Performance of Hollow Load Process Challenge Devices (HLPCDs) for the determination of air removal and steam penetration in porous load steam sterilization processes

Part 2 – An evaluation of a number commercially produced HLPCDs

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Steam sterilization Hollow Load Process Challenge Devices (HLPCDs) are designed to assess the adequacy of air removal and steam penetration in a porous load steam sterilization process including those used in both large and small sterilizers. A PCD should be used in every load to ensure adequacy of air removal and steam penetration. Use of PCDs is also an integral part of the quality assurance systems used to ensure the sterility of each batch of reusable medical devices. There are a number of HLPCDs commercially available which have various design features ranging from simple tubular helical designs compliant to EN 867-5 to more complex electronic measurement systems. The aim of this study was to assess seven commercially produced HLPCDs for their ability to detect residual air in a porous load steam sterilizer employing a range of air removal stages. In addition to testing in processes deemed to be satisfactory, assessment was also carried out in cycles in which increasing amounts of residual air was artificially induced. The performance of each HLPCD was compared to that of a Bowie and Dick (BD) textile test pack into which were inserted temperature sensors. All tests were carried out with a single device in an empty chamber. The BD textile pack was chosen as a reference because it is well established as reference device for both full load and empty chamber tests. Only one of the seven HLPCDs tested exhibited equivalent performance to the BD reference device. One HLPCD was overly sensitive, failing an acceptable process. Four HLPCDs were incapable of detecting large failures in sub/super atmospheric pulsing cycles. One HLPCD was insensitive to residual air introduced into the chamber as a bolus at a specific point in the cycle. The results of this study show an unacceptable variability in performance in HLPCDs claimed to meet EN 867-5. Users should be extremely cautious when selecting an appropriate PCD for use in their own Sterile Service Departments and where possible, evaluation should be carried out before selections are made. Some HLPCDs will lead to a false sense of security and may result in processed goods being released into use, the sterility of which may be compromised due to undetected process failures.

KEY WORDS
- steam sterilization
- steam penetration
- hollow load
- process challenge device
- HLPCD

Introduction

Reliable steam sterilization requires direct contact of moisture, usually delivered as saturated steam, onto the surfaces of the load which must then be held for a defined period of time at a defined temperature (1, 2). The presence of residual air impairs the penetration of saturated steam, particularly into devices with lumen, and prevents the formation of the moist conditions required for microbial inactivation. The design of modern medical devices with intricate components comprising closed or open lumens increases the probability of sterilization failure by virtue of trapping air. Every sterilization process is a unique event and even though validated some method for demonstrating the adequacy of air removal and steam penetration is required, along with evidence to show that exposure to moist heat for an accepted combination of temperature and time has been attained. Measurement of time and temperature alone is insufficient (3, 4, 5). Practitioners are therefore required to establish that, for each sterilization process, the adequacy of air removal and steam penetration is achieved so that when the surfaces of medical devices are exposed to saturated steam at a prescribed temperature for a prescribed length of time microbial inactivation takes place and sterility is attained (1). In order to fulfil this requirement practitioners are required to employ PCDs (1,2). There are a wide range of HLPCDs on the market some resembling the tubular PTFE HLPCD described in EN 867-5 (6), others are of a more complex design. Some of the HLPCDs on the market claim compliance to EN 867-5 (6) or EN ISO 11140-4 (7), or both.

In part one of this publication (8), a review of both the existing literature and an examination of the published standards was undertaken. The conclusions indicate that the custom and practice of using PCDs

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based on simple tubular devices (e.g. the tubular PCD described in EN 867-5, HLPCD) has become established despite there being little evidence to support use of such devices for testing fully loaded sterilizers. There is also some evidence to suggest their use in empty chamber testing has limited value and is highly dependent upon the rate of pressure change during the evacuation and steam admission stages (active air removal pulses) of the cycle. The aim of this study was to examine the performance of a number of HLPCDs when subjected to both pass and fail conditions most likely to be observed on sterilizers in current use. All tests were carried out with a single device in an otherwise empty chamber. Previous studies have shown that removal of air from an empty chamber is the most challenging condition (9) and therefore the sensitivity of PCDs is likely to be reduced in full load conditions.

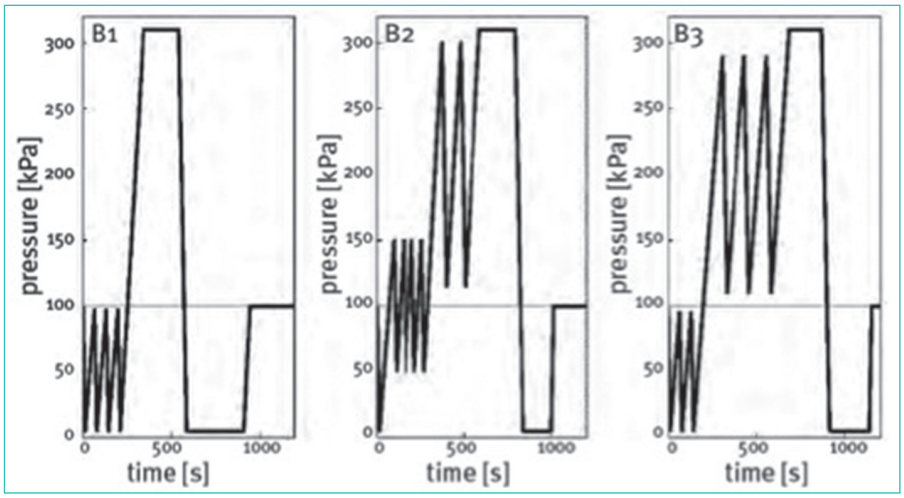

Fig. 1: Test cycles B1, subatmospheric, B2, transatmospheric and B3, superatmospheric described in BS EN ISO 11140-4 for demonstrating equivalence between the standard Bowie and Dick Test textile pack specified in BS EN 285 and alternative Bowie and Dick test packs and devices.

Materials

Sterilizer

A computer programmable 300L steam jacketed sterilizer (60 × 60 × 60cm – Lautenschläger Company, Cologne, 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 10 cm 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 (2). 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

Two cycle types were used during the study.

Sub/Super Atmospheric (Mixed) pulsing Operating Cycle (B3)

The mixed pulsing type operating cycle which included three sub atmospheric and three super atmospheric pulses (Type B3 as per EN ISO 11140-4 (7), 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 (see figure 3A). 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 and 200 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, 9.6, 20 and 30 mB/min). Air flow was monitored using a variable area flow meter. The chamber leak rate was determined using the method specified in EN 285 (2) and is reported in the results as chamber pressure rise rate, mB/min.

For operating cycles designed to create failures due to the injection of a defined volume of air into the chamber at a specified point in the cycle, the volume of air required to create a fail condition in the BDT textile pack was determined by preliminary experimentation. A volume of air equal to 500ml at standard temperature and pressure (STP), was introduced into the geometric centre of the sterilizer chamber at a point in the cycle representing the base of the final superatmospheric air removal pulse (see figure 1).

Sub Atmospheric pulsing Operating Cycle (B1)

The sub atmospheric pulsing type operating cycle consisted of four sub atmospheric pulses (Type B1 as per EN ISO 11140-4 (7), see figure 1). The control points for the sub atmospheric stage were adjusted to deliver pressure pulses of between 50 to 970 mB. When adjusted to these set points satisfactory air removal and steam penetration was observed in the BDT textile pack (see figure 3B). For operating cycles designed to create a failure due to inadequate evacuation, chamber leaks and air injection, the same method as described above was employed. For inadequate vacuum the set point was adjusted to 150 mB. For chamber leaks the leak rate was set to 1.0 and 2.0 mB/min. For air injection 200 ml of air at STP was injected at the base of the final subatmospheric pulse.

Steam Supply

A dedicated steam supply was used as described by Benoit et al (10). Potable water was purified using a mixed bed deionisation cartridge. The deionised water

was further purified using reverse osmosis producing water of < 0.5 microS/cm conductivity. Purified water was stored in a 1000 l 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 (Lautenschläger, Cologne, Germany) maintained at 5 ± 0.5 bar working pressure. Steam generated in the boiler passed into a steam manifold (11) held at 3.5 ± 0.2 bar pressure. Steam passed from the steam manifold into the sterilizer via a 2 m length of 3.75 cm diameter pipe.

Temperature and Pressure Measurements

Temperatures from within the sterilizer were measured using either PTFE insulated Copper Constantan thermocouples with welded tips (Class 1, 0.15 cm 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 2.5 cm 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 Gladbach, Germany). Data was further analysed using standard office spreadsheet software (Microsoft® Excel®).

Bowie and Dick Test Textile Pack (BDT)

BDT textile packs according to BS EN 285 (2) employing 30 towels per pack were used as a reference PCD, this being a known and well established challenge to air removal and steam penetration. Each BDT textile pack was exposed to several operating cycles so as to stabilize the response characteristics (12) 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 probe placed in the central fold of the 10th, 15th, 20th and 25th towels (13). 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 × 10 cm) 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) (14) 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.

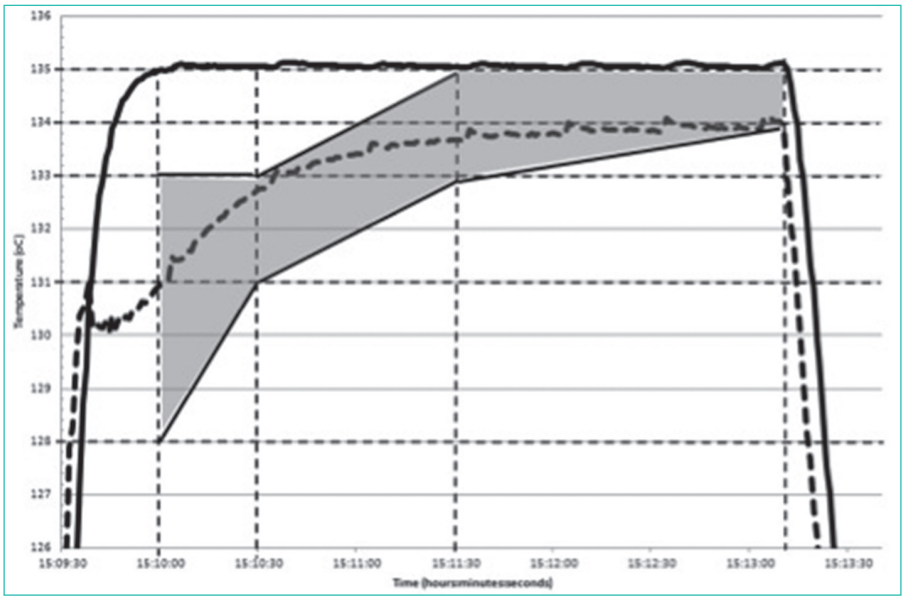

Fig. 2: The area (shaded) in which the temperature measured from within the Bowie and Dick Test (BDT) textile pack should fall in order to be classed as a fail condition for the purposes of demonstrating equivalence between the reference BDT textile pack and an alternative BDT pack or device. The chart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

Commercially Produced Process Challenge Devices

Commercially produced process challenge devices were purchased through normal distribution channels. The manufacturers of each PCD claimed compliance to one or a combination of EN 867-5, EN ISO 11140-1 and/or EN ISO 11140-4. Before and between uses, PC Ds were conditioned in an environment of 25 ± 5 °C and 45% ± 7% relative humidity. The test devices were used according to the manufacturer's 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 (2) specifies that if a temperature depression greater than 2oC 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 (7) requires an alternative BDT pack or device to show a fail if the residual air

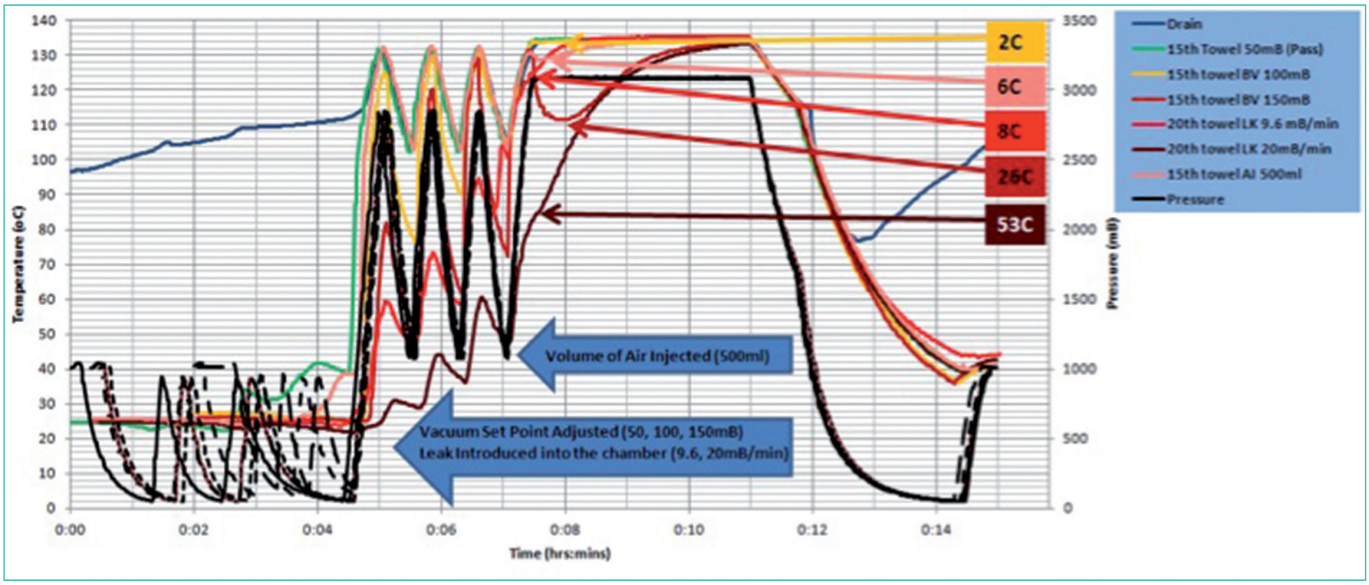

Fig. 3A: Chart showing the pressure profile (black line) for the mixed pulsing operating cycle used with vacuum set points of 50, 100 and 150mB on each of the first three sub atmospheric pulses, and a chamber leak rate of 9.6 and 20mB/min. The chart also shows the point at which 500ml of air was injected into the chamber in order to create a temperature depression within the textile pack. 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, 2 – orange, 26 °C – dark red, depression for set points of 50, 100 and 150 mB), chamber leaks (8 – red and 53 °C – dark purple, depression for chamber leak rates of 9.6 and 20 mB/min) and injection of 500 ml of air at the point shown on the chart (6 °C – pink) is shown.

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 HLPCD 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.

Assessment of commercially available HLPCDs

The method used to assess the performance of a number of commercially available electronic PCDs has been described previously (10). 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 EN 285 (2) (<1.3 mB/min, typically 0.5 to 0.8 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 HLPCD devices. A series of tests were then carried out in which the lower set point of the sub atmospheric pulsing stage of each operating cycle was raised. The response of the BDT textile pack and the HLPCD 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 the chamber leak rate was raised. A fourth series of tests were carried out in which a known volume of air was introduced into the geometric centre of the chamber at a specified point in the operating cycle. The response of the BDT textile pack and the HLPCD devices was determined for each volume of air injected. Each test was carried out with a single HLPCD in the chamber.

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 to ensure the reported temperature depression was taken from a point within the observed residual air pocket. 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 elliptical, in shape. The maximum temperature depression within the BDT textile pack during the first 30 seconds of the holding phase and the towel position, at which this occurred was recorded.

Results

Sub/Super Atmospheric (Mixed) pulsing Operating Cycle (B3)

The response of the BDT textile pack to the mixed pulsing operating cycle with increasing air retention due to poor vacuum levels (50, 100 and 150 mB pressure set points), chamber leaks (9.6 and 20 mB/

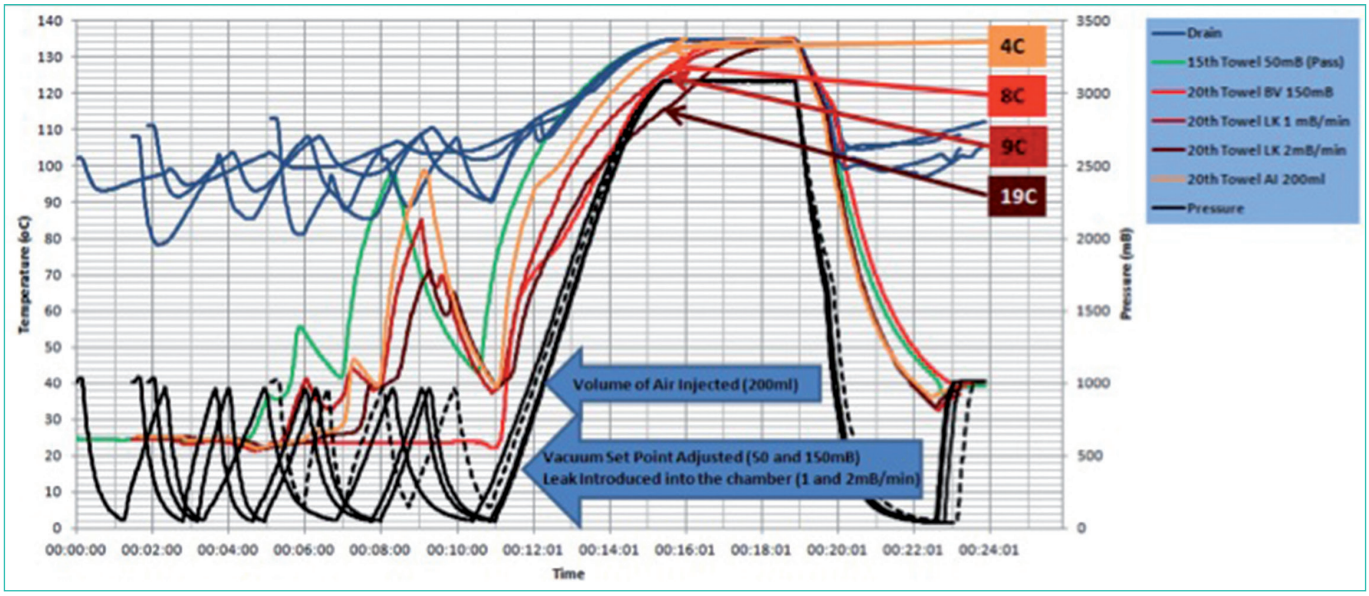

Fig. 3B: Chart showing the pressure profile (black line) for the subatmospheric pulsing operating cycle used with vacuum set points of 50 and 150mB on each of the subatmospheric pulses, and a chamber leak rate of 1 and 2 mB/min. The chart also shows the point at which 200ml of air was injected into the chamber in order to create a temperature depression within the textile pack. 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, 8 – red, depression for set points of 50 and 150 mB), chamber leaks (9 – dark red and 19 °C – dark purple, depression for chamber leak rates of 1 and 2 mB/min) and injection of 200 ml of air at the point shown on the chart (4 °C – orange) is shown.

min) and injection of a known volume of air (500 ml) at a specific point in the cycle, 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. The figure also shows the temperature from within the chamber drain, and the temperature measured from within the BDT textile pack for each of the operating cycles employed. At a 50 mB vacuum set point and an ambient chamber leak rate of < 0.8 mB/min, there was no observable temperature depression at the centre of the pack indicating adequate air removal and steam penetration. As the pressure set point was raised through 100 and 150 mB the maximum temperature depression observed, increased from 2 to 24 °C respectively at the 15th towel as the quantity of residual air increased. Since a 24 °C temperature depression was observed at the 150 mB set point it was assumed that an even greater temperature depression would be observed at the 200 mB set point and so tests using the BDT textile pack were not carried out at this setting (see table 3). When using a 200 mB setting in a previous study (13) in an identical mixed pulsing operating cycle a 97 °C depression was observed in the centre of the textile pack. As the chamber leak rate was raised (whilst maintaining the vacuum set point at 50 mB) to 9.6 and then 20 mB/min the maximum temperature depression observed, increased from 8 to 53 °C respectively at the 20th towel as the quantity of residual air increased. When 500 ml of air was injected into the chamber at the point shown in the figure, a 6 °C temperature depression was observed.

Sub Atmospheric pulsing Operating Cycle (B1)

The response of the BDT textile pack to the sub atmospheric pulsing operating cycle with increasing air retention due to poor vacuum levels (50, and 150 mB pressure set points), chamber leaks (1 and 2 mB/min) and injection of a known volume of air (200 ml) at a specific point in the cycle, is shown in figure 3B. The figure is in the same format as figure 3A. At a 50 mB vacuum set point and an ambient chamber leak rate of <0.8 mB/min, there was no observable temperature depression at the centre of the pack indicating adequate air removal and steam penetration. As the pressure set point was raised to 150 mB the maximum temperature depression observed was 8 °C at the 20th towel as a result of an increase in the quantity of residual air. As the chamber leak rate was raised (whilst maintaining the vacuum set point at 50 mB) to 1.0 and then 2.0 mB/min the maximum temperature depression observed, increased from 9 to 20 °C respectively at the 20th towel as the quantity of residual air increased. When 200 ml of air was injected into the chamber at the point shown in the figure, a 3.7 °C temperature depression was observed.

Hollow Load Process Challenge Devices

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

Table 3A shows the response of each test device towards mixed pulsing operating cycles in which the residual air level was increased by inadequate evacuation, chamber leaks and injection of a known volume of air at a specific point in the cycle. Table 3B shows the response of each test device towards a sub atmospheric pulsing operating cycles in which the residual air level was increased by inadequate evacuation, chamber leaks and injection of a known volume of air at a specific point in the cycle. The test points

Table 3A: The table show the results of tests evaluating the performance of the commercially produced Process Challenge Devices in a test operating cycle employing a combination of sub and superatmospheric (mixed) pulses whereby residual air was increased as a result of inadequate evacuation, chamber leaks and injection of a fixed volume of air at a specific point in the cycle (see figure 1).

			ETS	AB100	Valisafe	Interster	Steri-Tek	GKE Purple	GKE Blue
Test	BDT textile pack result		Device A	Device B	Device C	Device D	Device E	Device F	Device G
Vacuum set point [mB]	(Temperature difference) [°C]	Indicator sheet appearance (Size of the fail [cm])	(numerical output)	Indicator appearance (percentage of indicator surface showing a fail)					
50	Pass (0)	Pass (Even colour change)	Pass (97)	Pass	Pass	Pass	Pass	Pass	Pass
Operating Cycle Failures Due to Inadequate Vacuum (sub/super (mixed) atmospheric)									
75	NT	NT	Fail (–45)	Fail (5%)	NT	NT	NT	NT	Pass
100	Fail (2, 3)	Pass/Fail(1)	Fail (–67)	Fail (20%)	Pass	Pass	Pass	Pass	Fail (83%)
150	Fail (23, 26)	Fail (6, 5)	Fail (–1130)	Fail (100%)	Pass	Pass	Pass	Pass/Fail (1) (16%)	Fail (83%)
200	NT	NT	NT	NT	Pass	Fail (25%)	Fail (100%)	Fail (33%)	Fail (100%)
Operating Cycle Failures Due to Chamber Leaks (sub/super (mixed) atmospheric)									
Chamber Leak Rate [mB/min]									
9.6	Fail (6.6, 10)	Pass/Fail(1) (3,4)	Fail (–125)	Fail (100%)	Pass	Pass	Pass	Pass/Fail (1) (16%)	Fail (100%)
20	Fail (53, 50)	Fail (3, 4)	Fail (–1143)	Fail (80%)	Pass	Pass	Pass	Pass	Fail (100%)
30	NT	NT	NT	NT	Pass	Pass	Pass	Fail (16%)	NT
Operating Cycle Failures Due to Injection of a Volume of Air into the chamber during the cycle (sub/super atmospheric)									
Volume Air Injected [ml]									
500	Fail (6, 5.6)	Pass/Fail (1)	Fail (–27)	Fail (40%)	Pass	Pass	Pass	Pass	Pass

Device A was an electronic BDT/PCD, Device B was a device having both porous mass and lumened design elements, Device C – E were hollow load PCDs as per EN 867-5 (Helix), Device F and G were multi-chambered devices composed of plastic and stainless steel.

Column 1 indicates the test condition in terms of the vacuum set point on each of the three sub atmospheric pulses, the leak rate into the chamber or the volume of air injected into the chamber. 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 7 (labelled A to G) indicates the result obtained from the commercially produced PCD either as a numerical value indicated by the electronic device or the percentage of the indicator ink printed on the indicator strip which showed a Fail condition (inadequate air removal and steam penetration).

1 Indicates a marginal Fail which may be interpreted as a Pass or Fail.

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 PCDs.

Discussion

Sterilization standards require practitioners to utilise a means of establishing the adequacy of air removal and steam penetration for every sterilization cycle and this typically involves the use of PCDs. In practice a small number of designs of PCD have become established in common practice and one in particular predominates, namely the tubular PCD described in EN 867-5, HLPCD. In part 1 of this two part series (8) we review the published litera-

Table 3B: The table shows the results of tests evaluating the performance of the commercially produced Process Challenge Devices in a test operating cycle employing four sub atmospheric pulses whereby residual air was increased as a result of inadequate evacuation, chamber leaks and injection of a fixed volume of air at a specific point in the cycle (see figure 1).

			ETS	AB100	Valisafe	Interster	Steri-Tek	GKE Purple	GKE Blue
Test	BDT textile pack result		Device A	Pack B	Pack C	Pack D	Pack E	Pack F	Pack G
Vacuum Set Point [mB]	(Temperature difference [°C]	Indicator sheet appearance (Size of the fail [cm])	(numerical output)	Indicator appearance (Percentage of indicator surface showing a fail)					
50	Pass (0)	Pass (Even colour change)	Pass (101)	Fail (5%)	Pass	Pass	Pass	Pass	Pass
Operating Cycle Failures Due to Inadequate Vacuum (sub atmospheric Operating Cycle)									
150	Fail (8, 6)	Fail (5)	Fail (–108)	Fail (100%)	Pass	Fail (50%)	Fail (75%)	Fail (66%)	Fail (83%)
Operating Cycle Failures Due to Chamber Leaks (sub atmospheric Operating Cycle)									
Chamber Leak Rate (mB/min)									
1	Fail (9)	Fail (4)	Fail (–57)	Fail (100%)	NT	NT	Pass/Fail (1) (25%)	Fail (66%)	Fail (66%)
2	(20, 19)	Fail (5, 5)	Fail (–81)	Fail (100%)	Pass	Pass	Fail (50%)	Fail (66%)	Fail (83%)
Operating Cycle Failures Due to Injection of a Volume of Air into the chamber during the cycle (sub/super atmospheric)									
Volume Air Injected [ml]									
200 ml	Fail (3.7, 3.2)	Pass/Fail (1) (0, 4)	Fail (–5)	Fail (100%)	Pass/Fail (1) (5%)	Pass	Fail (50%)	Pass	Pass

Device identification as per table 3.

Column 1 indicates the test condition in terms of the vacuum set point on each of the four sub atmospheric pulses, the leak rate into the chamber or the volume of air injected into the chamber. 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 7 (labelled A to G) indicates the result obtained from the commercially produced PCDs either as a numerical value indicated by the electronic device or the percentage of the indicator ink printed on the indicator strip which showed a Fail condition (inadequate air removal and steam penetration).

1 Indicates a marginal Fail which may be interpreted as a Pass or Fail.

ture and standards to determine the scientific validity of using simple helical tubular PCDs for batch control. The result of the review suggests there is little evidence to support the use of simple helical tubular PCDs for batch control and the results from a number of empty chamber tests indicates variability in performance and a significant influence on sensitivity caused by the rate of pressure change during air removal and steam admission stages of the cycle.

We report the test results of seven commercially produced HLPCDs assessed for sensitivity towards residual air caused by inadequate evacuation, chamber leaks or injection of a known volume of air at a specific point in test cycles. Porous load sterilization processes employing either three sub atmospheric pulses followed by three super atmospheric pulses or just four sub-atmospheric pulses according to BS EN ISO 11140-4 (cycles B3 and B1 respectively) (7) were used. Comparisons in performance were made against a reference PCD (Bowie and Dick Textile test pack) into which was introduced temperature sensors (2). Of the seven HLPCDs tested only device A (an electronic Bowie and Dick type PCD) had an equivalent performance to that of the reference device. Device B (a complex design encompassing a combination of a metal sintered porous mass and a moulded tubular HLPCD) detected process failures but appeared to be overly sensitive in acceptable processing conditions. All the remaining devices tested (C to G) gave a satisfactory result in test cycles in which no residual air was detected by the reference PCD (Pass). However device C (a tubular HLPCD equivalent to that in EN 867-5) failed to detect process failures apart from the air injection test

in the sub atmospheric pulsing cycle. Device D (similar to device C) failed to detect process failures apart from inadequate vacuum in the subatmospheric pulsing cycle. Device E (similar to device C) and F (a multi-chambered tubular device) failed to detect process failures in the mixed pulsing cycle (B3, figure 1) but detected failures in the sub atmospheric pulsing cycle (B1, figure 1). Device G (similar to device F but with different tube lengths) detected process failures due to inadequate vacuum and chamber leaks but failed to detect residual air injected into the chamber in both test cycles used.

Porous load steam sterilizers employ validated processes which have been shown to deliver a sterile product. Routine monitoring is required to ensure ongoing process efficacy. Various international and national standards prescribe the types of routine tests which should be carried out as part of a monitoring schedule. This includes the daily Bowie and Dick Test which, independently of the sterilizer control system, monitors the effectiveness of the air removal stages of the process thereby ensuring adequate steam penetration. The standards also discuss the means by which appropriate process data can be collected. ISO 17665-2 discusses the use of air detectors, fitted to the sterilizer, which exert both monitoring and control capabilities and also process challenge devices which are typically free standing, commercially produced devices which present a challenge to the process. In many instances the commercially produced HLPCDs take the form a coiled tube, often 1.5 m long and 2mm in diameter at one end of which is mounted a capsule which contains an indicator device (HLPCD) and these are often claimed to be compliant to EN 867-5 and/or EN ISO 11140-4.

Review of the literature, standards and commercial technical information creates a confused picture with regard to the appropriateness of such claims. The review of the literature in part 1 of this two part series and the results presented in this publication indicate that some commercially produced simple tubular HLPCDs of the type described in EN 867-5 fail to detect failures which would give rise to process failures (but which are detected by the Bowie and Dick test). Other devices of a more complex design have a degree of sensitivity which is more appropriate. In the absence of a reliable standard which defines reference HLPCDs for use in batch control, their sensitivity and the method by which equivalence with commercially produced PCDs can be ascertained, users of such devices must satisfy themselves that manufacturers claims are appropriate and justified for their own particular circumstances (loads) as is clearly stated in EN ISO 17665-1 (1). ■

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Conflicts of Interest

The tests described in this study were carried out by the principle author Dr Brian Kirk 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 has been independently refereed.