STEAM STERILIZATION—THE RESPONSE OF THE TEST PACK

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Steam Sterilization — The Response of the Test Pack

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The authors obtained temperature recordings from nearly 400 experiments with the standard test pack as defined in the prEN 285 as a basis for methods to evaluate conditions influencing steam sterilization. A new method to scale the duration and the extent of an air pocket (penetration fault) is presented. This method proved suitable for the interpretation and quantification of substantial correlations between the effect of a fault, the volume of the sterilizer chamber, and the rate of pressure change in the chamber. The coolest spot was found near the center of the test pack in only 17% of the tests. The air pocket was found to be an anomaly best elucidated by statistical methods. The prevailing influence of the rate of pressure change does not allow the establishment of limiting values for any fault, such as leakage rate or air dilution in the chamber, except as applied to a well-defined sterilizer. The penetration fault caused by an air leak does not depend on the chamber volume. The effects of residual air and induced air on the penetration fault are fundamentally different. Faults caused by those different air sources should be distinguished from each other even though both cause air pockets. (BIOMEDICAL INSTRUMENTATION & TECHNOLOGY 1993;27:412–418)

The new European reference load for steam sterilizers, as defined in prEN 285, is a reusable textile pack of 7-kg mass of plain white cotton sheets. The sheets are washed when new and when soiled, and are not subjected to any fabric conditioning agent.[1]

Using this standard test pack, we tested to what extent a reproducible demonstration of faults could be achieved. The following defects were generated:

1. Air leakage
2. Constant flow of compressed air
3. Insufficient air removal

The second aim of this research was to find out whether the size of a fault was influenced by:

1. The volume of the sterilizer chamber
2. The rate of pressure change during evacuation
3. The rate of pressure change during steam admission

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The temperatures throughout the chamber and the load were measured and recorded using thermoelectric instruments. An optical assessment of temperature records generally gives a good impression of the scale of a fault. Therefore, we defined a new method to quantify this optical impression, using four temperature sensors in the test pack and two in the chamber, because normally a temperature deviation is observed at more than one position in the pack.

MATERIALS AND METHODS

We generally used the methods recommended in prEN 285. For the interpretation of the results we applied two different methods.

Test Procedure

The sheets in four standard test packs were washed and calendered like other hospital fabrics and stored unwrapped on an open shelf. After 100 hours, the stacked sheets, exposed to the humidity of air, had reached 3% to 3.5% of adsorbed moisture at equilibrium. Neither further storage for two more weeks nor unfolding and separately airing single sheets caused additional adsorption of moisture. Before the first use, all sheets were sterilized once to make sure no conditioning agent would affect the tests. After 60 experiments with each pack, the sheets were rewashed and conditioned in the same way, because they were discolored.[2]

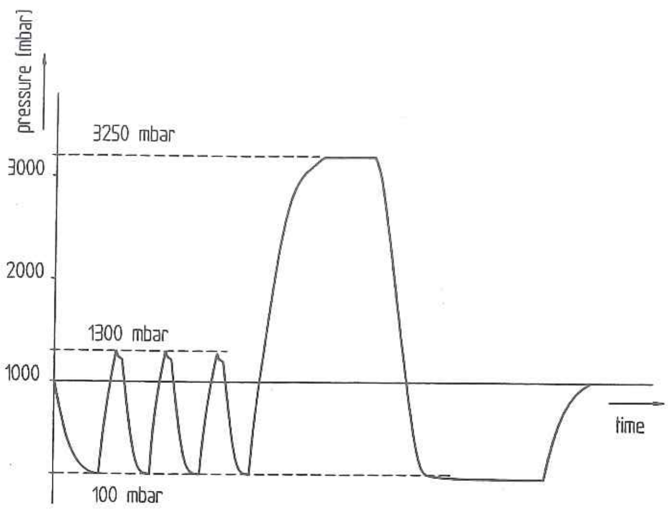

Figure 1. The sterilization process.

To meet the standardized test procedure, prior to any experiment, the sheets were separately laid out and aired for at least 90 minutes, then stacked to a mass of 7 kg ± 0.07 kg and a height of 25 cm. Before and after every experiment the test packs were weighed. The change of mass of the test packs was generally less than 0.02 kg (≤ ± 0.3%).

Only one special sterilization process (Figure 1) was used, modified to achieve a 1 : 22,000 fictitious degree of dilution[3] of the air in the chamber and to secure sterilization conditions in all sterilizers. Construction variations of the different sterilizers used in the series of tests and the programmed sterilization process could influence the results of the experiments only systematically, because we used sterilizers from only one manufacturer (Lautenschläger, Köln, Federal Republic of Germany), with steam supplied to the jacket and from the jacket to the chamber.

Pure steam was produced by electrically heated steam generators, working at a pressure of 4.5 to 5 bar (all pressure ratings refer to 0 bar as vacuum). To check the steam quality, we used the methods given in prEN 285. Noncondensable gases in the steam were restricted to < 3.0 mL gas per liter of condensate by deionizing the feed water to < 5 μS/cm and by switching off the feed pump during air removal and steam admission. The steam had dryness values ranging from 0.981 to 0.988 (i.e., 1.2 to 1.9% moisture). The real air leakages of all sterilizers were recorded regularly and were determined to be 150–200 ml/min.

Temperatures in the chamber and in the test pack were measured with six resistance thermometers, Pt-100 1/3 class B DIN IEC 751 (Groelle & Löbach, Hennef, Federal Republic of Germany), of the three-lead type. The thermometer response time was $t_{90\%} \leq 3$ sec, the flexible connecting wires had a major diameter of 0.5 mm, and the sensors had a diameter of 3 mm and a length of 30 mm. Data recording was carried out with an accuracy of 0.1% in the range of 0–150 °C, using a Chessel 346 printer (Chessel GmbH., Poing, Federal Republic of Germany).

Three sensors were placed in the positions required by prEN 285: the first at least 10 mm deep in the drain, the second in the center of the standard test pack, and the third 50 mm above the pack. The three additional sensors were placed as shown in Figure 2. All sensors were centered at their relative vertical positions in the test packs, because air pockets are most likely found along the vertical axis.[4] The standard test pack was placed on a grating in the geometric center of the chamber to allow unhindered penetration of steam from all sides.

The air leakage was set on a flowmeter with a needle valve (Type KDG-37, Kobold-Messring, Hofheim/Taunus, Federal Republic of Germany), protected by a swing-check valve. A constant flow of compressed air, regulated to 7.2 bar by a pressure-reproduction valve, was set on an appropriate flowmeter with a needle valve (Type KDG-07 and KDG-20, Kobold-Messring, Hofheim/Taunus, Federal Republic of Germany). Air admission to the chamber was checked conventionally as pressure increase, using an absolute-pressure gauge. Insufficient air removal was controlled by altering the vacuum-switch point of the programmed sterilization process.

Rates of pressure change during heating and cooling were determined by the times required for pressure to change between 0.5 bar and 1.5 bar, using a stopwatch.

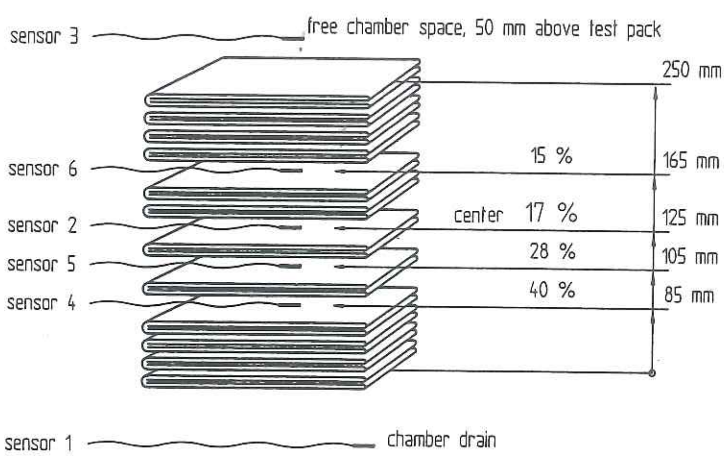

Figure 2. Positions of the sensors and coolest spot in the test pack.

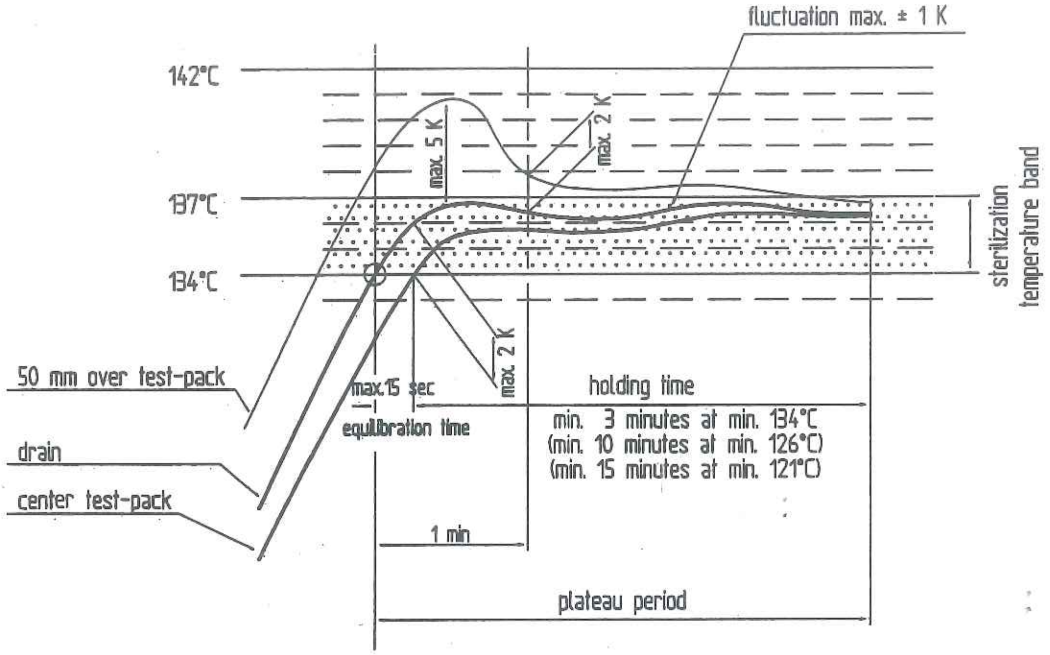

Figure 3. prEN 285: requirements concerning the course of tempeatures.

Interpretation According to prEN 285

The requirements of prEN 285 concerning the course of temperatures are illustrated in Figure 3. Throughout the holding time the temperatures measured in the chamber drain and at the nominal geometric center of a standard test pack shall not differ from one another by more than 2 K after a maximum of 15 seconds of equilibration time.[1] The difference of 2 K is regarded as a reference for other test equipment, too, e.g., air detectors[1] and alternatives to the steam-penetration test.[5] The equilibration time is considered the most important criterion to detect an air pocket.

Although equilibration time may easily be manipulated (see also the Discussion section), it is not a useful indicator of the effectiveness of steam penetration. Therefore, to scale the fault according to the standardized method, in a comparative analysis we used only the maximum temperature difference between the drain and the center of the test pack throughout the first three minutes of the plateau period.

Interpretation According to the Penetration-Fault Method

We developed a second interpretation method based on measurements in the drain and at several positions in the test pack. At least three sensors in the test pack are used. The courses of temperature with time, recorded from the individual sensors, are plotted as a temperature–time diagram (Figure 4). The hatched area between the curve related to the sensor in the drain and the curve related to the corresponding sensor in the test pack is calculated as an integral during 180 sec from the start of the plateau period. It has the dimension of time–temperature difference (s · K). A mean area, the "penetration fault," is calculated from the results determined for all sensors.

The penetration fault represents the duration and extent of an air pocket. The smallest possible penetration fault is zero for identical temperatures; the largest possible penetration fault is approximately 20,000 sK for 135°C in the drain and 23°C measured by all sensors in the test pack. A penetration fault of 150 sK approximately corresponds to a maximum temperature difference of 2 K during the plateau period between the drain and any place in the standard test pack. Typical temperature

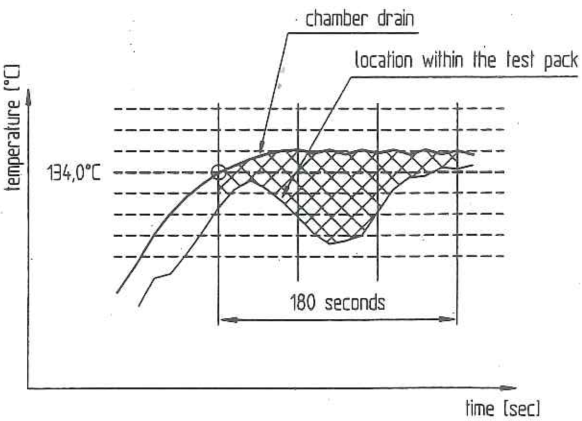

Figure 4. Penetration fault.

characteristics are shown in Figure 3 for a temperature difference of 2 K during the plateau period and at the center of the test pack; the penetration fault is 150 sK in this case.

RESULTS

To assess reproducibility, a test was repeated ten times with an adjusted air leakage of 1,700 ml/min into a 360-liter chamber (causing a pressure rise of 4.7 mbar/min). Between the center of the test pack and the drain, a mean temperature deviation of 18 K (standard deviation 17 K) was measured. Using four sensors in the test pack, the maximum temperature difference was found in the center of the pack in only two of the ten experiments.

Figure 2, which is applicable to all experiments using four sensors in the test pack, illustrates that in 17% of the tests the center of the air pocket was found near the center of the pack, if the center of the air pocket is assumed to be near the sensor measuring the lowest temperature.[6]

When the ten tests mentioned above are analyzed using the penetration-fault method, a mean penetration fault of 930 sK with a standard deviation of 350 sK is obtained. As the standard deviation increases exponentially with the scale of the fault, the reproducibility of the results near the limits of detectability will be even better.

Because the penetration-fault method is so accurate, it is used for all further evaluations.

During the experiments it became evident that an air pocket is not a stationary accumulation of air. An air pocket can drift through the test pack, more than one single air pocket may be generated, and an air pocket may have the shape of a dumbbell, i.e., it may be very different from spherical. Such "peculiarities" could be demonstrated in nearly 40% of the experiments and must be regarded as normal. The frequency of their occurrence depends to a great extent on the rate of pressure change during steam admission. With fast pressure changes, they appear in more than 65% of the experiments. In addition, the air pocket may deviate from the vertical axis of the standard test pack, as reflected in the results of the Bowie and Dick test.[7]

Air Leakage

Figure 5 plots the results of all experiments with rates of pressure change of −4 bar/min during evacuation and +2.3 bar/min during steam admission for chambers of 360 to 690-liter volume. Leakage is recorded as a flow rate. A relation between the air flow into the chamber and the penetration fault can be illustrated for all chambers with the same extrapolated function. Obviously,

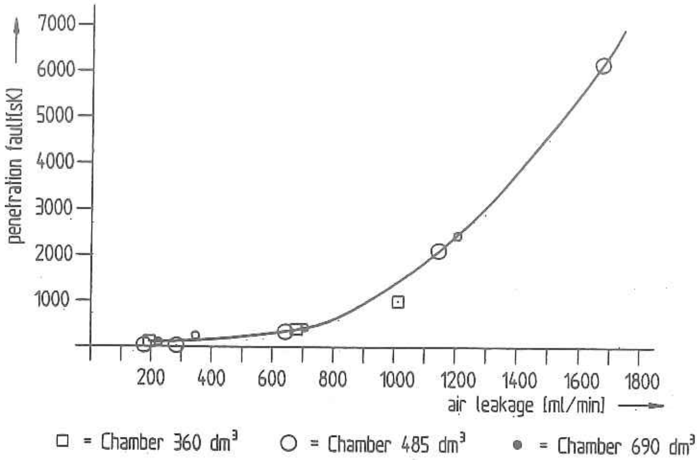

Figure 5. Air leakage, pressure increase: +2.3 bar/min; pressure decrease: −4 bar/min.

the volume of the chamber has no influence on the penetration fault caused by an air leak. The air pocket caused by a hole in a pipe, for example, becomes more dangerous with slower evacuation and faster steam admission. Slowing evacuation from 4 bar/min to 2 bar/min approximately quadruples the penetration fault. The fault is also affected by influences other than the mass of air.

Constant Flow of Compressed Air

Constant flow of air and air leakage are rather similar. The volume of the chamber does not influence the penetration fault. The air flow caused by leakage of a sterilizer must be added to the flow of compressed air, because, measuring at the limits of detectability, the influence of air from a leak is of the same order of magnitude as the influence of air from the flow of compressed air.

The longer the evacuation takes, the more air enters the chamber and the bigger the air pocket becomes. This was also found for air leakage, as a larger volume of air was accumulated during a longer evacuation period.

It may be expected that the time dependence of the fault would be the same during steam admission as during the evacuation period. Assuming air flow to be constant, the total mass of induced air depends on the duration of the sterilization process and on the pressure rate, respectively. The faster the pressure rises, the smaller is the effective mass of air. However, it was found that the faster the pressure rises, the larger became the fault (Figure 6): an injection of 375 mL/min air at a rate of 4 bar/min pressure change during steam admission caused a significantly larger fault than did the same air flow at a rate of 1 bar/min. This effect was found in combination with any fault: air leakage, injection of compressed air, or insufficient air removal. This implies that the influence of the pressure rise in the chamber on the size of an air pocket is even larger than that of the mass of injected air.

Insufficient Air Removal

Altering the vacuum-switch point from the preset cycle parameters (see Figure 1) to a higher value increases the mass of air remaining in the chamber. Even a variation of 10 mbar may cause an unacceptable penetration fault. Figure 7 shows the thermodynamic correlation of air dilution described by Spicher and Peters[3] and later by Galtier and Darbois,[4] i.e., the dependency of the degree of dilution on the volume of the chamber and the vacuum attained.

It was confirmed that the formation of air pockets was intensified by raising the rate of pressure change during steam admission. But, in contrast to the faults discussed below, slow evacuation minimized the penetration fault: slowing the evacuation from 4 bar/min to 2 bar/min approximately halved the penetration fault.

Insufficient air removal caused an air pocket in the standard test pack (of 16.5-liter volume) in a sterilizer of 73-liter volume in the same way as in other chambers (Figure 7).

However, neither leakage nor injection of compressed air caused a significant change of the penetration fault. When a smaller pack with a mass of 4.4 kg was used, an air leak caused an easily detectable air pocket in this small chamber, too.

DISCUSSION

Our findings confirm the theory of the small-load effect described by Henry and Scott[8]: the size of an air pocket depends on the mass of air remaining in the free chamber space that will re-enter the pack, provided the test pack is a small load.

However, an air leak is usually described as a rate of pressure increase that is observed in the evacuated chamber. A leak rate is commonly used to set a limiting value to the density of a sterilizer (prEN 285: 1.3 mbar/min[1]; DIN 58946: 1 mbar/min[9]; R6104: 0.5% of the chamber volume [10]). For a given rate of pressure increase as stated by the norms, the mass of air entering the chamber is a function of the chamber volume.

The standards should be reviewed: The definition of the size of an air pocket caused by an air leak must take into consideration the flow rate of air into the chamber and not the rate of pressure increase caused by this air flow.

It is known that the penetration fault depends not only on the mass of residual or injected air: "A failure of the Bowie and Dick test is therefore not conclusive proof that a fault is due to air retention, air leakage or noncondensable gases."[1] Other causes of failure may need to be eliminated.

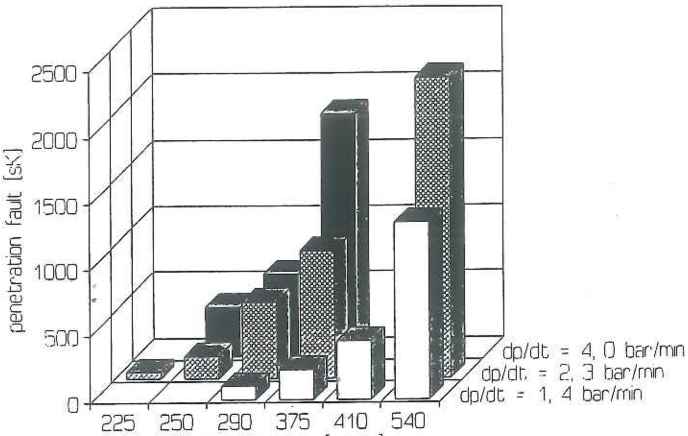

Figure 6. Compressed air flow: influence of pressure change during steam admission. Chamber volume: 690 L, pressure decrease: −4 bar/min.

Our study demonstrates that the rate of pressure change during steam admission is of major influence on the penetration fault, even more than the mass of air (Figure 6). This result is important because some standards, e.g., British Standard BS 3970[11] require a maximum cycle time, which includes a short time for steam admission. A rapid pressure rise may increase any small failure developing in the course of the time to a hazard in achieving sterility.

Whether a fault is caused by induced or residual air is important: on the one hand, slow evacuation increases the amount of air in the chamber and probably will produce a fault; on the other hand, slow evacuation will improve the diffusion of air and steam[12] and will help to eliminate an air pocket. Thus, depending on the kind of fault (i.e., induced or residual air), the same entity will either intensify or diminish an air pocket.

The mass of the challenge "small load" depends on the origin of air: in a sterilizer of 73-liter volume, residual air after insufficient air removal caused a penetration fault analogous to those in larger chambers. But neither leak nor injection of compressed air caused a significant change of the penetration fault. When a smaller pack with a mass of 4.4 kg was used, an air leak caused an easily detectable air pocket.

The definite difference between the influences of residual air after insufficient air removal on the one hand

and air induced into the chamber in the course of the process, e.g., air leakage, on the other hand was demonstrated with a sterilizer of 73-liter volume, where no leakage or injection of air caused a penetration fault.

An air pocket is an anomaly, and the characteristics of air pockets, such as shape, position, and number of air pockets in the test pack, cannot be predicted. The fundamental idea of the penetration-fault method is to analyze the prevalences of individual features with statistical methods.

prEN 285 requires only one sensor in the test pack. However, it is very unlikely that a single sensor will be positioned exactly in the coolest spot in the test pack (Figure 2). As early as 1961, Wilkinson and Peacock[6] stated that the coolest spot in the test pack could not be predicted, and reliable assessment of steam penetration would require at least three thermocouples in the pack. The German DIN 58946 part 3[9] requests four bioindicators and thermocouples in the test pack. Even using a number of sensors, the coolest spot will be detected only by chance. This is particularly relevant to small air pockets near the limits of detectability, whose detection is important for the validation of steam sterilizers.

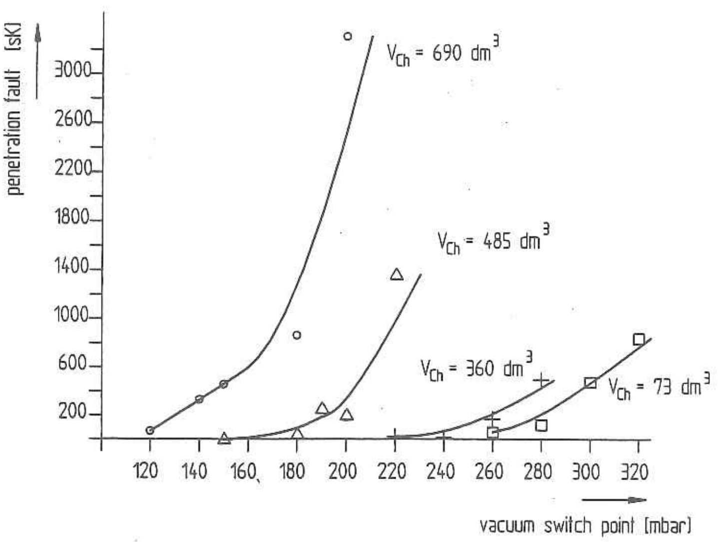

Figure 7. Insufficient air removal: influence of chamber volume. Pressure increase: +2.3 bar/min; Pressure decrease: −4 bar/min.

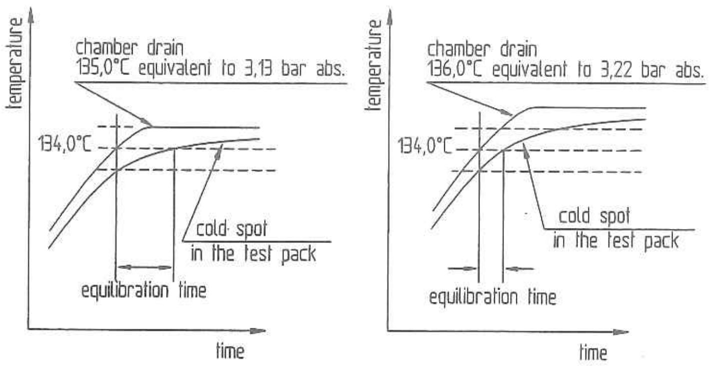

Figure 8. Influence of the operating temperature on the equilibration time.

The equilibration time may easily be manipulated. The equilibration time resulting from the same fault will be shorter as the difference between the operating temperature and the required sterilization temperature increases (Figure 8). Therefore, the equilibration time is not a suitable indicator of the effectiveness of steam penetration. In addition, the temperature difference measured between the drain and a relevant sensor in the test pack changes in the course of time, and the value of any specific time or temperature difference does not give a general idea of a fault.

The calculation of F_0 has not been considered. The F_0 value is a convenient reference value for relating the effectiveness of any sterilization process at a range of temperatures to the effects of exposure times in minutes at 121°C.[13] Because the F_0 depends on the operating temperature, it may be manipulated like the equilibration time.

Our measurements show that the new standard test pack can be used as a reference load for the testing of large steam sterilizers. Nevertheless, considerable variation exists, and therefore statistical analysis of the test results is necessary. The penetration-fault method facilitates a considerably better analysis of steam penetration. ■

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