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A comparison of four commercially available electronic steam penetration tests according to ISO 11140 part 4

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Over the last decade electronic test devices have been introduced to replace the original Bowie and Dick steam penetration test. To find out if these devices are equivalent in performance to the original Bowie and Dick test four commercially available electronic steam penetration test devices were tested according to the applicable standard ISO 11140 part 4: Sterilization of health care products – Chemical indicators – Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration.

The results show that three out of the four devices tested did not produce similar results as the Bowie and Dick-type test. Test results show also that in order to produce similar results for the steam penetration test measuring and interpreting temperature and pressure only is not sufficient. A device has to able to discriminate between steam and other gases possibly present such as air. Only one device makes use of differences in physical properties of steam and non-condensable gases and demonstrates equivalent performance to the original Bowie and Dick steam penetration test.

KEY WORDS
- steam sterilisation
- steam penetration
- electronic tests
- ISO 11140

Introduction

Before starting production with a steam sterilizer for surface sterilization of Medical Devices a steam penetration test must be performed according to the standard ISO 17665 part 1 (1). Bowie and Dick developed the first steam penetration test, the so-called Bowie and Dick test in the early 1960s (2). The test is addressed in literature frequently (3 – 8) and is still the standard for steam penetration tests (1, 9, 10). To show equivalence with the original standard Bowie and Dick test an alternative steam penetration test has to meet the requirements specified in the ISO 11140 part 4 (11). For approximately 10 years, electronic steam penetration tests have been introduced in the field of steam sterilization. Four commercially available electronic test devices were found claiming directly or indirectly to fulfil the requirements of the ISO 11140 part 4. Directly claiming means that it is stated that the product complies with the ISO 11140 part 4. Indirectly claiming means that it is suggested that a device can be used as penetration test without referring the correct and relevant standards. The four commercially available electronic steam penetration tests were evaluated to find if they generate equivalent results to the original Bowie and Dick test (9, 11).

For the original Bowie and Dick test (3), a towel pack with the dimensions of approximately 25 × 22 × 30 cm has to be composed with specified textile sheets (10). The stack of textile sheets forming the towel pack is specified as the standardized challenge for air removal and steam penetration. In order to rightfully claim equivalent performance of an alternative Bowie and Dick test to the original Bowie and Dick test a validation in accordance with ISO 11140-4 is required. In this validation equivalent performance must be demonstrated by direct comparison of the product under evaluation with a thermometrically measured standard towel pack.

In daily practice the towel pack may be used in combination with a chemical indicator located in the centre of the towel pack thus dividing the stack of towels into equally sized halves. The requirements for the chemical indicator are specified in the standards (9). When after a steam penetration test process the ink on the indicator sheet has changed evenly to a defined colour over the complete indicator sheet, a pass results for the B&D test is given; the sterilizer can be released for production. If after a steam penetration test process the indictor sheet has not changed colour evenly or completely the result is considered to be a fail; the steam sterilizer should not be used for production and corrective measures should be taken before using the sterilizer.

On the market four electronic steam penetration tests were found and these devices were tested as specified in ISO 11140 part 4. In the section Material and Methods, the design of the experiment and the materials used are addressed followed by the results of the experiments in the section Results. In the sections Discussion and Conclusion, the results are analyzed and conclusions are formulated.

Material and Methods

In figure 1 a flow diagram of the study is presented. The preparation is divided in 2 parts.

The first part comprises the identification and purchasing of the devices. Software

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belonging to each device was installed on a computer.

The four electronic steam penetration test devices included in this study were (fig. 2):

- WI SCAN, Sterlab, Vallauris, France
- EBI 15, Ebro Electronic GmbH, Ingolstad, Germany
- Digital Process Challenge Device – 3 (DPCD-3), Interster International BV, Wormerveer, the Netherlands
- 3M™ Electronic Test System 4108 (ETS), 3M Deutschland GmbH, Neuss, Germany

The second part of the preparation comprised the development of test processes as specified in ISO 11140 part 4 (11) on a dedicated test sterilizer. Suitability of the test sterilizer was demonstrated by an air leakage test and by steam quality and dryness fraction testing according to EN 285. Specified test processes are B1-, B2-, and B3-cycles (figure 3). According to the standard ISO 11140-4 pass and fail cycles have to be performed. Fail conditions specified in the standard are inadequate evacuation, air leakage and air injection. The conditions were verified using the thermometric standard towel pack test.

Before each experimental test session the test sterilizer was warmed up and the process parameters verified, to guarantee reproducibility. The devices were operated as described in their Instructions for Use (IfU). Each electronic penetration test device was used three times in each pass and fail process for statistical acceptance of the results, as shown in the flow diagram (figure 1). After each test the data acquired by a device was transferred to the device's software and the results were saved and are reported in table 1. Between uses devices were allowed to return to ambient conditions. After completion of all tests the results were analyzed.

According to the standards (9, 11) the test sterilizer used for testing has to meet the requirements specified in the ISO 11140 part 4. A dedicated test sterilizer Lautenschläger type 3119/4StE test sterilizer was used (F&M Lautenschläger, Cologne, Germany) with a chamber volume of 340 l. The requirements in standard ISO 11140 part 4 cannot be applied to hospital steam sterilizers specified in standards ISO 17665 and EN 285 (1, 10). For testing chemical and biological indicators specific additional requirements have to be met. Consequently a sterilizer fulfilling EN 285 and ISO 17665 cannot be used to test biological and chemical indicators.

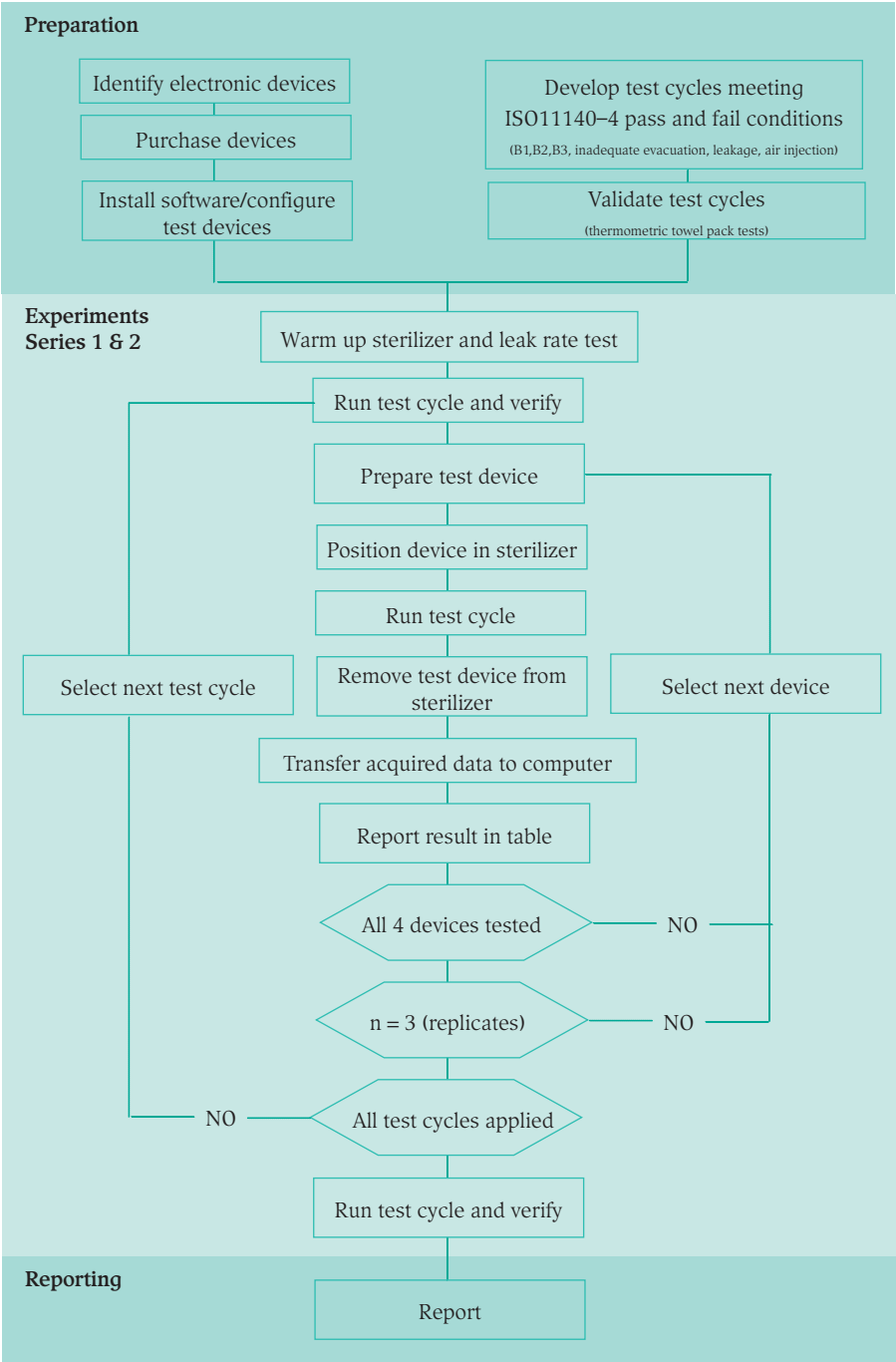

Fig. 1: Flow diagram of the study which is built up out of the preparation, the experiments and reporting. Test programs developed on the test sterilizer as defined in the ISO 11140 part 4 (11) and calibrated with the original B&D test. Before each use of the test sterilizer for testing, it was warmed up and the processes were verified. All devices were ran in separate test cycles. Cycles were repeated 3 times (see table 1). Test devices were used as described in the Instructions for Use for the specific device.

The quality of steam used for steam sterilization is of great importance. In preparation of the study the steam quality was tested according the standard EN 285, the result was 0.7 % non-condensable gases (NCGs). The used steam was generated from tap water in the lab. The water was filtered by a 10 µm 10" active carbon filter (Aktivokohleeinsatz Mikro Klean, Werner GmbH, Leverkusen, Germany) and subsequently subjected to a reverse osmosis system (Werner 40 with a Werner filter 5" Filterkerze absolut 1 µm). Additionally the

Table 1: Results of the 4 electronic devices tested in the B1, B2, and B3 cycles as specified in the ISO 11140 part 4 (11).

Pass 134 °C stands for a pass cycle with the set temperature of the sterilization phase at 134 °C, Pass 136 °C stands for a pass cycle with a temperature sterilization set point at 136 °C, BV stands for Bad vacuum with a vacuum set point of 150 mbar instead of 50 mbar, LK stand for simulated Leakage in the sterilizer chamber and AI stands for Air Injection. The amount of injected air was 340 ml at atmospheric pressure. The plus (+) and minus (–) show the result given by the electronic device. If the background is red, e. g., – or + , the result is not equivalent to the result with the original Bowie and Dick test. In the software of the EBI 15 and the DPCD–3 ten different tests can be chosen. In Table A all tests available in the software are switched on (default setting). In table B the tests are brought to a minimum of three of the tests to only perform a Bowie and Dick test as described in the standard.

Table A	B1															B2						B3					
	Pass 134			Pass 136			BV 150			LK			AI			Pass			BV			Pass			AI		
WI SCAN	+	+	+	+	+	+	+	+	+	+	+	+	–	–	–	+	+	+	+	+	+	+	+	+	+	+	+
EBI15	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	+	+	+	+	+	+	+	+	+	–	–	–
DPCD	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
ETS	+	+	+	+	+	+	–	–	–	–	–	–	–	–	–	+	+	+	–	–	–	+	+	+	–	–	–
Table B	**B1**															**B2**						**B3**					
	Pass 134			Pass 136			BV 150			LK			AI			Pass			BV			Pass			AI		
WI SCAN	+	+	+	+	+	+	+	+	+	+	+	–	–	–	–	+	+	+	+	+	+	+	+	+	–	–	–
EBI15	+	+	+	+	–	–	–	–	–	–	–	–	–	–	–	+	+	+	+	+	+	+	+	+	–	–	–
DPCD	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
ETS	+	+	+	+	+	+	–	–	–	–	–	–	–	–	–	+	+	+	–	–	–	+	+	+	–	–	–

Fig. 2: The sensing units of the four used electronic test devices.
A: WI SCAN Electronic Bowie and Dick, Sterlab, Vallauris, France,
B: EBI 15, Ebro Electronic GmbH, Ingolstadt, Germany,
C: DPCD-3, Digital Process Challenge Device version 3 professional, Interster International BV, Wormerveer, the Netherlands,
D: 3M Electronic Test System (ETS), 3M Deutschland GmbH, Neuss, Germany.
The data acquired of each unit was downloaded and interpreted with the specific software for each device.

water was further purified by two ion exchangers (Werner Aquadem). During use of the sterilizer and water system the typical value of conductivity was lower than 0.5 µS/cm while the maximum suggested value is equal or better then 5 µS/cm (10). The purified water is stored in a 1000 litre buffer container. Before admitting the purified water to the boiler the water is stored in a second buffer container in which it is degassed at 95 °C. The degassing equipment is an integral part of the boiler (Lautenschläger model ED144A).

Results

Results of the tests, presented in the tables 1 and 2, show that 3 out of 4 electronic test devices do not fulfil the claims as specified in ISO 11140 part 4. It was necessary to run two series of tests because in the software of both the EBI 15 and DPCD-3 respectively 8 and 10 tests can be selected and reported: Temperature sensors difference, exposure time, sterilization band, maximum equilibration time, maximum fluctuation, maximum variance, pressure band during exposure time, evacuation, residual air and notional degree of dilution. To perform a steam penetration test according to the

standards not all of the tests shall be included. All tests available in the software are selected by the software default. This setting was used in the first test series (table 1-A). In the second series of tests (table 1-B) only the criteria required to fulfil a steam penetration test were activated: temperature sensors difference, exposure time and sterilization band.

In the first series of tests the WI SCAN shows pass results in all test runs except in B1 air injection test runs (see table 1-A). In the second series (see table 1-B) fail results appeared in the B1 and B3 air injection test, and one out of three fail in the B1 leakage test. In both the first and the second series the fail conditions were verified and found to be in compliance with the required standard Towel pack fail result.

In contrast with three other test devices the WI SCAN unit could not easily be opened without destruction of the unit (figure 2-A). It was therefore not possible to study the measurement principle of the WI SCAN. Measurement data captured with the WI SCAN is only provided in the form of a single graph showing just one temperature curve. The basis on which a pass/fail decision is derived is not mentioned in the product information nor is it retrievable from the data set or graph. Consequently no explanation could be found for the results.

The EBI 15 showed differences in performance in the programmed and verified test cycles. In the first series (table 1-A), with all tests activated, passes and the B2-bad vacuum fail cycles are not properly detected. In the second series of tests (table 1-B) in which only the three criteria for a steam penetration test were activated only 4 out of 6 B1 pass cycles were detected. The B2 bad vacuum fail was still not detected.

Regardless whether or not the number of selected tests was reduced to only the tests relevant for the steam penetration test, the DPCD-3 showed fail results in all processes, including all pass cycles.

The measurement principle, and therefore the decision making process, of both the EBI 15 (figure 2-B) and the DPCD-3 (figure 2-C) is based on a temperature difference calculated from two temperature sensors and the theoretical temperature calculated from the pressure sensor readings (figure 4). Data measured by the EBI

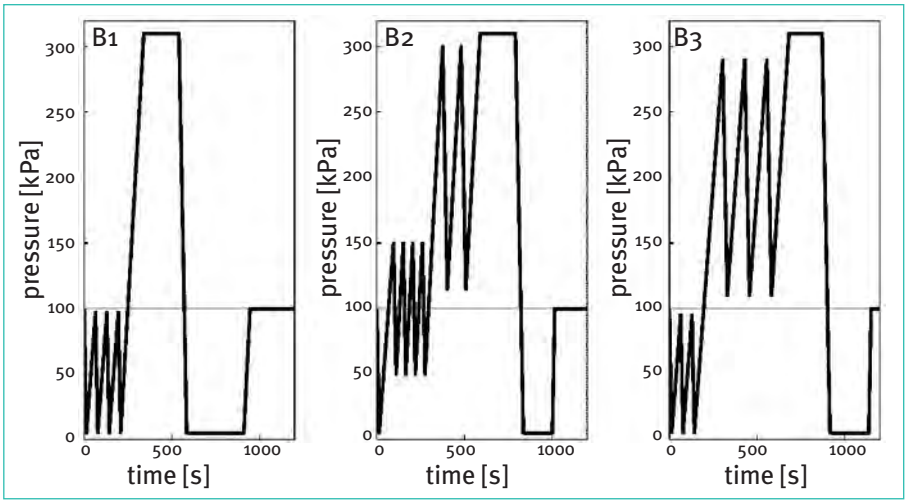

Fig. 3: Schematic presentations of the 3 test cycles for alternative Bowie and Dick-type test for detection of steam penetration according the ISO 11140 part 4 (11). Figure B 1 Sub-atmospheric air removal, figure B 2 Trans-atmospheric air removal, and, figure B 3 Super-atmospheric air removal. Shown are the pass cycles. Fail cycles variations are described in the standards and were calibrated to the original Bowie and Dick test.

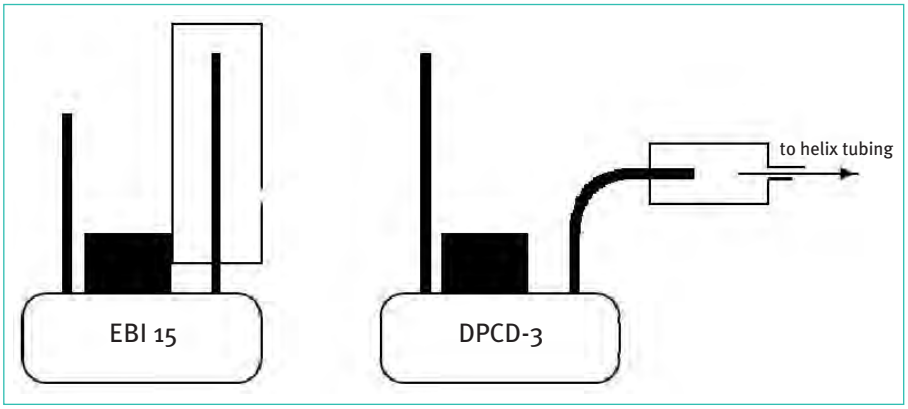

Fig. 4: Schematic representation of the EBI 15 (left) and DPCD-3 (right). Both devices have 2 temperature sensors in the tip of a metal housing, represented by the solid thick lines, and a pressure sensor represented by the black square. Both devices have a temperature sensor measuring the sterilizer chamber temperature and a temperature sensor the temperature in a challenge volume. In case of the EBI 15 the challenge volume is an actual volume with a small hole connecting the inside of the challenge volume with its environment, the sterilizer chamber. In case of the DPCD-3 it is a measurement in the receptacle of coiled or helix tubing. With the pressure sensor the pressure in the sterilizer chamber is measured. From the pressure the theoretical steam temperature is calculated. The measured temperatures and the calculated temperature are used to obtain a result.

Table 2: Numerical presentation of the results

Test device	Series 1 – table 1-A		Series 2 – table 1-B	
	Correct / Total	% Correct	Correct / Total	% Correct
WI SCAN	15 / 27	56	19 / 27	70
EBI 15	18 / 27	67	22 / 27	81
DPCD-3	15 / 27	56	15 / 27	56
3M ETS 4108	27 / 27	100	27 / 27	100

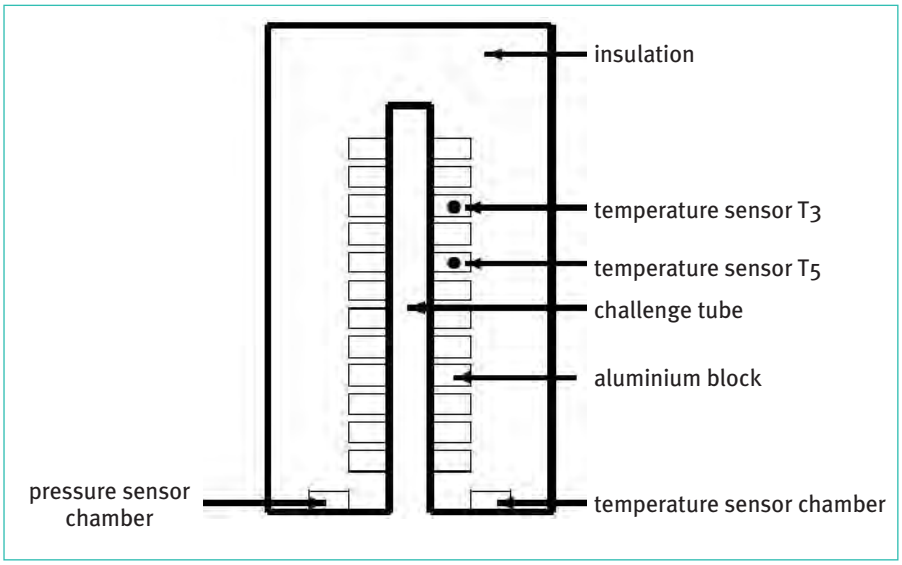

Fig. 5: Schematic representation of the NCG sensor of the 3M ETS 4108. The sterilizer chamber pressure and temperature are measured with the temperature and pressure sensor at the bottom of the device. Temperature sensors T3 and T5 measure the temperatures of the aluminium load in the 3rd and 5th position from the top.
The total thermal storage capacity of the entire aluminium load is large enough to enforce condensation of steam during the entire sterilization process on the inner wall of the challenge tube as long as steam is present. NCGs present in the steam cannot condense and will accumulate in the top of the tube. The difference in thermo-conductivity and heat transfer of condensing steam and NCGs at the location of T3 and T5 enables discrimination between steam and NCGs.

15 and DPCD-3 is presented by the software graphically and numerically as temperatures and pressure only. Although the result of the «Temperature sensors difference» test is indicated by «Passed» or «Failed», the actual temperature difference nor the allowed temperature difference are reported.

Out of the 4 tested electronic devices only the 3M ETS 4108 detected all the sterilization conditions correctly. All results of the 3M ETS 4108 are in compliance with the Bowie and Dick tests as specified in the standard ISO11140-4.

From the internal temperature sensors T3 and T5 the rate at which the temperature increases is calculated and used to determine the thermo-conductive behaviour of the NCG sensor (figure 5). Data measured by the 3M ETS 4108 is presented by its software graphically and numerically. The diagnostic section of the software provides thermal conductivity information required to explain the result. The result is therefore based on the differences in physical properties of NCGs and steam.

Discussion

Surface steam sterilization conditions and time-temperature combinations are well described in literature, e. g., saturated steam at 134 °C for 3 minutes (12 – 15). The intention of a steam penetration test is to prove that steam sterilization conditions are established on all surfaces to be sterilized and, once established, the steam sterilization conditions are kept for a predetermined time. The final phase, the drying phase, should not contribute to the result of the penetration test. To be able to claim compliance with the standard for steam penetration tests requirements described in the ISO 11140 part 4 (11) must be met. Testing four commercially available electronic steam penetration test devices show that only one of the four tested devices fully meets the performance requirements as defined in this standard.

Differences in ergonomics, use and user-friendliness between the four tested devices and their software are not addressed in this study. These topics are not specified in the ISO 11140-4 and therefore not reported here.

In one test device the measurement principle or how the result is generated was unclear. Two of the test devices use a temperature difference between sensors to come to a result. In the standard ISO 11140-4 specific performance requirements are given. In the software coming with these devices additional tests are added based on EN 285 (10). The tests in the EN 285 have little or no relevance to the Bowie and Dick test. If the results from both standards are mixed incorrect results may be produced. This makes the result of these devices unclear and may introduce a false sense of safety as shown by the results. Penetration tests are meant to check if satisfactory steam sterilization conditions are established and kept for a predetermined period of time. Additional information may be useful but should be presented separately from the penetration test results to avoid confusion. Standards for steam sterilizers define a band width for sterilization temperatures (10) for steam sterilization processes but not for penetration tests. Parameters specified in the various process and product standards (1, 10, 11) are not necessarily the same and shall therefore not be mixed.

Within the actual operating conditions of a steam sterilization process the temperature of a gas mixture such as steam-air can vary strongly, depending on the amount of available energy and the time allowed for heating up. The number and characteristics of the evacuation and steam pulses used during the air removal phase preceding the sterilization phase determine the temperature reached by the gas mixture. In well-defined conditions a correlation can be found between temperature and pressure to predict if saturated or 100 % steam is present in the sterilizer. To do so, the sensors used have to fulfil specific requirements (14). E. g., according to the standard EN 285 (10) response time must be smaller than or equal to 0.5 s ($\tau_{90} \leq 0.5$ s). If a sensor is meeting the requirement but is in a device in contact with the mass of the device the responds time of the sensor will increase. With the increase of the responding time the requirements in the standard may not be met. Conclusions drawn from sensors not meeting the requirements may be wrong.

Conclusion

From the four devices tested only one device meets the performance requirements of the steam penetration ISO 11140 part 4. This is the only device that does detect NCGs which clearly shows that measurements of temperature and pressure only are insufficient to adequately detect fail conditions as specified in the standard for steam penetration. It can therefore be concluded that to fulfil the performance requirements for steam penetration tests with an electronic test device detection of NCGs is a necessity. ■

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