Recommendations by the Quality Task Group (94)

Bowie & Dick Test

Authors: B. Amann, D. Diedrich, S. Fiedler, B. Früh, S. Krüger, K. Roth, U. Zimmermann
Guest authors: I. Kruse, R. Streller (WTW)
E-mail: qualitaet@dgsv-ev.de

1. Daily Bowie & Dick test

This present Recommendation is an updated version of Recommendation 18.

EN ISO 17665-1-2006-11, Section 12, focuses on "Maintaining Process Effectiveness", stating that the operator should perform periodic tests to that effect.

In addition to the call for leakage tests, the main focus is on effective ➜ **AIR REMOVAL** to ensure rapid and uniform steam penetration into the sterilizer load. Section 12.1.6, EN ISO 17665-1-2006-11 [1] clearly sets out the rules for implementation of the daily BD test on each working day.

➜ **AIR REMOVAL** must be effective.

More precise details of how to implement a BD test are given in standard EN ISO 11140-3 [2]. The introduction to that standard explains that the BD test is a performance qualification test for steam sterilizers which also serves to document compliance of steam sterilizers with EN 285.

Paragraph 17.1 of EN 285 lists the possible reasons why a BD test had not been successful. For example, persistence of air within the laundry pack may be due to:

Possible reasons why a BD test has not been successful.

– ineffective air removal phase
– a leak during air removal
– non-condensable gases in the supplied steam

It finishes off by explicitly pointing out that additional factors may have contributed to failure of the BD test. It may be necessary to have an expert assess the sterilization process to eliminate the source of interference.

2. The standard test pack (laundry pack), alternatives and other test systems

Implementation of the standard test pack (laundry pack) test is very time- and resource-consuming and calls for specially trained staff, hence this test is now performed only for validation.

The requirements governing alternative BD test systems are specified in EN ISO 11140-4, including for chemical BD tests (Sterilization of health care products – Chemical indicators). These systems must be checked in advance by the manufacturer or a test laboratory to ensure that they are able to undergo a change in colour and display a simulated error message at a temperature of 134 °C. The user can request such confirmation from the product manufacturer.

Electronic test systems are also available.

2.1 Chemical systems

The indicators form a unit containing the indicator system (test sheet) and test load (test packs, helix), designed for single use or reuse (Fig. 1). To perform the BD test, a chemical indicator is placed in the empty sterilizer chamber and the Bowie & Dick test cycle started at 134 °C/3.5 minutes. Only after successful air removal from the chamber and BD test system as well as optimum steam penetration into the system is it possible to verify a uniform colour change in the indicator system (generally from a dark

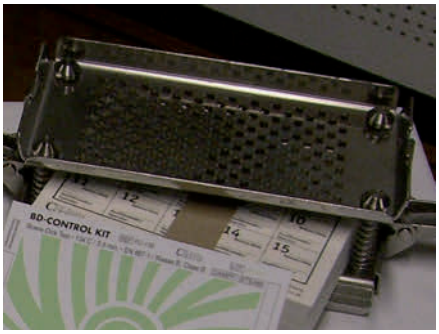

Fig. 1: BD Control Kit FC 102 – reusable test pack with stainless steel test pack holder (Früh-Consult factory photo)

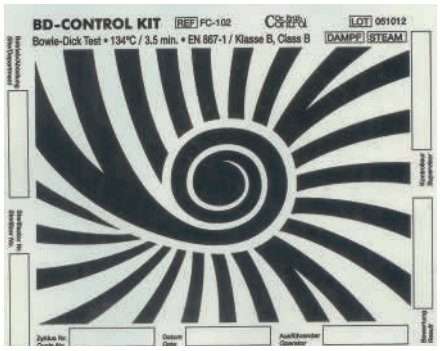

Fig. 2: Test sheet colour change in order

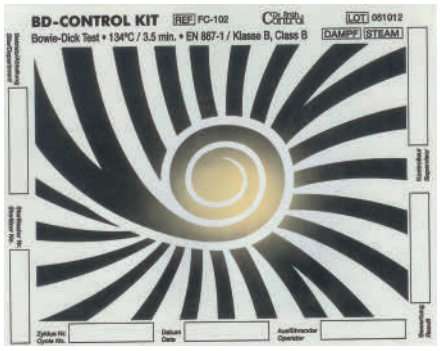

Fig. 3: Test sheet colour change not in order

Fig. 4: ebro electronic measurement system with workstation (WTW factory photo)

Fig. 5: Ebro EBI 16 electronic measurement device (WTW factory photo)

to a bright colour) on completion of the BD cycle (Fig. 2). If the BD test is not successful the colour change will not be complete or and/or there will be a visibly bright area at the centre of the test sheet (Fig. 3). The BD test will need to be repeated. If once again the test fails, the reasons for failure must be explored and the sterilizer taken out of service until these have been clarified.

2.2 Electronic system

Electronic systems are essentially composed of a data logger and a process challenge device (PCD)/test piece (Figs. 4 and 5). The time, steam pressure, steam temperature as well as the temperature within the PCD itself are measured and recorded. The entire BD cycle is documented at 134 °C/3.5 minutes. Air removal from the sterilizer chamber and PCD as well as steam penetration into the system are checked. Only after successful air removal from the chamber and BD test system as well as optimum steam penetration into the system is the message "BD test passed" generated on completion of the BD cycle. If the BD test was not successful, the message "BD test failed" is generated, possibly pointing to errors. The test result "passed/failed" is clearly displayed and archived by the system software in a database.

The document archived in the database contains the following details:

- Date and time
- Sterilizer No. (serial number)
- Bowie & Dick test device used (make and serial number)
- Cycle No.
- BD test passed/failed
- If "failed", the reason for failure may be given
- Digital signature of the authorized staff member
- If "failed", the remedial measures taken can be documented.

3. Implementation and documentation

The Bowie & Dick test based on the standard test pack or on alternative systems may only be performed by specially trained staff because of the need to assess the results in the light of the sterilizer parameters as well as due to the risk of incorrect implementation of this test.

The BD test result is recorded using an appropriate documentation system (e.g. IT system).

While according to German legal opinion there is no obligation to archive the indicator sheets, it is advisable to have the BD test documented by another qualified person.

4. Retention obligation

Pursuant to article Section 195 of the German Civil Code (BGB), claims based on the Physician-Patient Contract or the Hospital Admissions Contract become statute-barred after thirty years. Since pursuant to German law the burden of proof rests with the defendant, hospitals must prove that all duties of care were taken, e.g. those enshrined in standards, legal acts and recommendations. Hence the Central Sterile Supply Department (CSSD), too, is subject to the document retention obligation.

It is therefore advisable to provide for a secure, continuous, credible, tamper-proof and independent document archival system. This will make it easier to provide evidence in the event of litigation. ■

References

1 EN ISO 17665 – Sterilization of health care products – Moist heat
2 EN ISO 11140 – Sterilization of health care products – Chemical indicators