

gke Steri-Record[®] Process Monitoring System for ethylene oxide sterilization processes

Application

The process challenge device (PCD) can be used with biological indicator strips (*B. atrophaeus* 10⁶) and afterwards incubated by a microbiological laboratory. Self-contained biological indicators (SCBI) may be incubated directly after sterilization inside an incubator. For routine monitoring chemical indicators also can be used with the advantage that they can be checked immediately after the sterilization process has finished. In opposite to steam sterilization processes different ethylene oxide sterilization processes are used which differ in temperature, pressure, ethylene oxide concentration and inert gas mixtures, e. g. CO₂.

Biological and chemical indicators have been tested at 55°C under the following sterilization conditions:

EO/l [mg]	Pressure [bar]	CO ₂ [%]	EO [%]	Time [min]
500	1,7	85	15	90
600	5,5	94	6	60
250	1,7	94	6	180
1200	5,5	85	15	30
600	0,5	0	100	60

During the sterilization process it is absolutely necessary to monitor the relative humidity in addition, which should be above 30%. The ideal relative humidity during sterilization is between 60% and 70% RH.

gke offers a Compact-PCD[®]-Testset where PCDs with different penetration characteristics can be selected. Initially all PCDs can be used and checked which are penetrated and which are not and the most difficult one can be selected which is still able to pass. The validation of this process should be checked also with biological indicators.

Alternatively 6 different Bio-C-PCDs can be selected by using self-contained biological indicators SCBIs for ethylene oxide sterilization processes, see separate data sheet.

Sterilization processes which are carried out with ethylene oxide, the PCD should only be used if sufficient diffusion time for the penetration is guaranteed. Is there no penetration of the ethylene oxide gas in the PCD, put the indicators (depending on the packaging-material) of the other sterilizing goods in one or more tyvek pouches to assure difficult sterilizing conditions. In this case sterilizing of longer hollow-types cannot be detected.

Product Description

The PCD consists of a 4.55 m long stainless steel tube of 3 mm diameter connected with a capsule holding the indicator strip or self-contained biological indicator (SCBI) sealing one end.



Process Monitoring Systems (Helix-PCDs)

Performance Characteristics

The combination of a PCD and a biological or chemical indicator is a type 2 indicator system according to EN ISO 11140-1 consisting of a "specific test load" (PCD) and "indicator strip".

Sterilization programs are not standardized. Therefore, a validation with biological indicators (*B. atrophaeus* 10⁶) according to EN ISO 11138-1 + 2 is required before chemical indicators may be used for routine monitoring.

The validation of the load configuration (PQ = Performance Qualification) according to EN ISO 11135-1 ensures that the sterilization process meets the requirements to sterilize the load configuration.

General Benefits

- The use of this EO PMS allows the monitoring of sterility inside hollow instruments, tubes and porous goods not provided by recording pressure, temperature and EO concentration in the chamber and/or using exposed indicator strips.
- Cost effective. Only one indicator strip or one SCBI is required for each sterilization process instead of one in each pack.
- Easy interpretation of the results due to precise colour change.
- Environmentally friendly, no unnecessary waste. The test device can be used for an unlimited number of cycles. All important parts are made of stainless steel.
- Continuous reproducibility of the results over the lifetime of the PCD.
- For validation biological indicators are available according to EN ISO 11138-1 + 2
- Assurance that only sterile released packs are used.
- No microbiologic laboratory needed.

Benefits for PCD to be used with chemical indicators

- The batch can be released without opening the pack to check the internal packing indicator.
- All information relevant to release the load is supplied on completion of the process so that the person authorized can release the batch.
- The graduated colour change of the indicator bars shows the level of the penetration into the PCD.
- 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.
- **gke** self-adhesive labels simplify recording with the **gke Steri-Record®** documentation system.
- All **gke** chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed with normal garbage.

Order Information

Art.-No.*	Product code	Quantity	Content	Application
200-028	C-E-PM-HPCD	1	Stainless steel helix test device	to be used with chemical or biological indicator strips
300-028	B-E-PM-HPCD	1		to be used with self-contained biological indicators (SCBIs)
212-202	C-E-PM	250	Chemical integrating indicator strips, 1 seal ring	for all EO sterilization processes (for art.-no 200-028)
221-601	B-E-H-SS-10-6	100	<i>B. atrophaeus</i> spore strips on paper carrier, 10 ⁶	
326-605	B-E-MBP-10-6	50	Self-contained biological indicators (SCBI), 10 ⁶	for all EO sterilization processes (for art.-no 300-028)
326-610		100		

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