Steam penetration in thin-walled channels and helix shaped Process Challenge Devices

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J.P.C.M. van Doornmalen Gomez Hoyos[1,2], K. Kopinga[1]*

Introduction: Medical instruments with narrow channels are often sterilized in steam sterilization processes. Helix shaped Process Challenge Devices (PCDs) are used to mimic steam penetration in such medical devices. Little to no literature has been found indicating to which extent these devices correctly predict the steam penetration in medical instruments. The aim of the present study is to improve the understanding of steam penetration in narrow channels and helix shaped PCDs.

Materials and Methods: Using a local steam density measurement technique based on infra-red absorption, the steam penetration during a steam sterilization process has been measured in various dead-end channels and channels with an additional volume connected to the closed end.

Results: The steam fraction at the end of the tube at the start of the sterilization phase was found to be independent on the channel diameter in the region of 0.7 to 5 mm. Such diameters are representative for most channels in medical devices used for minimally invasive surgery. An added volume at the channel end changed the steam penetration drastically.

Conclusion: The results explain the observed, sometimes counter intuitive, behaviour of the steam penetration in hollow channels reported in the literature. Moreover they indicate that the behaviour of the so-called hollow A PCD is not yet sufficiently understood to use such a device as a steam penetration test.

KEY WORDS

- sterilization
- surgical instruments
- narrow channels
- steam penetration
- decontamination

Introduction

Medical devices used for minimally invasive surgery may contain narrow channels (e.g. rigid endoscopes). The diameter of these channels is in the order of one millimetre, the length is in the order of one meter. Often these instruments are steam sterilized before use in surgery. Although the sterility of such minimally invasive instruments is of utmost importance, no conclusive information is found on the topic of steam penetration into these instruments, neither in the literature, nor from manufacturers and users of these instruments. According to standards the steam penetration capacities of a sterilizer should be tested with a steam penetration test (1). In Europe, harmonized standards (2) make steam penetration testing mandatory. Bowie and Dick developed the first steam penetration test (3) in the early 1960s. This test was further developed and minimum performance requirements are defined in standards (4–6). In the current European standard (7) for small sterilizers with Type B and specific Type S processes it is suggested that a so called "Process challenge device for hollow instrument loads (hollow load process challenge device)" can be used as steam penetration test for hollow devices (8). Often these PCDs are helix shaped and are in practice referred to as helices or helix PCDs. To one end of the helical shaped channel a measuring chamber (receptacle) is attached, in which a biological or chemical indicator can be placed. Conclusive experimental evidence supporting the functionality of these PCDs for steam penetration has to our knowledge not been reported (9–13). A helix PCD constructed based on descriptions in standards (7, 8) and containing a chemical indicator (CI) does not meet the minimum requirements defined in the ISO standards (5, 14). Apart from this, it is not clear to which extent the steam penetration in a such a PCD is representative for the penetration in channels of actual medical devices, which generally have other diameters and lengths.

To elucidate this point, experiments were performed in which the vapour density at the end of various channels was directly measured by infra-red absorption (15). The experimental set-up will be described in the Materials and Methods section. First, two channels with a length of 0.5 m and an inner diameter of 3 and 5 mm, respectively, were investigated. The results of these measurements will be presented in the first part of the Results section. Next, measurements were performed on three channels with a length of 1.5 m, with inner diameters of 3, 1.5 and 0.7 mm, respectively. During a first series of experiments, the infra-red detector, having a volume of approximately 100 μL, was attached directly to the end of the channel. During a second series of experiments, a dummy chamber with a volume of 500 μL was inserted between the end of the chan-

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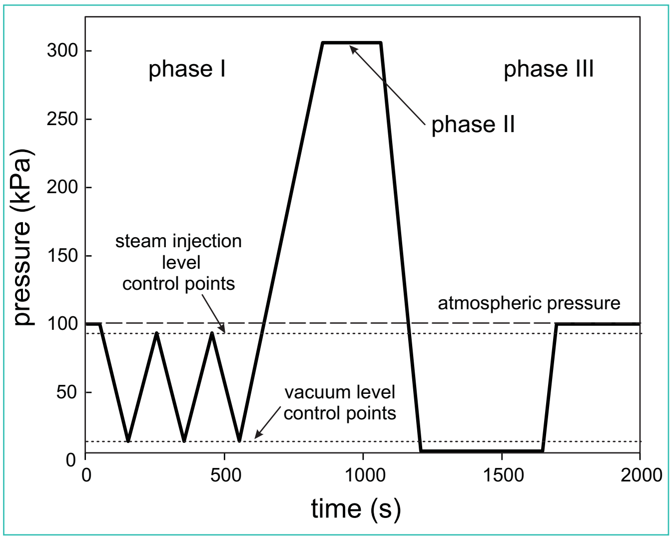

Fig. 1: Schematic pressure curve of a generic surface steam sterilization process. Phase I: replacement of air by steam; Phase II: actual sterilization phase involving a predetermined combination of temperature and pressure during a certain time; Phase III: returning the steam sterilizer to a safe mode and drying of the load.

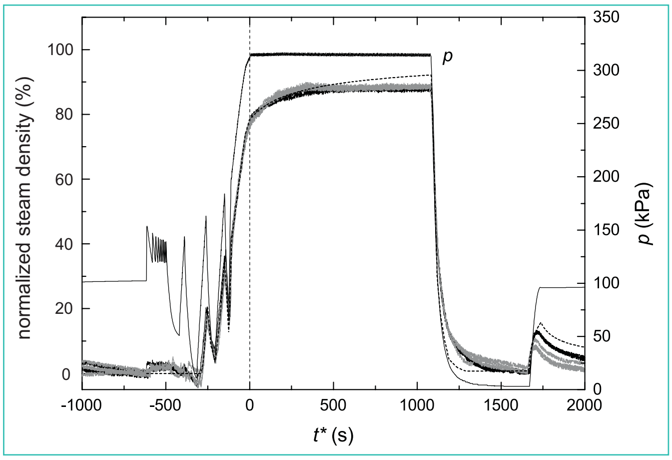

Fig. 2: Vapour density at the closed end of two different tubes with a length of 0.5 m. The three experimental data sets for a channel with a diameter of 3 mm are denoted by the gray curves, the two experimental data sets for a channel with a diameter of 5 mm by the black curves. The dashed curve represents the corresponding model prediction. The vapour density is normalized to the density of saturated steam of 134 °C. The pressure in the sterilizer chamber is depicted on the right vertical axis. The time is given relative to the start of the sterilization phase.

nel and the detector. This chamber mimics the effect of the receptacle containing a biological or chemical indicator which is present in helix PCDs defined in various standards. Intuitively, such an additional volume might act as some kind of "sink" for the air-vapour mixture, making steam penetration towards the end of the channel easier. These two series of measurements will be presented in the second part of the Results section. To be able to generalize the experimental results presented in this paper, these results were compared with predictions from a physical model (15), which was adapted to incorporate the additional volume of the receptacle. Possible consequences for the use of helical devices as PCDs will be discussed in the Discussion section.

Materials and Methods

Experimental Setup

The sterilizer used in the experiments was a Tuttnauer 2540-B. For the measurements presented here the preprogrammed air removal stage and sterilization phase of 1080 seconds (18 minutes) at 134 °C were used ("prion" program). The parameters of the air removal phase of the process were not changed, since the aim of the present study was a comparison between the steam penetration in various channels with or without an additional dummy chamber for the same process. The principle of the vapour detection by infra-red absorption as well as the corresponding set-up have been described already in literature (15). The detector chamber to which the optical fibres for the vapour absorption measurements were connected had an inner diameter of 3.0 mm and a length of 17.5 mm. This corresponds to a volume of about 100 μL, which has to be taken into account in the interpretation of the experimental data. For channels with an inner diameter of 3 mm, however, the only effect of the detector chamber is a small increase of the actual channel length. All channels used in our experiments were equipped with an adapter that smoothly fitted in the entrance of the detector chamber. Some high temperature resistant vacuum grease (Apiezon, type H) was used to prevent leaks between the adapter and detector.

The detector was calibrated by measurements in which no channel or a channel with a length of 10 cm was attached to the detector. In these situations the same maximum signal level was reached, indicating that essentially saturated steam is present, i.e., the deviations from steam saturation are one or two orders of magnitude smaller than the effects observed with channels with lengths of 0.5 m or 1.5 m, which will be discussed in the next section.

Channels of 0.5 m

First, the infra-red absorption detector was placed in the sterilizer chamber and the optical fibres and wiring of the detector chamber were connected to the respective optical and electronic circuits. Next the system was calibrated by connecting a vertically oriented channel with a length of 10 cm to the detector chamber and running the prion process outlined above. The maximum absorption signal was assumed to correspond to a situation with (nearly) saturated steam (with the used air removal sequence, the normalized vapour density in the sterilizer chamber at the start of the sterilization phase amounts to about 0.9991). Next, a series of measurements was performed on channels with a length of 0.5 m and an inner diameter of 3 mm and 5 mm, respectively. These channels were bent in a helical shape with a radius of about 20 cm and a height of about 7 cm. These helices were placed vertically in the centre of the sterilizer chamber, such that condense formed at the walls of the channel could run off freely. The detector chamber was connected to the upper end of the helix, effectively making it a tubular system with one open and one closed end. In all experiments the same prion process outlined above was used. After the steam penetration in these channels was measured, the detector was calibrated again.

The difference between the calibrations before and after the actual measurements was used to estimate the possible error in the experimental data. If we include the error which may result from a small drift of the signal baseline, which was observed during the measurements, we arrive at a total experimental uncertainty of about 4% of the maximum signal.

Channels of 1.5 m

Experiments were performed on channels with inner diameters of 3.0, 1.5 and 0.7 mm, respectively. The channels were also bent to a helical shape with a diameter of about 20 cm and a height of about 10 cm. Two series of measurements are reported here. During the first series, the channels were directly connected to the detector chamber, effectively adding a receptacle volume of 100 µL. During the second series, a dummy chamber with a volume of 500 µL was inserted between the channel and the detector chamber, yielding an effective receptacle volume of 600 µL. Each configuration was measured three times to check the reproducibility of the measurements. Before and after each measurement the sensitivity of the detector was checked according to the procedure outlined in the previous section. Also in these measurements, the total experimental uncertainty did amount to about 4% of the maximum signal.

Physical Model

The physical model which was used to describe the air-vapour transport within a channel with one open and one closed end has already been outlined in the literature (15). It essentially assumes a laminar flow in the channel and the absence of thermally driven transport. It is only valid for thin-walled channels. This implies that the temperature of the inner wall of the channel follows that of the outer wall rather rapidly. Consequently, condensation on the inner wall can be neglected, except during the sterilization phase. If a detector chamber or additional dummy chamber is attached to the (closed) end of the channel, a discontinuity in the radius will occur. This will give rise to non-laminar flow in part of the chamber, producing additional mixing of the air-vapour mixture entering the chamber from the channel and the mixture already present in the chamber. In order to keep the physical model manageable, the effect of the chamber was included by increasing the channel length with an additional section having a volume equal to that of the chamber. Next, the local physical constants in the additional section of the channel are adapted in such a way, that the time scale of the process in this section is identical to that of the chamber.

This is implemented as follows (16, 17). The length l_S of the additional channel section is given by $l_{section} = V_{chamber}/(\pi a^{2})$, where a is the channel radius and $V_{chamber}$ the chamber volume. The average velocity $\bar{u}$ of the air-vapour mixture within a channel is given by:

$$\bar{u} = -\frac{a^2}{8\eta}\frac{\partial p}{\partial x} \qquad (1)$$

with η the viscosity (Pa s) and p the pressure (Pa). In order to make the time-scale of the process within the additional channel section equal to that of the chamber, the average velocity $\bar{u}$ should be increased by a factor $f_{scale} = l_{section}/l_{chamber}$, where $l_{chamber}$ is the length of the detector and/or dummy chamber. This can be realized by decreasing the local viscosity η in the additional channel section by f_{scale}.

For the diffusion a similar approach is followed. The diffusion length l_D is given by $\sqrt{Dt}$. If the time-scale of the diffusion process in the "original" chamber and the additional channel segment has to be the same, the local diffusion constant in the channel segment should be increased by $(f_{scale})^2$. The results of this model will be compared with the experimental data in the Results section.

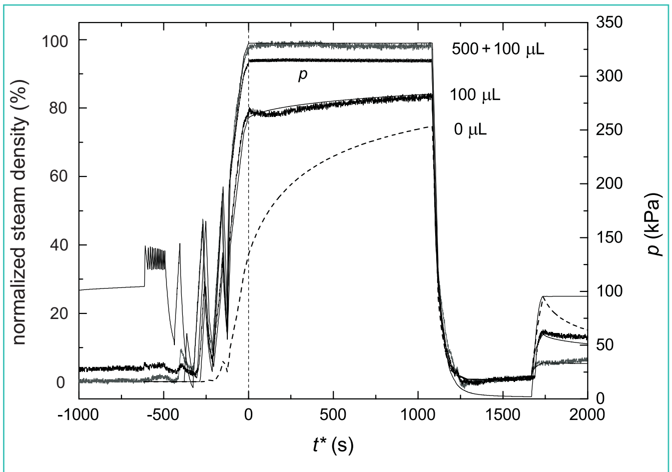

Fig. 3: Vapour density at the closed end of a channel with a length of 1.5 m and a diameter of 0.7 mm with and without an additional dummy chamber with a volume of 500 µL attached to the closed end of the channel. The vapour density is normalized to the density of saturated steam of 134 °C. The experimental data are given by the most fluctuating curves, the corresponding model predictions by the relatively smooth solid curves. The model prediction for a measurement chamber volume of zero is denoted by the dashed black curve. The pressure in the sterilizer chamber is depicted on the right vertical axis. The time is given relative to the start of the sterilization phase.

Results

Channels of 0.5 m

In figure 2 the results of three measurements on the channel with 3 mm inner diameter and two measurements on the channel with 5 mm inner diameter are plotted. Within experimental uncertainty, all five data sets coincide, indicating the good reproducibility of our experimental set-up and the independence of the steam penetration of the channel radius. This is corroborated by the results of calculations based on the model outlined in the previous section, which agree very nicely with the experimental data. It should be noted that these calculations yield essentially the same results for both channel diameters, whereas the inclusion of an additional detector chamber volume of 100 µL at the end of the channel hardly changes these results. The small deviations between the model and the experimental data near the end of the sterilization phase may result from the approximations made in the model. However, they do not affect the conclusion that the steam penetration in these channels does not depend on the channel diameter. The figure also shows that the preprogrammed air removal stage of the used sterilizer results in a steam fraction of about 80% at the end of a 50 cm channel at the start of the sterilization phase.

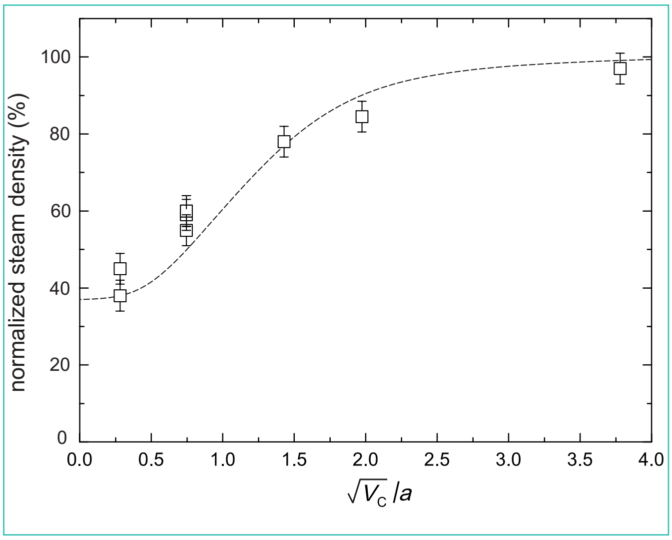

Fig. 4: Vapour density at the start of the sterilization phase (see figure 3) at the closed end of channels with a length of 1.5 m for various volumes of the measurement chamber and channel diameter. The open squares with error bars denote the experimental data, the dashed curve the results from calculations based on the physical model. The vapour density is normalized to the density of saturated steam of 134 °C. The data are plotted as a function of the square root of the chamber volume V_c divided by the radius *a* of the channel.

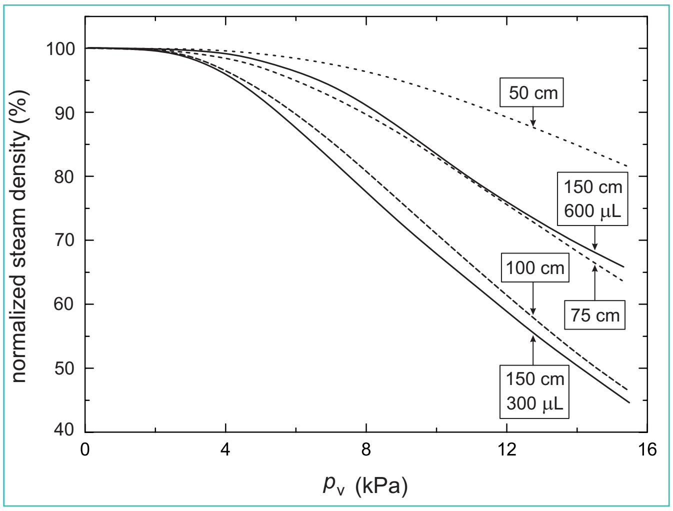

Fig. 5: Calculated vapour density at the start of the sterilization phase (see figures 2 and 3) at the closed end of various channels as a function of the pressure p_v of the vacuum level control points of a generic sterilization process with 4 identical vacuum pulses. The solid curves denote the results for channels with a length of 1.5 m and a diameter of 2 mm connected to a measurement chamber of 300 and 600 µL, respectively. The dashed curves denote the results for channels of 50, 75 and 100 cm without an additional volume at the closed end. The vapour density is normalized to the density of saturated steam of 134 °C.

Channels of 1.5 m

For all channel diameters, the presence of an additional dummy chamber of 500 µL appeared to significantly enhance the steam penetration, the increase being largest for the smallest channel diameter. In figure 3 the results for this most extreme case are plotted. The figure shows that for a chamber volume of 600 µL (500 + 100 µL), the steam at the end of the channel (and also in the chamber) is almost fully saturated at the start of the sterilization phase. For a chamber volume of 100 µL, the steam fraction at the start of the sterilization phase only amounts to about 80%. This tendency is corroborated by calculations based on the physical model outlined in the Materials and Methods section , which are denoted by the smooth solid curves. These calculations also reveal that if no detector chamber or receptacle would be present at all, the steam fraction at the start of the sterilization phase would only amount to about 40%. This is indicated by the dashed curve in the figure.

Inspection of this figure shows an excellent agreement between the experimental data and the results of the model calculations. For less extreme cases (not plotted in the figure), however, differences up to about 8% between the experimental data occurred, which most likely result from the simplifications made in the physical model. The most obvious simplification is the way the effect of the chamber is translated to an extra channel section with adapted values of the viscosity and diffusion constant. However, it should also be noted that for the preprogrammed air removal stage the pressure increase after the last evacuation cycle is very fast, which is not taken into account in the model. Nevertheless, the experiments and model predictions appeared to have the same tendency, which is illustrated in more detail in figure 4. In this figure the steam penetration at the end of the channel at the start of the sterilization phase is plotted for all six experimental configurations.

The results of the physical model do not change when both the chamber volume and the channel volume per unit length are multiplied by the same factor (see section Materials and Methods, where f_{scale} remains the same). Consequently, if the model describes the actual process accurate enough, in a plot of the experimentally observed steam saturation at the start of the sterilization phase against $V_{chamber}/a^2_{channel}$ all observed data can be represented by a single master curve. To avoid compressing the majority of the experimental data in a small part of the figure, the data are plotted as $\sqrt{V_{chamber}}/a_{channel}$. The master curve for the used process resulting from our theoretical model for a channel length of 1.5 m is denoted by the dashed curve. The overall agreement of the experimental data with this curve is satisfactory. Both experiment and theory clearly show the same tendency within the present range of channel diameters and chamber volumes, indicating a strong dependence of the steam fraction on the chamber (receptacle) volume.

Discussion

Several investigations show that the steam penetration decreases with increasing channel length (15, 18, 19). Numerical calculations of the transport of air and steam in a channel in the absence of condensation on the inner wall of the channel indicate that the diameter of the channel is of minor importance for diameters between 0.1 and 10 mm. At very low diameters, the steam penetration decreases because of the increasing effect of the viscosity of the air-vapour mixture. However, experiments by Kaiser and Göman (13) on channels with various lengths and diameters, connected to a receptacle with a CI, suggest that the steam penetration in a channel increases for decreasing diameters. As a possible mechanism to explain this counter-intuitive behaviour, they hypothesized a condensation-evaporation sequence on the inner wall of the channel during successive air removal cycles. This mechanism would be more effective for channels with a smaller radius, because the surface to volume ratio is larger.

For the thin walled metal channels used by Kaiser it can be shown (15) that condensation on the inner wall will only occur in a region of about 1 cm close to the entrance of the channel. This results from the fact that the outer surface of the channel is immediately heated up, since it is directly exposed to the steam. The transfer of the heat from the outer to the inner surface of the channel occurs within about one second. Since the velocity of the steam-air mixture entering the channel is rather low, the temperature of the mixture is only below that of the wall over a short distance. Apart from this, if condensate formed on the inner wall of the channel would evaporate again during the subsequent evaporation cycle, the motion of the resulting vapour in the channel would be directed outward, not inward.

The results presented in the previous sections strongly indicate that for dead-end channels with diameters in the range 0.7 to 5 mm the steam penetration is independent of the channel diameter. A receptacle or detector volume attached to the channel, however, dramatically increases the steam penetration. This effect may serve as an alternative and evidence based explanation for the tendency observed in the experiments of Kaiser and Göman (13) since in the presence of a receptacle the steam penetration indeed increases as the channel diameter decreases. This observation has important consequences for the application of helix PCD's.

To illustrate this point, we have plotted in figure 5 the steam penetration in a hollow A PCD with dimensions according to the standard EN 867 part 5 (8). This is basically a channel with a length of 1.5 m and an inner diameter of 2 mm. The steam penetration was calculated for volumes of the receptacle of 300 and 600 μL. The results are represented by the solid curves in the figure. The dashed curves represent the calculated steam penetration for dead-end channels of 50, 70, and 100 cm without any additional volume at the closed end. Inspection of the figure shows that the steam penetration for a channel of 100 cm is significantly below that of a hollow A PCD with a receptacle of 600 μL.

Consequently, even if the biological or chemical indicator in the receptacle would be perfect, a pass of a hollow A PCD of 150 cm does not guarantee that the steam penetration in channels with a smaller length will actually be sufficient to ensure steam sterilization conditions. More generally phrased, it is demonstrated that helix devices with chamber do not represent narrow channels without "chambers". Moreover, calculations similar to those presented here indicate that for other types of air removal cycles, the results for dead-end channels with various lengths as well as the hollow A PCD may change significantly, also relative to each other. Therefore, the results obtained with a hollow A PCD cannot be used to predict the steam penetration in other channels, as long as the receptacle is not accurately specified. This includes the net volume (receptacle minus indicator), which should be the same for all hollow A PCDs and all tests. As long as these points are not adequately addressed, a hollow A PCD is not mature enough to be used as a standard steam penetration test.

References

1 Standard ISO 17665-1, Sterilization of health care products – Moist heat, international organization for standardization (2006).
2 http://ec.europa.eu/growth/single-market/european-standards/harmonisedstandards/medical-devices/index en.htm, last visited: 10-11-2015.
3 Bowie JH, Kelsey JC, Thompson GR. The Bowie and Dick autoclave tape test, The Lancet 281 (1963) 568–569.
4 Standard ISO 11140-3, International organization for standardization Sterilization of health care products – Chemical indicators – Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (2007).
5 Standard ISO 11140-4, International organization for standardization Sterilization of health care products – Chemical indicators – Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration (2007).
6 Standard ISO 11140-5, International organization for standardization Sterilization of health care products – Chemical indicators – Part 5: Class 2 indicators for Bowie and Dick-type air removal tests (2007).
7 Standard EN 13060, European committee for standardization Small steam sterilizers (2004).
8 Standard EN 867-5, European committee for standardization Non-biological systems for use in sterilizers – Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S (2001).
9 Esen S, Tessarolo F, Hermsen RJ, van Doornmalen JPCM. Current reference devices for hollow instrument loads as defined in standards are not a valid steam penetration test, Central Service 4 (2012) 256–260.
10 Metzing J. Testing the performance of process challenge devices (PCDs) used to check air removal from hollow instruments and effectiveness of sterilisation in steam sterilisation process, Central Service 2 (2011) 196–198.
11 Kaiser D, Kaiser U, Vogel H. A quantitative description of air removal from hollow devices in steam sterilization processes, Central Service 14 (2006) 275–288.
12 Borchers U, Mielke M. How material, length, wall thickness and diameter of hollow devices affect the inactivation behaviour of biological indicators when subjected to moist-heat treatment, Central Service 12(5) (2004) 314–322.
13 Kaiser U, Göman D. Investigation of air removal from hollow devices in steam sterilisation processes, Central Service 6 (1998) 401–413.
14 van Doornmalen JPCM, Hermsen RJ, Kopinga K. Six commercially available class 6 chemical indicators tested against their stated values 6 (2012) 400–404.
15 van Doornmalen JPCM, Verschueren M, Kopinga K. Penetration of water vapour into narrow channels during steam sterilization processes, Journal of Physics D: Applied Physics 46 (2013) 065201.
16 Baehr HD, Stephan K. Heat and Mass Transfer, 2nd Edition, Springer, Berlin, 2006.
17 Bird RB, Stewart WE, Lightfoot EN. Transport Phenomena, 2nd Edition, John Wiley & Sons Inc, New York, 2007.
18 Young JH, Sterilization of various diameter dead-end tubes, Biotechnology and Bioengineering 42 (1993) 125–132.
19 Young JH, Lasher WC, Gaber R. Transport processes during sterilization of vertical and 5 degree horizontal dead-leg, Bioprocess Engineering 12 (1995) 293–304.