

Instructions For Use

u-test BDS

Bowie-Dick Simulation (BDS) Test



STEAM

#81192- BDS Test Kit (PCD + 100 Test Strips)

#81191- BDS Test Strips (100 Test Strips)



Intended Use: The maxill u-test Bowie-Dick Simulation (BDS) test is to be used daily at start up to check functionality (type test, test non-sterility) of pre-vacuum dynamic-air-removal sterilizers. The BDS test does not replace regular monitoring. The BDS process challenge device (PCD) is required to perform the test.

Product Description: The BDS u-test PCD consists of an outer plastic case with inner stainless steel tube and capsule to house the indicator strip. The u-test PCD device is applicable for an unlimited number of cycles without changing the functional properties or performance.

Performance Characteristics: Air removal test according to AAMI/ANSI ST79 standard (4kg test package) and validated according to the test method in the standard ISO 11140-5 + 1, type 2.

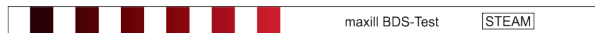
Handling Instructions

1. Open the cap and inspect the ring seal in the cap is in good condition.
2. Remove **ONE** indicator strip from the packaging and fold it so that the indicator bars are facing each other, and insert into the while holder with the folded end towards the screw cap. The indicator strip does not fit fully into the white holder. End of the indicator will remain outside.
3. Insert the white holder into the PCD and tighten the cap.
4. Place the loaded PCD in the sterilizers chamber on the bottom, near the chamber door. The PCD can be placed horizontally on a stainless steel tray, or vertically hung on the loading racks lowest section near the door. The PCD does not need to be put into a pack, pouch, or cassette.
5. Run the pre-programmed Bowie-Dick Test Cycle at 132-137°C (270-279°F); 1 - 3.5 min or 121°C (250 °F); 15 min.. If a pre-programmed cycle is not available you can use a normal or custom cycle of 132-137°C (270-279°F) for up to 9 minutes without losing sensitivity.
6. After the cycle is complete, carefully remove the test device. Condensate inside the PCD may come out if not placed horizontally.
7. Allow the PCD to cool completely before removing test strip. Remove the indicator and check results:

A successful Bowie-Dick Simulation (BDS) Test proves rapid and even steam penetration. The result does not guarantee that all subsequent sterilization cycles achieve the same process conditions.



All colour segments are black - **sufficient steam penetration.**



Colour segments are black at one end, and red-brownish at the other end - **insufficient steam penetration and air removal**



All colour segments are brownish, but not black - **temperature achieved, but no steam penetration and air removal**



All colour segments are red - **insufficient temperature and no steam penetration and air removal**

Troubleshooting Help:

- If the first Bowie-Dick Simulation test fails - repeat the test. If the test continues to fail the sterilizer must be checked and if necessary, repaired. Fail conditions may be due to various reasons. In that case, sufficient steam penetration to all inner surfaces of the load may not be achieved.
- A failure of the BDS Test is not conclusive source of proof that the fault is necessarily associated to the sterilizer itself (insufficient air removal or leakages), but may be due to external causes such as unpurged steam pipes at the start of the process, non-condensable gases in the external steam supply or changing temperature of the cooling water. Therefore, BDS Tests made in subsequent cycles may show different results.

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8. An authorized person will interpret the results and decide whether the sterilizer can be released for normal operation, or whether it is necessary to repeat the test.
9. The indicator is self-adhesive and can be adhered onto a monitoring log sheet with the date, sterilizer and batch number. along with the signature of the authorized person recording the results.
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 instructions to replace seal ring:

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, dental scaler 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 groove.
5. Screw the white teflon holder in the cap again.

Technical Information

Where a central steam supply exists, the amount of NCG (non-condensable gases) 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 operation immediately and call for technical service.

Storage and Disposal

1. For longer storage periods, keep all indicators in original packaging.
2. Always store indicators at temperatures of 5-30°C (41-86°F) and maximum relative humidity of 70%
3. Vapours of chemical substances, especially hydrogen peroxide, can affect the indicator before or after sterilization. Therefore it is important you **DO NOT** store them together with other chemicals.
4. Do not use the indicators 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 cycle should not exceed longer than **9 minutes**.
3. The results of the BDS-test is only valid for the test cycle itself. Conclusions on previous or future cycles cannot be made.
4. The results of the 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 the 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 with a new



Spaulding's Classifications

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