

	<b>Technical Information</b>	<b>730-072-EN</b>		<b>V08</b>
	<b>Use of the BD- and hollow load test in large and table-top steam sterilizers</b>	Created	24.03.2006	JM
		Changed	02.09.2021	KP
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<b>File no.: 0.3</b>				

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 compared to hollow devices. To assure that hollow devices are safely sterilized as well, in 2008 a hollow test device according EN 867-5 (new EN ISO 11140-6) has been added to the standard EN 285 as a second type test. Type tests are typically used to test the conformity of a steam sterilizer according to a standard but they are not automatically used for routine monitoring.

The standard for validation and routine monitoring EN ISO 17665-1 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.

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 (new EN ISO 11140-6), 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 in the validation standard EN ISO 17665-1, 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.

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.

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Therefore batch monitoring test systems must be used that do not represent the function of the sterilizer, but the requirement of the load. There are two procedures to select a batch monitoring system. A test can be used whose test requirement for the test method has been compared with a defined load according DIN 58921 ("Medical Device Simulator"). Alternatively, test systems with different levels of difficulty can be used in the validated process on a trial basis. Among those tests that provide a satisfactory result, the one with the highest test requirements can then be selected for batch monitoring.

In this test selection it may turn out that the sterilizer has a considerably higher air removal capacity than the minimum capacity required in the standard.