
gke Steri-Record[®] Testsets and PCDs for validation, process and batch monitoring of sterilization processes



Compact-PCD[®]-Testset



Helix-PCD-Testset

Application

Process Monitoring Systems (PMS) are process challenge devices that are used to test sterilizers according to a defined standard, called type tests. A PMS checks if a sterilizer fulfils the requirements of the standard (e.g. BD Test according to EN 285 and Helix-Test according to EN 867-5). PMS are used for routine monitoring of sterilizer process parameters to proof insufficient air removal, leakage or non condensable gases (NCG).

The **gke Steri-Record[®]** PCD-Testsets (PCD = process challenge device) include various PMS and have been developed to test the penetration characteristics of the sterilization agent to ensure penetration inside hollow devices e.g. minimal invasive surgical (MIS) instruments and tubes. For a successful sterilization process the sterilizing agent must contact all inside and outside surfaces of the goods to be sterilized. Air and NCG must be removed from inside of hollow devices before they can be sterilized. Experience has demonstrated that most hollow devices and MIS instruments are more difficult to sterilize than porous loads (e.g. Bowie-Dick-Test).

Sterility inside hollow instruments cannot be checked with parametric release and can only be correctly detected by using microbiological methods with direct inoculation. The results have to be evaluated in a microbiological laboratory after sterilization.

This procedure is the only meaningful validation procedure but not feasible for routine monitoring. To circumvent direct inoculation alternatively a Testset can be used with biological or chemical indicators for steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes. The PCDs have different sensitivities and simulate simple solid instruments up to complex hollow devices.

Depending on the selected Testset, the sterilizer must have a program with an appropriate fractionated vacuum or a deep single vacuum to enable air removal and sterilant penetration in the PCD. This characteristic depends on the sterilizer program used and differs from sterilizer brand to sterilizer brand.

gke offers different Helix and Compact-PCD-Testsets, see order information table 1 + 2. The use of the **gke Steri-Record[®]** Testsets allows a simple and inexpensive method to validate sterilization processes with hollow instruments.

Information for steam sterilization processes:

The Process Monitoring System (PMS) and Batch Monitoring System (BMS) for steam sterilization processes have been developed to monitor each cycle. BMS are validated according to the load configuration and are used for routine monitoring

of each batch. A PMS can also be used as a BMS if the penetration performance of the sterilizer exceeds the penetration performance of the load to be sterilized.

As described before a selected PMS can be used for process or batch monitoring. The PMS has to be selected according to the sterilizer program, the BMS according to the load configuration.

Small steam sterilizers, not operating with fractionated vacuum, are unable to remove air from longer hollow devices. In that case the PCD-Testset 200-013 or 200-210 for small sterilizers should be used to determine the length of inner lumens being able to get penetrated.

Information for formaldehyde sterilization processes:

The PMS for formaldehyde sterilization processes has been developed to monitor each cycle. According to EN 14180 the type test for formaldehyde sterilization processes is a hollow load test to be used as a process monitoring system according to EN 867-5 (Hollow Load Test).

The chemical indicator set has been tested under the following conditions:

15 gas pulses	between 53 and 200 mbar for 15 s each
Total sterilization time	60 min
Evaporating solution	2% formaldehyde in water
Temperature	60 °C

There are various sterilization programs on the market. Before using a PCD as a PMS or BMS with other sterilization programs, validate the test using direct inoculation of the most difficult instrument by using biological indicators. For sterilization cycles without pressure difference processes, the PCD may not be suitable because of insufficient gas penetration. In this case seal indicator in one or more pouches without using the PCD.

Information for ethylene oxide sterilization processes:

The process challenge device (PCD) can be used with chemical or biological indicators (*B. atrophaeus* 10⁶). The biological indicators must be incubated by a microbiological laboratory afterwards. Alternatively self-contained biological indicators (SCBI) can be used with special

Bio-Compact-PCDs with the advantage that no laboratory is necessary to incubate the SCBIs. For routine monitoring chemical indicators are recommended 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. When chemical indicators are used, the monitoring system should be validated with biological indicators.

The chemical indicator has been tested at 55°C under the following sterilization conditions:

EO/l	Pressure	CO ₂	EO	Time
[mg]	[bar]	[%]	[%]	[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 EO-sterilization process it is absolutely necessary to monitor the relative humidity, which should be above 60% . The ideal relative humidity during sterilization is between 70% and 90% RH.

If the standard type test (art.-no. 200-028) according to EN 1422 demonstrates successful ethylene oxide penetration the sterilizer meets the standard specifications for EO-penetration.

Information for hydrogen peroxide (plasma) sterilization processes:

The process monitoring system (PMS) for hydrogen peroxide (plasma) ensures that the H₂O₂ gas penetrates into the most difficult locations of the load. The air removal and hydrogen peroxide penetration conditions differ heavily depending on the sterilization process/sterilizer used.

Therefore, **gke** does not offer a fixed combination of biological or chemical indicator strip 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.

For selecting the appropriate test device your local **gke** sales partner or the **gke** laboratory may support you. 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 tubes become less difficult if the diameter of the tubes increases. Tube diameters below 4 mm are extremely difficult to be sterilized in hydrogen peroxide sterilization processes.

The standard EN ISO 11140-1 defines six different indicator types. The **gke** hydrogen peroxide chemical indicator turns from blue to green (former purple to pink). Under the same conditions biological indicators (*Geob. Stearothermophilus* 10⁶ CFU per strip) are inactivated.

Since the hydrogen peroxide-/plasma sterilization processes are currently not standardized there are several different processes with different process parameters on the market. Therefore, it is recommended to validate a PMS once using biological indicators before routine monitoring with chemical indicators.

Product Description

gke produces two types of PCDs. Historically, so-called Helix-PCDs have been used which consist of a PTFE tube and a capsule to host the indicator. **gke** has decided to manufacture all capsules in stainless steel since they are more durable than plastic capsules. Also stainless steel has no negative catalytic effect with any of the sterilants used. The cap with the seal ring is durable in low and high temperature sterilization processes up to 140°C.

Helix-PCDs are durable for about 1.000 cycles while the most important parts of the patented Compact-PCD[®]s are made of stainless steel and have an almost unlimited life span.

1. Helix-PCDs

The **gke Steri-Record**[®] PCD-Testsets contain different hollow test devices, consist of a tube with metal capsule, that can accommodate biological or chemical indicators with dimensions of 6 x 40 mm. The test devices are made of PTFE-tubes with different lengths and inner diameters, see table order information.

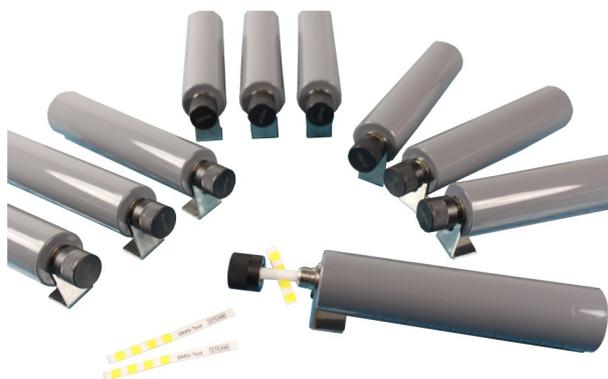
Three different Testsets are offered. The PCD-Testset, 200-017, for sterilizers with fractionated vacuum contains 13 PCDs which are relatively hard to sterilize. The Testset, 200-013, for gravity displacement or overpressure cycles contains five PCDs with less demanding characteristics and the Testset, 200-016, contains 10 PCDs with tube dimensions that are optimized for hydrogen peroxide/plasma sterilization processes. All Helix-PCDs of the Testsets are available separately as well.



2. Compact-PCD[®]s

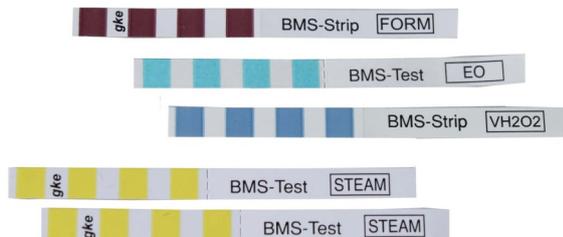
The **gke** Compact-PCD[®] Testset contains 10 different Compact-PCD[®]s. The specially designed and patented **gke** Compact-PCD[®] consists of a large volume plastic case with stainless steel tubes of different lengths inside, with a minimal capsule volume at the end holding the indicator. They can be used with special **gke** chemical or biological indicators to monitor different sterilization processes. They can be put either vertically on a loading rack or placed horizontally on the bracket.

All PCDs of the Testset are available separately as well.



3. Chemical Indicators

Indicators for all PCDs are available for steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes. All chemical indicators are protected by a polymer binder coating and therefore, do not release toxic substances and conform with EN ISO 11140 series. For colour change separate colour reference charts are available.



4. Biological Indicators

gke offers biological indicators with different population and D-value for steam, formaldehyde, hydrogen peroxide, ethylene oxide and dry heat sterilization processes. Technical details are available in the data sheet for biological indicators. Biological indicators (spore strips) for H₂O₂ sterilization processes contain a plastic carrier (free of cellulose) while other biological indicators are made of paper materials.



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” (indicator strip). The chemical indicators have the performance characteristics of a type 5 indicator but the combination with a PCD is a type 2 indicator being able to monitor NCGs additionally not possible of a type 5 indicator only.

The Hollow Load Test is described in the European Standard EN 867-5 and originally designed to test the steam penetration characteristics of class B table-top sterilizers according to EN 13060 and large sterilizers according to EN 285. However, in the meantime they are used for other applications as well.

For formaldehyde sterilization processes this test is described as the hollow load test in EN 14180.

The Helix-PCD (Art.-No. 200-150) as well as the Compact-PCD® (Art.-No. 200-218) are hollow load tests according to EN 867-5. The Helix- and the Compact-PCD have been validated by an accredited laboratory according to EN ISO 17025.

All chemical indicators comply with the standard EN ISO 11140-1.

All **gke** biological indicators comply with the standard EN ISO 11138 series. A standard for hydrogen peroxide/plasma is not published yet.

Operational Description

The PCD-Testset with the appropriate indicator inside is sterilized together with the load. At the end of the process the indicators are checked. As a result some PCDs show good penetration characteristics while some more demanding PCDs indicate fail conditions. The PCD that has passed with the highest hollow penetration resistance provides information about the best penetration characteristics of the process and may be used for routine monitoring. However it has to be demonstrated that this PCD has higher penetration characteristics than the load configuration. In case of doubt, validation according to DIN 58921 must be carried out.

The selected PCD is also available as a single test device and can be used with the corresponding indicator strips for routine monitoring (see order information).

Benefits for Helix- and Compact-PCDs

- Testsets and PCDs are suitable for steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes using the correct *gke* indicator strip.
- Simple and easy method to find out the limitations of the penetration characteristics of a sterilizer.
- Only the use of a BMS allows the monitoring of sterility inside of complex hollow instruments, like tubes and porous goods not provided by recording pressure, temperature and steam quality in the chamber and/or using exposed indicator strips.
- PCDs are cost-effective due to multiple use. 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.
- Continuous reproducibility of the results.
- Environmentally friendly, no unnecessary waste.
- All information relevant to the process is supplied on completion of the process so that the authorized person can release the batch without opening the packs.
- The graduated colour change of the indicator bars provides information about the magnitude of air removal and sterilant penetration inside the sterilizer.
- The indicator colour chemistry is a non-reversible chemical reaction and remains colourfast over time.
- All *gke* chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed off with normal garbage.
- *gke* self-adhesive labels simplify recording with the *gke Steri-Record*[®] documentation system.
- The screw-cap consists of a highly thermal resistant material and stainless steel sandwich-construction that protects hands from high temperatures. The indicator may be easily removed and evaluated on completion of each cycle.

Additional benefits for Compact-PCD[®]s:

- The advanced international patented “multi-stage” technology combines the penetration characteristics of hollow and porous loads simulating the Bowie-Dick test, Helix devices or various batch monitoring systems representing the characteristics of real loads such as textiles, tubes and even minimal invasive surgical (MIS) instruments.
- Compact-PCD[®]s can be used for an unlimited number of cycles. The durable materials ensure reproducible results.
- The outside parts of the Compact-PCD[®]s are made of thermal insulating material and protect the hands from high temperatures after taking the test device out of the sterilizer chamber. Results can be checked immediately at the end of the cycle.

Order information

Helix-PCD-Testsets and single Helix-PCDs

Art.-No.*	Product code	Content		Application
200-017	PM-HPCD-TS-13	Testset consisting of 13 Helix-PCDs with metal capsule (see below)		To test steam and LTSF sterilization processes with fractionated vacuum
		Tube diameter [mm]	Tube length [cm]	
200-150	PM-HPCD-2-150	2	150	
200-302	PM-HPCD-2-300		300	
200-452	PM-HPCD-2-450		450	
200-153	PM-HPCD-3-150	3	150	
200-303	PM-HPCD-3-300		300	
200-154	PM-HPCD-4-150	4	150	
200-304	PM-HPCD-4-300		300	
200-155	PM-HPCD-5-100	5	100	
200-205	PM-HPCD-5-200		200	
200-305	PM-HPCD-5-300		300	
200-405	PM-HPCD-5-400		400	
200-505	PM-HPCD-5-500		500	
200-605	PM-HPCD-5-600		600	
200-013	PM-HPCD-TS-5	Testset consisting of 5 Helix-PCDs with metal capsule (see below)		To test all sterilization processes with low demanding penetration characteristics
200-025	PM-HPCD-2-25	2	25	
200-050	PM-HPCD-2-50		50	
200-075	PM-HPCD-2-75		75	
200-100	PM-HPCD-2-100		100	
200-150	PM-HPCD-2-150		150	
200-016	PM-HPCD-TS-10	Testset consisting of 10 Helix-PCDs with metal capsule (see below)		To test hydrogen peroxide sterilization processes
200-025	PM-HPCD-2-25	2	25	
200-325	PM-HPCD-3-25	3		
200-350	PM-HPCD-3-50		50	
200-425	PM-HPCD-4-25	4	25	
200-450	PM-HPCD-4-50		50	
200-475	PM-HPCD-4-75		75	
200-525	PM-HPCD-5-25	5	25	
200-550	PM-HPCD-5-50		50	
200-575	PM-HPCD-5-75		75	
200-510	PM-HPCD-5-100		100	

Compact-PCDs Testset and single PCDs

Art.-No.*	Product code	Content	
200-210	PM-RCPCD-TS	Testset consisting of 10 Compact-PCDs (single PCDs see below)	
		Sensitivity	Reference load
200-211	PM-RCPCD-1	Equivalent to gke Tattoo-BMS (black)	Tattoo
200-212	PM-RCPCD-2	PCD with higher penetration characteristics of the Tattoo-BMS and lower of the Dental-BMS	No reference
200-213	PM-RCPCD-3	Equivalent to gke Dental-BMS (yellow)	Dental
200-214	PM-RCPCD-4	PCD with higher penetration characteristics	No reference
200-215	PM-RCPCD-5		
200-216	PM-RCPCD-6	Equivalent to gke Ophthal-BMS (white)	Ophthalmology
200-217	PM-RCPCD-7	Equivalent to gke BMS (green)	7 kg BD-cotton pack EN 285 with biological indicators
200-218	PM-RCPCD-8	Equivalent to gke hollow load test (orange)	Hollow load test according to EN 867-5
200-219	PM-RCPCD-9	High demand hollow load test (red)	More demanding penetration characteristics than hollow load test according to EN 867-5
200-220	PM-RCPCD-10	Very high demand hollow load test (brown)	

Chemical and biological indicators for use in all testsets and PCDs

The biological indicators for steam, formaldehyde and ethylene oxide sterilization processes are also available in larger quantities. Please see our product catalogue for biological indicators or ask for special quotation with staggered prices depending on the quantity.

Art.-No.*	Product Code	Sterilization Process	Content	Description	
Chemical Indicators					
211-255	C-S-PM-SV1	Steam	500	Refill pack with chemical indicator strips to be used in testsets and PCDs (see tables above)	
211-252					
212-202	C-E-PM	Ethylene oxide	250		
213-202	C-F-PM	Formaldehyde			
214-202	C-V-PM	Hydrogen peroxide			
Biological Indicators			Pop.	Spore strips	Content
223-501	B-S-SS-10-5	Steam	10 ⁵	<i>G. stearothermophilus</i> on paper carrier	100
223-601	B-S-SS-10-6	Steam, Formaldehyde	10 ⁶		
332-601	B-V-SS-10-6	Hydrogen peroxide		<i>G. stearothermophilus</i> on PET plastic carrier	
221-601	B-E-H-SS-10-6	Ethylene oxide, Dry heat		<i>B. atrophaeus</i> on paper carrier	

* A three digit letter code is added to the 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 with the article number in the above tables.

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