# Improving parametric load release with the Non-Condensing Gasses sensor

## In steam sterilization for medical equipment

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# Abstract

Currently, steam sterilization is the most commonly used method due to its high efficacy and cost-effectiveness. However, the current parameters used in steam sterilization - time, temperature, and pressure - are not sufficient for proper monitoring, as steam composition is not actively measured. Additionally, pressure is not a steam sterilization parameter and steam composition is. This thesis aims to investigate the use of a Non Condensing Gasses (NCG) sensor to actively measure steam composition, potentially improving the parametric load release process.

The sterilization conditions were originally derived from research in the 1960s and are still being used. These conditions are:

$$\begin{cases} \text{in chamber and load:} & 134\ °C & \leq & T_{\text{sterilisation}} & \leq & 137\ °C \\ \text{in the load} & & & \text{NCGs} & \leq & 5\ \% \\ \text{in the free space} & & & \text{NCGs} & \leq & 0.1\ \% \\ \text{time} & & & t & \geq & 3\ \text{minutes} \end{cases}$$

In addition, the following criterion is included in the standard on steam composition: 3,5 % $V_{NCGs}/V_{100\ ml\ condensate.}$ This is based on measurements in the 1960s made in the steam supply line and not in the sterilization chamber.

A device called the NCG sensor is used to measure the amount of NCGs in the sterilization chamber, which indicates the steam quality, time and temperature. Based on these parameters the sensor provides a pass or fail result for the sterilization cycle.

In this study, experiments were conducted using a sterilizer, which was equipped with an NCG sensor, and a needle valve used to manually create air leaks. Four programs were used. Each program started with a cycle without a leak and then included cycles with leaks at different points during the conditioning phase. The leaks were created by opening the needle valve, allowing air and NCGs to enter the chamber. Additionally, two cycles were conducted with a load in the chamber to examine the effect of the load on the number of NCGs. Theoretical calculations of the percentage of NCG per 100 ml of condensate in the chamber were also performed using the dilution factor.

A total of 37 sterilization cycles were performed. The results were evaluated based on time, temperature, and percentage of NCGs in the chamber during the holding phase. The three key findings were: steam composition varies greatly with each cycle, air leakage after the final vacuum draw leads to the highest peaks in NCGs, and a cycle may pass based on duration and temperature alone but fails when steam composition is considered. In this study all cycles met the time and temperature criteria, but 9 out of 37 failed due to the amount of NCGs in the chamber.

The use of an NCG sensor enhances the parametric load release process in steam sterilization by accurately measuring the amount of NCGs in the sterilization chamber in real-time. This is crucial as the study revealed fluctuations in steam composition during each cycle and cycles being approved while not meeting steam composition requirements. The sensor provides immediate feedback on the success or failure of the sterilization cycle, allowing for corrective actions if needed. The NCG sensor also reduces the need for unnecessary re-sterilization, saving time and resources, and extending the lifespan of the equipment.

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# Introduction

In hospitals, medical equipment that comes into contact with blood or human tissue inside the body must be sterilized. This typically includes tools used in surgery or internal examinations [1]. Some of this equipment is designed for single-use and is discarded after use, while other instruments are reusable. For the reusable equipment, it is crucial to ensure that it is entirely free of fluids, tissues, or bacteria before reuse to prevent the spread of infection [2], [3]. Achieving this requires proper cleaning and sterilization of the reusable medical equipment.

The cleaning and sterilization process occurs in the Central Sterile Supply Department (CSSD) of a hospital, where the equipment is taken after use. Here, the medical equipment undergoes initial washing and disinfection. It is then wrapped before being placed into the sterilizer. The wrapping is critical to prevent recontamination during storage after sterilization, as the processed load can be re-contaminated as soon as the sterilizer door is opened.

Sterilization entails the complete eradication of all forms of life, including bacteria, viruses, fungi, and spores, from a surface or fluid. Once this process is completed, the medical equipment is considered sterile. Sterile is defined as 'free of all viable organisms' [4], [5] and an item is deemed sterile when the likelihood of encountering a living organism on its surface is equal to or less than one in a million [6].

To ensure that the equipment released from the steam sterilizer is sterile, the process must meet three parameters of steam sterilization. These three parameters are time, temperature, and the presence of adequate steam, also known as steam composition. At present, the parameters considered and measured for steam sterilization are time, temperature, and pressure. However, steam composition, a critical parameter in steam sterilization, is not currently being actively measured. This thesis examines whether the steam composition can be actively measured and how this impacts parametric load release compared to the current method.

## Steam sterilization

There are several methods available for sterilizing medical equipment, including heat, gases, chemicals, radiation, and filtration [6]. Among these, the most commonly used methods are steam sterilization, chemical sterilization, ethylene oxide sterilization, and radiation sterilization [7].

Steam sterilization is widely favored in the healthcare sector for sterilizing medical equipment. This preference is due to the high efficacy of steam in eliminating microorganisms and spores, its relatively rapid process, and its cost-effectiveness. Additionally, as no chemicals are required, steam sterilization is safer for both operators and instruments [6], [8].

In steam sterilization, water is heated to produce steam. Although water normally boils at 100 °C, steam sterilization uses higher temperatures. This is to shorten the time of killing the bacteria. To raise the boiling point of water, pressure must be increased. This higher pressure hinders the evaporation of water molecules.

When the steam encounters a colder material, it immediately condenses. During condensation, all the heat used to boil the water is transferred to the colder material, which heats up the material quickly. In this process, the steam will condense which creates condensate. The presence of moisture is essential in killing the bacteria. Because of the high heat of condensation and condensate formation, steam is an effective sterilization method [6].

A steam sterilization cycle consists of three phases, as shown in Figure 1. In the first phase, the air initially present in the sterilizer chamber is evacuated and replaced with steam. This phase is also called the conditioning phase. The removal of air is one of the most important stages in the cycle [6]. This is because the presence of air in the steam sterilizer can drastically reduce heat transfer in porous materials or narrow channels [6], [9]. During this phase, the chamber is first vacuumed to a certain predetermined pressure. This removes the air from the chamber. In Figure 1, the predetermined pressure is indicated by the vacuum level control points ($p_v$). After this, steam is injected up to the steam injection level control point ($p_s$). After this first vacuum pulse, both steam and air will be present in the chamber. By repeating this process, the amount of air in the chamber further reduces. After the last vacuum suction, more steam enters the sterilizer and pressure will be built up until the desired pressure and temperature are reached.

For steam to effectively eliminate bacteria, the medical equipment must be exposed to a specific temperature for a defined duration. This is the second phase of the cycle, and it is where the actual sterilization takes place. This phase is also called the holding phase. The standard temperatures and times used in steam sterilization range between 121 °C for 15 minutes and 134 °C for 3 minutes [6]. This means that, in addition to the presence of steam, time and temperature are also critical parameters for proper steam sterilization.

The final phase of the cycle involves reducing pressure and allowing the load to dry. Vacuuming removes steam from the chamber, leading to depressurization. At lower pressure, water evaporates at a reduced temperature, facilitating drying of the load. Once the load is dry, pressure is returned to atmospheric levels ($p_a$), ensuring the sterilizer can be safely opened.

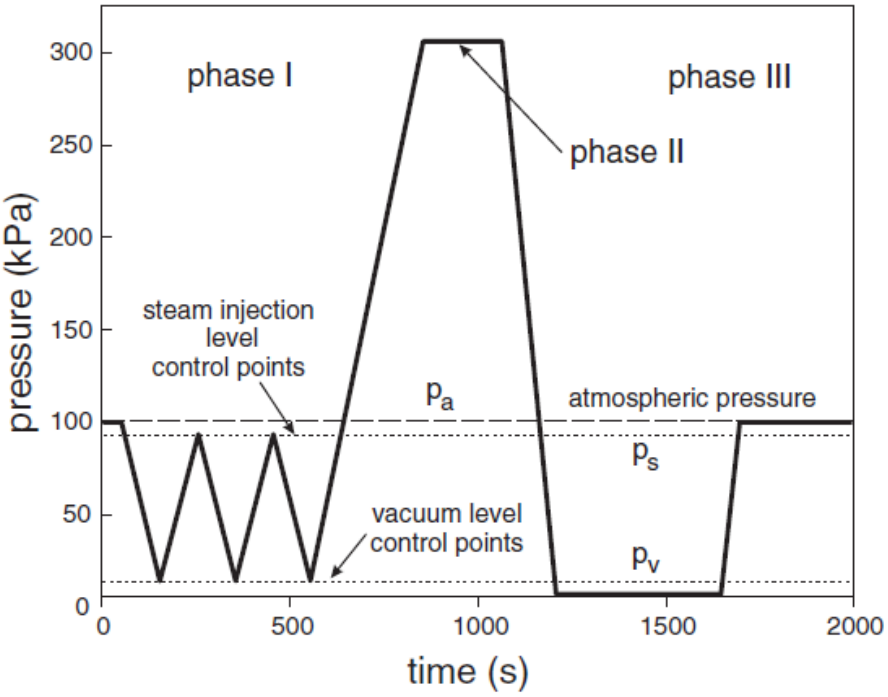


*Figure 1. The three phases of a steam sterilization cycle. In the first phase the air will be replaced by steam by pulses from $p_v$ to $p_s$. The sterilization takes place in phase two and in phase three the load is dried, and the pressure reduced to atmospheric pressure* [9].

## Monitoring load release

Monitoring is employed during the sterilization cycle to ensure the sterility of the load exiting the sterilizer. There are three options for achieving this: physical measurements, also referred to as 'parametric load release'; a biological indicator (BI); or a chemical indicator (CI).

With parametric load release, the parameters used are time, temperature, and pressure [6], [10], [11]. Using the temperature and pressure parameters, the steam composition is then calculated via the theoretical temperature [10]. If the theoretical temperature is not more than 2 Kelvin from the measured temperature, this would indicate that saturated steam was present during the cycle [12]. The formula used for this is:

$$T = 42{,}677\ - 3892{,}70 * \ (\ln P - 9{,}48654)^{-1} \quad (1)$$

The P is the measured pressure in megapascals (MPa), time averaged to result in a time constant between 1 s and 2,5 s and the T is the saturated steam temperature in Kelvin (K) [12].

The advantages of this method are that the parameters provide a clear understanding of how the cycle went. This method does not cost any extra money because the sterilizer indicates the parameters during and after the cycle. However, a major disadvantage of this method is that the pressure and temperature parameters cannot be used to calculate the steam composition [10], [11], [13], [14]. In fact, to calculate the theoretical temperature, the composition of the steam in the chamber is needed. As a result, one of the steam sterilization parameters is missing in this load release method. In addition, pressure is not a sterilization parameter [10], [11]. This is because pressure is only a parameter to control the process of evaporating water at a higher temperature. Killing bacteria does not require pressure, but it does require the right temperature and time and presence of moisture provided by the steam. Therefore, these three are the steam sterilization parameters and not pressure.

A biological indicator consists of spores that are difficult to kill and a growth medium. For steam sterilization, the most used spore is the Bacillus Stearothermophilus. After the biological indicator has been processed in a steam sterilizer, it is placed in an incubator for 24 hours or for a few hours in case of a rapid readout biological indicator to give any bacteria present time to grow. After such time, the indicators are inspected to see if the spores showed growth after the sterilization cycle. If it did, it means the cycle has failed. The biological indicator gives a reliable result, but the incubation time is a major disadvantage. The incubation time has been shortened with a rapid readout biological indicator, but it will still take a few hours before the result is known.

Another indicator that can be used is the chemical indicator. With this indicator, a chemical reaction takes place when one or more parameters are met. These parameters include time, temperature, or the presence of steam. If the chemical indicator has been exposed to the sterilization cycle in a steam sterilizer, the indicator will show a "Pass" or "Fail" result. The chemical indicator is cheap and easy to use, but does not measure the parameters well enough compared with the biological indicator.

Currently, there is no method that does not have drawbacks. Table 1 outlines the advantages and disadvantages of the various methods. Literature also shows that in creating and testing the BI and CI, the theoretical temperature has sometimes been used to calculate the steam composition. As a result, the accuracy of these indicators cannot be guaranteed [14].

*Table 1. Pros and cons of the different methods of load release.*

| Method of load release | Pros | Cons |
|---|---|---|
| Parametric load release | Cheap, Know the real actual values of the steam sterilization parameters | Steam composition cannot be calculated via pressure and temperature. |
| Biological indicator | Measures the lethality of the cycle | Takes several hours before result is known |
| Chemical indicators | Cheap, Easy to use and quick result | Not sensitive enough, Only returns “Pass” or “Fail” |

## Standards

The standards for steam sterilization are currently based on literature from the 1960s [15]. The most challenging equipment to be sterilized at that time were mainly textiles, and that has changed tremendously with what we sterilize now, for example, hollow tubes from minimally invasive techniques. However, the standards[12], [16], [17] have not changed accordingly.

In the 1960s, the technology for directly measuring steam sterilization conditions within the chamber or load was not yet available [11]. As a result, standards included tests that could indirectly measure steam sterilization conditions, for example, the Bowie and Dick test [18]. However, these tests are only used at the beginning of the day and not during each cycle.

Currently, there are technologies on the market that can measure real time sterilization conditions in the chamber or load. An example is the NCG sensor, which stands for Non-Condensing Gases sensor. This sensor measures gases that do not condense in the pressure and temperature domain of steam sterilization processes (for example nitrogen, oxygen, carbon dioxide, etc.). This sensor can be used to determine the steam composition during the parametric load release method. In addition, this sensor also measures its own temperature, time, and pressure during the cycle.

As indicated earlier, parametric load release is now dependent on temperature and pressure measurement. These values are used to calculate the steam composition via the theoretical temperature while it has been demonstrated that the steam composition cannot be calculated with this method [14]. Therefore, the purpose of this thesis is to investigate if the NCG sensor can improve the parametric load release for steam sterilization.

The research question is therefore:

*How can an NCG sensor improve parametric load release?*

To answer this research question, several cycles will be run with an NCG sensor. During some cycles, air will be let into the chamber during different times in the conditioning phase. The results of the NCG sensor will be compared with the results of parametric load release.

# Background

## Sterilization conditions

As mentioned in the introduction, the common temperatures and times used in steam sterilization are between 15 minutes at 121 °C and 3 minutes at 134 °C [6]. But where did these values come from?

In 1956, Perkins described the minimum sterilization conditions needed to sterilize medical equipment [19]. These conditions are derived from temperature-time combinations for the sterilization of aqueous liquids [20], [21]. These are based on various research on the killing times of different bacteria, mainly heat-resistant bacteria in aqueous solution. They also take into account the design of surgical devices at the time and the prevention of damage to devices from long exposure to high temperatures. These minimum time-temperature combinations are shown in Table 2.

*Table 2. Minimum sterilization conditions according to Perkins* [19].

| Temperature (°C) | Time (min) |
|---|---|
| 132 | 2 |
| 125 | 8 |
| 121 | 12 |
| 118 | 18 |
| 116 | 30 |

*Table 3. Minimum sterilization conditions according to Working Party on Pressure Steam Sterilizers of the Medical Research Council* [15].

| Temperature (°C) | Time (min) |
|---|---|
| 134 | 3 |
| 126 | 10 |
| 121 | 15 |

After a series of incidents and reports about unsatisfactory results in steam sterilizing the Working Party on Pressure Steam Sterilizers of the Medical Research Council (MRC) looked again at the time and temperature range of the exposure phase. They wrote that ‘The quality of steam is known to vary with the degree of saturation, the amount of water-fog carried in it, and the amount of air it contains’. This means that saturated steam is therefore not always present in steam sterilization, instead a mixture of steam, water and NCGs is present in the chamber [4], [15].

The Working Party elucidated that a steam mixture, containing 10% volume of air, operating at a pressure of approximately 103 kPa, and a steam temperature of 121°C, yields a temperature of only 118°C in dry saturated steam at this pressure [15]. This makes it uncertain whether the load in the sterilizer actually reaches 121 °C and thus achieves the sterilization conditions.

Therefore, the MRC added a safety margin to Perkins' time and temperature. These time and temperature combinations can be found in table 3. The Working Party on Pressure Steam Sterilizers of the MRC also mentions that the amount of air/NCGs in the steam in any part of the load should not exceed 5% of its volume. They give no explanation or reasoning as to why this should be 5%.

It is well known that you want to have the lowest possible concentration of NCGs around the load because this deteriorates the heat transfer, on which steam sterilization is based. If there is air

around the load, the steam cannot reach the surface properly. This reduces the heat transfer from the warm wet steam to the colder surface of the load. Another important reason to have as few NCGs in the chamber as possible is to get the fastest possible warm-up in the chamber. This allows the cycle time to be as short as possible and this is better for the medical equipment in the sterilizer. The longer medical equipment is exposed to high temperatures, the faster the devices wear out [11].

As for how much air should be in the free space of the sterilizer, the MRC does not specify. However, this can be found in other literature. Other research shows that heat transfer from steam to devices decreases by a factor of 2 if there is a 0.1% volume fraction of NCGs in the steam [9], [11]. This means requiring the lowest possible amount of NCGs in free space is very important to get a fast and proper heat transfer. With this, the sterilization time can be kept short, which is better for the medical equipment as described above.

From the literature described above, current sterilization conditions were established. These can be described as follows:

$$\begin{cases} \text{in chamber and load:} & 134\ °C & \leq & T_{\text{sterilisation}} & \leq & 137\ °C \\ \text{in the load} & & & \text{NCGs} & \leq & 5\ \% \\ \text{in the free space} & & & \text{NCGs} & \leq & 0.1\ \% \\ \text{time} & & & t & \geq & 3 \text{ minutes} \end{cases} \quad (2)$$

The literature does not specifically state what the steam composition may be with respect to the number of NCGs. The standards did eventually include the following [12]: “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 equals 3,5 % $V_{NCGs}/V_{100\text{ ml condensate.}}$

This value comes from experiments from the United Kingdom in the 1960s that are no longer documented. At the time there were no methods to measure the steam composition in the chamber instead the steam composition was measured in the steam supply line near the chamber. However, there are drawbacks to this, one of which is already included in the standard EN285:2015+A1:2021 [12]:

*“This method does not necessarily express the true content of NCG in steam. The limiting value was defined experimentally in the 1960s in relation to the sensitivity of air detectors commonly used in the UK at that time. Repeated measurements give an idea of the true picture of NCGs in the steam supply.”*

Other disadvantages are that the thermodynamic conditions in the supply line are different from those in the chamber itself. For example, the pressure in the supply line is higher than the pressure in the chamber and the steam is stationary in the chamber during the holding phase while the steam moves in the supply line [10]. Furthermore, it is not known when the experiments were conducted. The amount of NCGs in the supply line can vary over the day, as a result, each steam sterilization cycle is unique [10].

The Working Party on Improving Parametric Load Release of Steam Sterilization has calculated the volume fraction of 3.5 ml NCGs in 100 ml condensate. This equals 0.006% volume fraction in the chamber which is much smaller than the 0.1% in the previously mentioned criteria. However, the NCG fraction in the chamber is always higher than in the steam supply line because the steam condenses on the colder parts such as the charge. To keep the pressure high enough, additional steam with additional NCGs must be added and this causes the amount of NCGs to become more [11].

## Validation of steam sterilization cycle

To validate a steam sterilization process, the process must be reproducible and the physical conditions during the process must be recorded [6]. For this, it is important that all three steam sterilization parameters (time, temperature, and steam composition) are known from a cycle.

In addition to the three parameters of steam sterilization, there are additional factors that must be considered. These factors are necessary because it is not feasible to measure steam sterilization parameters at every point within the sterilizer for each cycle. During the performance qualification (PQ), the steam sterilization parameters are measured to ensure they meet the requirements in all locations. In this process, the following factors are documented: the sterilizer itself, the sterilization process, the load, the loading method, and the sterile barrier [10], [17]. The term 'sterile barrier' refers to the minimal packaging form of a product to be sterilized, which acts as a barrier against microorganisms and ensures that the contents remain sterile until the time of use [6]. Throughout all cycles, these factors should remain consistent with those established during PQ and be meticulously controlled to guarantee proper sterilization and the preservation of sterility until use [6], [7], [10], [11], [22].

## Monitoring steam sterilization conditions

When the Performance Qualification requirements are met, routine monitoring and control should be performed on each operating cycle. Two tests can be employed for this purpose: the air leakage test and the steam penetration test.

The air leakage test in a steam sterilizer is conducted to verify the absence of leaks in the sterilizer chamber or door seal that might compromise the effectiveness of the sterilization process. This test is performed weekly or daily at the beginning of the day [22], [23].

During the air leakage test, the sterilizer valves are closed, and the pressure is set to approximately 7 kPa. The pressure is then maintained for a specified duration, usually between 10 and 30 minutes [22]. The leak rate is determined by the pressure difference between the start and end of the hold period of the test. It is important to note that a pressure increase does not always indicate a leak; it can, for example, result from the evaporation of chamber condensate or the warming up of chamber gas [11], [22].

The steam penetration test aims to assess steam quality, the ability to remove air from the test package, and whether steam can enter the test package. This test is performed daily at the start of the day [12].

During the steam penetration test, a test pack based on the original Bowie and Dick test is placed in a challenging location within the sterilizer chamber for steam penetration [18]. The sterilizer then undergoes a standard sterilization cycle. After the cycle, the test package is evaluated to determine whether steam effectively penetrated and sterilized the items within the chamber [11], [17], [22].

However, the steam penetration test, being based on the Bowie and Dick test pack, is not suitable to determine sterilization of contemporary equipment like hollow instruments. This is because the Bowie and Dick test was developed in 1963. At that time, textile was the most difficult object to sterilize. Today, textiles are no longer put in a sterilizer and hollow instruments are the most challenging devices to sterilize. This limitation is substantiated in the literature and is also noted in the EN 285:2015 standard [11], [12], [24].

## NCG Sensor

As mentioned earlier, knowing the steam composition is one of the steam sterilization parameters. To know this parameter, it is important to measure the steam quality. The NCG sensor (Figure 2) measures gases in the sterilizer chamber that do not condense in the pressure and temperature domain of steam sterilization processes [25]. The system comprises an NCG sensor and a controller. The NCG sensor connects to a validation port on the steam sterilizer. The controller manages the NCG sensor, collects data, and transmits it to a computer equipped with NCG software [26].


*Figure 2. The NCG system. Left the NCG sensor that is connected to the chamber and right the controller* [27].

When the sterilization chamber fills with steam, the NCG sensor's internal tube also fills with steam from the chamber. A cooler at the top of the tube maintains the top at a designated temperature (as shown in Figure 3). This causes steam to condense against the cooler inner wall of the sensor. The sensor then dissipates the resulting heat. The sensor measures the heat from the steam in the top of the tube per second via the measuring block at its top. T1 remains at a fixed temperature, while T2 measures the temperature of the heat of the steam at the top. The temperature difference between T1 and T2, called dTsink, reflects the amount of NCGs in the sterilization chamber [25], [26].

NCGs accumulate at the top of the tube, forming an insulating layer that impedes heat transfer since steam cannot condense there. The larger this insulating layer, the smaller the temperature difference (dTsink), indicating a greater presence of NCGs [25], [26].

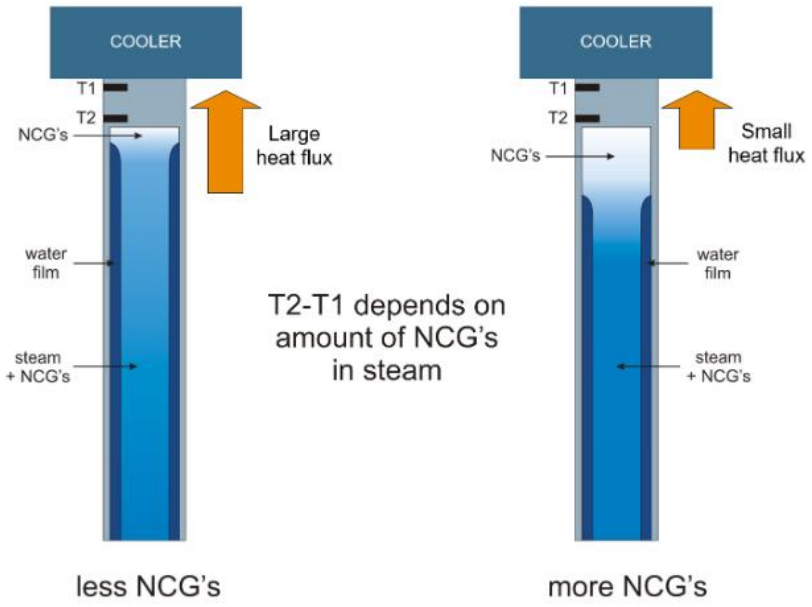


*Figure 3. The working principal of the NCG sensor* [25].

Consequently, the NCG sensor can quantify the amount of NCGs in the chamber during the sterilization cycle. The controller connects to a computer via USB, enabling immediate data processing after each cycle and yielding results within minutes. An example of a result is presented in Figure 5

As mentioned earlier, the NCG sensor measures dTsink. This can be converted to mass fraction via a calibration that allows the NCG sensor to measure the exact amount of NCGs in the chamber. An example of a calibration is shown in Figure 4. The company SolidToo performed calculations using the highest and lowest values of temperature and pressure permissible for the sensor's operation, given that the density of air depends on both temperature and pressure. This ensures that the mass of the 3.5 ml NCGs is not always the same [27]. The results of these calculations are shown by the dashed horizontal line in Figure 4.

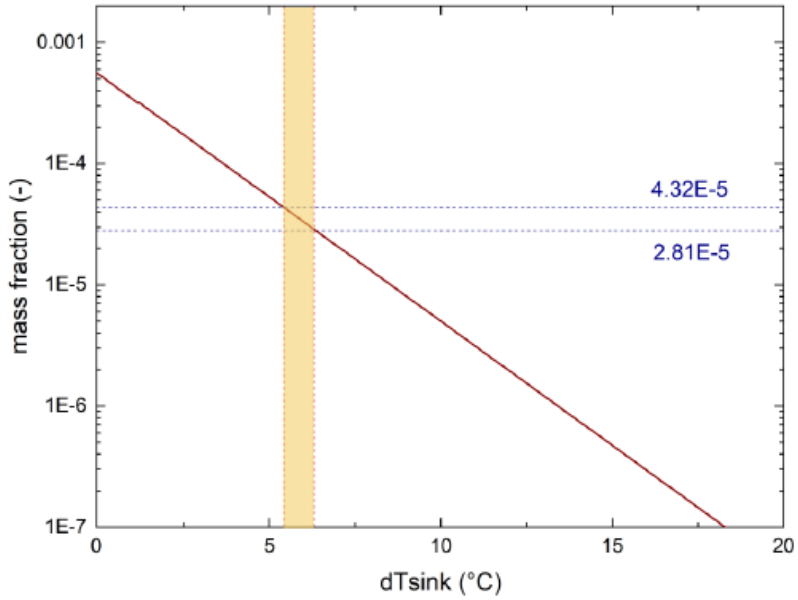


*Figure 4. An example of a calibration of dTsink against mass fraction of the NCGs. The calibration is shown by the solid red line. The 3.5 ml of air in 100 ml of condensate that corresponds to the NCG mass fraction is indicated by the horizontal dashed lines. The vertical yellow bar is the region between these mass fraction restrictions expressed in dTsink* [27].

The yellow band in Figure 4 indicates the dTsink values that fall within the established margin of deviation specified in the standards. If the dTsink values fall within this band during the holding phase, an "Orange Pass" is awarded. If the dTsink values are higher than the yellow band, a "green pass" is given. Conversely, dT sink levels that are lower than the yellow band result in a "Fail."

Figure 5 also shows this yellow band. Here, the green line of the dTsink must be completely above the yellow band in the holding phase to give a “Green Pass”. If a small portion of the line is in the yellow band, an “Orange Pass” is already given. If the line or part of the line goes below the yellow band during the holding phase, a “Fail” will be given.

As described earlier, steam composition is not the only steam sterilization parameter. The cycles must also comply with time and temperature. The NCG sensor also measures this, and therefore, the “Orange Pass” or “Fail” can also be assigned if any other sterilization parameter (time or temperature) falls within or below the established deviation margin. An example of a “Green Pass” and “Fail” can be found in Appendix D.

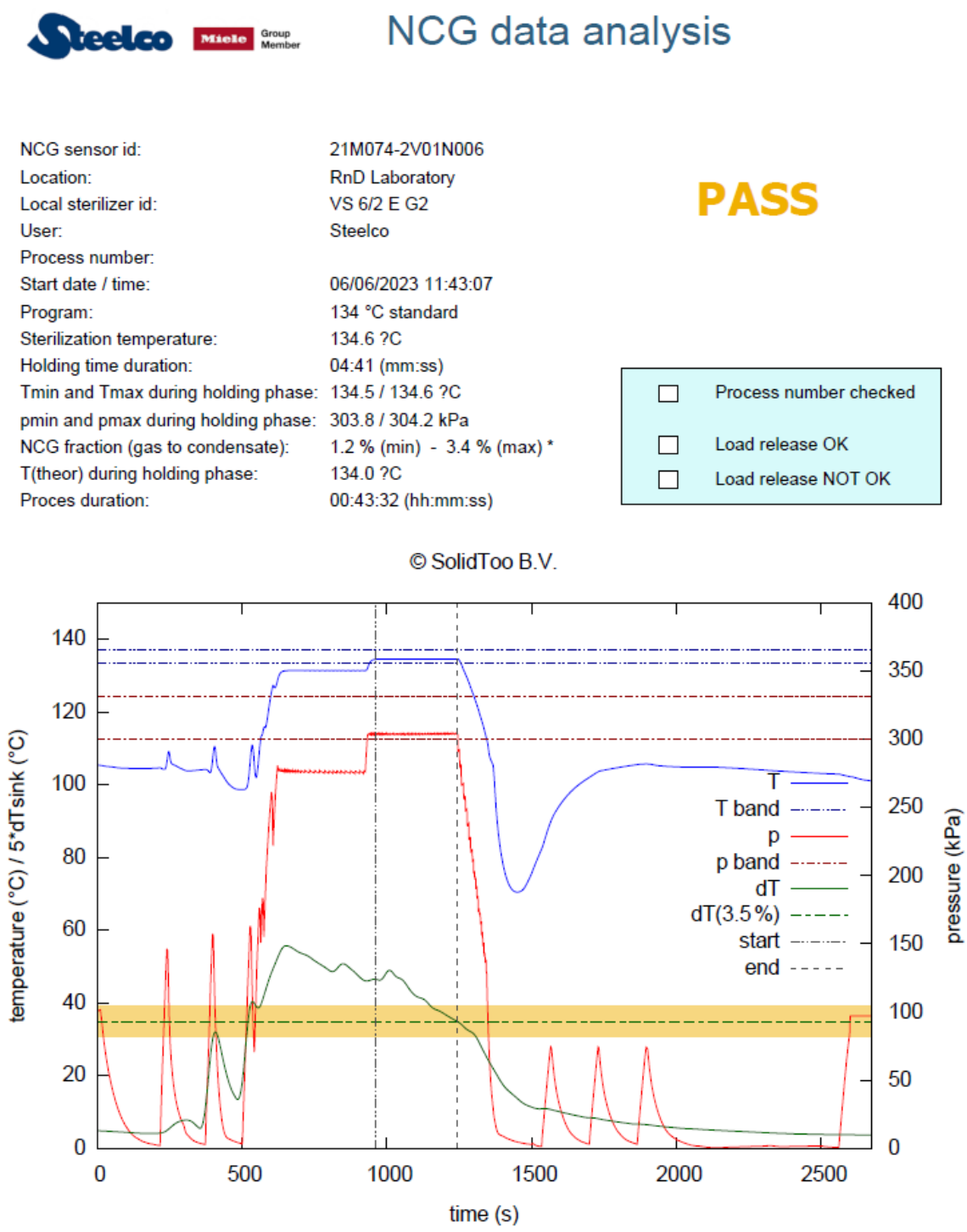


*Figure 5. The NCG-ELM protocol of the NCG sensor. This shows the different values during the holding phase of the cycle in text and in addition in a graph form showing the amount of NCGs in dTsink, the temperature and pressure of the whole cycle. It also indicates whether it is a "Green Pass" (better than standards), an "Orange Pass" (within the established deviation margin) or a "Fail" (worse than the standards).*

# Method

The experiments were conducted using a sterilizer located in a research and development laboratory at the Steelco factory in Italy. The sterilizer used was the Steelco VS 6/2 E G2 ECO1, which has a capacity of 474 liters. The sterilizer was equipped with an NCG sensor and a needle valve (Tognella FT 2251/2-01 ) (Figure 6), the latter being used in manually creating air leaks during the air removal stage. The needle valve was calibrated at a leak rate of 10 mbar per minute. The calibration was done from 70 to 200 mbar vacuum and for every minute the leak should be 10 mbar (+/- 0.5 mbar).


*Figure 6. The NCG (red square) and needle valve (green square) installed on the sterilizer.*

## The different programs

Four distinct sterilization programs were employed during the study:

1. Program 134 °C normal: The standard program utilized for sterilization at 134 °C.
2. Program 134 °C vacuum pump off: This program closely mirrors the normal program, except for the vacuum pump being turned off when the vacuum control point is reached till the steam injection level control point is reached.
3. Program 134 °C sub atmospheric: In this program, only sub atmospheric pulses were administered during the conditioning phase, with four pulses instead of the standard three.
4. Program 134 °C no degassing: This program is similar to the normal program, except the degassing system is deactivated.

Examples of each cycle are illustrated in Figure 7. A more detailed view of these cycles can be found in Appendix A.

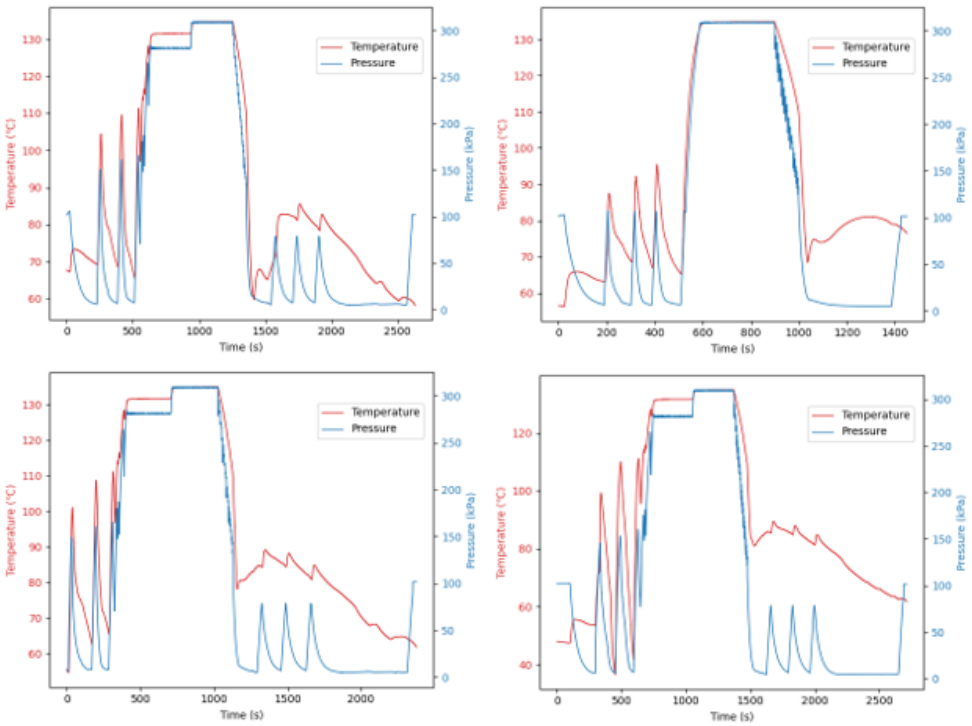


*Figure 7. The different cycles. Top right is the normal cycle. Bottom right is vacuum pump off cycle. Top left sub atmospheric cycle and bottom left degassing off cycle.*

Each program began with an initial cycle without introducing a leak, followed by subsequent cycles with leaks introduced at different moments during the conditioning phase. The leaks were done manually by opening the needle valve for a predetermined number of seconds. The valve was opened when the lowest point of the vacuum was reached, and steam was introduced. This allows air, and thus NCGs, to enter the chamber during the conditioning phase. The moments when the leak was introduced during the vacuum pulse are shown in Figure 8.

For the normal program, leaks of one to five seconds were introduced, while for the vacuum pump off and sub atmospheric programs, a consistent three second leak was applied across different vacuum pulses. The degassing system off program incorporated only a three-second leak during the third vacuum pulse. Under optimal conditions, all programs would have included leaks of 1 to 5 seconds. However, due to time constraints, it was decided to introduce a leak of only 3 seconds for the other programs compared to the normal program. 3 seconds was chosen because it is in the middle of 1 to 5 seconds. A flow chart of the experiments performed can be found in Figure 9. For each cycle, the time, temperature, and maximum NCG fraction during the holding time are examined.

These specific programs were chosen because the vacuum pump affects air removal from the chamber during the conditioning phase. The vacuum pump was turned off only during steam inlet. The degassing system ensures that the water from which the sterilization steam is made is almost free of NCGs. Water naturally contains NCGs, and these are removed in the degassing system located in the water supply line for the steam generator inlet. Thus, turning off this system affects the quality of the steam and the NCGs present in the steam. The sub atmospheric program was chosen to see what effect air intake has with only sub atmospheric pulses in the conditioning phase. This is because these pulses are needed to remove air from hollow tubes.

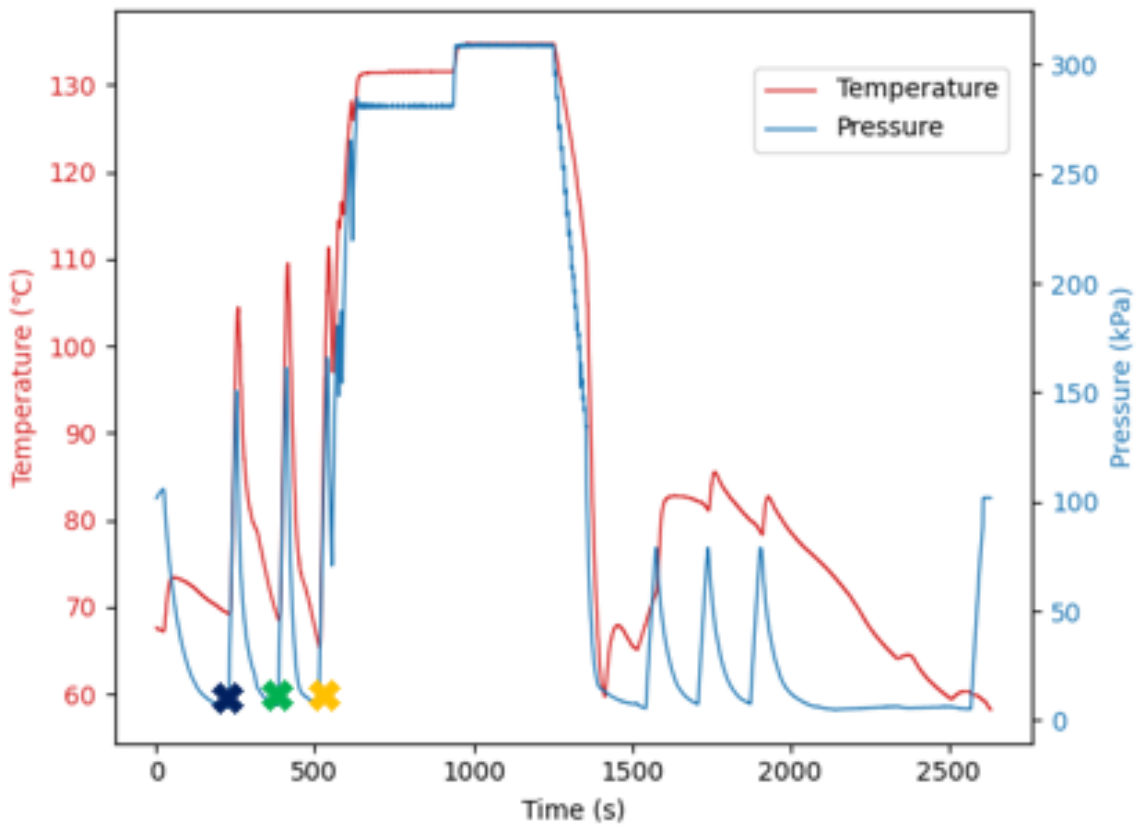


*Figure 8. Moments of leak, indicated by X. The blue X indicates the leak in the first pulse, the green in the second and the yellow in the third.*

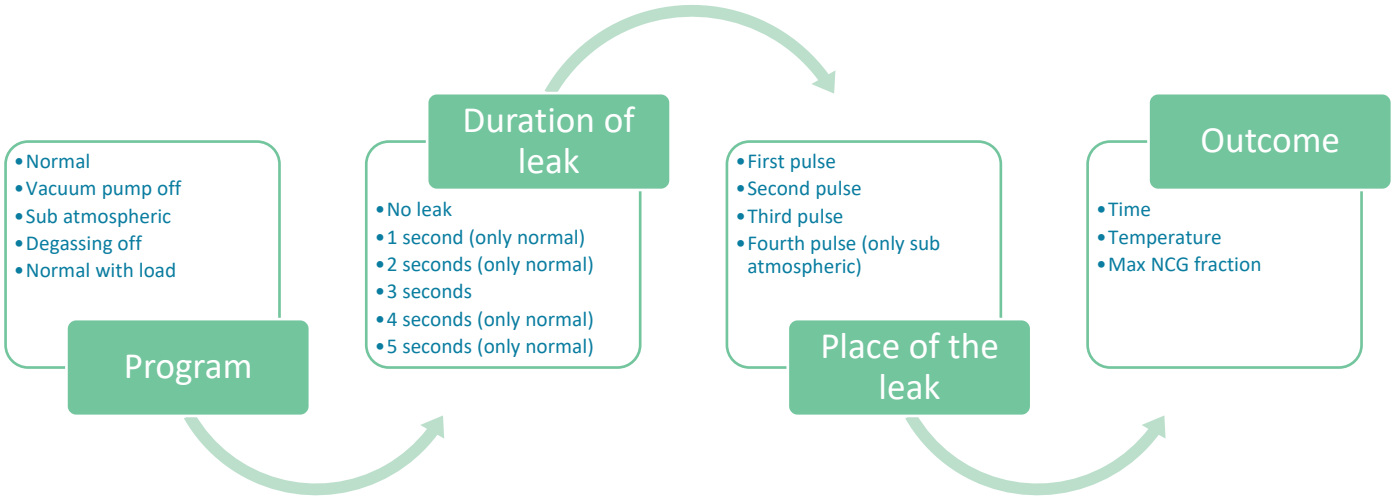


*Figure 9. The experiment flow. For the degassing program and normal with load only the third pulse is used of the leak.*

*Figure 10. The load used for the cycles with load.*

Two additional cycles were conducted with a load present in the chamber. A cycle with load was chosen because the presence of load affects the number of NCGs in the chamber. This is because the steam will condense on the load, and this causes more steam and therefore more NCGs to be let into the chamber. These cycles comprised one normal program cycle and another with a 3-second leak introduced during the third vacuum pulse. The load, as shown in Figure 10, was at room temperature before entering the sterilizer. The exact temperature and weight of the load is not known.

To ensure consistent testing conditions, each testing day began with a warm-up cycle before the test cycles were initiated. Between cycles, the door of the sterilizer was intentionally left open for two minutes to simulate loading and unloading scenarios. Leaving the sterilizer open affects entry of air into the chamber which must then be removed. Mimicking this will simulate the amount of NCGs which can normally enter the chamber during loading and unloading.

## Dilution factor

In addition to the experiments, the theoretical percentage of NCG per 100 ml of condensate that could be in the chamber when using 100% steam was also calculated using the dilution factor. This also assumes that at the start of the cycle the chamber contains 100% NCGs.

The pressure is read from the pressure measurement done by the sterilizer itself.

Formulas used for this purpose are:

$$dilution\ factor = \frac{pv1}{ps1} * \frac{pv2}{ps2} * \frac{pv3}{ps3} * \frac{pv4}{ps4} \tag{3}$$

$$Volume\ NCG = \ dilution\ factor * volume\ sterilizator \tag{4}$$

$$\%\frac{V(NCG)}{V(steam)} = \left(\frac{Volume\ NCG}{\text{Volume sterilizer}}\right) * 100\% \tag{5}$$

$$\%\frac{V(NCG)}{V(100\ ml\ condensaat)} = \%\frac{V(NCG)}{V(steam)} * \frac{\rho\ water\ at\ 135\ °C}{\rho\ steam\ at\ 135\ °C} \tag{6}$$

# Results

The study involved conducting 37 cycles over a period of five days (June 6 to 9 and June 12, 2023). For detailed test configurations on each day, refer to Tables 1 through 5 in Appendix B.

During the testing phase, the results were briefly reviewed, and it was decided to redo some tests as the initial results did not match expectations compared to the no leak cycle. By running additional tests, it was possible to see if this was a one-time outlier or if this is normal behavior. Additionally, errors were made in three tests. The first error is that in one test, it was not certain if there was a leak. This test was included in the assessment of whether the test passed or failed. However, it was not included in the assessment of the number of NCGs in the chamber because it was not known if there was a leak and how long the leak took. This is because the test cannot be compared to the other tests based on duration and place of the leak. The second error involved choosing an incorrect program. This caused an additional test of the vacuum pump from a program done with a 3-second leak during the first vacuum. The last one was forgetting to introduce a leak in one test, so an additional normal program with no leaks was run.

From each cycle, the time, temperature, and the percentage of NCGs per 100 ml of condensate in the chamber during the holding phase were examined. The results of the NCG sensor of every cycle can be found in Appendix C.

The amount of NCGs in the sterilization chamber during the holding phase was also analyzed relative to the other cycles with the same program. While all cycles were successful in terms of time and temperature, 9 out of 37 cycles failed to meet the requirements for the amount of NCGs in the chamber and therefore returned a “Fail” (see Table 4).

*Table 4. Summary of the results of the different cycles according to the NCG sensor.*

| | “Pass” | “Fail” | Total cycles |
|---|---|---|---|
| Normal program | 17 | 5 | 22 |
| Vacuum pump off | 5 | 0 | 5 |
| Sub atmospheric | 5 | 1 | 6 |
| Load | 1 | 1 | 2 |
| Degassing | 0 | 2 | 2 |

## Normal program

In Figure 11, the results of the maximum NCG fraction are displayed. The maximum NCG fraction of these cycles is compared with the cycles where no leak was made, as shown in Figure 12. The average of the two cycles without a leak is considered as having a value of 0. Additionally, for cycles where more than one leak was introduced, the average value is also taken.

For the normal program, when observing the cycles with one second of leakage in all three vacuum pulses, they are similar to the cycles without any leak. Figure 12 also indicates that the line of leaks in

the second vacuum pulse remains almost the same as the cycles without a leak, and the leak in the first vacuum pulse performs better than the normal cycle without a leak. As anticipated, leaks in the third vacuum pulse show the highest NCG fraction. This is expected because once the leak is introduced, vacuum pressure is not drawn again. This prevents the introduced air from leaving the chamber.

When comparing the same cycles with load and the average values without load (Figure 13), the distance between both no leak and the three-second leak in the third vacuum pulse is about the same. Looking at the actual values, it can be seen that one of the 'no leak without load' values is approximately equal to the 'no leak with load' value, and that the value of the 3-second leak with load falls between the two. It is expected that values with a load would be higher than without a load, as steam condensation on the load causes a higher amount of NCGs in the chamber.

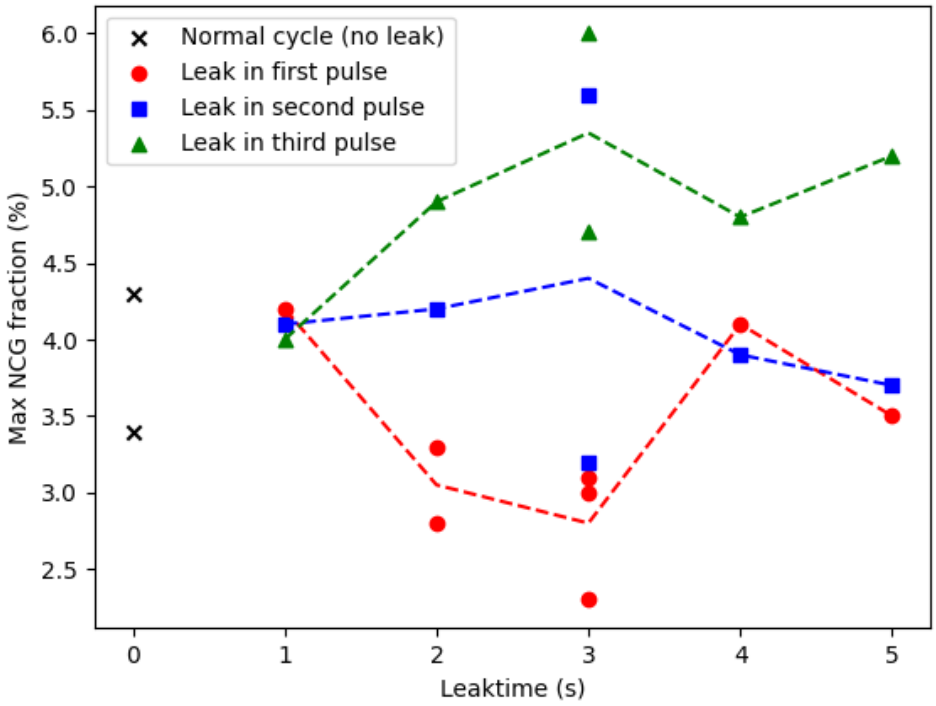


*Figure 11. Max NCG fraction of the cycles with the normal program. Dotted lines are averages.*

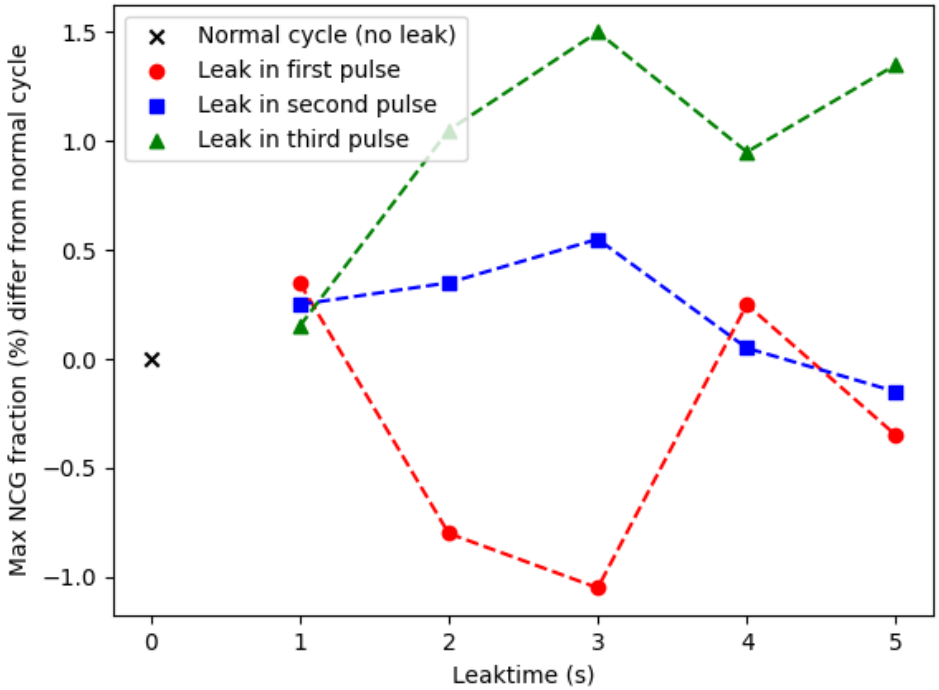


*Figure 12. Difference in max NCG fraction compared to cycles without leak in normal program. Here the average values were taken.*

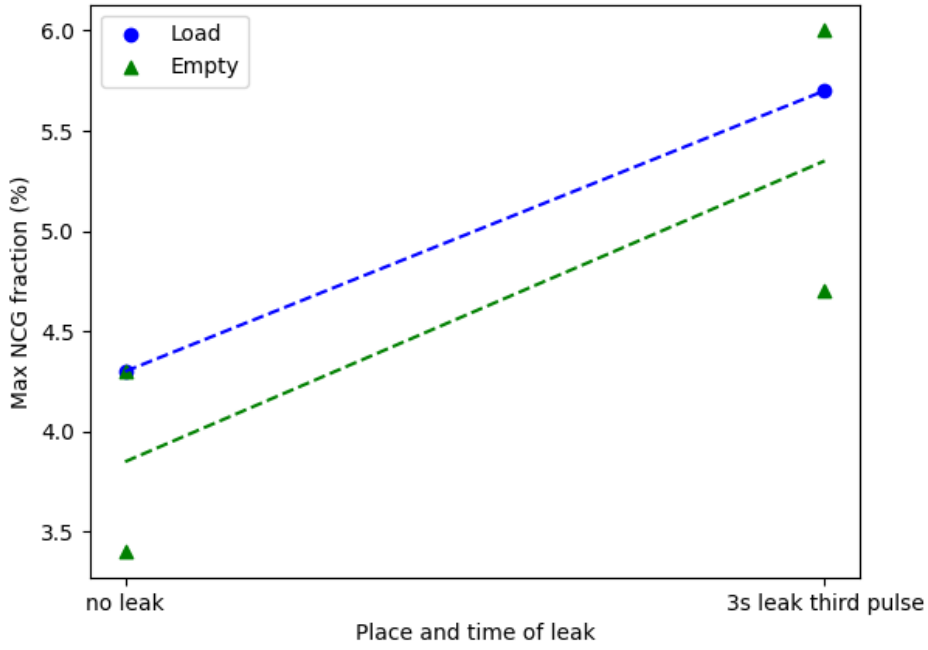


*Figure 13. Max NCG cycles of the cycles with load compared to the same cycles without load. Green dotted line is the average of the green points.*

## Vacuum pump off and sub atmospheric program

Figure 14 shows the maximum NCG fractions of the cycles with the sub atmospheric and vacuum pump off programs. Here the value is also highest at the last vacuum pulse. This is the third in the vacuum pump off program and the fourth in the atmospheric program. In both programs, the values of the cycles without a leak are significantly higher than the cycles with a leak in the first to the second-last vacuum pulse.

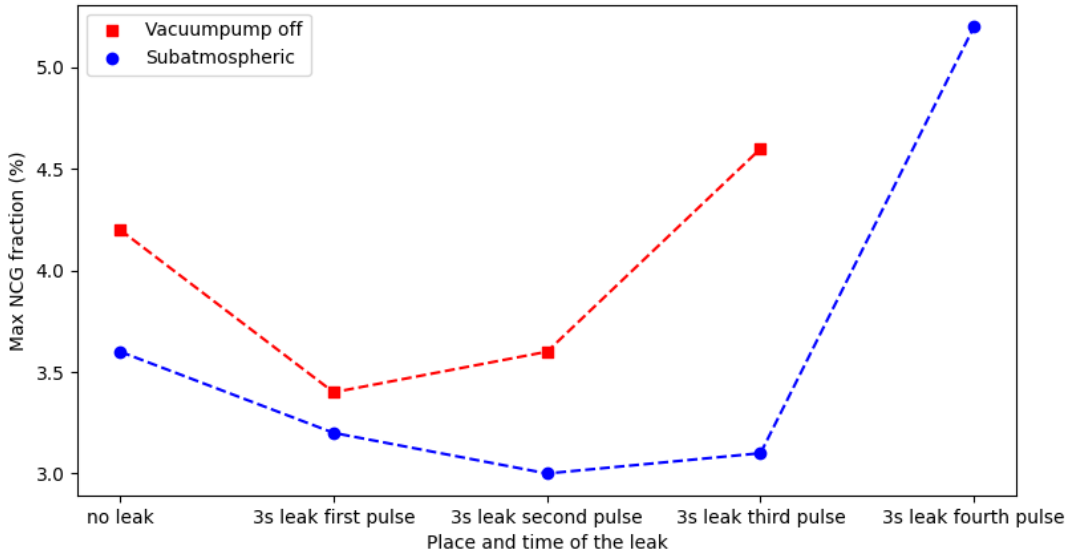


*Figure 14. Max NCG fraction of the cycles with sub atmospheric and vacuum pump off program.*

## Degassing system off program

The maximum NCG fraction of the cycles with the degassing system off is shown in Figure 15. These two cycles both result in a “Fail”, which is expected because the NCGs are not removed from the steam beforehand, and because of this, the steam quality is much worse.

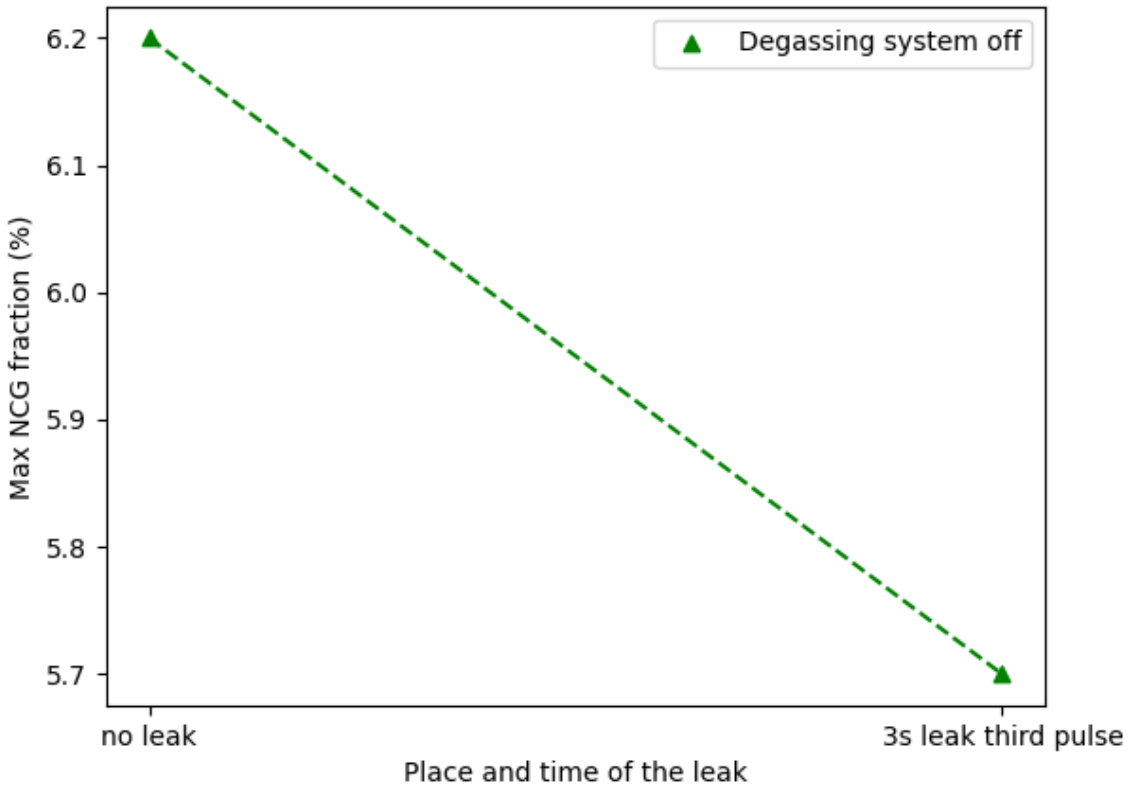


*Figure 15. Max NCG fraction of the cycles with the degassing system off.*

## Dilution factor

Table 5 shows the calculations using the dilution factor. Here, for the sub atmospheric cycle without leakage, the percentage of NCG per 100 ml of condensate is estimated if 100% steam is used. This comes to 0.27% NCGs per 100 ml of condensate at the beginning of the holding phase, while the measured value of this cycle is about 0.88%. This is the minimum value that gives the result (see Figure 16) and from the beginning of the holding phase, the number of NCGs only increases.

It was also calculated how many NCGs there could be in the worst-case scenario of hysteresis of the pressure sensor. The maximum deviation is 6.4 kPa, as stated in standard EN285:2015+A1:2021. The second row of Table 5 shows the result of this calculation. The maximum error, as shown in the table, can reach almost 5%.

Within the sub atmospheric program there is one cycle that gave a "Fail" result. This was the cycle with a 3 second leak in the fourth pulse. For this cycle, the theoretical number of NCGs in the chamber was also calculated and can be found in the third row of Table 5.

The NCGs were also calculated for the other cycles that resulted in a “Fail”. These can be found in Tables 6 and 7. Table 6 includes all the cycles part of the normal program that failed, along with a 'no leak' cycle from the normal program for comparison. Table 7 shows the calculations for the two failed cycles when the degassing system was off.

*Table 5. The % NCG in 100 ml condensate calculated via the dilution factor of sub atmospheric cycles. The first row is the measured pressure of the sub atmospheric cycle without leak and the other calculated parameters. The second row are the values in the worst-case scenario. The last row is the calculations of the sub atmospheric cycle with 3s leak in fourth pulse.*

| pv1 (kPa) | ps1 (kPa) | pv2 (kPa) | ps2 (kPa) | pv3 (kPa) | ps3 (kPa) | pv4 (kPa) | ps4 (kPa) | Dilution factor (-) | Volume NCG (L) | % V(NCG)/ V(steam) | % V(NCG)/V(100 ml condensate) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 6,5 | 105,9 | 6,5 | 105,3 | 6,6 | 106,9 | 6,6 | 308,3 | 5,01E-06 | 0,0024 | 0,00050 | 0,27 |
| 12,9 | 99,5 | 12,9 | 98,9 | 13 | 100,5 | 13 | 301,9 | 9,42E-05 | 0,0446 | 0,00942 | 5,10 |
| 6,4 | 106,2 | 6,5 | 105,8 | 6,5 | 107,2 | 6,3 | 308,8 | 4,58E-06 | 0,0022 | 0,00046 | 0,25 |

*Table 6. The % NCG in 100 ml condensate calculated via the dilution factor of normal cycles. The first row is the measured pressure of the normal cycle without leak and the other calculated parameters. The other rows contain normal cycles that gave a "Fail" result.*

| Cycle | pv1 (kPa) | ps1 (kPa) | pv2 (kPa) | ps2 (kPa) | pv3 (kPa) | ps3 (kPa) | Dilution factor (-) | Volume NCG (L) | % V(NCG)/ V(steam) | % V(NCG)/V(100 ml condensate) |
|---|---|---|---|---|---|---|---|---|---|---|
| no leak | 5,3 | 150,6 | 6,5 | 160,7 | 7,2 | 309,2 | 3,31E-05 | 0,0157 | 0,003315 | 1,79 |
| 3s second | 5,5 | 145,8 | 5,9 | 154,9 | 6,6 | 309,7 | 3,06E-05 | 0,0145 | 0,003062 | 1,66 |
| 2s third | 5,3 | 149,8 | 6,5 | 159,3 | 7,4 | 309,2 | 3,46E-05 | 0,0164 | 0,003455 | 1,87 |
| 3s third | 5,3 | 150,7 | 5,8 | 162,2 | 6,9 | 310 | 2,80E-05 | 0,0133 | 0,002799 | 1,51 |
| 4s third | 5,4 | 150,5 | 5,6 | 160,7 | 6,3 | 309,1 | 2,55E-05 | 0,0121 | 0,002548 | 1,38 |
| 5s third | 5,4 | 149,9 | 5,8 | 163,2 | 6,6 | 309,8 | 2,73E-05 | 0,0129 | 0,002727 | 1,48 |
| Load 3s third | 5,7 | 142,9 | 7,6 | 153,4 | 7,4 | 309,6 | 4,72E-05 | 0,0224 | 0,004723 | 2,56 |

*Table 7. The % NCG in 100 ml condensate calculated via the dilution factor of degassing system off cycles. The first row is without the leak and the second row is with the 3s leak in the third pulse.*

| Cycle | pv1 (kPa) | ps1 (kPa) | pv2 (kPa) | ps2 (kPa) | pv3 (kPa) | ps3 (kPa) | Dilution factor (-) | Volume NCG (L) | % V(NCG)/ V(steam) | % V(NCG)/V(100 ml condensate) |
|---|---|---|---|---|---|---|---|---|---|---|
| Degassing | 5,5 | 145,5 | 5,9 | 153,2 | 6,6 | 309,6 | 3,10E-05 | 0,0147 | 0,003103 | 1,68 |
| Degassing with leak | 5,7 | 146,7 | 5,9 | 155,8 | 6,8 | 309,9 | 3,23E-05 | 0,0153 | 0,003229 | 1,75 |

# NCG data analysis

| | |
|---|---|
| NCG sensor id: | 21M074-2V01N006 |
| Location: | RnD Laboratory |
| Local sterilizer id: | VS 6/2 E G2 |
| User: | Steelco |
| Process number: | |
| Start date / time: | 07/06/2023 16:37:07 |
| Program: | 134 SubAtm |
| Sterilization temperature: | 134.6 ?C |
| Holding time duration: | 04:55 (mm:ss) |
| Tmin and Tmax during holding phase: | 134.1 / 134.6 ?C * |
| pmin and pmax during holding phase: | 303.5 / 305.0 kPa * |
| NCG fraction (gas to condensate): | 0.88 % (min) - 3.6 % (max) * |
| T(theor) during holding phase: | 134.0 ?C |
| Proces duration: | 00:23:46 (hh:mm:ss) |

**PASS**

☐ Process number checked

☐ Load release OK

☐ Load release NOT OK

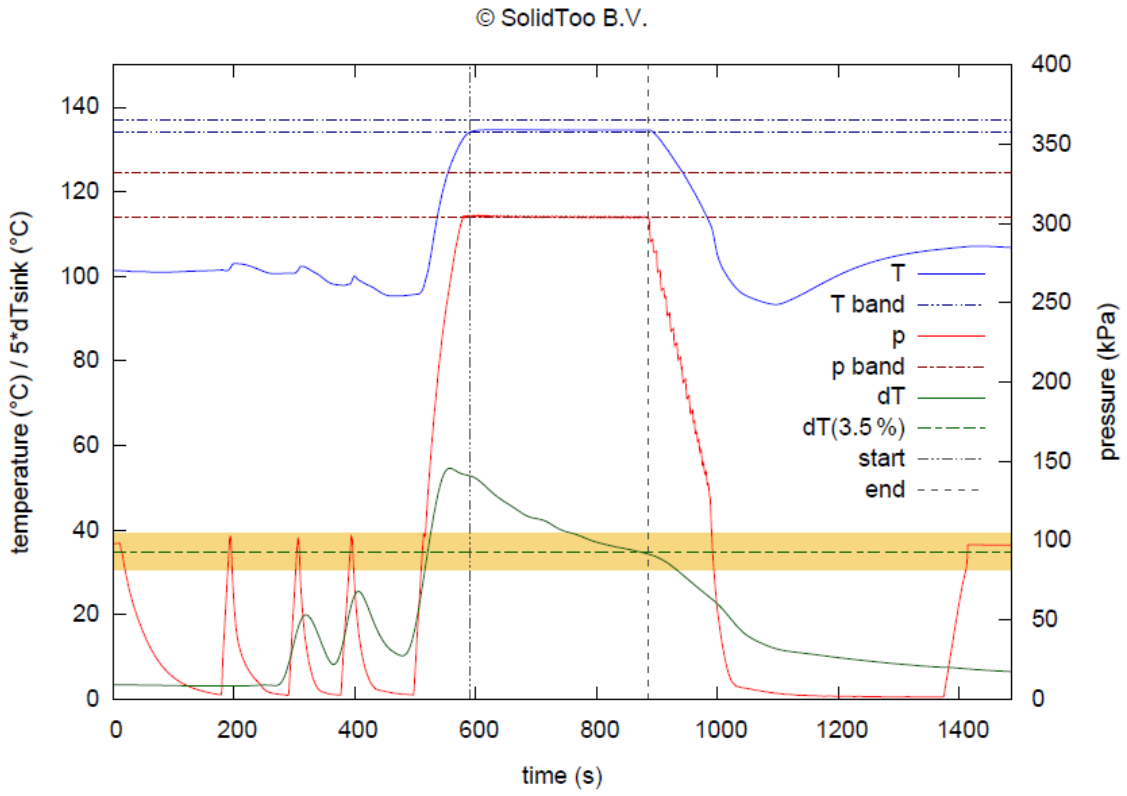


*Figure 16. The NCG data of the no leak sub atmospheric cycle.*

# Discussion

Reviewing the experimental findings reveals three key findings:

- It is impossible to anticipate the steam composition for each cycle because it can fluctuate greatly.
- The biggest peaks in the maximum NCG fraction are produced by air leakage following the final vacuum draw.
- A cycle may be incorrectly approved based on duration and temperature alone, as this does not allow the steam composition to be properly assessed.

Figures 11 to 15, but especially in Figure 11 this is clearly visible, show that the steam composition is different in each cycle, regardless of whether a leak is introduced or not. It fluctuates around certain values, and even cycles performed twice have different results. This is consistent with what has been found in the literature and stated in the standards, that in each process the steam composition is different and therefore each cycle is unique [10], [11], [13]. To validate a cycle, you need to register all the steam sterilization parameters. If each cycle is unique, it remains important to measure each steam sterilization parameter (time, temperature, and steam composition). Thus, this means that it is important to continue to measure the NCG during each cycle.

It is also noticeable that in Figures 11 to 15 some cycles do not match expectations. In all the different programs, you would expect an upward trend, because the longer the leak, or at a later stage of the conditioning phase, the more NCGs. However, in Figure 14 you can see that the lines first run downward only to run upward again at the last peak and Figure 15 even shows a downward line.

Introducing the leak after the last vacuum pulse seems to have the most effect on the presence of NCGs during the holding phase. All figures show that the maximum NCG fraction is highest at the leak after the last vacuum pulse. The red line in Figure 11 shows that a leak in after the first vacuum pulse is about equal or even better than the values of the no leak cycles. This also shows how important it is to perform multiple vacuum pulses to have good air removal.

The last key finding is important, because it demonstrates that using an NCG sensor and thereby constantly monitoring the steam composition during a cycle is important. When comparing the NCG fraction results with the time and temperature results during the holding phase, nine cycles did not meet the required standards because in these cycles there was an excessive presence of air. These nine cycles would have been approved if only time and temperature had been considered. This could have caused the equipment that was in those cycles to be used while not sterilized well enough.

## Steam quality factors

Among the results, only one "Green Pass" was given, and the other successful results were an "Orange Pass". This may be because a number of factors were affecting the steam quality. These factors are:

- the number of cycles in a day
- the time of day
- no distilled water used to make the steam.

There were a lot of cycles done one after another in a day with little time in between. This may have reduced steam quality because the sterilizer did not have time to vent.

Differences may also have been influenced by when the cycles were done. For example, the no-leak sub-atmospheric cycle was done at the end of the day (after 9 other cycles), and the 3-second leak in the first vacuum pulse of the sub-atmospheric cycle was the second cycle of the day. This could also explain the lower NCGs in the leak cycle than in the no-leak cycle.

Lastly, the process did not utilize distilled water, which is typically used in hospitals to create steam. Therefore, the water used in the experiments already contained more NCGs than would normally be present with distilled water.

## Dilution factor

When examining the results of the dilution factor, no major differences appear among the results of the same programs. This is expected because the measured pressure points are close together and are preset in the program.

All failed cycles, except for one, have a leak. These leaks are not included in the calculations because it is assumed that 100% steam is admitted into the chamber.

In both cycles of the degassing system off, which both resulted in a ”Fail”, there is also no difference seen when compared to the result of the normal program no-leak cycle. This can be explained by the fact that the same settings in the sterilizer were used for both the degassing system off cycles and the normal program. However, the steam quality in the degassing off cycles is considerably worse than in the normal program, since the degassing system is turned off.

## Role of NCG sensor

In the current way of working with the weekly air leakage test and the daily steam penetration test and then releasing the load via the parametric load release, which only looks at time, temperature, and pressure, the 9 cycles rejected by the NCG sensor would be successful. If the next day the steam penetration test and/or the air leakage test shows that the sterilizer is no longer working properly, all cycles of the previous day would have to be rejected. With the NCG sensor, it is possible to see exactly which cycle went wrong and well-sterilized medical equipment does not have to be re-sterilized unnecessarily. Additionally, the daily steam penetration test would also no longer be necessary because the NCG sensor measures steam composition during each cycle. This saves on cost and time [28].

With the NCG sensor, cycle validation can also be more effectively achieved. The three steam sterilization parameters (time, temperature, and steam composition) are recorded, and thus you know immediately after the cycle whether the load is safe to release or not. When using the NCG sensor in parametric load release, the disadvantage of this method described in the introduction is negated.

Another additional advantage over the other methods is that the NCG sensor can last for several years. According to the manufacturer, the NCG lasts at least 10 years and must have preventive maintenance once every 5 years [25]. The indicators, described in the introduction, which can also be used for load release are single use. Due to the long life of the NCG, this does save material compared to using indicators and daily steam penetration testing.

## Limitations of the study

This study had several limitations that must be taken into account when interpreting the results.

The main limitation was the limited number of test days, which limited the number of sterilization cycles that could be performed. Consequently, the findings of the study are based on a relatively small sample size, so it was not possible to perform all the different leaks (duration and place) at all the different programs.

Another limitation to highlight is the fact that the study was conducted in a factory setting in Italy. This environment differs from a typical hospital setting where sterilization procedures would commonly be performed. As a result, it was not possible to replicate the exact conditions and characteristics of a hospital sterilizer. For example, the water quality at the factory differed from that used in hospitals. As also mentioned earlier, the used sterilizer for this study did not use distilled water, which is normally used in sterilizers in hospitals. The quality and type of water and thus steam may have influenced the sterilization process by having higher NCGs values by default than is normally used in hospitals.

## Future studies

While investigating the steam sterilization conditions, it was noticed that the value of 3.5 ml NCG in 100 ml of condensate, included in the standards, is based on studies from 1960. At that time, it was not possible to measure NCGs in the chamber and the best possible alternative was found by measuring it in the steam supply line. As described by the Working Party on Improving Parametric Load Release, this 3.5 ml NCG per 100 ml condensate is a pragmatic criterion to ensure that the steam delivered to the sterilizer is of good quality [11]. However, today's standards and thus the NCG sensor still uses this criterion for assessing the steam quality in the chamber.

Nowadays, with the NCG sensor, we do have a device that can measure the number of NCGs in the chamber. A follow-up study could be to investigate if the 3.5 ml per 100 ml of condensate is still a valid criterion or whether it needs modifying based on current research instead of 60 year old research that does not measure in the chamber itself.

# Conclusion

The process of parametric load release can be enhanced with the use of an NCG sensor. This device is capable of accurately measuring the quantity of NCGs present in the sterilization chamber. This improves the parametric load release process, since not all three steam sterilization parameters, but only time and temperature, are actively measured in current methods.

The NCG sensor takes measurements in real-time during the sterilization cycle. This feature offers immediate feedback on the success or failure of the sterilization process. This study revealed fluctuations in steam composition during each cycle, emphasizing the importance of continual monitoring of steam composition throughout each cycle.

This real-time feedback is a major advantage as it provides the ability to confirm the success of the sterilization cycle right after its completion. In situations where the cycle was not successful, immediate corrective actions can be taken, thus reducing the risk of using improperly sterilized equipment. In this study, 9 of 37 cycles were rejected by the NCG sensor, whereas they would have been approved if these 9 cycles had been assessed by the current method based on time and temperature. The use of equipment from these cycles could potentially pose the risk of being improperly sterilized.

Moreover, the use of the NCG sensor can reduce the amount of equipment that needs to be re-sterilized. If a steam penetration test, which is used in the current load release method, indicates that there is a leak, all devices that have been sterilized between the last good test and the negative test must be re-sterilized because it is uncertain whether the previous sterilization processes were successful. By providing immediate and accurate feedback on the success of the sterilization cycle, the NCG sensor eliminates this uncertainty, reducing unnecessary re-sterilization. This not only saves time and resources but also extends the lifespan of the equipment, as frequent re-sterilization can cause wear and tear.

To summarize, the NCG sensor offers a more effective and efficient way to improve the process of parametric charge release in steam sterilization. It provides real-time, accurate measurements of the key parameters, ensures better patient safety by eliminating uncertainties, and reduces the need for unnecessary re-sterilization of equipment.

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# Appendix A

The different programs used.

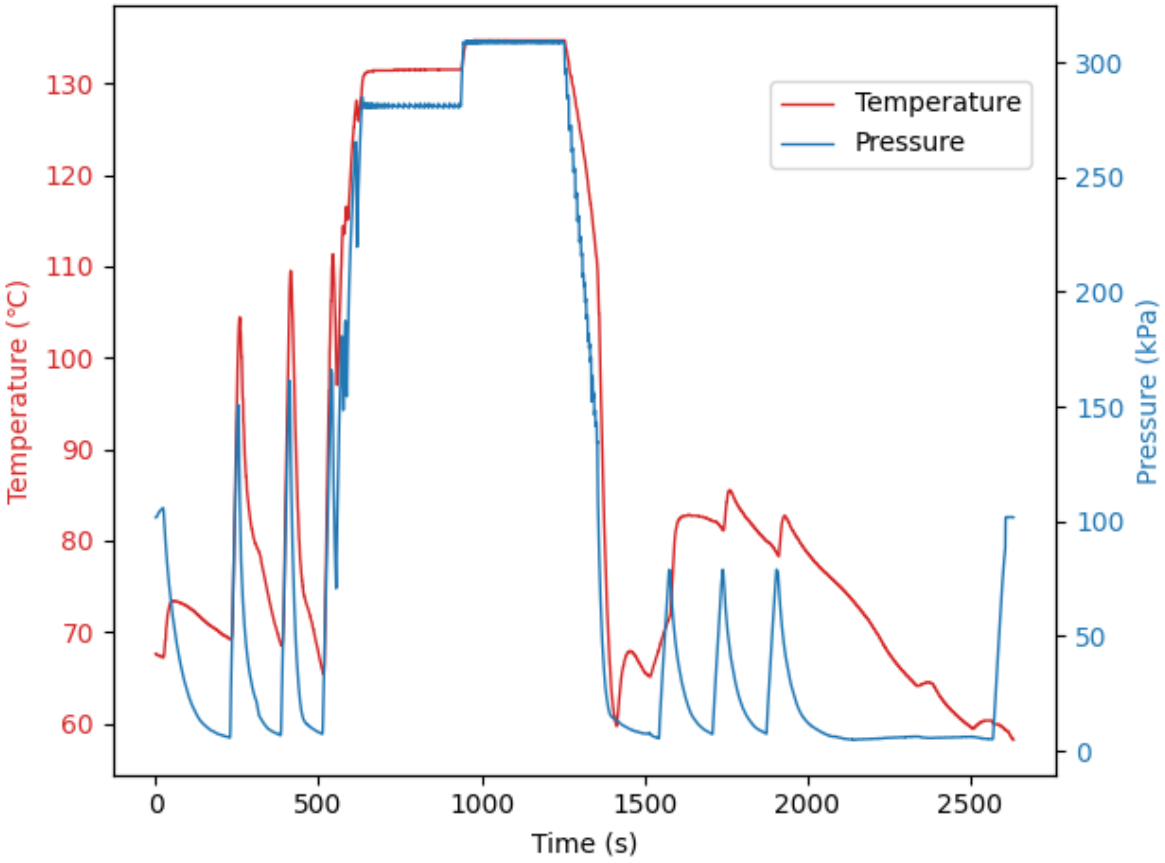


*Figure 1. The normal program cycle.*

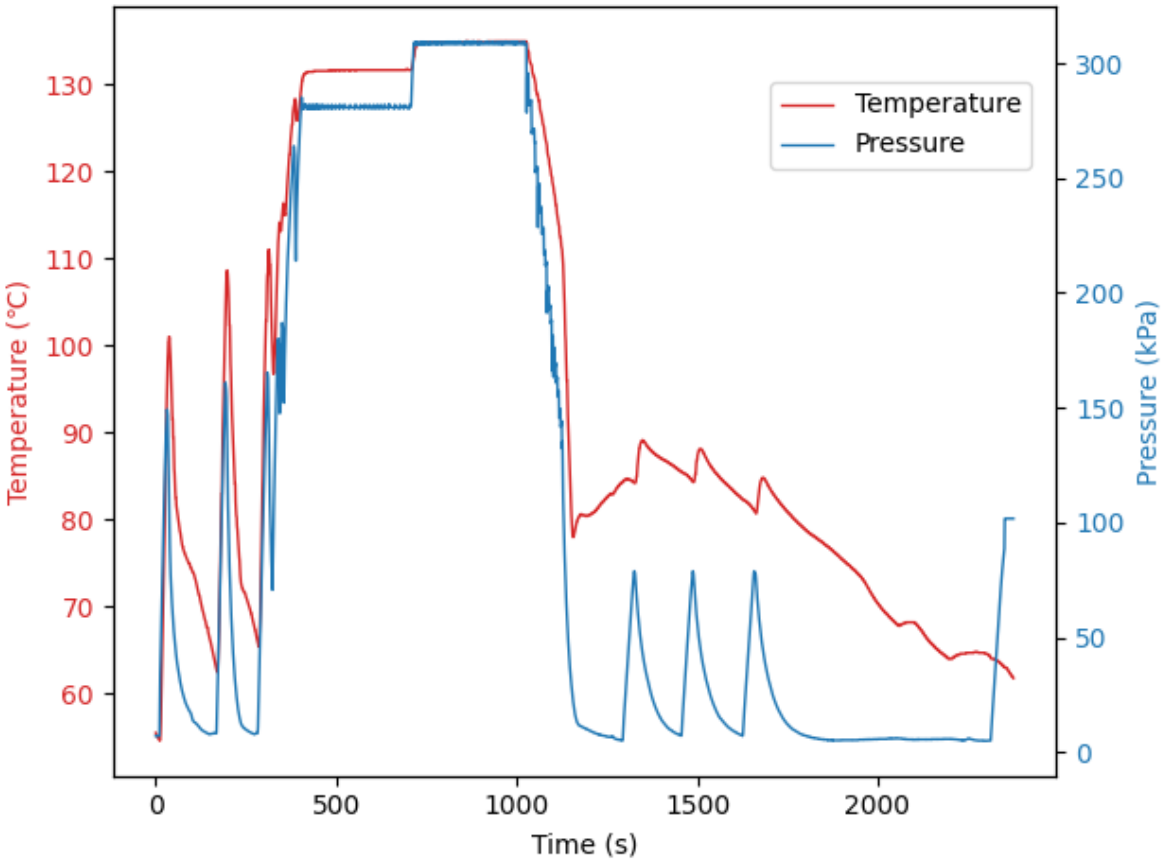


*Figure 2. The vacuum pump off program cycle*

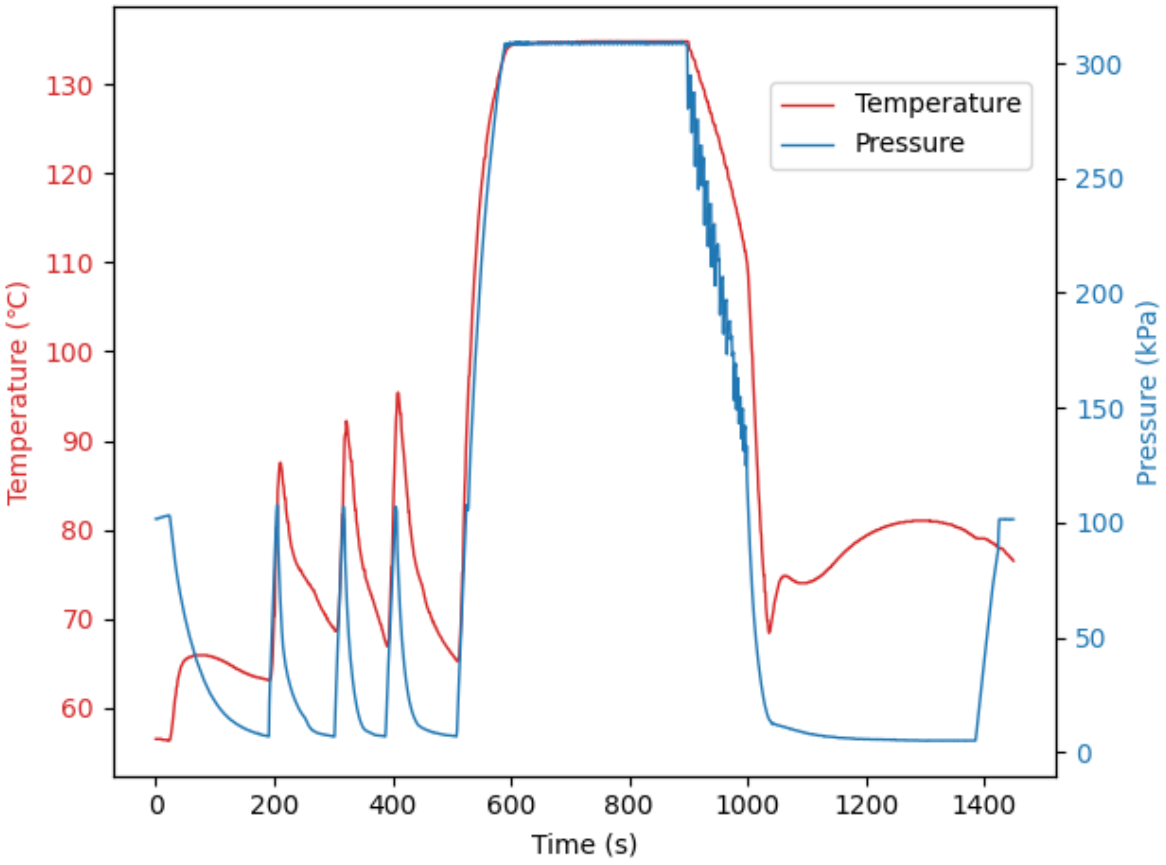


*Figure 3. The sub atmospheric program cycle*

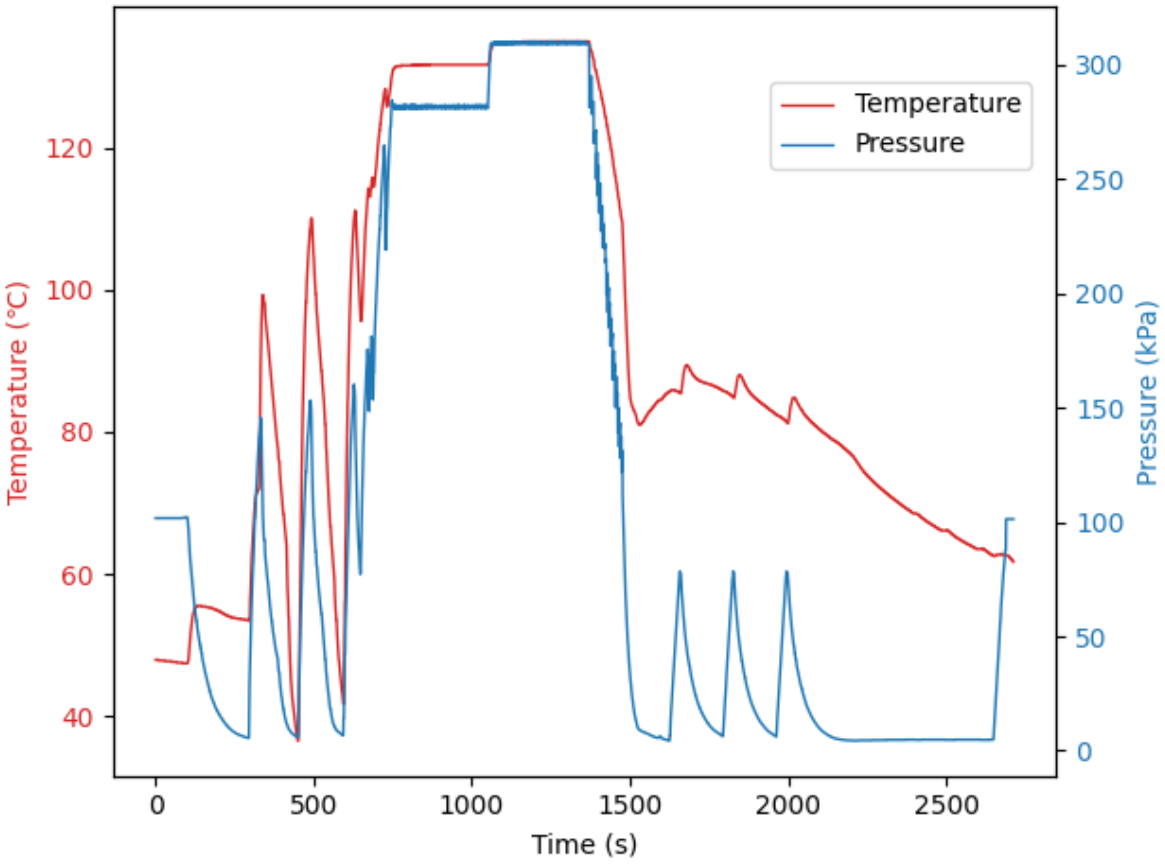


*Figure 4. The degassing system off program cycle*

# Appendix B

The cycles for each day.

*Table 1. Cycles of day 1*

| | Program | Leak time | Leak in vacuum pulse |
|---|---|---|---|
| **1** | 134 normal | - | |
| **2** | 134 normal | 1 sec | First |
| **3** | 134 normal | 2 sec | First |
| **4** | 134 normal | 3 sec | First |
| **5** | 134 normal | 1 sec | Second |

*Table 2. Cycles of day 2*

| | Program | Leak time | Leak in vacuum pulse |
|---|---|---|---|
| **1** | 134 normal | 2 sec | Second |
| **2** | 134 normal | 3 sec | Second |
| **3** | 134 normal | 1 sec | Third |
| **4** | 134 normal | 2 sec | Third |
| **5** | 134 normal | 3 sec | Third |
| **6** | 134 vacuum pump off | - | |
| **7** | 134 vacuum pump off | 3 sec | First |
| **8** | 134 vacuum pump off | 3 sec | Second |
| **9** | 134 vacuum pump off | 3 sec | Third |
| **10** | 134 sub atmospheric | - | |

*Table 3. Cycles of day 3*

| | Program | Leak time | Leak in vacuum pulse |
|---|---|---|---|
| **1** | 134 vacuum pump off | 3 sec | First |
| **2** | 134 sub atmospheric | 3 sec | First |
| **3** | 134 sub atmospheric | 3 sec | Second |
| **4** | 134 sub atmospheric | 3 sec | Third |
| **5** | 134 sub atmospheric | Not sure | Not sure |
| **6** | 134 sub atmospheric | 3 sec | Fourth |
| **7** | 134 normal | 4 sec | First |
| **8** | 134 normal | 5 sec | First |
| **9** | 134 normal | 5 sec | Second |
| **10** | 134 normal | 4 sec | Second |
| **11** | 134 normal | 4 sec | Third |

*Table 4. Cycles of day 4*

| | Program | Leak time | Leak in vacuum pulse |
|---|---|---|---|
| **1** | 134 normal | - | |
| **2** | 134 normal | 5 sec | Third |
| **3** | 134 normal with load | 3 sec | Second |
| **4** | 134 normal with load | 3 sec | Third |
| **5** | 134 normal | 3 sec | Second |
| **6** | 134 normal | 3 sec | First |
| **7** | 134 normal | 2 sec | First |
| **8** | 134 normal | 3 sec | First |
| **9** | 134 normal | 3 sec | Third |

*Table 5. Cycles of day 5*

| | Program | Leak time | Leak in vacuum pulse |
|---|---|---|---|
| **1** | 134 no degas | - | |
| **2** | 134 no degassing | 3 sec | Third |

# Appendix C

Results of NCG sensor

| # | cycle number | Start time | program | leak (time and place) | Result | NCG fraction (min-max) | Holding time | Temperature (min/max) |
|---|---|---|---|---|---|---|---|---|
| 1 | 194 | 11:43 | Normal | No | Pass | 1.2-3.4 | 04:41 | 134.5/134.6 |
| 2 | 195 | 13:37 | Normal | 1s first | Pass | 2.6-4.2 | 04:41 | 134.5/134.6 |
| 3 | 196 | 14:32 | Normal | 2s first | Pass | 1.4-3.3 | 04:42 | 134.5/134.6 |
| 4 | 197 | 15:20 | Normal | 3s first | Green Pass | 1.1-2.3 | 04:42 | 134.5/134.6 |
| 5 | 198 | 16:10 | Normal | 1s second | Pass | 2.4-4.1 | 04:42 | 134.6/134.6 |
| 6 | 200 | 08:59 | Normal | 2s second | Pass | 2.5-4.2 | 04:41 | 134.6/134.6 |
| 7 | 201 | 09:44 | Normal | 3s second | Pass | 1.3-3.2 | 04:41 | 134.6/134.6 |
| 8 | 202 | 10:31 | Normal | 1s third | Pass | 2.3-4.0 | 04:41 | 134.5/134.6 |
| 9 | 203 | 11:24 | Normal | 2s third | Fail | 3.0-4.9 | 04:41 | 134.6/134.6 |
| 10 | 204 | 12:16 | Normal | 3s third | Pass | 2.7-4.7 | 04:42 | 134.5/134.6 |
| 11 | 205 | 13:19 | Vacuum pump off | No | Pass | 2.4-4.2 | 04:41 | 134.5/134.6 |
| 12 | 206 | 14:04 | Vacuum pump off | 3s first | Pass | 1.7-3.4 | 04:41 | 134.6/134.6 |
| 13 | 207 | 15:01 | Vacuum pump off | 3s second | Pass | 1.9-3.6 | 04:41 | 134.6/134.6 |
| 14 | 208 | 15:49 | Vacuum pump off | 3s third | Pass | 2.9-4.6 | 04:39 | 134.6/134.6 |
| 15 | 209 | 16:37 | Sub atmospheric | No | Pass | 0.88-3.6 | 04:55 | 134.1/134.6 |
| 16 | 211 | 08:45 | Vacuum pump off | 3s first | Pass | 2.5-4.3 | 04:42 | 134.6/134.7 |
| 17 | 212 | 09:35 | Sub atmospheric | 3s first | Pass | 0.49-3.2 | 04:55 | 134.2/134.7 |
| 18 | 213 | 10:05 | Sub atmospheric | 3s second | Pass | 0.59-3.0 | 04:56 | 134.1/134.7 |
| 19 | 214 | 10:32 | Sub atmospheric | 3s third | Pass | 0.43-3.1 | 04:56 | 134.1/134.7 |
| 20 | 215 | 11:09 | Sub atmospheric | Not sure | Pass | 0.46-2.8 | 04:55 | 134.2/134.7 |
| 21 | 216 | 11:34 | Sub atmospheric | 3s fourth | Fail | 1.5-5.2 | 04:56 | 134.1/134.6 |
| 22 | 217 | 12:06 | Normal | 4s first | Pass | 2.7-4.1 | 04:41 | 134.6/134.7 |
| 23 | 218 | 13:27 | Normal | 5s first | Pass | 1.9-3.5 | 04:41 | 134.6/134.7 |
| 24 | 219 | 14:13 | Normal | 5s second | Pass | 2.1-3.7 | 04:41 | 134.6/134.7 |
| 25 | 220 | 15:13 | Normal | 4s second | Pass | 2.6-3.9 | 04:41 | 134.6/134.7 |
| 26 | 221 | 15:58 | Normal | 4s third | Fail | 2.9-4.8 | 04:40 | 134.6/134.6 |
| 27 | 223 | 08:38 | Normal | No | Pass | 2.7-4.3 | 04:42 | 134.6/134.7 |
| 28 | 224 | 09:21 | Normal | 5s third | Fail | 3.3-5.2 | 04:40 | 134.6/134.6 |
| 29 | 225 | 10:11 | Normal + load | No | Pass | 1.7-4.3 | 04:54 | 134.3/134.7 |
| 30 | 226 | 11:54 | Normal + load | 3s third | Fail | 3.7-5.7 | 04:56 | 134.3/134.7 |
| 31 | 227 | 13:25 | Normal | 3s second | Fail | 3.7-5.6 | 04:41 | 134.6/134.7 |
| 32 | 228 | 14:11 | Normal | 3s first | Pass | 1.4-3.1 | 04:40 | 134.6/134.7 |
| 33 | 229 | 14:54 | Normal | 2s first | Pass | 1.0-2.8 | 04:41 | 134.6/134.7 |
| 34 | 230 | 15:38 | Normal | 3s first | Pass | 1.5-3.0 | 04:41 | 134.6/134.7 |
| 35 | 231 | 16:21 | Normal | 3s third | Fail | 4.0-6.0 | 04:41 | 134.6/134.6 |
| 36 | 233 | 11:05 | No degassing | No | Fail | 3.2-6.2 | 04:42 | 134.6/134.7 |
| 37 | 234 | 14:12 | No degassing | 3s third | Fail | 2.9-5.7 | 04:43 | 134.6/134.6 |

# Appendix D

The printout of NCG sensor

Steelco Miele Group Member

## NCG data analysis

| | |
|---|---|
| NCG sensor id: | 21M074-2V01N006 |
| Location: | Area Test |
| Local sterilizer id: | VS12 G2 |
| User: | Steelco |
| Process number: | |
| Start date / time: | 06/06/2023 15:20:15 |
| Program: | 134 °C standard |
| Sterilization temperature: | 134.6 ?C |
| Holding time duration: | 04:42 (mm:ss) |
| Tmin and Tmax during holding phase: | 134.5 / 134.6 ?C |
| pmin and pmax during holding phase: | 303.3 / 303.8 kPa |
| NCG fraction (gas to condensate): | 1.1 % (min) - 2.3 % (max) |
| T(theor) during holding phase: | 133.9 ?C |
| Proces duration: | 00:42:33 (hh:mm:ss) |

**PASS**

☐ Process number checked

☐ Load release OK

☐ Load release NOT OK

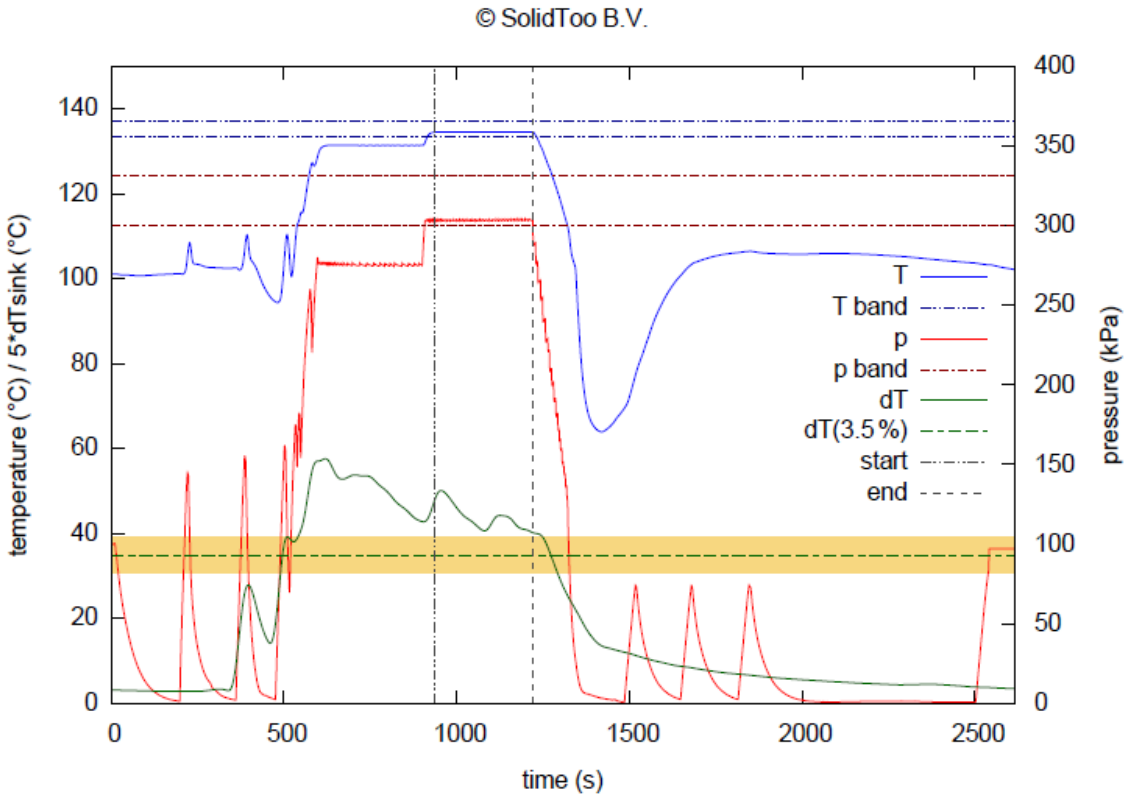


*Figure 1. A "Green Pass" of a sterilization cycle*

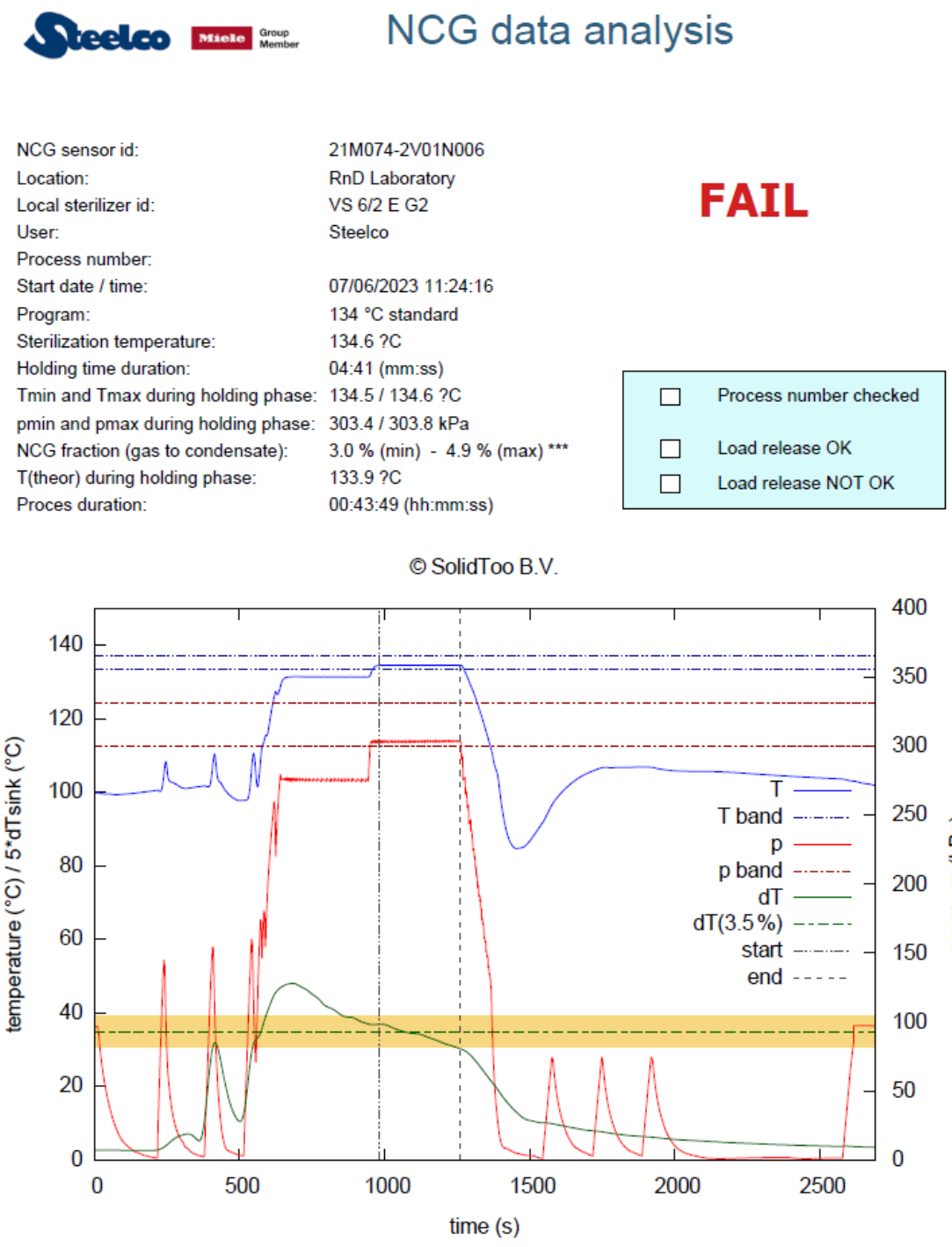


*Figure 2. A "Fail" of a sterilization cycle.*