

Monitoring of Hydrogen Peroxide Sterilization Processes

Application

The H₂O₂ Process and Batch Monitoring System (BMS) ensures that the H₂O₂ gas penetrates into the most difficult locations of the load. The air removal and hydrogen peroxide penetration conditions differ depending on the sterilizer used. Therefore, **gke** does not offer a fixed combination of indicator strips and process challenge device (PCD) but the selection of the PCD depends on the effectiveness of the hydrogen peroxide/plasma sterilization process and on the requirements of the load. It must be secured that the selected PCD represents the most difficult penetration characteristics of the load. After the right PCD is selected it can be ordered separately as a single PCD for routine monitoring together with biological or chemical indicators.

In contrast to steam sterilization processes the penetration characteristics of H₂O₂ in hydrogen peroxide sterilization processes into hollow devices become less difficult if the diameter of e.g. the tubes increases. Tube diameters below 4 mm are extremely difficult to be sterilized in hydrogen peroxide sterilization processes.

By using the selected Type 2 indicator system, biological or chemical indicators are not necessary in each pack, assuming that the BMS represents the load. Using the BMS, the results of the process can be evaluated immediately after the process is finished without waiting, until the indicators inside the packages are checked after opening the packs in the operation theatre. The whole load can be released after checking the indicator inside the PCD.

If no type 2 indicator systems are used, package monitoring indicators have to be placed in the worst-case position inside each package. The release can only take place after opening the package.

The result of the release has to be documented with a label on each pack with the batch number, production and expiry date to inform the staff in the operation room about the sterilization.

Product Description

The BMS indicator strip contains four indicator bars and is placed inside a **gke** PCD and put into the sterilizer chamber. Those indicator strips can only be used with **gke** PCDs. The use of other PCDs leads to wrong results.

The package monitoring indicators / type 4 indicators are self-adhesive and available on sheets with 16 indicators.

The chemical substances of the indicators are protected to bleed by a polymer binder coating and therefore, do not release toxic substances.

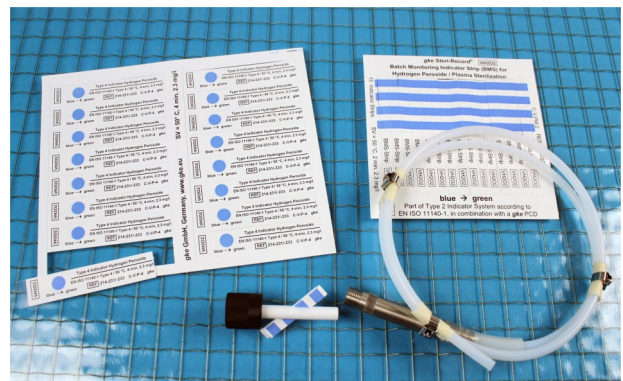


Image 1: H₂O₂ Indicators and PCD

Performance Characteristics

The **gke** PMS is a type 2 indicator system according to EN ISO 11140-1, consisting of a „specific test load“ (Process Challenge Device = PCD) and “indicator” (BMS indicator strip).

The package monitoring indicators are type 4 indicators according to EN ISO 11140-1. Type 5 indicators for hydrogen peroxide are not defined in the Standard.

The indicators are available with different specifications/doses: 50 °C, 2.3 mg/l H₂O₂ / 2 min, 4 min or 6 min. The indicators can also be used for longer sterilization times, higher temperatures and higher concentrations.

Benefits

- Monitoring of all critical parameters concerning sterilization and disinfection.
- Environmentally friendly, no unnecessary waste.
- All **gke** chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed with normal garbage.
- Innovative design and rationalized production provides cost-effective indicators
- Easy interpretation of the results due to precise colour change.

Order Information

The indicators are available in different versions. Our application laboratory will help you to select the correct indicator.

Art.-No.	Product Code	Quantity	Size [mm]	Dose at 50°C	Product
214-202	C-V-PM-2	250	6 x 38	2.3 mg/l H₂O₂ /2 min	BMS (Batch Monitoring System) indicator strips
214-221	C-V-P-6	400	65 x 14	2.3 mg/l H₂O₂ /6 min	Type 4 Package Monitoring Indicators
214-223		3.200			
214-231	C-V-P-4	400		2.3 mg/l H₂O₂ /4 min	
214-233		3.200			
214-241	C-V-P-2	400		2.3 mg/l H₂O₂ /2 min	
214-243		3.200			

gke GmbH
Auf der Lind 10
65529 Waldems
Germany

 +49 (0) 61 26 94 32 0
 +49 (0) 61 26 94 32 10
 info@gke.eu
 <http://www.gke.eu>

Your **gke** sales partner: