The Evolution of the Bowie Dick Test Method

Validation & Monitoring Solutions

Ellab White Paper - 12/19

The Bowie Dick test has come a long way since being developed in the 60's, having gone from a large test pack of towels to a small handheld test device. While the original test was ground for the naming and general concept, the current reference method is an evolution of that test.

The concept was a method of testing whether steam sterilizers properly managed to reach saturated steam, and thereby ensured proper sterilization. This required a setup that would challenge the steams ability to penetrate and reach hard-to-reach areas. If successful, the steam penetration ability was then sufficient enough to be considered saturated.

For a new test device to live up to the reference method, EN285 and ISO 11140-4, several test criteria have to be met. Particularly, PASS and FAIL scenarios that have to match the result of the reference method, as test devices that have not been tested against these norms, cannot be considered verified Bowie Dick tests.

Ellab's new electronic Bowie Dick test, SteriSense®, has been tested and approved by a third party institute in accordance with these standards and the certified reference method.

Have a look at our other white papers, application notes and product spotlights at ellab.com

Validation & Monitoring Solutions

Table of Contents

The Origins of the Bowie Dick Steam Penetration Test

The original Bowie Dick test pack was developed by Dr. J. Bowie and Mr. J. Dick and was first described in an article in 1963. The test was designed to monitor the air removal efficiency of pre-vacuum as well as the pressure pulse system of an autoclave to ensure proper sterilization.

The original design was based on 29-36 huckaback towels, each folded and stacked to a height of 10-11 inches. A sheet of paper was then applied to the center of the stack of towels, equipped with chemical indicator tape in the shape of a St. Andrew's cross. Once prepped, the towel stack would be placed inside a metal dressing casket or equivalent container.

The idea was to simulate the sterilization of porous loads by testing whether or not the steam could accurately reach and penetrate the towels. If successful, the chemical indicator tape would change color accordingly – if not, the tape would remain unchanged. This would indicate if the level of steam penetration within the autoclave was sufficient enough to sterilize.

Replacing the Original Components of the Bowie Dick Test

During the 1970's, the Bowie Dick test pack went through several alternate configurations, partly due to the lack of materials. The huckaback towels were first substituted by 100% cotton surgical towels, and the cross patterned indicator tape was replaced by pre-printed chemical indicator sheets. And finally, the metal casket was replaced by non-woven surgical wrap material.

Becoming the Bowie Dick Test Reference Method

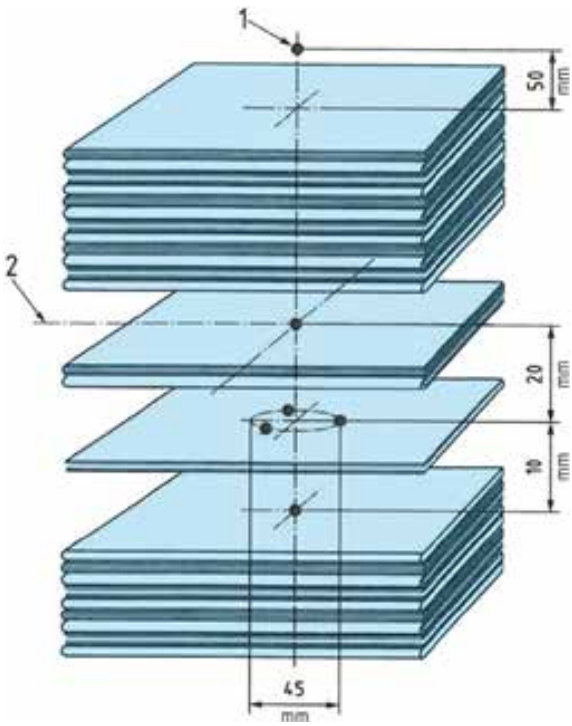
With the release of the EN285 standard, which specified the test procedures and acceptance criteria for manufacturing sterilizers larger than 60 L, a new and revised definition of the Bowie Dick test pack was revealed. Temperature measurements were now introduced both outside and inside the test pack in a defined pattern, requiring thermocouple sensors to appropriately gather the data.

The position of sensors had to follow the definition mentioned in EN285, section 16.1.3:

- 1 sensor had to be placed at the regulating sensor (reference measuring point)
- 1 sensor placed 50 mm above the test pack.
- 5 sensors within the test pack distributed the following way:
  - 3 sensors placed as a circular pattern in the center
  - 1 sensor placed 20 mm above the center
  - 1 sensor placed 10 mm below the center

By measuring all seven temperatures simultaneously, it was possible to form a complete graph showing the “development” of each individual sensor. Thereby evaluating the sterilizer’s ability to remove air and non-condensable gasses (NCG’s), and consequently, document the steam penetration performance. The whole arrangement would then have to be positioned inside the sterilizer 100-200 mm above the chamber base.

This new Bowie Dick test method defined in EN285, allows for a more in-depth analysis of the steam penetration and air removal capability of the sterilizer. It is used as the general reference method today for conformity tests of chemical indicators and electronic Bowie Dick test systems as specified in ISO/EN 11140-4.



Complying with the Bowie Dick Reference Method

Different autoclaves use different vacuum pulsing systems and therefore also different Bowie Dick test programs for the daily routine control. The differences in profiles often depend on the type of load that needs to be sterilized. This is why ISO 11140-4 defines some standard test cycles in Annex B that covers this.

- Sub-atmospheric pulsing (Type B1) – the most common
- Trans-atmospheric pulsing (Type B2)
- Super-atmospheric pulsing (Type B3)

To be approved as a “Bowie Dick Test Method”, that being a chemical indicator or electronic test device, it must comply with a test program. These programs are based on temperature/pressure profiles defined in one of the aforementioned cycles (B1, B2 or B3). From here, the device has to present a pass when the Bowie Dick reference test passes, and more importantly, it must show a fail when this reference method fails.

Failed results typically occur when the vacuum/steam injection is insufficient (also known as the modified air removal stage), when introducing a leak or when injecting air (a strong sudden pulse). All three fail scenarios are mandatory for type B1 testing. For type B2 tests, the modified air removal is the only scenario that is tested. Whereas type B3 only tests the air injection, due to the different vacuum profiles.

Developing SteriSense®, the Ultimate Bowie Dick Test

Ellab’s measuring device, SteriSense is the most comprehensive electronic Bowie Dick test on the market to date. SteriSense has been tested according to the aforementioned test types and provides a far more in-depth view of the sterilization process. Thereby eliminating any guesswork, which is otherwise found when using chemical indicators for routine control.

The description below showcases the conformity tests that our SteriSense unit successfully passed at the SAL test facility in Germany:

- The equivalence test was carried out against the standard cotton test package according to EN 285 and ISO 11140-4
- The test package composed of plain cotton sheets, each bleached to white:
  - Approximate dimensions of sheets: 900x1200 mm
  - Number of threads per centimeter in the warp: 30 ± 6
  - Number of threads in the weft: 27 ± 5
  - Mass: 185 ± 5 g/cm²
  - Edges: Non-selvedge and non-hemmed
- The sheets were not subjected to any fabric conditioning agent during laundering and had a relative humidity of 40-60% and a temperature of 20-30 °C. They were folded and equilibrated for at least 2 hours under the aforementioned conditions before testing
- After equilibration, the sheets were folded to approximately 220x300 mm, compressed by hand and stacked to a height of 200-250 mm. The pack was then wrapped in a similar fabric and secured with tape - not exceeding 25 mm in width
- Finally, the package was weighed, keeping the total mass of the pack at 7.0 kg ± 2%
- After processing, the pack needed to be aired, while the inner conditions of the pack had to be within 20-30 °C and 40-60% relative humidity

An extract of the EN ISO11140-4 certificate can be found on the following page. The certificate includes the final conclusion of the tests performed with SteriSense.

Results for process B1 according to DIN EN ISO 11140-4, Annex B:

Process	run	Result BD-test pack	run	Result Ellab BD-test	Conform?
B1 PASS 1/3	2425	PASS	2440	PASS	CONFORM
B1 PASS 2/3	2426	PASS	2441	PASS	CONFORM
B1 PASS 3/3	2427	PASS	2442	PASS	CONFORM
B1 FAIL 1/3 Modified air removal	2434	FAIL	2443	FAIL	CONFORM
B1 FAIL 2/3 Modified air removal	2435	FAIL	2444	FAIL	CONFORM
B1 FAIL 3/3 Modified air removal	2436	FAIL	2445	FAIL	CONFORM
B1 FAIL 1/3 Leakage	2608	FAIL	2613	FAIL	CONFORM
B1 FAIL 2/3 Leakage	2609	FAIL	2614	FAIL	CONFORM
B1 FAIL 3/3 Leakage	2610	FAIL	2615	FAIL	CONFORM
B1 FAIL 1/3 Injection	2560	FAIL	2563	FAIL	CONFORM
B1 FAIL 2/3 Injection	2561	FAIL	2564	FAIL	CONFORM
B1 FAIL 3/3 Injection	2562	FAIL	2565	FAIL	CONFORM

Results for process B2 according to DIN EN ISO 11140-4, Annex B:

Process	run	Result BD-test pack	run	Result Ellab BD-test	Conform?
B2 PASS 1/3	2463	PASS	2467	PASS	CONFORM
B2 PASS 2/3	2464	PASS	2468	PASS	CONFORM
B2 PASS 3/3	2465	PASS	2469	PASS	CONFORM
B2 FAIL 1/3 Modified air removal	2632	FAIL	2641	FAIL	CONFORM
B2 FAIL 2/3 Modified air removal	2633	FAIL	2642	FAIL	CONFORM
B2 FAIL 3/3 Modified air removal	2634	FAIL	2643	FAIL	CONFORM

Results for process B3 according to DIN EN ISO 11140-4, Annex B:

Process	run	Result BD-test pack	run	Result Ellab BD-test	Conform?
B3 PASS 1/3	2450	PASS	2453	PASS	CONFORM
B3 PASS 2/3	2451	PASS	2454	PASS	CONFORM
B3 PASS 3/3	2452	PASS	2455	PASS	CONFORM
B3 FAIL 1/3 Injection	2575	FAIL	2580	FAIL	CONFORM
B3 FAIL 2/3 Injection	2576	FAIL	2581	FAIL	CONFORM
B3 FAIL 3/3 Injection	2577	FAIL	2582	FAIL	CONFORM

Validation & Monitoring Solutions

Ensuring that Your Solution is Compliant

Even though the original Bowie Dick test method has undergone several changes during the past 60-70 years, it is still the only valid reference. As this is the case, it is highly important that traceability documentation is readily available for this method, to ensure that chemical indicators and alternative electronic tests covered by the ISO 11140-4 norm are in fact compliant.

SteriSense is such an electronic Bowie Dick test - fully ISO 11140-4 compliant with complete traceability to the reference method.