

gke Steri-Record[®] Dental-BMS

STEAM

Batch Monitoring System (Dental-BMS) for steam sterilization processes

The first load-related batch monitoring system worldwide

The **gke Steri-Record[®]** Dental Batch Monitoring System (BMS) is the first BMS tailored to monitor dental loads in steam sterilization processes.

Quick evaluation of the results

The outside parts of the Dental-BMS are made of thermal insulating material and protect the hands from high temperatures after taking the test device out of the sterilizer chamber. Results can be checked immediately at the end of the cycle.

Durable and resistant

All important parts are made of stainless steel and are protected by an outside durable plastic case of highly thermal resistant materials.

Cost-effective and environmentally friendly

In contradiction to conventional systems the chemical indicator strip is the only consumable. Most conventional type 2 indicators are single-use systems where the PCD is disposed. The construction of the Dental-BMS requires only one indicator strip. The indicator is self-adhesive and can be placed on a documentation sheet after sterilization.

No Pollution and Non-Toxic

All **gke** chemical indicator strips are protected from bleeding by a polymer binder and surface coating and can be disposed with normal garbage.

Easy usage

Only one indicator strip is placed into the Dental-BMS secured by a screw cap. Afterwards the loaded test device is placed on a tray in the lower area of the steam sterilizer.

Easy interpretation

The indicator strip can be evaluated easily. Errors in the sterilization process are quickly identified. The graduated response allows the user to evaluate the magnitude of malfunction, i.e. insufficient steam penetration or an inadequate temperature-time integral.

Type 2 indicators

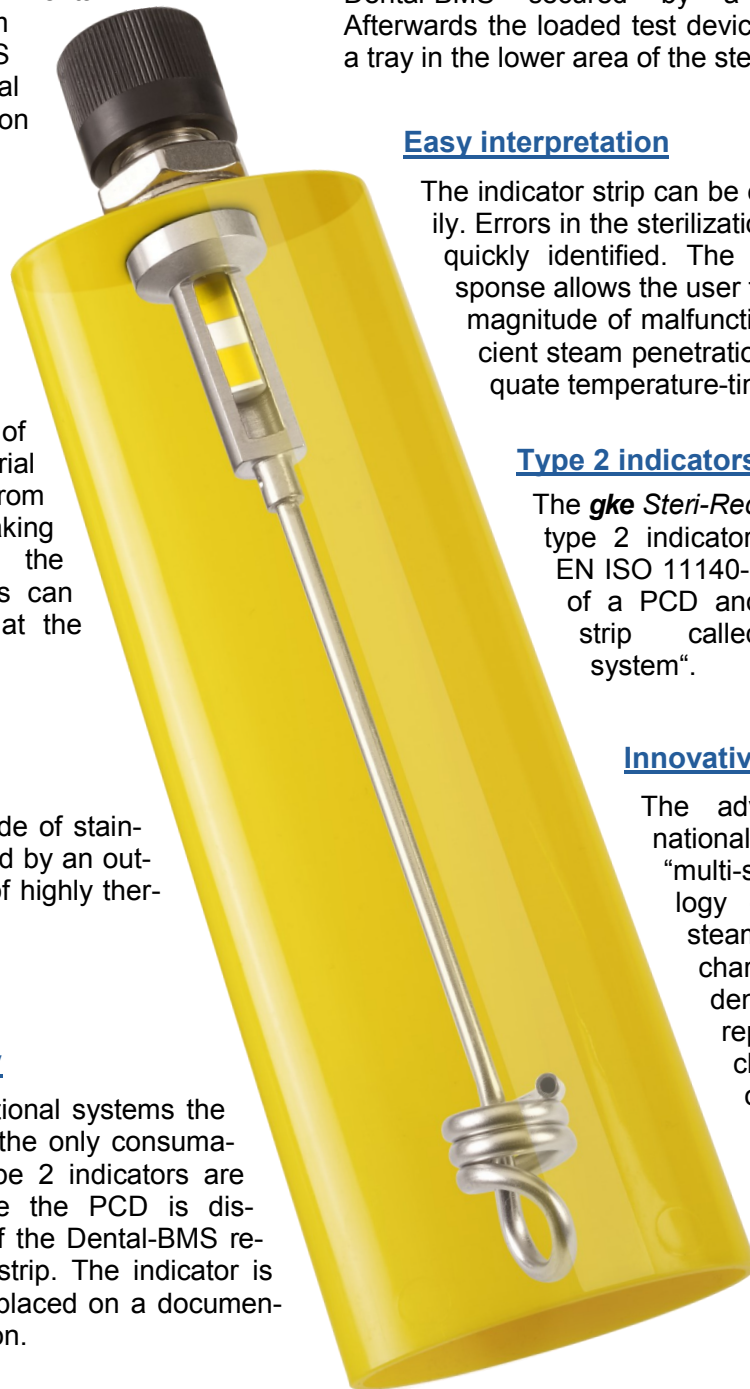
The **gke Steri-Record[®]** BMS is a type 2 indicator according to EN ISO 11140-1 and consists of a PCD and an indicator strip called "indicator system".

Innovative design

The advanced international patented "multi-stage" technology combines the steam penetration characteristics of dental loads BMS representing the characteristics of real loads such as hand pieces etc.

Reproducible results

The process challenge device (PCD) can be used for an unlimited number of cycles. The durable materials ensure reproducible results.



Application

This 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 the **gke Steri-Record®** 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.



Dental-BMS with hand pieces

Product Description

This **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.

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

Background Information

gke presents the next generation of BMS: the **gke Steri-Record**[®] Dental-BMS is especially designed for dental applications: extremely durable and resistant against mechanical stress and heat, easy to handle and usable for an unlimited number of test cycles. The process challenge device has been developed to monitor air removal and steam penetration in steam sterilization processes inside typical dental loads. Not only the surfaces but also the interior of dental hand pieces are checked for sterility.

In the past PCDs were used to check if the requirements of sterilizer standards (type test according to EN 285 BD-Test or EN ISO 13060 "Hollow Load Test") are met to ensure that the sterilizer is working properly. However, the assurance that a sterilizer is working according to the sterilizer standard specification does not ensure that the load inside the sterilizer is sterilized successfully. The efficacy of the sterilizer could be sufficient or insufficient according to the requirements of the load.

Therefore, the Dental-BMS is not calibrated to the requirements of a sterilizer standard but to the requirements for a typical packaged dental load.

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 pre-cautiously 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.

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.*	Product code	Quantity	Content	Application
211-281	C-S-BMS-Dental-OCPCD-KIT	1 + 100	Compact-PCD® Dental BMS <u>oval</u> cross section (colour: yellow), integrating indicator strips	Monitoring Dental loads in steam sterilization processes
200-081	C-S-BMS-Dental-OCPCD	1	Compact-PCD® Dental BMS <u>oval</u> cross section (colour: yellow)	
211-252	C-S-PM-SV1	250	Refill pack integrating indicator strips, + 1 sealing kit	for all gke BMS and PMS to be used in standard cycles
211-255		500		
211-211	C-S-PM-SV2	100		for all gke BMS and PMS to be used in prion cycles
211-212		250		
211-215		500		

* To the article numbers a 3-digit alpha code is added. The additional letter code refers to the language and/or customized version. It is only added on the outside label, the inside of the pack is identical to the article numbers on the above table.

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