Process Challenge Device (PCD)

TO MONITOR STEAM STERILIZATION PROCESSES



Application

The sterilizer manufacturer standards EN 285 (big sterilizers) and EN 13060 (small tabletop sterilizers) define so-called type tests, e.g. Bowie Dick (BD) Test or Helix Test according to EN ISO 11140-6. Type tests represent minimum requirements and have no relation to the load that is actually to be sterilized.

Although type tests are often offered as routine tests, successful test results do not allow to assume automatically that complex goods and difficult loads can be sterilized. Many sterilization loads present significantly different challenges compared to these type tests.

For a test system to be suitable for batch monitoring, its test characteristics must therefore relate to the load and not to the minimum requirement that the sterilizer must meet according to its standard.

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 Mesa Germany offers a variety of different PCDs (process challenge devices) with different sensitivities in order to be able 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).

Mesa Germany 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

The Compact-PCD consists of an external plastic case with an internal stainless steel tube and a capsule holding the indicator.

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

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

All PCDs can be used for several thousand cycles.

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. Biological indicators can be used alternatively, but in this case the PCD shall not be opened after sterilization but aseptically transferred in a microbiological laboratory.

Performance Characteristics

The 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 by an accredited laboratory (EN ISO 17025).

Mesa Germany offers a variety of PCDs with

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different levels of difficulty. Using a test with the highest level which will still pass in a validated process ensures that the sterilizer is always tested at its limits. Failures that are not detected with standard methods will become 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. The release of a batch by only recording the physical data as measured by the sterilizer is not possible because the sterilizer printout does not contain information regarding “steam penetration”.

The identification of a suitable PMS to monitor sterilization has to be verified during process validation depending on the load.

1. Compact-PCD, color: green
This PMS Compact-PCD, color: 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 ISO 11140-6.

2. Compact-PCD, color: orange
The PMS Compact-PCD, color: orange, simulates the hollow load test according to EN ISO 11140-6. 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 ISO 11140-6 describes a test cycle with 4 injections of steam to 950 mbar. In this test cycle the hollow load test will be successfully penetrated, if a vacuum of 180 mbar will be reached in between each steam pulse.

3. Compact-PCD, color: red
The Compact-PCD, color: red, (High Demand Hollow) is used for routine monitoring of complex instruments or long tubes, in which the hollow load test according to EN ISO 11140-6 is no longer sufficient.

To successfully penetrate the GKE HDH-PMS in the same test cycle a vacuum of at least 110 mbar is necessary.

4. VHDH-PMS Compact-PCD, color: brown
The VHDH-PMS Compact-PCD, color: brown, (Very High Demand Hollow) requires even higher performance regarding air removal and steam penetration. The test cycle according to EN ISO 11140-6 with 4 injections of steam requires vacuum cycles of at least 70 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 air removal and steam penetration are strictly defined in such a program and must remain unchanged in all test cycles.

Under real sterilization conditions the differences in performance between type test according to EN ISO 11140-6 and the GKE HDH-PMS or GKE VHDH-PMS may change considerably because routine programs differ from the above mentioned test cycle.

Operational 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 oder 121 °C, 15 min (standard)
2. 134 °C, 18 min (Prion cycle)

Sterilization was successful when all four bars of the indicator strip have turned from the initial color to black.

Color change of a standard indicator strip. If using an indicator strip for prion programs the initial color is pink.

Sufficient temperature, time and steam penetration



Insufficient air removal and steam penetration



Temperature achieved, but no air removal and no steam penetration



Insufficient temperature, no air removal and no steam penetration



This result ensures air removal and steam penetration into the whole load under the condition that the PCD is representing the load configuration.

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Benefits

- Indicator strips for standard and prion steam sterilization cycles are 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, one indicator strip is sufficient per batch - independent from the number of packs.
- Easy interpretation of the results due to precise color 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 color 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 color chemistry is a non reversible chemical reaction and remains color-fast over time if they are not stored with other chemicals.
- Easy documentation because of self-adhesive indicator strips.
- All chemical indicators are protected from bleeding by a polymer binder and surface coating.
- Selection between four different versions of 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 high-quality plastics.

Order Information

Each start-up kit contains a Compact-PCD and 100 integrating standard indicator strips. The PCDs are also available separately. The indicator strips are available as refill pack (without PCD) for standard and prion programs. With appropriate care the PCD can be used for several thousand sterilization cycles. A seal ring for the screw cap is included in each refill pack.

Start-up kit and PCDs / Process Monitoring Systems (PMS)

Art. No.	Quantity	Product Code	Content
211-253	1+100	C-S-PM-SHL-RCPCD-KIT	Compact-PCD round section (Color: green), integrating indicator
211-254		C-S-PM-SHL-OCPCD-KIT	Compact-PCD oval section (Color: green), integrating indicator strips
200-020	1	PM-SHL-RCPCD	Compact-PCD round section (Color: green)
200-024	1	PM-SHL-OCPCD	Compact-PCD oval section (Color: green)
211-263	1+100	C-S-PM-HL-RCPCD-KIT	Compact-PCD round section (Color: orange), integrating indicator strips
211-264		C-S-PM-HL-OCPCD-KIT	Compact-PCD oval section (Color: orange), integrating indicator strips
200-021	1	PM-HL-RCPCD	Compact-PCD round section (Color: orange)
200-026	1	PM-HL-OCPCD	Compact-PCD oval section (Color: orange)
200-029	1	PM-HDH-RCPCD	Compact-PCD round section (Color: red)
200-030	1	PM-VHDH-RCPCD	Compact-PCD round section (Color: brown)

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Refill packs indicator strips for all above PMS

Art. No.	Quantity	Product Code	Content	Stated Value	Application
211-251	100	C-S-PM-SV1	Integrating indicator strips, 1 seal ring	134°C, 3 min 121°C, 15 min	Refill pack with integrating indicator strips for all GKE process monitoring systems
211-252	250				
211-255	500				
211-211	100	C-S-PM-SV2		134°C, 18 min	
211-212	250				
211-215	500				

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