SEGO® | SOFT
Process Documentation

Requirements of the HTM 01 05 regarding the documentation of the medical devices processing

Compliance

SegoSoft® 6.0 and SegoSoft 2010
Process Documentation

White paper

Document:

„Declaration of Compliance: Requirements of the HTM 01 05 regarding the documentation of the medical devices processing“

Released:

	Name	Function	Date, Sign
created / changed:	M.Becker		
checked / released:	Manfred Korn	General Manager	

History:

Rev.	Date	Author	Action	check QB
1.0	20.11.08	M.Becker	Created	20.11.08 M. Korn
1.1	12.12.09	M.Becker	Changed	12.12.09 M. Korn
1.2	22.04.10	M.Becker	Correction, literal error	22.04.10 M. Korn

Referenced documents:

“Health Technical Memorandum 01-05: Decontamination in primary care dental practices ”

Requirements of the HTM 01 05 regarding the documentation of the medical devices processing.....1

Compliance.....1

3.19 Records.....4
4.3 Types of sterilizer.....4
4.13 Small Sterilizers: Use and testing of small sterilizers, section 2.....5
4.13 Small Sterilizers: Use and testing of small sterilizers, sections 3 and 4.....6
4.14 Small sterilizers.....6
4.16 Small sterilizers.....7
4.18 – 4.19 Small sterilizers: Daily testing and housekeeping tasks 7
4.21 Small sterilizers.....8
4.22 Small sterilizers.....8
4.23 Small sterilizers.....8
4.26 Packaging and related decontamination strategy.....9
10.9 Decontami-nation equipment: washer-disinfectors and sterilizers.....9
11.14 Documentation.....9
11.15 Documentation.....10

"Health Technical Memorandum 01-05: Decontamination in primary care dental practices"			
3.19 Records	Washer-disinfector logbooks and records should be kept by the designated "user" – an identified member of the practice staff. Cycle parameters should be recorded together with details of routine testing and maintenance of the equipment used. The use of automated data-loggers or interfaced small computer-based recording systems is acceptable, provided the records are kept securely and replicated. It is recommended that records be maintained for not less than two years.	SegoSoft includes release for use with checking of the process parameters (including those over the entire course of the process), batch-specific documentation of the preparation process, batch-specific documentation of the daily routine tests, and labelling of the packaged goods. Released goods are checked (visual inspection) (checking that the packaging is intact and dry, etc.) by the authorised personnel and stored in a tamper-proof way in the SegoSoft documentation. The document format corresponds to ISO standard PDF/A (ISO 19005-1:2005) for long-term archiving of the documented data. This ensures that the data remains available during the retention period. SegoSoft automatically synchronises the database in the network backup drive.	
4.3 Types of sterilizer	" ... prion infectivity. In the case of newer machines, the parameters monitored for each cycle of use will be stored and/or available as a print-out to provide a short-term record. The use of automated data- loggers or interfaced small computer-based recording systems is acceptable provided the records are kept securely and replicated. These records should be photocopied, as the quality of the print-out fades over time..... The record should, at minimum, document the absence of a failure warning or the temperature/pressure achieved as appropriate to the indications provided. It is recommended that records be maintained for not less than two years."	SegoSoft documents all process-relevant process parameters (including those over the entire course of the process). SegoSoft automatically synchronises the database in the network backup drive. Data is archived in PDF format. This format is provided for long-term archiving in accordance with ISO 19005-1. This ensures that the data can be read and checked over the prescribed retention period. It is the customer's responsibility to define the backup procedure for records during the retention time. Comcotec is glad to help with this. SegoSoft documents are digitally archived (paperless documentation). Sego document protection and the Sego long-term archiving format are based on public standards and can be checked publicly (e.g., on the authorities' PCs) by simple and freely available means.	

"Health Technical Memorandum 01-05: Decontamination in primary care dental practices"			
4.13 Small Sterilizers: Use and testing of small sterilizers, section 2	„... Parametric release is defined as the release of a batch of sterilized items based on data from the sterilization process. All parameters within the process have to be met before the batch can be released for use."	SegoSoft includes release for use with checking of the process parameters (including those over the entire course of the process), batch-specific documentation of the preparation process, batch-specific documentation of the daily routine tests, and the labelling of the packaged goods. Released goods are checked (visual inspection) (checking that the packaging is intact and dry, etc.) by the authorised personnel and stored in a tamper-proof way in the SegoSoft documentation. The releasing person is responsible for carrying out the prescribed visual inspection on the product to be released. Release in SegoSoft only becomes possible once the result of the visual inspection is confirmed, and can only be made by authorised personnel. SegoSoft documents are electronically signed. The electronic signatures are embedded components of the PDF documents. They cannot be removed, copied, or tampered with without this being immediately detectable.	

"Health Technical Memorandum 01-05: Decontamination in primary care dental practices"			
4.13 Small Sterilizers: Use and testing of small sterilizers, sections 3 and 4	„3. Testing is an integral part of ensuring that a small sterilizer consistently performs to operating parameters set during the machine's commissioning. Failure to carry out routine periodic tests and maintenance tasks could compromise safety and have legal and insurance-related implications for the Registered Manager (see paragraph 9.3). 4. A schedule for periodic testing should therefore be planned and performed in accordance with Section 3. The schedule should provide details of daily, quarterly and yearly testing or be in accordance with manufacturers' guidelines. Each sterilizer should have a logbook (file) in which details of the following are recorded: – maintenance; – validation; – faults; – modifications; – routine tests (see Appendix 3).	SegoSoft documents the measurements of process parameters recorded during preparation in a tamper-protected document, and allows them to be compared with the parameters specified in the validation protocol for every process record. SegoSoft includes batch-specific documentation of the daily routine tests, and indicates deviations from the correct course of the process as well as errors and labelling of the packaged goods. SegoSoft documents the measurements of process parameters recorded during preparation in a tamper-protected document, and allows them to be compared with the parameters specified in the validation protocol for every process record.	
4.14 Small sterilizers	„Health Service Circular (HSC) 1999/053 and the subsequent 'Records management: code of practice parts 1 and 2' (April 2006) provide guidance on the length of time for which records should be retained. Reference should be made to the time period of legal rights of patients, and all relevant documentation should be retained for the practice to meet any request within these rights. The code requires that these records be maintained for not less than two years, although longer periods may be applicable subject to local policy-making at PCT level.	The data is archived in PDF format. This format is provided for long-term archiving in accordance with ISO 19005-1. This ensures that the data can be read and checked over the prescribed retention period. It is the customer's responsibility to define the backup procedure for records during the retention time. Comcotec is glad to help with this.	

"Health Technical Memorandum 01-05: Decontamination in primary care dental practices"			
4.16 Small sterilizers	„If the sterilizer has an automatic printer, the print- out should be retained or copied to a permanent record. If the sterilizer does not have a printer, the user will have to manually record the following information in the process log: – date; – satisfactory completion of the cycle (absence of failure light); – temperature/pressure achieved; – signature of the operator;"	SegoSoft documents the measurements of process parameters recorded during preparation in a tamper-protected document. SegoSoft includes release for use, batch-specific documentation over the preparation process, batch-specific documentation of the daily routine tests, and labelling of the packaged goods. Sterile goods can only be released by authorised personnel, and this requires confirmation of visual inspection in SegoSoft. SegoSoft includes documentation of the release decision and process when there are deviations from the correct process sequence. SegoSoft includes privileges-based user and group administration that includes exact naming and specification of the persons authorised to make the release.	
4.18 – 4.19 Small sterilizers: Daily testing and housekeeping tasks	4.18 The daily tests should be performed by the operator or user and will normally consist of: – a steam penetration test – Helix or Bowie-Dicktests (vacuum sterilizers only); – an automatic control test (all small sterilizers) in line with manufacturers' instructions. 4.19 These outcomes should be recorded in the logbook together with the date and signature of the operator."	SegoSoft documents the measurements of process parameters from routine tests and controls recorded during preparation in a tamper-protected document, and allows them to be compared with the parameters specified in the validation protocol for every process record. A release can only be made by authorised personnel and is stored with a reference to the unique batch number and the releasing person. SegoSoft documents are electronically signed. The electronic signatures are embedded components of the preparation documents. They cannot be removed, copied, or tampered with without this being immediately detectable. Every signature uniquely identifies a releasing person.	

"Health Technical Memorandum 01-05: Decontamination in primary care dental practices"			
4.21 Small sterilizers	„Sterilizers should not be used until the daily tests and housekeeping tasks have been carried out and the results found to be satisfactory."	SegoSoft documents the measurements of process parameters from routine tests and controls recorded during preparation in a tamper-protected document, and allows them to be compared with the parameters specified in the validation protocol for every process record. After carrying out the routine tests and documenting them in SegoSoft, the releasing person is responsible for releasing the medical device for daily operation. The release decision is stored with a reference to the releasing person	
4.22 Small sterilizers	„Before carrying out the daily tests, the user should: – clean the rubber door seal with a clean, damp, non-linting cloth; – check the chamber and shelves for cleanliness and debris; – fill the reservoir with freshly distilled water or RO water; – turn the power source on."	SegoSoft allows tamper-protected documentation of the daily manual routine tests	
4.23 Small sterilizers	„If the sterilizer fails to meet any of the test requirements, it should be withdrawn from service and advice should be sought from the manufacturer and/or maintenance contractor."	SegoSoft documents the measurements of process parameters from routine tests and controls recorded during preparation, and allows them to be compared with the parameters specified in the validation protocol. If the medical device does not meet the requirements, the authorised person is responsible for blocking the operation of the medical device after carrying out the routine tests and documenting them in SegoSoft. The failed tests are documented in SegoSoft with a reference to the person authorised to make the decision.	

"Health Technical Memorandum 01-05: Decontamination in primary care dental practices"			
4.26 Packaging and related decontaminatio n strategy	„Regardless of the packaging used, where instruments are to be stored, the date by which they should be used or by which they are subject to a further decontamination cycle should be clearly indicated on the packaging."	SegoSoft includes labelling of the goods intended for storage (barcode label printing, including: device name, device serial number, expiry date, releasing person, unique batch number as a number and barcode, and free text). Labelling by SegoSoft is only possible after release.	☑
10.9 Decontami-nation equipment: washer-disinfectors and sterilizers	„... process data capture (that is, chart recorder/data recorder/printer): this information is needed to clarify the audit process on product release – manual recording of displayed parameters at the end of a cycle should be recorded to an appropriate log. "	SegoSoft documents are digitally archived (paperless documentation). Sego document protection and the Sego long-term archiving format are based on public standards and can be checked publicly (e.g., on the authorities' PCs) by simple and freely available means. SegoSoft includes documentation of the entire course of the process, batch-specific documentation of the preparation process, and batch-specific documentation of the daily routine tests. A release can only be made by authorised personnel.	☑
11.14 Documentation	Documentation provides the only evidence of completed work. Absence of documentation for any work item will indicate omission of that item. It is important that all documentation relating to decontamination equipment is up-to-date and is retained locally for audit/inspection purposes.	SegoSoft documents are digitally archived (paperless documentation). Sego document protection and the Sego long-term archiving format are based on public standards and can be checked publicly (e.g., on the authorities' PCs) by simple and freely available means. SegoSoft documents are electronically signed. The electronic signatures are embedded components of the PDF documents. They cannot be removed, copied, or tampered with without this being immediately detectable. The data is archived in PDF format. This format is provided for long-term archiving in accordance with ISO 19005-1. This ensures that the data can be read and checked over the prescribed retention period.	☑

"Health Technical Memorandum 01-05: Decontamination in primary care dental practices"			
11.15 Documentation	The following documentation should be retained for the equipment and be readily/freely available at any time: – specification; – validation report, where the preferred option (option A) is selected – independently monitored by the Authorising Engineer (Decontamination). Where option B is followed, a service report (validation) signed by the service engineer or Competent Person (Decontamination) on behalf of the manufacturer's agent; – performance qualification details – loading patterns and required parameter values; – logbook of periodic testing; – logbook of plant history, component replacement etc; – process log; – training and competency records; – documentation for Pressure Systems Safety Regulations 2000 including written scheme of examination and examination reports; – list of all named designated responsible persons; – other relevant documentation.	SegoSoft documents the measurements of process parameters (entire course of process) from preparation processes, routine tests and controls recorded during preparation in a tamper-protected document, and allows them to be compared with the parameters specified in the validation protocol for every process record. Released goods are checked (visual inspection) (checking that the packaging is intact and dry, etc.) by the authorised personnel and stored in a tamper-proof way in the SegoSoft documentation. Sterile goods can only be released by authorised personnel, and this requires confirmation of visual inspection in SegoSoft. SegoSoft includes documentation of the release decision and process when there are deviations from the correct process sequence. SegoSoft includes privileges-based user and group administration that includes exact naming and specification of the persons authorised to make the release. The user is responsible for separate storage of additional documents that are produced not on a daily basis but rather a single time (e.g., the validation protocol). The SegoSoft record allows comparison with the parameters specified, e.g., in the validation protocol, for every process record.	

Legend:

	Requirements fulfilled
	Participation of the customer needed / duty of the customer to fulfill requirements
n. a.	Not applicable