CLEANING
STERILIZATION

Ophthal-BMS
Batch Monitoring System to monitor ophthalmologic loads

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 the directions for use. It is recommended that users should request detailed reprocessing information from the manufacturer to ensure that instruments can be reprocessed properly.

Product Description
The Ophthal-BMS is a type 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 table-top sterilizer.

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
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 replaced by 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 result in non-sterility. These instruments cannot be reprocessed in steam sterilization processes.

GKE-GmbH | Auf der Lind 10 | 65529 Waldems | Germany
mail info@gke.eu | **web** www.gke.eu

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.

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® Ophthal BMS is the first Batch Monitoring System tailored to monitor ophthalmologic loads in steam sterilization processes.
- 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.
- 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.

GKE-GmbH | Auf der Lind 10 | 65529 Waldems | Germany
mail info@gke.eu | **web** www.gke.eu

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
211-291	1 + 100	**C-S-BMS-Ophthal-OCPCD-KIT**	Compact-PCD® Ophthal BMS oval cross section (colour: white), integrating indicator strips	Monitoring ophthalmologic loads in steam sterilization processes
200-091	1	**C-S-BMS-Ophthal-OCPCD**	Compact-PCD® Ophthal BMS oval cross section (colour: white)	
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			

GKE-GmbH | Auf der Lind 10 | 65529 Waldems | Germany
mail info@gke.eu | **web** www.gke.eu

700-028 EN V07 03-2023