

Segosoft® **Miele Edition** Process Documentation



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Dos and Don'ts - Information for the Administrator!

Responsibilities:

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

The administrator only issues user administrator rights to trained staff, and instructs the user on the use of electronic signatures. He thereby ensures that a user confirms the certificate he has generated in writing.

Process validation:

Process validation is explicitly required in the QM systems (DIN EN ISO 9001, DIN EN ISO 13485, GMP, DIN EN ISO 15189), in the guidelines of the federal medical association (RiliBÄK) and in the medical devices operator ordinance (MPBetreibV). It involves the development of documented evidence that a process always produces a result or a product which meets the defined requirements.

The following qualifications are to be carried out with SegoSoft within the context of this legally required process validation:

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

Comcotec can provide assistance creating those documents.

All references to codes and regulations to the versions actually in effect.

Device driver:

Selecting the **right** device driver is a key factor in the smooth and correct recording of process data by SegoSoft. The operator is obliged to enter the exact information in terms of the device manufacturer and the device type when setting up the device.

Release dialogue user:

Only persons who because of their training and practical occupation have the necessary specialist knowledge (qualified person) may be tasked. The release decision for a user is documented in the SegoAssurance module of the SegoSoft process documentation, where a PDF document about the release of the user is generated and saved with a digital signature. The certificate specifically assigned to the user is used for this.

Intended use:

SegoSoft is a modern process documentation system for medical and laboratory application that is independent of the device manufacturer. All relevant parameters and data from cleaning, disinfection and sterilisation are recorded in a complete documentation trail.

The process documentation is tasked with the collection and administration of data sent to the system by external devices termed 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 the 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).

Validity of the digital signature:

The coding algorithms have to be renewed every two years so that the risk of the signed data failing to comply with legal requirements is largely ruled out. 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).

Maintenance window

The check up window is automatically opened directly after SegoSoft is started up. The user is given information on the security status of the practice and user certificates and the activation status of the processing devices.



- If, for example, the digital signature has expired **“Contact your software support!”** appears in the check up window
- After selecting the checkbox “The legal security is not guaranteed” the user confirms that he has acknowledged the information.



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

To ensure the legal compliance of the process data it is essential to renew the code algorithms of the digital signature.

Please **“Contact your software support!”**

Maintenance information:

The head / operator of the facility is responsible for the maintenance information for the specific processing devices in SegoSoft. The maintenance intervals specified by the manufacturer must be taken into account.

Requirements of the application environment:

The PC system on which SegoSoft is installed, is placed, so that only authorised persons have access. Persons who are not or can no longer be considered trusted will have no local access or network access to the PC system and no clearance may be set up for persons who are not trusted. It is also important to ensure that only trusted persons have access by means of remote administration, that the remote administrators have a sufficiently strong password and that strong coding is secured. The administrators ensure that the PC system has the necessary operating system and is not compromised

Items supplied:

The product SegoSoft is supplied with the following components:

- PC-Software SegoSoft (SegoSoft from Version 7 with Sego Assurance Module Version 1.2 and SegoSoft user manual)
- **SegoSoft Manual Installation and Administration**

CE label



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

1. Installation of SegoSoft on the computer

Please ensure

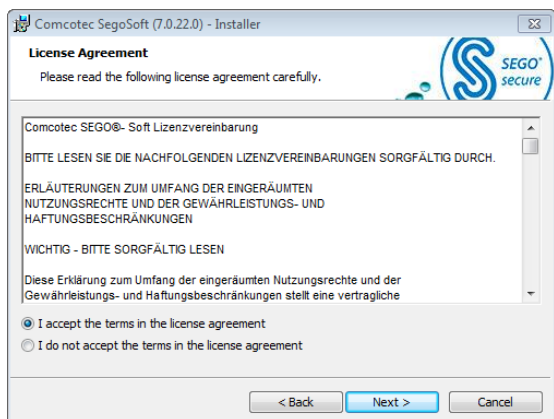


- that the computer has the interface required for the device recording (COM Port, USB, Ethernet)
- that no other software program is occupying this interface
- that the integrity of SegoSoft is ensured (see annex)
- that the operating system has up-to-date virus protection.

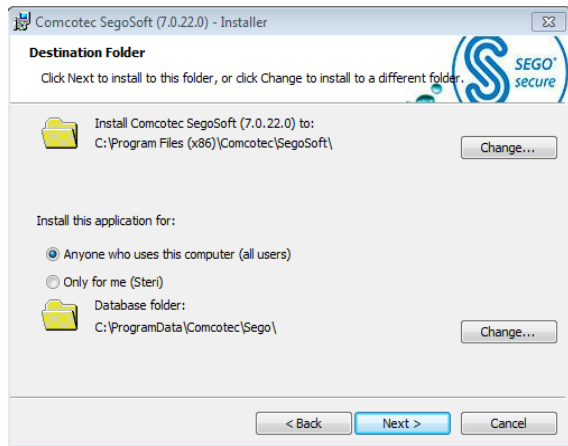


- Insert the SegoSoft program CD
- The installation start screen automatically appears
- If the start screen does not automatically appear, start the file "Setup.exe" on the SegoSoft program CD

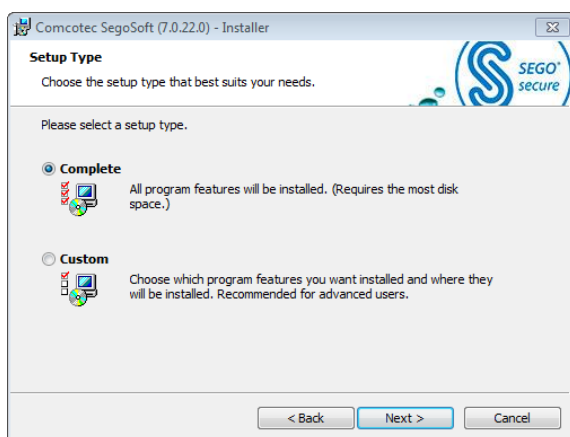
The Comcotec SegoSoft installation program guides you through the entire installation. You can accept the predefined standard settings.



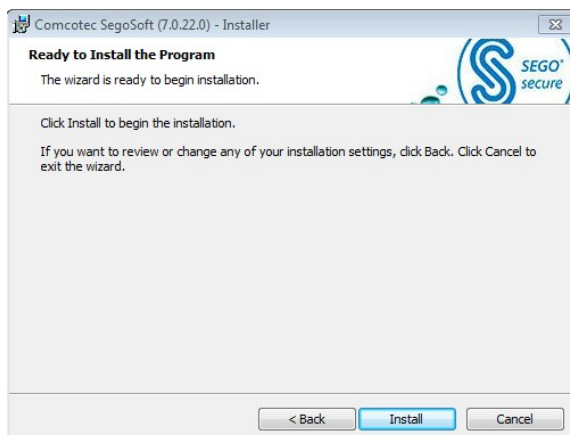
- Select "I accept the terms in the license agreement" and then click on the "Next" button



- If appropriate, select if SegoSoft is to be installed for the current user or for anyone who uses the computer



- Select setup type: "Complete"



- Select "Install"



- After the installation is complete the entry "Comcotec", "SegoSoft" appears in the Windows® start menu under "programs"



To be able to use the software, please carry out the steps described below for the configuration, to create a company certificate, for user administration and for device licensing.

2. First start



Please ensure that the computer used for the first installation of the software has working internet access. This makes setting up and activation much easier.

The first time the software is started the following maintenance dialogue is shown.



- Tick “The legal security is not guaranteed” and then select “Next”.
- The following dialogue opens.

2.1 Master data configuration

The company data and the device details can be entered manually and/or with a configuration file provided by Comcotec.



Company data must be properly maintained. Company information is printed in all recording documentation, and the electronic signature is created based on the company data.

Maintenance

Service Card

-

< Prev Next > Cancel Help

- Enter the number of the service card
- Select “Next”.
- The following dialogue opens.

SegoSoft then scans the current product status from the Comcotec server. Here again select “Next”. The configuration source is then selected

Maintenance

Configuration source

Please select, how to configure your stock data

☒ Downloading data from Comcotec-Server
☐ Use existing data from a file
☐ Enter data manually

< Prev Next > Cancel Help

- Here, select the point “Downloading data from Comcotec Server”

2.2 Setting up company data

If you do not administer the company data via the assistant, select the subject “Master data/Company data” in the user administration.



- If you are online your company

data are entered automatically. If not:

- Enter the company name and address, select country
- After entering the company data: Select the “Accept” / “OK” or “Next” button (user prompt via assistant)



- The generated company certificate initially has the status: “Invalid signature”
- Only once the device is activated does the status change to “Valid”

2.3 User administration

The company data and user data are stored in the user administration. It is possible to organise various users in groups. The user groups and thus the associated users can be assigned or denied different rights.

The company data and the device details can be entered manually and/or with a configuration file provided by Comcotec.

The configuration file is available via the service card. This service card bundles all services required for smooth operation.

All steps in the administration of user and company data can be carried out with an assistant. This assistant starts automatically after the installation. You can manage your users and user groups at any time after the software is set up by opening the menu point “Extras/Settings”. Here select “Master data” and the point “Users” or “groups”.

The assistant guides you through the following set-up steps. Use the “Next” or “OK” buttons to store the data that have been entered and to open the next preference window.



- The proper maintenance of the users and their data is an important factor in proper documentation.

2.4 Set up users

Proceed as follows to set up a user. Repeat the steps described here for every user to be set up. You can set up additional users at any time.

If you do not administer the user administration via the assistant, select the subject “Master data/user” in the user administration.

The screenshot shows a 'Maintenance' window with a 'User' tab. The form contains the following fields: 'First name', 'Last name', 'Title', 'Position', 'Group', and 'Change Password' (which has a checked checkbox). At the bottom of the window, there are four buttons: '< Prev', 'Next >', 'Cancel', and 'Help'.

- Set up user data
(The first name and surname and the group must be entered)
- Only users of the group with the rights “User/create, process, delete” (e.g. group “Administrator”) may set up, process and delete users.
- After entering the user data:
Select the “Accept” / “OK” button or select “Next”

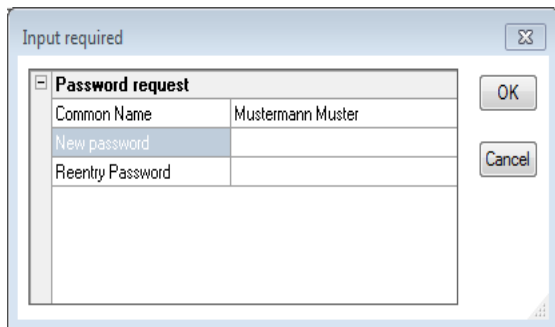
NB:



The first user has to be added to the group “Administration”. There are two predefined groups. Administration and operators. Every user may only belong to one group. The user rights are administered via their assignment of the user into a group.



- Select a clearance password after entering the user data.
- Every user has his or her own clearance password.
- Please note: Without a release password it is not possible to carry out the hygiene documentation properly!



The screenshot shows a dialog box titled "Input required" with a close button (X) in the top right corner. Inside the dialog, there is a section titled "Password request" with a minus sign icon to its left. Below this title is a table with three rows: "Common Name" with the value "Mustermann Muster", "New password" (which is highlighted with a blue background), and "Reentry Password". To the right of the table are two buttons: "OK" and "Cancel".

- Enter password of your choice
- Confirm password
- Click "OK"



The following password rules apply to the administrator:
The password must be at least 6 characters and may not consist of only upper case or only lower case letters.

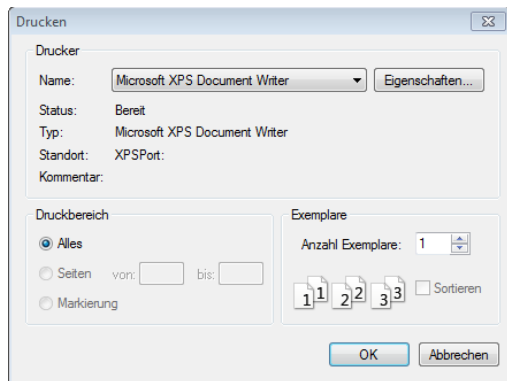


In the "master data/settings" the requirements for the user authentication with regard to the password length, the logout time and the validity of the password (password ageing) can be defined. No default settings are defined. To change the settings the right "user settings/process" is required.

When the password is issued a clearly identifiable user certificate is generated. With this certificate the hygiene documentation is protected from change. This protection can be checked in the document, e.g. by the monitoring authorities.



- The generated user certificate now has the status: "Valid"
- Set up all necessary users in this way



- Once the certificate has been generated the signature verification key of the certificate should be printed out along with the training form. The generated certificate document is to be printed.

The certification document contains the user's name (certificate holder), but also the validity period of the certificate, the public key, the party issuing the certificate and the certificate fingerprint.

The user is to be instructed according to the information in the certificate document. After this, to secure the integrity of the data, the paper document is to be signed by the party responsible for the process (administrator) and the user.

The user certificate can be shown at any time through SegoSoft (menu "Extras/Options" and in the tree structure "Master data/User", and issued by activating the button "Display certificate").

NB:



Set up another user in the group "Operators" after the first user (Administrator). This user only has the right to release a process or product. Because of the restricted user rights, this user cannot change the master data, so they are protected from unwanted modification.

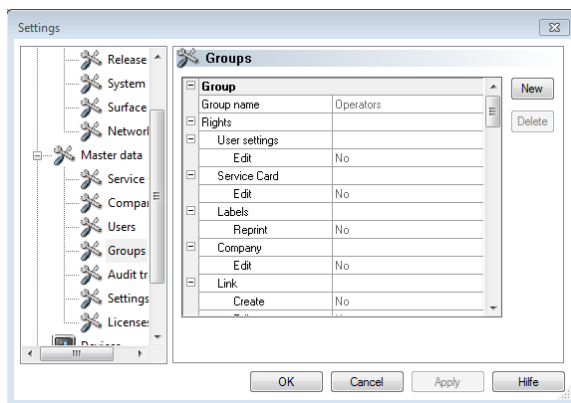
When you have set up the users (a person of the group Administrator and a person of the group Operators) you can end the assistant. You can set up other users at any time in the user administration (menu "Extras/Options") or modify existing users (with the exception of the first name and surname).

2.5 Set up groups

By organising users in user groups it is possible to issue various user roles to various groups of people.

Proceed as follows to set up a group. Repeat the steps described here for every group to be set up. You can set up additional groups at any time.

In Extras - Options select the subject Master data - Groups.



- Enter group data



NB:

If group rights are changed, the rights of the users who belong to this group are automatically changed. Therefore be cautious when changing the rights of a group.

- Only users of the group with the rights "Group/create, process, delete" (e.g. group "Administration") may set up, process and delete groups.
- The following groups are predefined by SegoSoft and cannot be changed:

"Administrator":	has all rights
"Operators":	Can release documentation for the sterilisation- and disinfection cycles

With the group data the administrator can define the rights the members of a group should have. The following security-relevant rights are implemented. They should be issued with caution:

User/ Create, Process, Delete	These rights are required to set up, process and delete users.
Group/ Create, Process, Delete	These rights are required to set up, process and delete groups.
User settings/ Process	With this right the requirements for the user with regard to the password length, the logout time and the validity of the password (password ageing) can be defined
Records/ Clear	With this right users can release records and create the release document.

These security-relevant rights can be activated and deactivated for every group, with the exception of the initial group “Administrator” and “Operators”. The rights of the “Administrator” and “Operators” cannot be changed.

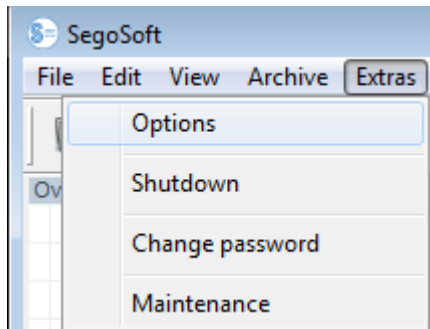
The initial groups have the following rights:

Administrator	A user in the group “Administrator” has all security-relevant rights
Operator	A user in the group “Operator” can undertake release documentation for the sterilisation and disinfection cycles, and the only user attributes he can change is his password.

As well as rights, guidelines for the password can be specified for a group (default: no requirements):

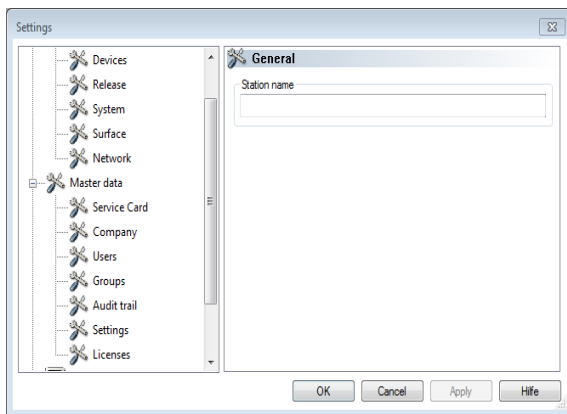
Edit	Yes
<input type="checkbox"/> Password policies	
Password valid (days)	0
Min. pwd. length	6
Upper-case letters req...	<input checked="" type="checkbox"/>
Lower-case letters req...	<input checked="" type="checkbox"/>
Numerical digits required	<input checked="" type="checkbox"/>

3 Software configuration



- Menu "Extras/Settings"

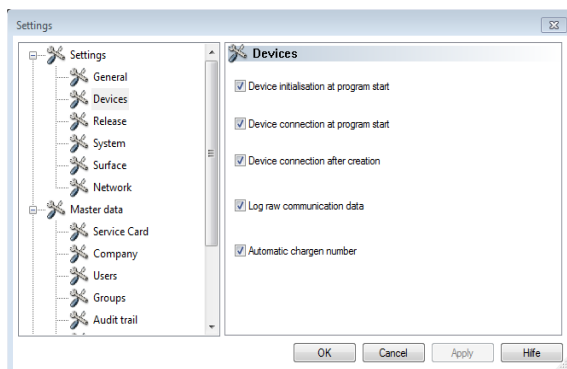
3.1 General settings



- Select "General" in the settings tree
- In the field "Station name" enter the desired description

The station name appears in the SegoSoft title bar.

3.2 Device settings



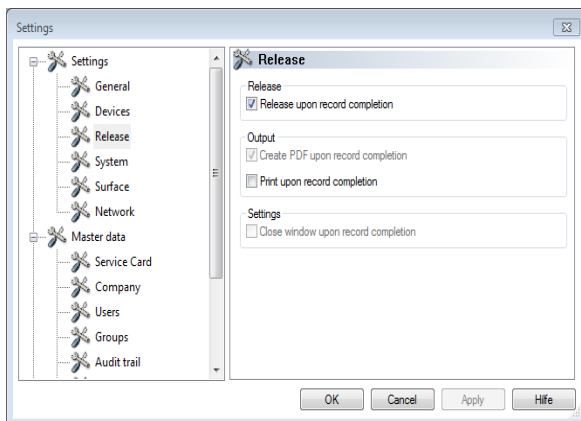
- Select "Devices" in the settings tree

It is recommended that you use the settings shown.

3.3 Release settings



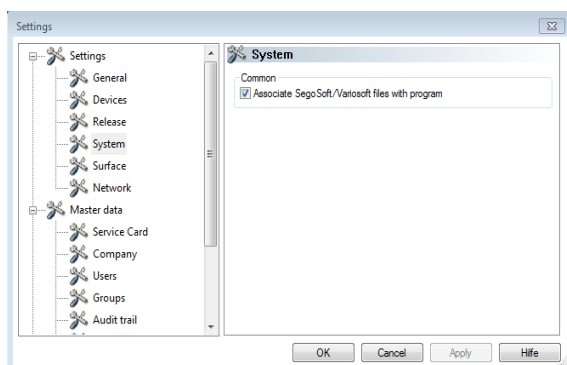
The head / operator of the facility is responsible for the release (release upon record completion).



- Select “Release” in the settings tree
- It is recommended that you use the setting “Close window upon record completion”. After ending the processing
- program the release dialogue window appears automatically on the screen and the release can then be carried out in due course.
- For long-term archiving the setting “Create PDF upon record completion” is recommended.

3.4 System settings

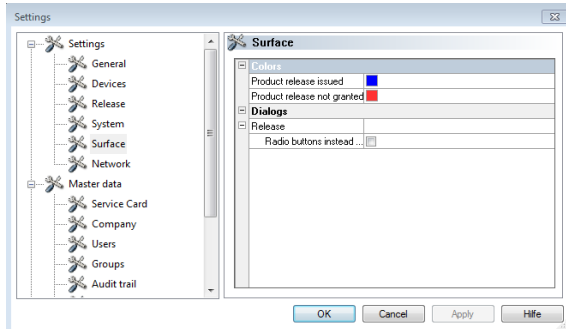
SegoSoft files on the computer are, for example, opened automatically with the program “SegoSoft” by left clicking the mouse.



- Select “System” in the settings tree
- Mark: “Associate SegoSoft / Variosoft files with program”

3.5 Surface settings

- Select “Surface” in the settings tree



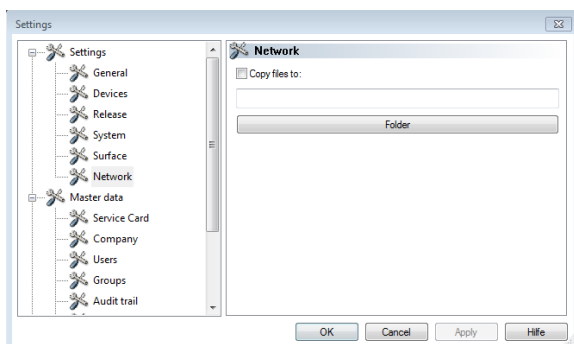
In the register “**Surface**” the colours for the entries “**Product release issued**” and “**Product release not granted**” are selected.

Colour selection: Left click on the coloured box and a separate selection window opens.

The tabular process data in the archive (records and PDF) are then green if product release is issued and red if release is not granted.

The writing “Product release issued” and “Product release not granted” is also coloured accordingly in the release dialogue.

3.6 Network settings



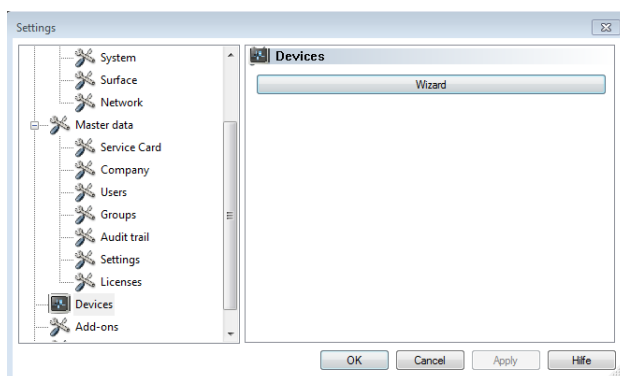
- Select “Network” in the settings tree
- An automatic backup of the files generated by SegoSoft is created via the register “**Network**”. The file backup can be on the server (recommended) or on an external storage medium (USB stick). The condition for this is that the field “**Copy files to**” is marked and the location for the backup copy is set up via the directory.
- **If the network is temporarily interrupted when storing on the server, SegoSoft saves the newly generated files with regular prompts on restoring the network connection.**
- **Click on “OK”**

4. Setting up new devices

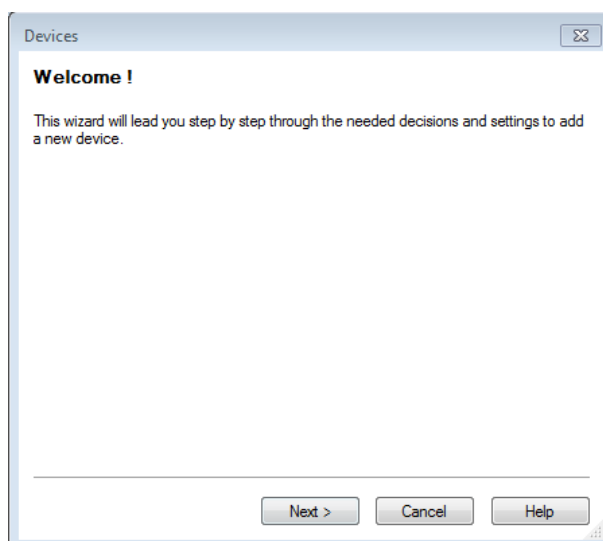


Selecting the **right** device driver is a key factor in the smooth and correct recording of process data by SegoSoft. The operator is obliged to enter the exact information for the device manufacturer and device type when setting up the device.

Repeat the steps described here for every device to be installed.



- Select Menu "Extras/Settings"
- Select "Devices" in the settings tree
- Start the device wizard by clicking "wizard"



- This installation wizard will guide you through all necessary decisions and settings.

Device manufacturer

Please select the manufacturer of the device.

- 3M
- A. J. Costa (Imãos), Lda
- Aeskulap AG & Co KG
- Belimed
- BHT Hygienetechnik GmbH
- Biotoool AG
- C.B.M. S.r.l.
- CISA S.p.A.
- Comcotec GmbH**
- Cominox S.r.l.
- Dental X Srl
- Dentares GmbH
- Durr Dental AG
- Enthral Medical GmbH
- Euronida SPA
- F. & M. Lautenschläger GmbH & Co. KG
- Faro Spa.
- Generic Inc.

Next > Cancel Help

- Select the manufacturer of your device

Select device

Please select the device.

- Demo Generic
- Demo Profironic+
- Demo PS**
- Sego Sensor Module
- Sego Sensor Module (Sterilizer)
- Sego Sensor Module TD

< Prev Next > Cancel Help

- Select your device type

Device properties

Please edit the device properties due to your needs.

Information	
Device Name	DMS -
Manufacturer	Comcotec GmbH
Type	Demo PS
Version	1.0
Location	
Device ID	
Cycle	
Enabled	Yes
Device category	Demo

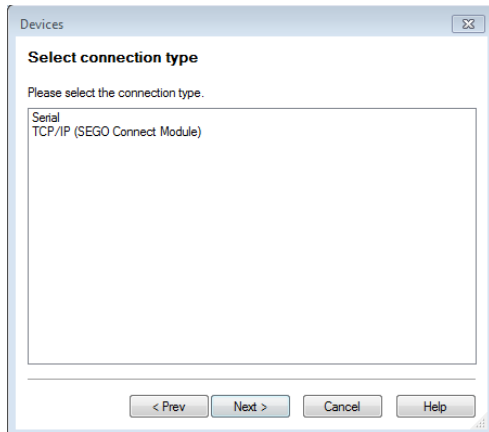
< Prev Next > Cancel Help

- Enter the device name and location

“Device name: The device name can be freely selected. Only the recording documentation is printed and is used, for instance, for the simple identification of the device to be released after sterilisation

“Location”: Here you can enter the location of the device, e.g. “Sterilisation room 2nd floor”

All other fields cannot be edited

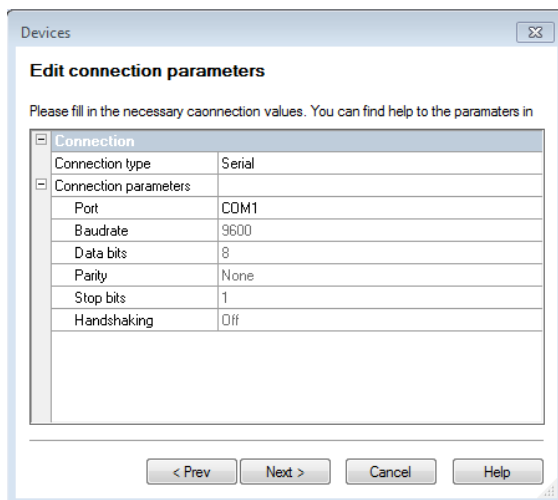


- Select the connection type:

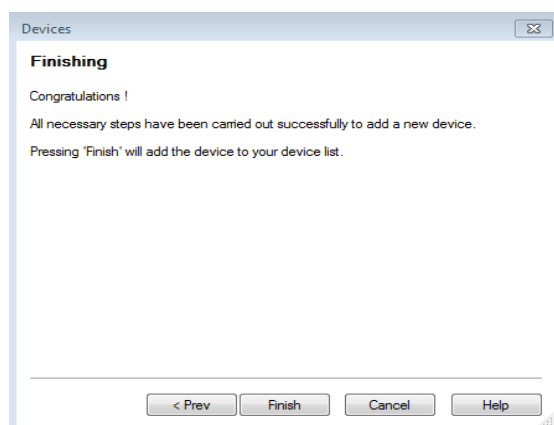


NB:

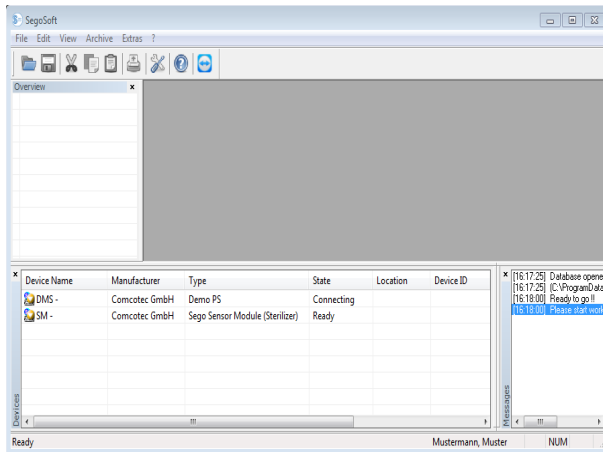
Ensure that the right serial interface (COM Port) is selected.



- Connection parameters:
Select the serial interface to which the device is connected



- Once the device installation assistant is finished the device is installed in SegoSoft

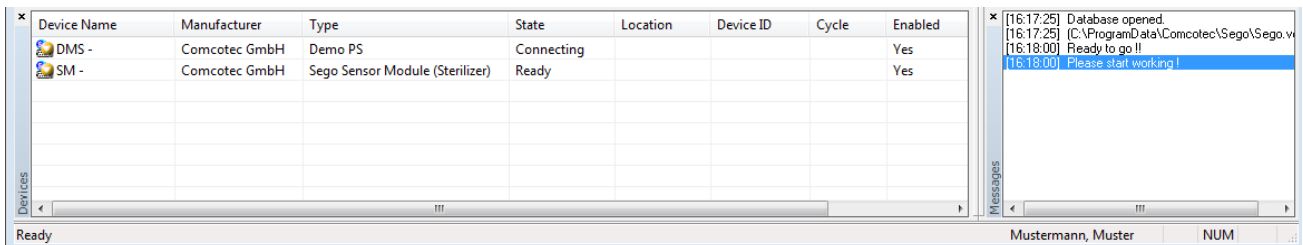


- The installed device is shown in the Segosoft “device window”

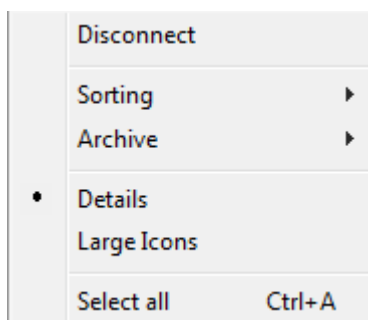


Important:

Segosoft cannot be used until the device is released.



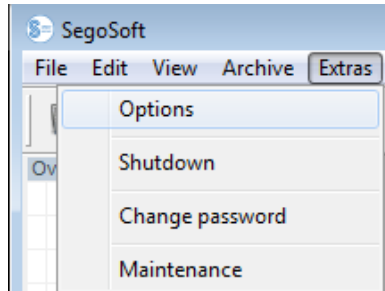
Detailed information on the connected device can be shown via the device window:



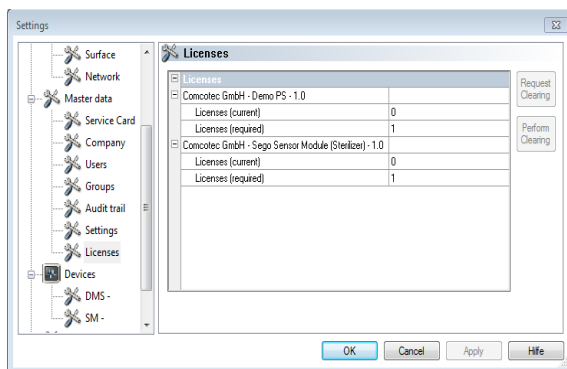
- Select the installed device in the device window
- Right click
- Select “Details” in the context menu

5. Release new devices

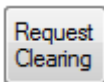
To release all installed device drivers for use, proceed as follows:



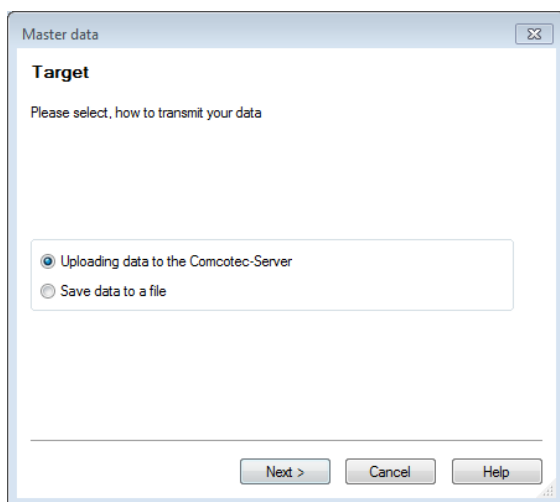
- Menu Extras - Options



- Subject Master Data - Licenses
- or
- Master Data - Service Card

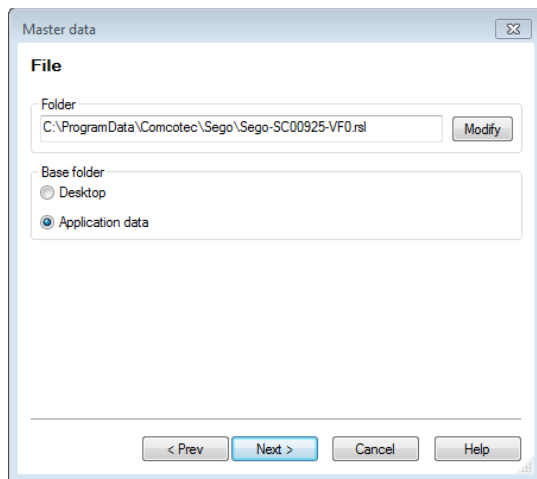


- Request clearing



- Select if the release should be by uploading the data (internet connection required) or by sending the data as a file.

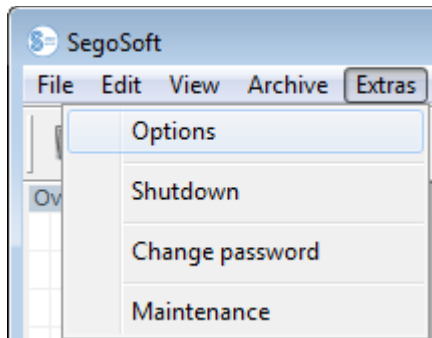
If you have selected the option “Save data to a file”:



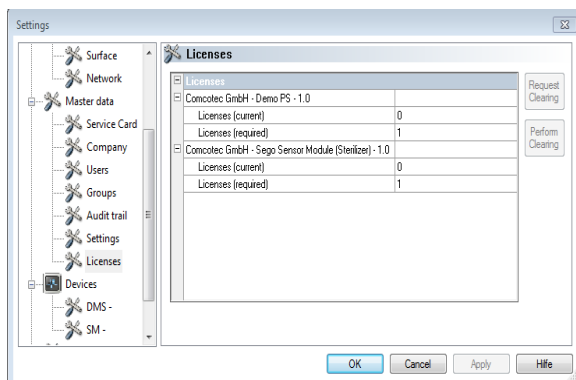
- If necessary click on “Modify” and select the path
- Click on “Complete” to save the file in the defined path

- Email the saved file (file extension *.rsl) to the following address:
info@segosoft.info
- Also enter the following information in the email:
 - > Your sender data
 - > Telephone number for queries
 - > License number(s) - these are in the hologram (CD sleeve, licence card)
- Sie erhalten per E-Mail die Zertifizierungsdatei; Bitte speichern Sie diese Zertifizierungsdatei auf Ihren Rechner (z. B auf den Desktop).

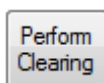
After you have received the activation files from Comcotec (by email or download file) you can carry out the activation of the installed device driver.



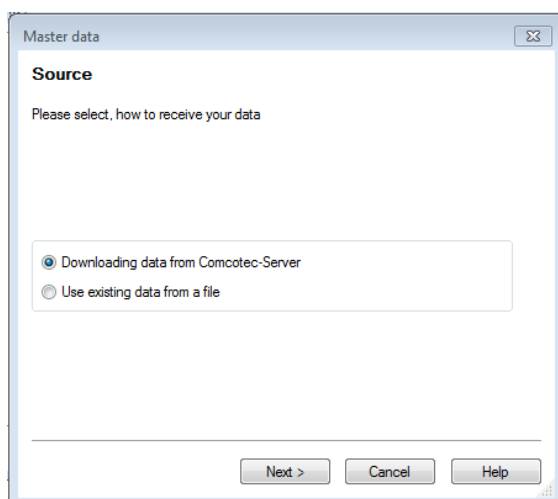
- Menu Extras - Options



- Subject Master Data - Licenses
- or
Master data - service card

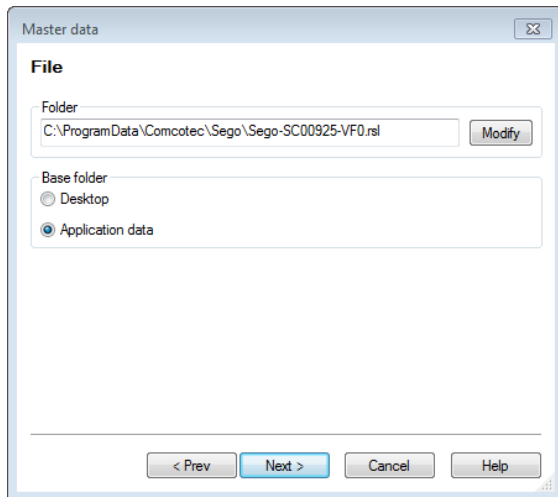


- Carry out release
-

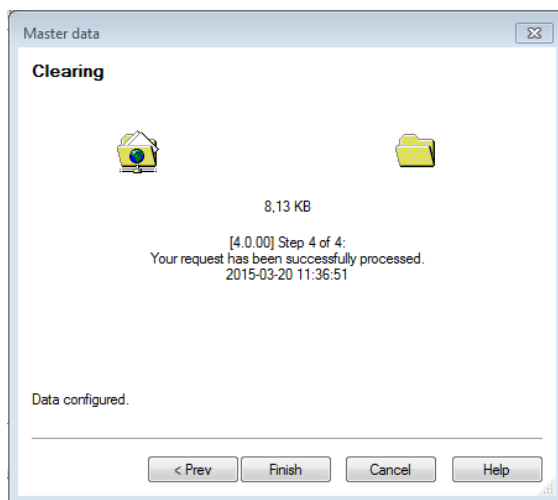


- Select if the release should be by downloading the data (internet connection required)
- or by the file received from Comcotec.

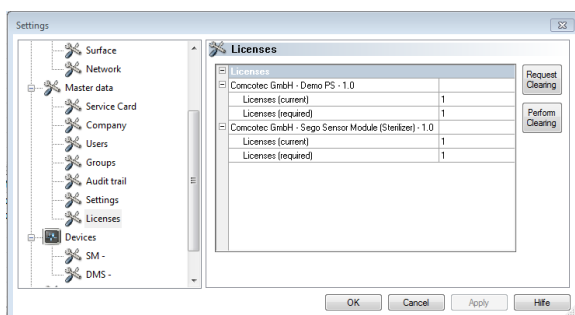
If you have selected the option “Use existing data from a file”:



- If necessary click on “Modify” and select the path



The devices are released and the licenses are updated.



The current licenses are shown after successful release.

- Restart SegoSoft
- The company certificate is now valid and the devices are released.

Congratulations, you can use SegoSoft and all its features!

6. Annex

6.1 Ensuring system integrity

It is essential to ensure that the released software can only be installed unchanged. This is to prevent desired or inadvertent changes from being made over the course of time, such as computer viruses, bit errors because of technical errors or manipulations in configuration files.



The installation may therefore only be carried out with original storage media or a version cleared by Comcotec Messtechnik GmbH.

A checksum is to be formed via the installation files (Windows Installer files) of the original storage medium or the version cleared on the website of Comcotec Messtechnik GmbH, based on which the integrity of the storage media used or the downloaded version can be checked prior to installation.

To carry out the checking process a suitable checksum should be calculated based on the MD5 and SHA-256 algorithm. Microsoft Windows operating systems do not feature a program to calculate the MD5 or SHA-256 checksums as standard.

There are however, various free tools that can be used for the calculations, such as the "File Checksum Integrity Verifier" from Microsoft or free software available online, such as MD5sum, MD5 File Hasher, to name but a few.

Now generate the MD5 checksum for the installation files (Windows installer files, data extension .msi) of the original storage media or the version of SegoSoft cleared by Comcotec Messtechnik GmbH.

Now check the checksums you have calculated against the Comcotec Messtechnik GmbH checksums.

To do this enter the MD5 checksum you have calculated in the text field at a website provided by Comcotec <https://www.segosoft.info> under ServiceCenter / Certificates

If this checksum complies with the correct checksum from SegoSoft, the certificate for the installation file can be downloaded. This document holds information on the version, file name, file size and hash values (MD5, SHA-256).

To ensure the integrity of the installation file, it is important to establish the SHA-256 checksum of the installation file and to check this against the SHA-256-Hash value on the certificate.



Only run the installation of Segosoft if the calculated checksums comply with those provided by Comcotec.

6.2 Cryptographic procedure

SegoSoft uses the Microsoft Crypto-Library of the operating system to generate the user certificates and to create the digital signatures. The following functionalities are used:

- Generating cryptographically secure RSA key pairs (key length 3072 Bit)
- Generating X.509 certificates for public RSA keys, saving the X.509 certificates
- Generating cryptographic hash values in accordance with SHA-2 (SHA256)
- Generating digital RSA signatures based on the above mentioned X.509 certificates to be embedded in the PDF/A documents

If necessary the Microsoft Crypto-Library can be exchanged with secure random number generation, if there is a compatible interface to the cryptography API: Implement Next Generation (CNG) from Microsoft. For further information please contact Comcotec Messtechnik GmbH.

6.3 Manufacturer information



Comcotec Messtechnik GmbH
Gutenbergstr. 3
D- 85716 Unterschleißheim
Germany

6.4 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:

<div>CHREP</div>	<div>CHRN-AR_20003589</div> <div>QSMed.ch GmbH, Hotzestrasse 14, CH-8006 Zürich</div> <div>authorised representative CHE282895126</div> <div>Public communication data info@qsmmed.ch, +41 43 543 44 44</div> <div>Contact person Dr. Markus Fehr, +41 43 543 44 44, info@qsmmed.ch</div> <div>PRRC Dr. Markus Fehr, +41 43 543 44 44, info@qsmmed.ch</div>
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Phone: +49 (0) 180 230 31 31*
email: info@miele-professional.com

*0,06€ per call from a German fixed network, cell phone rates max. 0,42€

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For further international contacts, please have a look at: www.miele-professional.com

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