Parametric validation of steam sterilizers in Dutch hospitals

Working Party of Vereniging Deskundige Medische Hulpmiddelen
on validation of surface steam sterilisers[1]

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Summary

Within a Working Party of the Dutch association VDSMH the value of a (yearly) parametric validation of steam sterilizers for medical devices in health-care facilities according to the standard ISO 17665-1 was studied. To this end, a literature study was performed, followed by a survey of validation reports of 13 steam sterilizers over a period of 5 years. The trends in the validations of steam sterilizers indicated that the results of a parametric validation are predictable, as long as the combination of sterilizer, process, load, loading pattern and wrapping does not change. Monitoring of actual steam sterilization conditions in every load appears to provide better information than the current parametric validation regime.

Introduction

Surface steam sterilization is the most applied method for sterilization of medical instruments in health-care facilities such as hospitals. Conditions for surface steam sterilization conditions are specified in the literature [1–4]. According to the standards [5, 6] steam sterilization conditions of steam sterilizers should be assured by monitoring and validation. The status of the yearly validation of sterilizers in the Netherlands is reported in the public domain [7, 8].

Process monitoring and validation in the Netherlands are based on pressure and temperature measurements. However, the literature indicates that the steam quality of steam sterilization cannot be determined from pressure and temperature only and that steam quality and steam penetration varies between processes [9–11]. This raised the question within a Work Party of the Dutch association of experts on medical devices ('Vereniging van Deskundigen Steriele Medische Hulpmiddelen' [12]) if a periodic (yearly) validation based on pressure and temperature would be sufficient to ensure surface steam sterilization conditions in every process.

The success of a surface steam sterilization process depends on the combination of the sterilizer, process, load, loading pattern and the wrapping. All the sterilizers included in this survey need and are attached to facilities such as, the steam supply, vacuum system, compressed air, and water. The quality of these facilities influence the success of steam sterilization cycles. Therefore these facilities are regarded as part of the sterilizer during the validation activities.

The sterilization process is programmed in the controller of the sterilizer. Modern sterilizers are often controlled by pressure. The temperature, moist content and time are essential sterilization parameters. The pressure is not an essential parameter [1, 5, 6, 13]. Because the temperature is one of the essential sterilization parameters it is used to judge the sterilization process. More specific, the temperature is often used to judge the plateau period and holding time [5]. If the temperature criteria are not met, the process is aborted and the load is qualified as not sterile.

The loads to be processed are defined by the user of the sterilizer. In Dutch hospitals these loads consist mainly out of medical/surgical instruments. The loading patterns have to be described in procedures. These procedures should specify the position and orientation of medical instruments in a load [14–16]. The wrapping is the microbiological barrier to prevent recontamination after sterilization. This barrier can vary from crepe sheets to rigid containers.

The standards [5, 17] recommend a periodic validation program for surface steam sterilization. Even though the ISO 17665 series [6, 17] warns against it, in the Netherlands these standards are interpreted such that when the pressure and the temperature are measured, loads can be released based on these parameters [18]. The rationale behind this would be that the gas composition of a steam sterilization process can be determined from the pressure and temperature measurements. Not only in standards a warning against this interpretation, but it is also published in the literature that this interpretation is not correct [13, 19, 20]. More precisely, the literature states the theoretical relation between the pressure and the temperature can only be applied then and only then when 100 % water molecules are present. In steam sterilization processes it is likely that other gases (Non-Condensible Gases (NCGs)) will be present. For example, the standards EN285 [5] states:

> 'The sterilizer shall be designed to operate with saturated steam containing up to 3,5 ml non-condensible gases collected from 100 ml condensate when tested as described in 21.1'.

and other standards have similar phrases and specifications [6, 21]. Other sources that can induce the presence of NCGs in a sterilizer chamber can be bad air removal in the conditioning of the a process, or, a leak in the sterilizer system. As mentioned above the sterilizer system includes also the connected facilities. Because it is likely that NCGs are present in a steam sterilization process the term 'saturated steam sterilization' may lead to misinterpretation. As suggested in the title of the standard ISO17665-1 [6] in this manuscript the term 'Moist heat sterilization' is used instead of 'saturated steam sterilization'.

Further, the standards specify the allowed inaccuracies for the pressure, temperature and time measurements. This means that differences between cycles can

occur and that the conditions in a steam sterilizer of load, may not be reproducible, even when the values from the measurements meet the tolerances specified in the standards. For example, the measurement in a pressure switch points can be lower or higher because of hysteresis in the pressure sensor, or, the pressure sensor is sensitive for temperature (changes) . The temperature and the time to reach a vacuum state may vary. A longer conditioning phase may lead to a better steam penetration [9, 22]. Unfortunately, such differences between processes may lead to differences between conditions of the sterilization (plateau) period. This would make a parametric validation based on pressure and temperature merely a sample in time, with limited value to ensure the effectiveness and reproducibility of steam sterilization processes.

Methodology

Each hospital participating in the Working Party (section 'Working Party') submitted the results of the last five reported validations of one of the steam sterilizers located in their Central Sterile Supply Department (CSSD). To acquire a homogeneous dataset the survey was limited to tests that are specified in the standards [5, 6] and processes that are similar on all thirteen in this survey included sterilizers. This resulted in a dataset that consisting out of measurements of the 'air leakage test' [5], 'steam penetration test' [5] and the production processes at 134 and 121 °C. In this study all steam penetration tests are based on the 'Standard test pack' [5]. All used steam penetration tests claim to be compliance with the standard ISO 11140-4 [23].

In the Netherlands it is common practice to measure 0 % (empty load), 50 % and 100 % loads during the Performance Qualification (PQ), often called 'initial validation'. During the Performance re-Qualification (PrQ) or re-validation the 0 % load is used as a 'reference load' for the temperature mapping in a sterilizer chamber. The 0 % ('empty load') and 100 % ('full load') production processes were included in the dataset. Furthermore, the results of 'reproducibility', 'technical state' and the 'deviations' were collected as reported in the validation reports (table I). The resulting dataset was analyzed.

To collect data that could be compared, an example overview was provided to all participants. Based on this example the data of each individual sterilizer was submitted and added to the dataset.

Results

In total 13 sterilizers were included in this study and comprised the results of 64 validation reports (table I). For twelve sterilizers the validations appeared to be performed yearly, from 2013 to 2017. One sterilizer was taken into production in 2014. The results from the last four years of this sterilizer were included.

On all but one sterilizers the air leakage test [5] was performed. For one sterilizer (in 2016) it was reported that an air leakage test did not comply with the standards

[5] (table I). It was not reported what the reason for this deviation was or which corrective action was taken. As a result 59 out of 60 sterilizers (98 %) complied with the requirements for the air leakage test in the standards. This is despite the fact that for one sterilizer it was reported that the initial pressure was not below 7 kPa, as specified in the standards [5]. This issue was neither reported as a deviation nor reported as 'not compliant with the standards' in the validation report.

As mentioned above, all used steam penetration tests used during validation were based on the the textile test pack as specified in the standard [5, 24] and electronic alternative steam penetration tests claiming to fulfill the performance requirements in the applicable standard [23]. Because all used steam penetration tests claim similar performance requirements no distinction was made between tests. All reported steam penetration tests (100 %) complied with the standards [5, 6] (table I).

On all included sterilizers a 134 °C standard processes was installed. In the 134 °C standard production processes without a load (empty) 54 out of 58 processes (93 %) complied with the standards. In the four not compliant processes the 2 K or 3 K temperature bands [5] were exceeded. In the summaries of the validation report no corrective actions for these deviations were reported. Possibly corrective actions were taken and handled within the quality system of the hospitals. These quality systems were not within the scope of this study. With 100 % (or full) load, 55 out of 64 processes (86 %) complied with the standards. In eight (8/64) cases (13 %) the cause of not complying was a delay of the temperature in the channel of phaco hand-pieces. In one (1/64) case (1 %) it was slow warming up of polymer material.

In 2013 on 7 of the 12 (58 %) sterilizers a 121 °C standard production processes was installed. This number decreased to 5 out of 13 (39 %) sterilizers in 2017. For the 121 °C processes, 35/36 (97 %) of the empty loads complied with the standards and for the 100 % or full loads this number was 29/31 (94 %). Also here the reason for not complying with the standards was exceeding the temperature bands. In one case the temperature in a phaco hand piece entered the temperature band with a significant delay. The precise time was not included in the corresponding dataset. In the other case it was mentioned that the 3 K temperature band was exceeded [5]. No corrective actions were reported in the summary of the validation reports.

The above results reveal that 7 out of 13 (54 %) of the sterilizers did not show any deviations from the standards over the last five validations. In case a deviation was recognized, the cause of the deviation was known by the end-user of the sterilizer, e.g., deviations shown by measurements in phaco hand-pieces or in a medical instrument made of polymer material.

The reproducibility of the sterilizer was judged in 38 summaries. In all 38 (100 %) reports the sterilizer was judged to be 'reproducible'. It was not specified for which tests or production processes the reproducibility was assessed. In none of the validation reports it was exactly specified how the reproducibility was judged.

Checks of the 'technical state' of the sterilizer showed that 100 % of the reported recorder/registration printers, temperature displays and pressure displays complied with the standards. In the 'pressure registration' 62/64 (97 %) complied with the standards. In both cases which did not comply the cause was known. That is, one

deviation was caused by the installed software and in the other case the pressure was indicated 25 kPa too high.

The 'indicating pressure gauge' did not comply in 1 out of 61 (2 %) validations. According to the validation report this particular sterilizer did not have an indicating pressure gauge. If this sterilizer without indicating pressure gauge was not included, 100 % of the sterilizers would comply with this requirement. Overall, when all 'technical state' checks were included, 98 % of these checks complied with the standards. If the sterilizer without 'indicating pressure gauge' is not included 99 % of the checks would comply. All these deviations of the standards appeared to be known deviations by the 'owner' of the sterilizer before the validation was started.

In 47 out of 50 reports (94 %) the summary in the validation report included a section that reported deviations from the standards. In 14/50 summaries (28 %) no section about deviations was present, possibly because no deviations were recognized during these validations. In 11 out of the 47 (23 %) summaries corrective actions for the deviations were reported. The proposed actions for correction were addressed in different ways and varied from a documented explanation why a standard was not fulfilled to re-calibration of sensors.

In all summaries of the validations it was advised to perform the next validation within one year without giving an explicit reason or explanation. The informative guide [17] of the standard ISO 17665-1 [6] indicates for example that a yearly re-qualification may be applied. However this is not a mandatory period of time. In the discussion and interviews within the working party it became clear that some hospitals plan a yearly validation after major maintenance of a sterilizer. However, it was also shared that major maintenance was performed twice a year, whereas the validation was performed only once a year.

A closer inspection of the results over the last five validations of each sterilizer indicates that when the combination of the steam sterilizer, process, load, loading pattern and wrapping was not changed, the result of the validation did not change either.

Discussion

The trend over a five year period of 12 sterilizers and a four year period of one sterilizer demonstrates that the result of a validation can be predicted as long as the combination of the sterilizer, process, load, loading pattern and wrapping is not changed. This indicates that as long as this combination is not changed the time between successive validations can be increased. Also the standards [6, 17] do not specify a yearly validation (Performance (re-) Qualification). Only when one or more components of a combination of a sterilizer, process, load, loading pattern or wrapping combination are changed, a mapping of the temperature in the load could have added value.

In the cases that a deviation from the standards [5, 6] was recognized during a validation the deviation was known to the 'owner' of the sterilizer before the valida-

year of validation		2017	2016	2015	2014	2013
number of sterilisers		13	13	13	13	12
performed measurement	criteria					
air leakage test	EN 285	12/12	11/12	12/12	12/12	12/12
steam penetration test	EN 285	13/13	13/13	13/13	13/13	13/13
134 °C standard process empty	ISO 17665	11/12	11/12	11/12	12/12	9/10
134 °C standard process 100 % load	ISO 17665	10/13	12/13	9/13	12/13	12/12
121 °C standard process empty	ISO 17665	6/6	7/7	6/7	8/8	8/8
121 °C standard process 100 % load	ISO 17665	5/5	6/6	4/6	7/7	7/7
reproducibility	-	9/9	9/9	7/7	7/7	7/7
technical state of the steriliser	criteria					
recorder/registration printer	EN285	13/13	13/13	13/13	13/13	12/12
temperature registration	EN285	13/13	13/13	11/13	13/13	12/12
pressure registration	EN285	13/13	13/13	12/13	13/13	12/12
temperature display	EN285	13/13	13/13	13/13	13/13	12/12
pressure display	EN285	13/13	13/13	13/13	13/13	12/12
indicating pressure gauge	EN285	12/13	12/13	11/12	11/12	10/11
reports reporting deviation		10	10	10	10	10
reported deviations in summary		9	13	9	15	1
proposed reported actions		2	1	4	3	1

Table I: Categorized validation results of 13 steam sterilizers. In total 64 validation reports are included. Results of the tests and processes are denoted by (number of results complying with the standards)/(total number of results).

tion. Examples are a pressure gauge which was indicating too high and temperature deviations in phaco hand-pieces. Hardware issues such as malfunctioning pressure gauges could be avoided by replacing the gauge. In case of issues with phaco hand-pieces the process could be adjusted [10].

In parametric validations, measurements of pressure and temperature only are not sufficient to determine the composition of the gas present in the steam sterilizer [19, 20]. Implicitly, it cannot be judged if steam sterilization conditions as specified in the literature [1] and standards [5] are met. Therefore it is recommended that when a validation is performed the gas composition in the steam sterilizer chamber is measured, as well [10]. Furthermore, literature demonstrates that the steam content between processes [11] varies. Therefore, it is advised to measure the actual steam sterilization conditions in every process.

Methods to qualify the sterilization conditions are commercially available, e.g.,

measurements of the amount of NCGs in the sterilizer chamber [11]. Examples of available methods are measuring the steam penetration of a process in a challenge tube [25] and measuring the biological killing in an evidence based PCD. These methods, together with measurements of the temperature and time of a sterilization process, would provide a better way to ensure steam sterilization conditions in individual steam sterilization processes.

The fact that twice per year major maintenance is performed on sterilizers, whereas only once a year a validation is carried out, indicates that validation after maintenance would not be necessary if the functioning of the sterilizer could be adequately verified after maintenance. If the essential parameters (actual steam sterilization conditions) are similar to those before the maintenance, complete validation has no added value. It should be considered to use the results of the validations to determine an adequate period between subsequent validations. The underlying analyses and motivation for this period should be given in the validation report. It should be kept in mind that as long as the combination of sterilizer, process, load, loading pattern and wrapping do not change and in every load the essential sterilization parameters (sterilization conditions) can be demonstrated, a validation (PrQ) is not necessary.

Conclusion

When adequate every load monitoring is performed, validation is only necessary when the sterilizer, process, load, loading pattern or wrapping is changed. It is advised to measure actual steam sterilization conditions in every process.

Working Party

The 'Vereniging Deskundigen Steriele Medische Hulpmiddelen in Nederlandse Ziekenhuizen' is the 'association of experts on sterile medical devices in hospitals' in the Netherlands (`https://www.vdsmh.nl/`). Participants of the Working Group contributing to this manuscript are in alphabetic order on the last name:
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