Letters |

B&D Test results – comments on a current study

Letter to the Editor from Ulrich Kaiser, gke-GmbH, Auf der Lind 10, 65529 Waldems, Germany, and Matías Pilasi Pendás, Exteriliza S.A., Alcalde Guzmán 1441, Quilicura, Santiago, Chile, on the publication by Laranjeira PR, Bronzatti JAG, Bruna CQdM, de Souza RQ, Graziano KU, Lusignan V: False positive results of Bowie and Dick type test used for hospital steam sterilizer with slower come-up ramps: A case study. PLoS ONE 2020; 15(1): e0227943. https://doi.org/10.1371/journal.pone.0227943

We have read with a lot of interest the following publication [1]: "False positive results of Bowie and Dick type test used for hospital steam sterilizer with slower come-up ramps: A case study".

Study summary

The objective of the mentioned article was to determine if the standardized Bowie and Dick (B&D) type test for hospital steam sterilizers is correctly indicating cycle failures in slower come-up ramps cycles.

For this purpose, the authors challenged two commercially available B&D test packs in a special test sterilizer by running 2 different cycles and simulating the same failure on each one: injecting 1050 mL of air between 75 kPa and 105 kPa during the heating phase of the cycle. The difference between both cycles was the speed of the pressure increase during the steam injection on the heating phase. The first cycle, labelled cycle B, has a pressure increase speed of 250 kPa min^{-1} whereas the second cycle (cycle C) has a slower pressure increase speed with a value of 80 kPa min^{-1}. The test was repeated 3 times for each B&D test pack and 3 times for each cycle (B and C).

As for the results, the authors found that both B&D test packs were only able to detect the presence of non-condensable gases if the heating phase had a pressure increase speed of 250 kPa min^{-1} (come-up ramp of 1.7–1.9 min.) This means that wrong results were obtained with come-up ramp time of 3 min (pressure increase speed of 80 kPa min^{-1}).

These results lead the authors to conclude that sterile processing department professionals must include the come-up ramp time as an additional criterion when evaluating the cycle before releasing the machine for production.

Comments on the study

First of all we are very happy to see that more scientists in the world try to understand the basics of steam sterilization processes. What they have found, that a low gradient come-up cycle is influencing B&D test results, has been known for more than 15 years in Europe, already before EN ISO 11140-4 [2] and -5 were developed.

It is very well-known that a porous B&D test only works correctly if the plateau period at 134 °C is not longer than 3 – 3.5 minutes, because non-condensable Gases (NCG) can only be detected when short plateau periods are used. For this reason, a special B&D test program is installed on all hospital steam sterilizers and configured with a plateau period of maximum 3.5 min (also described in the standards). There are even some manufacturers using a test cycle with a plateau period of only 1 min. When longer times are used, a failure that is normally seen at 3.5 min, will then disappear when the plateau period is > 5 min. Basically, with longer sterilization periods in porous loads there is a possibility to get a slow diffusion into the pack. This is eliminating a failure when there are longer plateau periods, because there is a diffusion area inside of the pack of more than 100 cm^2 around the air bubble. By the way, there are B&D test devices using different construction characteristics that also simulates hollow devices as well, which will not show a false result under these conditions even after 9 minutes at 134 °C, as opposed to the porous loads of paper packs and the original B&D textile pack.

Since a slow come-up gradient in reality ocurrs above 2 bar absolute, artificially increasing the plateau period has the same effect as described above. Therefore this is nothing new and can be predicted in advance. Moreover, ISO 11140-4 [2] already establishes that the rate of pressure rise during steam admission shall be between 100 kPa min^{-1} and 250 kPa min^{-1}, because this phenomenon is already known.

It is very good that the authors recommend the users to have a look into the machine parameters when releasing the B&D test result. Indeed this is something that always has to be done for a production batch release as well, and not only by checking the come-up ramp time. There are several "variables and their parameters" that must be verified before releasing a batch. Particulary the quantity of vacuum pulses, the "depth" of the vacuum points, the pressure pulses, and the speed of vacuum and pressure increase – they all have an effect on air removal and steam penetration, especially when hollow instruments are processed. Therefore, it is always advisable to validate steam sterilization processes and release production batches only if the pressure and temperature profiles are within the tolerances defined during the validation (for the whole cycle and not only verifying the plateau period).

It is also advisable to verify that the air removal phase of the B&D test cycle is exactly the same as the air removal phase of the production cycle (this is clearly written in EN 285 [3]). Only the plateau period and the drying time may be different. Otherwise, what is checked with the B&D test would not be applicable to the production cycle. Therefore, when releasing a production batch it must also be verified that the parameters are in compliance with those of the B&D test cycle as well as with the parameters recorded for the cycle used during the process validation. It does not make sense to have a "pass" B&D test but then on the next production cycle have a different pressure/temperature profile. The purpose of using a BD test is to check that the level of NCG are safe for the porous load. But what would be the sense of doing a B&D test if the next production cycle could have a different performance?

As mentioned by the authors, the B&D test was developed in 1963 when little to no hollow devices were used in surgery. Nowardays, almost every load of a hospital sterilizer will contain lumens. It is then recommendable to also do a test simulating a lumened device and not only the B&D test, which just simulates a porous package. It is very well known that air removal and steam penetration in hollow devices are much more complex than in a porous pack, thus the use of a process challenge device (PCD) with a higher demand than the most challenging device in the chamber is also advisable for batch release.

Last, but not least, in the USA and in South America it is very common to see PCDs consisting of a porous load simulation pack (paper pack) including a biological indicator inside for batch release. What the authors have seen for the B&D test will also apply for this kind of PCDs. It means that wrong BI results may be obtained when NCG are present on the load but slow pressure increases are used (or extended plateau periods). This reinforces that the evaluation of the cycle parameters and the use of an adequate PCD must always be part of the load release. It does not make sense to release loads with hollow instruments with a porous load simulation PCD.

Since the sterilization conditions cannot be measured on each device during routine production, process validation in addition with a proper PCD for batch release is the safest practice to predict that 100% of the processed medical devices are sterile.

References

1 Laranjeira PR, Bronzatti JAG, Bruna CQdM, de Souza RQ, Graziano KU, Lusignan V. False positive results of Bowie and Dick type test used for hospital steam sterilizer with slower come-up ramps: A case study. PLoS ONE 2020; 15(1): e0227943. https://doi.org/10.1371/journal.pone.0227943

2 ISO 11140-4:2007 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

3 EN 285:2015 Sterilization – Steam sterilizers – Large sterilizers