

# DIRECTIONS FOR USE



## GKE Steri-Record® Bowie-Dick Simulation Tests



Art.-No. *	Product Code	Quantity [pc]	Product Description	Stated Value (SV)	Application
211-150	C-S-BDS-EUH-RCPCD-KIT	1+100	Compact-PCD® (blue) + indicator strips	121°C, 15 min 134°C, 3,5 min	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
211-151	C-S-BDS-EUH-RCPCD	1	Compact-PCD® (blue)		
211-120	C-S-BDS-EU-RCPCD-KIT	1+100	Compact-PCD® (purple) + indicator strip	121°C, 15 min 134°C, 3,5 min	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
211-121	C-S-BDS-EU-RCPCD	1	Compact-PCD® (purple)		
211-130	C-S-BDS-USA-RCPCD-KIT	1+100	Compact-PCD® (light blue) + indicator strips	132-134°C, 3,5 min	Air removal test according to AAMI/ANSI ST 79 (4 kg test pack) and validated according to the test method of ISO 11140-5 + 1 Type 2
211-131	C-S-BDS-USA-RCPCD	1	Compact-PCD® (light blue)		
211-111	C-S-BDS	100	Indicator strips + 1 seal ring	121°C, 15 min 134°C, 3,5 min	Integrating indicator strips for all GKE Bowie-Dick Simulation Tests
211-112		250			
211-115		500			

(\* All GKE products contain a 6-digit article number, added by an additional letter code that refers to the language and/or customized version. It is only added on the outside label; the inside of the pack is identical to the article numbers on the above table.

### Application

The GKE Steri-Record® BDS-Test is used daily 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 Process/ Batch Monitoring Systems (PMS/BMS) validated according to the load configuration or type 5 or 6 indicators in each load 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 request the daily use of a BDS-test during start-up. The Compact-PCD® (colour: blue) combines the Bowie-Dick Test and hollow load test in one test system.

### Performance Characteristics

GKE offers BDS-Tests with different performance characteristics. The sterilizer standards describe three different type tests:

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 (European BD-Test)
2. A hollow load test described in EN 867-5 required as an additional type test in EN 285.
3. Air removal test according to AAMI/ANSI ST 79 (4 kg test pack) and validated according to the test method of ISO 11140-5 + 1 Type 2 (American BD-Test)

The table below shows the conformity of the GKE BDS Tests:

	EN 285 (7 kg test pack)	Hollow Load Test EN 867-5	AAMI/ANSI ST 79 (4 kg test pack)
Compact-PCD®, blue	x	x	
Compact-PCD®, purple	x		
Compact-PCD®, light blue			x

### Sterilizer program requirements for BDS-Tests

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

### Product Description

All GKE Steri-Record® BDS-Tests are used with the same integrating indicators. The Compact-PCD® consists of an external plastic casing with an internal stainless-steel tube and a capsule to hold the indicator strip. The Compact-PCD® lasts for an unlimited number of cycles without changing its performance.

### Handling Information

1. Depending on the sterilizer used, select the appropriate BDS test device (European or American version). In case hollow loads are sterilized it is recommended to use the European BD-Test including the hollow load characteristics. The test conditions of the European version are harder to fulfil than the test condition of the American version.
2. Open the cap and make sure that the seal ring in the cap is in good condition.
3. Take out the indicator strip from the card and fold it that the indicator bars are inside and place it in the white holder with the fold toward the screw cap. The indicator strip does not fully fit into the white holder. The end of the indicator remains outside.
4. Insert the white holder into the PCD and tighten the cap.
5. Place the test device close to the bottom and near the door of the chamber horizontally on a stainless-steel tray or hang it 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 special Bowie-Dick Test program 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.
7. On completion of the cycle remove the test device carefully. Condensate inside the PCD may come out if the test device is not placed horizontally.
8. After cooling down, remove the indicator strip and check the results:
  - If all 6 bars have turned from yellow to black the sterilization process has been successful.
  - If one of the bars is yellow or has a colour between yellow and brown, it is an indication for residual air remaining in

the sterilizer. For easy interpretation use the colour-pass/fail reference chart. The reason for a failure may be insufficient air removal, leaks in the sterilizer or non-condensable gases (NCG) in steam. In this case repeat the BDS Test once or twice again until NCG disappears. If the BDS-test does not pass after the third test do not use that sterilizer anymore and call for technical service.

9. The person authorized will decide whether to release the sterilizer for production or to repeat the test.
10. The indicator is self-adhesive and can be adhered onto the GKE documentation sheet with date, sterilizer and batch number and the initials of the person authorized to do so (see Documentation Information).
11. If using a program without a drying cycle the PCD may contain water condensate. In this case open the test device when it is still warm, blow air through and leave it open for drying.

### Maintenance Information

All Compact-PCD® consist of an external plastic casing with an internal stainless-steel tube and capsule holding the indicator. They 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. Use the following procedure for exchange:

1. Unscrew the cap of the PCD containing the white teflon holder.
2. Unscrew the white teflon holder from the cap.
3. Remove the seal ring inside the cap with a pointed object (e.g. small screwdriver, needle etc.)
4. Insert a new seal ring of the same size in the cap. Use the white teflon holder to push the seal ring down into the slid.
5. Screw the white teflon holder in the cap again.

Older PCDs (e.g. Compact-PCD® purchased before 2009) have a smaller screw cap and require a different seal ring. In this case please contact GKE or your local dealer.

### Technical Information

Where a central steam supply exists, the amount of NCG in long pipes may increase when pipes cool down over night or during weekends. Therefore, a higher level of NCG during the first cycles may occur showing poor Bowie-Dick-Test results. To circumvent this problem, we recommend to run one or more cycles in an empty chamber to heat up the sterilizer and purge the steam pipes containing NCG. If the BDS-Test is only successful after several pre-cycles, the sterilizer itself has no technical deficiencies but the problem is associated with the steam supply as mentioned above.

If the BD-test was previously successful and is showing problems after several cycles the sterilizer or poor steam quality may cause the problem. In this case, stop the sterilization production immediately and call for technical service.

### Documentation Information

A documentation sheet 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 batch monitoring strips and the BDS-test 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 GKE 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.

### Storage and Disposal

1. For longer periods store all indicators in the original package.
2. Store indicators always between 5-30 °C or 41-86 °F and a humidity of 5-80% RH.
3. The vapour of chemicals especially hydrogen peroxide may change the indicator before or after sterilization. Therefore, do not store them together with other chemicals.
4. The indicators should not be used after expiry date. They may be disposed with normal waste.

### Safety Precautions

1. PCD and indicator strips are precisely 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.
2. The sterilization time at 132-137°C in the test program should not be longer than 9 minutes.
3. The result of the BDS-test is only valid for the test cycle itself. Conclusions on previous or future cycles cannot be made. For ongoing cycle monitoring, we recommend one of the GKE Process/ Batch Monitoring Systems.
4. The GKE Steri-Record® BDS-Test is no replacement for validation of the process. The sterilizing process must be validated before initial start-up, after each major repair, after a certain amount of sterilization cycles or a certain period according to international and national laws (MDR).
5. In small sterilizers steam is generated inside the sterilization chamber. The walls and the bottom may heat up above 180°C if there is not enough 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.
6. If the opening of the Compact-PCD® is not in lowest position during sterilization, condensate may come out of the PCD during removal from the sterilizer burning your skin.
7. Do not open the screws of the Compact-PCD®. An unscrewed 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](http://www.gke.eu) for more information.

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