INSTRUCTIONS FOR USE

Bowie-Dick & Hollow Load Simulation Test

Manufactured and labelled by GKE in accordance with ISO 11140-4 and ISO 11140-6

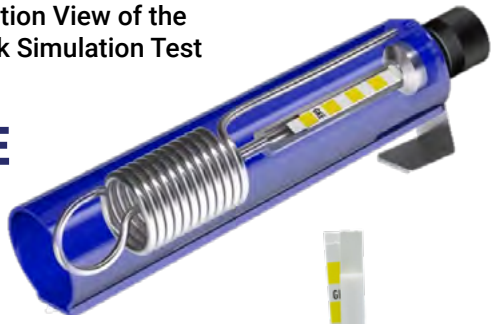
Indication for Use

This Bowie-Dick & Hollow Load Simulation Test is a type 2 indicator system according to ISO 11140-1, consisting of a Process Challenge Device (PCD) and an indicator strip inside, which complies with ISO 11140-4 and ISO 11140-6 for air removal and steam penetration. The Bowie-Dick Test is carried out daily as a functional test before using the sterilizer, in accordance with ISO 17665 and EU GMP Annex 1. This product is not intended for sale or use within the United States.

Operation description

1. Open the Blue Compact PCD cap and ensure the seal ring in the cap is in good condition.
2. Remove the indicator strip from the card. Fold the strip so that the indicator bars are on the inside. Place the folded strip into the white holder with the fold facing toward the screw cap. The indicator strip will not fit entirely into the white holder; the end of the strip should remain outside.
3. Insert the white holder into the PCD and securely tighten the cap.

Cross-Section View of the Bowie Dick Simulation Test



Placement of chemical indicator in the holder

4. The PCD should be placed in the lower part of the chamber, near the door, horizontally on a stainless-steel tray or hung vertically on a loading rack in the lower section near the door. The PCD does not need to be put into a pack, pouch, or container.
5. This test can be used in Bowie-Dick test programs at 132–137°C for 1–3.5 minutes or at 121°C for 15–30 minutes. The test may also be used in sterilizers without Bowie-Dick test programs and with longer sterilization times without losing sensitivity. The sterilization time at 132–137°C in the test program should not exceed 9 minutes.
6. At the end of the cycle, carefully remove the test device. Condensate inside the PCD may leak out if the test device is not positioned horizontally.
7. After cooling down, remove the indicator strip and inspect the results (refer to Figure 1 on page 2):
   - If all six bars have changed from yellow to black, the sterilization process was successful.
   - If any bar remains yellow or is a color between yellow and brown, this indicates residual air within the sterilizer. For easier interpretation, use the color pass/fail reference chart. Failure may result from insufficient air removal, leaks in the sterilizer, or the presence of non-condensable gases (NCG) in the steam. In this case, repeat the Bowie-Dick test once or twice until NCGs are eliminated. If the test still does not pass after three attempts, discontinue use of the sterilizer and contact your technical service.

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

Figure 1. Interpretation of Chemical Indicator strips results

8. The self-adhesive chemical indicator strip can be affixed to documentation sheets for record-keeping purposes.

Blue Compact PCD Maintenance

The blue compact PCDs consist of a stainless-steel tube and a stainless-steel capsule inside, which are welded to be corrosion-free, and an external plastic case that is temperature-stable up to approximately 200°C.

The PCD has a durability of at least 10,000 cycles for the specified PCD when handled properly. A seal ring is included in each bag of chemical indicator strips (ref-211-111); It is recommended to replace the seal ring with each new bag to prevent deterioration. If not replaced with every bag, the cap seal must be changed at least every 500 to 1,000 cycles.

Seal ring replacement procedure:

1. Unscrew the cap of the PCD that contains the white Teflon holder.

2. Unscrew the white Teflon holder from the cap.

3. Carefully extract the old seal ring from inside the cap using a pointed tool (such as a small screwdriver or needle).

4. Insert a new seal ring of the correct size into the cap. Use the white Teflon holder to gently press the seal ring into its designated groove.

5. Reattach the white Teflon holder to the cap by screwing it back in place.