Short report:

A new parametric release method for steam sterilization

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Introduction

The literature and authorities in the field of steam have shown that the gas composition of steam cannot be determined by measuring pressure and temperature [1,2,3]. This also applies to the steam used in steam sterilization [4]. In addition, the literature shows that every steam sterilization process is a unique event and that steam composition is different in every process [5,6]. Given these data, it appears that load release protocols based on pressure and temperature measurement are insufficient to release loads after steam sterilization if the applicable standards are to be met [7,8]. This limits patient safety. The Catharina Hospital has therefore developed a parametric release protocol with which the sterilization conditions as specified in the applicable standards [7,8] can be monitored in every process.

To make parametric release possible, it was necessary to identify the criteria for essential parameters for steam sterilization according to the standard [7] and then find a method to measure them. The temperature and pressure can already be measured using existing measurements methods. A method had to be found to measure the steam composition in the sterilizer chamber and in every process. To this end, a method has been identified with which the steam composition can be measured in addition to temperature and pressure.

When Non-Condensing Gases (NCGs) can be identified in steam, the composition of the steam can also be identified. This means that all the essential parameters for steam sterilization can be tested against the standard [7] and patient safety can be increased.

Method

The essential parameters for steam sterilization are described in the literature [9,10]. In the 1950s and 1960s these parameters were converted to standards. These criteria are still included in the current standards [7]. When the standard EN285: 2015 [7] is used, the steam sterilization conditions in the sterilization chamber can be described as follows:

$$\begin{cases} 134\ °C \leq T_{chamber} \leq 137\ °C \\ |\Delta T_{chamber}| \leq 2\ °C \\ 304\ \text{kPa} \leq p_{chamber} \leq 332\ \text{kPa} \\ \text{NCG}_{chamber} \leq 3.5\ \% \\ t \geq 180\ \text{s} \end{cases} \quad (1)$$

Sterilizer:	CZE-2			
NCG serial number	402			
Period	from	7-5-2020	to	16-4-2021

		cause of alert	
Air leakage test	96	*t*	*p*
pass	96		
conditional	1	0	1
fail	4	0	4

		cause of alert				
Steam penetration test	processes	*t*	*p*	*T*	ΔT	NCGs
Pass:	217					
Conditional:	11	0	0	0	0	11
Fail:	4	0	0	2	2	4

		cause of alert				
134 °C standard process	processes	*t*	*p*	*T*	ΔT	NCGs
Pass:	1565					
Conditional:	70	0	0	0	0	72
Fail:	20	0	0	3	3	18

Table 1: Summary of the results of sterilizer CZE-2 at the CSSD of the Catharina Hospital, in the period 07-05-2020 to 16-04-2021. The tables indicate how many "pass", "conditional" and "fail" processes were run per process in this period. A 'pass' process is defined as a process that meets the criteria in the standard [7], a 'conditional' is defined as satisfying the standard but falls within the specified measurement accuracy of the criteria as specified in the standard [7], and a ' fail' process is defined as a process that does not meet the criteria standard [7]. "Cause of alert" indicates the cause of the deviation from the standard. In the table:

t stands for the time,
p for the pressure,
T for the temperature,
ΔT for the instantaneous temperature band (difference between the measured T and the theoretical temperature calculated from the pressure), and,
'NCGs' the amount of NCGs.

Where $T_{chamber}$ is the temperature, $p_{chamber}$ is the pressure and $NCG_{chamber}$ is the amount of Non-Condensing Gases (NCGs) in the chamber during the holding phase [3]. The $|\Delta T_{load}|$ is the instantaneous temperature difference in the load and *t* the time of the holding phase.

Pressure and temperature could already be measured, so only a method for measuring NCGs had to be found. An NCG sensor system has been identified to measure the NCGs in each process and in the chamber (Figure 1). Once the NCGs have been identified, the composition of the steam can also be identified because the NCGs and the water molecules in the steam together form all of the gas in the chamber. Or, summarized in an equation:

$$\text{water vapor } \% + \text{NCGs } \% = 100\ \% \text{ gas in the sterilizer chamber} \qquad (2)$$

The identified system is the SolidToo NCG sensor system (Veldhoven, The Netherlands, Figure 1). An NCG sensor has been installed on each of the five steam sterilizers of the Catharina Hospital. The five

NCG sensors, together with a computer to which the 5 NCG sensors are connected and on which the NCG software runs, form the NCG sensor system.

Results

After installation of the NCG sensor system, the system was first tested parallel to the existing release protocol. During this period the release protocol with the NCG sensor system was also developed. Figure 2 shows a printout of the developed Every Load Monitoring protocol.

A summary of the results of Sterilizer 2 over a period of almost a year is included in Table 1. The protocols in this period show that the pressure and temperature in the holding phase are often the same. The amount of NCGs, on the other hand, is different in every process.

If the percentage of the '134 °C standard processes' that does not meet the criteria in the period of Table 1 (equation 1 and [7]) is calculated, it is 1.3% (= 20/1560 x 100%). In 1.2% (= 18/1560 x 100%) of the processes, the cause is an excessive amount of NCGs according to the standard [7]. This result demonstrates that measuring pressure and temperature is not sufficient to determine steam sterilization conditions according to the standard EN285: 2015 [7].

Discussion

It has been reported in the literature that each process is a unique event [5,6]. The NCG sensor system described here makes it possible to measure the essential steam sterilization parameters in every process. Thus, these parameters can be immediately checked against the criteria in the standard (equation (1) and reference [7]). Because this happens in every process, the standard ISO17665-1: 2006 [8] is also met. This stands in contrast to the previously applied release protocol, which was based only on pressure and temperature.

The results show that in the case of Sterilizer CZE-2, 1.3% of the 134 °C standard processes do not meet the criteria. This is in the order of the values reported in the literature [6] and confirms these earlier findings. In 1.2% the cause was high values of NCGs. This confirms that, in order to claim that standards [7,8] have been met, the NCGs must be measured. An alternative would be to measure the water concentration (Equation 2). It has again been confirmed that measuring temperature and pressure is not enough to claim sterilization conditions [7], as had previously been reported in the literature [4]. This makes it necessary to measure the essential sterilization parameters for steam sterilization as specified in the standard EN285: 2015 (equation (1)) in order to claim compliance with the standards.

In the parametric methods based on pressure and temperature measurements, use is made of a theoretical temperature calculated from the pressure. However, this calculation can only be used if it is confirmed that only water molecules (water vapor) are present in the gas. By definition, the composition of the gas in a steam sterilization process cannot be known. Therefore, this method cannot be used to determine whether NCGs are present in the sterilizer chamber. This has also been reported in the literature [4,5,6] and is confirmed by authorities in the field of steam [2,3]. As a result, pressure and temperature measurements cannot be used to check whether the specifications in standard [7] are met.

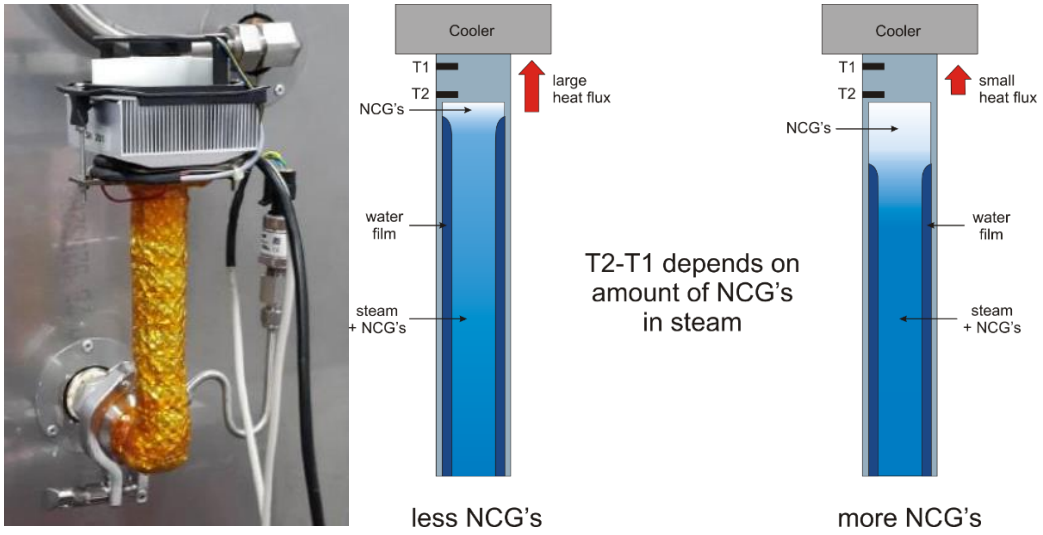

Figure 1: On the left a SolidToo NCG sensor mounted on a steam sterilizer. On the right the measuring principle of the NCG sensor system. During a sterilization process, steam enters the measuring tube of the NCG sensor. The top of the tube is cooled to a lower fixed set temperature, for example 40 °C. As a result, the steam will condense and be discharged from the measuring tube along the wall of the tube. The Non-Condensing Gases (NCGs) will remain in the top of the tube. These will then form an "insulation layer". The more NCGs, the larger the insulating layer. Over the measuring block between the measuring tube and the cooler, the temperature difference is measured with T2-T1. This temperature difference is called 'dTsink'. 'dT' stands for the delta (Δ) temperature and sink for 'cold well'. The larger the insulating layer of NCGs, the smaller the dTsink becomes. The dTsink is therefore a measure of the amount of NCGs in the measuring tube and thus also of the sterilizer chamber. In its calibrated state, the NCG sensor measures the absolute NCG amount in the sterilizer chamber.

Furthermore, the literature shows that pressure is not, in fact, a steam sterilizer parameter [6,7]. Pressure is used in modern steam sterilizers to control the process. It is therefore not necessary to include the pressure level in the essential parameters for steam sterilization. Thus, the pressure could be omitted from both the equation (1) and the standard [7] as an essential parameter for steam sterilization.

In practice, it is often said that the Bowie and Dick is a steam penetration test. However, the literature shows that the Bowie and Dick test is a postulated relative NCG measurement, based on temperature measurements [11,12] and measured in a standard textile package [7]. Since the Bowie and Dick test is a relative NCG measurement, it is possible with an absolute NCG measurement to comply with the steam penetration test as described in the EN285: 2015 clause 8.1 [9]. Thus, the NCG sensor system complies with EN285: 2015 [7] clause 8.1 "steam penetration".

Because absolute measurements are taken with the NCG sensor system, EN285:2015 clause 13.3.1 [7] is also addressed. In this clause, a criterion is given for the amount of NCGs in the steam supply to the sterilizer. The measurement was specified for the steam supply [7] during the development of the first standards (in the UK in the 1950s and 1960s). At that time there was no method available that could measure the NCGs or the concentration of 'water-vapour' in a sterilizer chamber. Now, about 60 years later, it has become possible to measure the NCGs in the sterilizer chamber and in every process (Figure 1).

The new method of monitoring the pressure, temperature and NCGs gives a reason to investigate the added value of routine tests and procedures, such as the steam penetration test and vacuum leak test, as well as the methods of validation that are used. A study addressing these topics is currently in progress.

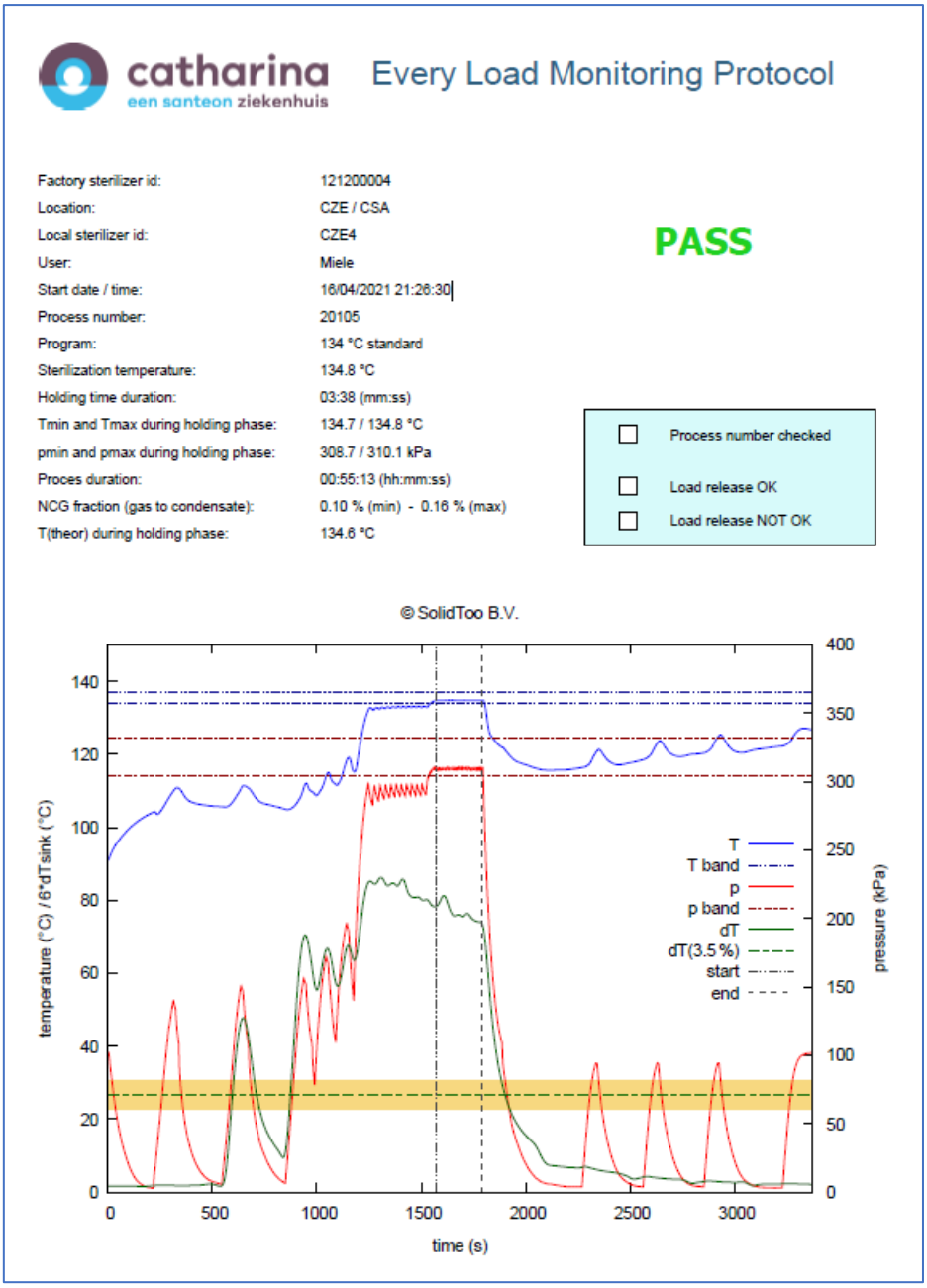

Figure 2: Printout of an Every Load Monitoring (ELM) protocol of the NCG sensor system. In the header of the protocol, the sterilizer data and numerical measurement results are given. For easy interpretation against EN285: 2015 [7], temperature, pressure and NCG data are displayed in the holding phase. The vertical lines in the graph indicate the holding phase. The horizontal lines indicate the criteria of the standard EN285: 2015 for pressure and temperature. The pressure and temperature curves must be in these boxes during the holding phase for a "pass" result. The orange bar indicates the criteria with the allowed inaccuracy for the NCG quantity from EN285: 2015 [7]. If during the holding phase the curve of dT is above the orange bar then it is a good result for the NCGs. If the values of the NCGs enter the orange bar during the holding phase, the measurements fall within the accuracy specified in the standard [7] and is it still a pass result. When the values of the NCGs fall below the orange bar, there are too many NCGs present according to the criteria in EN285: 2015 [7]. In the graph, the dT (sink) is multiplied by 6 (6 x dTsink). This is done to keep the graph legible. In the numerical values in the header of the protocol, the values for the NCG are expressed in ml NCG in 100 ml condensate, so that it can be easily compared with the criterion for NCGs in the standard [7].

Conclusion

By measuring and assessing the essential parameters for steam sterilization temperature and NCGs (steam composition) and pressure, as specified in EN285: 2015 [7], the certainty of steam sterilization is increased. This makes processes more transparent and increases patient safety. When these parameters are measured and assessed in each process, the monitoring of each process as described in ISO17665-1: 2006 [8] is also met.

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