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

Part 1 – The evolution of HLPCDs in standards and a review of the current supporting published evidence

B. Kirk, A. Smith[1], S. Winter[1]*

Steam sterilization Process Challenge Devices (PCDs) are devices which present a defined challenge to a sterilization process. In part one of a two part series the authors review the published literature covering studies evaluating the removal of air and penetration of steam into hollow tubular devices and then discuss the relevance of the material in support of the current custom and practice of utilising simple tubular PCDs (Hollow Load Process Challenge Devices HLPCDs) as a means of monitoring production loads for adequacy of air removal and steam penetration. This review places such data in the context of the evolution of HLPCDs in the standards for small and large porous load steam sterilizers. With regard to the apparent acceptance of the HLPCD in EN 867-5 into custom and practice for batch monitoring the literature suggests this may be misleading. The literature review concludes that there is an urgent need for an International Standard which describes how a HLPCD can be developed and tested against real medical devices in a range of sterilization processes representing current state of the art in full load conditions.

KEY WORDS
- thermolabile flexible endoscopes
- cleaning efficacy
- test pieces
- residual protein content
- validation
- acceptance criteria

Introduction

Steam sterilization is achieved in a sterilizer consisting of a sealed chamber in which load items are exposed to saturated steam of suitable quality at specified temperatures and times (e.g. 134 to 137 °C for 3 minutes [1]). If air is not removed from the sterilizer chamber before the sterilization stage commences, particularly in processes designed to sterilize porous loads or instruments with complex cavities and lumens, the steam will not come into contact with the surfaces which need to be sterile. European/International standard 17665-1 (1), identifies a series of steps designed to ensure robust and reliable processes. Process design, specification, validation and most importantly, routine monitoring leading to safe product release, are key elements. Having validated a sterilization process it is then imperative to ensure routine monitoring takes place. Every sterilization process is a unique event which requires data to confirm efficacy (1, 2). Kirk (3), van Doornmalen et al (4) and Dennhöfer (5) showed that the measurement of pressure and temperature alone cannot be used to verify the efficacy of a porous load steam sterilization process. Some method for demonstrating the adequacy of air removal and steam penetration is also required along with evidence to show that exposure to moist heat for an accepted combination of temperature and time has been attained for each sterilization cycle. International standards recognise these requirements (1). Thus, for example, EN 285 (2) states "Each sterilization process is a unique event. Whilst a steam penetration test carried out on a periodic basis provides a very useful equipment control function, provision should be made to ensure adequate steam penetration occurs during every cycle" and EN ISO 17665 (1) states "… In addition to the measurement of process parameters, steam penetration should be assured for each operating cycle, for example by using an air detector or a process challenge device. Both devices should be verified as valid for the product in the sterilization load."

Definition of Process Challenge Devices

Process Challenge Devices (PCDs) are devices which present a defined challenge to a sterilization process and should be used to assess the performance of such processes (1). In saturated steam sterilization processes (i.e. those employed to sterilize the surfaces of simple and complex re-usable medical devices as opposed to contained liquid products) air must be removed before steam can enter and effect microbial inactivation. The PCD should have a defined capability to detect process failures arising from chamber leaks, inadequate evacuation and the presence of non condensable gases in the steam supply and, if appropriate, the attainment of adequate sterilizing conditions at the point of measurement (e.g. time and temperature).

* Dr Brian Kirk BSc, MSc, PhD, MRPharmS, FIHEEM, AE(D), Senior Technical Service Specialist, Sterilization and Monitoring, 3M Health Care, Loughborough UK
E-mail: bkirk1@mmm.com

1 Professor Andrew Smith BDS, Dr Sandra Winter, College of Medical, Veterinary & Life Sciences, Glasgow Dental Hospital & School, University of Glasgow
378 Sauchiehall Street, Glasgow G2 3JZ, UK

Early Process Challenge Devices

PCDs are not a new concept. One of the most well recognised PCDs, although not universally regarded as such, is the independent daily Bowie and Dick Test (BDT) (2). Described by Bowie et al in 1963 (6, 7), it is specifically used to establish adequacy of air removal and steam penetration in an empty chamber which is the most challenging case for a porous load sterilizer (8). The BDT is almost universally accepted as an independent reference for routine testing on a daily basis. The previous UK standard for steam sterilizers, BS 3970 (9), specified the requirement for "air detectors" (considered a specific form of PCD) to be fitted to every porous load sterilizer in order to establish sufficient air had been removed from the chamber to allow subsequent attainment of sterilizing conditions. These devices perform both a monitoring and control function since they are able to abort the process if excessive quantities of air are detected. The various air detector designs was critically reviewed by Newton (10) who commented that such devices were generally fitted to the drain of the machine rather than sampling from the chamber and the results inferred adequacy of sterilizing conditions being met rather than by direct measurement.

Development of PCDs leading to HLPCDs

After a series of publications by Spicher and Borcher in 1983 (13) investigating the characteristics of penetration of low temperature steam and formaldehyde into tubular challenge devices the 1985 edition of German standard DIN 58948 part 13 described tests for Low Temperature Steam with Formaldehyde vapour sterilizers (14). This document described a hollow test device consisting of a capsule capable of holding a biological indicator spore strip (38 × 6 × 0.7 mm) attached to a length of polytetrafluoroethylene (PTFE) tubing 1500 mm long with a 2 mm inner diameter and 3 mm external diameter.

Young et al (20 – 22) in a series of publications from the mid '90s examined the inactivation of *Geobacillus stearothermophilus* biological indicators (BIs) in stainless steel tubes of 9.4 cm length and varying internal diameter from 0.4 to 1.7 cm and wall thicknesses of 0.1 to 0.135 cm in an attempt to create a model for steam in place sterilization. The tubes were attached to a steam supply pipe such that flowing steam passed the open end of the tubes which were at either 5° or 90° to the direction of steam flow. The results indicated that small diameter tubes were more difficult to sterilize than large diameter tubes, which seems to contradict later studies (see Kaiser and Göman 1998 [23]). However no active air removal took place and so penetration of moisture into the tube was similar to a gravity displacement type process rather than an active air removal process associated with porous load sterilization as used in later studies. The dynamics of air removal under such conditions will be very different to those encountered in porous load sterilization and Young proposed that convective displacement of air due to density differences would be the predominant effect which would explain why air was displaced more readily from a wider bore tube.

Kaiser and Göman (23) conducted extensive tests on the air removal and steam penetration into PTFE tubing of various lengths (500 to 4500 mm) and internal diameters (1 to 5 mm) using a sub atmospheric pulsing cycle (100 to 950 mB, pressure change rate ca 1000 mB/min). The chemical indicator results indicated that, rather counter intuitively, long, wide diameter tubes were harder to penetrate than short narrow diameter tubes. For a given length of tube wider diameter tubes were more resistant to steam penetration. The product of length × internal diameter indicated penetration resistance and equations were described to predict the relationships. The authors also commented on the fact that slow (0.5 to 1.5 Bar per min) had an effect although no data was provided.

Gömann et al (24) examined the performance of the HLPCD in steam test cycles employing subatmospheric air removal pulses (Cycle B1, see EN ISO 11140-4) or purely super atmospheric pulsing cycles employing 7 to 11 pulses. They found that the sub atmospheric pulsing cycle was able to achieve sufficient air removal to allow steam penetration resulting in biological indicator inactivation and chemical indicator colour change whereas the super atmospheric pulsing cycles did not. In all three cycles the BDT textile pack indicated adequate air removal and steam penetration and this may be a qualitative indication of the mechanisms of air removal involved. In the case of load items which allow free gas flow, gravity displacement can take place due to the density differences between cold air and hot steam. In a closed ended tube very different physical mechanisms are involved which may be influenced by process variables but also orientation effects as shown by Young and recently by van Doornmalen (20 – 22 and 25).

Developing standards for HLPCDs

In the development of EN 285 (2) describing requirements for, and testing of, large steam sterilizers, CEN TC 102 working group 2 and 3 described a number of PCDs designed to challenge various aspects of the processing cycle. Thus the BDT and the small load thermometric test were included to challenge air removal and steam penetration and the performance of the optional air detector system was linked to these fundamental tests of process efficacy. Other PCDs were also included to challenge the capability of the process to sterilize and dry challenging load items including a small and full load of textiles and a heavy metal load representing, for example, an orthopaedic implant instrument set.

In addition the early versions of EN 285 (2006) also included a test for air removal and steam penetration into a tubular PCD (microbiological test, rubber load), thought to have derived from a French proposal, consisting of a red rubber tube, 1500 mm long, with an external diameter of 5 mm and an internal diameter of 3 mm. The inactivation of a biological indicator compliant with EN ISO 11138-1 and 3 (15) was used to indicate the adequacy of air removal and steam penetration and processing time and temperature. Three biological indicators were placed into each PCD such that one was located in the centre of the tube ie 750 mm from an open end. The other two were positioned 200 mm in from each open end. In 2004 it was proposed to replace the tubular rubber load test in EN 285 with the HLPCD described in EN 13060 and EN 867-5 (16). This proposal resulted in an inter-laboratory trial to demonstrate the relative sensitivity of the HLPCD with that of the tubular rubber PCD and a number of other tubular

devices. This work resulted in the adoption of the HLPCD as a replacement for the tubular rubber PCD in a subsequent revision of EN 285.

The results of the inter-laboratory tests have been communicated privately (17). In summary tests were carried out in large steam sterilizers using relatively "fast" processes ie those employing pressure transition rates on air removal and steam injection pulses of > 800 mB/min. Tests were carried out using the three cycles described in EN ISO 11140-4 (18, then known as EN 867-4). The Bowie and Dick Test was used as a reference by which to assign Pass or Fail criteria and the other PCDs were then judged against this. Variable results were obtained. However the rubber load test proved to be extremely insensitive to residual air yielding pass results in the majority of test conditions (compared to the BDT) and this led to its replacement in EN 285. The remaining PCDs gave a confused mix of Pass and Fail results. When compared to the BDT the HLPCD did not give directly comparable results in that in some cycles, fails were indicated which should have been passes and in others, passes were indicated which should have given fails.

In the late 1990s the European Standards Organisation, CEN, commissioned a work item to develop a standard for small steam sterilizers which was eventually published as EN 13060 (12). Along with a miniature version of the BDT, the committee developing this document also decided to adopt a tubular PCD based on the design described in DIN standard 58948, part 13 (13). It is unclear whether or not any evidence was provided to support the adoption of the HLPCD for use in small steam sterilizers. In conjunction with the work undertaken by the small steam sterilizer committee, technical committee 102 working group 7 was asked to develop a chemical indicator system for use in the textile and HLPCD. This work resulted in the publication of EN 867-5 (11) which, despite its age, is current today. The tubular HLPCD described in EN 867-5 is the same as that described in DIN 58948, with the exception that the free capsule volume is specified as being not more that 6% (ca 0.282 ml) of the total volume of the tube and capsule when the indicator is present (see table 1).

Table 1: Specification for the hollow load process challenge device (HLPCD) described in EN 867-5

Material of Construction	Polytetrafluoroethylene (PTFE)
Length	1500 ± 15 mm
Wall Thickness	0.5 ± 0.025 mm
Internal Diameter (ID)	2.0 ± 0.1 mm
Capsule Mass	10 ± 0.1g
Free Capsule Volume	6 ± 1% of total internal volume minus (capsule volume minus the volume occupied by the indicator system)

The rationale for the adoption of the HLPCD by CEN TC 102 in EN 13060 appears to be unclear. Its further adoption by EN 285 as a replacement for the rubber load test has a rationale but it must be noted the evidence relates to cycles which employ relatively fast pressure transition rates. It should be noted that, in the modern era, the engineering community are designing sterilizers which economise on vacuum and steam generation plant. This results in the delivery of processing cycles which utilise slower evacuation and steam admission pressure change rates. In adopting the HLPCD, EN 285 prescribes its use as a type test to ensure cycle characteristic included attributes (ie sub atmospheric stages, 24) which would remove air from tubular devices (and hence it is assumed, lumened medical devices). Since this time, custom and practice appears to have arisen whereby the HLPCD is used as a batch monitoring device. There is limited evidence to support this use (27, 31).

EN 867-5 is a standard for chemical indicators and PCDs for use in small steam sterilizers. The standard has two elements. The first is a simple definition of the physical attributes of the HLPCD along with the porous challenge pack. The second is the test methods which should be used to show capability of the HLPCD for detecting process failures. These methods, and in particular the test cycles, bear no relationship to the operating cycles typically found in large steam sterilizers, nor is there any requirement to establish performance in full loads nor the relationship with real medical devices. Similarly EN 285 replaced the rubber load test with the EN 867-5 HLPCD as a type test intended to show some capability to remove air and introduce steam into a lumened device. Again the test is carried out in an empty chamber and there is no requirement to establish a relationship between the performance of the HLPCD and full loads or real instruments. EN ISO 11140-4 is a standard for demonstrating that a commercially produced Bowie and Dick Test is equivalent to the standard BDT textile pack (18). Again no mention is made of performance in full loads or equivalence to real devices. The only standard which discusses equivalency testing between a PCD and a medical device is DIN 58921(37). The standard, which describes a test method for showing equivalence between a medical device and a medical device simulator, employs a single test cycle using sub atmospheric pulsing and a single failure mode, inadequate vacuum. Comparison with EN ISO 11140-4, which utilises three test cycles and three failure modes, indicates the inadequacy of the DIN standard claims of conformance which could very easily lead users to a false sense of security.

More recent developments influencing HLPCDs

Borchers and Mielke (26) examined air removal and steam penetration into tubular devices using a subatmospheric test cycle employing different numbers of pulses between 100 and 1000 mB. Biological indicators were used to assess presence of steam. Tubing made from silicone rubber proved easy to sterilize probably due to a combination of air removal and steam penetration down the lumen but more importantly moisture permeation through the tube walls. PTFE tubing (2 mm ID) proved more resistant with longer lengths

being most difficult to sterilize (250 to 1500 mm). The effect of wall thickness (0.25 to 2 mm with 1 and 2 mm ID) appeared to have a complex effect. When using two pulses very little inactivation of the BI took place (spore log reduction) indicating presence of residual air at the closed end of the tube. However when 6 pulses were used the spore log reduction taking place in different wall thicknesses (with constant length and internal diameter; 1 mm ID, 1000 mm length) was 0.25 > 2.0 > 0.5 > 1 mm. It should be noted that there was considerable variability in some of the data obtained as judged by the error bars included in the figures but no statistical evaluation was used to identify the significance of differences. The effect of tube ID was also complex with log reduction in the BI in the order 1 = 4 > 2 >> 6 = 8 (mm ID) for a tube of 1000 mm length and 0.5 mm wall thickness. These results are similar to those found by Göman and Kaiser (23) i.e. that large diameter tubes are more difficult to sterilize than small diameter tubes. Stainless steel appeared to be less resistant than PTFE although again variation was high and no statistical analysis carried out to establish significance. The authors concluded that the most difficult to sterilize tube was 1500 mm long, 8 mm ID and a wall thickness of 0.5 mm.

In a complex multi-faceted field study, de-Bruijn and van Drongelen (27) examined the performance of a number of sterilizers in 20 hospitals within the Netherlands. By virtue of the study design they also highlighted some interesting characteristics of the PCDs used to assess sterilizer performance. Four tubular helical devices of commercial origin and claiming to be compliant (in fact none where) with EN 867-5 were used. Tests were carried out in empty chamber, partial and full load conditions. The helix devices were used unwrapped, wrapped in non woven material, with and without additional metal mass or enclosed within sterilization pouches. The study highlighted problems with both the helix devices used and the performance of the sterilizers tested. General conclusions were made. Of the four types of sterilization cycle used the most effective at yielding a Pass (positive) result from all helices was that which employed sub atmospheric pulses similar to that described in EN ISO 11140-4 (see B1 in EN ISO 11140-4). Whilst this cycle utilised three sub atmospheric pulses employing low vacuum the remaining cycles used only a small number of deep evacuations. This work suggests processes employing deep vacuum will be more efficient at removing air from lumened devices and confirms the work of Göman et al (24) (unfortunately no mention was made of the rate of pressure change during the processes). A greater number of pass results was obtained from tests carried out in an empty chamber with the helix unwrapped. The number of pass results significantly fell when the helices were placed inside a DIN instrument basket and double wrapped in a non woven sterilization wrap. This is a significant finding since it suggests the sensitivity of the helix devices was increased by including an additional free volume estimated by this author to be between 10 and 20 litres surrounded by a semi-permeable barrier system which would restrict gas flow. There was also an increase in sensitivity by double wrapping in sterilization pouches which again would create a barrier to gas flow but would not create the same free space as was created in the double wrapped basket. From a practitioners perspective the most surprising outcome of the tests was the number of departments operating sterilizers which failed to achieve adequate air removal and steam penetration despite the fact that the sterilizers were passing the daily BDT. Unfortunately the authors failed to identify the type of BDT in use and as has been shown by Kirk (28) the sensitivity of commercially produced BDTs varies enormously despite claims of compliance to EN ISO 11140-4 (18).

Manhart (29) discussed the ideal attributes of a PCD suggesting that a good design would have a tubular feature surrounded by material of high thermal mass and low thermal conductivity. This would ensure steam would enter the tube and condense, releasing any admixed NCG into the tube volume which in turn would prevent steam penetration. This is in contrast to the HLPCD described in EN 867-5 which has low thermal mass and capacity (other than the capsule).

Kaiser et al (30) conducted a series of experiments and determined a relationship which would predict the penetration of steam into tubular devices based on the vacuum and steam pressurisation level achieved and the number of pulses employed for a subatmospheric pulsing cycle having relatively fast pressure change rates (ca 1500 mB/min). As in previous studies the results indicated that a tube with a wider bore (5 mm) was more difficult to penetrate than a tube with a narrower bore (2 mm) for a given length of tubing (1500 and 3000 mm).

Haas et al (31) examined the penetration into a number of PCDs one of which was a "hose" type PCD consisting of a 4000 mm hose open at each end with a central capsule containing a BI. The hose ID was 1 mm. An insert was introduced into the coupling chamber to reduce free volume although by what proportion was not mentioned. Tests were carried out in both a resistometer (presumably employing fast pressure change rates) and a large sterilizer (presumably a slower cycle) using a cycle consisting of four subatmospheric pulses to 120 mB followed by steam injection to between 1200 and 1500 mB. In the resistometer studies even 15 minutes exposure at 134 °C failed to completely inactivate BIs (42 out of 45 showed growth). Similar results were obtained in the large sterilizer with 3 mins exposure. Increasing exposure times were needed to effect inactivation of the BI.

Kremmel et al (32) discussed the value of PCDs, when used in conjunction with BI and CI indicators for monitoring every load advising that this was required and documented in local (Robert Koch Institute guidance) and International standards (EN 285, EN ISO 17665). It was noted that the performance of the HLPCD in EN 867-5 was highly dependent on the sterilization cycle in which it was used and that users should establish the sensitivity of the PCD in their own organisations rather than assume the helix was universally applicable. Experiments were described in which a number of PCDs were subjected to test conditions which included an acceptable cycle (sub atmospheric pulsing cycle with 4 pulses between 50 and 970 mB (cycle B1, EN ISO 11140-4) and those which had been adulterated so as to create inadequate air removal and/or time at temperature. Fourteen PCDs were tested some of commercial origin. A textile pack was used as a reference device. All devices showed an acceptable result when exposed to a

"Pass cycle" (4 × 50 – 970 mB, 134 °C for 5 minutes). When exposed to a variety of fail conditions the authors concluded that 40% failed to detect even a single fault and that only 27% of the faults were clearly detectable. The authors also concluded that the simple helix device according to EN 867-5 was only capable of detecting the most serious of faults, if any at all.

In an elegant study utilising thermometric methods to assess air removal and steam penetration into the HLPCD described in EN 876-5, Hermsen and Schumacher (33) demonstrated that when using relatively fast pressure transition rates (> 700mB/min evacuation and 2500mB/min steam entry) in a large sterilizer (ca 300 l) employing a sub atmospheric cycle using 4 pulses of 50 – 970 mB resulted in a measurable temperature difference between the chamber and the interior of the capsule (ca 3 °C). This was assumed to be a result of residual air in the capsule chamber, evidence from chemical indicators supporting this conclusion. Extending the number of pulses firstly to 8 then 16 resulted in a diminution in the temperature difference until it was virtually eliminated (16 pulses).

In a well referenced discussion Esen et al (34) warn the reader that there is considerable contradictory evidence surrounding the performance of, particularly, the simple hollow PCDs described in standards (EN 285, EN 13060 and EN 867-5). In a later publication, Esen et al (19) described a study to examine the performance of the HLPCD described in EN 867-5. Helix devices were mounted on a carrier so as to retain separation between each coil of the helix and to ensure the capsule was mounted above the tube opening to allow free drainage of any condensate forming. The devices were then subjected to a test cycle in an 11l small chambered vessel and 342 l large chambered vessel, employing four sub atmospheric pulses (see EN ISO 11140-4 B1) and a pressure change rate of 400 mB/min (relatively slow). For comparison, tests were also carried out using a standard BDT textile pack with temperature sensors. The results indicated that in order to get consistent pass results in the textile pack a vacuum set point of 50 mB was required. Consistent fails were attained (i.e. greater than a 2 °C depression in the textile pack) when the vacuum set point was adjusted to ca 130 mB. For the HLPCD consistent passes, i.e. a full colour change on the CI were attained even with a vacuum set point of 300 and 320 mB for the large and small chambers respectively. With the vacuum set point adjusted to 350 mB 30% of CIs showed pass in the small chamber and 53% in the large chamber. Only when the vacuum set point was adjusted to 400 mB was 100% fail reliably indicated. This represents a residual air level of 8.7 l of air in the large chamber and 0.28 l in the small chamber.

An extension of this work was also carried out (35, private communication) in which the capsule was removed from the HLPCD and BIs on wire carriers sealed into the tube. The wires were contaminated with 10^6 *Geobacillus stearothermophilus* spores having a D_{121} value of at least 1.5 minutes. Whilst a high degree of variability was noted in replicate tests, the results generally indicated a similar pattern ie that the BIs survived in cycles employing a vacuum set point up to approximately 300 mB and only when a vacuum set point of 400 mB was employed did reliable BI inactivation take place. These results indicate that in slow cycles (< 400 mB/min) only moderate vacuum levels are required in order to create conditions at the closed end of the HLPCD tube which cause CI colour change and BI inactivation (adequate moisture penetration). This suggests that in slow cycles the HLPCD is significantly less sensitive than the BDT which would fail at ca 130 mB vacuum set points.

Van Doornmalen et al (36) developed a model and employed software to predict the removal of air and penetration of steam into a tube 540 mm long and 3 mm diameter with a wall thickness of 0.5 mm. An infra red sensor was located at the closed end of the tube in order to monitor permeation of moisture. The tube was mounted vertically in a sterilizer chamber and subjected to a sub atmospheric pulsing sterilization cycle employing 3 pulses between 50 and 1000 mB or 4 pulses between 100 to 1000 mB at a pressure change rate of ca 540 mB/min (relatively slow). Results indicated incomplete attainment of saturated steam at the beginning of the sterilization phase with a gradual increase in the moisture content of the medium trapped at the closed end of the tube (presumably air). It would be invaluable to ascertain the microbiocidal properties of this medium by examining the inactivation of BIs enclosed within since this describes a similar situation to that observed by Young et al (20–22). Whilst this report does not directly relate to air removal and steam penetration into the HLPCD in EN 867-5 it does present a theoretical model which suggests time is required to enable diffusion to take place thereby enabling moisture to penetrate the lumen. Cycles employing relatively slow pressure change rates will therefore enhance the diffusive elements of a given process. The paper also describes an extremely valuable means of measuring the moisture content of enclosed spaces within tubular devices. This work has been extended to model the steam penetration into lumen devices to which are attached capsule enclosures (40).

Discussion

With regard to the apparent acceptance of the HLPCD in EN 867-5 into custom and practice for batch monitoring the literature suggests this may be misleading. With the exception of two publications (27, 31), the majority of evidence has been ascertained from tests carried out in empty chamber conditions. The evidence firstly suggests that for a given length of tube a wider diameter will be more challenging than a narrow diameter. The evidence also suggests that penetration into tubes is highly dependent on the rate of pressure change during the air removal pulses and that some pulses must enter the sub atmospheric pressure range, the deeper the vacuum level used, the better the outcome. In fast cycles it appears more difficult to remove air from tubular devices than in slow cycles. The van Doornmalen model (36) identifies this factor and suggests that process changes which allow time for diffusion to take place and enhance moisture penetration should be considered (e.g. adding a dwell time at the base or top of the pulses to enhance diffusion) (van Doornmalen personal communication). The rate of pressure change on steam penetration efficacy is a factor which requires further examination and which is largely ignored by the standards for steam sterilization. Similarly devices with specific design attributes which have high thermal mass to allow considerable concentration of residual air in steam and low thermal conductivity such that the heating is directed

towards the internal surfaces of the tube are likely to exhibit greater sensitivity than simple tubular devices (38). The results reported in previous work clearly indicate a significant lack of sensitivity towards process failures as measured by chemical and biological indicators (19, 35). The results presented in part two of this publication also show a severe lack of sensitivity towards process failures in commercially supplied simple helix type devices but a greater sensitivity in devices which have some of the design attributes discussed above (29). Finally it is widely asserted that the Bowie and Dick test has little relevance to the types of loads processed in a modern decontamination department (27), particularly with regard to devices having complex shapes and lumens. Whilst in terms of physical appearance this may be the case, the evidence of performance is the very opposite. In general, data demonstrates that the BDT has similar performance attributes to the HLPCD described in EN 867-5 in relatively fast cycles (pressure change rates ≥ 800 mB/min) (17) but far better capability of fault detection in relatively slow cycles (pressure change rates < 400mB/min) (19) however, this is dependent on the nature of the processing cycle (23). In conducting an independent daily BDT the sterilizer user is establishing and confirming a reference level of performance which is based on scientific evidence and a long history of practical implementation. Literature citations to the contrary often fail to recognise that not all commercially produced BDTs perform at an acceptable level of sensitivity (28). Users should be extremely cautious when selecting an appropriate PCD for use in their own departments and where possible evaluation should be carried out before selections are made. Some PCDs 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.

As a matter of urgency the standardisation bodies must begin to pay attention to the development of a standard for the specification of batch control PCDs in the same way that they have for product families (ISO 17665-3, 39) taking into account the many design attributes encountered in modern medical devices and equipment and the characteristics of modern steam sterilization processes. The recently published DIN 58921 standard (37) covering this subject is wholly inadequate in this respect due to the limited equivalency testing prescribed. Further work is also required on defining a hollow PCD for the evaluation of small sterilizer using a more fundamental approach in which the literature and data from the inter-laboratory trials are taken into account leading to a design which:

1. Considers a wider tube diameter (Kaiser et al, 23)
2. Dispenses with the capsule (this is not needed in a reference device).
3. Considers the inclusion of mass of defined thermal mass and conductivity around the lumen (Manhart, 29, Kuepper and Kirk, 38).
4. Considers a physical method of detection which is independent of one particular manufacturers CI or BI product (Hermsen and Schumacher, 33).

Clearly there is a significant need for an International Standard which describes how a HLPCD can be developed and tested against real medical devices in a range of sterilization processes representing current state of the art in full load conditions. ■

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