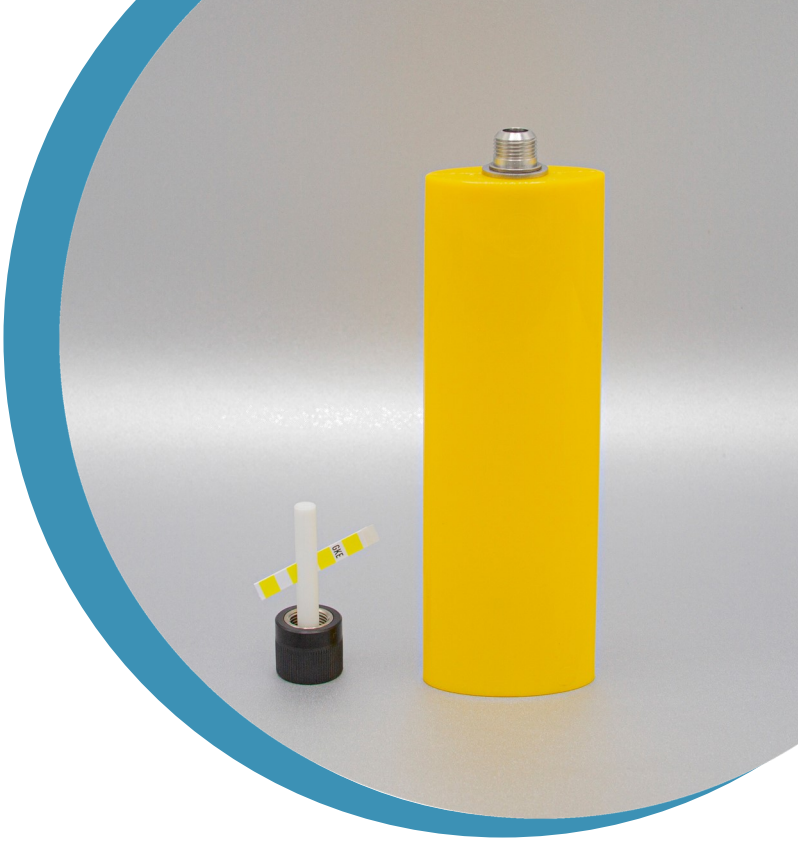
CLEANING
STERILIZATION



Dental-BMS
Batch Monitoring System to monitor dental loads

Application
The GKE Steri-Record® batch monitoring system (BMS) is used for routine monitoring of dental instruments in each cycle. The process challenge device (PCD) is designed to prove the steam penetration requirements of each load in order to get a successful test result where hand pieces are the most difficult instruments to sterilize. If more complex instruments are used that are not included in the dental load configuration of the Dental-BMS, it is recommended to use a process monitoring system (PMS), art.-no. 211-264. It is required that the instruments have been cleaned and disinfected in advance and the design of the instruments is validated so it can be sterilized in steam sterilization processes.

If a new instrument is launched into the market the European Medical Device Directive (MDD) requires a validated reprocessing procedure according to the European Standard EN ISO 17664 stated in the directions for use.

It is strongly recommended that the users assure that the reprocessing procedure according to EN ISO 17664 is available from the manufacturer when ordering new instruments, e.g. hand pieces.

Product Description
The GKE Steri-Record® Dental-BMS is a type 2 indicator according to EN ISO 11140-1 consisting of a "specific test load" (process challenge device = PCD). A specifically designed external case contains an internal stainless steel tube connected with a stainless steel capsule holding the "indicator system" (indicator strip) inside. The oval cross section of the PCD with a flat height of 2.5 cm allows the PCD to be placed horizontally in a table-top sterilizer.

Performance Characteristics
This Dental-BMS is validated with an "equivalence test" according to DIN 58921 using a typical dental instrument load configuration. The "equivalence test" is carried out in a laboratory accredited according to the standard EN ISO 17025. A test report is available on request. The inside of hand pieces is the most difficult part of an instrument to be sterilized. The successful sterilization of hand pieces does not only depend on the efficiency of the sterilizer program but also on the construction of the hand piece.

There are instruments on the market which cannot be sterilized with the most efficient steam sterilization processes due to inappropriate constructions preventing steam penetration in sealed areas resulting in non-sterility. These instruments are unsuitable and cannot be used in steam sterilization processes.

The use of the Dental-BMS ensures that typical dental load configurations are sterilized successfully.

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Operation Description

If all four bars of the chemical indicator turn from yellow to black it is an indication of sufficient steam penetration inside the PCD. This result ensures air removal and steam penetration into the whole load under the condition that the PCD is representing the load configuration.

Sufficient temperature, time and steam penetration

Insufficient air removal and steam penetration

Temperature achieved, but no air removal and no steam penetration

Insufficient temperature, no air removal and no steam penetration

Benefits

- The GKE Steri-Record® Dental BMS is the first Batch Monitoring System tailored to monitor dental loads in steam sterilization processes.
- The use of this Dental-BMS allows the monitoring of sterility inside of hand pieces not provided by recording pressure, temperature and steam quality in the chamber and/or using exposed indicator strips.
- The batch can be released without opening the pack to check the internal packaging indicator.
- All information relevant to release the load is supplied on completion of the process so that the person authorized can release the batch.
- Cost effective. Only one indicator strip is required for each sterilization process instead of one in each pack.
- Easy interpretation of the results due to precise colour change.
- The graduated colour change of the indicator bars informs about the magnitude of air removal and steam penetration into the PCD.
- Environmentally friendly, no unnecessary waste.
- GKE self-adhesive labels simplify recording with the GKE Steri-Record® documentation system.
- The indicator colour chemistry is a non-reversible chemical reaction. The indicator strip can be documented proof for several years without changing back to its original colour.
- The screw-cap consists of a highly thermal resistant material and stainless steel sandwich-construction that protects hands from high temperatures. The chemical indicator may be easily removed and evaluated on completion of each cycle.
- The innovative design and rationalized production provide a sensitive and cost effective test, where the PCD can be used for a considerable number of cycles. Its specifications remain constant over the lifetime of the device.
- All important parts are made of stainless steel or thermal resistant polymers. Seals are replaced easily.
- Continuous reproducibility of the results over the lifetime of the PCD if seals are precautiously replaced .
- All GKE chemical indicators are protected from bleeding by a polymer binders and surface coating and can be disposed with normal garbage.
- Assurance that only sterile released packs go into the operating room.

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Order Information

Each start-up kit contains one Compact-PCD® and 100 integrating indicator strips. Test devices are available separately as well. The indicator strips are available as refill packs without test devices containing a seal ring for the screw cap.

Art. No.	Quantity	Product Code	Content	Application
211-281	1 + 100	**C-S-BMS-Dental-OCPCD-KIT**	Compact-PCD® Dental BMS oval cross section (colour: yellow), integrating indicator strips	Monitoring Dental loads in steam sterilization processes
200-081	1	**C-S-BMS-Dental-OCPCD**	Compact-PCD® Dental BMS oval cross section (colour: yellow)	
211-251	100	**C-S-PM-SV1**	Refill pack integrating indicator strips, + 1 sealing kit	for all GKE BMS and PMS to be used in standard cycles
211-252	250			
211-255	500			
211-211	100	**C-S-PM-SV2**		for all GKE BMS and PMS to be used in prion cycles
211-212	250			
211-215	500			

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