

	Technical Information	730-080-EN		V06
	The GKE Bowie-Dick-Simulation Test replaces the BD cotton pack as well as the hollow load test	Created	30.01.2008	JM
		Changed	02.09.2021	KP
		Checked	02.09.2021	UK
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File no.: 0.3 + 1.1.1				

In the European standard for large sterilizers, EN 285, test methods are defined to secure that a large sterilizer achieves a defined minimum performance. This standard defines two so-called type tests, which a sterilizer has to pass successfully. These tests are the original Bowie-Dick Test (7 kg cotton pack with a chemical indicator sheet or thermo-electrical tests) and now additionally a hollow load test with a Helix Process Challenge Device (PCD) according to EN 867-5. This hollow load helix test was used already as a type test in small sterilizers (class B autoclaves according to EN 13060) and is mandatory also for large sterilizers since January 2008.

Both tests complement each other and shall not replace each other.

1. Background

GKE has published in 2001 that a BD cotton pack does not represent the requirements necessary for a secure sterilization of hollow devices. Sterilization of hollow instruments cannot be secured with the historical porous test alone.

After the publication of GKE in 2001 the results have been verified and confirmed by several other companies in a round robin test within a European standard working group. As a result the hollow load test (hollow load helix test) has been added to EN 285 in 2008.

2. GKE BDS (Bowie-Dick-Simulation Test)

Therefore GKE offers a test which combines requirements of both tests in one test system (Bowie-Dick Simulation Test and hollow load helix test).

That both requirements are fulfilled is secured because of the following reasons:

a. Replacement for the BD cotton pack of 7 kg

The Bowie-Dick-Test, originally a 7 kg cotton pack with an indicator sheet inside, has been developed already in the 1960s as function test before startup. In practice since years the complex and labour-intensive manufacturing of the original cotton pack is replaced by using so-called Bowie-Dick Simulation Tests having an identical or even higher sensitivity than the original test, being user-friendly and providing reproducible results.

To make a BD Simulation Test at least as sensitive as the original cotton pack has been made, EN ISO 11140-4, a special test standard, describing exact test procedures to prove equivalence of a Bowie-Dick Simulation Test in comparison to the original cotton pack. There are no specifications how the BD Simulation Test has to be constructed, it can be designed as porous test system – e.g. using paper packs -, but it also can be designed completely different, e.g. as “cheque card”, as electronic measuring system, as filled plastic tube, etc., it only must be secured that the requirements of EN ISO 11140-4 are fulfilled to use a BD Simulation Test instead of the BD cotton pack.

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The GKE BD Simulation Test fulfills the requirements of EN ISO 11140-4 and can therefore be used alternatively to the cotton pack.

b. Hollow load test

The hollow load test according to EN 867-5 is already used since years in small sterilizers according to EN 13060 Type B as a type test. This standard allows to use other materials and designs under the condition that the alternative test is equivalent. Equivalence is tested according the requirements inside this standard. The GKE test system is a hollow load test already because of its design. In comparison to the test system with a hollow load Helix-PCD according to EN 867-5 the GKE BDS shows higher requirements in the test cycles.

3. Summary

With the GKE BDS test system both test requirements prescribed in the new standard can be fulfilled. Using it as functional test at startup, two parallel single tests are not necessary. A test report from an accredited test laboratory is available on request to prove equivalence for both tests.

(*) Publications relating to the studies referred to, are available on the GKE homepage www.gke.eu or can be sent by e-mail or as paper version.