Directions for Use

Batch Monitoring Systems (BMS) to monitor ophthalmologic instruments

STEAM

1. Indicator systems Type 2 according to EN ISO 11140-1

Art.-No.*	Content [pc]	Product Code	PCD Version	Stated Value (SV)	Description
211-281	1+100	**C-S-BMS-Ophthal-OCPCD-KIT**	Compact oval (white)	121°C, 15 min 134°C, 3 min	Batch Monitoring System for Ophthalmologic loads
200-081	1	**BMS-Ophthal-OCPCD**		-	

2. Indicator strip refill packs

Art.-No.*	Content [pc]	Product Code	Stated Value (SV)	Description
211-251	100	**C-S-PM-SV1**	121°C, 15 min 134°C, 3 min	Integrating indicator strips for all GKE batch and process monitoring systems in standard steam sterilization processes
211-252	250			
211-255	500			
211-211	100	**C-S-PM-SV2**	134°C, 18 min	Integrating indicator strips for all GKE batch and process monitoring systems in prion programs
211-212	250			
211-215	500			

3. Spare parts

Art.-No.*	Content [pc]	Product Code	Description
200-111	5	**Replacement screw cap**	For all PCDs with M12 thread, colour: black
200-114	5	**Replacement screw cap**	For all PCDs with M12 thread, colour: transparent
200-102	5	**Replacement teflon holder**	for all PCDs to hold the indicator strip

(*) On all GKE packages, an additional letter code has been added to the 6-digit article number. 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 and the above table.
(**) Each refill pack contains one seal ring. For exchange see "Maintenance Information".

Application

GKE Steri-Record® BMS Process Challenge Devices (PCD) with indicator strips have been specially developed to monitor each cycle of a steam sterilization process, to ensure successful sterilization of a defined ophthalmologic instrument load configuration. There always is the possibility of physical changes in the relevant process conditions that could occur during sterilization cycles throughout the day. Risks that may occur may be insufficient vacuum, air leaks in the sterilizer or entrained air or non-condensable gases (NCG) in the steam. In addition, lower temperature and/or a shorter heating time could cause a malfunction of the sterilization process as well. (134°C, holding time 3-9 min. or 121°C, 15-30 min. are suitable sterilization processes.) Physical data such as pressure, temperature etc. are very important, however, they are not sufficient to guarantee a successful sterilization cycle. Non-condensable gases (NCG) are the most frequent reason for failure of the sterilization process and cannot be identified from the physical data recorded by the sterilizer printout. GKE Steri-Record® BMS-PCDs with indicator strips are used in each batch to ensure steam penetration and air removal in the worst-case locations in a sterilizer. This BMS is validated with an "Equivalence Test" using a typical ophthalmology instrument load configuration.

Handling information

1. Select the right indicator for the sterilization process used (for standard or prion program).
2. Open the cap and make sure the seal ring in the cap is in good condition.
3. Take out indicator strip from the card and fold it that the indicator bars are inside and place it in the white holder with the fold toward the screw cap.
4. Insert the white holder into the PCD and tighten the cap.
5. Place test device close to the bottom and near the door of the chamber horizontally on a small stainless-steel tray or hang it vertically on a loading rack in the lower section near the door. The PCD does not require to be put into a pack, pouch or container.
6. Run the sterilization program.
7. On completion of the cycle remove the test device carefully. Condensate inside the PCD may come out if the test device is not placed horizontally.
8. After cooling down, remove the indicator strip and check the result:
   - If all four bars have turned to black the sterilization process has been successful.
   - If one or more bars remain yellow/pink or have not turned to black completely indicates a presence of non-condensable gases in the steam supply and/or in the chamber of the sterilizer. In this case do not release the batch. For easy interpretation please use the colour-pass/fail reference chart available for both versions.
9. The person authorized will decide whether to release the batch or to re-sterilize the load.
10. The indicator is self-adhesive and can be adhered onto the GKE documentation sheet with date, sterilizer and batch number and the signature of the person authorized to do so (see documentation information).
11. If using a program without a drying cycle or the drying of the PCD failed, the PCD may contain water condensate. In this case open the test device when it is still warm, blow air through and leave it open for drying.

Maintenance Information

All Compact-PCD®s consist of an external plastic casing with an internal stainless-steel tube and capsule holding the indicator. They can be used for an unlimited number of cycles. There is no preventive maintenance necessary.

Each indicator refill pack contains one seal ring for the screw cap of the PCD which needs to be exchanged after approximately 500 cycles to prevent leakage. Use the following procedure for exchange:

1. Unscrew the cap of the PCD containing the white teflon holder.
2. Unscrew the white teflon holder from the cap.
3. Remove the seal ring inside the cap with a pointed object (e.g., small screwdriver, needle etc.)
4. Insert a new seal ring in the cap. Use the white teflon holder to push the seal ring down into the slid.
5. Screw the white teflon holder into the cap again.

Older PCDs (e.g., Compact-PCDs purchased before 2009) have a smaller screw cap and require a different seal ring. In this case, please contact GKE or your local dealer.

Documentation Information

A documentation sheet is available for download:
https://www.gke.eu/en/downloads-en/documentation-system/16-documentation-sheet

For each day and sterilizer one page is required. Adhere all the indicator strips and the BDS indicator strip of one day from the same sterilizer on the documentation sheet. To link batch monitoring and sterilized goods, GKE offers a documentation system with a label print device. The documentation label contains the date of production, expiry date, lot and content number as well as the user's initials. Those labels are placed on all sterile goods and also onto the documentation sheet. After using the sterile goods in the operating room the labels are removed and are placed onto the patient documentation sheet (all labels are double self-adhesive). This easy process offers a cost-effective documentation system for all sterilized goods used on a patient in the operation room. In case of a nosocomial infection the result of the used sterile instruments can be traced back. This procedure fulfils the requirements of quality standard EN ISO 13485 for batch related documentation.

Storage and Disposal

1. For longer periods store all indicators in the original package.
2. Store indicators always between 5-30 °C or 41-86 °F and a humidity of 5-80% RH.
3. The vapour of chemicals especially hydrogen peroxide may change the indicator before or after sterilization. Therefore, do not store them together with other chemicals.
4. The indicators should not be used after expiry date. They may be disposed with normal waste.

Safety Precautions

1. Process monitoring systems are no replacements for the Bowie-Dick-Test to start with. The GKE Bowie-Dick-Simulation test can be used.
2. The use of a process monitoring system does not replace the validation of the sterilization process after start-up, major repairs or changes of the load configuration (see EN ISO 17665-1).
3. PCD and indicator strips are closely adjusted to achieve the required sensitivity. If the test device is used with other indicator strips, or GKE indicator strips are used with other test devices, GKE cannot guarantee proper results.
4. In small sterilizers steam is generated inside the sterilization chamber. The walls and the bottom may heat up above 180 °C if there is no water inside. Therefore, the test device should not be placed at the bottom or close to the walls in those sterilizers to prevent melting of the outside plastic case.
5. The standard indicators should not be used in sterilization processes with a holding time more than 9 min at 134 °C or 30 min at 121 °C. Indicators for prion programs are suitable for longer sterilization times.
6. If a sterilizer is switched on for a long time without being used, e.g., standby overnight, and then start automatically in the morning, the PCD shall not remain inside the sterilizer. The indicator strip in the PCD would be exposed to hot air for several hours in the standby mode and the indicator colour would thereby darken and change its recovery specifications (corresponds to faulty storage conditions overnight). Therefore, PCDs should only be placed in the sterilizer prior to sterilization.
7. If the opening of the Compact-PCD® is not in the lowest position during sterilization hot condensate may come out of the PCD during removal from the sterilizer burning your skin.
8. Do not open the screws of the Compact-PCD®. An unscrewed PCD cannot be reassembled and must be replaced by a new one.

For further technical details please contact your local dealer or the GKE application laboratory. We will assist you with any technical questions. Also visit our website www.gke.eu for more information.

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