SEGO® secure

A smart, hygienic decision

SEGO®

Instrument reprocessing
documented securely

Bundesamt
für Sicherheit in der
Informationstechnik

Deutsches
IT-Sicherheitszertifikat

Zertifikat Nummer:
BSI-DSZ-CC-0930-2014

bis EAL 4

Foreword

Hygiene is one of the foundations of medical treatment and the most important precaution when it comes to protecting the health of your patient and staff.

As such, compliance with the specified hygiene regulations and complete documentation of the hygiene chain has been the top obligation of every doctor and healthcare professional for some time already.

The purpose of the specified regulations, laws and standards is to avoid diseases, identify infections as early as possible and prevent their spread.

As the criteria are constantly being modified and adjusted, it is not always easy to implement them in day-to-day practice and maintain a clear overview. In addition to personal motivation, the awareness of the personnel and clear structures, automated processes above all help to avoid errors and integrate the necessary adaptation to evolving criteria in day-to-day practice.

Which is exactly why the SEGO® Range was developed. The modern documentation of the instrument reprocessing is both digital and time-saving. The process documentation forms the basis for the documentation of the instrument reprocessing. Using the SEGO® Range, it is child's play for users to comply with the RKI guidelines quickly, simply and efficiently and to avoid errors at the same time. It is the first product of its kind to be awarded a CE mark as a medical device and be certified by the German Federal Office for Information Security (BSI).

The SEGO® Range can thus be described as a defence insurance for the practitioner. But SEGO® is much more than that. With its user-friendly structure, it reduces the necessary administrative efforts to a minimum, saving the personnel crucial time that can be better invested in other areas of day-to-day practice.

That's by no means the only reason that SEGO® is an important milestone on the road to the digital future.

The SEGO® Range

SEGO® is the solution for highly automated and secure documentation of the reprocessing of your instruments:

- **more efficient than any other system**
- **certified security**
- **expandable at any time**

What SegoSoft can do for you

- Documented release decisions in accordance with the guidelines issued by the Robert Koch Institute (RKI)
- Fully automated documentation of the cleaning and sterilization procedures
- Minimal workload for your personnel when it comes to documenting the instrument reprocessing
- Network-compatible and compatible with all popular devices and manufacturers

SegoLabel

SegoLabel is the solution for guideline-compliant, traceable and unambiguous labelling of reprocessed instruments that are sterile when used on patients:

- **Fully automatic following every instrument release**
- **Simple and self-explanatory**

What SegoLabel can do for you

- Only printing labels on positively released instruments safeguards the reprocessing process
- Avoiding manual inputs eliminates labelling errors

SegoAssign plus

SegoAssign plus is the solution for efficient documentation of the instruments used on the patient:

- **independent and quick**
- **detailed and comprehensive**

What SegoAssign can do for you

- Simple and detailed instrument-specific assignment to patient
- Self-explanatory management of sterile goods
- Comprehensive tracking of the instruments/batches used on the patient displayed on the screen or as a printout
- Rapid identification of all patients treated with a batch
- Compatible with all the standard practice management software

The ideal tool for documentation

The user-friendly SEGO®-products are easy to install and run. It offers reliable documentation of the **disinfection** and **sterilization process** which can be traced precisely at any time. Complete documentation is indispensable for **quality assurance** and protects you against liability risks.

The SEGO® Range – Unlimited possibilities

SEGO® allows the simple, comprehensive and time-saving documentation of the reprocessing procedure. **SEGO® is completely medical device vendor independent!**

This makes it possible to document as many different medical devices, e.g., sterilizers, cleaning machines, disinfection devices and sealing machines, as you like at the same time and without creating too much work for your personnel.

SegoLabel automates the printing of barcode labels and ensures clear and correct labelling of all the sterile goods to be stored.

SegoAssign plus “talks” to all standard practice and patient management systems and, in addition to the efficient assignment of the instruments to the patient, also allows you to call up and print out extensive patient-related assignment data.

The SEGO® Range
can do much more:

- Format of the documents is suitable for **long-term preservation**
- **Cooperation with the standard software systems** in the fields of patient, material and medical device management
- All the batch-related data are available in a **tamper-proof document**

The SEGO® range integrates seamlessly into your hygieneconcept and your familiar workflow. Efficient, secured processes and compatibility with all standard practice management systems ensure that you always have everything firmly under control when complying with the hygiene specifications!

SEGO® allows you to prove your compliance with hygiene standards at any time – **simply and reliably!**

Your protection against liability risks

If an allegation arises in the course of medical treatment, it is a question of shifting the burden of proof and the attending doctor must prove that the instruments were reprocessed in accordance with the pertinent regulations. **Inadequate documentation can be seen as equivalent to malpractice,** which is viewed as negligence or even gross negligence by courts and can result in the loss of insurance cover. **SegoSoft removes this uncertainty** for you in a very simple way.

SegoSoft is certified security – tested and certified by the German Federal Office for Information Security (BSI). With this globally recognized security certification, which is unique in the documentation of medical device reprocessing, a federal office confirms the high quality and security standard of SegoSoft as an independent authority not affiliated with the manufacturer.

SegoSoft is a Class IIb active medical device.

§

The **legal provisions** are precisely regulated:

- Medical Device Directive
- Medical Devices Act **(MPG)**
- Medical Devices Operator Ordinance **(MPBetreibV)**
- Infection Protection Act **(IfSG)**
- Occupational Safety and Health Act **(ArbSchG)**
- Accident prevention regulations **(UVV)**
- Robert Koch Institute guidelines on hygiene and reprocessing

Digital documentation

The digital form offers the ideal solution for minimizing the documentation efforts for instrument reprocessing. However, it has to be as fail-safe as manual documentation.

With the introduction of the advanced electronic signature, the legislative authority created the possibility of signing documents
electronically. **It is created and assessed by a publicly recognized,**
verifiable and standardized, cryptographic procedure.

Long-term preservation is ensured by the PDF/A-1 format used, which is defined by the ISO 19005-1:2005 standard. The format is electronically signed and as such is tamper-proof and thus legally valid.

§

Digital documents are **legally admissible,** if:

- The **authorship** of the documentation is always clear
- The **authenticity of the document** can always be checked
- Any subsequent **modifications are easily identifiable**
- The **documentation is traceable**

§

The following applies for **digital documents**:

- German Digital Signature Act **§ 2 No. 2 SigG**
- German Code of Civil Procedure **§ 144, 371 f. ZPO**
- German Code of Criminal Procedure **§ 86 StPO**
- German Code of Administrative Court Procedure **§ 96 Para. 1 VwGO**

SEGO® – the **efficient and secure method** for implementing the statutory requirements

The rapid, efficient solution

If the thermal disinfector or sterilizer is started, **the processdocumtation records all the relevant data from the reprocessing procedure automatically.**

Following unloading and visual inspection, the only task the professional personnel needs to do is judge the automatic reprocessing with a few clicks on the computer, release the products and complete the release dialogue by entering a password.

No further working steps are required for secure documentation with SegoSoft.

Resources are saved by:

- **Simple handling**
- **Fully automatic** data recording
- Personal **release decision**
- **Easily navigated archive**
- **Personalized documentation fields,** e.g., Helix test, previous manual cleaning

Unique – SEGO® service – more than just support

In this digital era, in which technologies are evolving at a breathtaking rate and we are confronted with new innovations practically every day, customer care and support performed by trained professionals is completely indispensable.

When you choose the SEGO® Range, you also get access to an extensive range of knowledge. In addition to the application-specific help that goes without saying, this also includes

- ☑ network administrators
- ☑ medical device consultants
- ☑ employees with the professional knowledge of the technical sterilization assistant "Fachkunde I" course and who have completed the "Fachkunde II" course
- ☑ process validation and its areas (DQ, IQ, OQ, PQ, MQ), as explicitly required in the QM systems
- ☑ configuration management – customer-specific data transfer / device connection

The SEGO® sophisticated configuration management fulfils all the requirements placed on a medical device and allows us to offer you tailored support at all times. Whatever your problem, we can advise you and develop a customized solution based on your system and software environment.

In addition, Comcotec offers its service in three languages (English, French and German).

The Service Card offers you rapid, targeted assistance, as the SEGO® Service then knows what devices and configurations you are using and can update the program without any problems.

By the way: We don't keep our expertise to ourselves. Comcotec hosts regular training sessions and courses all across Germany, communicating its expertise to everyone who wants to improve hygiene standards in medicine and other fields.

Our training programme

- > Online user training courses – whenever you like
- > Further training for technicians
- > Hygiene courses for your practice team
- > Expert knowledge in dental and medical practices

Carefree thanks to Service Card

Comcotec offers SegoSoft users a comprehensive software maintenance and support contract for optimal customer care.

The Service Card bundles all services required for smooth operation in a transparent and easily calculable package.

You also can reach us by phone!
Use our service phone

+ 49 89 3270 889 10
info@segosoft.info | www.segosoft.info

com|GO|tec®

We ensure that your hygiene documentation is always up to date.

What your **Service Card** offers you:

- **Support via telephone, remote maintenance** (TeamViewer) and **e-mail**
- **SEGO® product updates**
- **Continuous software updates** to reflect the latest documentation specifications
- The **renewal of the digital signature as stipulated by the BSI**

SEGO® – **Technology leader** in the documentation of the instrument reprocessing

Products

With the SEGO® range we offer you coordinated and innovative software and hardware modules that you can expand at any time.

SEGO® secure

Software

SegoSoft* – The SegoSoft process documentation system allows the simple and **time-saving documentation of reprocessing procedures.** This makes it possible to document as many different devices, e.g., sterilizers, cleaning machines, disinfection devices and sealing machines, from **as many different manufacturers** as you like at the same time.

SEGO® SOFT Process Documentation

Add-ons

SegoLabel* – Barcode label printing for correct labelling of your instruments for storage and patient-specific assignment.

SEGO® LABEL Process Documentation

SegoAssign plus* – The **treatment documentation** allows efficient and complete digital assignment.

SEGO® ASSIGN plus Sterile Goods Management

Hardware

Sego4Star* - is the web-based solution for the digital documentation of up to 4 processing devices. Platform independent.

Sego4Star**

SegoConnect Module Advanced* – is a specially designed serial to network converter, which makes your medical devices network compatible.

SegoConnect Modul Advanced*

SegoSerial Industrial Grade Converter* – is a specially designed dual serial to USB converter, which guarantees a secure connection to medical devices.

SegoSerial Industrial Grade Converter*

SegoLabel Starter Kit* – Complete package comprising hardware, software and accessories. The labels are printed with SegoLabel as soon as the products are released. All the process-relevant data and the name of the person releasing the products are transferred to the tickets automatically.

SegoLabel Starter Kit*

* Detailed information on our recommended software solutions can be found at www.segosoft.info.
** only available through certified dealers

SEGO® – eine Marke von Comcotec®

www.segosoft.info

comcotec® Messtechnik GmbH

SEGO®

Process validation is an essential and critical element for the security and correct functioning of medical devices and laboratory trials.

- Process validation is explicitly required in QM systems (DIN EN ISO 9001:2008, DIN EN ISO 13485:2003, GMP, DIN EN ISO 15189:2007), in the guidelines of the German Medical Association (RiliBÄK:2008) and in the German Medical Devices Operator Ordinance (MPBetreibV:2002).
- It includes preparation of documentary confirmation that a process will always create a result or product which conforms to the set requirements.

Process validation areas	Contains the	In short
Design qualification (DQ)	documentary confirmation that the product (device) is suitable for the intended use in accordance with the planned requirements/ specifications	Defines the criteria for a purchase decision
Installation qualification (IQ)	documentary confirmation that the version of the product (device) specified in the job and installed corresponds to the intended use and manufacturer's specifications	Describes all the installation steps for installing the product (device) and commissioning it
Operational qualification (OQ)	documentary confirmation that the version of the product (device) installed functions in accordance with its specifications	Ensures the basic functioning of the product (device) under the conditions and the place it is installed and in the working environ-ment
Performance Qualification (PQ)	documentary confirmation that the product (device) functions in accordance with the regulations and in compliance with the requirements (specifications) when operated under real (routine) conditions	Confirms the reproducible and permanently positive performance of a product (device) in accordance with the specifications when used under normal circumstances
Maintenance Qualification (MQ)	documentary confirmation of regular main-tenance. Description of all the necessary cle-aning, maintenance and servicing measures	Description of the necessary efforts for maintenance of the product (device)

SegoSoft® is certified security: tested and certified by the German Federal Office for Information Security (BSI).

Bundesamt für Sicherheit in der Informationstechnik

Deutsches IT-Sicherheitszertifikat

bis EAL 4

Zertifikat Nummer: BSI-DSZ-CC-0930-2014

Class IIb
active medical device.

SEGO®

SEGO® secure

System requirements

The system performance for the SEGO®- range should exceed the recommended minimum depending on the number and type of connected devices. This will ensure trouble-free operation. SEGO® is designed to run on standard personal computers. The configurations given here have been tested on a number of different systems.

Recommended

- Adobe Acrobat Reader*, recommended Version 11.08 or higher
- Backup system

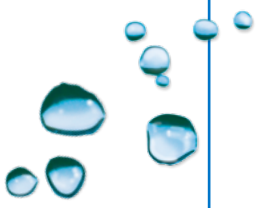
Operating systems

- MS Windows 7 SP1*
- MS Windows 8.1*
- MS Windows 10*

SEGO®'s data security and access management functions may be restricted if used with other operating systems.

Hardware

- CPU frequency of min. 2 GHz, higher recommended
- Min. 2 GB RAM, 4 GB recommended
- SVGA graphics system with 1,024 x 768 pixels, 17" monitor, HD 1,920 x 1,080 recommended
- Hard drive with min. 64 GB free memory, 256 GB and above recommended
- CD ROM drive**
- RS 232 C serial interface, SB interface with SegoSerial Industrial Grade Converter (in connection with serial end devices) recommended
- Internet***; Ethernet recommended



* *All the brand names and designations used are registered trademarks and brands of the respective owners and are used here merely for descriptive purposes*

** *Only required for installation CDs*

*** *Urgently required for Internet-ready devices; with corresponding add-ons and with remote support – it is otherwise not possible to guarantee the full and correct function of the system!*

**** *The latest system requirements can be found at: www.segosoft.info*

*Last amended on: January 2017*****

com|co|tec®

Messtechnik GmbH

Gutenbergstr. 3 | D-85716 Unterschleißheim | Phone: +49 89 3270 889-0 | Fax: +49 89 3270 889-89