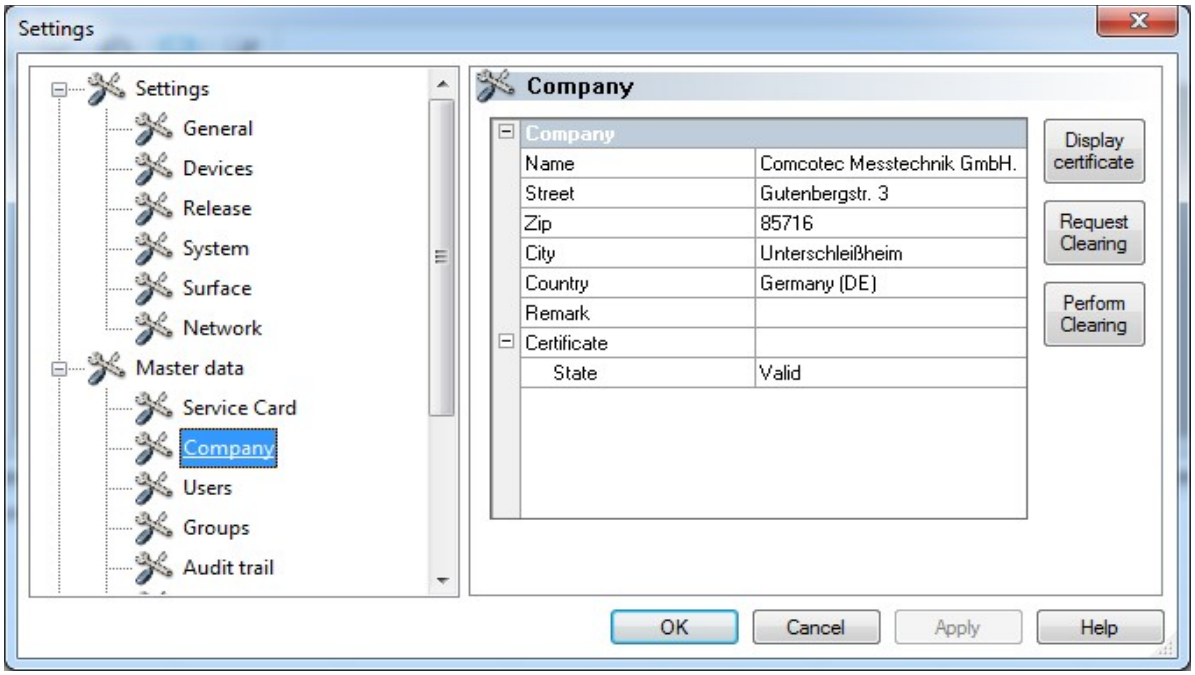
If the company name is changed, the SegoSoft certificate must be renewed.

Service card: Displays the service-card number recorded at installation. More detailed information on entering data and the **Automatic configuration**, **Request clearing**, **Carry out release** functions are described in the **Installation and Administration Manual**.



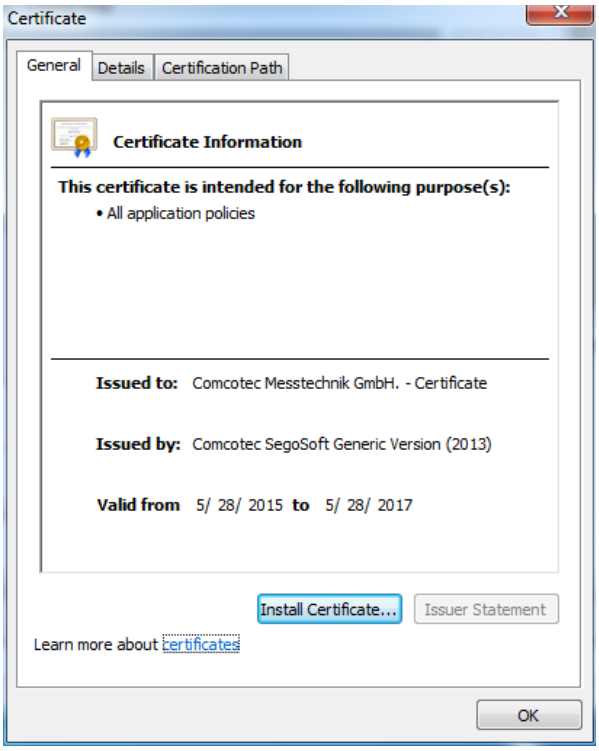
Company data: Displays the company data that was entered at installation. The company data are shown in the record documentation and the electronically signed PDF documents. The “Valid” status is based on the digital signature created at release. No other certificate status is permitted for correct use.

More detailed information on entering data and the **Request clearing** and **Carry out release** functions are described in the **Installation and Administration Manual**.

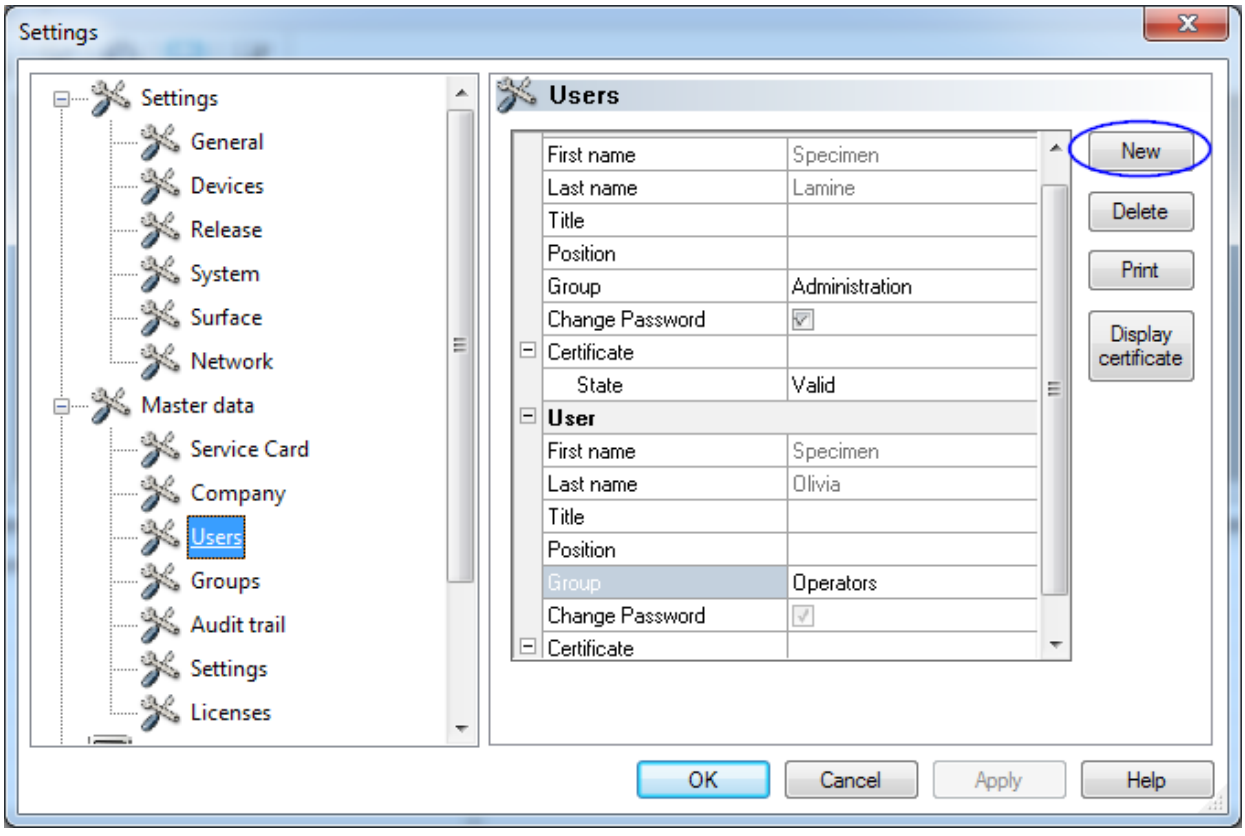


Display company data/certificate

Opens a separate window in which the certificate data can be viewed.



Users: Shows the current users. The subsequent execution of functions in the program depends on the selected group when the user was created.



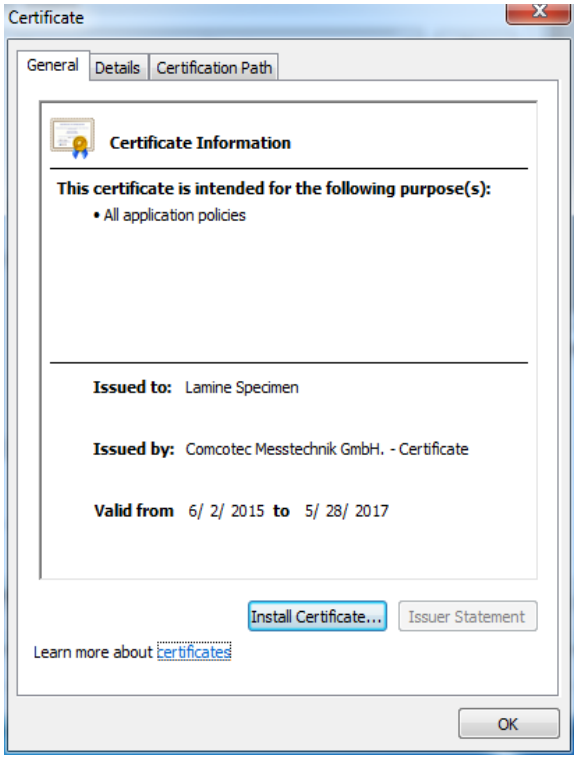
*"**Users/New**"*
Precondition for activating the command: The user must have corresponding group rights, must be logged in and the "**Master data/Users**" tree structure must be selected. When the "**New**" function is selected the input fields for adding a new user are displayed.

First name, last name and group are mandatory fields. Title and position can be used to show the role of the user. After completing the input fields, the information is saved with **"Accept"** and a dialogue opens to prompt the input of a password for the user. After entering the password, a certificate (electronic signature) is generated for the user and the status of the certificate is displayed in the user status. The new user now has a unique user certificate as identification and can administer the hygiene documentation in accordance with the rights assigned to the user.

"**Users/Delete**"
Precondition for activating the command: The user must have corresponding group rights, must be logged in and the "**Master data/Users**" tree structure must be selected. Selection of the "**Delete**" function deletes the selected user. Deletion of a user has no effect on the records documents.

"**Users/Print**"
Once the certificate has been generated the signature verification key of the certificate should be printed out along with a training form.

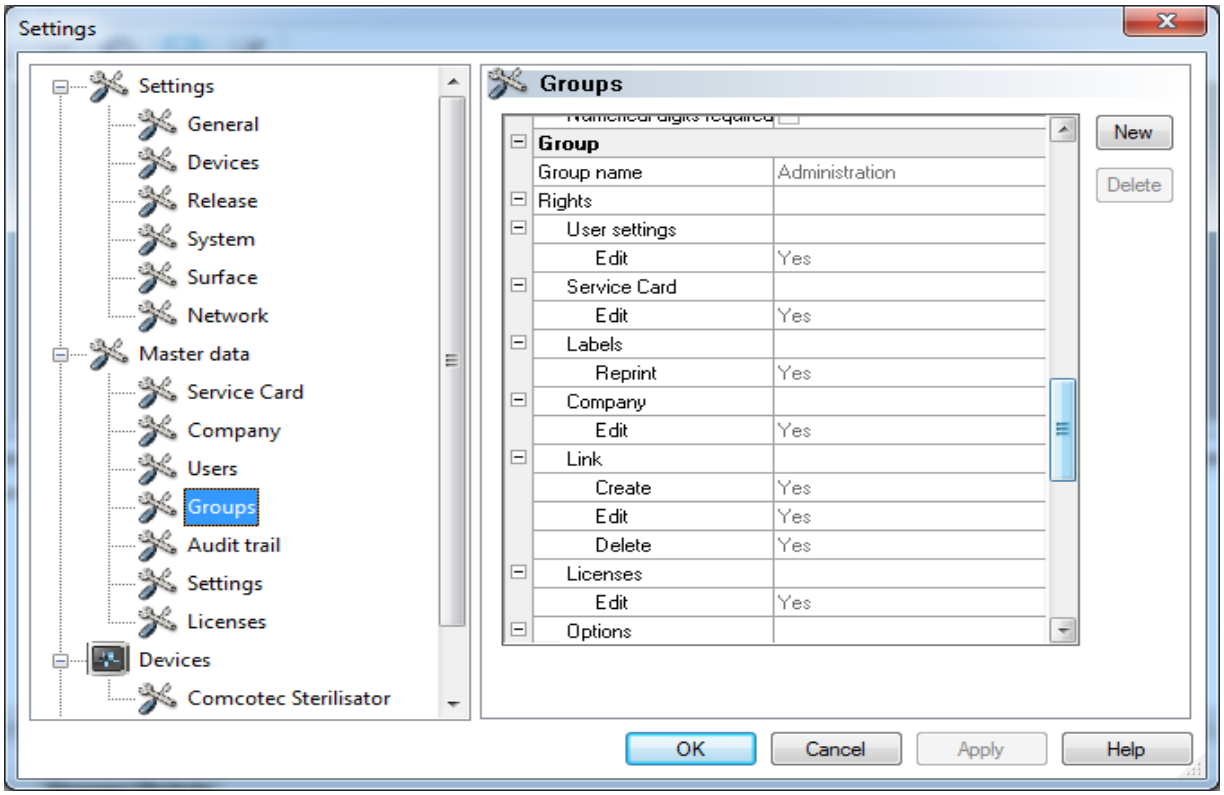
*"**Users/Display certificate**"*
Opens a separate window in which the certificate data of the user can be viewed.



An accredited signature can be imported into SegoSoft with "Install certificate".

More detailed information on editing user data is described in the **Installation and Administration Manual**.

Groups: Displays the groups and rights set up at installation. The assignment of a group to a user controls the user's authorisation for executing functions in the program.

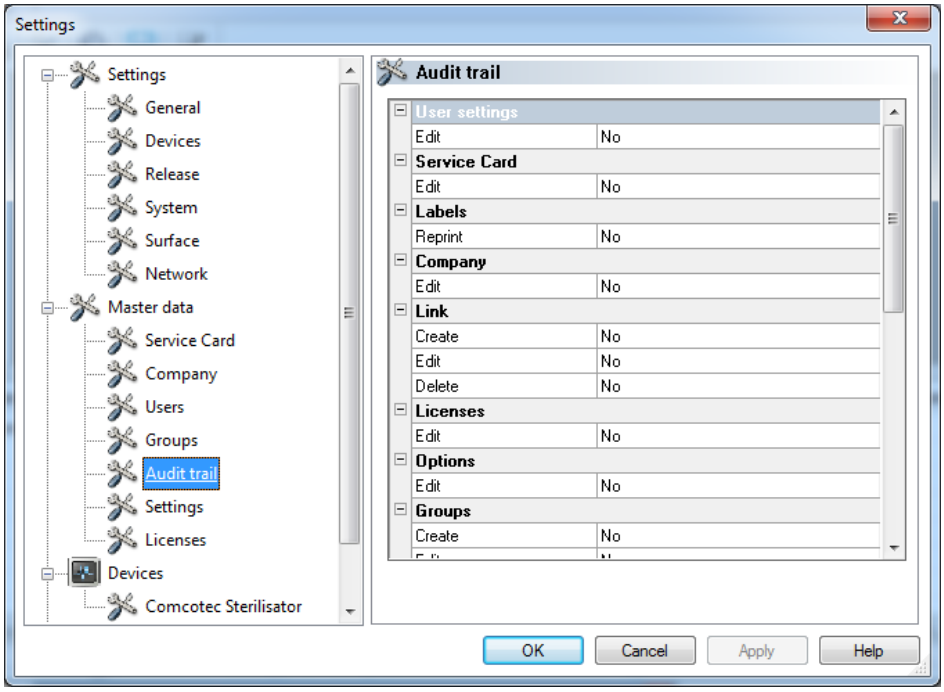


"***Groups/New***"
Precondition for activating the command: The user must have corresponding group rights, must be logged in and the "**Master data/Groups**" tree structure must be selected. Selection of the "**New**" function adds a new group and details of the authorisations of the new group can be defined in the program.

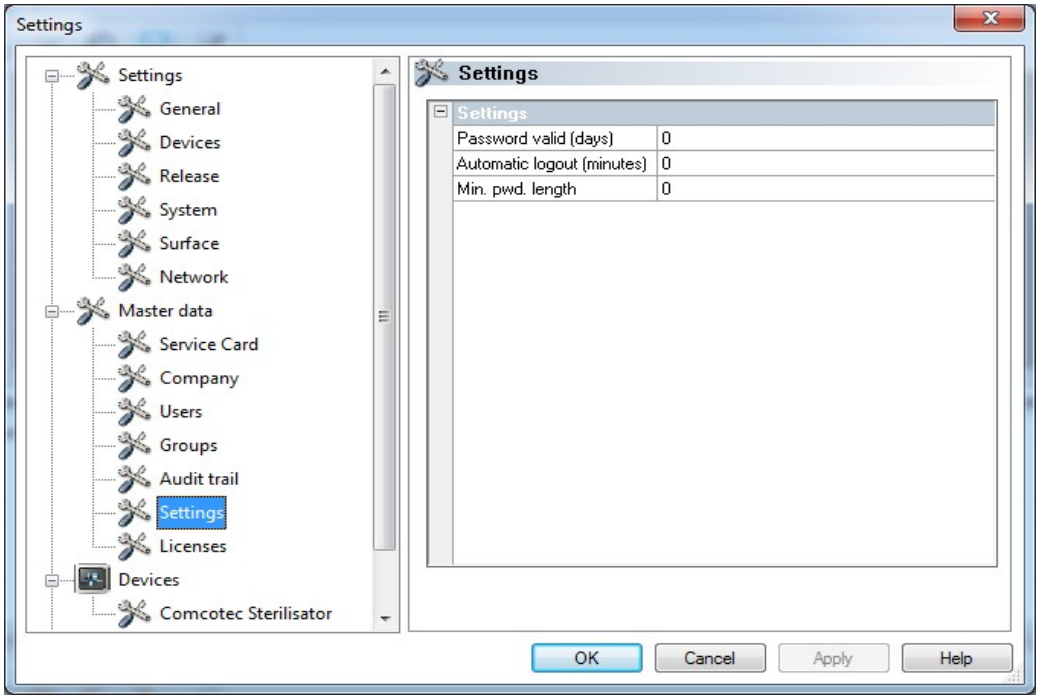
"***Groups/Delete***"
Precondition for activating the command: The user must have corresponding group rights, must be logged in and the "**Master data/Groups**" tree structure must be selected. A selected group can be deleted with the "**Delete**" button. The default groups in the program cannot be deleted.

More detailed information on editing groups is described in the **Installation and Administration Manual**.

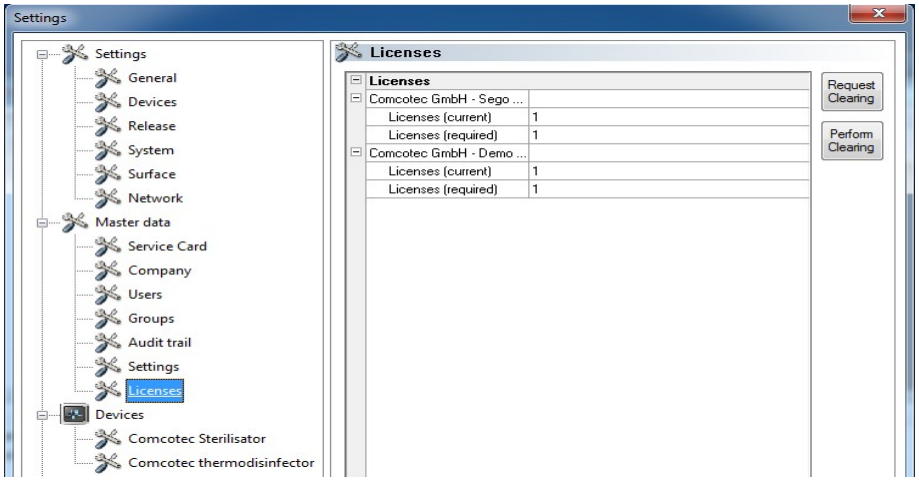
Audit trail: Shows which information is logged in the audit trail and will therefore be displayed when the audit trail view is opened.



Settings: Shows the settings for using passwords and automatic log-out.



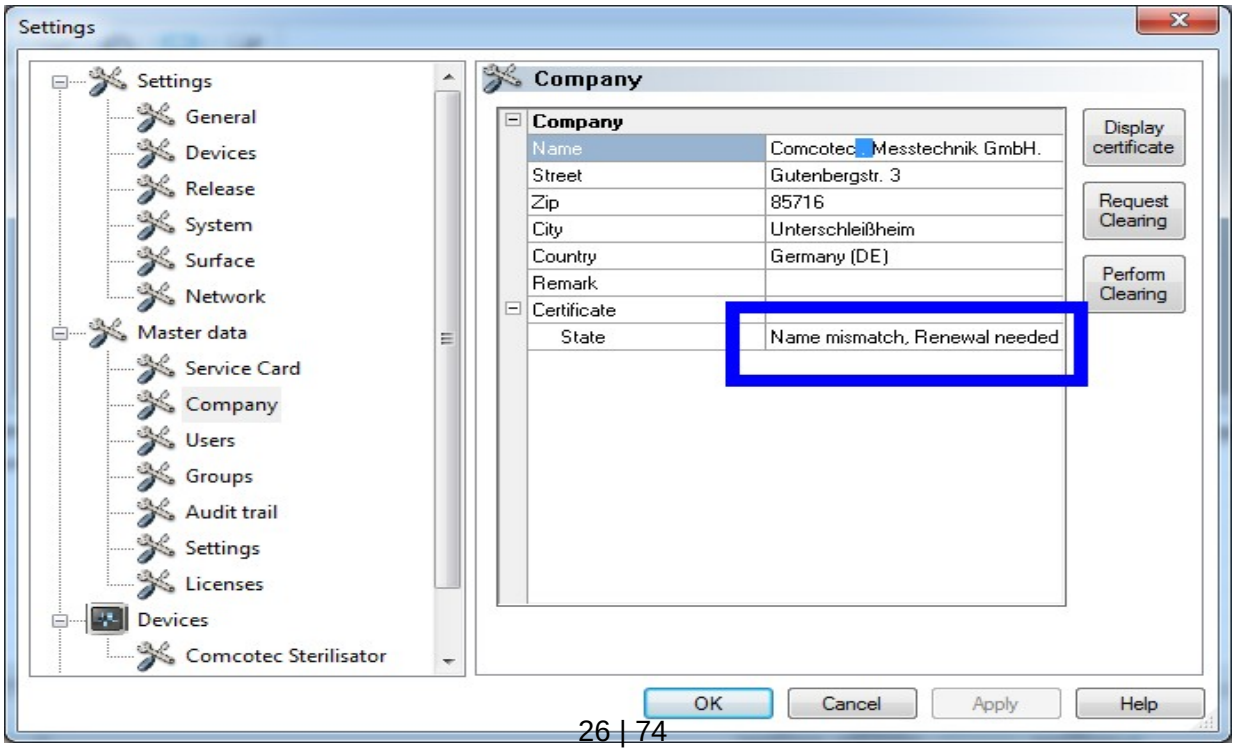
Licences: Shows the licences for the devices configured in the program.



More detailed information on releasing new devices is described in the **Installation and Administration Manual**.

Renewing certificates after changing the company name

If the company name is changed, the company certificate must be renewed. This is done in "***Master data/Company data/Request release"***.



For example: if the name of the company has been changed, the “**Company data**“ tab shows under the status of the certificate the entry “**Name changed, renewal required**“ and then also “**Signature invalid**“.

Records for devices without a licence are documented for a short time only, which makes them legally invalid.

Run a release if the company name has been changed or for devices without a licence. See the Installation and Administration manual for the required procedure.

You will be able to renew the licences and certificates automatically.

“**Tools/Shut down**“

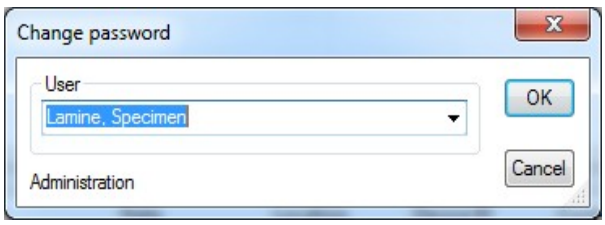
The head / operator of the facility is responsible for deactivation of the release dialogue window.

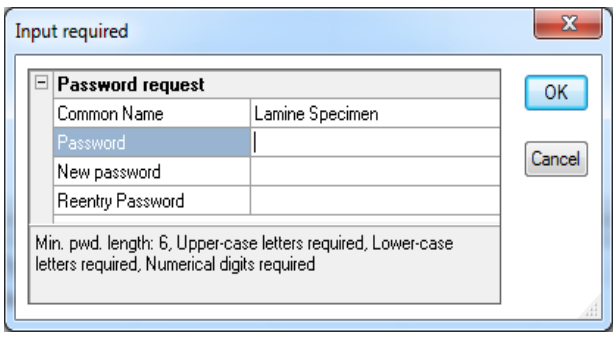
When this command is selected, SegoSoft shuts down the computer after the process of the device (e.g. steriliser) that is still in operation is finished. A checkmark is shown before the command as confirmation.

The release dialogue window must be deactivated before the computer can be shut down. This requires a disciplined user, because the last completed record must be manually released **first** on the following work day. The release dialogue window should also be reactivated.

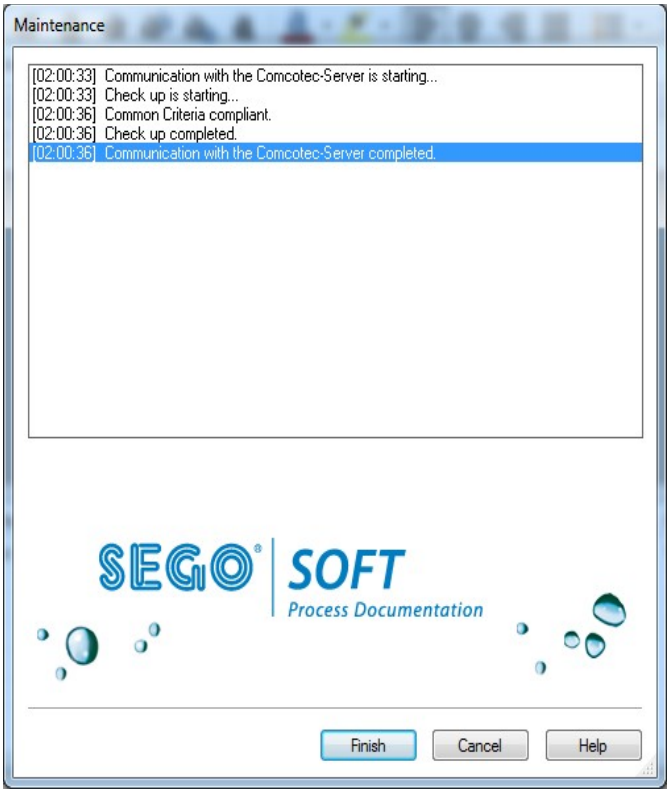
In “**Tools/Settings**“ “ the “**Release on completion of record**“ function and the “**Output as PDF on completion of record**“ output can be deactivated with the corresponding group rights (password prompt) in the “Settings/Release” tree structure. The functions are also reactivated.

“**Tools/Change password**“





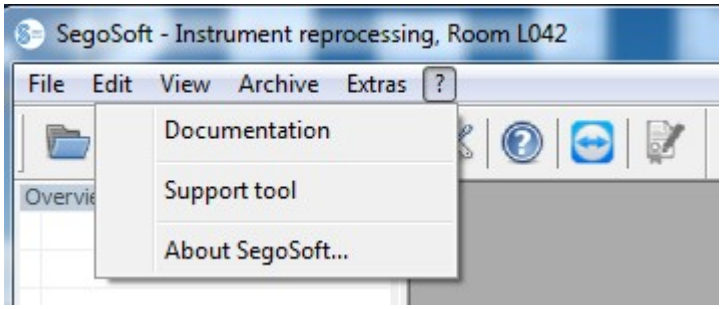
This menu function is used to change user passwords. A user selection is opened first after selecting this menu entry. Then the dialogue for changing the password is opened. The user must first enter the old password and then the new password.



“**Tools/Maintenance**“

A maintenance dialogue can be opened with this function. When it is opened the software settings are checked and the result of the check is displayed.

“?”menu:



“**?/Documentation**“
The SegoSoft user manual is opened.

“**?/Support tool**“
This dialogue window can be used to contact Comcotec support over an internet connection. The support person can access your computer by remote service and assist with problems on the computer. This function can also be used for courses and presentations.

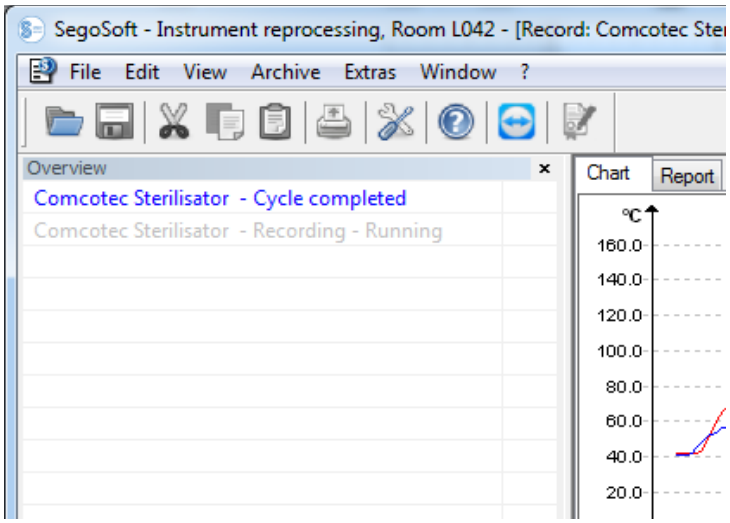
“**?/About SegoSoft**“
Shows the current version of SegoSoft and the service card number. It also shows the CE mark with the Notified Body, the IT security certificate of the German Federal Office for Information Security (BSI), and other certificates for the software.

3.2 Function bar

The function bar contains icons for the most important functions, which are thus always immediately available. All functions can also be reached from the menu.

3.3 SegoSoft windows

3.3.1 Overview of windows



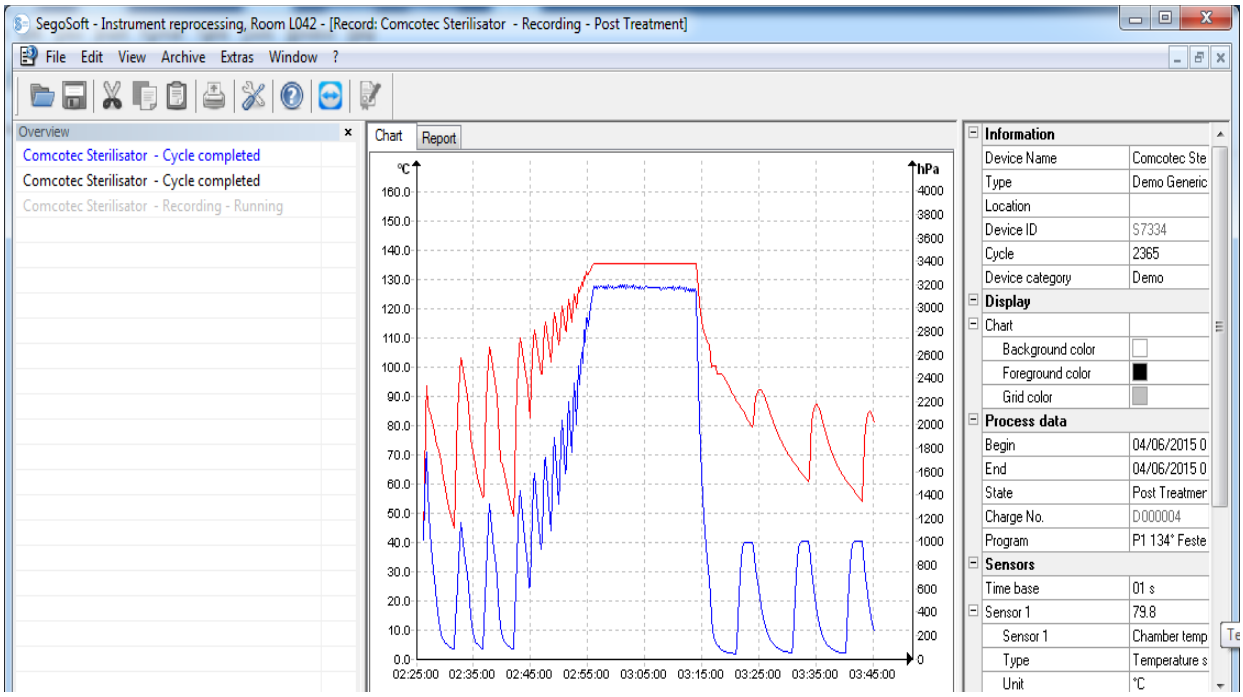
If it is not displayed, it can be reactivate with "**View/Overview**".

The overview window shows the current status of current records or records opened for viewing. The colour shows whether the record is currently running, finished or has been released. The colours correspond to the settings made in "**Tools/Settings/Interface**". Finished records without release are displayed in black, current records are shown in grey. When multiple devices are in use, the window has an overview function, which can display all current devices and records and their status at a glance.

3.3.2 Record window

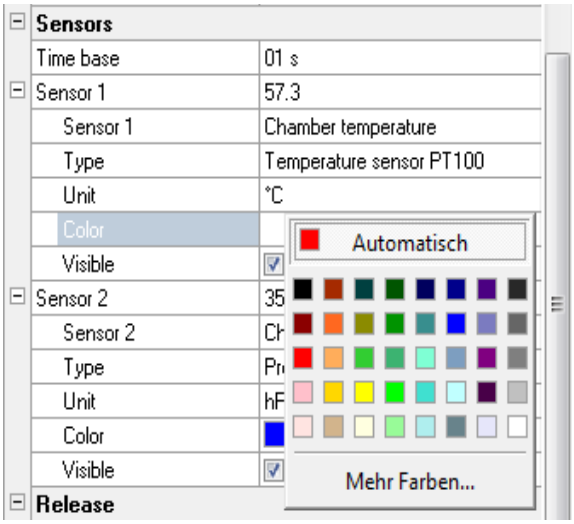
Open with: it opens automatically as soon it detects that a device program is running. It also opens if a saved record is opened from the archive**.**

"**Chart**" tab:
The record window consists of a curve section (left) and a data section (right).



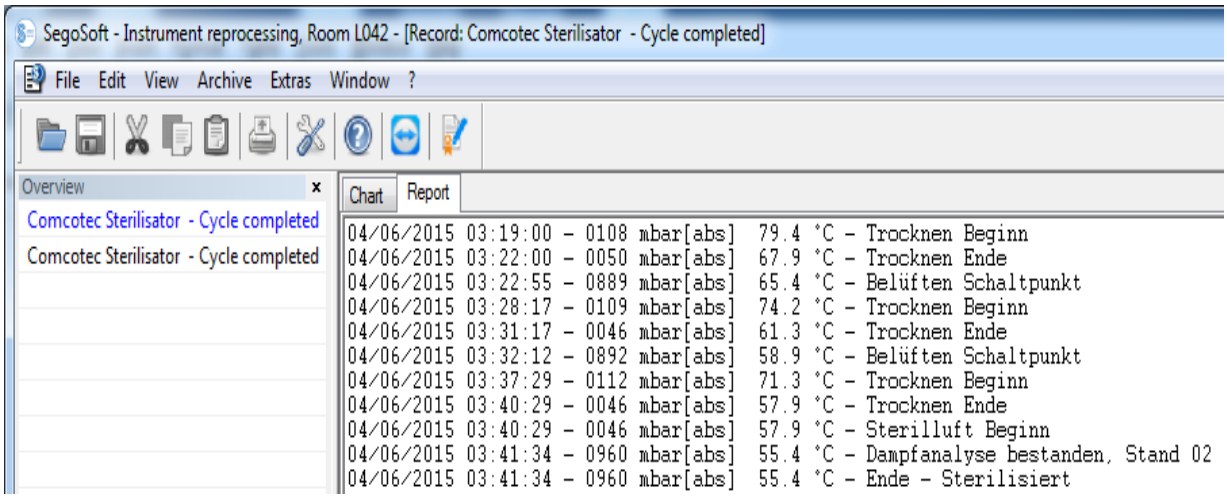
In the **curve section** the measured values are shown as a graph. The x-axis shows the time. Depending on the connected device, the y-axis shows the temperature, e.g. in degrees Celsius (°C), and the chamber pressure, e.g. in hectopascals (hPa). The curves show the data transferred to in the program from the connected device and the sensors.

The **data section** lists information on the device, the display, the processing data, the sensors, the user-defined fields and the release status.



The colour of the sensor curve is changed in the "**Colour"** field. Click on the desired field with the left mouse button and select a colour from the colour palette. The sensor curve is shown in the newly selected colour.

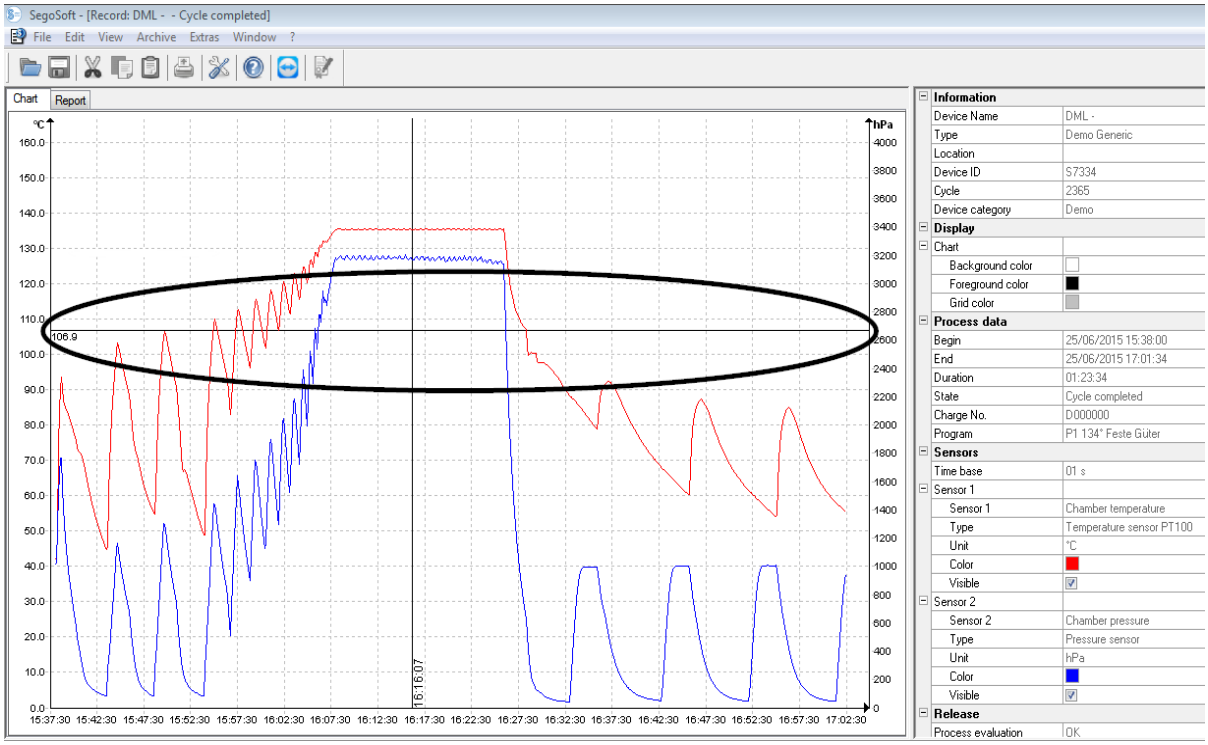
"**Report**" tab:
The Report tab shows the protocol data transferred from devices.



Functions for the Chart tab

Generate help lines of the x-axis and y-axis

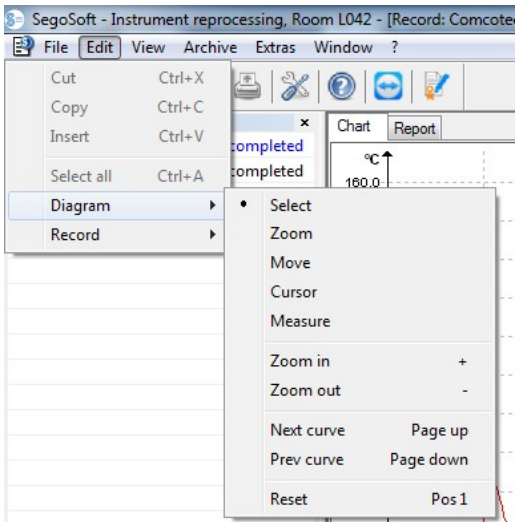
Select an axis by clicking on it with the left mouse button. It is surrounded by a dashed line. Press and hold the left mouse button to drag the axis to the centre of the record window. A help line appears. The line can be moved anywhere along the selected axis by pressing and holding the left mouse button. The front section of the help line shows the exact numerical value of the axis on which the help line is located.



For example, the user can check on the curve whether a specified temperature was reached at a specific time.

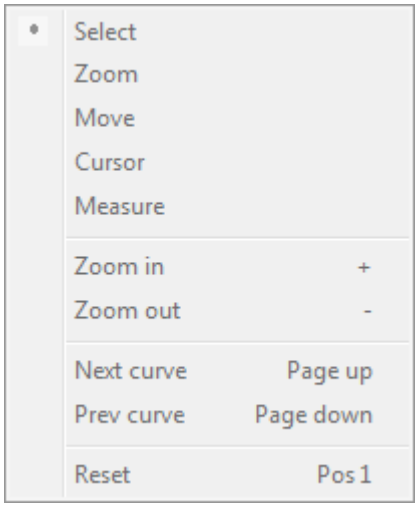
Delete help line: Select the help line with the mouse cursor and press the right mouse button. The chart command context menu opens and the help line is deleted.

Additional menu commands for the Chart tab with the record window open



When records are displayed in the **record window**, the "**Edit**" commands also appear for further processing: "**Chart**" and "**Record**" and in the main menu bar: "**Window**". The commands for the chart can also be opened from the context menu (right mouse button on chart).

"***Chart***" *context menu*



"***Chart/Select***"
With this command activated the curve of a specific sensor can be selected with the mouse cursor. The selected curve changes colour (inverse colour). If the inverse colour is difficult to see, the colour setting can be changed in the data section of the record window. The selection is a condition for using the "**Cursor**" command.

"***Chart/Zoom***"

A selected section of a curve is magnified to any level required. This function provides the option of examining a section of the displayed curve in more detail.

The curve section is selected by pressing and holding the mouse button and drawing a rectangle and is magnified when the mouse button is released. This process can be repeated as often as required.

The original size is restored with the "**Chart/Reset**" command.

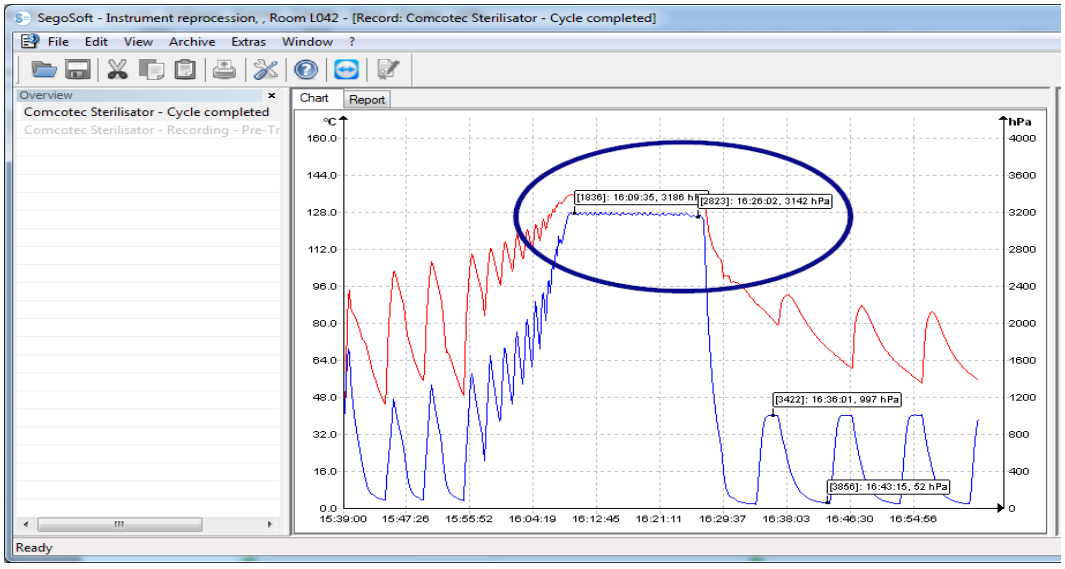
"Chart/Move"
Precondition for activating the command: The record window must be activated by clicking it with the mouse.

With the command activated the complete image of the record curves within the axes can be moved by pressing and holding the left mouse button.

"Chart/Cursor"
This function can be used to determine exact curve values for a specific time in the record and to show them on the curve.

Precondition for activating the command: Select the desired curve with "**Chart/Select**". With the command activated a magnified cursor appears in the record window, which follows the curve when the mouse is moved horizontally. A field with the exact records of the time, temperature and pressure is shown in the top section of the record window. Other information may also be visible depending on the connected medical device.

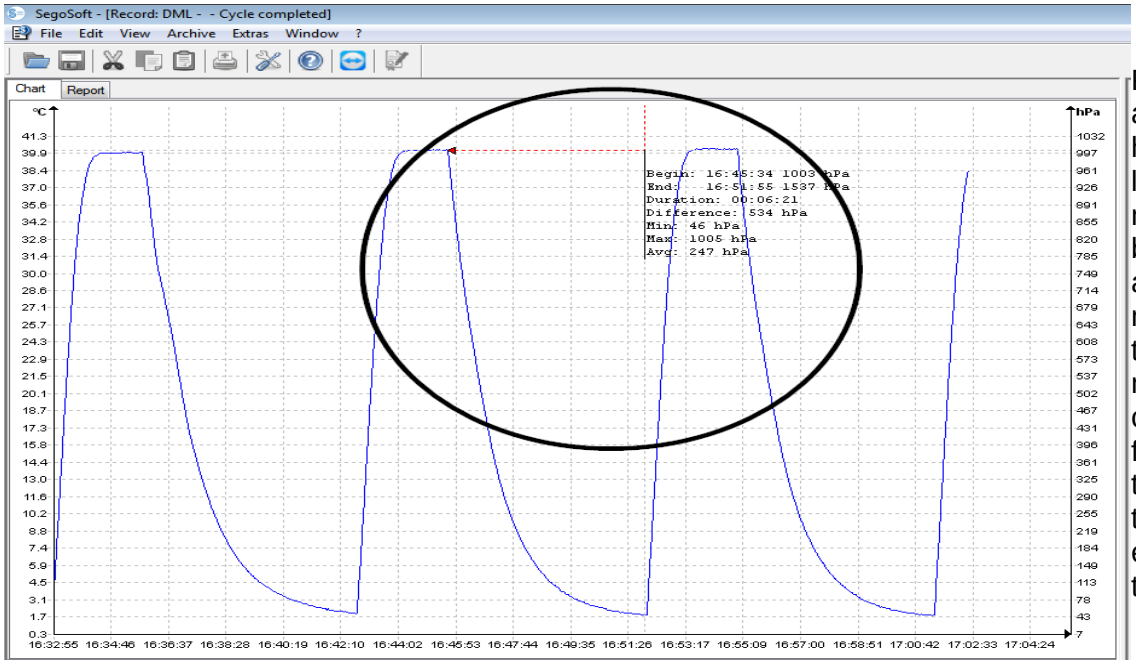
If an important point of the curve is reached, the relevant values (time, temperature or pressure) can be fixed in writing on exactly the selected point of the curve. The resulting document can be saved as a file with "**File/Create PDF**".



"Chart/Measure"

The exact line of the measured curve must be followed to prevent incorrect measurement results over many measured curves.

This function allows curve sections (e.g. holding time of the sterilisation phase) to measured precisely. The command should be activated from the context menu (right mouse button).



Press and hold the left mouse button and move the mouse cursor from the start to the end of the measured curve section and release it. The measured numerical values for time and temperature or time and pressure appear. The resulting document can be saved as a file with "**File/Create PDF**".

"***Chart/Magnify***"
Activation of this command magnifies all curves of the record window in stages.

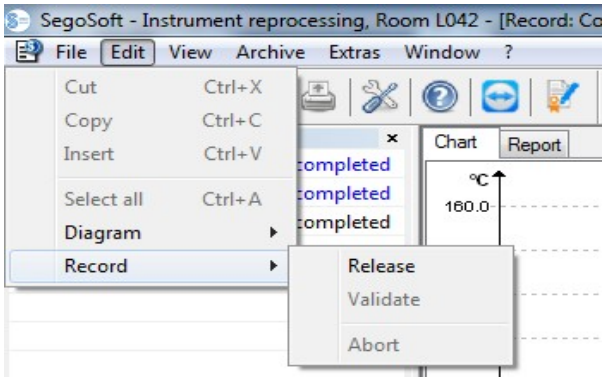
"***Chart/Shrink***"
Activation of this command shrinks all curves of the record window in stages.

"***Chart/Next curve***"
In records with multiple sensor curves, when one curve is selected the above curve (Page Up) can be selected.

"***Chart/Previous curve***"
In records with multiple sensor curves, when one curve is selected the lower curve (Page Down) can be selected.

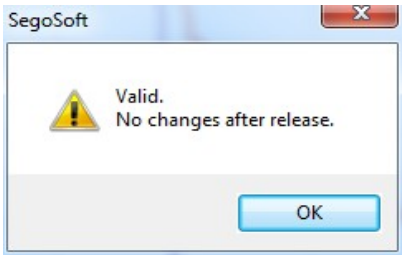
"***Chart/Reset***"
The original curve view in the record window is restored.

"***Edit/Record***" *supplementary menu (available on display of a record)*



"***Record/Release***"
Opens the release dialogue for release of the record.

"***Record/Validate***"
Precondition for activating the command: The record that is to checked in the archive must have been released and the corresponding record window must be open. SegoSoft checks whether a change has been made after release (validity status)



"***Record/Abort***"
Precondition for activating the command: A medical device without a defined program end (e.g. osmosis system, sealing unit) must be connected.
On activation of the command the record is terminated manually.

"***Window***" *supplementary menu.*
In the "**Window**" supplementary menu the layout and view of the SegoSoft windows can be changed.

Supplementary menu commands in the "File" menu when opening the record window
The "**Create PDF**", "**Print**" and "**Print preview**" commands are available.

"***File/Create PDF***"

The PDF file created with this command should only be considered a supplement to the released record in the archive. PDF files of records that are not released also do not have a positive release status.

A supplementary PDF file can be created from a record opened from the archive or a record marked "**Cycle completed**" from a dialogue box. A PDF file is created after selection of the save location and the file name and a password prompt. By default the file shows an image of

the complete curve over the duration of the record. Selecting “**Print measured values**“ in the dialogue window saves in addition to the measured curves the measured values, process data and additional information in the PDF file.

“***File/Close***“

The data of the current record are lost when this command is run. Loss of information.

Activation of the command and confirmation of the prompt dialogue closes the currently running or open record.

“***File/Print***“

A record can be opened from the archive or a record marked “**Cycle completed**“ can be printed out to a connected printer from a dialogue box. The printed image by default shows the complete curve over the duration of the record. Single parts of curves can be shown magnified and also printed with “**Chart/Zoom**“. Selecting “**Print measured values**“ in the dialogue window saves in addition to the measured curves the measured values, process data and additional information.

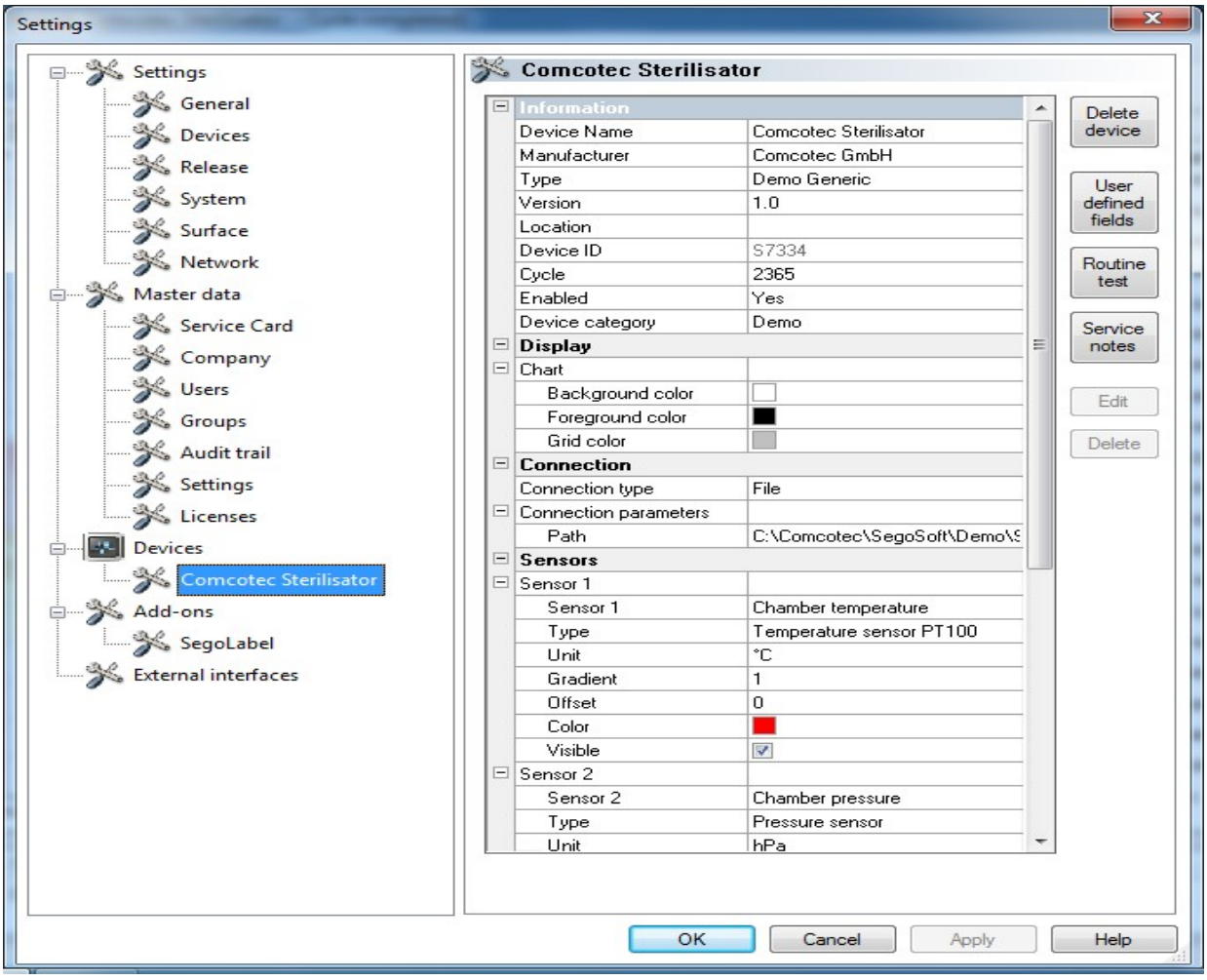
“**File/Print preview**“

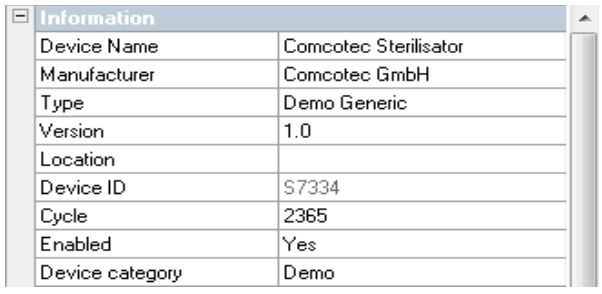
Activation of the command shows a preview of the printed version of the open record.

3.3.3 Device settings

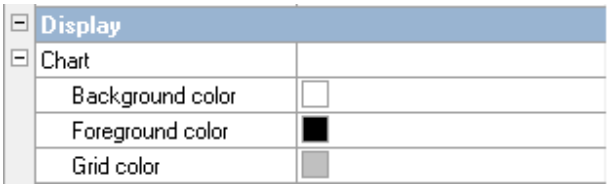
To be opened with: Tools/Settings“

Then select the applicable device in the “Devices” tree structure.

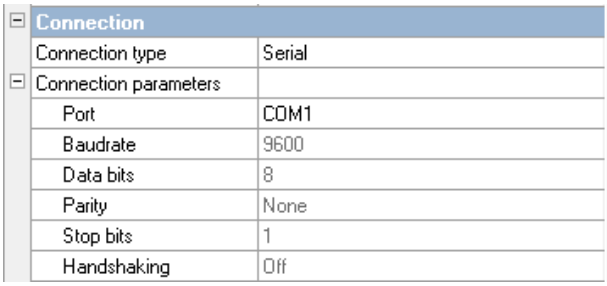
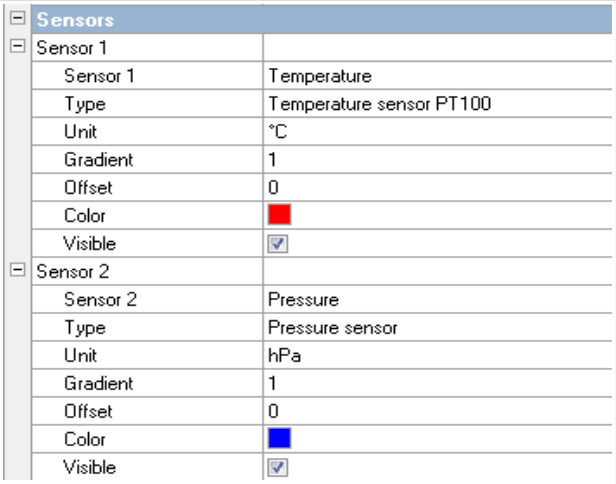
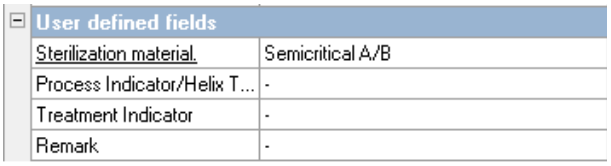
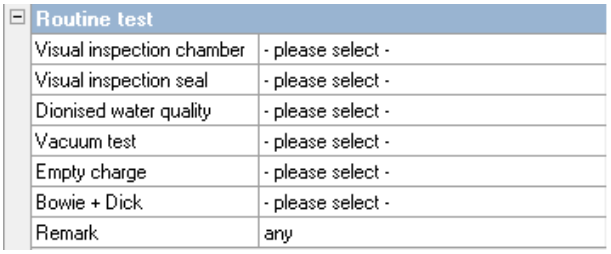
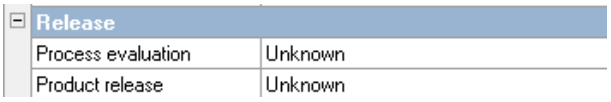
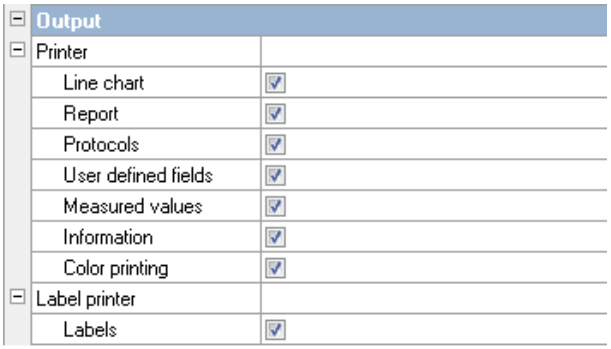


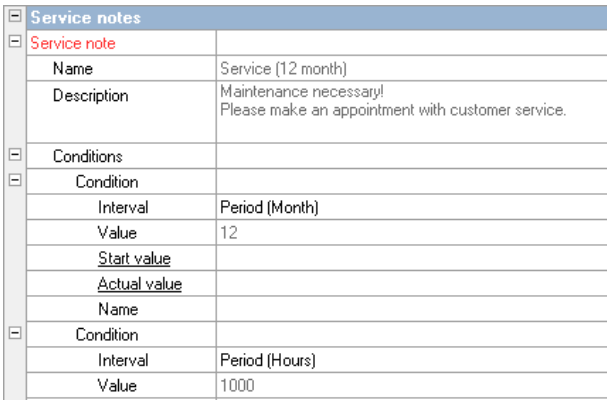


Information: List of information recorded when the device was created. Changes can also be made in enabled fields subject to the corresponding group rights. Device name, manufacturer number and cycle counter are listed in the release dialogue.

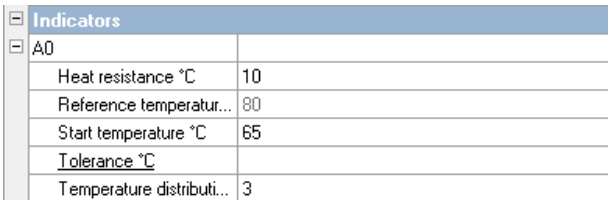
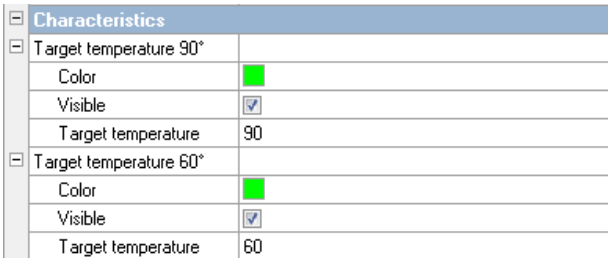


Display: Background colour, foreground colour and grid colour of the record curve can be changed with the corresponding group rights. Click on the desired field with the left mouse button and select a colour from the colour palette.

 **Connection** Connection type: Serial Connection parameters Port: COM1 Baudrate: 9600 Data bits: 8 Parity: None Stop bits: 1 Handshaking: Off	**Connection**: The connection type and parameters are displayed. If a serial connection is used, the com port is displayed. Changes can also be made in enabled fields subject to the corresponding group rights. Changes to, for example, the com port can be accepted directly with the **Port** dropdown list..
 **Sensors** Sensor 1 Sensor 1: Temperature Type: Temperature sensor PT100 Unit: °C Gradient: 1 Offset: 0 Color Visible Sensor 2 Sensor 2: Pressure Type: Pressure sensor Unit: hPa Gradient: 1 Offset: 0 Color Visible	**Sensors**: The various sensors are displayed depending on the connected device (steriliser). Changes can also be made in enabled fields subject to the corresponding group rights. Hiding or showing the checkmark in the **Displays** field hides or shows the sensor curve during processing of a device. The colour of the sensor curve is changed in the **Colour** field. Click on the field with the left mouse during processing of the device and select a colour from the palette.
 **User defined fields** Sterilization material: Semicritical A/B Process Indicator/Helix T...: - Treatment Indicator: - Remark: -	**User fields**: Display of fields defined by the user. User-defined fields are generally displayed in the release dialogue.
 **Routine test** Visual inspection chamber: - please select - Visual inspection seal: - please select - Dionised water quality: - please select - Vacuum test: - please select - Empty charge: - please select - Bowie + Dick: - please select - Remark: any	**Routine testing:** Entries regarding the “single device release before starting work” are displayed in the device settings window.
 **Release** Process evaluation: Unknown Product release: Unknown	**Release:** Process evaluation and product release are prompted in the release dialogue.
 **Output** Printer Line chart Report Protocols User defined fields Measured values Information Color printing Label printer Labels	**Output, printer:** The “line chart, report, protocols etc.“ sections are based on the sections of the same name in the record document. The default settings for output to the printer are defined by switching on and off. **Output, label printer:** This switches label printing for the device on or off. The SegoLabel add-on must also be selected in the add-ons section in the tree structure for the label printing function.

	**Maintenance information:** The maintenance information is displayed in the device settings window with descriptions and intervals. If a service is due, a reminder window is automatically displayed on the monitor to remind the user of the service. After the service the maintenance prompt can be acknowledged and documented.

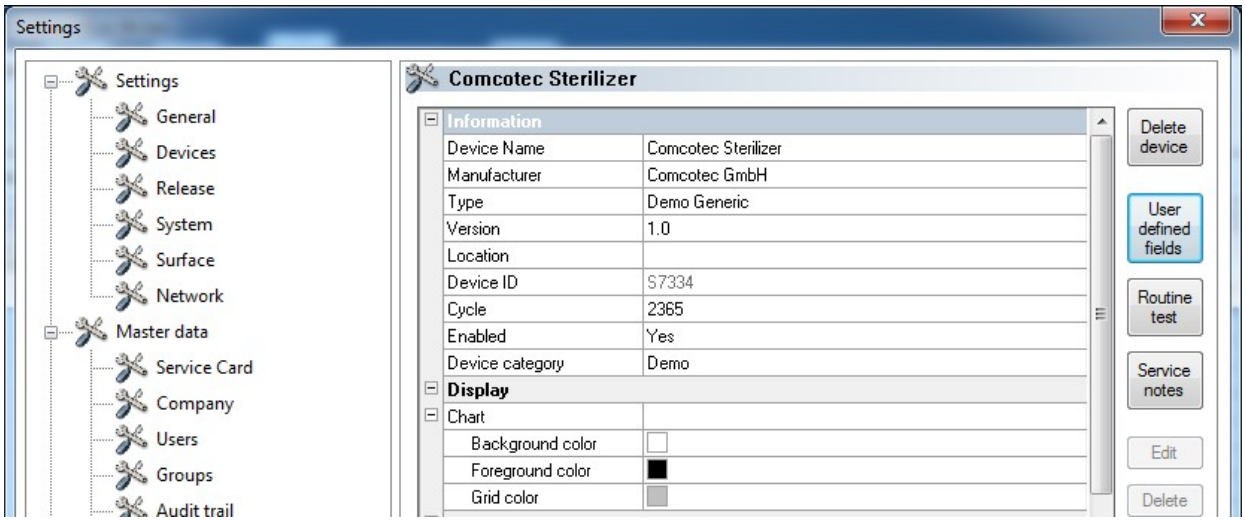
Additional folders depending on the connected device (e.g. disinfector):

	**Indicators**: The A_0 value (germ reduction number) is calculated in seconds with the created values. Changes can also be made in enabled fields subject to the corresponding group rights.
	**Characteristic curves**: Lines that mark the specified temperatures that must be reached by the device so the process data conform to the requirements.

Additional functions in the device settings window

The device settings are opened with "**Tools/Settings**" and selecting the device in the device tree.

Devices additional function



User fields
The user fields are listed in the device settings window and depending on the setting may be listed in the release dialogue. Important decision functions for the requirements can be defined and saved for every device process (batch-related routine test).

"**Function: user fields (Insert field)**"
A new field can be inserted in a dialogue window with the corresponding group rights (password prompt), which will be listed in the device settings window after the input.

"Routine testing"
The daily routine testing before starting work in accordance with manufacturers' directions can be defined specifically for individual devices. A specially created menu item in SegoSoft can be saved as a document with the applicable process data records as a
PDF file.

"**Function: Routine testing (Insert field)**"
A new routine testing field can be inserted in a dialogue window with the corresponding group rights (password prompt), which will be listed in the device settings window after the input. The marked routine texting field can be edited with the corresponding group rights (password prompt) in a dialogue window.

"Maintenance information"
The maintenance information reminds the user when service is required. It can be both services that the user can perform or service that must be performed by customer service.

"**Function: Maintenance information (Insert field)**"
A new maintenance information form can be inserted in a dialogue window with the corresponding group rights (password prompt), which will be listed in the device settings window after the input.

"**Function: Delete (field)**"
Precondition for activating the command: The field that is to be deleted (user field, routine testing or maintenance information) must be marked.

"**Function: Edit (field)**"
Precondition for activating the command: The maintenance form that is to be edited (user field, routine testing or maintenance information) must be marked.

3.3.4 Devices window

To be opened with: "View/Devices"

All installed devices are shown in the devices window.
There are two views that can be displayed with "**Devices/Device details"** and "**Devices/Device icons**" or by clicking a device in the devices window with the right mouse button to open "**Device details**" or "**Device icons**" from the context menu.

The "**Device details**" view shows a table with the device information, some of which was entered when the device was created. (Device name, Company, Type, Status, Location, Manufacturer number, Activated and Status counter). A device icon is displayed with the device names, and also shows the status of the device.

The “**Device icons**“ view shows icons for the various devices with the names of the devices. The icon also shows the status of the device.

3.3.5 Messages window

To be opened with: “View/Messages“

The messages window lists information on events and status changes occurring during operation of the program. This includes messages regarding the status of the serial port, current records, files that have just been loaded and fault reports.

3.4 Status bar

To be opened with: “View/Status bar“

The status bar shows the status of SegoSoft, descriptions of the icons on the tool bar, information on menu commands and the log-in status.

4 Maintenance information

The maintenance information reminds the user when service is required. It can be both services that the user can perform or service that must be performed by customer service.

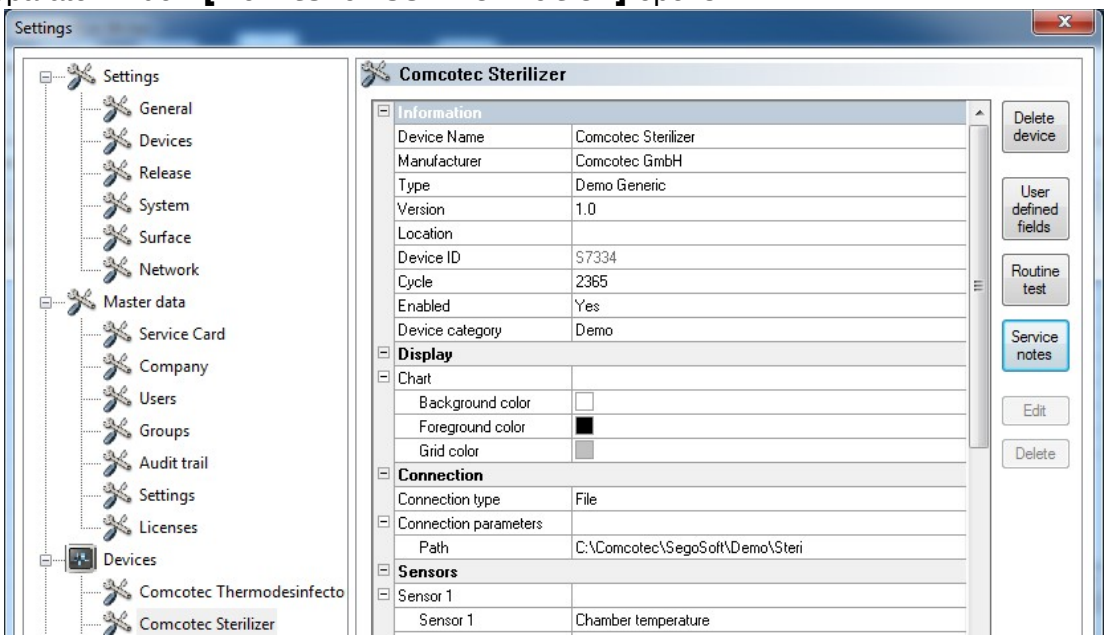
The manufacturer’s requirements for maintenance (see maintenance manual) for the specific device can be input into the maintenance information form.

4.1 Creating maintenance information form

Precondition for activating the command: The user must have corresponding group rights and must be logged in. The applicable preparation device has been created and the device settings window is open (“**Tools/Settings**“ for selection of the device in the device tree) .

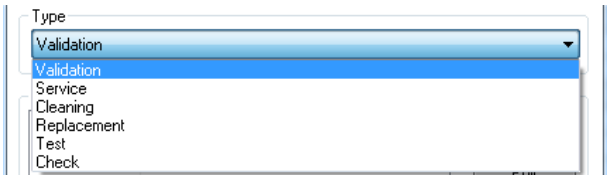
To be opened with: “Function (button): Maintenance information“

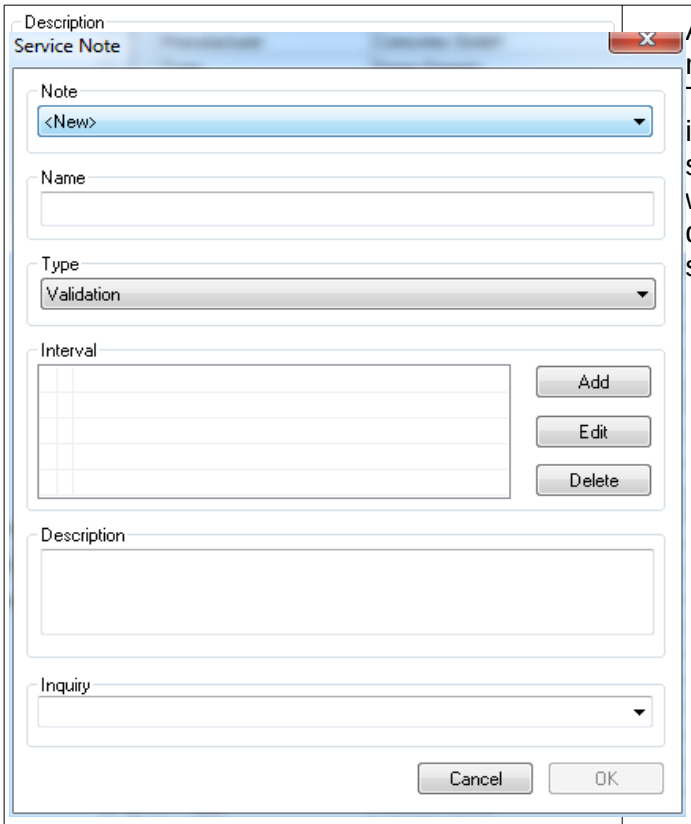
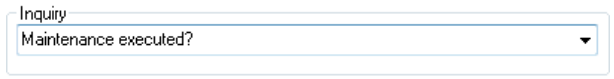
A separate window **[Maintenance information]** opens.



The **<New>** entry must be selected to create new information.

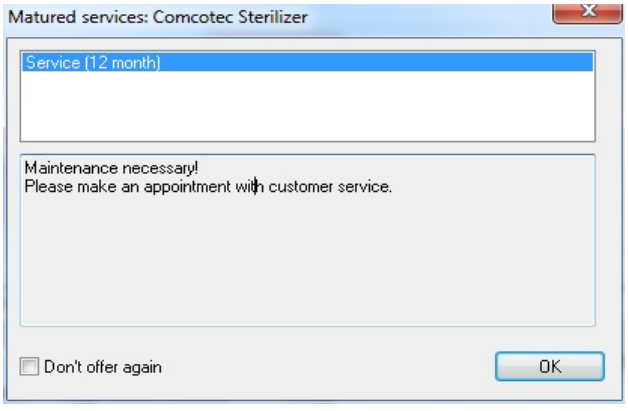
The contents of the **Information** field are preconfigured for some preparation devices. When a service or validation is selected, entries appear in following fields.
They can be confirmed with **OK**.

	Actual name of the maintenance information, e.g.: Service (12 months). Appears in the device settings window with the reminder window when a service is due and the dialogue window for acknowledging the service (release window).
	Selection of type of service. **Validation**, **Service**, **Cleaning**, **Replacement, Test** and **Inspection** can be selected. The information is shown in the device settings window.
	Select **Insert** to open a new dialogue window **Maintenance interval** auf. In **Interval** the maintenance interval can be selected by time or by device run time (hours, days, weeks, months, years and after every program run). Select **Values** for more precise specifications. In **All** a positive value >0 (e.g. 1000 with the time setting (hours)) and with **Start value** the start date with the start time (e.g. 1.10.10 ␣ 15:30) must be input. The actual value is automatically calculated. The intervals are shown in the device settings window and the reminder window when a service is due.

	A detailed description of the maintenance information is given here. The description of the maintenance information is shown in the device settings window with the reminder window when a service is due and the dialogue window for acknowledging the service (release window).
	A detailed description of the result prompt is given here.The description of the result prompt is shown in the device settings window and it is requested in the dialogue window for acknowledging the service (release window).

4.2 Reminder window for services

If a service is due, a reminder window is automatically displayed on the monitor to remind the user that a service is due.

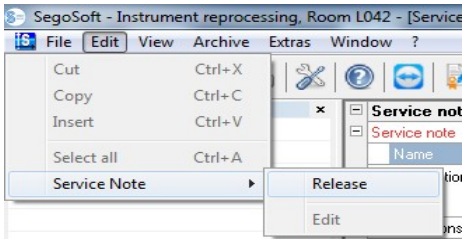


The reminder window is shown again at the first preparation run of the next day until the service has been acknowledged or the “**Do not show information again”** field is enabled.

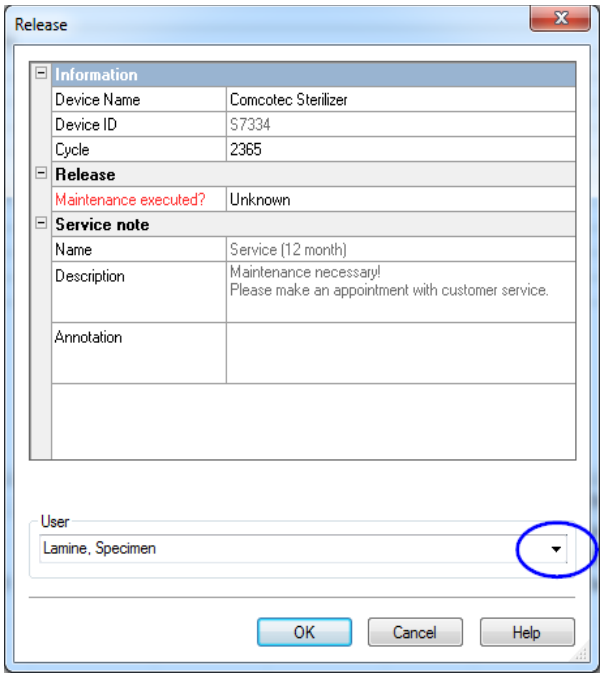
4.3 Acknowledging the service (release window)

Precondition for activating the command: The user must have corresponding group rights and must be logged in. The maintenance information window is open and the reminder that is to be acknowledged is selected.

To be opened with: "Edit/Maintenance information/Release"



A separate window **[Release]** opens.



The completed service must be acknowledged in the dropdown list "**Inspection passed**".

An entry can be made in the "**Comment**" field if necessary.

The completed maintenance information form is saved in the archive as a PDF file.

5 Routine testing

Routine testing includes a periodic series of checks and tests in the periods between performance tests. According to the recommendations of the RKI (Robert Koch Institute), a distinction is made between the routine testing of a steriliser every work day and every batch. The daily tests are referred to as "**single device release**" **before starting work**. In

contrast, the batch-related tests, as the test indicates, must be performed at every process run. **The operator is responsible for performing and documenting checks and tests.** For more information see the device instructions for use of the device manufacturer.

5.1 Daily routine testing

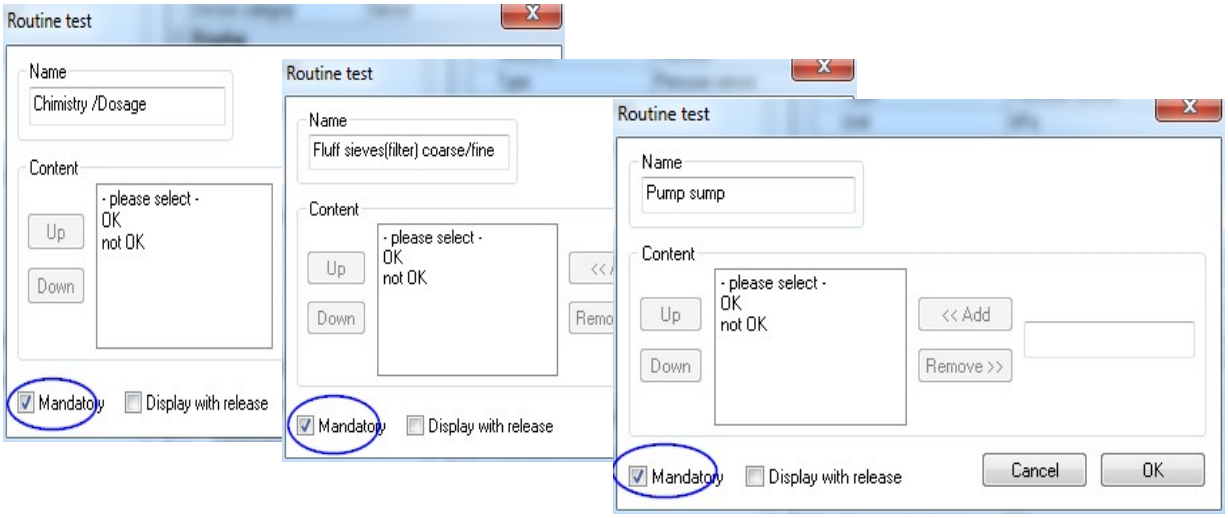
Example of a washer disinfector (WD)

The guidelines of the DGKH (German Association for Hospital Hygiene), the DGSV (German Association for Sterile Goods Supply) and the AKI (Instrument Preparation Working Group) for validation and routine monitoring of automated cleaning and disinfection processes for thermostable medical devices (2nd edition, November 2006) specify the following items for daily testing of the WD.

Fluff sieves (filters) coarse/fine	Clean all fluff sieves and check that they are undamaged and correctly installed.
Pump sump	Inspect and clean, remove small parts, e.g. scalpel blades, needles etc. while following the rules for health and safety
Rotating arms/spray nozzles	Check that they rotate freely and evenly in the WD and the load trolley, check that nozzles are not blocked and clean if necessary
Trolley	
Attachment	Correct attachment of the trolley in the WD
Connections/adapters/ plugs/nozzles	Check that Luer Locks, hose connections, plugs and nozzles on the trolley are functional and complete
Rollers	Check that rollers are functional and complete
Trolley label	Code, if present check
Visual inspection of inside and outside of WD	Check that interior is clean and free from deposits (e.g. lime, silicates, rust)
Door seal	Inspect door seal to ensure that it is clean and does not leak
Additional daily checks specified in the instructions for use	As directed by the manufacturer
Deionised water quality (conductivity measurement)	Daily measurement of conductivity, should not exceed 15 µS/cm
Signature of employee	Initials of the employee
To ensure trouble-free processing, the levels in the supply containers must be checked (integrated containers, disposable canisters, dosage systems have different requirements).	

Creating routine testing form

Open “Tools/Settings” (select the device in the device tree, then select **“Function (button) routine testing"**), the input dialogue box for inserting a new field opens.

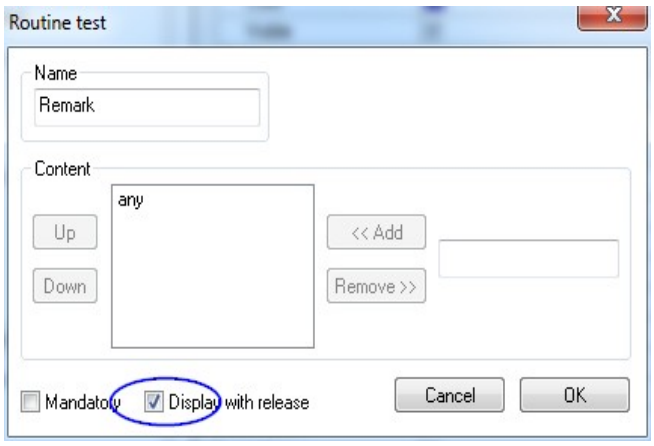


Mandatory fields:
Form fields (lists) in routine testing that **must** be completed by hygiene personnel. Hygiene personnel **must** always complete an evaluation of the results, i.e. the evaluation criteria are used as a checklist from which the applicable statement can be selected. To ensure that a

selection is made, the evaluation criteria always start with a general statement such as “Please select”. This is followed by the actual criteria, such as "OK" or “Not OK". If the list is not completed, the missing information is shown in red. The routine testing form cannot be acknowledged and closed until it has been completed.

Release fields:
The contents of the fields are taken from the release dialogue for routine testing and are queried during
the release of the routine testing.

The documentation of the reaction to unexpected process sequences should be included in the routine form for washer disinfectors.



Deviations in the daily routine check can be recorded in the “Remarks” field. E.g.: Faulty fluff sieve was replaced.

Example for a steriliser

According to the recommendations of the RKI (Robert Koch Institute) the tests should include: visual inspection of the chamber, seal, feed water (quality) and the feed water tank (volume of water).
Most manufacturers recommend a daily program run:

1. Vacuum test program

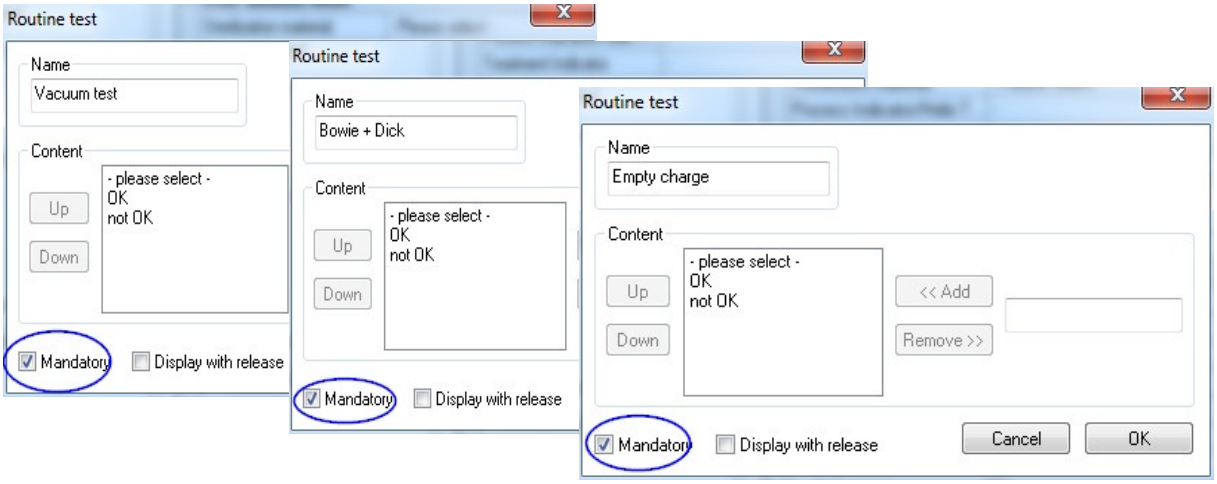
2. Empty batch program
3. Bowie + Dick test program (steam penetration test)

Creating routine testing form

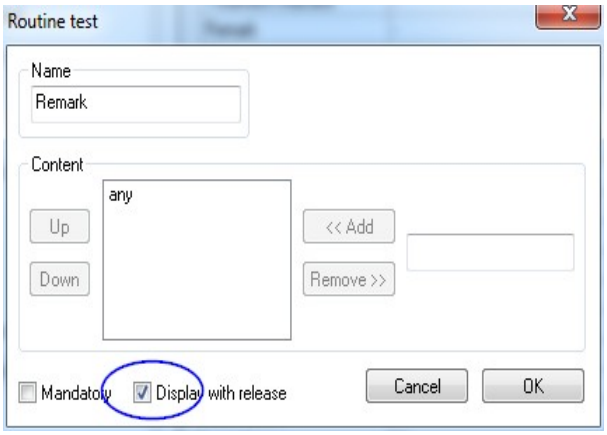
Open “Tools/Settings” (select the device in the device tree, then select **“Function (button) routine testing"**), the input dialogue box for inserting a new field opens.

Mandatory fields:
Form fields (lists) in routine testing that **must** be completed by hygiene personnel. Hygiene personnel **must** always complete an evaluation of the results, i.e. the evaluation criteria are used as a checklist from which the applicable statement can be selected. To ensure that a selection is made, the evaluation criteria always start with a general statement such as “Please select”. This is followed by the actual criteria, such as "OK" or “Not OK". If the list is not completed, the missing information is shown in red. The routine testing form cannot be acknowledged and closed until it has been completed.

Release fields:
The contents of the fields are taken from the release dialogue for routine testing and are queried during
the release of the routine testing.

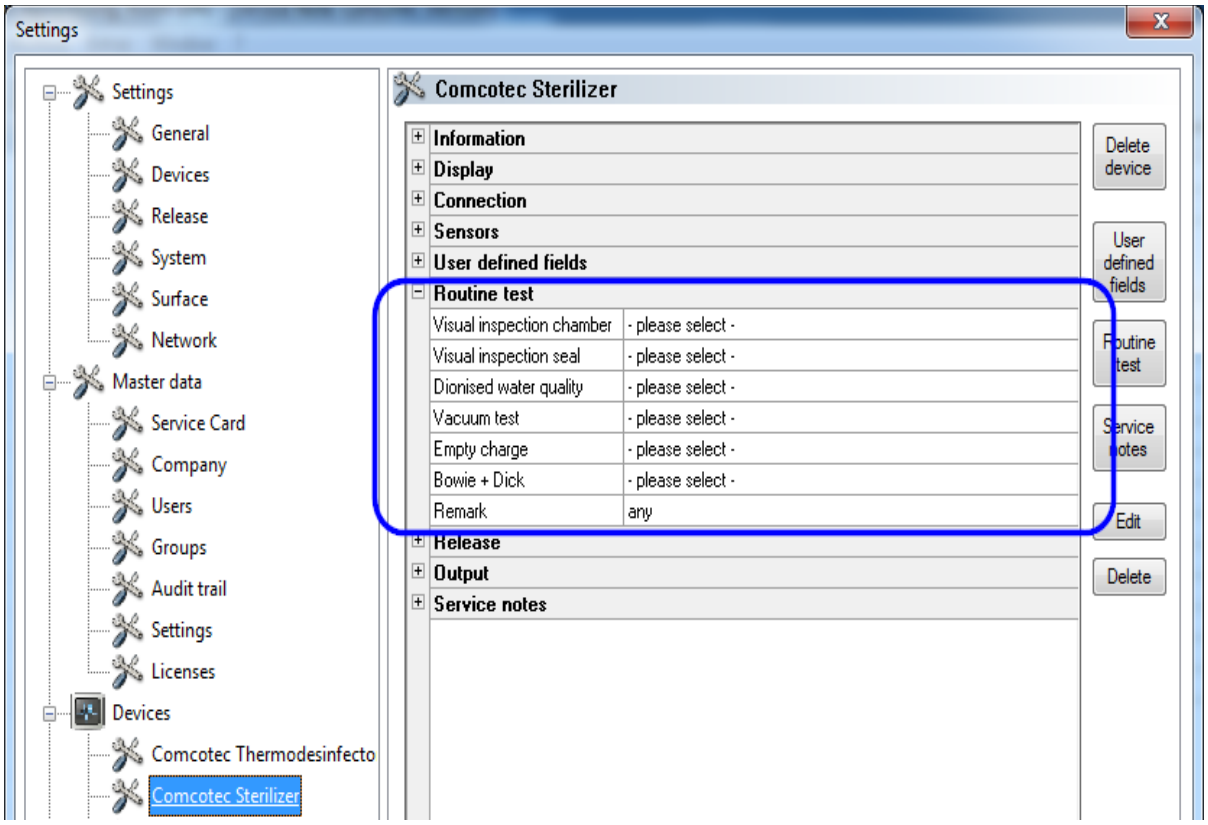


The documentation of the reaction to unexpected process sequences should be included in the routine form for sterilisers.



Deviations in the daily routine check can be recorded in the “Remarks” field.
e.g.: vacuum test not OK -> test was repeated.

The input information is listed in the device settings window.



5.1.1 Routine testing window

The routine testing form is opened from the routine testing window. Completing the form documents the routine testing.

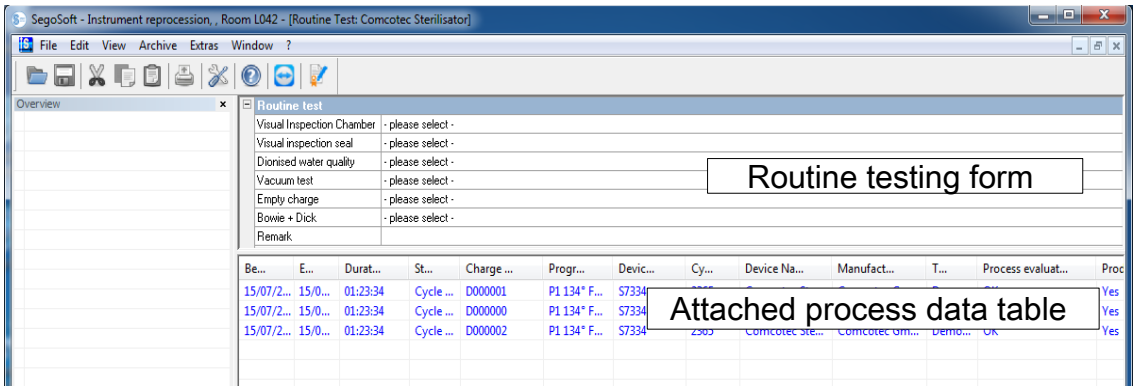
To be opened with:

Double-click on the desired device in the device window with the left mouse button or click the right mouse button on the desired device in the device window to select "**Routine testing**" from the context menu

Steriliser

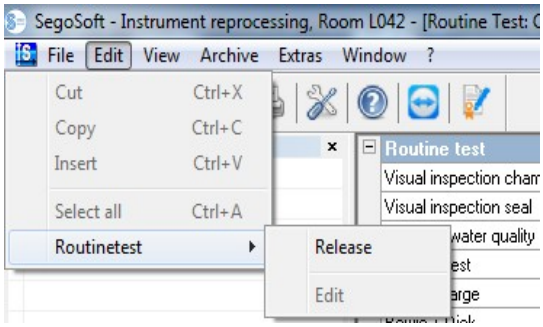
After the released daily test batches (vacuum test, empty batch and Bowie + Dick test) on a **steriliser**, the routine testing form is opened from the routine testing window. The test batches with the basic information (batch no., date, time) are documented in the attached process data table. The routine testing form is completed and released with a dialogue window.

Example: Steriliser routine testing window

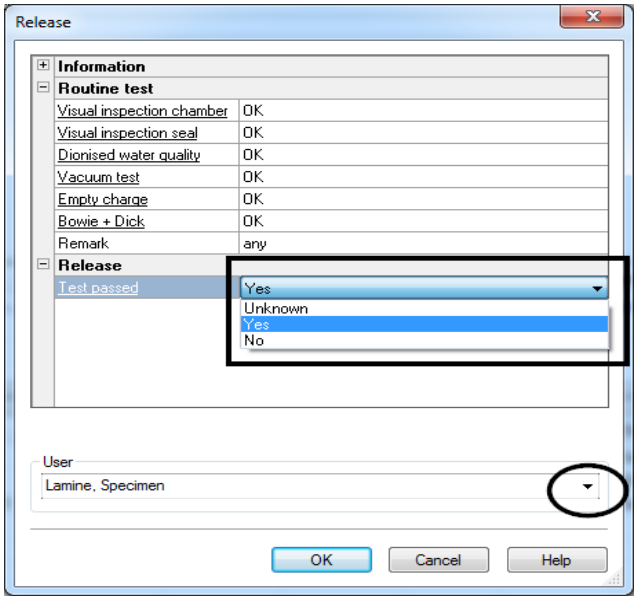


Open dialogue field of routine testing form

“Edit/Routine testing/Release“



A separate window **[Release]** opens



The routine testing can be released after editing the dropdown lists of the listed tests.

Select the person responsible for the release from the password prompt. Then the digital signature with name, date and time is created for the person responsible for the release.

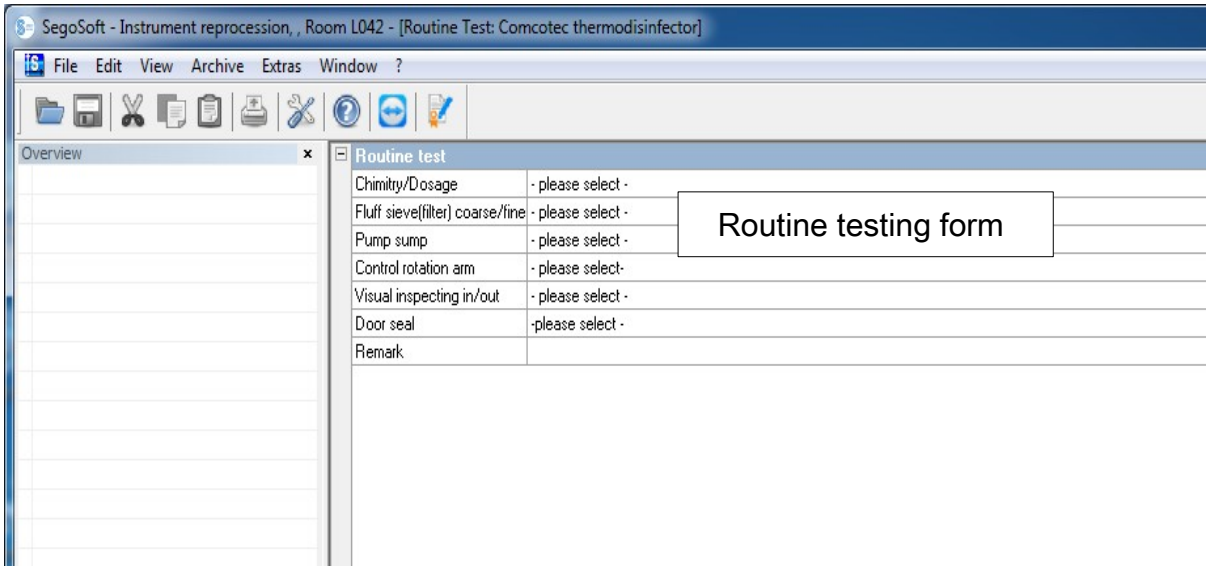
The completed form and the attached process data table are saved in the archive as PDF file.

Washer disinfector

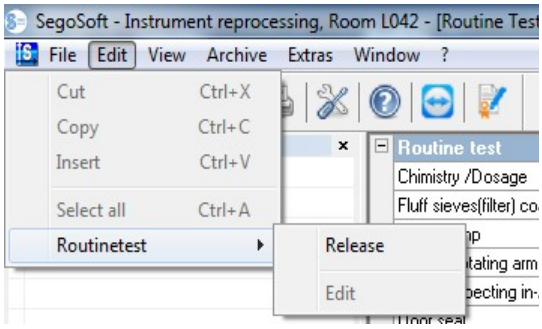
The routine testing form for a **washer disinfector** is opened from the routine testing window. The routine testing form is completed and released with a dialogue window.

Example: Routine testing window thermodisinfector

Open dialogue field of routine testing form

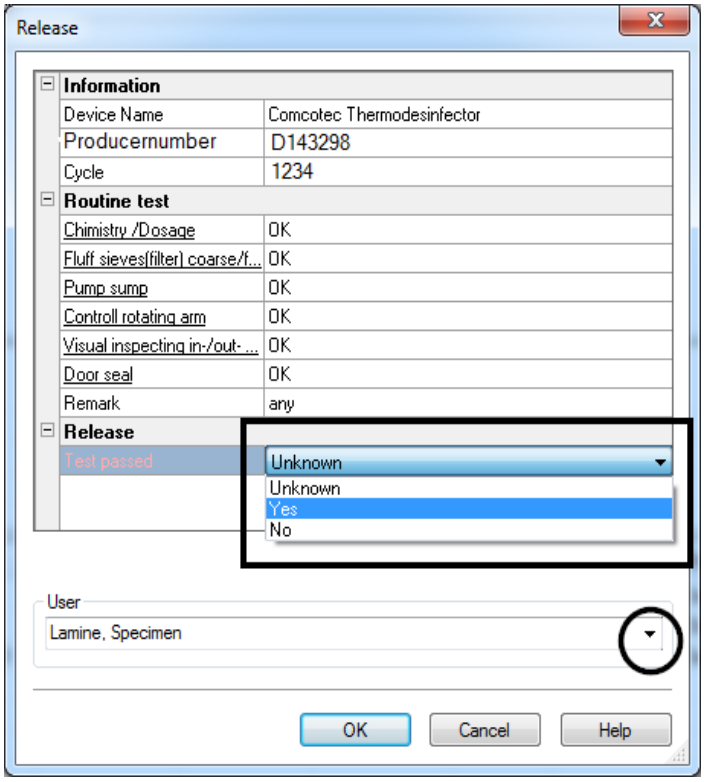


6 "**Edit/Routine testing/Release**"



A separate window **[Release]** opens.

The routine testing can be released after editing the dropdown lists of the listed tests.



Select the person responsible for the release from the password prompt. Then the digital signature with name, date and ime is created for the person responsible for the release.

The completed form is saved in the archive as a PDF file.

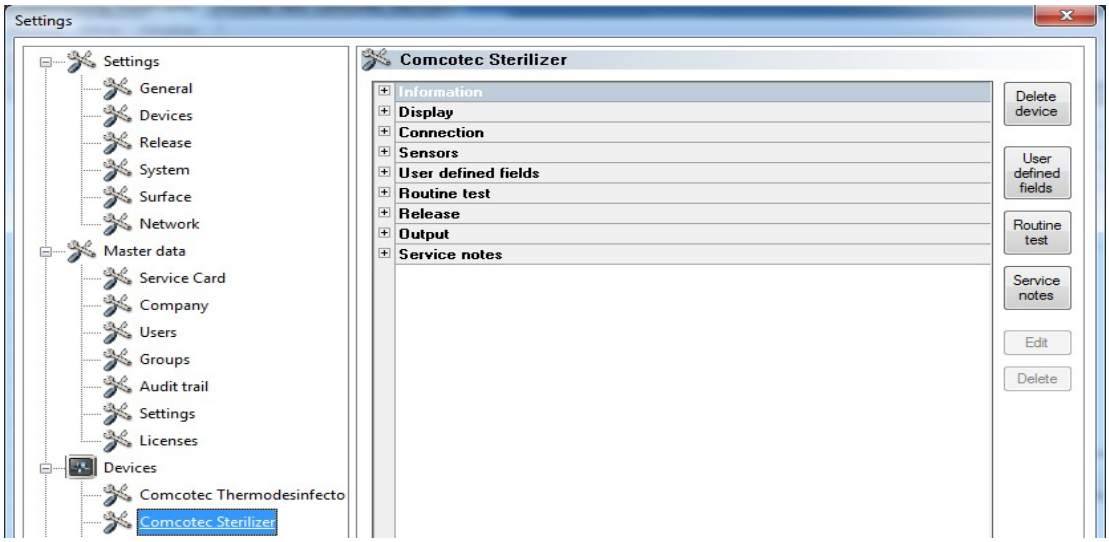
6.1 Batch-based routine testing

User fields

Sample release dialogue

In accordance with the RKI (Robert Koch Institute) and the recommendations of the DGSV (German Association for Sterile Goods Supply e.V.) and the AKI (Instrument Preparation Working Group), the following items for every device run should be included in the release dialogue.

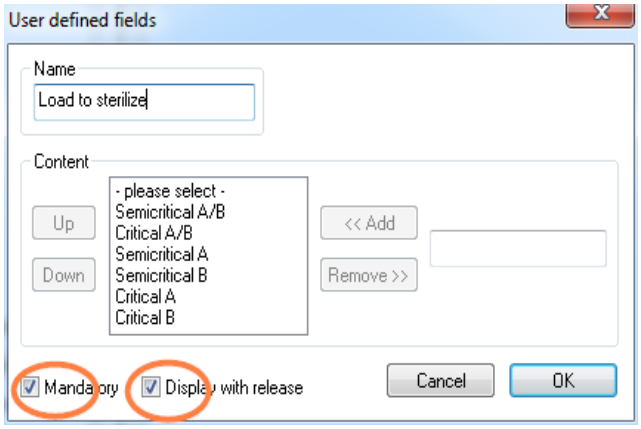
Open the device settings window from **Tools/Settings** (select the device in the device tree, then select “Function (button) routine testing"), the input dialogue box for inserting a new field opens.



Example: Information on load

Please enable the mandatory and release field in the load field.

Mandatory fields:

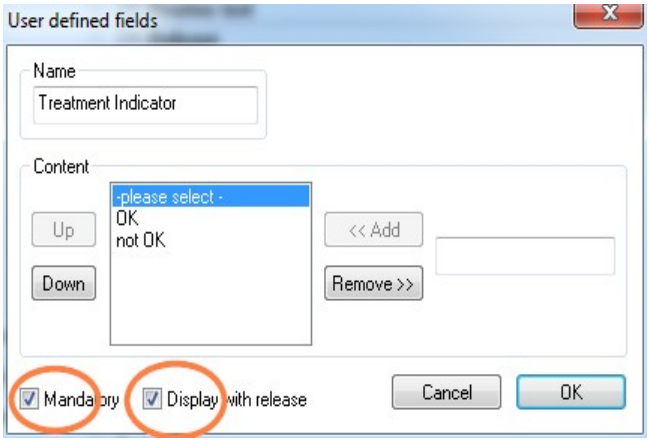


Form fields (lists) in routine testing that **must** be completed by hygiene personnel. Hygiene personnel **must** always complete an evaluation of the results, i.e. the evaluation criteria are

used as a checklist from which the applicable statement can be selected. To ensure that a selection is made, the evaluation criteria always start with a general statement such as “Please

select”. This is followed by the actual criteria, such as such as "OK" or “Not OK". If the list is not completed, the missing information is shown in red. The routine testing form cannot be acknowledged and closed until it has been completed.
Release fields:
The contents of the fields are taken from the release dialogue and are queried during batch release.

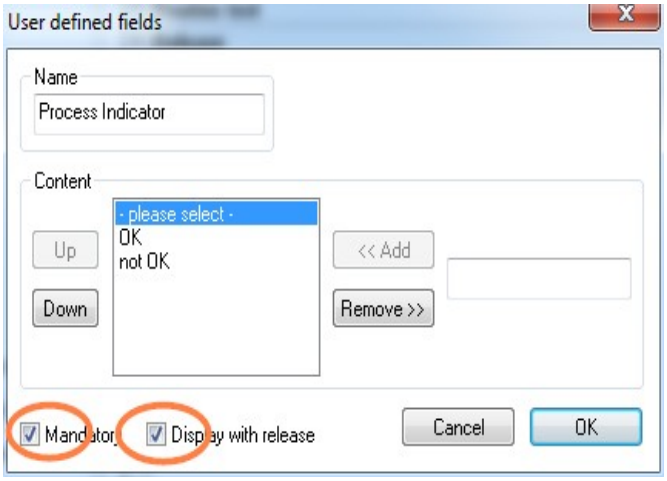
Example: Documentation of the treatment indicator



A treatment indicator (Class 1, DIN EN ISO 11140-1) should be used as per RKI recommendations in every device process on the steriliser load to ensure that a sterilised item can be distinguished from an unsterilised item.

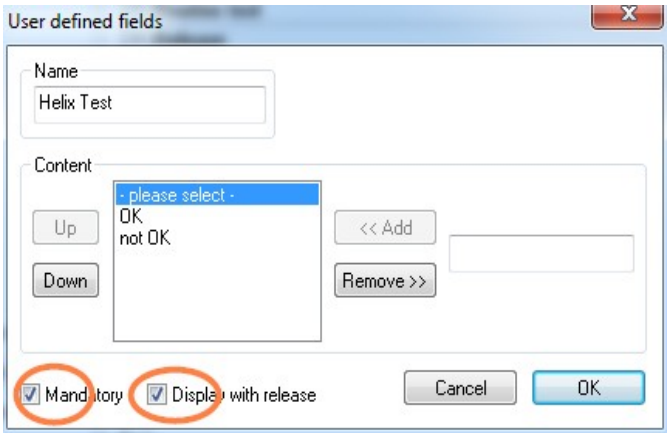
The indicator is evaluated and documented in SegoSoft by the release dialogue.

Example: Documentation of the process indicator



A process indicator (chemo-indicator Class 5, DIN EIN ISO 11140-1) should be included with critical A products in every device process as per RKI recommendations. After evaluation and documentation of the indicator in the SegoSoft release dialogue, the indicator strips can be discarded, because the information value of the strip decrease over time.

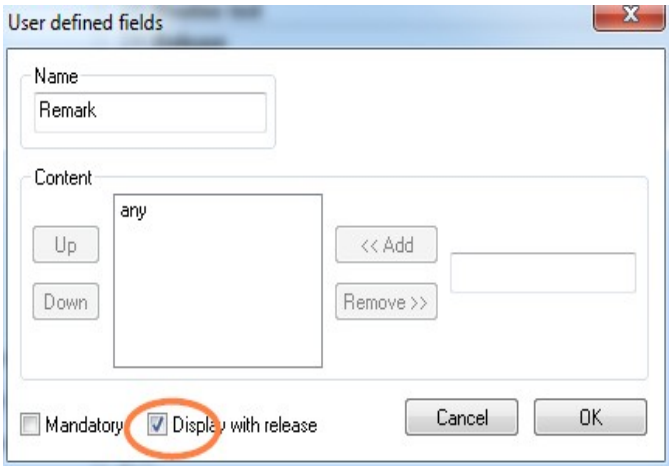
Example: Documentation of the helix test



A PCD process indicator (helix test) should be included with critical B products in every device process.

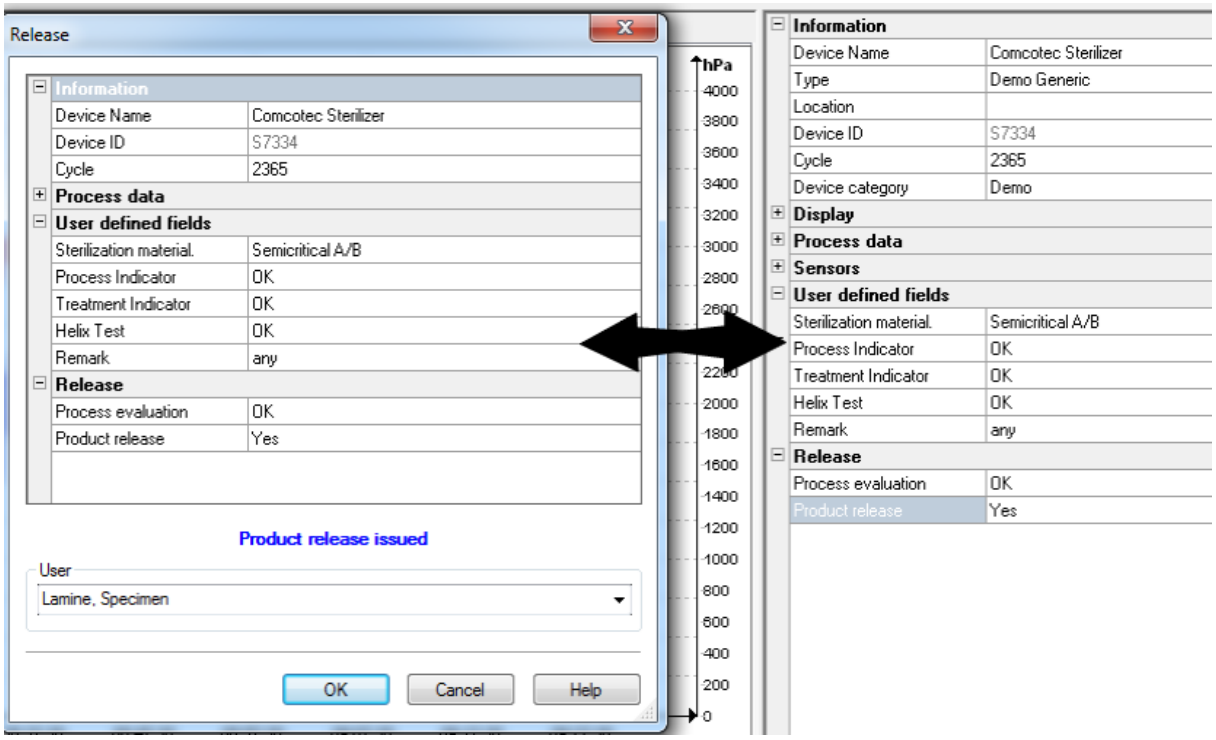
After evaluation and documentation of the indicator in the SegoSoft release dialogue the indicator strips can be discarded, because the information value of the strip decreases over time.

Example: Documentation of the reaction to unexpected process sequences



Deviations in the daily routine check can be recorded in the “Remarks” field. E.g.: Helix test not OK -> preparation process is repeated.

Please enable only the release field in the remarks field.



The entries in the user fields are queried in the release dialogue as soon as the device program is complete and the product release can be issued.
The prerequisite for the appearance of the user fields in the release dialogue is an **enabled release field.**

7 Release

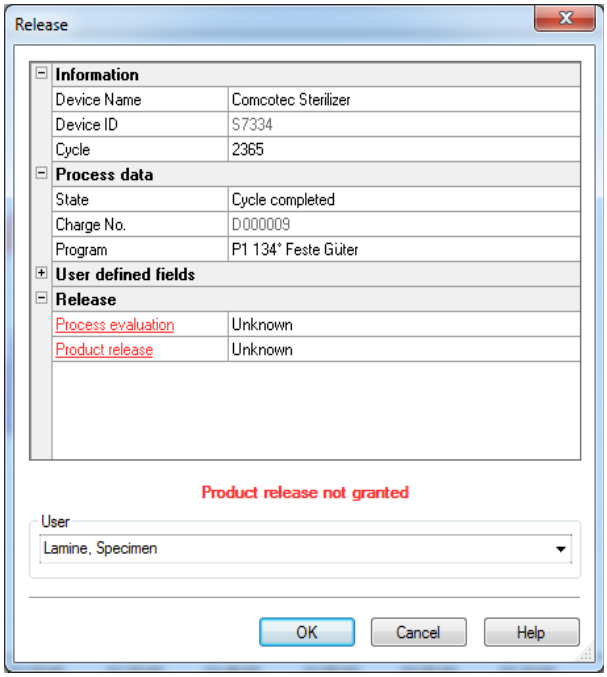
Before releasing medical devices, the recorded process data must be checked to ensure that the process was complete and correct. Check for any errors and warning messages on your preparation device.

The preparation of medical devices is complete with the release for use. The release issued based on the conformance of the process parameters during preparation with those of the validation protocols and includes performance and documentation of the daily routine testing, checking and documentation of the complete and correct process (batch-based routine testing and batch documentation), checking that packaging is undamaged and dry, and checking the labelling.
The user must also check that no error and warning messages were output by the connected preparation device. Check the manufacturer's instructions for use if error and warning messages are output.

SegoSoft is by default set up to open a dialogue window automatically at the end of every program in which the release for use of the medical devices described above is completed.

7.1 Release dialogue window

Open with: opens automatically by default at the end of every program.

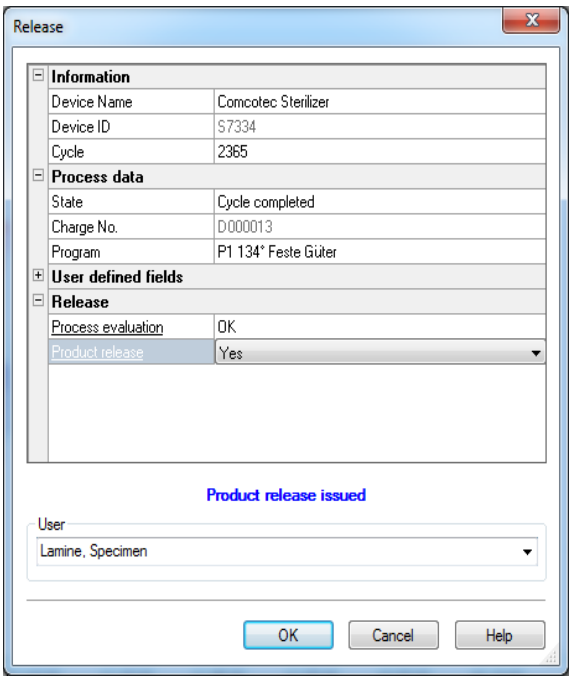


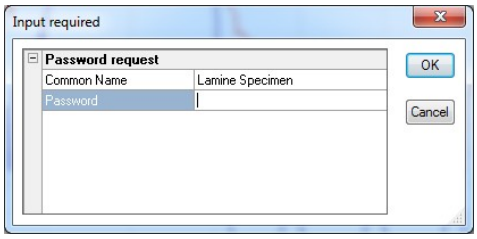
Release dialogue window with the important information for the release of the medical device, the process data, the user-defined fields for completion and the release with the process evaluation and the product release.

The size of the release dialogue window can be adjusted as required with the left mouse button. The setting is saved.

Only after the user fields and release fields have been edited from the dropdown lists does the entry "**Product release issued**" or "**Product release not issued**" appear. After completed editing of the release window, pressing "**OK**" opens a password prompt for the person responsible for release.

The person responsible for the release is selected from a password prompt. Then the digital signature with name, date and time is created for the person responsible for the release.



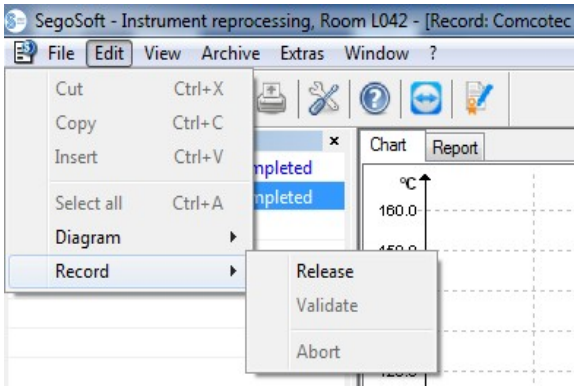


After entering the password and clicking "**OK**", the released record is automatically converted to PDF format (if the default settings have not been changed) and saved to the PDF archive.

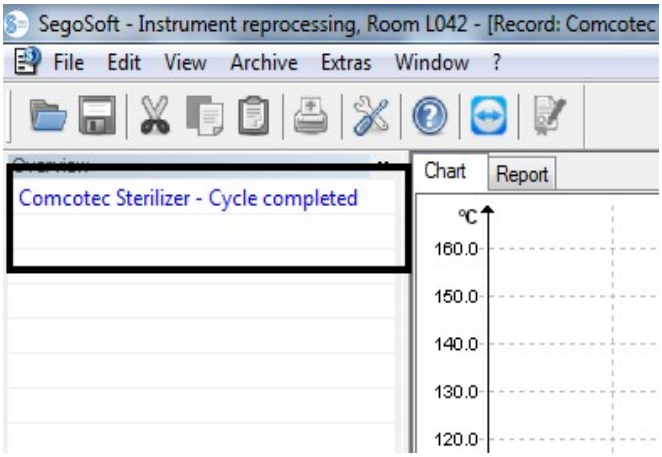
Manually opening the release dialogue:

If the dialogue window was closed by “Cancel” or if automatic release at the end of the record is disabled, the release dialogue can be opened manually.

To be opened with:
If the dialogue window was closed by “Cancel”:
With open record window with “**Edit/Record/Release**“

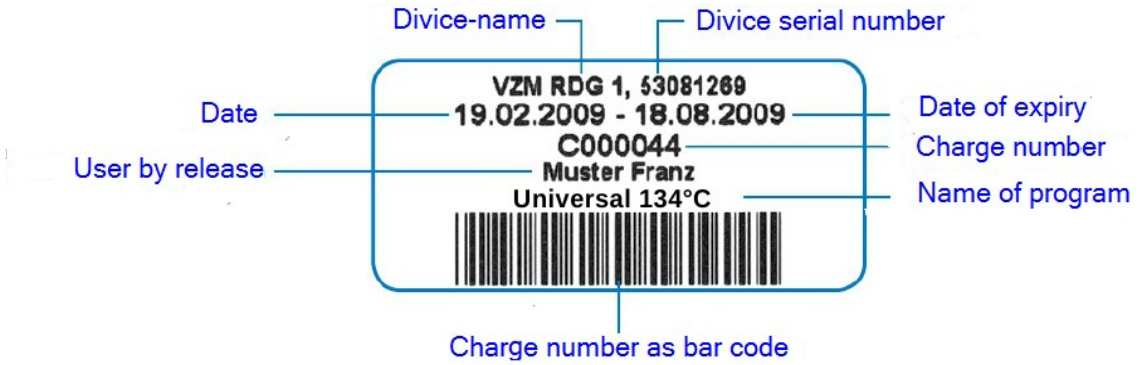


or from the overview window by double-clicking on the entry “**Device name/Cycle complete**“



8 Label print

The SegoSoft label print barcode identifies the sterile stored instruments with the unique SegoSoft batch number and allows tracing of the batch of prepared instruments to the specific preparation process. The program automatically calculates the expiration date of the prepared batches.



8.1 Barcode label

8.2 Label print dialogue

The label print dialogue opens automatically on completion of product and process release in SegoSoft.

"**Cancel**" cancels label print.

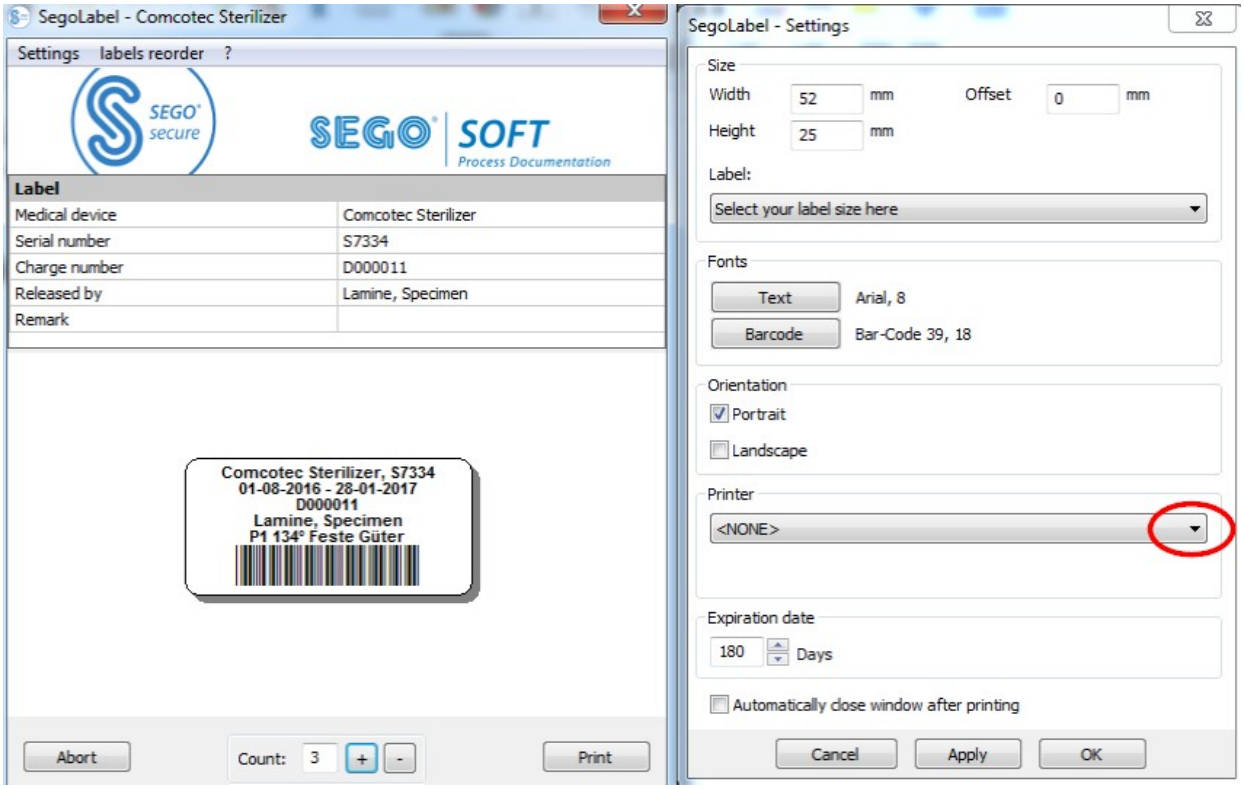
"**Number**" selects the required number of labels.

"**Print**" prints the required number of labels.

8.3 Settings dialogue

Open the settings dialogue with **"Settings/Label"**

The settings dialogue opens beside the main dialogue.



8.4 Functions of the settings dialogue

“Size” menu group: enter the specifications of the height and width of the label and also the offset of the label. The offset is the distance between the top margin of the label and the start of the printed information.

“Fonts” menu group: Select the font for the label text and the barcode.

“Alignment” menu group: define the alignment of the label, portrait or landscape

“Printer” menu group: Select the printer for the barcode label.
“Expiration date” menu group: Enter the required number of days for shelf life. The program automatically calculates the correct expiration date for the batch.

When setting the expiration date, please note the specifications for the maximum storage life depending on the sterile packaging.
See the “Storage duration” table in DIN 58953-7 “**Sterilisation – sterile goods disposal – Part 7: Use of sterilisation paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels”**

For paper bags according to DIN EN 868-4 and sealable pouches and reels according to DIN EN 868-5 or similar packages the maximum storage time is 6 months under correct storage conditions (dry, away from light, dust-free) according to 4.3 in DIN 58953-8.

Checkbox **“Automatically close window after printing”**: If the checkbox is selected, the barcode label print dialogue is automatically closed after printing the labels.

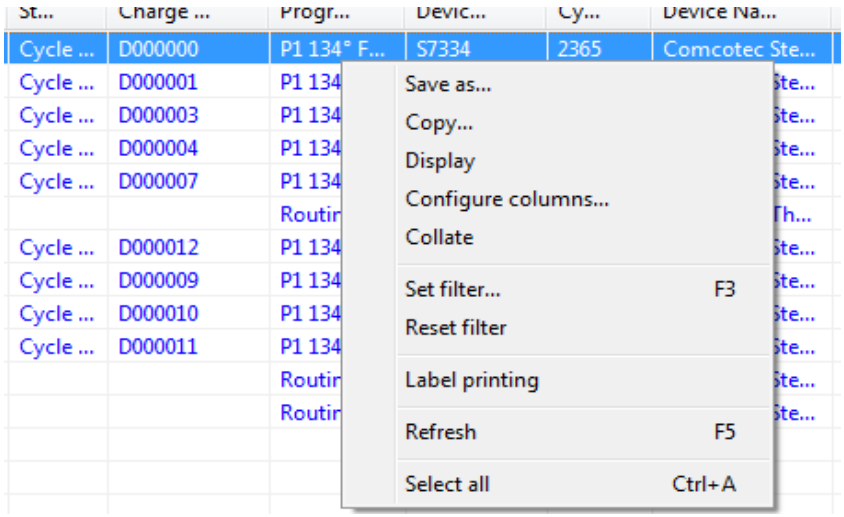
“Accept” Select “Accept” to check your changes in the label preview.

“OK” Select “Save” to save the settings permanently.

“Cancel” closes the settings dialogue.

8.5 Label reprint

Reprinting barcode labels is only possible for processes and batches that have been positively released.
Only users who belong to a group authorised to reprint labels can reprint labels.
In SegoSoft PDF Archive select the process for which you wish to reprint labels with the right mouse button.



Select **“Label print”** to reprint barcode labels for the selected process.

9 Archive

The measured data are temporarily saved immediately on receipt from the connected device in an internal proprietary system format that is not open and is protected from manipulation. The raw data are listed in “**Archive/Records**“ and are available for purposes such as analysis on completion of the record. Double-click with the left mouse button on the required record to open a separate window **[Record],** referred to as the record window.

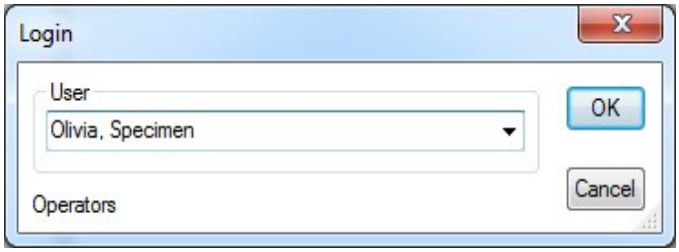
After release in the release dialogue the raw data are converted to PDF format. The PDF files are listed in “**Archive/PDF Archive**“ and can also be opened by double-clicking on the required record with the left mouse button. A separate window **[PDF Archive]** opens with the chart, the report, the protocol, the list of measured values and the information on the process data of the record.

The **audit trail** records the information that was specified in “**Tools/Settings**“.

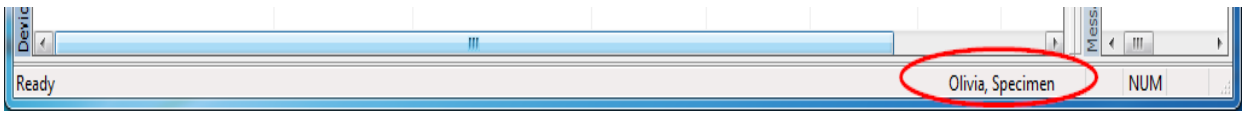
10 Authentication

10.1 Session-oriented log-in

With all important steps for traceable documentation, e.g. when releasing and signing documents the user is prompted for user name and password.



The log-in status is shown at the status bar at the bottom right.



To prevent unauthorised access, a time interval defining the number of minutes after which the user will be automatically logged-out can be set with corresponding group rights in “**Tools/Settings**“ in the “**Master data/Settings**“ tree structure.
SegoSoft logs the logged-in user out of the system automatically after a specified time to prevent unauthorised access.

Segosoft checks the number of failed authentication attempts since the last successful authentication after starting the program. If the maximum number of failed authentications is reached, the user can no longer be authenticated for a period of 2 x n (n = number of failed authentication attempts).
The maximum number of failed authentications is 5.

If the authentication fails, the following message is displayed: “Error during log-in. Incorrect password?”
The time interval when the maximum number of failed authentications is not displayed; logging-in is not possible during this interval.

10.2 Changing the password

To be opened with: “Tools/Change password“

After entering the current password the selected user can select a new password.

The requirements for the password are allocated by the group and it is defined by the administrator.

The following password rules apply to the administrator:
The password must be at least 6 characters and must include upper case and lower case letters and also numbers.
If the password cannot be changed, the dialogue message “Password was not changed” and additional details of the reason for the failed change are displayed (e.g. “Password too short”, “Lower-case required”, “Upper-case required”).

Select a strong password and keep it confidential.

11 Annex

11.1 Checking the signature of the release document

The signature is checked with the following process in Adobe Reader (Adobe Acrobat Reader from Version 11.0.8).

After the release document has been signed, changes may make the signature invalid. Do not save the PDF release document after opening with the “Save as?” command.

11.1.1 Before the first signature check

Import of a trusted certificate

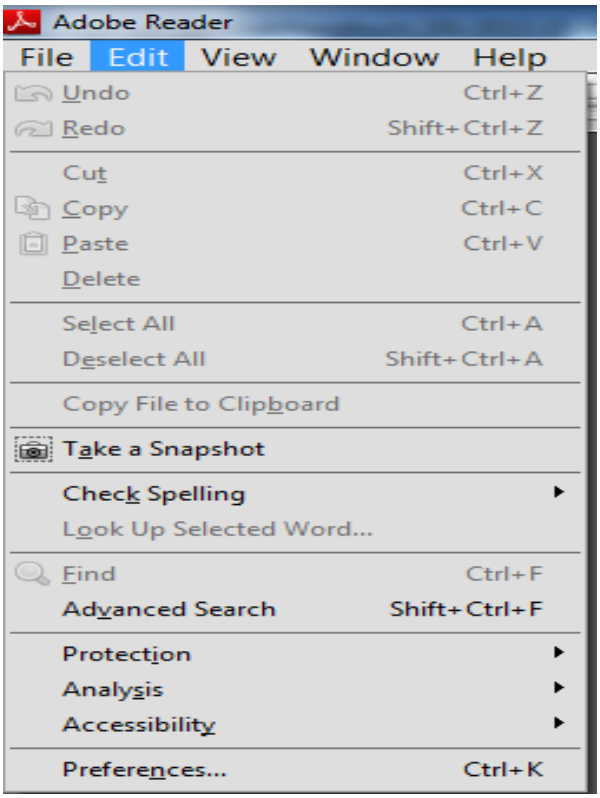
The user’s certificate must be classified as trusted before the first check. The certificates of Comcotec Messtechnik GmbH are not known to Adobe Reader in delivery status. For this reason, a signature check with a new installation of Adobe Reader will indicate that the validity of the signature and the identity of the signer are unknown. The certificate must therefore be classified as trusted before checking the signature.

The root certificate can be downloaded from the web site of Comcotec Messtechnik GmbH. The root certificate must be imported to the trusted certificates in Adobe Reader.

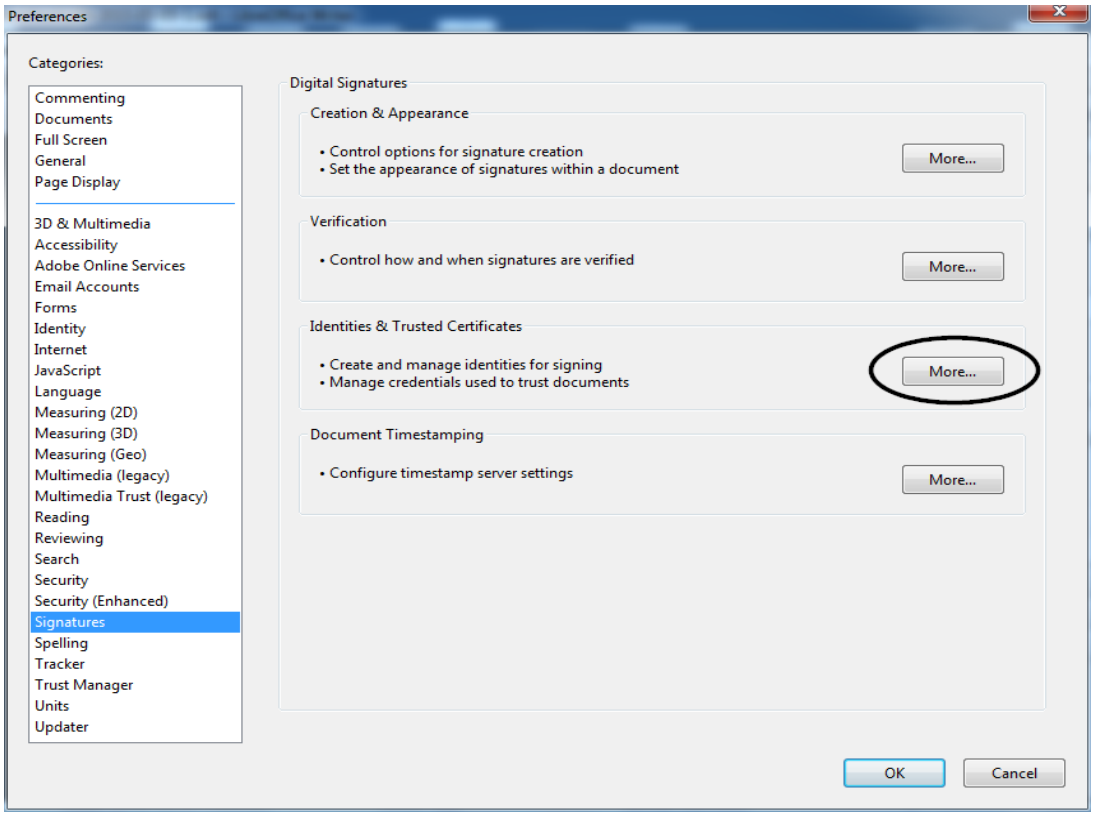
This is done by importing the trusted certificate. The following steps are required*:
*As of March 2014 in Adobe Reader XI. Depending on the version of Adobe Reader, the import of the trusted certificate may be done with different methods. Please import the certificate as specified by the specific version of Adobe Reader.

1) Download the root certificate (Comcotec Root CA) from https://www.segosoft.info to your computer and check it for integrity with the checksum specified on the web site. You can also use the root certificate included with Segosoft for this purpose.

2) Open Adobe Reader and select under **Edit** the **Default** option

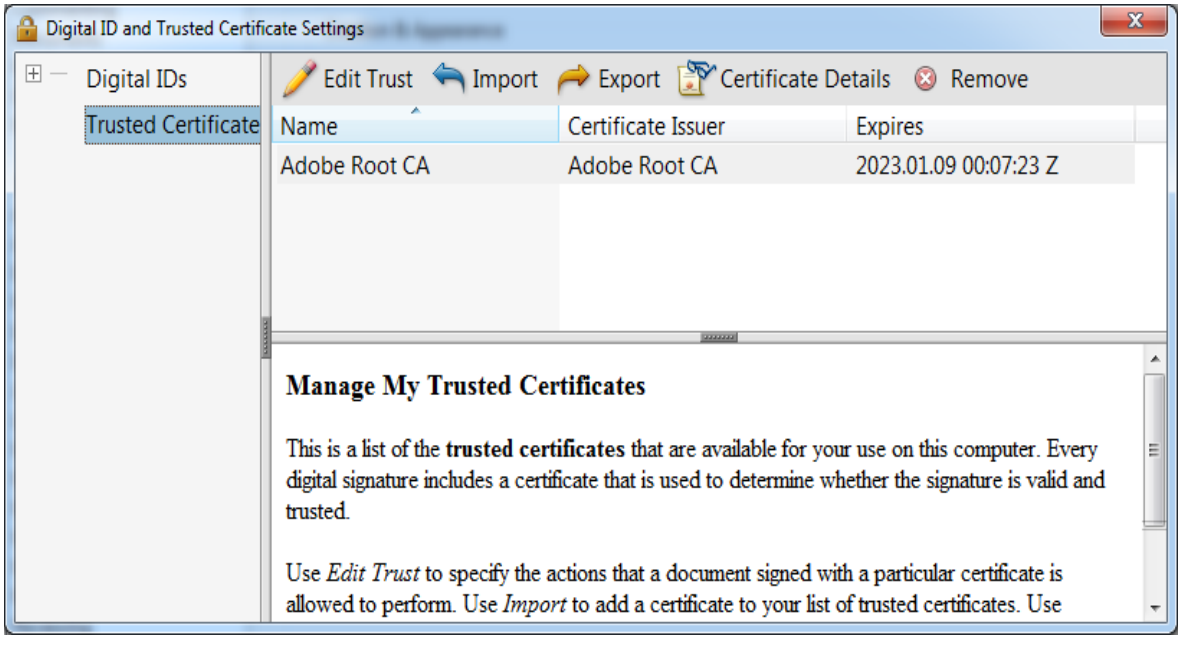


3) In the left window under categories select the signatures option and in the identities and trusted certificates click the **Next** button

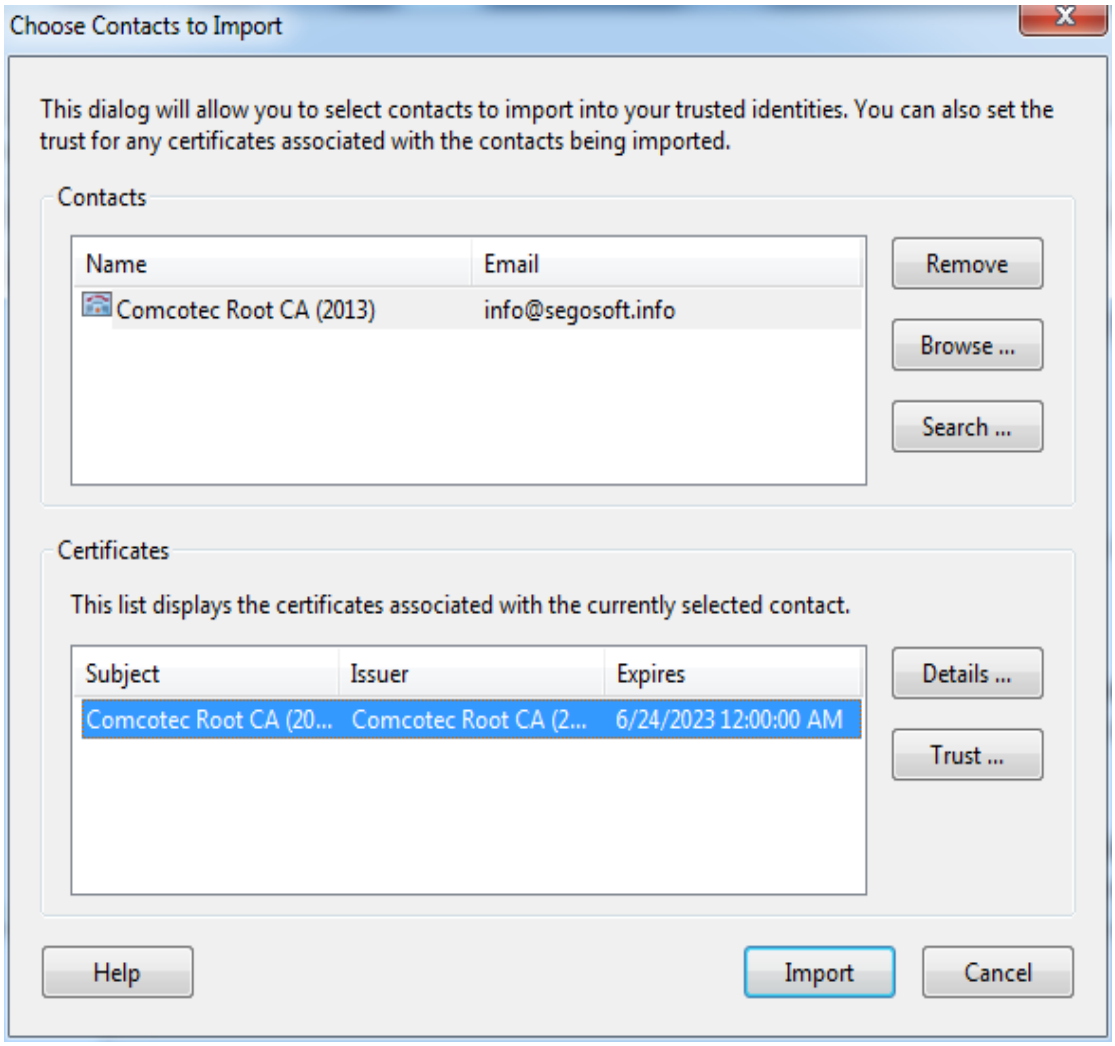


4) The “Settings for digital IDs and trusted certificates” window opens

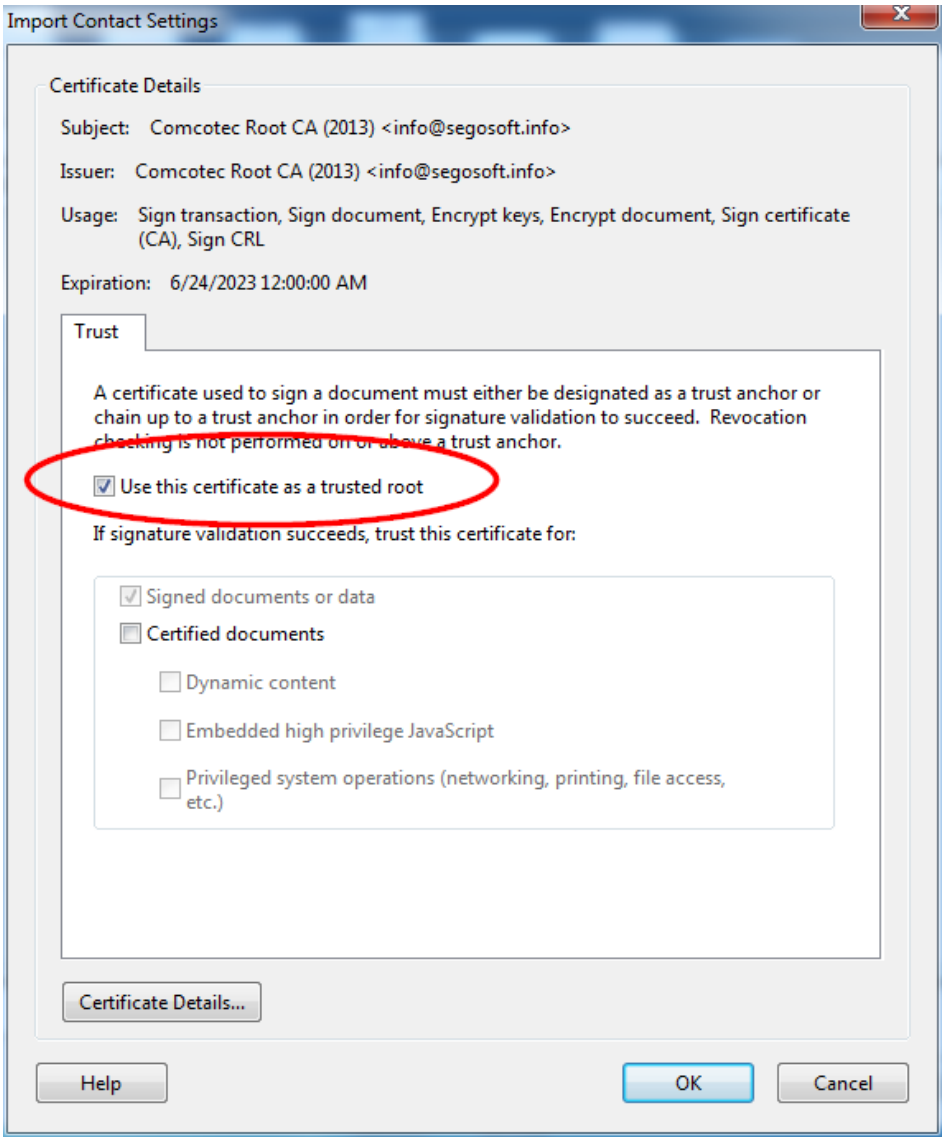
   In the navigation menu on the left click on **Trusted certificates** and selected the **Import** button:



5) In the “Select imported contacts” window click on the **Search** button and open the downloaded certificate. The entry “Comcotec Root CA” and after selecting the “Comcotec Root CA (2013)” contact the certificate is opened in the certificates section.



6) Select the **Trustworthy** button and use the trusted Comcotec certificate as the trusted master for signed documents and data

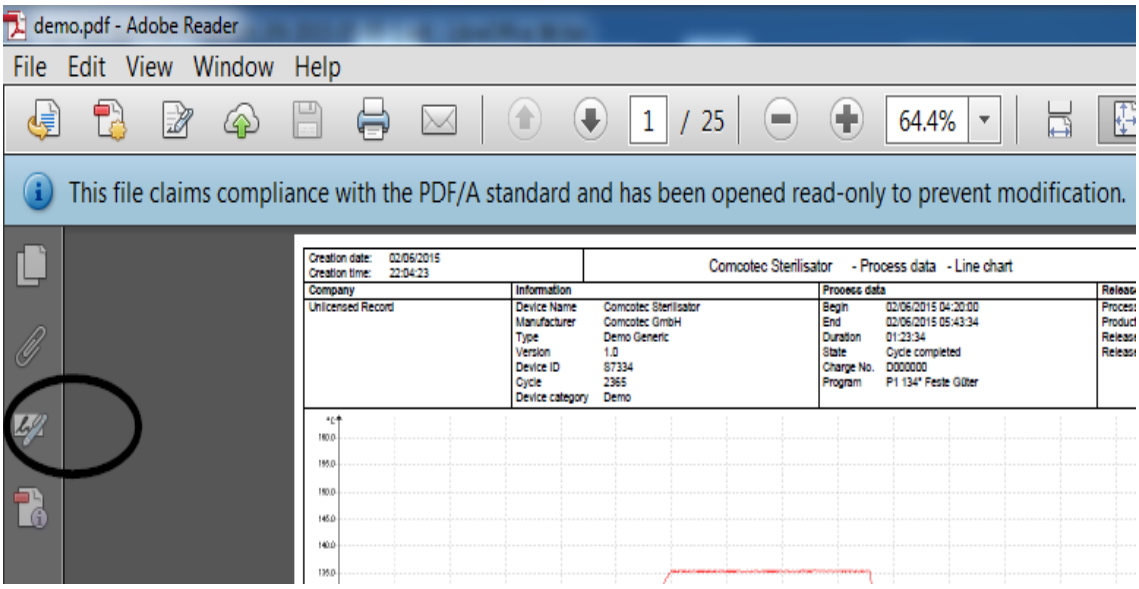


7) After confirming this setting with **OK** you import the certificate by clicking on the **Import** button. A message confirming the successful import will be displayed.Comcotec Root CA is now listed as a trusted certificate in the “Setting for digital IDs and trusted certificates” dialogue window.

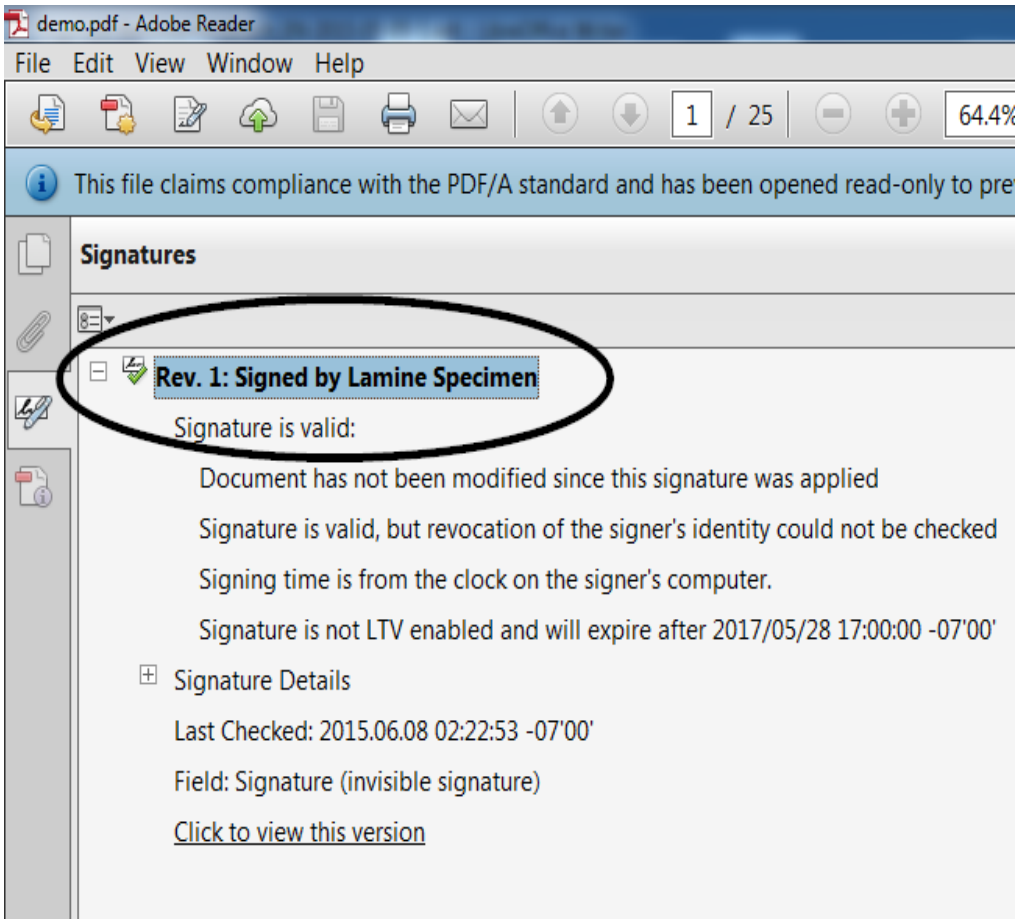
11.1.2 Checking the signature

The validity of signatures on other documents can now be checked in Adobe Reader:

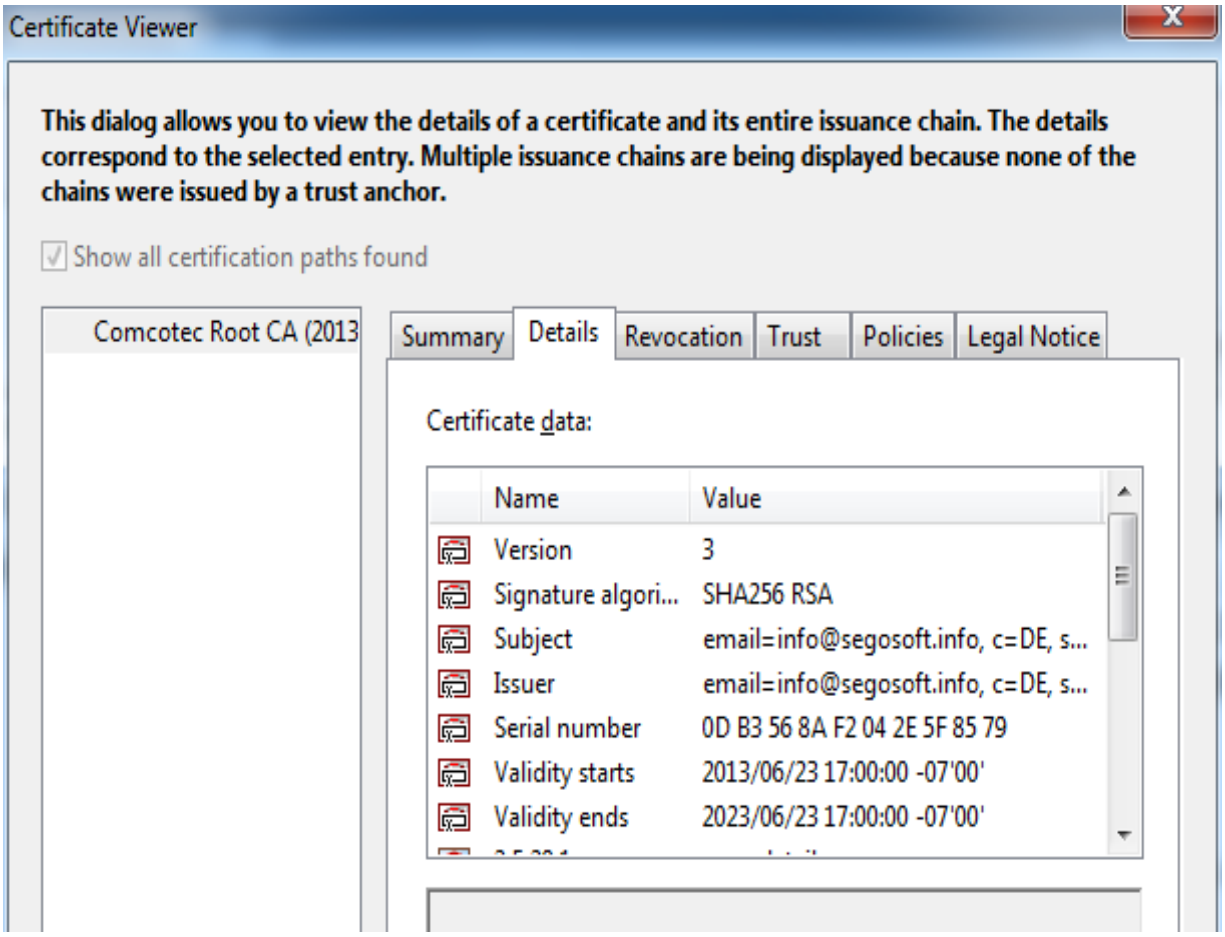
This requires displaying the properties of the signature, *Signatures* icon in left column.



The user can check that the signature is valid and has not be changed or corrupted. If a signature is valid, “Signature is valid” is displayed.



To check that the certificate is from the trusted source, the properties of the certificate can be compared with the trusted certificate:
Signature information -> Certificate details → Details tab:



Now the displayed values (Applicant, Issued by, Serial number, Validity, SHA256 checksum) can be compared with the printed certificate document:

12 Obligation to report

The operator of this software is obliged to report any serious incidents regarding this product to their local competent authority or to the above mentioned manufacturer.

Users from Switzerland also report directly to Comcotec Messtechnik GmbH. This ensures that the necessary reports are made to the Swiss representatives and to Swissmedic.
The Swiss representative and the CHRN (Swiss Single Registration Number) are as follows:

CH REP	CHRN-AR_20003589 **QSMed.ch GmbH, Hotzestrasse 14, CH-8006 Zürich** authorised representative CHE282895126 Public communication data info@qsmed.ch, +41 43 543 44 44 Contact person Dr. Markus Fehr, +41 43 543 44 44, info@qsmed.ch PRRC Dr. Markus Fehr, +41 43 543 44 44, info@qsmed.ch

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