

<b><i>gke</i> - Technical Information</b>	<b>730-072-EN</b>	
<b>Use of the BD- and hollow load test in large and table-top steam sterilizers</b>	<b>Version 05</b>	
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The Bowie-Dick-Test (BD-Test) is a so-called type test for large sterilizers and is defined in the standard EN 285 using a 7 kg cotton pack with an indicator page inside described in EN ISO 11140-3. This test is a functional test to assure air removal and steam penetration in large sterilizers. The BD-Test is a porous load test and has different air removal and steam penetration characteristics comparing to hollow devices. To assure that hollow devices are safely sterilized as well, in 2008 a hollow test device according EN 867-5 has been added to the standard EN 285 as a second type test. Type tests are typically used to test the conformity according to a standard but they are not automatically used for routine monitoring.

The standard for validation and routine monitoring requests that before daily start-up of a sterilizer a steam penetration test has to be done to assure that the air is removed in the steam generator, the sterilizer chamber and the pipes between. For this purpose usually type tests (BD-Test and hollow load test) defined in the standard EN 285 for large sterilizers and the standard EN 13060 for table-top sterilizers are used.

However those tests only test the functionality of the sterilizer after start-up. Even after the type tests in the morning have been successful, it is not automatically secured that all consecutive sterilization batches produce sterile goods, especially the sterilization of hollow devices like tubes, minimal-invasive- surgical instruments and dental hand pieces is very critical, if extreme small amounts of non condensable gases(NCG) are present. To assure sterility of such devices special batch monitoring systems (BMS) have to be used. These BMS are not validated against the performance of an EN 285 / EN 13060 sterilizer but against the air removal requirements of the load. The validation of such BMS is carried out based on the German DIN 58921.

In table top sterilizers the original BD-cotton pack cannot be used because of its size and is not required in standard table-top sterilizers according EN 13060. The type test for table top sterilizers class B is a hollow load test which is also mandatory for large sterilizers. However, many table-top sterilizers contain a so-called "BD-Test program", which is a special test cycle.

Therefore for the function test in the morning – the BD-Test – assuring that the table-top sterilizer is ready for operation, the following tests can be used alternatively in the BD-Test program if it is a sterilizer class B:

- Helix-Test according to EN 867-5, since this test is mentioned in the standard EN 13060 as a type test.
- Batch monitoring system adapted to the difficulty sterilizing the load using the method according to DIN 58921, since this secures a sufficient capability to sterilize the load.

Both tests assure that the sterilizer is ready for operation and the standard requirements are fulfilled completely. However, even the function test at start-up in the empty table-top sterilizer is formally required, it does not make much sense from a technical process point of view, since table-top sterilizers do not have large connection pipes between steam generator and sterilizer chamber and steam generator.