gke *Steri-Record*® Ophthal-BMS

Batch Monitoring System (BMS) for ophthalmology instruments in steam sterilization processes

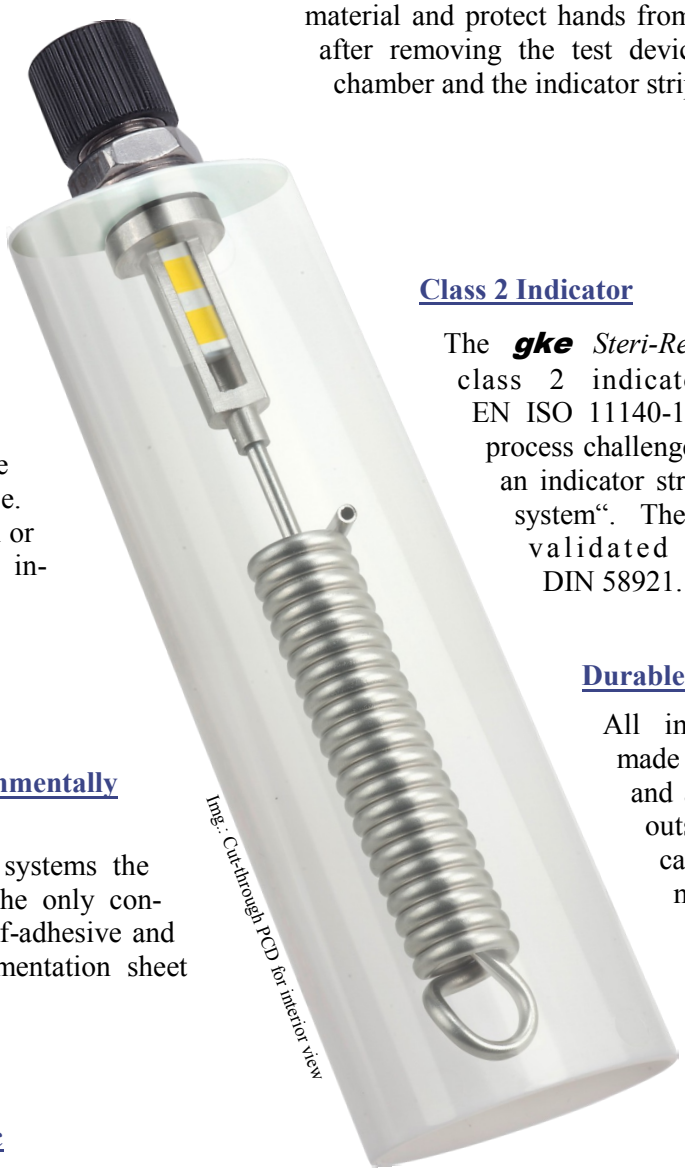
STEAM

Innovative design

A BMS using the advanced international patented "multi-stage" technology connecting different lengths and volumes simulates the steam penetration characteristics of ophthalmology loads.

Simple handling

Only one indicator strip is placed into the Ophthal-BMS secured by a screw cap. Afterwards the loaded test device is placed horizontally on a tray on the bottom of the steam sterilizer. The outside parts of the Ophthal-BMS are made of thermal insulating material and protect hands from high temperatures after removing the test device of the sterilizer chamber and the indicator strip out of the PCD.



Img.: Cut-through PCD for interior view

Quick, easy and clear evaluation

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 inadequate temperature-time integral.

Class 2 Indicator

The gke *Steri-Record*® BMS is a class 2 indicator according to EN ISO 11140-1 and consists of a process challenge device (PCD) and an indicator strip called "indicator system". The Ophthal-BMS is validated according to DIN 58921.

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 contrast to conventional systems the chemical indicator strip is the only consumable. The indicator is self-adhesive and can be adhered on a documentation sheet after sterilization.

Non 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.

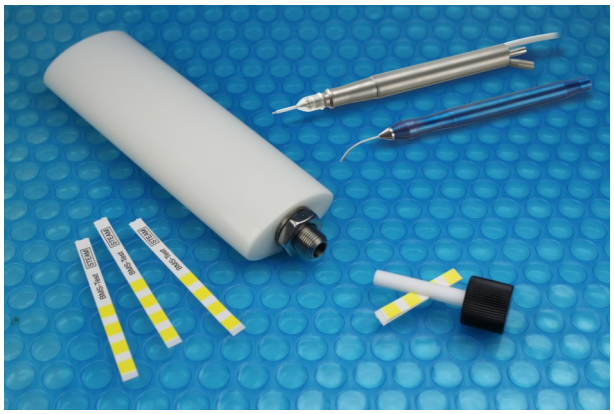
Reproducible results

The Ophthal-BMS can be used for an almost unlimited number of cycles. The high quality and the durable materials used ensure reproducible results.

Application

This Ophthal-BMS is used for routine monitoring of typical ophthalmologic loads in each cycle. The device is designed to verify steam penetration inside all typical ophthalmologic instruments. It has to be ensured that the instruments are cleaned and disinfected before the sterilization procedure. The directions for use of the manufacturer shall specify steam sterilization processes.

The European Medical Device Directive (MDD) requires from manufacturers offering reusable medical devices to the market that they are validated by a test laboratory according to EN ISO 17664. This test should ensure that a medical device can be reprocessed reproducibly (cleaned, disinfected and sterilized) with the methods described in his directions for use. It is recommended that users should request detailed reprocessing information from the manufacturer to ensure that instruments can be reprocessed properly.



Img.: ***gke*** *Steri-Record®* Ophthal-BMS

Product Description

The Ophthal-BMS is a class 2 indicator according to EN ISO 11140-1 consisting of a "specific test load" (process challenge device = PCD) and an "indicator system". 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 PCD is called ***gke*** *Steri-Record®* Compact-PCD® and consists of patented "multi-stage" technology connecting different lengths and volumes simulating the steam penetration characteristics of ophthalmology loads. The oval cross section of the PCD with a flat height of 2,5 cm allows the PCD to be placed horizontally in a tabletop sterilizer .

Performance Characteristics

The Ophthal-BMS is validated with an "equivalence test" according to German Standard DIN 58921 using a typical ophthalmologic 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 load configuration contains a maximum tube length of 50 cm. Long tubes are extremely critical goods to be cleaned and sterilized as well. In most cases they are exchanged as disposables.

Provided that tubes of more than 50 cm length are used as disposables and not re-sterilized, complex hollow instruments e.g. phaco hand pieces are the goods most difficult to be sterilized. These instruments have been used as a reference to configure the specification of the ***gke*** Ophthal-BMS. As a test method the validation procedure according to DIN 58921 is applied. The successful sterilization of an instrument does not only depend on the efficiency of the sterilizer program but also on the construction of the instrument. There are instruments on the market which cannot be sterilized with the most efficient steam sterilization processes due to inappropriate construction which prevent steam penetration inside sealed areas and therefore result in non-sterility. These instruments cannot be reprocessed in steam sterilization processes. Therefore it is required that the instruments are validated according to EN ISO 17664 and a verification is available from the manufacturer.

If an Ophthal-BMS is used to monitor a steam sterilization process it is ensured that all typical ophthalmic instruments including phaco hand pieces are successfully penetrated with steam and sterilized. Tube material of 50 cm lengths and longer cannot be monitored with the Ophthal-BMS. Either disposable tubes or a BMS with more demanding penetration characteristics shall be used in this case. The ***gke*** application laboratory may support you.

Operational 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

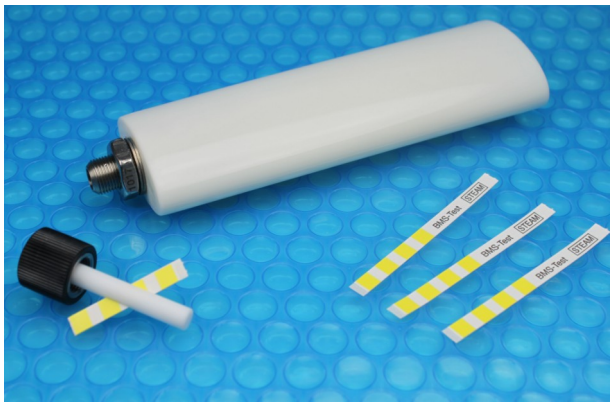
Insufficient air removal and steam penetration

Temperature achieved, but no air removal and no steam penetration

Insufficient temperature, no air removal and no steam penetration

Background Information

gke presents as the next generation the **gke** *Steri-Record*® Ophthal-BMS which is especially designed for ophthalmic 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 (PCD) has been developed to monitor air removal and steam penetration in steam sterilization processes inside typical ophthalmologic loads. Not only the surfaces but also the interior of hollow instruments, e.g. phaco hand pieces, are checked for sterility.



Img.: Ophthal-BMS

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" Helix-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 newly developed Ophthal-BMS does not relate to a sterilizer specification but to the requirements of ophthalmologic instruments in their packaging. Therefore the air removal efficacy of the sterilizer has to be sufficient enough for ophthalmologic loads.

Benefits

- The use of this Ophthal-BMS allows the monitoring of sterility inside of typical ophthalmologic instruments not provided by recording pressure, temperature and steam quality in the chamber and/or using exposed indicator strips. The PCD is validated according to DIN 58921 (typical ophthalmologic load).
- 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.
- Indicators in each package are not anymore necessary.
- 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.
- The colour change of the chemical indicator is based on a non-reversible chemical reaction. The indicator strip can be documented for several years without changing back to its original colour.
- Continuous reproducibility of the results over the lifetime of the PCD if seals are replaced precautiously.
- Environmentally friendly, no unnecessary waste.
- **gke** self-adhesive labels simplify recording with the **gke** *Steri-Record*® documentation system.
- The PCD is designed with an advanced international patented "multi-stage" technology.
- 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 Ophthal-BMS can be used for a large number of cycles. All important parts are made of stainless steel or thermal resistant polymers. Seals are replaced easily.
- Its specifications remain constant over the lifetime of the device.
- All **gke** chemical indicators are protected from bleeding by a polymer binders and surface coating during and after sterilization.

Order Information

Each start-up kit contains one Compact-PCD® Ophthal-BMS and 100 integrating indicator strips as well as a documentation sheet to be copied before daily use. Test devices are available separately as well. The indicator strips are available as refill packs without test devices since the test devices can be used for thousands of sterilization cycles. Seal rings for the screw cap are included in each refill pack.

Art.-No.	Product Code	Content	Application
211-291	**C-S-BMS-Ophthal-OCPCD-KIT**	1 Compact-PCD® Ophthal-BMS (colour: white), 100 integrating indicator strips	Monitoring ophthalmologic loads in steam sterilization processes
200-091	**BMS-Ophthal-OCPCD**	1 Compact-PCD® Ophthal-BMS (colour: white)	
211-252	**C-S-PM-SV1**	250 integrating indicator strips, 2 seal rings	Refill pack with integrating indicator strips for the Ophthal-BMS
211-255		500 integrating indicator strips, 2 seal rings	

gke GmbH
Auf der Lind 10
D-65529 Waldems
Germany
☎ +49 61 26 - 94 32- 0
🖷 +49 61 26 - 94 32- 10
✉ info@gke.eu
🌍 http://www.gke.eu

Your gke-sales partner: