Short report:

The theoretical temperature introduces a false sense of safety in steam sterilization

Introduction

After a new method for parametric release of steam sterilized loads [1] was introduced in the Catharina Hospital in Eindhoven (NL), it was not clear why the pressure was still used. Further research on this topic is described in this white paper. The results of this research have far-reaching consequences, in the sense that they show that the pressure and the theoretical temperature calculated from this pressure should not be used as sterilization parameters and even introduce a false sense of safety.

The consequences of these results are even more dramatic. They reveal that the conditions at which chemical and biological indicators (CIs and BIs) are developed and tested cannot be guaranteed. Consequently, also the accuracy of these CIs and BIs cannot be guaranteed.

Method

The use of the pressure as a steam sterilization parameter has been investigated by means of a study of the relevant literature [2-5]. The results of this research are used in the derivation given below.

The results also showed that it is necessary to identify methods to determine the steam composition in the sterilizer chamber during a steam sterilization process.

Result

In steam sterilization the 'theoretical temperature' is calculated from the measured pressure p_{tot} [5]. If this theoretical relation is used to determine the temperature from the pressure, no other gases than water vapour should be present [2-4].

The derivation proceeds as follows:

- The total pressure (p_{tot}, [kPa]) in a vessel (sterilizer chamber) can be determined by adding together the partial pressures of the gases which are present:

$$p_{tot} = \sum p_i \qquad (1)$$

  where p_i is the partial pressure [kPa] of each individual gas.
- In a steam sterilizer with water vapour (wv) and Non Condensing Gasses (NCGs) this means:

$$p_{tot} = p_{wv} + p_{NCGs} \qquad (2)$$

- The general gas law can be written as:

$$pV = nRT \qquad (3)$$

  with V the volume [m^3], n the number of molecules [mol] en R the gas constant [J/(K· mol)].

- By combining equations (2) and (3) the pressure in a steriliser chamber can be written as:

$$p_{tot}V = n_{wd}R_{wv}T + n_{NCGs}R_{NCGs}T \qquad (4)$$

- Physical quantities which can be measured or found in the literature or via internet are marked by a red colour in the following equation (5):

$$p_{tot}V = n_{wv}R_{wv}T + n_{NCGs}R_{NCGs}T \qquad (5)$$

- If only pressure and temperature are measured, two quantities (n_{wv} and n_{NCGs}) are unknown.
- According to mathematics one equation with two unknown variables cannot be solved.

Because of the two unknown variables in equation (5) more gases than only water vapour can be present without any change of the temperature and pressure. Therefore, with only measurements of pressure and temperature the steam composition in a sterilizer chamber cannot be determined.

At least three methods have been identified which can be used to measure the steam composition in the sterilizer chamber during a sterilization process. The results of these methods can be compared with the relevant criteria, for example the criteria given in the standards [5]. Because these methods are commercially available, they will not be explained here any further.

Discussion

It has been shown that using a theoretical temperature calculated from the measured pressure makes no sense in steam sterilization. Therefore, pressure and temperature measurements cannot be used to determine the steam composition during a steam sterilization process. In practice, however, this is done in parametric release and parametric validation. In this way, using a theoretical temperature introduces a false sense of safety.

The fact that measurements of pressure and temperature alone are not sufficient has dramatic consequences for, amongst others, chemical and biological indicators used for steam sterilization. Nowadays, the test vessels (test sterilizers) for these indicators are controlled using pressure and temperature measurements. The theoretical temperature calculated from the measured pressure is used to determine the steam composition. Because this is not possible, it is not known at which steam sterilization conditions the chemical and biological indicators (CIs and BIs) [7-12] have been developed and tested. Because the traditional Bowie and Dick tests are based on chemical indicators [7-12], this also holds for Bowie and Dick tests.

Because the air detectors as specified in the standards [5] are based on measurements of the pressure and/or the temperature of the gas present in a ‘challenge tube’, also these detectors cannot give unambiguous information about the steam composition.

Conclusion

Pressure and temperature measurements alone cannot be used to determine the steam composition during a steam sterilization process. Using a theoretical temperature calculated from the pressure suggests that the steam composition can be determined from measurements of the pressure and temperature. In this way, a false sense of safety is introduced in steam sterilization.

Because the theoretical temperature is also frequently used during the testing and development of CIs and BIs, the accuracy of CIs and BIs cannot be guaranteed. This also holds for the Bowie and Dick tests and air detectors which are commercially available.

Methods have been identified which can be used to measure the steam composition during each steam sterilization process. Combined with temperature measurements, these methods offer the possibility to determine the actual steam sterilization conditions.

References

[1] van Kemenade D, Janse-van Dinter K, Siep C, Martens D. Nieuwe methode van parametrische vrijgave voor stoomsterilisatie, white paper 23-04-2021.

[2] Irvine TF Jr and Liley PE. Steam and gas tables with computer equations. Academic press, Inc., Boca Raton (FL), 1984.

[3] http://www.iapws.org/, laatste website bezoek 23-07-2021.

[4] https://webbook.nist.gov/chemistry/fluid/, laatste website bezoek 23-07-2021.

[5] Standard EN285:2015 Sterilization - Steam sterilizers - Large sterilizers.

[6] Standard ISO 11138-1:2017: Sterilization of health care products—Biological indicators—Part 1: General requirements.

[7] ISO 11138-3:2017: Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes.

[8] Standard ISO11140-3:2007 Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test.

[9] Standard ISO11140-4:2007: Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to Bowie and Dick test for detection of steam penetration.

[10] Standard 11140-5:2007 (R2012): Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.

[11] Standard ISO/DIS 11140-6: Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers.

[12] Standard EN 867-5:2001 Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S.