DIRECTIONS FOR USE

CLEANING
STERILIZATION

GKE Steri-Record® Compact-PCD Testset | Compact-PCD®s

for validation and routine monitoring of sterilization processes

STEAM EO FORM VH2O2

Product | Art.-No.

200-210, 200-211, 200-212, 200-213, 200-214, 200-215, 200-216, 200-217, 200-218, 200-219, 200-220

Application

The GKE Steri-Record® process challenge devices (PCDs) and Testsets 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 other non-condensable gases (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 devices cannot be checked with parametric release and can only be correctly detected by using microbiological methods with direct inoculation. The results have to be checked in a microbiological laboratory after sterilization. This procedure is only meaningful for validation but not for routine monitoring. To circumvent direct inoculation alternatively a PCD 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.

The sterilizer must have a program with an appropriate fractionated vacuum or a deep single vacuum to enable air-removal and sterilant agent penetration in the PCD. This characteristic depends on the sterilizer and the program used and differs from manufacturer to manufacturer.

Information for formaldehyde sterilization processes:

The C-PCD 200-218 can be used with a chemical indicator as a Process Monitoring System (PMS). This PMS represents a test for heavily wrapped and hollow sterilization goods. The indicator has been tested under the following conditions:

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

There are various sterilization programs on the market. Before using the batch monitoring with other sterilization programs, validate the test 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 a PCD.

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Information for ethylene oxide sterilization processes:
All Compact-PCDs can be used with chemical or biological indicators (B. atrophaeus 10^6) and the biological indicators must be incubated by a microbiological laboratory afterwards. 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 processed are used which differ in temperature, pressure curve, ethylene oxide concentration and inert gas mixtures, e. g. CO_2. When chemical indicators are used, the monitoring system should be validated with biological indicators.

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

EtO/l [mg]	Pressure [bar]	CO_2 [%]	EtO [%]	Time [min]
600	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, which should be above 60%. The ideal relative humidity during sterilization is between 70% and 90% RH.

Information for hydrogen peroxide (plasma) sterilization processes:
The process monitoring system (PMS) for hydrogen peroxide (plasma) ensures that the H_2O_2 gas penetrates into the most difficult locations of the load. The air removal and hydrogen peroxide penetration conditions differ depending on the sterilization process 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 H_2O_2 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.

If the indicator is left close to any product which has been in a H_2O_2 sterilizer or even in the surrounding of the H_2O_2 chemicals, they are integrating the H_2O_2 and providing a pass overnight or over a longer period depending on the concentration. Therefore we recommend to keep the indicators always completely separate from H_2O_2 and insert the H_2O_2 indicators just before they are put in the sterilizer and be taken out immediately at the end of the sterilization process.

The GKE hydrogen peroxide chemical indicators change its colour from blue to green or red to yellow. Under the same process conditions biological indicators (Geob. Stearothermophilus 10^6 CFU per strip) are inactivated. Since 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
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 tray.

Operational Description (Testset)

The Testset 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 single test device and can be used with the corresponding indicator strips for routine monitoring.

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 better performance characteristics of a type 5 indicator but the combination with a PCD is a type 2 indicator being able to monitor NCG additionally, type 5 indicators alone cannot do.

The Compact-PCD® (Art.No. 200-218) is a hollow load test according to EN 867-5. This test has been validated by an accredited laboratory according to EN ISO 17025. For formaldehyde sterilization processes this test is described as the hollow load test in EN 14080, for steam sterilization processes in EN 13060 and EN 285.

Handling Information to select the appropriate PCD | for routine monitoring with the selected PCD

1. Select the right biological or chemical indicator for the sterilization process used.
2. Open the caps of the PCD(s) and make sure the seal ring in the cap in each PCD is in good condition.
3. If using chemical indicators, take out indicator strip from the card, number it with the PCD number and fold it that the indicator bars are inside and place it in the white holder with the fold toward the screw cap. Alternatively biological indicator strips but no self-contained biological indicators may be used. The strips have to be taken out of the glassine envelope. The PCDs are designed for standard spore strips of dimensions of 38 or 40 mm x 6 mm. The septic loading of the biological indicator is non-critical. (It is much easier to sterilize the germs of your fingers than the test germs on the strips.) It is recommend to pack the PCD into a sterilization pouch to prevent re-contamination by means of the tube after sterilization, if the biological indicators are not developed within one day.
4. Insert the white indicator holders into the PCDs and tighten the caps.
5. Place test devices close to the bottom and near the door of the chamber horizontally on a small stainless steel tray or hang the Compact-PCD® 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 devices carefully. Condensate inside the PCD may come out if the test device is not placed horizontally.
8. After cooling down, remove one chemical indicator strip after the other and adhere them onto the documentation evaluation sheet related to the PCD of the right number (available as download https://www.gke.eu/en/testsets-templates.html). Check the result:
   - If all four bars have turned to its final colour the sterilization process has been successful.
   - If one or more bars remain the original colour or have not turned to its final colour this indicates insufficient air removal and penetration. For correct interpretation please use the GKE-colour-pass/fail reference chart which you can order from GKE free of charge.
9. At the end of the process condensate droplets may remain in the PCD. In this case open the test device when it is still warm, blow air through and leave it open for drying.
10. The person authorized will decide whether to release the batch or to re-sterilize the load.
11. If biological indicators are used, do not open the PCD and bring the PCD to a microbiological laboratory. The biological indicators have to be taken out aseptically and should be transferred in glass tubes with growth media. The glass tubes need to be marked with the numbers of the PCDs. After incubation record the result in the documentation sheet.
12. Select the PCD with the highest number that has been successfully penetrated. This PCD can be used for routine monitoring only if the PCD has higher penetration characteristics than the most difficult instrument in the load. In case of doubt the procedure in the standard DIN 58921 should be applied to validate the PCD against the load.
13. 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).

Maintenance Information for the PCDs

All Compact-PCD®s contain a tubing system made of stainless steel and 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.

Documentation Information

One documentation sheet (evaluation sheet) is included in each testset. The template is also available for download: https://www.gke.eu/en/testsets-templates.html
A documentation sheet for routine monitoring is available for download:
https://www.gke.eu/en/documentation-system-video.html. For each day and sterilizer one page is required. Adhere all the indicator strips and the BDS indicator strip for 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.

Safety Precautions

1. In steam sterilizers batch monitoring systems are no replacements for the Bowie-Dick-Test to start with. The GKE-Bowie-Dick-Simulation test can be used.
2. This batch 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, 11135-1, 25424 and 14937).
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 non-conformed small steam 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. If the opening of the Compact-PCD® is not in the lowest position during sterilization condensate may come out of the PCD during removal from the sterilizer burning your fingers.
6. Do not dismount the Compact-PCD®. An dismounted PCD cannot be reassembled and must be replaced by a new one.

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

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