Abstract

Can the Bowie-Dick-Test be Replaced by Temperature and Pressure Loggers?

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«If you don't get the air out, you can't get the steam in» is an adage familiar to all sterilization practitioners throughout the world. However this phrase is often spoken glibly and with a degree of contempt which belies its importance. In practice what are the implications of this phrase. Essentially, like oil and water, steam and air do not mix together particularly well.

This physical phenomenon has important implications in steam sterilizers which are used to process porous loads including textiles and cannulated instruments. When such loads are placed inside a steam sterilizer the interstitial spaces are filled with air. Unless this air is removed, the steam which effects sterilization, will not be able to penetrate to all of the surfaces requiring sterilization resulting in the survival of micro organisms and the potential for infection and possibly death in patients on whom inadequately processed articles are used.

All porous load sterilization processes will therefore consist of three fundamental stages. The first being air removal, the second, sterilization and the third post sterilization drying. Stage one, air removal, is carefully designed to ensure sufficient air is removed from loads so that stage 2, sterilization can be carried out effectively. Any failure in stage one, will lead, with increasing probability, to failure of stage 2. As such it is vital that we, as practitioners, validate and then routinely monitor the efficacy of air removal and thence steam penetration.

Over the years a number of methods have been developed to validate air removal and then steam penetration. The universally accepted work of Bowie and Dick is known throughout the industry. This work lead to the definition of the Bowie and Dick Test which has been used in a variety of forms for many years. The BD test is one form of air removal and steam penetration test available which is widely used within the sterile service department as a daily equipment qualification test. There are others which are specific to particular industries and load types. The recently published ISO/CD 17665 describes in greater detail the types of air removal and steam penetration test. Every steam sterilization cycle is a unique event and as such it is imperative that the efficacy of air removal and steam penetration is monitored not only as a daily test but also during every cycle. A variety of process challenge devices are available for this purpose.

In recent years great developments have been made in the sensor technology used to monitor steam sterilization processes. The development of high accuracy, robust pressure and temperature sensors and associated monitoring equipment has lead to suggestions that the correlation between steam temperature and pressure according to steam table values can be used as an alternative means of monitoring the level of air removal from the sterilization process. This assertion is based on the fact that dry saturated steam, at a given, pressure, will have a known temperature according to the values given in steam tables. Thus it is asserted that if the measured temperature is the same as the calculated temperature derived from the pressure measurements then the presence of dry saturated steam with no residual air is demonstrated and therefore adequate air removal has taken place. These assertions are based on the application of Daltons Law of partial pressures which states that the total pressure observed in a mixture of gases will be equivalent to the sum of the partial pressures exerted by the individual gases comprising the mixture. Thus application of this law to steam sterilization suggests that in an air steam mixture the measured temperature will be lower than the derived temperature from the measured pressure.

On the surface this would appear to be a reasonable assertion however there are complicating factors.

- The response time of the pressure and temperature sensors must be measured in milliseconds and closely matched otherwise there will be a phase shift between measured pressure and temperature which will introduce serious inaccuracies in the technique.
- The accuracy of the temperature and pressure sensors must be very high otherwise measurement errors will be introduced.
- The volume of air required to create a steam penetration test failure and therefore a potential sterilization failure is very small (eg 800ml in a 300l chamber) and will only cause a small virtually immeasurable lowering of steam temperature based on Daltons Law.

Within the presentation the issues outlined above will be discussed, partial pressure calculations will be explained and experimental data will be presented to illustrate the conclusion that the volume of air required to cause a steam penetration test failure does not depress temperature by a measurable amount and therefore this techniques cannot be used as a replacement for a more traditional air removal and steam penetration test.

Extrakt (D)

Können Datalogger den Bowie-Dick-Test ersetzen?

«Wenn Sie die Luft nicht raus kriegen – bekommen Sie keinen Dampf hinein» – dies ist die fundamentale Erkenntnis, die zum weltweiten Standard des Bowie-Dick-Tests geführt hat. In der kürzlich veröffentlichten ISO/CD 17665 werden Luftentfernungs- und Dampfdurchdringungstests ausführlich beschrieben.
Die Entwicklung hoch genauer Sensoren und die Tatsache, dass trockener, gesättigter Dampf bei einem bestimmten Druck eine definierte Temperatur aufweist, hat zum Vorschlag geführt, dass die Messung der Temperatur und des Druckes in der Kammer im Vergleich zum theoretischen Wert nach der Dampftabelle als alternative Messmethode für das Erreichen ausreichender Luftentfernung herangezogen werden kann. In der Präsentation wird auf die damit verbundenen Probleme hingewiesen. Es werden Daten vorgelegt, die nachweisen, dass trotz Vorhandensein von ausreichend Luft um einen Penetrationsfehler zu ergeben, kein messbarer Temperaturunterschied darstellbar ist. Deshalb ist diese Methode nicht als Ersatz für den traditionellen Bowie-Dick-Test geeignet.

Condensé (F)

Dataloggers - peuvent-ils remplacer le test Bowie-Dick ?

«Si vous ne faites pas sortir l'air – vous n'arrivez pas à faire entrer la vapeur» - c'est cette conclusion qui menait au standard mondial du test Bowie-Dick. Dans la publication récente ISO/CD 17665 on décrit précisément des tests pour l'élimination d'air et la pénétration de la vapeur.
Le développement des senseurs de haute précision et le fait, que la vapeur saturée sèche ait une température définit à une pression donnée mène à la proposition de remplacer le test Bowie-Dick par un métrage de température et de pression.
Dans la présentation on discutera les problèmes qui sont liés à une telle démarche. Vous verrez des données qui prouvent, que des résidus d'air suffisants à mener à un défaut du test Bowie-Dick ne soient pas visibles dans le métrage avec des loggers. Cela démontre clairement, que des loggers ne peuvent pas substituer le test Bowie-Dick.

Dr. Brian Kirk

Dr Brian Kirk is qualified as a Pharmacist. His post graduate studies include a Masters Degree in Pharmaceutical Analysis and research into the application of computer technology for modelling steam sterilization processes and monitoring and controlling steam sterilizers.

He worked for over 10 years in the UK NHS as a quality control pharmacist for a hospital pharmaceutical sterile supply manufacturing department. He joined 3M Health Care in 1989 as a development scientist for sterilization products with a special responsibility for monitoring the development of National and European standards relating to sterilization.

During his time with 3M he has held a number of additional responsibilities including European Technical service for sterilization supporting customers. Product Service being responsible for a number of manufactured products. Brian Kirk is also a member of a number of BSI, CEN and ISO committees responsible for developing standards for chemical and biological sterilization indicators and steam sterilization processes.