An evaluation of nine Bowie and Dick test products available in the United Kingdom

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Abstract

The Bowie and Dick test (BDT) is designed to assess the adequacy of air removal and steam penetration in a porous load sterilization process. The test is carried out daily as mandated by International (BS EN ISO 17665, 2006) and national (HTM2010, 1998, CFPP 01-01-C, 2012) standards and guidance. It is also an integral part of the quality assurance systems used to ensure the sterility of reusable medical devices. The BDT is described in BS EN 285 (BS EN 285, 2009) and consists of a stack of cotton towels into the centre of which is placed a pre-printed indicator sheet complying with BS EN ISO 11140-3 (BS EN ISO 11140-3, 2007). The majority of sterile service departments use alternative commercially produced BDT packs or devices which should comply with BS EN ISO 11140-4 (BS EN ISO 11140-4, 2007); a standard which compares the performance of the alternative product to that of the standard BDT textile pack. In the study described in this publication nine alternative BDT packs or devices claiming to be compliant to BS EN ISO 11140-4 were assessed for the capability to detect residual air in a porous load steam sterilizer employing an air removal stage consisting of three sub atmospheric pulses and three super atmospheric pulses. Residual air was induced by either adjusting the vacuum levels on each of the three sub atmospheric pulses (50, 75, 100, 150, 200, 250 and 300 mB set points) or by creating a chamber leak through a needle valve and flow meter attached to the chamber (<1.3, 9.5, 20, 42 and 55 mB/minute chamber leak rate). Nine products were tested. Four were capable of detecting residual air causing a 2°C or greater temperature depression within a reference BDT textile pack. The remaining five products were incapable of detecting residual air causing a greater than 80°C depression within the centre of the BDT textile pack; a condition in which there was so much residual air the centre of the pack did not reach the minimum sterilizing temperature of 134°C.

Introduction

Steam sterilization is achieved in a sterilizer consisting of a sealed chamber in which load items are exposed to saturated steam. If air is not removed from the sterilizer chamber, load items and packaging before the sterilization stage commences, the steam will not come into contact with the surfaces of the load which need to be sterilized.

The problem of residual air in steam sterilizers used to process porous loads was recognised by Dr Bowie and Mr Dick and they described experiments in which they examined the removal of air and penetration of steam into textile materials commonly used in surgical procedures (Bowie, 1961). Their findings suggested many sterilizers at the time were malfunctioning and as a consequence described a simple test which could be carried out daily to ensure satisfactory performance of a porous load steam autoclave (Bowie Kelsey and Thomson, 1963). The test consisted of a stack of surgical huckaback towels into the centre of which was placed a sheet of paper on which a cross of autoclave tape was affixed. When satisfactory air removal and steam penetration took place the indicator ink on the tape changed completely black in colour. If residual air remained in the centre of the pack, steam would not penetrate and the indicator ink on the tape would remain unchanged. This simple test was adopted by the National Health Service in the United Kingdom and was described in Hospital Technical Memorandum (HTM)10 (HTM 10 1968). Several other countries around the world also adopted the test. As a further adaptation a hybrid BDT was developed for use by engineers when routinely testing sterilizers which was based on the method described by Bowie (Bowie, 1961) and involved the insertion of temperature sensors into the centre of the stack of textiles. The small load thermometric test relied on the fact that air trapped within the centre of the test pack would create a difference in the temperature measured in the centre of the pack when compared to that in the chamber drain. A new requirement was then developed around this phenomenon which specified that the difference in temperature between the pack centre and drain should be not more than 2°C throughout the holding phase of the sterilization cycle.

As the European single market evolved, standard-isation took place leading to the publication of EN

285 (BS EN 285, 2009) describing requirements for, and testing of, large steam sterilizers. The European standard described a BDT and also a small load thermometric test almost identical in nature to those described in HTM 10 (HTM 10, 1968) and subsequently HTM 2010 (HTM 2010, 1998) and more recently CFPP 01-01 (CFPP 01-01, 2012). The EN however described a denser test pack composed of plain cotton sheets weighing 7kg (±0.14kg) with a pre-printed indicator sheet complying with EN ISO 11140-3 (BS EN ISO 11140-3, 2007) rather than huckaback towels weighing 5-6kg, with an autoclave tape cross. For adequate air removal and steam penetration to be demonstrated, the results from the small load thermometric test must show less than a 2°C difference in temperature between the reference measurement point (usually the chamber drain) and any location within the BDT textile pack during the holding period (BS EN 285, 2009). The temperature difference between the drain and the centre of the BDT textile pack is often termed the 'Temperature Depression'.

The sterilization of medical devices using moist heat sterilization is specified in BS EN ISO 17665 and this internationally agreed standard recognises the ongoing value of the BDT by requiring a daily air removal and steam penetration test (BS EN ISO 17665, 2006).

Whilst the BDT described in BS EN 285 acts as a reference test, the majority of practitioners use commercially produced test packs and devices for conducting the daily test. In recent times electronic versions have also become available and recently evaluated by Benoit et al (Benoit et al, 2011).
In order to standardise the performance of alternative BDT devices a new standard was developed (BS EN ISO 11140-4, 2007). The standard specifies the requirements for alternative BDT packs based on class 2 chemical indicators (BS EN ISO 1114-1, 2009). The standard requires alternative BDT packs to have equivalent performance to the BDT textile pack when measured using thermometric methods (*cf*, small load thermometric test in BS EN 285 –BS EN 285, 2009). The alternative BDT pack must show a pass when there is less than a 2°C temperature depression within the centre of the BDT textile pack. The alternative BDT pack should show a fail when there is greater than a 2°C temperature depression within the BDT textile pack under the test conditions prescribed in the standard.

The standard BS EN ISO 11140-4 specifies a series of tests in which the alternative BDT pack is compared to the BDT textile pack. Tests are carried out in three types of sterilizer process (see figure 1).

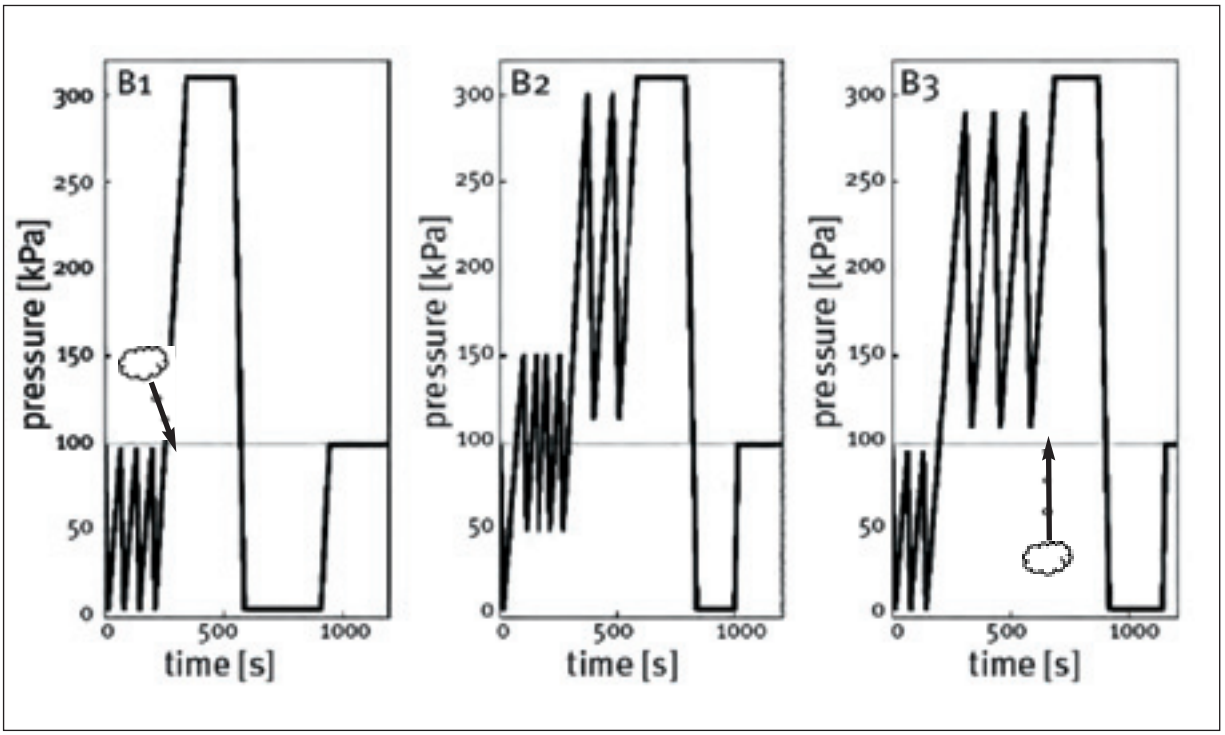

Figure 1: *Test cycles B1, subatmospheric, B2, transatmospheric and B3, superatmospheric described in BS EN ISO 11140-4 for demonstrating equivalence between the standard Bowie and Dick Test textile pack specified in BS EN 285 and alternative Bowie and Dick test packs and devices.*

The arrow and cloud symbol indicate the point of air injection when testing for sensitivity towards residual air by injection of a known volume of compressed air (only applies to B1 and B3 see table 1).

The alternative BDT packs are challenged under pass and then fail conditions created by one of three methods;

- Changes to the vacuum or pressure set points during the pulsing stage or removal of pulses.
- Chamber leaks through a leak valve.
- Injection of a defined volume of compressed air at a specific, defined point in the cycle (see Figure 1) from a compressed air cylinder.

The combination of cycle type and the challenge to residual air induced by the defined failure mode which must be used is shown in Table 1.

Test Condition	Test Cycle (see Figure 1)		
	Sub Atmospheric	Trans Atmospheric	Super Atmospheric
Pass Condition	Test required	Test required	Test required
Fail Condition - modified vacuum	Test required	Test required	Test not required
Fail Condition - chamber leak	Test required	Test not required	Test not required
Fail Condition - air injection	Test required	Test not required	Test required

Table 1: *The test conditions required to demonstrate equivalence between the Bowie and Dick test textile pack as defined in BS EN 285 and alternative Bowie and Dick test packs as specified in BS EN ISO 11140-4.*

In conducting the tests the sterilizer is first shown to be capable of achieving rapid and even steam penetration into a BDT textile pack. Air removal and steam penetration is measured using temperature sensors inserted into specified locations within the pack. The temperature profile measured from within the test pack and the chamber drain, should show no difference (pass condition). The alternative BDT pack is then exposed to the same sterilizer process. The alternative BDT pack should produce a pass condition as defined by the manufacturer.

The sterilizer process is then changed so that air remains within the chamber and the BDT textile pack is exposed to the test cycle. The temperature difference measured from within the textile pack and the drain must meet the following criteria for the operating cycle to be regarded as a fail condition (see figure 2);

- A 2 to 7 °C depression when the set temperature is achieved.
- A 2 to 4 °C depression 30 seconds after the hold period begins.
- A 0 to 2 °C depression 90 seconds after the hold period begins.
- A 0 to 1 °C depression at the end of the hold period.

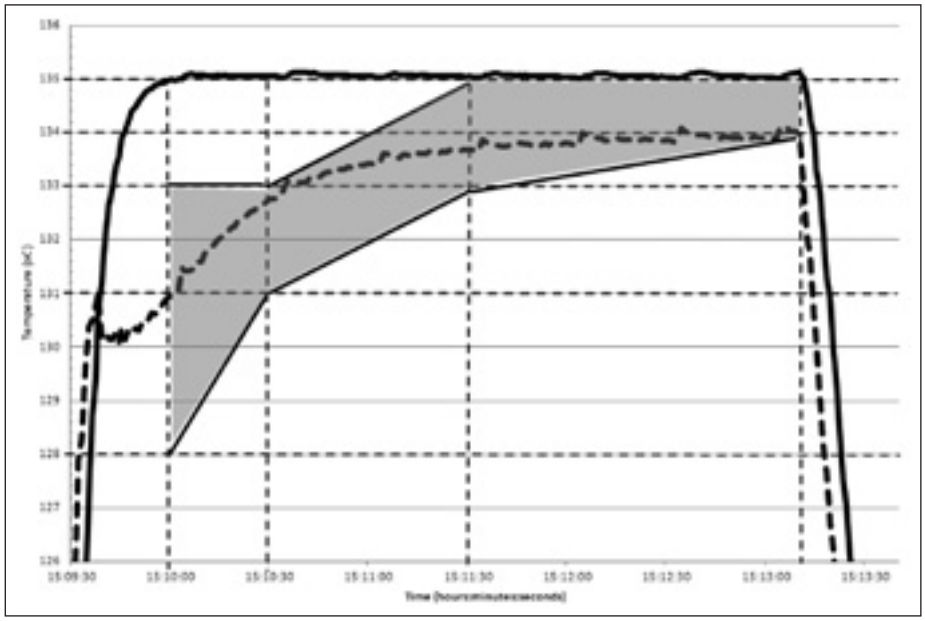

Figure 2: *The area (shaded) in which the temperature measured from within the Bowie and Dick Test (BDT) textile pack should fall in order to be classed as a fail condition for the purposes of demonstrating equivalence between the reference BDT textile pack and an alternative BDT pack or device. The chart shows the temperature from the chamber reference point (drain – solid line) and the centre of the BDT textile pack (dotted line).*

The alternative BDT pack is then exposed to the same operating cycle at which point a fail response should be observed as defined by the manufacturer.

A series of replicate studies are carried out on three batches of manufactured product to establish the reproducibility of the device.

Several electronic versions of the BDT have now become available (Benoit et al, 2011) and in the absence of a specific standard for these devices manufacturers have cross referenced the performance requirements specified in BS EN ISO 11140-4.

Purpose of the described study

Alternative BDT packs and devices used within UK hospitals should comply with the requirements of BS EN ISO 11140-4 (see clause 13413 in CFPP 01-01 part C, 2012). BS EN ISO 11140-4 specifies a super atmospheric test cycle which utilises three sub atmospheric pulses and three super atmospheric pulses (see figure 1). Sterilizers in the UK typically employ this type of sterilization cycle but usually use a larger number of pulses in each region of the pressure curve. Typically between 3 and 6 sub atmospheric pulses and 3 to 6 super atmospheric pulses are used. Examination of Table 1 indicates that an alternative BDT pack need only be tested in a pass condition and then a fail condition induced by air injection when using the sub/super atmospheric pulsing cycle. The air injection method is an artificial method which employs the introduction of a bolus of compressed air at a specific point in the cycle (see cloud symbol in Figure 1). The air injection method does not bear any resemblance to a failure mode likely to be found in a production sterilizer because the point of introduction is usually directly over the device under test.

All of the alternative BDT packs and devices used in this study were claimed to conform to BS EN ISO 11140-4 which means the manufacturer must have evidence that the test device gives a satisfactory result in a pass condition and a fail result in a fail condition according to table 1 and in particular the air injection method in combination with the sub/super atmospheric pulsing cycle, B3 (Figure 1). There is no requirement to establish performance in the other two failure modes specified, inadequate evacuation and chamber leaks, which are more representative of fail conditions observed on production sterilizers.

The purpose of this study was to examine the performance of a number of alternative BDT packs and devices when subjected to fail conditions most likely to be observed on production sterilizers, i.e. inadequate evacuation or a chamber leak.

Materials

Sterilizer

A computer programmable 300L steam jacketed sterilizer (Lautenschlager Company, Koln, Germany) was used. The sterilizer control system was programmed from a desktop PC using a custom designed program.

Air removal was achieved using a condenser and water ring vacuum pump connected to two drain ports located along the centre line of the base of the chamber and equidistant from the back wall and door. The chamber reference sensor was located 10cm down in the rear drain port. A wire mesh shelf positioned 10 to 15 cm above the chamber floor was used to support test samples.

The chamber leak rate was determined using the method described in BS EN 285 (BS EN 285, 2009). Throughout the study the leak rate remained well within the limit of 1.3 mbar per minute (typically between 0.4 and 1.0 mbar per minute) for “pass” cycle conditions.

Sterilizer Operating Cycle

A mixed pulsing operating cycle was used which included three subatmospheric and three super atmospheric pulses (see figure 1). The control points for the sub atmospheric stage were adjusted to deliver pressure pulses of between 50 to 950 mB and for the super atmospheric stage, 1100 and 2880. When adjusted to these set points satisfactory air removal and steam penetration was observed in the BDT textile pack. For operating cycles designed to create a failure due to inadequate evacuation the lower set point on each of the three sub atmospheric pulses was adjusted through a series of steps (50, 75, 100, 150, 200, 250 and 300 mB) in order to gradually increase the level of residual air remaining in the sterilizer chamber.

For operating cycles designed to create failures due to chamber leaks, the pressure set points used for the “pass” condition remained constant whilst air was allowed to enter the chamber through a needle valve which was adjusted to allow an increasing flow of air resulting in greater levels of residual air in the chamber (leak rates of <1.3, 9.5, 20, 42 and 55 mB/min). Air flow was monitored using a variable area flow meter. The chamber leak rate was determined using the method specified in BS EN 285 and is reported in the results as chamber pressure rise rate, mB/min.

Steam Supply

A dedicated steam supply was used as described by Benoit (Benoit et al, 2011). Potable water was purified using a mixed bed de-ionisation cartridge. The deionised water was further purified using reverse osmosis producing water of <0.5 microS/cm conductivity. Purified water was stored in a 1000l tank. Prior to use, the purified water was degassed by heating in a hot well maintained at 95°C. Water was pumped from the hot well into an electrically powered steam generator (Lautenschlager, Koln, Germany) maintained at 5 +/- 0.5 bar working pressure. Steam generated in the boiler passed into a steam manifold (CFPP 01-01 part C, clause 13458) held at 3.5 +/- 0.2 bar pressure. Steam passed from the steam manifold into the sterilizer via a 2m length of 3.75cm diameter pipe.

Temperature and Pressure Measurements

Temperatures from within the sterilizer were measured using either PTFE insulated Copper – Constantan (type T) thermocouples with welded tips (Class 1, 0.15cm diameter) or miniature four wire platinum resistance sensors, introduced into the chamber via a steam tight gland. The pressure from within the sterilizer chamber was measured using a precision pressure transducer having an accuracy of 0.15%, a response time of 3 ms and a range of 0 to 4 Bar Absolute. The pressure sensor was maintained at a constant temperature of 55 +/- 2.5°C using electrically heated and controlled jackets so as to minimise inaccuracies caused by temperature coefficient effects. The pressure sensor was mounted on a manifold which was in direct connection with the sterilizer chamber via a 2.5cm pipe and isolation valve.

The temperature and pressure sensors were calibrated using instruments traceable to the German national standard.

Data Management

The various sensor systems were connected to a multi channel data management system (Delphin Technology AG, Bergisch Gladback, Germany). Data was further analysed using standard office spreadsheet software (Microsoft® Excel®).

Bowie and Dick Test Textile Pack

BDT textile packs in accordance with BS EN 285 employing 30 towels per pack were used. Each BDT textile pack was exposed to several operating cycles so as to stabilize the response characteristics (Denhoffer, 2000) and then allowed to equilibrate to ambient conditions (25 +/- 5°C and 45 +/- 7% RH). Immediately before use the temperature and relative humidity inside the centre of the pack was measured using a sword probe digital thermometer/hygrometer (Rotronic, Germany).

During sterilizer cycles the temperature profile within the pack was determined from a single probe placed in the central fold of the 10th, 15th, 20th and 25th towels (Denhoffer, 2000). Each sensor was introduced into the pack as a helical coil so as to minimise steam tracking. A piece of BDT indicator sheet (3M™ Comply™ Bowie and Dick Test Indicator Sheet, 1227, 3M, Neuss, Germany, 10 x 10cm) was located one layer of fabric below the measurement point of the sensor in the 10th, 20th and 25th towel. A BDT Indicator sheet (Comply Bowie and Dick Test Indicator Sheet, 1227, 3M, Neuss, Germany) complying with BS EN ISO 11140-3 (A4 size) (BS EN ISO 11140-3, 2007) was located two layers of textile material below the temperature sensor located in the 15th towel (mid point). The purpose of the indicators was to highlight the relative position of any air pocket which formed in the pack to the point where the measurement sensor was located.

Commercially Produced Alternative Bowie and Dick Test Packs and Devices

Alternative BDT packs and devices were purchased through normal UK distribution channels (NHS Supply Chain or independent distributors). All test packs claimed compliance to BS EN ISO 11140-4. Before use test packs were conditioned in an environment of 25 +/- 5°C and 45% +/- 7% relative humidity. The test devices were used according to the manufacturers' instructions.

Definition of a fail condition within a textile pack

The presence of an air pocket within a BDT textile pack causes a temperature depression within the pack and the appearance of an incomplete colour change on a chemical indicator test sheet.

BS EN 285 specifies that if a temperature depression greater than 2°C is observed in the BDT textile pack during the holding period of the small load thermometric test, air removal and steam penetration is inadequate. BS EN ISO 11140-4, Annex M (BS EN ISO 11140-4, 2007) requires an alternative BDT pack or device to show a fail if the residual air within the chamber creates a similar temperature depression within the BDT textile pack (see Figure 2). In this study no attempt was made to create a defined temperature depression in the BDT textile pack but rather increasing quantities of air were introduced into the sterilizer chamber in order to create increasing temperature depressions during the holding phase of the operating cycles employed. The maximum temperature depression

observed during the first 30 seconds of the holding phase is reported. The response of the alternative BDT pack when subjected to the same cycle conditions is also reported. A temperature depression greater than 2°C at the commencement of the holding phase was judged to be a failed BDT.

Methods

The method used to assess the performance of a number of commercially available alternative BDT devices has been described previously (Benoit et al, 2011). Initial calibration checks were carried out using reference instruments traceable to the German national standards. The steam supply was energised and allowed to heat up to a stable temperature and pressure. A series of warm up operating cycles were then carried out. Once warm the chamber leak rate was determined to ensure compliance with BS EN 285 (<1.3 mB/min). Further warm up cycles were then carried out. An initial series of tests were then carried out in which an operating cycle known to achieve a pass condition in a BDT textile pack was used to assess the performance of the alternative BDT packs and devices. A series of tests were then carried out in which the lower set point of the sub atmospheric pulsing stage of the operating cycle was raised from an initial setting of 50 mB to 75, 100, 150, 200, 250 and 300 mB. The response of the BDT textile pack and the alternative BDT packs and devices was determined at each of the vacuum set point settings. A third series of tests were carried out in which the operating cycle pressure set points remained constant but in which the chamber leak rate was raised from an initial value of <1.3 to 9.5, 20, 42 and 55 mB/min. The response of the BDT textile pack and the alternative BDT test packs and devices was determined at each leak rate setting.

Results

Bowie and Dick Test Textile Pack

After exposure to the operating cycle the textile pack was removed from the chamber and carefully disassembled. The measurement point of the temperature sensor was then marked on the chemical indicator sheet located beneath the towel. A description of the chemical indicator colour change was immediately recorded and where appropriate the size of any light area measured as a diameter, if circular, or major and minor axis, if

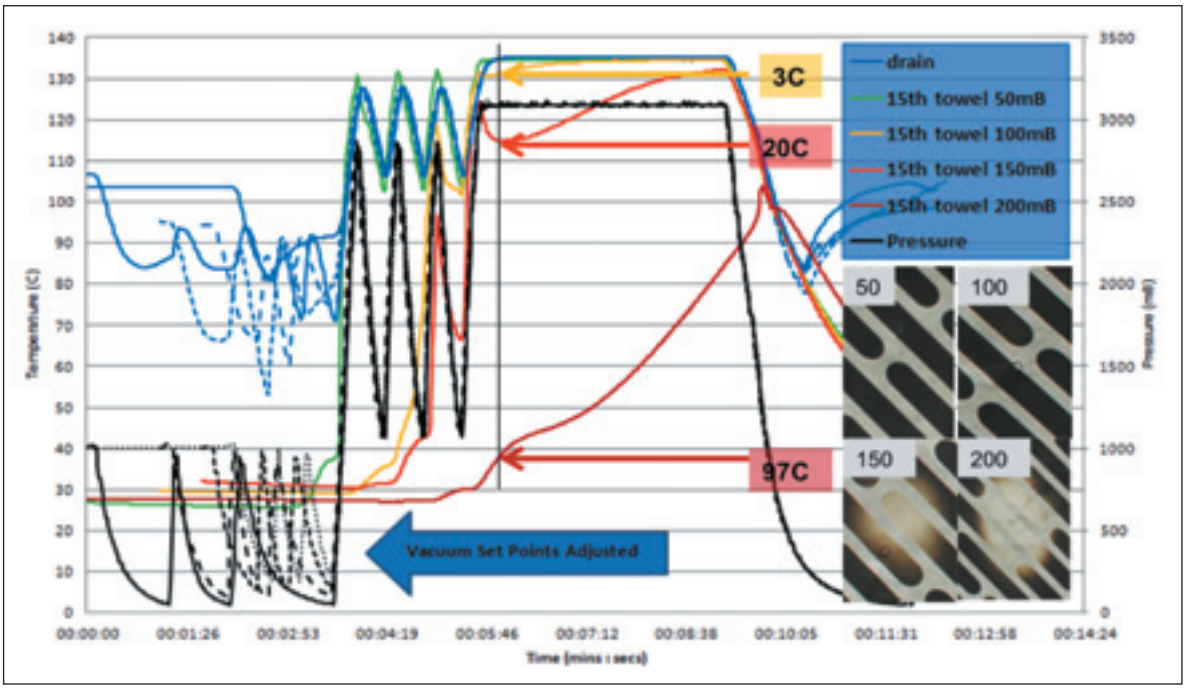

Figure 3A: Graph showing the pressure profile (black line) for each of the operating cycles used with vacuum set points of 50, 100, 150 and 200 mB on each of the first three sub atmospheric pulses. The temperature from the chamber drain (blue) and the centre of the Bowie and Dick test textile pack showing the temperature difference between the centre of the pack and the drain in response to the changes in vacuum set point (0 - green, 3 - orange, 20- red, 97- dark red °C depression for set points of 50, 100, 150 and 200 mB). The appearance of the central area of the chemical indicator sheet placed at the centre of the pack and the position of the temperature sensor measurement point (small circular mark) is also shown.*

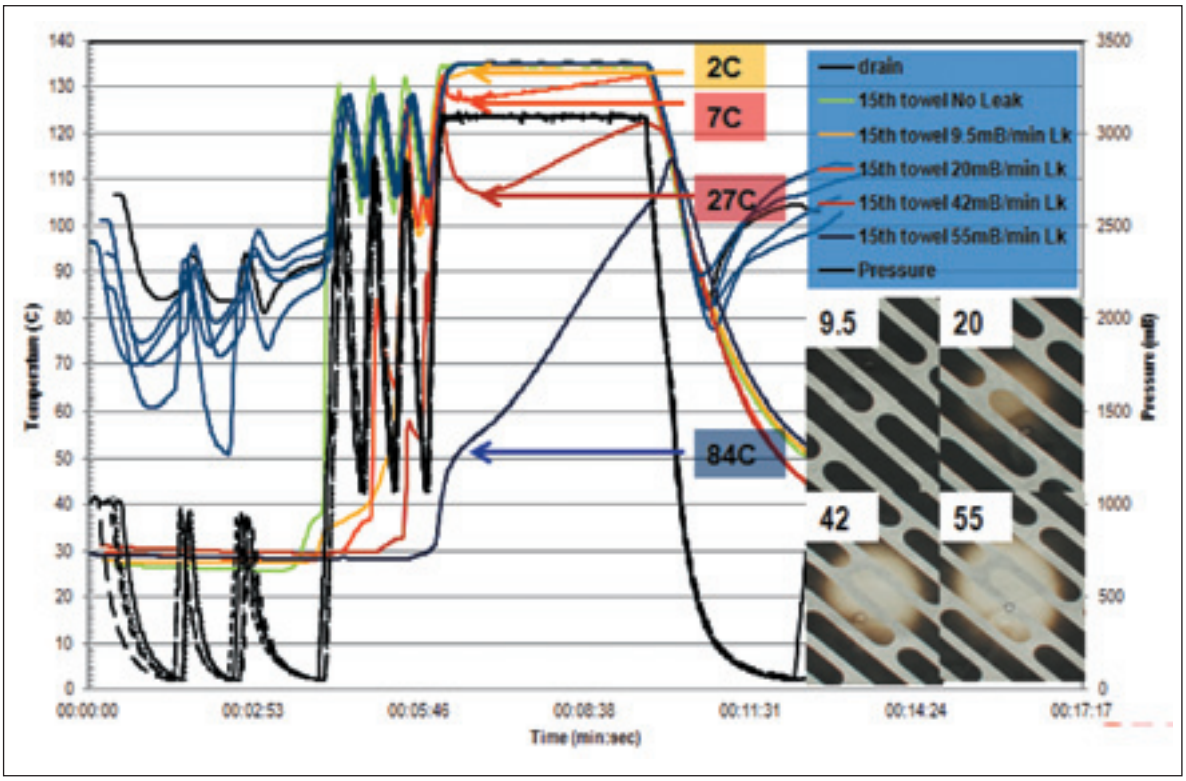

Figure 3B*: *Graph showing the pressure profile (black line) for each of the operating cycles used with a vacuum set point of 50mB and a chamber leak of <1.3, 9.5, 20, 42 and 55 mB/min. The temperature from the chamber drain (blue) and the centre of the Bowie and Dick test textile pack showing the temperature difference between the centre of the pack and the drain in response to the changes in chamber leak rate (0 - green, 2 - orange, 7- red, 27- dark red and 84 – blue °C depression for leak rates of <1.3, 9.5, 20, 42 and 55 mB / min). The appearance of the central area of the chemical indicator sheet placed at the centre of the pack and the position of the temperature sensor measurement point (small circular mark) is also shown.*

elliptical, in shape. The maximum temperature depression within the BDT textile pack during the first 30 seconds of the holding phase was recorded and the towel position at which this occurred.

The response of the BDT textile pack to an operating cycle with increasing air retention due to poor vacuum levels is shown in figure 3A. The figure shows the operating cycle pressure profile for each of the different vacuum set points employed on the first three sub atmospheric pulses (50, 100, 150 and 200 mB). The figure also shows the temperature from within the chamber drain, and the temperature measured from the geometric centre (15th towel) of the BDT textile pack after exposure to each of the operating cycles employed. At a 50 mB vacuum set point there was no observable temperature depression at the centre of the pack. As the pressure set point was raised through 100, 150 and 200 mB the maximum temperature depression observed increased from 3, 20 and 97 °C respectively at the 15th towel. The figure also shows the appearance of the central portion of the indicator sheet placed in the centre of the BD test pack for each of the pressure set points employed. The small dot observable on the indicator sheet indicates the position of the temperature sensor measurement point. Since a 97 °C temperature depression was observed at the 200 mB set point it was assumed that an even greater temperature depression would be observed at the 250 and 300mB set points and so tests using the BDT textile pack were not carried out at these settings.

The response of the BDT textile pack to an operating cycle with increasing air retention due to chamber leaks is shown in figure 3B. The format of the chart is the same as that for figure 3A. At an ambient leak rate of <1.3 mB/min no temperature depression was observed within the BDT textile pack. As the leak rate was increased from 9.5, 20, 42 and 55 mB/min the temperature depression increased from 2, 7, 27 and 84 °C respectively. The appearance of the central portion of the indicator sheet is also shown.

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Alternative Bowie and Dick Test Packs and Devices

The response of the BDT textile pack, the indicator sheet placed within the centre of the pack, an electronic BDT device and a number of commercially available disposable BDT packs to increasing process failures are shown in tables 3A and B.

Table 3A shows the response of each test device towards operating cycles in which the residual air level was increased by inadequate evacuation. Table 3B shows the response of each device towards chamber leaks. The first column of the tables shows the test condition i.e. cycle 3B (see above and BS EN ISO 11140-4) with the vacuum set point on each of the three sub atmospheric pulses, 50 mB producing a pass, followed by set points of 75, 100, 150, 200, 250 and 300 mB (table 3A) or a chamber leak rate of <1.3, producing a pass, 9.5, 20, 42 and 55 mB/min (table 3B). In both tables the second column shows the response of the BDT textile pack in terms of the temperature depression at the centre of the pack. The third column describes the appearance of the indicator sheet placed in the centre of the BDT textile pack along with the size of any light area observed. The remaining columns labelled A to I identify the

Table 3A

Test	BDT textile pack result		Device A	Pack B	Pack C	Pack D	Pack E	Pack F	Pack G	Pack H	Pack I
Vacuum set point (mB)	(Temp difference °C)	Indicator sheet appearance (Size of the fail cm)	(numerical output)	Indicator sheet appearance (size of fail in cm)							
50	Pass (0)	Pass (Even colour change)	Pass (54, 87)	Pass	Pass	Pass/Fail(1)	NT	NT	NT	NT	NT
75	NT	NT	Fail (-50)	Fail (3)	Fail (2.5)	Fail (5)	NT	NT	NT	NT	NT
100	Fail (0.5, 3)	Pass/Fail(1)	Fail (-53)	Fail (3)	Fail (2)	Fail (4)	Pass	Pass	Pass	Pass	Pass
150	Fail (8, 20)	Fail (4.5, 4.0)	Fail (-1122, -1143)	Fail (4)	Fail (7)	Fail (4.5)	Pass	Pass	Pass	Pass	Pass
200	Fail (97)	Fail (6.5)	Fail (-1160)	Fail (5)	Fail (8)	Fail (6)	Pass	Pass	Pass	Pass	Pass/Fail (3)
250	NT	NT	Fail (-1175)	NT	NT	NT	Pass	Fail (3)	Pass	Fail (6)	Fail (3)
300	NT	NT	Fail (-1169)	NT	NT	NT	Fail (1.5)	NT	Fail (2)	Fail (3)	Fail (4)

Table 3A and B: *The tables show the results of tests evaluating the performance of the commercially produced alternative Bowie and Dick Test devices in test cycles whereby residual air was increased as a result of inadequate evacuation (Table 3A) and as a result of chamber leaks (Table 3B).*

Column 1 indicates the test condition in terms of the vacuum set point on each of the three sub atmospheric pulses. Column 2 indicates the temperature difference observed between the drain and the centre of the Bowie and Dick test textile pack including replicates. Column 3 indicates the appearance of the indicator sheet included in the test pack. Column 4 to 12 (labelled A to I) indicates the result obtained from the commercially produced BDT device either as a numerical value indicated by the electronic device or the size of the air pocket indicated by the indicator sheet found inside the disposable test pack. Initial studies were carried out as individual "sounding shot" tests in order to establish a fail condition which would be regarded as a significant fail (in this case an 8 and 20 °C depression in the BDT textile pack). The shaded row on the table shows the point at which replicate tests were carried out. NT indicates Not Tested at the test condition described.

(1) Indicates duplicate tests where one result indicated a pass and the second a fail result.

Table 3B

Test	BDT textile pack result		Device A	Pack B	Pack C	Pack D	Pack E	Pack F	Pack G	Pack H	Pack I
Chamber leak rate mB/min	(Temp difference °C)	Indicator sheet appearance (Size of the fail cm)	(numerical output)	Indicator sheet appearance (size of fail in cm)							
<1.3	Pass (0)	Pass (Even colour change)	Pass (54, 87)	Pass	Pass	Pass/Fail(1)	NT	NT	NT	NT	NT
9.5	(1.2, 2)	Fail/Pass (2.5/even)(1)	Fail (-79, -85)	Fail (2.5)	Fail (5)	Fail (4)	Pass	Pass	Pass	Pass	Pass
20	(7, 15)	Fail (3.5, 2.5)	Fail (-1154, -1153)	Fail (3)	Fail (6)	Fail (5)	Pass	Pass	Pass	Pass	Pass
42	Fail (27)	Fail (6.5)	NT	NT	NT	NT	Pass	Pass	Pass	Pass	Fail (?)
55	Fail (84)	Fail (7)	NT	NT	NT	NT	Fail (?)	Fail (?)	Pass	Fail (3)	Fail (3)

Table 3B: *The table shows the results of tests evaluating the performance of commercially sourced alternative Bowie and Dick test devices in test cycles whereby residual air was increased as a result of chamber leaks. The columns are as per table 3A.*

(?) Indicates an uncertain result from the indicator sheet interpreted as a marginal fail.

NT Indicates Not Tested at the test condition described.

(1) Indicates duplicates tests one giving a pass, the second a fail.

response of the alternative BDT test device and packs interpreted according to the manufacturer's instructions. In the case of the electronic device (column A) the numerical value associated with the pass or fail status of the result is shown. A positive value represents a pass and a negative value, a fail. In the case of the disposable BDT packs the result (pass or fail) along with the size (diameter) of any observable unchanged area on the indicator sheet is shown.

The shaded rows indicate test conditions where replicate tests were carried out to ascertain reproducibility of the result. The test points identified were chosen since they represent conditions where sufficient air was retained to create a large temperature depression within the BDT textile pack and therefore a fail response would be expected from the alternative BDT device or pack.

Discussion

The Bowie and Dick Test

The BDT is described in BS EN 285 and consists of a stack of towels into which is placed a chemical indicator sheet. The BDT is of vital importance in ensuring a porous load sterilizer is functioning correctly and as such is a daily requirement (BS EN ISO 17665, 2006, HTM 2010, 1998, CFPP 01-01 part C, 2012). The BDT is independent of the sterilizer's control system and provides essential information about the performance of the machine. The results from a BDT form an integral part of the equipment and process history file and the quality assurance records showing continued satisfactory performance. A sterilizer should not be used in production until it has passed a BDT. Whilst all sterilizers supplied into the UK market have air detectors fitted, these devices depend on careful adjustment initially and then ongoing testing on a periodic basis to ensure satisfactory performance. Accidents happen; equipment breaks or goes out of

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calibration. The BDT, in conjunction with the use of an appropriately adjusted and validated air detector along with carefully calibrated independent temperature and pressure sensors, ensures ongoing process efficacy and security. Practitioners typically use commercially produced alternative BDT's for convenience. Their expectation is that such products will have the same performance as the reference BDT textile pack described in BS EN 285.

Commercially produced Bowie and Dick test products and BS EN ISO 11140-4

The performance of commercially produced alternative BDT packs and devices must be linked to the performance of the standard BDT textile pack described in BS EN 285. This is achieved by demonstrating conformance to BS EN ISO 11140-4 which describes the performance requirements and test methods for the demonstration of equivalence. BS EN ISO 11140-4 describes the use of three test cycles, one of which has similarities to the types of cycle used on production sterilizers found in the UK. The standard does not require the manufacturer to check the performance of the alternative BDT pack or device in the three well known failure modes commonly encountered in production sterilizers; chamber leaks, inadequate vacuum and non condensable gases in the steam supply (CFPP 01-01, part C, 2012). Instead, the standard requires a test employing a single injection of compressed air immediately prior to the process entering the heat up and sterilization stage. The results described in this publication suggest this may be a flaw which requires attention by the standards committee. All of the BDT packs and devices tested in this study claimed to conform to BS EN ISO 11140-4 or the performance requirements of the standard. The results of the tests indicate that only four of the nine products tested were capable of detecting residual air causing a 2°C or greater temperature depression within the BDT textile pack. Some of the alternative BDT test packs were so insensitive that they were unable to detect residual air causing a temperature depression within the BDT textile pack of more than 80°C, with a concomitant air pocket causing a light area on the indicator sheet of >6.5 cm in diameter. Under these test conditions the centre of the pack never reached sterilizing temperature (134°C). These results are of very great concern and suggest faulty sterilizers may be in routine production due to lack of fault detection.

Bowie and Dick test products are not regulated as medical devices and therefore are not subjected to the same design controls as a medical device (i.e. CE marking process). CFPP 01-01 part C (CFPP 01-01, part C, 2012) recommends practitioners should use BDT products compliant with BS EN ISO 11140-4. However, compliance to the standard is largely through self certification and declarations of conformity issued by the manufacturer, although some suppliers do invest in third party performance certification (e.g. the British Standards Institute kite mark scheme). In many instances purchasers assume that manufacturer's claims are valid without auditing manufacturer's test data or conducting tests themselves. As the NHS moves more towards procurement driven purchasing decisions in order to save costs the individuals with the necessary expertise required to make informed judgements relating to the adequacy of product performance may not have an influence on purchasing decisions. As a result, inadequately performing products may find their way into everyday use. This situation should be regarded as wholly unsatisfactory and remedial action should be taken. As a minimum, users should satisfy themselves that the alternative BDT packs or devices in use in their departments have an acceptable degree of sensitivity to the residual air they are supposed to be detecting.

Conclusions

Nine commercially produced alternative BDT packs and devices were assessed for sensitivity towards residual air caused by inadequate evacuation or chamber leaks in a porous load sterilization process employing three sub atmospheric pulses and three super atmospheric pulses according to BS EN ISO 11140-4. Of the nine tested, four detected residual air which caused a 2°C or more depression within the reference BDT textile pack described in BS EN 285. The remainder were so insensitive that they were incapable of detecting an amount of residual air causing a greater than 80°C temperature depression within the BDT textile pack; an amount of air which even prevented the centre of the pack reaching the minimum sterilization temperature of 134°C. This is of great concern and users should endeavour to assure themselves that the alternative BDT packs and devices in use in their department are capable of achieving an acceptable level of sensitivity under the conditions in use.

References

- Benoit F, Merger D, Hermsen R J and van Doornmalen J P C M, 2011, A comparison of four commercially available electronic steam penetration tests according to ISO 11140 part 4, *Zentral Sterilisation*, 3, 180-185
- Bowie J H 1961, The Control of Heat Sterilizers. In *Recent Developments in the Sterilization of Surgical Materials, Report of a symposium organised by the department of pharmaceutical sciences of the Pharmaceutical Society of Great Britain and Smith and Nephew Research Ltd at the School of Pharmacy, University of London,* London, The Pharmaceutical Press.
- Bowie J H, Kelsey J C, Thompson G R, 1963. The Bowie and Dick autoclave tape test, *The Lancet*, 16, 586-587
- British Standards Institute 2006, *British Standard BS EN ISO 17665 - 1: 2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices,* London, British Standards Institute.
- British Standards Institute 2007, *British Standard BS EN ISO 11140-3:2007, Sterilization of health care products – Chemical indicators. Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test.* London, British Standards Institute.
- British Standards Institute 2007, *British Standard BS EN 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.* London, British Standards Institute.
- British Standards Institute 2009, *British Standard BS EN 285: 2006 +A2:2009, Sterilization – Steam sterilizers – Large sterilizers,* London, British Standards Institute.
- British Standards Institute 2009, *British Standard BS EN ISO 11140-1:2009, Sterilization of health care products – Chemical indicators. Part 1: General requirements (ISO 11140-1:2005).* London, British Standards Institute.
- Denhoffer, E, 2000, The response of the Test Pack – personal communication, Lautenschlager, Koln, Germany
- Her Majesty's Stationery Office, 1968. Hospital Technical Memorandum 10, Pressure Steam Sterilizers, London, Her Majesty's Stationery Office (HMSO).
- Her Majesty's Stationery Office, 1995, *Health Technical Memorandum 2010, Part 2: Design considerations, Sterilization,* London, Her Majesty's Stationery Office (HMSO).
- Her Majesty's Stationery Office, 1998, *Health Technical Memorandum 2010, Part 3 (Including Amendment 1): Validation and Verification,* London, Her Majesty's Stationery Office (HMSO).
- Department of Health, 2012. *Choice Framework for local Policy and Procedures. CFPP 01-01: Management and decontamination of surgical instruments(medical devices) used in acute care. Part C – Steam sterilization),* Version: 1.0: England, London, Department of Health.

Declaration of Interest

The tests described in this study were carried out by the author Dr Brian Kirk, an employee of 3M Healthcare, using the test equipment located at the Medical Markets Laboratory, 3M Germany, Neuss, Germany. All raw data and results are available for examination on request. The manuscript was independently assessed by a suitably qualified referee.

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