



Bowie and Dick test and validation?

VSZ

Mechelen

16 oktober 2008

Bowie and Dick

- ““This test is essentially a test of steam penetration, not of time-at-temperature”
- ““A satisfactory test will indicate rapid steam penetration, adequate air removal and freedom from significant air leaks.””

J. H. *Bowie, et al.* in the Lancet, Mar. 16, 1963,ps 586-587

EN 285 § 7.1.13

- A separate test cycle shall be provided if the exposure time specified for the indicator used to determine the efficacy of steam penetration is different to the plateau period used for the sterilization cycle used for production.

This cycle shall have the same air removal stage as the one used for the sterilization cycle for production.

Bowie and Dick

- EN 285 § 17
 - 17.1 Retention of air due to
 - an inefficient air removal stage
 - the presence of an air leak during the air removal stage
 - the presence of non condensable gases in the steam supply

are circumstances which can lead to failure of the test

- 17.2.1 Test pack as described in §24.1 for sterilizers exceeding one module...
- 17.2.2 Indicator in accordance with 11140-3

Bowie and Dick

- EN 285 § 24 Describing the standard Bowie and Dick test pack
 - 24.1 Standard test pack
 - 24.1.8 Test packs comprising different materials and of different sizes and weights can be used provided equivalence with the requirements for the test in which the standard test pack is used is demonstrated

Actual situation

- EN-ISO 17665: A steam penetration test per day the great sterilizer is used (§ 12.1.6)
- In practice alternative test according to EN ISO 11140-4

EN ISO 11140-3

- Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test.
 - Indicator must show uniform colour change after exposure to dry saturated steam at 134°C (+1,5, -0) for 3,5 min ± 5s or to dry saturated steam at 121°C (+1,5, -0) for 15 min ± 5s or both.

EN ISO 11140-4

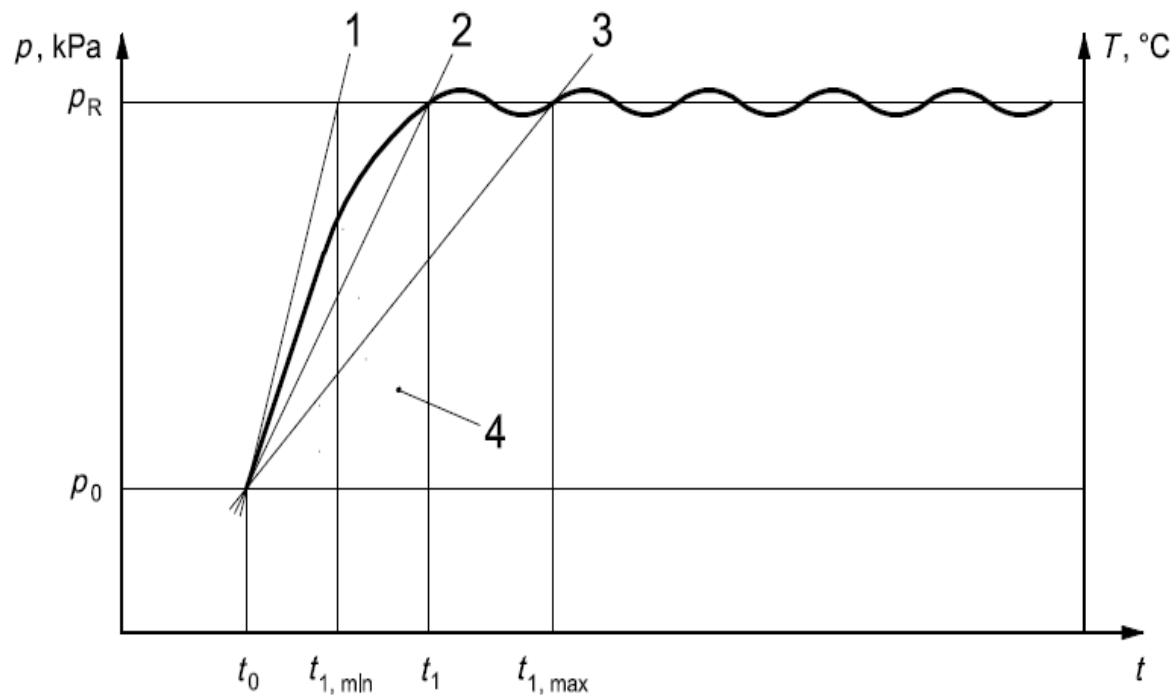
Sterilization of health care products –Chemical indicators- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
(ISO 11140-4:2007)

EN ISO 11140-4

- Annex B4

- Acceptance limits during steam admission
- Integrated Come-up Exposure (ICE) is for reference temperature
 - » 134°C; 2312 sK (second – Kelvin)
 - » 121 °C; 882 sK

“These limits are intended to ensure that steam admission does not contribute to excessive exposure of the indicator to atypical conditions.”



Key

- 1 maximum rate of pressure rise during steam admission $\frac{(p_R - p_0)}{t_{1min}}$
 - 2 rate of pressure rise
 - 3 minimum rate of pressure rise during steam admission $\frac{(p_R - p_0)}{t_{1max}}$
 - 4 Integrated Come-up Exposure: area bounded by T_0 and the curve traced by T_c over the time t_0 to t_1
- t_{1max} is the come-up time at the minimum allowed rate of pressure rise of 100 kPa min^{-1}
 t_{1min} is the come-up time at the maximum allowed rate of pressure rise of 250 kPa min^{-1}
 p_R is the pressure of saturated steam, corresponding to the set operating temperature, in kilopascals
 p_0 is the pressure of saturated steam, corresponding to the temperature T_0 , in kilopascals
 T_0 is 100°C or the lowest temperature of the last positive pulse, in degrees centigrade
 T_c is the chamber reference temperature, in degrees centigrade

Figure B.4 — Steam admission

Situation in validated steamsterilizers

- ICE
 - S1: 13.832 sK(= ICE x 6)
 - S2: 6.400 sK(= ICE x 2)

In both the indicator had a full colour change at the start of the plateau period of the cycle



International discussion

Porous loads vs complex hollow instruments

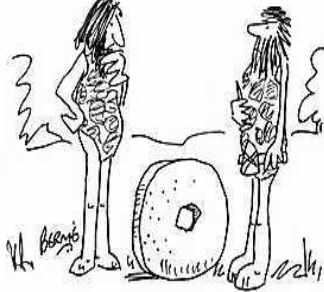
EN 285

- §15 Hollow load test
- Is used to demonstrate good air removal in specified challenge device
- Has its place next to B&D

Questions

- Can we rely on the alternative Bowie and Dick in cycles with “high ICE”?
 - *Are alternatives needed and/or available?*
- Is Bowie and Dick the best daily test with the new types of sterilization cycles and new kind of loads?
- Does validation confirm compliance to regulations?

© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com



"I suppose it would be o.k. as a
little runaround for the wife....."

