

## Bowie-Dick Simulation (BDS) Test



STEAM

### Instructions for Use

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

Stated Value (SV) = 132 - 134 °C (270 - 273 °F), 3.5 min

The Process Challenge Device (PCD) is an external plastic casing with an internal stainless steel tube and a capsule to hold the indicator strip.

### Application

The maxill u-test Bowie-Dick Simulation (BDS) test is to be used daily after start up as a functionality check (type test, no sterility test) for steam sterilizers. The test must be completed in an empty sterilizer chamber. The BDS test is no substitution for routine monitoring.

### Product Description

The u-test PCD consists of an external plastic casing with an internal stainless steel tube and a capsule to hold the indicator strip. The u-test PCD lasts for an unlimited number of cycles without changing its performance.

### Performance Characteristics

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

### Handling Information

1. Open the cap and make sure that the seal ring in the cap is in good condition.
2. Remove ONE indicator strip from the card and fold it in half so the indicator bars are on the inside. Place the indicator in the white holder with the folded end towards the screw cap. The indicator strip does not fit fully into the white holder. The end of the indicator remains outside.
3. Insert the white holder into the PCD and tighten the cap.
4. Place the PCD in the chamber of the sterilizer close to the bottom and near the door of the chamber. The PCD can be placed 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. 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.
6. 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.
7. Allow the PCD to cool then remove the indicator strip and check the results. If all 6 bars have turned from red to black the sterilization process has been successful. If one of the bars is red or has a colour between red 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 the steam. In this case repeat the BDS Test once or twice until NCG disappear. If the BDS-test does not pass after the third test do not use the sterilizer and call for technical service.
8. The person authorized will decide whether to release the sterilizer for production or to repeat the test.
9. The indicator is self-adhesive and can be adhered onto a documentation sheet with date, sterilizer and batch number and the signature of the person authorized to do so.
10. 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

The u-test PCD consists 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.

## 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 running 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.

## 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 u-test indicator strips are used with other test devices, maxill 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.
4. The maxill u-test BDS-test is not a 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 and in accordance with applicable regulations.
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. CAUTION If the opening of the u-test 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 u-test PCD. An unscrewed PCD cannot be reassembled and must be replaced by a new one.