

# *gke Steri-Record*<sup>®</sup> Bowie-Dick-Simulation (BDS) Tests

STEAM

## STEAM PENETRATION

EU-Version  
Simulating 7 kg cotton pack according to EN ISO 11140-4 and hollow load test according to EN 867-5

EU-Version  
Simulating 7 kg cotton pack according to EN ISO 11140-4

USA-Version  
Simulating 4 kg cotton pack according to ISO 11140-5

## AIR REMOVAL



*gke Steri-Record*<sup>®</sup> Bowie-Dick-Simulation Tests

### Application

The *gke Steri-Record*<sup>®</sup> Bowie-Dick-Simulation (BDS) Test is daily used after start up as a functionality check (type test, no sterility test) for steam sterilizers. It has to be carried out in an empty sterilizer chamber. The BDS test is no substitution for routine monitoring. For routine monitoring batch/process monitoring systems or type 5 or 6 indicators in each package should be used.

Table top sterilizers according to EN 13060 type B do not require a Bowie-Dick Test but a hollow load type test according to EN 867-5. However, some sterilizer manufacturers demand the daily use of a BDS-test during start-up. The Compact-PCD<sup>®</sup> (colour: blue) combines the BD- and hollow load test in one test system.

### Product Description

All three *gke Steri-Record*<sup>®</sup> BDS-Tests are type B 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. The same indicator strip is used in all three BDS versions and is self-adhesive for daily documentation.

### 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 described in EN 867-5 required as an additional type test in EN 285.

All **gke** BDS-tests are type 2 indicators according to EN ISO 11140-1. **gke** offers three different BDS-Tests with the following performance characteristics. The table below shows the conformity of the **gke**-BDS Tests.

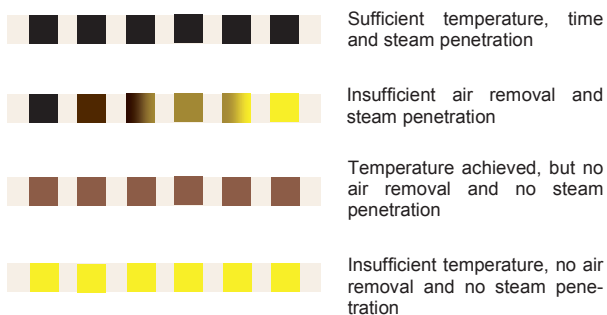
<b>gke</b> BDS-Tests	BD-Test EN 285 (7 kg test pack)	Hollow Load Test EN 867-5	BD-Test AAMI/ANSI ST 79 (4 kg test pack)
Compact-PCD® (colour: blue)	x	x	
Compact-PCD® (colour: purple)	x		
Compact-PCD® (colour: light blue)			x

All above mentioned BDS-Tests can be used in BD test programs at 132-137°C, 1-3.5 min or 121°C, 15-30 min. If these BD-cycle are not available, a normal cycle of 134°C for up to 9 min may be used.

### Operation Description

A **gke** BD indicator strip has to be placed into the PTFE holder of the Compact-PCD® and the cap has to be tightened. The test device should be placed close to the bottom and near the door of the chamber on a stainless steel tray into an empty sterilizer chamber. 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 min. If this BD-cycle is not available, a normal cycle of 132-137°C for 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.



### Sterilizer program requirements

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

### Benefits

- The innovative patented “multi-stage” design of the Compact-PCD®, colour blue, simulates the porous Bowie-Dick cotton pack and the Helix-Test.
- 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 old 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 colour change.
- Continuous reproducibility of the results.
- The graduated colour change of the indicator bars informs about the magnitude of air removal and steam penetration inside the sterilizer and non-condensable gases in steam.
- Environmentally friendly, no unnecessary waste.
- Indicator strips can be disposed with normal garbage.
- The indicator colour chemistry is a non-reversible chemical reaction and remains colour-fast over time.
- All **gke** 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 Steri-Record®** 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 867-5

Art.-No.	Product Code	Quantity	Content	Application
211-150	C-S-BDS-EUH-RCPCD-KIT Start-up kit	1 + 100	Compact-PCD® (colour: blue) integrating indicator strips	BDS air-removal and steam-penetration test for hollow and solid instruments and also porous loads.
211-151	C-S-BDS-EUH-RCPCD	1	Compact-PCD® (colour: 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.	Product Code	Quantity	Content	Application
211-120	C-S-BDS-EU-RCPCD-KIT Start-up kit	1 + 100	Compact-PCD® (colour: purple) integrating indicator strips	BDS air-removal and steam-penetration test for porous loads and solid instruments (not recommended for hollow instru- ments)
211-121	C-S-BDS-EU-RCPCD	1	Compact-PCD® (colour: purple)	





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

Art.-No.	Product Code	Quantity	Content	Application
211-130	C-S-BDS-USA-RCPCD-KIT	1 + 100	Compact-PCD® (colour: light blue) integrating indicator strips	BDS air-removal test for porous loads
211-131	C-S-BDS-USA-RCPCD	1	Compact-PCD® (colour: light blue)	

### 4. Indicator strip refill packs for all above mentioned BDS-Tests

Art.-No.	Product Code	Quantity	Content	Application
211-111	C-S-BDS-SV1	100	Integrating indicator strips, 1 seal kit	Refill pack with integrating indicator strips for all <b>gke</b> BDS tests.
211-112		250		
211-115		500		

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