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PERFORMANCE STUDY OF PACK BOWIE-DICK TEST READY: CASE STUDY OF FIVE MARKS

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ABSTRACT

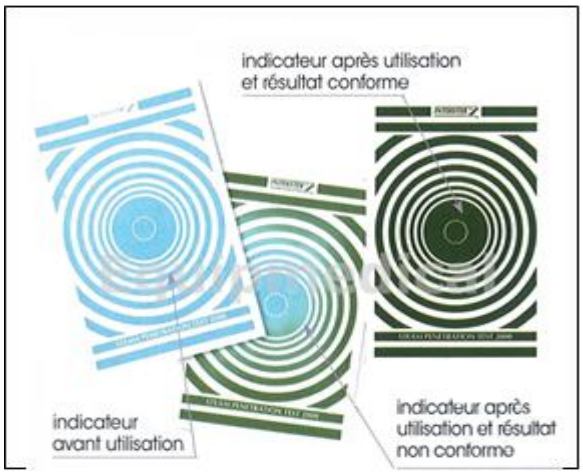
Sterilization is one of the special processes whose results cannot be fully verified by a final control of the product. For this reason it is necessary to ensure the validation of sterilization processes before implementation and monitoring or routine checks. The Bowie-Dick test is one of the controls of the steam penetration in sterilization process. A device widely used but subject to various interpretations especially with the multiplicity of brand and suppliers. To answer some number of questions about the quality of the brands available in our public hospitals, we conducted a comparative analysis of five brands of the Bowie-Dick test under standardized conditions and with a qualified autoclave and varying the two parameters of this test: the temperature and time. The results obtained showed that the different tests were fired completely for the ten different combinations time/temperature. This suggests that the applied temperature exceeds the T° of the turn of the indicator of the test and therefore the shift occurs because the temperature is high despite the time is specified. The BD test is an essential test but insufficient to validate a sterilization cycle, hence the need of a set of additional controls to release sterilization load.

KEYWORDS: Bowie-Dick, Sterilization, Control.

INTRODUCTION

Sterilization is one of the special processes whose results cannot be fully verified by a final product control. For this reason it is necessary to ensure the validation of sterilization processes before their implementation and monitoring or routine checks of process. These

controls are based on the use and verification of physical and chemical indicators and verification of good penetration of water vapor in the heart of the medical device. The Bowie-Dick test (BD) is one of the controls of steam penetration. A device widely used but subject to various interpretations especially with the multiplicity of brands and suppliers.



Several assumptions are challenged whenever an unsatisfactory test of the turn is found or the clear and objective interpretation does not carry out: the performance of the autoclave itself, expiration and conditions conservation of this test in the structures of use?.

In our opinion, the interest of this work was to find explanations to the practical problems of employees in 'services/units' sterilization. On the other hand convince employees on the interest and the service rendered by this device in the control of a sterilization cycle.

MATERIALS AND METHODS

The work was done in the central sterilization service of the Instruction Military Hospital Mohamed V in Rabat (HMIMV), on one day, Saturday first March 2014.

The work was carried out by an autoclave which has been subject of operational qualification and with adjustable parameters (Time and Temperature) and with an instrument cycle.

The goal of this work was to make a comparative study of the curve of a test batch of several brands BD by standardizing exposure conditions (same cycle, same autoclave), and varying the two parameters of this test: the temperature and time. The work was carried out by an autoclave - Lequeux Mark, reference KCL46 and the volume of the tank is two baskets-which has been subject of operational qualification and with adjustable parameters (Time and Temperature) and with an instrument cycle.

The design of the study was with two series: i) the first: The fixing temperature to the value of 134°C on the sterilization tray and changing the time by 5 seconds. ii) the second: Fixing the time at 3 minutes 30 seconds (3'30 ") and decrease in temperature from 134°C by one unit to each test. Thus giving a protocol with 10 tests.

To conduct the study, we conducted 10 assays of 5 units per test by brand with the same lot and the same expiration date (avoid intra-lot variability). All trademarks suffered along each of the 10 tests. With each test two physicochemical integrators calibrated to 134°C and 3 minutes 30 seconds and a recording chart were recovered. Ten tests were carried out successively on the same day, beginning with the first series (T°134°C and variable time) followed by the second series (at fixed time 3'30 " and T° variable). A complete and uniform color change of the ink is regarded as a satisfactory test by reference to EN ISO 11140 standard.

The symbol «✓» was assigned when the turn is complete and «⊗» when is incomplete. Batch files were made for each test. The file contains the following information: Date, N° of autoclave, N° of cycle, Result, release.

RESULTATS

In total five brands were recovered that are marked MI, MII, MIII, MIV and MV. All tests were carried out as it was planned the same day and with the same operator. The results are summarized in Figure 1.

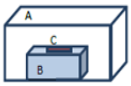
Table : Rapport des résultats de l'étude de virage du test BD, cas de cinq Marques.

Date de l'étude : Le 01 Mars 2014 Heure de l'étude: début du 1er essai: 10H00 Fin du dernier essai: 18H30

Autoclave : KCL 46 (type de cycle: instrument)

Emplacement des tests dans la cuve de l'autoclave : au centre de la chambre

Interprétation des résultats: ✓:Virage complet ⊗:Virage incomplet



A : Chambre d'autoclave

B : Panier

C : Emplacement des tests BD

Bowie-Dick Test 134°C 3,5Minute											
Essais			Essais 1[1]	Essais 2	Essais 3	Essais 4	Essais 5		Essais 6	Essais 7	Essais 8	Essais 9	Essais 10
Condition▶ Marque▼			134°/ 3'. 30''	134°/ 3'. 15''	134°/ 3'. 00''	134°/ 2'. 45''	134°/ 2'. 30''		133°/ 3'. 30''	132°/ 3'. 30''	131°/ 3'. 30''	130°/ 3'. 30''	129°/ 3'. 30''
I	134° 3,5min	Variation du temps	✓	✓	✓	✓	✓	Variation du Température	✓	✓	✓	✓	✓
II	134° 3,5min		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
III	134-137° 3,5min		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
IV	134° 3,5min		⊗	✓	✓	✓	✓		✓	✓	✓	✓	✓
V	134-137° 3,3 -3,5min		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
N° Cycle			12838	12839	12840	12841	12842		12843	12844	12845	12846	12847

EN ISO 11140: Stérilisation des produits de santé – indicateurs chimiques

[1]Type de cycle : liquide

Figure 1: Report the results of the study turn the BD test case of five brands.

DISCUSSIONS

This work was carried out with an aim to provide possible explanations in cornering test Bowie & Dick difference from one test to another and from one brand to another and this to respond at request reported by hospital users.

In this context, we have set and standardized working conditions: qualified equipment, working day, staff and we studied five different brands of the BD test of 10 combinations: hold time / temperature; by changing either the time or the T°; according to the requirements of the standards in relation to the tolerances of the test: holding time is 3'30 " +/- 5s and temperature (134°C) 0/+ 1.5°C.

The results obtained showed that the different tests were fired completely (except one unit of the brand IV at 134 °C 3'30") under different combinations time / temperature.

watching the first series with T° at 134°C (the temperature of the sterilization tray) and the holding time exchange between 3'30" to 2'30": The set temperature well above the value at which is changing the color indicator of the test and therefore the indicator changes color regardless of the time which could have a positive influence on the results (false positive). It is believed that the indicator will tend to turn in any case because the temperature is much high.

With the second series (time at 3'30" and temperature increases from 134°C to 129°C in steps of one degree) we can always assume that the applied temperature exceeds the T° of the turn of the indicator of the test and therefore the shift occurs because the temperature is high and the time is the specified time.

These suggestions are at the root of the continuity of this work by expanding the number of units of each brand/combination (T°:Time) and introducing other brands to define the optimal T° for the test; knowing that the standards do not specify indication on the optimal T° to the test but remains to be specified by the manufacturer.

To check the operation of the sterilizer, a leak test was useful to achieve before starting the tests. Electronic tests can also be considered for temperature control during the retention period. These tests have the advantage of providing more information about the quality of the cycle and the homogeneity of the temperature and the pressure inside the chamber of the

sterilizer, or better yet use embedded sensors operational qualification for the performance qualification of each cycle of scheduled tests.

The proposed protocol does not make judgments, and view that the main purpose of the Bowie-Dick test is to verify the steam penetration; it is interesting to check how to make changes in settings if we vary the number of pre-vacuum applied prior to the holding phase. Such a test can only be achieved with a sterilizer giving the possibility to adjust the number of pre-empty the pretreatment phase and the value of the temperature cycle.

CONCLUSION

The most important phase to look in the interpretation of recording a Bowie & Dick test, is the preprocessing phase in which the split vacuum where empty the importance of the leak test in practice. BD test is an essential test but insufficient to validate a sterilization cycle, hence the need of a set of additional controls to release sterilization load.

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