
gke Steri-Record[®] Indicator System according to EN ISO 11140-1 Type 2 to monitor sterilization processes



Fig. 1: Different sensitive process challenge devices, round section

Application

In the sterilizer standards EN 285 and EN 13060 type tests are described, e.g. BD-Test or Helix Test according to EN 867-5 (new EN ISO 11140-6). They are only testing the standard requirements of the sterilizers without any relation to the load.

They are quite often used as so-called batch monitoring systems and sold as various test systems on the market to monitor the load. However, these tests have no relation to the load. Therefore, it cannot be automatically concluded that difficult loads can be sterilized successfully. A monitoring system for the load should not just pass a sterilizer but must represent the load.

This adoption can be achieved in two ways:

1. **Process Monitoring System (PMS):**
The sterility of the load is assured if the sterilization process has been validated with a worst-case load. The continuous monitoring of the load shall be carried out with a test system which monitors the maximum performance of the sterilizer. Modern sterilizers provide much better performance than the required type tests mentioned above. For this purpose **gke** offers a variety of different PCDs (process challenge devices) with increasing sensitivities to monitor the process at highest level. These test devices are called process monitoring systems (PMS).

2. **Batch Monitoring System (BMS):**
If the characteristics of the load to be sterilized are known, a PCD can be designed and validated to be more difficult to sterilize than the defined load using the method according to DIN 58921 (medical device simulator). **gke** has already tested several typical loads with the method according to DIN 58921 and offers special PCDs for Tattoo, Dental and Ophthalmic loads. For these test systems separate data sheets with detailed information are available.

Product Description

1. **Process Challenge Device:**
The **gke Steri-Record[®] Compact-PCD[®]** consists of an external plastic case with an internal stainless steel tube and a capsule holding the indicator.

The four colour-coded PCDs are available in two different construction versions:

- round version with stainless steel bracket. This PCD can be put vertically on a loading rack or placed horizontally on the bracket.
- oval version (green and orange): This PCD can be placed horizontally on the flat side of the PCD, suitable for small sterilizers (2.5 cm height).

All PCDs are re-usable and can be used for a considerable number of sterilization cycles.

2. Indicator Strip:

The indicators have a size of 40 x 6 mm and fit into the PTFE holder of the capsule. This size is identical to standard biological indicators according to EN ISO 11138 series and fit also in those PCDs and can be used alternatively, but shall not be opened after sterilization and aseptically transferred in a microbiological laboratory. Chemical indicators for all sterilization processes can be ordered from **gke**. For details see our product catalogue.

Performance Characteristics

The **gke** PCDs are type 2 indicator systems according to EN ISO 11140-1, consisting of a „specific test load“ (Process Challenge Device = PCD) and „indicator“ (indicator strip). They have been validated from a laboratory accredited according to the standard EN ISO 17025 (test reports on request).

gke offers a variety of PCDs with different levels of difficulty. Using a test with the highest level which will still pass in a validated process the sterilizer is always tested at its limits. Failures that are not detected with standard methods will now be visible and the maximum possible safety to test sterilization processes can be guaranteed. If a process has been validated with a defined load and a suitable test system, this method secures the sterilization at the most difficult locations. This is not possible by only recording the physical data with documentation, e.g. with a printer.

The identification of a suitable PMS to monitor sterilization has to be verified during process validation depending on the load. The **gke** representatives support in the selection of the test system depending on the load.



Fig. 2: PCDs, round and oval construction

1. PMS Compact-PCD®, colour: green

This PMS Compact-PCD®, colour: green, represents a challenging test concerning air removal and steam penetration that can be used for routine monitoring of simple hollow devices, tubes, porous loads and solid instruments. However, this PMS is less demanding regarding air removal and steam penetration than the hollow load test described in EN 867-5.

2. PMS Compact-PCD®, colour: orange

The PMS Compact-PCD®, colour: orange, simulates the hollow load test according to EN 867-5. This type test is included in the standard for large sterilizers (EN 285) as well as in the standard for small class B sterilizers (EN 13060).

The standard EN 867-5 describes a test cycle with 9 injections of steam to 950 mbar. In this test cycle the hollow load test will be successfully penetrated, if a vacuum of 450 mbar will be reached in between each steam pulse.

3. HDH-PMS Compact-PCD®, colour: red

The HDH-PMS Compact-PCD®, colour: red, (High Demand Hollow) is used for routine monitoring of complex instruments or long tubes, whereas the hollow load test according to EN 867-5 is not anymore sufficient.

To successfully penetrate the **gke**-HDH-PMS in the same test cycle a vacuum of at least 210 mbar is necessary.

4. VHDH-PMS Compact-PCD®, colour: brown

The VHDH-PMS Compact-PCD®, colour: brown, (Very High Demand Hollow) makes increasing demands on the air removal performance. The test cycle according to EN 867-5 with 9 injections of steam requires vacuum cycles of at least 160 mbar to successfully penetrate the VHDH-PMS.

These data are only valid under laboratory conditions using a reproducible process in a test sterilizer according to EN ISO 18472. All other variables that affect the air removal and steam penetration are strictly defined in such a program and must remain unchanged in all test cycles.

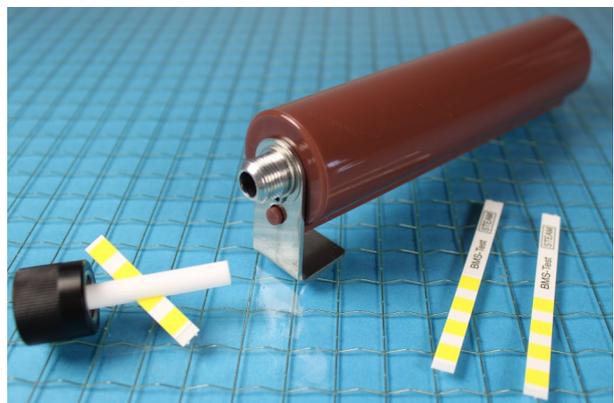


Fig. 3: VHDH-PMS Compact-PCD®, colour brown, round

Under real sterilization conditions the differences in performance between type test according to EN 867-5 and the **gke** HDH-PMS or **gke** VHDH-PMS may change considerably because day-to-day programs differ from the above mentioned test cycle. Usually less but deeper vacuum cycles are used.

Operation Description

Two indicator strips for steam sterilization processes can be selected according to the program used and are available with different stated values:

1. 134°C, 3 min or 121°C, 15 min (standard cycle)
2. 134°C, 18 min (prion cycle)

If all four bars of the chemical indicator turn from yellow (standard cycle) /pink (prion cycle) to black it is an indication of sufficient steam penetration inside the PCD.

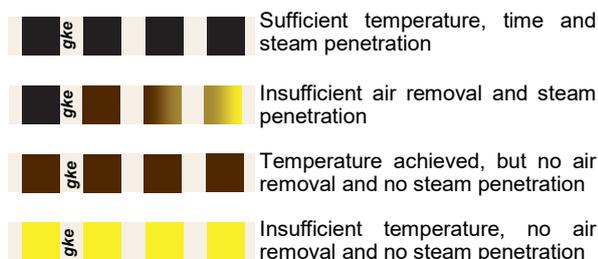


Fig. 4: Colour change of a standard indicator strip. If using an indicator strip for prion programs the initial colour is pink

This result ensures air removal and steam penetration into the whole load under the condition that the PCD is representing the load configuration. Alternatively chemical indicator strips can be used for other sterilization processes.

Benefits

- Indicator strips for standard and prion steam sterilization cycles are available.
- Biological and chemical Indicators for LTSF, ethylene oxide and hydrogen peroxide sterilization processes are also available.
- Test of a sterilizer, if the specification requirements are according to the standard, lower or higher.
- Monitoring of sterility inside of complex hollow instruments, tubes and porous goods not provided by recording pressure, temperature and steam quality in the chamber and/or using exposed indicator strips.
- Cost effective due to multiple use. Only one indicator strips is required for each sterilization process instead of one in each pack.

- Easy interpretation of the results due to precise colour change.
- Reproducibility of the results for a long period of time.
- 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.
- Environmentally friendly, no unnecessary waste.
- The graduated colour change of the indicator bars informs about the kind and magnitude of air removal and steam penetration inside the sterilizer and non-condensable gases in steam.
- The indicator colour chemistry is a non reversible chemical reaction and remains colour-fast over time if they are not stored with other chemicals.
- **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 can be disposed with normal garbage.
- Selection between four different versions of PMS Compact-PCD® depending on the air removal program used and the load to be sterilized.
- 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 Compact-PCD® can be used for a considerable number of cycles. All important parts are made of stainless steel or thermal resistant polymers.

Order Information

Each start-up kit contains of a Compact-PCD and 100 integrating indicator strips for standard steam sterilization processes. All test devices are also available separately. The indicator strips are available as refill packs for standard and prion steam sterilization processes and also contain a sealing kit for the screw cap.

1. Start-up kit and process challenge devices / Process monitoring systems (PMS)

Art.-No.*	Product Code	Quantity	Content	Stated Value	Application	
211-253	C-S-PM-SHL-RCPCD-KIT	1 +	Compact-PCD® <u>round</u> section (colour: green), integrating indicator strips	134° C, 3 min 121°C, 15 min	for simple hollow devices, porous loads and solid instruments	
211-254	C-S-PM-SHL-OCPCD-KIT		Compact-PCD® <u>oval</u> section (colour: green), integrating indicator strips			
200-020	PM-HL-RCPCD	1	Compact-PCD® <u>round</u> section (colour: green)	-		
200-024	PM-SHL-OCPCD		Compact-PCD® <u>oval</u> section (colour: green)			
211-263	C-S-PM-HL-RCPCD-KIT	1 +	Compact-PCD® <u>round</u> section (colour: orange), integrating indicator strips	134° C, 3 min 121°C, 15 min	Hollow Load Test according to EN 867-5	
211-264	C-S-PM-HL-OCPCD-KIT		Compact-PCD® <u>oval</u> section (colour: orange), integrating indicator strips			
200-021	PM-SHL-RCPCD	1	Compact-PCD® <u>round</u> section (colour: orange)	-		with higher requirements than EN 867-5
200-026	PM-HL-OCPCD		Compact-PCD® <u>oval</u> section (colour: orange)			
200-029	PM-HDH-RCPCD		Compact-PCD® <u>round</u> section (colour: red)		with extremely high requirements than EN 867-5	
200-030	PM-VHDH-RCPCD		Compact-PCD® <u>round</u> section (colour: brown)			

2. Refill packs indicator strips

Art.-No.*	Product Code	Quantity	Content	Stated Value	Application
211-251	C-S-PM-SV1	100	Refill pack Integrating indicators + 1 sealing kit	134° C, 3 min 121°C, 15 min	Indicator strips for all gke PMS in standard steam sterilization processes
211-252		250			
211-255		500			
211-211	C-S-PM-SV2	100		134° C, 18 min	Indicator strips for all gke PMS in steam sterilization processes ("prion programs")
211-212		250			
211-215		500			

* To all article numbers a 3-digit alpha code is added. The additional letter code refers to the language and/or customized and plug version. It is only added on the outside label, the inside of the pack is identical to the article numbers on the above tables.

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