

Keywords

- steam sterilisation process
- hollow device A
- Bowie-Dick test pack
- air removal

Air Removal from Porous and Hollow Goods using Different Steam Sterilisation Processes

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The difference between the air-removal characteristics from a porous and a hollow device was investigated in steam sterilisation processes using vacuum and trans-atmospheric air-removal procedures. The standard Bowie-Dick test pack based on European Standard EN 285 was selected as a reference porous load and a process challenge device as described in EN 867-5 was selected as a hollow device. Air-removal measurements were carried out according to the requirements of European standard EN 867-4. To demonstrate correct air removal and hence successful steam penetration, thermoelectrical measurements as well as chemical and biological indicators were used.

Both the porous and the hollow device demonstrated successful air removal in the standard vacuum air-removal procedure (see figure 1).

Tests conducted under otherwise similar conditions in two trans-atmospheric air-removal cycles (figure 2 and 3) showed adequate steam penetration of the porous laundry pack, but air was not successfully removed from the two hollow devices (process challenge devices – PCDs) under these conditions, and growth of biological indicators was seen after sterilisation in all hollow PCDs.

In standard EN 285 the porous test pack is currently the only mandatory test to evaluate the sterilisation process in respect of the quality of air removal. However, the experiments carried out clearly demonstrate that sterilisation processes that successfully remove air from porous loads show quite different air-removal characteristics from hollow devices. Because hollow devices of the most diverse designs meanwhile account for an important portion of the sterile goods used in the healthcare service and a steriliser must, pursuant to EN 285, furnish proof that it meets minimal performance requirements in order to quali-

fy for use in the healthcare sector, its performance capabilities must be defined also in respect of hollow instruments.

To assure successful sterilisation also of these hollow devices and instruments such as tubes and minimally invasive surgical (MIS) instruments etc. in sterilisers as per EN 285, suitable reference test systems for hollow devices must be used for type testing, validation and routine monitoring of steam sterilisation processes.

Introduction

The requirements for a successful steam sterilisation process are:

(a) Sufficient kill ability of the steam sterilisation process

Based on general experience, as enshrined in the European and US pharmacopoeiae, it is established that sterilisation is assured at surfaces exposed for at least 15 min at 121 °C to steam resulting in water condensation, provided that the items being sterilised have undergone appropriate pre-cleaning (low bioburden).

(b) Steam penetration

However, successful steam penetration is assured only if the condensing steam reaches all external and internal surfaces to be sterilised. Steam penetration may be prevented by air pockets, made of inert gas, so that the steam does not reach all surfaces to be sterilised.

The formation of inert gas air pockets during steam sterilisation processes depends essentially on the efficiency of the air-removal process, on the steam quality (amount of non-condensable gases in the steam) and on any leaks in the steriliser.

Furthermore, steam penetration depends on the structure of the goods be-

ing sterilised. Non-wrapped solid instruments, wrapped solid instruments, porous instruments and hollow devices show a completely different behaviour in steam sterilisation processes with different methods of air removal (1), e.g.:

(b₁) Gravity displacement

In those places where gas flow is possible, the air is displaced by steam. In areas where no convective gas flow is possible, no air removal takes place.

(b₂) Differential-pressure processes

Differential-pressure processes can be roughly classified into sub-atmospheric and super-atmospheric air-removal processes. This form of differentiation does not make much sense because once the steriliser door is closed, the outside pressure does not play any role for the process itself. Sub-atmospheric air-removal cycles require vacuum pumps, while super-atmospheric cycles produce differential pressure without a pump by using only the steam generator. This is the only reason for differentiating between sub- and super-atmospheric air-removal cycles. All combinations of both versions are used in health care. Air removal becomes more efficient, the higher the pressure difference and the more pulses used. This is characterised by the dilution factor which is a good yardstick for determining air removal in porous loads (2).

Bowie, Kelsey and Thompson (3) noticed in the early sixties that steam penetration depends on successful air re-

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removal and they developed a corresponding test pack, which constitutes the basis for the standard test pack according to EN 285. Today, this porous test pack is used as a reference to determine the efficiency of steam sterilisation processes and was used over a long period of time as a reference for sterilisation of goods under worst-case sterilisation conditions. Standard EN 867-4 describes how alternative tests must be tested in order to be deemed comparable with the standard Bowie-Dick test pack.

The increased usage of hollow instruments such as catheters, minimally invasive surgical (MIS) instruments etc. in sterilisation raises the question as to whether these complex instruments can be safely sterilised. Very little information is available on the penetration of steam in hollow devices. Young (4) investigated air removal from hollow devices in steam-flushed tubes containing a dead-ended T. Kaiser and Gömann (5) investigated air removal from different hollow devices with changing tube dimensions under sub-atmospheric air-removal conditions. The results have shown that for a given material the product of length \times diameter is a comparable value for the steam penetration. In a publication by Kaiser (6) 10 different process challenge devices (PCDs) were presented with different lengths and tube diameters, which can be used to roughly estimate the efficiency of different steam sterilisation processes. Peters, Schwabke, Simon and Bönisch (7) demonstrated that the dilution factor of a sterilisation process is a good value to determine air removal from porous loads. However, the dilution factor cannot be applied to hollow devices. On the whole very little has been published so far on steam penetration in hollow devices.

Objectives of the Investigations

The objective of our investigations was to compare the air removal characteristics from porous loads and hollow devices. The standard Bowie-Dick test pack according to EN 285 was selected as being representative of porous loads and the process challenge device described in EN 867-5 as being representative of hollow devices. Under otherwise similar test conditions, these two representatives were

tested in a sub-atmospheric air-removal cycle as per EN 867-4 (see fig. 1) and in two super-atmospheric air-removal cycles as per EN 867-5 (see figs. 2 and 3). The results of these two tests were then compared.

Material and Methods

Test loads

The standard test pack according to EN 285 was used to represent porous loads. Before using them, the sheets were conditioned at a relative humidity of $45\% \pm 10\%$ and a room temperature of $22^\circ\text{C} \pm 1^\circ\text{C}$ and after folding them, they were weighed. The folded packs weighed between 6.96 and 7.07 kg. Manteled thermocouples with a 0.5 mm diameter were placed inside the laundry pack as per the requirements of EN 867-4 in order to make provision for thermoelectrical measurements during the sterilisation process.

EN 867-5 contains a definition of a hollow process challenge device. It consists of a 10 g PTFE capsule connected to a PTFE tube with a length of 1.5 m and with a 2 mm inner and a 3 mm outer diameter. European Standard EN 285 describes a hollow device for rubber loads, consisting of a 1.5 m long rubber tube with a 3 mm inner diameter and a central glass tube that is inoculated with the biological indicator suspension. The penetration length to the centre is equal to the half of the total length used here.

The length \times diameter value (5) for the PCD as per EN 867-5 is $150\text{ cm} \times 0.2\text{ cm} = 30\text{ cm}^2$ and the corresponding value for the rubber PCD as per EN 285 is $0.75\text{ cm (half length)} \times 0.3\text{ cm} = 22.5\text{ cm}^2$.

We therefore decided to use for our investigations the PCD according to EN 867-5 because it has more difficult air-removal characteristics. The process challenge device used (manufactured by gke-mbH, Waldems-Esch, Germany) consists of a 10 g PTFE capsule connected to a PTFE tube with a length of 1.5 m and with a 2 mm inner and 3 mm outer diameter. In conformance with European Standard EN 867-5 this process challenge device is designated in the following text as PCD Hollow A.

In addition a second hollow PCD, derived from PCD Hollow A was used (gke-mbH). This PCD, designated as PCD-B

below, consists of a chromium-plated brass capsule, a PTFE holder for accommodating the indicator, a synthetic closure as well as a PTFE tube similar to that of PCD Hollow A.

The rubber tube model described in EN 285 was not used because the dimensions of this challenge device suggest that it is easier to remove air from it than from the challenge device in EN 867-5.

Conditioning of the test loads

Prior to each sterilisation cycle the laundry packs were taken apart and re-conditioned according to the conditions described above for at least 24 h.

Before using them, the hollow PCDs were flushed with hot air at 70°C for 1 hour and then cooled to room temperature, in order to rule out residual condensate from previous tests. They were then loaded with biological or chemical indicators.

Air-removal test method

The porous load was tested thermoelectrically according to the requirements of EN 867-4. The measurement principle is based on simultaneous measurement of the temperature in the centre of the test pack and outside it. If air pockets are formed during the heat-up phase, no steam will condense within this air bubble. This thus prolongs the heating-up phase at this location and a temperature difference can be detected between the centre of the bubble and the chamber.

While under specific circumstances temperature differences may also be detected in hollow devices, they do not permit conclusions to be drawn due to the fact that, compared with the tiny inner air volumes, relatively large surfaces are present which are heated up so quickly from the outside that only small temperature differences occur which do not allow correct and reproducible interpretations. Therefore the air-removal test in the hollow PCDs was carried out using chemical and biological indicators placed at the dead-end of the capsule.

Test Apparatus

A specifically designed test steriliser (Lautenschläger, Cologne, Germany), developed to conform to the requirements of EN 867-4, was used. The steam genera-

tor was fed with demineralised water with a conductivity below 0.5 mS/cm and a pH value of 6.9.

The pressure gauge of the steriliser was calibrated before and after measurements with two calibrated pressure gauges with a range of 0–400 mbar (precision class 1) and 0–4,000 mbar (precision class 0.2), respectively. The temperature measurements were carried out with nickel-chromium sheathed thermocouples of precision class 1 as per IEC 584 with a diameter of 0.5 mm. The thermocouples were adjusted and re-calibrated in a metal-bloc calibrator (Isotech, Fulda, Germany) with an accuracy of 0.03 °C before and after each test day. All data were recorded in the analogous mode with a 16-channel recorder (Eurotherm Chessel, Limburg, Germany) and digitalised.

To measure the temperature in the test pack (porous load), 7 sensors were placed in the test pack in accordance with the requirements of EN 867-4. To measure the chamber reference temperature, a thermocouple was placed 2 cm inside the chamber condensate drain such that it did not touch the wall and that draining condensate could not falsify the measurements. To measure the air removal from the hollow PCDs, biological and chemical indicators (gke-mbH) were used. Paper strips inoculated with *B. stearothermophilus* (batch: 3162843) with a population of 1.4×10^6 cfu/strip and a $D_{121^\circ\text{C}}$ value of 2.3 min (F_{BIO} value of 14.1 min) were used as biological indicators. For the measurements with a sterilisation temperature of 121 °C, biological indicators with a lower resistance and a population of 1.0×10^6 cfu/strip and a $D_{121^\circ\text{C}}$ value of 2.0 min and an F_{BIO} value of 12.0 min were used (batch: 3163831). The biological indicators were incubated in TSB medium according to DAB (German Pharmacopoeia) 10 (Heipha, Heidelberg, Germany).

The chemical indicators used (batch: 100564) are specially prepared for use in hollow PCDs and show a colour change from yellow to black at total steam penetration. If air is present, the yellow colour remains unchanged or changes to brown if exposed to hot air over a long period of time. The temperature-colour change window of the indicator is between 10 and 13 minutes at 121 °C and between 1.5 and 2.5 minutes at 134 °C.

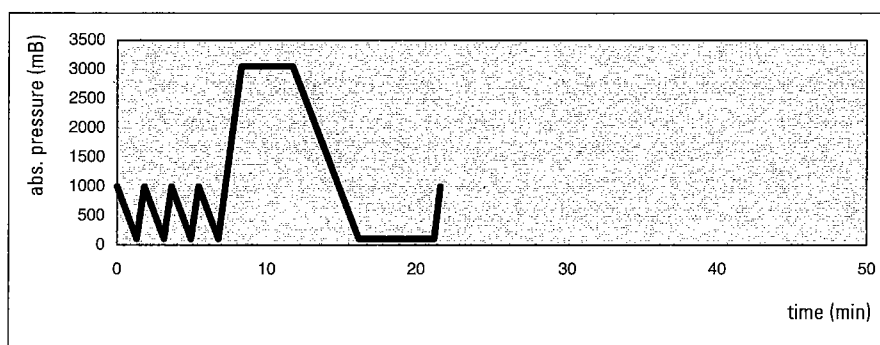


Fig. 1 Pressure minima and maxima used for the sub-atmospheric air-removal cycle according to EN 867-4, B.1

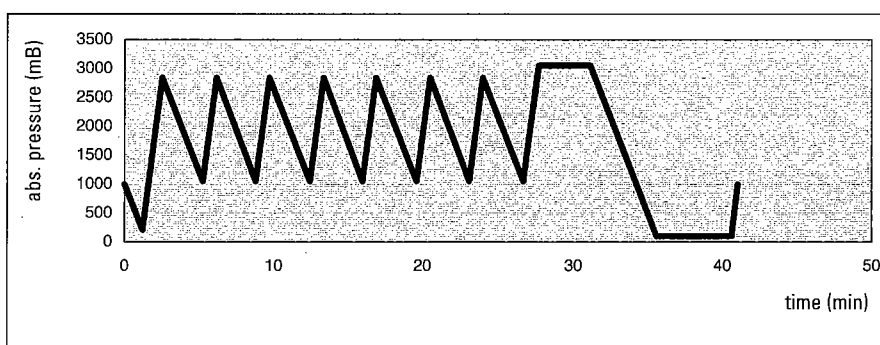


Fig. 2 Pressure minima and maxima used for the trans-atmospheric air-removal cycle according to EN 867-5, B.3 with a sterilisation temperature of 134 °C

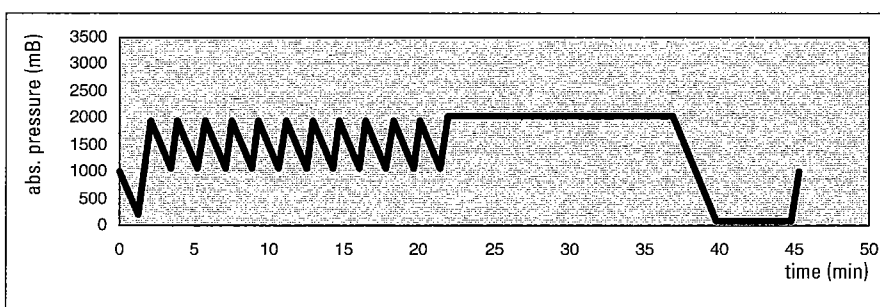


Fig. 3 Pressure minima and maxima used for the trans-atmospheric air-removal cycle similar to those of EN 867-5, B.3, but with a sterilisation temperature of 121 °C

Test cycles

Sub-atmospheric test cycle

The sub-atmospheric air-removal cycle presented in B.1 of EN 867-4 was used (figure 1). For air removal the absolute pressure points 1000, 50, 970, 50, 970, 50, 970 and 50 mbar were programmed. The plateau time was 3.5 minutes at 134 °C.

Trans-atmospheric test cycles

EN 867-4 does not present a purely super-atmospheric air-removal method. Therefore the trans-atmospheric test cycle de-

fined in EN 867-5, B.3 was used (figure 2). The pressure points 1000, 200 and $7 \times (2840, 1050)$ mbar were used. The plateau time was again 3.5 minutes at 134 °C.

In addition a method for sterilisation at 121 °C was derived from the trans-atmospheric air-removal cycle presented above (figure 3). To this effect, the maximum pressure values were reduced during the air-removal phase from 2840 to 1950 mbar, in order to avoid temperatures above 121 °C during air removal. Furthermore, the number of air-removal steps had to be increased so as to ensure suc-

cessful air removal from the standard test pack. This resulted in a cycle that used the pressure points 1000, 200 and 11 × (1950, 1050) mbar. The plateau time was 15 minutes at 121 °C.

To dry the test loads, the chamber was evacuated for 2 minutes for the test packs and for 5 minutes for the hollow PCDs to a pressure of 50 mbar or below.

For all tests the steriliser was set such that the limit values specified in EN 867-4, B.4 for the differential-pressure velocity and the temperature-time integral during the integrated-come-up exposures (ICE) were complied with. For the sub-atmospheric air-removal process the average differential-pressure velocity and the average ICE value were 2155 mbar/min and 1485 Ks, respectively. For the trans-atmospheric cycle at 134 °C these values were 2146 mbar/min and 1473 Ks, respectively, and 1946 mbar/min and 542 Ks, respectively, at 121 °C.

Test method

The three air-removal methods described above (figures 1 – 3) were used. For the measurements the air-removal characteristics of all three test loads described were checked in two consecutive steps according to EN 867-4:

Confirmation of Pass (Fault-Free) Conditions of the Bowie-Dick Test Pack in the Test Cycle

Whether fault-free air removal from the standard test pack was effected during the test cycles was determined as per Chapter F.2.3 "Pass Conditions". The reproducible measurements of the "pass

conditions" in this publication made it possible to reduce the number of measurements required from in each case ten to three measurements on two consecutive days. Measurements were based on thermoelectric monitoring of the test pack.

Comparison of the Pass Conditions of the Bowie-Dick Test Pack and of the Hollow PCDs in the Test Cycle

The air-removal characteristics of the standard test pack were compared with those of the hollow device loads in accordance with Annex E of EN 867-4 "Method for determining the equivalence of the Bowie-Dick test and of the alternative indicator".

To this effect, the results of the standard test pack and those of the "alternative indicator" were compared in 13 test sterilisation cycles (here the PCD Hollow A and PCD-B with biological or chemical indicators). For measurements with the trans-atmospheric air-removal method at 121 °C, measurements were reduced to three per test load.

Results

In the sterilisation processes checked with the standard test pack, a temperature difference of 0.0 K to 0.8 K (average 0.3 K) was measured at the time at which the sterilisation temperature was reached. Since air removal from the test pack is considered successful up to a temperature difference of 1 °C, it follows that air can be successfully removed from the porous load "standard test pack" both with the

sub-atmospheric air-removal method as per EN 867-4 (134 °C) and with the trans-atmospheric air-removal method as per EN 867-5 (134 °C and 121 °C), thus assuring reliable sterilisation. Air was successfully removed from the hollow devices "PCD Hollow A" and "PCD-B" based on standard EN 867-5 only with the sub-atmospheric air-removal method described above (fig.1).

In the trans-atmospheric air-removal methods (figs. 2 and 3) the inserted indicators demonstrated a significant steam penetration problem in both hollow devices. The chemical indicator did not change colour from yellow to black and all biological indicators showed growth after incubation. This points to incomplete steam penetration and thus to inadequate sterilisation of the hollow PCDs. The results are listed in table 1.

Interpretation of results

The results (table 1) demonstrate that, using sub-atmospheric air-removal cycles, air can be successfully removed from porous as well as hollow devices with these dimensions. The same information is provided by thermoelectrical measurements as well as by biological and chemical indicators. In both trans-atmospheric air-removal cycles tested, air was successfully removed from the laundry pack (porous load) but not from the two hollow PCDs. This result demonstrates that porous test systems such as the standard (Bowie-Dick) test pack do not permit any

| Test load | Test method | Results | | |
|--|-----------------------------------|--|--|--|
| | | Sub-atmospheric air removal cycle according to EN 867-4 at 134 °C (fig. 1) | Trans-atmospheric air removal cycle according to EN 867-5 at 134 °C (fig. 2) | Trans-atmospheric air removal cycle according to EN 867-5 at 121 °C (fig. 3) |
| Standard test pack (Bowie-Dick test) according to EN 867-4 | Thermo-electrical | No air pockets can be detected | No air pockets can be detected | No air pockets can be detected |
| Hollow PCD according to EN 867-5 ("PCD Hollow A") | Biological indicator | No growth | Growth | Growth |
| | Chemical indicator, colour change | Black | Yellow | Yellow |
| Hollow PCD according to EN 867-5 ("PCD B") | Biological indicator | No growth | Growth | Growth |
| | Chemical indicator, colour change | Black | Yellow | Yellow |

Table 1 Results of steam penetration in the three test loads in accordance with the air-removal method used in the sterilisation process

definite conclusion to be drawn as regards steam penetration in hollow devices in all sterilisation processes. Successful penetration of a porous load such as the Bowie-Dick simulation test pack or other porous Bowie-Dick simulation tests does not automatically guarantee that air will be successfully removed from hollow instruments under the same conditions, i.e. that these are reliably sterilised.

Conclusions

The conclusion to be drawn in respect of assessment of sterilisation processes is that steam sterilisation processes using very different types of air-removal methods require several different test devices. European draft standard prEN 13060 already takes this into account by using in addition to porous loads also hollow test loads which are defined in European Standard EN 867-5. It is important that these results should be also integrated in the older standards governing steam sterilisation and that correspon-

ding reference loads for hollow devices be introduced.

Our results demonstrate that a single representative test system such as the Bowie-Dick test pack is not sufficient to assure correct sterilisation of all the sterile items currently used in the healthcare service. Therefore different types of PCDs should be used to simulate as closely as possible all the types of instrumentation used. The approach adopted in prEN 13060, which uses different porous and hollow devices, is a step in the right direction.

Standardisation organisations should define a greater number of PCDs to simulate a wider range of instruments. These different PCDs could then be used to better define the different groups of small sterilisers listed in prEN 13060. If comparisons between PCDs and instruments are available, using appropriate tables it would be possible to predict to what extent different instrument groups would lend themselves to sterilisation in different sterilisation processes. This would facilitate validation of sterilisation.

These results can be extrapolated to other sterilisation processes using steam such as the low-temperature steam and formaldehyde (LTSF) sterilisation process.

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