Steam sterilisation according to EN 285:2015

Article *in* Zentralsterilisation - Central Service · February 2020

CITATION
1

READS
9,783

6 authors, including:

JPCM Van Doornmalen
Eindhoven University of Technology
38 PUBLICATIONS **205** CITATIONS
SEE PROFILE

Ralph van Wezel
Catharina Ziekenhuis
12 PUBLICATIONS **66** CITATIONS
SEE PROFILE

Thomas Onsea
Ziekenhuis Netwerk Antwerpen
1 PUBLICATION **1** CITATION
SEE PROFILE

Harry Oussoren
Amsterdam UMC locatie AMC
8 PUBLICATIONS **75** CITATIONS
SEE PROFILE

Steam sterilisation criteria according to EN 285:2015

J.P.C.M. van Doornmalen Gomez Hoyos[1,2,3,*], R.A.C. van Wezel[3], T. Onsea[4,5], H. Oussoren[6,7], K. Henrotin[4,8], K. Kopinga[1]

[1] Eindhoven University of Technology, PO Box 513, 5600 MB Eindhoven, The Netherlands, [2] Steelco S.p.A, Via Balegante, 27, 31039 Riese Pio X (TV), Italy, [3] Catharina Hospital, Michelangelolaan 2, 5623 EJ Eindhoven, The Netherlands, [4] VSZ (Flemish Association for Decontamination of Medical Devices in Hospitals), [5] Hospital Network of Antwerp (ZNA), Leopoldstraat 26, 2000 Antwerp, Belgium, [6] VDSMH (Dutch Association of Experts of Sterile Medical Devices), [7] Academic Medical Centre, Postbus 22660, 1100 DD Amsterdam Zuidoost, The Netherlands, [8] Ghent University Hospital, C. Heymanslaan 10, 9000 Gent, Belgium

Summary

Background: Steam sterilisation conditions are not unambiguously quantified in the literature and standards. In practical situations, it would be helpful if a set of criteria to assess the actual surface steam sterilisation conditions would be available.

Aim: To define numerically quantified steam sterilisation conditions based on the literature and standards. This means that the combinations of temperature, water vapour fraction, and time are specified in terms of numerical values, including their possible inaccuracies.

Methodology: A review of the literature and standards is performed. Results from this review, combined with basic physical calculations, are used to determine numerically quantified steam sterilisation conditions.

Results: Steam sterilisation conditions can be specified in terms of quantified physical parameters. For example, to comply with European standard EN 285:2015 these parameters are a holding time of 3 minutes or more, at measured temperatures between 134.5 and 136.5 °C, and a minimum water vapour fraction depending on load temperature and pressure.

Conclusion: The standard EN 285:2015 allows parameter regions where sterilisation conditions are not met, even in the absence of non-condensable gases. If the inaccuracies in the temperature measurements are properly taken into account and the water vapour fraction is measured, sterilization conditions can be guaranteed.

Introduction

In most healthcare facilities steam sterilisation is used to sterilise medical devices. The literature [1] specifies steam sterilisation conditions in terms of time-temperature combinations (table I) based on sterilisation of aqueous liquids [2, 3]. It was already recognised by the Medical Research Council [1] that the steam is not necessarily saturated, e.g.:

'To allow for deviations in steam quality a further (safety) period is added'.

The standards for steam sterilisation specify similar time-temperature combinations and allow a small amount of non-condensable gases (NCGs) in the supplied steam [4, 5]. For example, clause 13.3.1 of the standard EN 285:2015 [5] reads:

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

This corresponds to a fraction of less than 0.01% in the gas-steam mixture supplied to the steriliser chamber. However, the actual amount of non-condensable gases in the steriliser chamber may be higher than that in the supplied steam. This may be caused, for instance, by residual NCGs in loads, insufficient evacuation of the steriliser chamber prior to steam inlet, or leaks in gaskets or valves.

The standard EN285:2015 [5] refers to the so-called 'theoretical temperature' (T_p). This T_p is calculated from the measured pressure using the liquid-vapour phase diagram of water, e.g., tab-

Keywords
- steam sterilization
- EN 285
- non-condensable gases

Corresponding author:
Josephus P.C.M. van Doornmalen Gomez Hoyos
Eindhoven University of Technology, PO Box 513,
5600 MB Eindhoven,
The Netherlands

j.p.c.m.v.doornmalen@tue.nl

Conflict of interest:
All authors confirm that there is no conflict of interest according to the guidelines of the International Committee of Medical Journal editors (ICMJE).

Citation:
van Doornmalen Gomez Hoyos JPCM, van Wezel RAC, Onsea T, Oussoren H, Henrotin K, Kopinga K. Steam sterilisation criteria according to EN 285:2015. Zentr Steril 2020; 28 (1): 51–54

Manuscript data:
Submitted 28 August 2019
Revised version accepted:
7 November 2019

ulated data for saturated steam [6, 7]. However, when other gases than water vapour can be present, this theoretical temperature does not provide unambiguous information on the steam properties. As a consequence, steam sterilisation conditions cannot be determined from pressure and temperature measurements only [8]. For example, in some part of the pressure and temperature region allowed by the standards [5], sterilisation conditions can be met for water vapour fractions as low as 92% [9]. It is also reported [10, 11] that each steriliser process is a unique event, which cannot be assumed to be fully reproducible. These observations trigger the question for which water vapour fractions steam sterilisation conditions can still be claimed. This point will be addressed in the present study.

Methodology

A literature study was performed to search for quantification of the water vapour fraction (f_v) or, alternatively, the fraction of NCGs ($f_{NCG} = 1\text{-}f_v$) in sterilization processes. No useful numbers could be found for these parameters. Therefore, the standard EN 285:2015 [5], basic physical laws and the saturated steam tables from the National Institute for Standards and Technology (NIST, e.g., [6]) are used to numerically quantify the steam sterilisation conditions. This includes the maximum fraction of NCGs that may be present.

In the literature it has been shown [12] that using the criteria specified in the standard EN 285:2015 [5], including the allowed inaccuracies in the measurements of pressure and temperature, sterilisation conditions cannot always be guaranteed. Nevertheless, temperature regions have been identified where these conditions can be met. In that paper the effect of the presence of NCGs has not been quantified. Below we will present a calculation based on the temperature tolerance bands specified in the standard EN 285:2015 and basic physical gas laws, which includes the effect of NCGs.

Results

No experimental inaccuracies

First a (hypothetical) situation without any inaccuracies in the measured pressure and temperatures will be considered.

The relevant criteria specified in the standard EN 285:2015 [5] are:

- The temperature band within the holding phase should not exceed 2 K (which equals 2 °C), e.g., clauses 8.2.1.2.2 and 8.2.1.2.3. This defines the temperatures in a steriliser during the holding phase as:
$$T_{low} \leq T_c \leq T_{low} + 2, \quad (1)$$
with T_{low} the lowest temperature in the steriliser chamber [°C] and T_c the temperature at an arbitrary point in the chamber [°C]. The theoretical temperature T_p, calculated from the pressure in the steriliser chamber, should be considered as one of the temperatures T_c.
- The sterilization temperature band should have a lower limit defined by the sterilization temperature (T_{ster}) and an upper limit of T_{ster} + 3 °C (clause 8.2.1.1).

This results in the following temperature criteria for the sterilisation phase:
$$T_{ster} \leq T_c \leq T_{ster} + 3\ °C \quad (2)$$

For example, for a 121 °C sterilisation process these criteria are 121 °C ≤ T_c ≤ 124 °C and for a 134 °C process 134 °C ≤ T_c ≤ 137 °C.

During a steam sterilisation process, the load will be effectively warmed up by condensation of steam (water vapour), since the heat transferred to the load by a non-condensing vapour is negligible. At the start of the sterilisation phase, the load has just been warmed up and a liquid film will be present on the surface. If the temperature of the load (T_l) is equal or larger than T_{ster}, the sterilisation conditions are met at that moment in time. According to the standards, the theoretical temperature T_p should satisfy equations 1 and 2. If the theoretical temperature is higher than the temperature of the load ($T_p > T_l$), the pressure in the sterilizer chamber is larger than that corresponding to T_{ster}. In principle, this may be caused by supersaturated steam [12], but also by the presence of NCGs. This point will now be addressed in more detail.

The physical law for the total gas pressure (p_{tot}) reads that the total pressure equals the sum of the partial pressures (p_i) of all gases that are present:

$$p_{tot} = \sum_i^N p_i = p_1 + p_2 + p_3,\ldots,p_N. \quad (3)$$

For steam sterilisation this can be written as:

$$p_{tot} = p_v + p_{NCG}. \quad (4)$$

In the latter equation p_v denotes the partial pressure of water vapour [kPa] and p_{NCG} the partial pressure of non-condensable gases [kPa]. As long as p_v is higher than or equal to the saturated steam pressure corresponding to T_l, the surface of the load will be wet. In a (rather extreme) case allowed by the standard, the temperature of the load equals T_{ster} and the theoretical temperature equals T_{ster} + 2 °C. If this difference is due to the presence of NCGs, the partial pressures are given by p_v = 304.23 kPa and p_{tot} = 322.45 kPa for a 134 °C process [6]. The water vapour fraction f_v is given by

$$f_v = \frac{p_v}{p_{tot}} \quad (5)$$

which yields for the present case f_v = 304.23/322.45 = 0.943 = 94.3%. This example shows that within the temperature tolerance bands specified in the standard EN 285:2015 [5] sterilisation conditions can be met in the presence of substantial amounts of NCGs. However, it also shows that the theoretical temperature T_p, which is obtained from p_{tot}, not only depends on the saturated steam temperature, but also on the fraction of NCGs. Therefore, T_p cannot be used to assess the steam quality and, consequently, the sterilisation conditions.

This point can be illustrated by a situation similar to the example discussed above, where the load has been warmed up to, for instance, T_{ster} + 0.5 °C at the start of the sterilisation phase. It is now assumed that some NCGs are introduced in the steriliser chamber during the holding phase by, for instance, a leaking valve. In a steriliser which is controlled by pressure, this will have no effect on p_{tot} and, consequently, the theoretical temperature T_p. However, the partial pressure of water vapour p_v will decrease, causing the water film which is present on the load to evaporate. In principle, this evaporation may cause a decrease of the temperature of the load T_l. However, except in situations where the load temperature is measured in detail, for instance, during a validation of the steriliser, this effect will not be

detected. As soon as the water film has evaporated sterilisation conditions are no longer met, although all temperatures T_c still comply with the standard.

With experimental inaccuracies

Next the inaccuracies in the measured pressure and temperatures will be included. The standard EN285:2015 allows inaccuracies in the temperature measurements up to 0.5 °C, e.g., clauses 6.4.2 e), 23.3.3.2.1 e), and 23.3.4.1.2. This means that the actual temperatures T_c may be up to 0.5 °C higher or lower than the measured temperatures. Consequently, the temperature band of the actual temperatures T_c, including the theoretical temperature, increases from 2 °C to 3 °C. The allowed inaccuracy of the theoretical temperature T_p, expressed in terms of a pressure variation, amounts to about 9 kPa. This can be illustrated by the following example, where the temperature set point of the sterilisation phase is chosen equal to 135 °C. The measurement inaccuracy of the temperature is 0.5 °C. In that case the actual temperature might be as low as 134.5 °C, which corresponds to a saturated steam pressure of 308.7 kPa [6, 7], whereas it might also be as high as 135.5 °C, corresponding to 317.8 kPa [6,7]. The corresponding difference in pressure is 317.8 – 308.7 kPa = 9.1 kPa. Since generally the inaccuracy of the pressure measurement amounts to 1 or 2 kPa, this will not be considered as a separate error source, but included in the inaccuracy of T_p.

If the temperature set point is chosen equal to 134.5 °C, the actual temperature of the load T_l may be as low as T_{ster} and the actual theoretical temperature may be as high as T_{ster} +3 °C. If this difference is due to the presence of NCGs, the pressures in equation 4 are given by p_v = 304.23 kPa and p_{tot} = 331.88 kPa for this 134 °C process [6]. The water vapour fraction f_v equals 91.7%. For a 121 °C process, the water vapour fraction may be as low as 91.1%. These limits are included in table 1, together with those for a 126 °C process.

To obtain a translation of the criteria specified in the standard [5], which can be used in practical situations to assess the sterilisation conditions, a 134 °C process will be considered. If all measured temperatures (T_m) in the sterilizer chamber and the theoretical temperature T_p are equal within the inaccuracy allowed by the standard (0.5 °C), no NCGs should be present to ensure sterilisation conditions. Note that in this case the actual load temperature may be as high as 135 °C. This corresponds to a partial vapour pressure of 313.23 kPa. If in such a situation the theoretical temperature (T_p) equals the maximum limit (136.5 °C), and also for this parameter an inaccuracy of 0.5 °C is used, the minimum value of p_{tot} equals 322.45 kPa (136 °C). In that case, the fraction of NCGs may be as high as 2.9% without impairing sterilisation conditions. For intermediate temperatures, the maximum fraction of NCGs can be calculated with sufficient accuracy by linear interpolation, i.e.,

$$f_{NCG} = f_{max} \times (T_p - T_m) = 2.9 \times (T_p - T_m). \quad (6)$$

It has to be noted that this equation is only valid if the temperature of the load is within the range of the measured temperatures T_m. Preferably, a temperature which is representative for the load should be used in this equation instead of T_m. In practice, this should be the reference temperature of the steriliser. For other sterilisation temperatures the corresponding value of f_{max} has to be used.

Discussion

The results shown above demonstrate that steam sterilisation conditions can be specified in terms of quantified physical parameters. For example, to comply with European standard EN 285:2015 [5] and to ensure sterilisation conditions, these parameters are a holding time of 3 minutes or more, at measured temperatures between 134.5 and 136.5 °C, and a water vapour fraction between 97% and 100%, depending on load temperature and pressure. One should note that this standard includes parameter regions where sterilisation conditions are not met, even in the absence of non-condensable gases [12]. If, however, the inaccuracies in the temperature measurements are properly taken into account and the water vapour fraction is measured, sterilization conditions can be guaranteed. In some specific cases the steam composition may not be exactly known, for example, water droplets might be present in the steam. In these cases, it may be helpful to use the maximum allowed amount of NCGs instead of the minimum water vapour fraction.

In a steam sterilisation process the temperature has to comply with the

Table 1: Parameters of three common steam sterilisation processes of medical devices. The first two columns show the time-temperature combinations advised by the 'Working Party on Pressure Steam Sterilizers of the Medical Research Council' [1], based on the findings of Precht [2] and Perkins [3]. In these combinations it is assumed that 'sufficient' water vapour is present. In the third and fourth column the minimum water vapour fraction (f_v) and maximum fraction of non-condensable gases (f_{NCG}) allowed by the standard EN 285 [5] are shown. The values between brackets are rounded numbers. These limiting fractions will generally not yield sterilisation conditions, as explained in the text.

T [minutes] [a]	T [°C] [a]	f_v [%] [a]	f_{NCG} [%] [b]
3	134	91.7 (92)	8.3 (8)
10	126	91.3 (91)	8.7 (9)
15	121	91.1 (91)	8.9 (9)

[a] Minimum value, [b] Maximum value

temperature criteria, e.g., equations 1 and 2. These requirements have to be met on all locations which have to be sterilised. This also holds for the minimum water vapour fraction f_v. These requirements include the locations in porous loads and the inner surfaces of medical devices. Especially in channelled devices, steam penetration may be difficult. This issue has been the subject of various studies (see, for instance, [13, 14]) and is beyond the scope of the present paper.

One might argue that in order to account for the accidental presence of NCGs in the steriliser chamber, the pressure should always be set at a 'safe level' close to the maximum pressure derived above, for instance, 327 kPa for a 134 °C process. Indeed, for NCGs which are present in the steriliser chamber just before the start of the sterilisation phase, e.g., because of bad air removal, this approach may be useful. It has the drawback that in the absence of NCGs the load temperature is 2 °C higher than necessary, which will require additional energy and reduces the lifetime of delicate medical devices. More important, however, is the fact that also in this case NCGs may be introduced in the steriliser chamber after the start of the sterilisation phase. These NCGs may cause the sterilisation conditions to be no longer satisfied. This problem can only be solved properly by measuring the water fraction or, alternatively, the amount of NCGs during every process run in a steriliser.

Conclusion

Based on the literature and the standards the steam sterilisation conditions for surfaces can be specified in terms of a sterilisation time and a range of temperatures (T) and water vapour fractions (f_v). The standard EN 285:2015 allows parameter regions where sterilisation conditions are not met, even in the absence of non-condensable gases. If the inaccuracies in the temperature measurements are properly taken into account and the water vapour fraction is measured, sterilization conditions can be guaranteed, according to the standards [5]. To claim sterilization these (T–f_v) combinations have to be present throughout the load to be sterilised during the entire holding time.

References

1 Working party on Pressure Steam Sterilizers of the Medical Research Council. Sterilisation by steam under increased pressure. The Lancet 1959; 273:425–435.

2 Precht JCH. Temperatur und Leben. Springer Verlag, Berlin, 1955.

3 Perkins JJ. Principles and Methods of Sterilization. Charles C Thomas, Springfield (IL), 1956.

4 Standard ANSI/AAMI ST79. Association for the Advancement of Medical Instrumentation/American National Standards Institute: Comprehensive guide to steam sterilizations and sterility assurance in health care facilities, 2017.

5 Standard EN 285. European Committee for Standardization: Sterilization – Steam sterilizers – large sterilizers, 2015.

6 National Institute of Standards and Technology (NIST). Saturated Steam Table 120 to 141.5 °C. https://webbook.nist.gov/cgi/fluid.cgi?Action=Load&ID=C7732185&Type=SatP&Digits=5&THigh=143&TLow=120&TInc=.5&RefState=DEF&TUnit=C&PUnit=bar&DUnit=mol%2Fl&HUnit=kJ%2Fmol&WUnit=m%2Fs&VisUnit=uPa*s&STUnit=N%2Fm#Vapor, last assessed: 08-08-2019.

7 International Association for the Properties of Water and Steam. http://www.iapws.org/, last assessed: 08-08-2019.

8 van Doornmalen JPCM, Tessarolo F, and Kopinga K. Measurements of only pressure and temperature are insufficient to monitor steam sterilization processes: a case study. Zentr Steril 2014; 4: 250–253.

9 Doornmalen JPCM, Paunovic A, and Kopinga K. Steam sterilisation does not require saturated steam. J Hosp Inf 2017; 97(4): 331–332.

10 Lapanaitas N and van Doornmalen Gomez Hoyos JPCM. Case study: Correlation between the duration of a steam sterilisation, process and the weight of the processed, load. Zentr Steril, 2018; 26 (4): 225–230.

11 van Wezel RAC, van Gastel A, de Raniitz A, and van Doornmalen JPCM. Following trends in steam sterilizer performance by quantitative monitoring of non-condensable gases. J Hosp Inf 2017; 97(4): 357–362.

12 van Doornmalen JPCM and K Kopinga. Review of steam sterilization for validation purposes. Am J Inf Control, 2008; 36: 86–92.

13 van Doornmalen JPCM, Verschueren M, and Kopinga K. Penetration of water vapour into narrow channels during steam sterilization processes. J Physics D Applied Physics 2013; 46: 065201+7.

14 van Wezel RAC, van Doornmalen HWJM, de Geus J, Rutten S, and van Doornmalen JPCM. Second case study on the orientation of phaco hand pieces during steam sterilization. J Hosp Inf 2016; 94(2): 194–197, 2016.

Symbols and abbreviations

$f_{NCG,max}$	%	Maximum fraction of NCGs
f_{ncg}	%	Non condensable gas fraction
f_v	%	Water vapour fraction
i	-	The i-th gas in the gas present in a sterilizer chamber
N	-	Total number of present gases
NCG	-	Non condensable gas
p	kPa	Pressure
p_i	kPa	Partial pressure of the i-th gas
p_{NCG}	kPa	Non condensable gas pressure
p_v	kPa	Water vapour pressure
p_{tot}	kPa	Total gas pressure
T	°C	Temperature
T_m	°C	Temperature measured in the steriliser chamber (often the reference temperature)
T_{max}	°C	Maximum temperature limit using inaccuracies and the theoretical temperature
T_{min}	°C	Minimum temperature limit using inaccuracies and the theoretical temperature
T_{low}	°C	Lowest temperature in the sterilizer chamber
T_p	°C	Temperature calculated from the total pressure (theoretical temperature)
T_{ster}	°C	Aimed sterilization temperature, e.g., 134 °C