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Short report

Following trends in steam sterilizer performance by quantitative monitoring of non-condensable gases

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SUMMARY

Standards require a daily steam penetration test before starting production with a steam sterilizer. In many cases the results of steam penetration tests are not used for improvements or optimization of processes. This study aimed to detect whether trend analysis with an objective and quantifying steam penetration test has added value for the end-user. The databases of an objective quantifying steam penetration test, from the hospital and the manufacturer, are coupled and analysed. In this study, the databases included five steam sterilizers and approximately a four-year period. Based on the analysis, the process of the sterilizers was optimized. The results of the steam penetration tests became more stable over longer periods. This may result in lengthened periods between maintenance and validation. The analysis demonstrates that an objective, quantifying steam penetration test delivers more insights and knowledge of the functioning of the steam sterilization process. This knowledge may be used to optimize the process and reduce costs for the end-user.

Introduction

To ensure that steam penetration capacities of a steam sterilization process meet the standard ISO 17665 part 1 (clause 12.1.6), it is specified that 'a steam penetration test shall be carried out each day before the sterilizer is used' [1]. The rationale to perform a daily steam penetration test is that components of steam sterilizers may wear out over time or break down unexpectedly. Currently, many steam penetration tests are ink-based [2]. It is known that the visual interpretation of chemical indicators is highly subjective, depending on numerous factors such as ambient lighting, visual acuity and mental state of the observer. These factors together make reliable, accurate, objective interpretation very difficult [3]. Furthermore, a paper indicator sheet makes it difficult to recognize trends in the steam penetration capacities of the steam sterilizer process. Analysing trends in steam penetration results may be helpful to gain insights in the steam penetration capacities of the steam sterilizer, and to improve processes and procedures, such as planning maintenance of the sterilizer and reducing costs of usage.

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The current standard ISO 11140 part 4 for steam penetration specifies performance requirements for steam penetration in countries applying the European standards [4]. The specified requirements find their origin in the Bowie and Dick test, reported in 1963 [5]. The original Bowie and Dick test is a textile pack of huckaback towels (22×30 × 25 mm). Before loading it in a steam sterilizer for the test, a chemical indicator sheet is positioned, halfway. After the steam penetration test process, the colour change of the indicator must be 'uniform to visual observation' [6]. Performance requirements for alternative penetration tests are defined in the ISO 11140 part 4 [4]. To assess how a steam sterilizer is performing it is useful to analyse the acquired data of steam penetration tests over time. With an ink-based indicator this would be awkward, if not impossible. This is because a method has yet to be developed on how to objectively interpret the indicator sheets and record these data in a database. Therefore a 3M™ 4108 Electronic Test System (ETS) (Neuss, Düsseldorf, Germany) was used [2,7,8]. An ETS delivers an objective result and quantifies the steam penetration using a number. This number can be used for trend analyses.

Methods

The five steam sterilizers included in this study were Miele, type PS 5662 and located on the Central Sterile Supply Department (CSSD) of the Catharina Hospital (Eindhoven, The Netherlands). The sterilizers were periodically (yearly) validated to ensure compliance with the applicable standards [1,9].

The 3M 4108 and 4208 Electronic Test System (ETS) were used because they were the only steam penetration test devices that produce a quantifiable result and which have principles explained in the literature [7,9,10]. The results of the ETS measurements were downloaded using a reader (model 3M 4109) through the accompanying ETS software (software 3M 4110). In the ETS device a so-called 'Bowie and Dick value' (BD-value) was calculated. This value is correlated with and calibrated to the performance requirements as defined for steam penetration tests in the ISO 11140 part 4 [4]. This means that when the defined test pack for steam penetration indicates a fail result according to the standard, the ETS would also indicate a fail; and, when the original test pack indicates a pass result according to the standard, the ETS would indicate a pass [4]. This was captured in an algorithm which calculated the BD-value. When the BD-value was ≤0, the steam penetration was inadequate and the ETS indicated a fail result. If the BD-value was >0, the steam penetration was adequate and the ETS indicated a pass result. The higher the BD-value, the better the steam penetration of the process. Because the ETSs are individually calibrated, they are interchangeable.

The results generated by the ETS were exported to Matlab® (version R2014a) for data analyses. In the analyses of the data, the maintenance databases of the hospital and manufacturer were consulted to assess whether changes revealed by ETS could be explained.

Results

In Table I the BD-values of the steam penetration tests of the five steam sterilizers are presented. Overall the results showed that ∼0.7% of the steam penetration tests resulted in a failure. The number of 'no results' over the five sterilizers was ∼1.1%. This means that in ∼1.7% of the steam penetration tests performed, the sterilizer could not be immediately released for use. Before the release of the sterilizer, an action had to be taken. For example, a second steam penetration test had to be run or the responsible person had to specify why the sterilizer could be used.

Reasons for 'no results' were that the ETS was too warm to calculate a BD-value and that the ETS had not started correctly. The core temperature of the ETS had to be lower than 35°C before use in a steam penetration test. When the core temperature was higher, a 'no result' was presented. Another reason for a 'no result' was that the ETS was not switched on by the user before starting a steam penetration process or it was waiting too long in the sterilizer. This happened when the ETS was started but not used in a process within 10 min and hence entered a 'sleep' mode to save the battery. When the ETS was in a sleep mode (and not switched on), it would automatically start itself when the temperature of the ETS became higher than ∼65°C. The moment of switching on was frequently too late to calculate a valid BD-value, yielding a 'no result'. The majority of these latter results appear to be mistakes of the operator.

In Figure 1 the BD-values per sterilizer are presented. At the red and green vertical 'marker' lines, a change in the trend of the BD-values was noticed between the results before or after the line. With the use of the sterilizer maintenance databases of the hospital and the manufacturer, all the noted changes in trends could be explained (Table II). All the red lines are related to events on the sterilizer. The green lines indicate

Table I
'Bowie and Dick values' of the five sterilizers for an approximately four-year period (March 2012 until March 2016)

Sterilizer	No. of processes [a]	No. of passes [b]	No. of fails [c]	No. of 'no results' [d]	Total no. of 'no passes' [e]
1	1192	1176 (98.7%)	5 (0.4%)	11 (0.9%)	16 (1.3%)
2	1174	1155 (98.4%)	9 (0.8%)	10 (0.9%)	19 (1.6%)
3	1187	1169 (98.5%)	5 (0.4%)	13 (1.1%)	18 (1.5%)
4	1215	1189 (97.9%)	11 (0.9%)	15 (1.2%)	26 (2.1%)
5	1169	1144 (97.9%)	10 (0.9%)	15 (1.3%)	25 (2.1%)

[a] Total number of processes run in this period.
[b] Number of pass steam penetration tests.
[c] Number of failing steam penetration tests.
[d] Number of steam penetration tests without an ETS result.
[e] Number of results of steam penetration tests that cannot be used to release a sterilizer for use.

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