



Bowie-Dick-Simulation Test

FOR STEAM STERILIZERS

Application

The Bowie-Dick simulation test (BDS) is carried out daily as a function test before using the sterilizer. It is a type test (not a sterility test) described in EN 285 (standard for large sterilizers). The BDS is not a substitute for routine monitoring, which can only be carried out with a batch or a process monitoring system or with type 5 or type 6 indicators in each package.

The standard for small table-top sterilizers, EN 13060, does not mention a Bowie-Dick test. The type test for B-class small sterilizers is the hollow load test ("Helix") according to EN ISO 11140-6. Nevertheless, the manufacturer's specifications for some small sterilizers require a morning test run in the Bowie-Dick test cycle. The test system with the dark blue Compact-PCD (Process Challenge Device) combines the test requirements as a BDS and a hollow load test in a single system.

Product Description

All BDS-Tests are type 2 indicator systems according to EN ISO 11140-1 consisting of a "specific test load" so-called Process Challenge Device = PCD and a detector" (indicator strip) inside. The PCD consists of an external highly durable case containing an internal stainless steel tube connected with a capsule holding the indicator. The highly durable PCD can be used for several thousand applications. Only one indicator strip is required for each test and used in all three GKE BDS versions.

Performance Characteristics

The sterilizer standards EN 285 and AAMI/ANSI ST79 describe three different type tests:

1. American BD-Test
Air removal test according to AAMI/ANSI ST79 (4 kg test pack) and validated according to the

test method of ISO 11140-1 + 5.

2. European BD-Test
Air removal and steam penetration test validated according to the test method of EN ISO 11140-1 + 4 with reference to the 7 kg test pack in EN 285.
3. Hollow load test (Helix-Test) described in EN ISO 11140-6 required as an additional type test in EN 285.

Mesa Germany offers three different GKE BDS-Tests with the following characteristics.

Depending on the sterilizer BD-test program, the correct BDS-Test has to be selected.

GKE BDS-Tests	BD-Test EN 285 (7 kg test pack)	Hollow Load Test (helix) ISO 11140-6	BD-Test AAMI/ANSI ST 79 (4 kg test pack)
Compact-PCD blue	x	x	
Compact-PCD purple	x		
Compact-PCD light blue			x

Operation Description

After opening the screw cap of the Compact-PCD, a BD indicator strip is placed in the PTFE holder and the screw cap is closed again. The PCD should be placed in the lower part of the chamber, near the door. This test can be used in Bowie-Dick-Test programs at 132-137°C (270-279°F); 1-3.5 min or 121°C (250°F); 15-30 min. If no specific BD-cycle is available, a normal cycle of 132-137°C with holding time up to 9 min may be used without losing sensitivity.

If all six bars of the chemical indicator turn from yellow to black it is an indication of sufficient steam penetration inside the PCD. A positive result ensures that the sterilizer works according to the sterilizer specifications.



Sufficient temperature, time and steam penetration



Temperature achieved, but no air removal and no steam penetration



Insufficient air removal and steam penetration



Insufficient temperature, no air removal and no steam penetration



Benefits

- The “multi-stage” design of the Compact-PCD, color blue, simulates the porous Bowie-Dick cotton pack and the Helix-Test in one system.
- To be used in 132-137°C and 121°C-Bowie-Dick-Test programs according to EN 285 and EN ISO 11140-3. The test may also be used in sterilizers without Bowie-Dick Test programs and longer sterilization times without losing sensibility.
- Simple application - the chemical indicator may be easily removed and evaluated on completion of each cycle.
- Easy interpretation of the results due to precise color change.
- Continuous reproducibility of the results.
- The graduated color change of the indicator bars provides information about the performance in

terms of steam penetration.

- Environmentally friendly, no unnecessary waste.
- Indicator strips can be disposed with normal garbage.
- The indicator color cchange is the result of an irreversible chemical reaction, so that the indicator can be archived permanently.
- All chemical indicators are protected from bleeding by a polymer binder and surface coating.
- Cost-effective due to multiple use of the PCD.
- The screw-cap consists of a highly thermal resistant material and stainless steel sandwich-construction that protects hands from high temperatures.
- GKE self-adhesive labels simplify recording with the GKE documentation system.

Order Information

Each start-up kit contains one Compact-PCD and 100 integrating indicator strips. Test devices are available separately as well. The indicator strips are available as refill packs and contain a seal ring for replacement in the screw cap.

1. Air removal and steam penetration test, validated according to the test method of EN ISO 11140-4 + 1 Type 2 with reference to the 7 kg test pack in EN 285 and the hollow load test exceeding the requirements of EN ISO 11140-6

Art. No.	Quantity	Product Code	Content
211-150	1+100	C-S-BDS-EUH-RCPCD-KIT	Compact-PCD (color: blue) integrating indicator strips
211-151	1	C-S-BDS-EUH-RCPCD	Compact-PCD (color: blue)

2. Air removal and steam penetration test, validated according to the test method of EN ISO 11140-4 + 1 Type 2 with reference to the 7 kg test pack in EN 285

Art. No.	Quantity	Product Code	Content
211-120	1+100	C-S-BDS-EU-RCPCD-KIT	Compact-PCD (color: purple)integrating indicator strips
211-121	1	C-S-BDS-EU-RCPCD	Compact-PCD (color: purple)

3. Air removal test according to AAMI/ANSI ST79 (4 kg test pack), validated according to the test method of ISO 11140-5 + 1 Type 2

Art. No.	Quantity	Product Code	Content
211-130	1+100	C-S-BDS-USA-RCPCD-KIT	Compact-PCD (color: light blue) integrating indicator strips
211-131	1	C-S-BDS-USA-RCPCD	Compact-PCD (color: light blue)

Indicator strip refill packs for all above mentioned BDS-Tests

Art. No.	Quantity	Product Code	Content
211-111	100	C-S-BDS-SV1	Integrating indicator strips, 1 seal ring
211-112	250		
211-115	500		

