NCG SENSOR
measurement of Non Condensable Gases (NCGs) and evidence-based steam sterilization monitoring
NCG Sensor:
The importance of monitoring the amount of non-condensable gases (NCGs) in every sterilization process

Driven by customer feedback, Steelco develops, manufactures and supplies solutions that maximize infection control safety, optimize processes and minimize costs.

Already an innovation leader in areas such as automation, the integration of Steelco with Miele organization further increased the pace of technology development for the benefits of operators and patients.

The NCG sensor is another innovation breakthrough in steam sterilization, resulting in an impressive step forward in the safety of instrument reprocessing.

Steelco is the exclusive distributor of NCG Sensor by: SolidToo
How this guide works

Questions and Answers. To quickly get into the topic on how the NCG sensor technology can improve sterilization process safety

Scientific literature and additional comments

Deep dives and related topics

Documents mentioned within i1 and i2 notes are additional publications available online.
Do we need to monitor the amount of NCGs during the sterilization process? In every load?

Yes, the amount of NCGs is an essential factor for a successful sterilization process!

- In standards worldwide, the maximum limit of NCGs is specified at 3.5% in 100 ml of condensate (EN 285:2015 and ANSI/AAMI ST79: 2017).

The value of 3.5% is specified for the steam entering the chamber. It is assumed that during the conditioning phase, ambient air is removed from the chamber. Therefore a maximum of 3.5% of NCGs is allowed to be present during the sterilization phase (plateau period).

During the development of standards in the 1960’s, no method of measuring the amount of NCGs in steam sterilization chambers was available.

With the NCG sensor this is now possible!

Current practice is that the amount of NCGs is usually measured during the commissioning (Performance Qualifications) and the installation of the sterilizer as well as periodically, e.g., annually and during performance re-qualification/re-validation.

This means the current NCG-measurements are a sample at an arbitrary moment in time, "i.e. a snapshot". Consequently, the amount of NCGs not known during daily processes.

Literature demonstrates that in every process the amount of NCGs is different. This makes NCG-measurements in every process essential.

Additional information:


Why is the amount of NCGs in sterilization processes important?

Steam sterilization of medical devices depends on adequate steam quality for the sterilizer chamber and the medical devices such as surgical instruments during every sterilization process.

During the exposure of the medical devices to the sterilizing agent (water vapor), the sterilization process depends on a number of critical parameters. The most important factor is the ability for steam (moist heat) to reach all relevant internal and external surfaces of the device bringing these to the required sterilization temperature. The required temperature and steam quality must be maintained for during the sterilization plateau (holding time).

This process depends on air removal and dynamic steam injection pulses prior to the sterilization holding phase. The air present in the chamber and the packaged medical devices needs to be removed by vacuum pulses and replaced by steam.

Air is considered an NCG and the presence of an amount above 3.5 % in 100 ml condensate will prevent proper sterilisation conditions according standards.
Saturated steam is our sterilant, how is it defined in the norms?

According to the current international standards ISO 17665-1:2006, EN 285:2015 and ANSI/AAMI ST79:2017, when using saturated steam (moist heat) as the sterilizing agent these are the requirements for physical steam quality:

**Non-condensable gases**\(^1\) - EN 285:2015 clause 13.3.1

The sterilizer shall be designed to operate with saturated steam containing up to 3.5 ml non-condensable gases collected from 100 ml condensate.

NOTE: This method does not necessarily express the true content of NCGs 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.

**Dryness value** - EN 285:2015 clause 13.3.2

EN 285: The sterilizer shall be designed to operate with saturated steam with a dryness value not less than 0.95, where the dryness value denotes the mass of the gas fraction in the mass of saturated steam.

ST79: The dryness of the steam, expressed as a dryness fraction. Steam dryness should be between 97% and 100%.

**Superheat** - EN 285:2015 clause 13.3.3

When the supplied steam is expanded to atmospheric pressure the superheat shall not exceed 25 K.(Kelvin)

\(^1\) In the standards the general term “Non-Condensable Gases” is used but every gas will condense in the right range of pressure and temperature. Therefore a better term for “Non-Condensable gases” would be “Non-Condensing gases” in steam sterilization pressure and temperatures ranges.

Additional information:

The standards refer to saturated steam, but at the same time allows 3.5 % NCGs in 100 ml condensate. By definition the steam is not saturated because other gases are present. (http://www.iapws.org/, https://webbook.nist.gov)
What is the NCG sensor?

The NCG sensor measures independently from the sterilizer controls, the quality of the steam inside the chamber. The measuring of NCGs in the steam sterilizer chamber exceeds the requirements of EN285:2015 clauses 8.1, 13.3.1, 13.3.2 and 13.3.3. It goes beyond an independent, periodical steam penetration and air leakage tests as defined in the EN285:2015.

Example of NCG sensor protocols

Steelco Steam Sterilization NCG Sensor

PASS

• Process number checked
• Load release OK
• Load release NOT OK

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Factory sterilizer id: id01
Location: CSA-OLVG
Local sterilizer id: ster01
User: OLVG
Start date / time: 29/11/2021 09:55:37
Process number: 926
Program: 134 °C standard
Sterilization temperature: 135.6 °C
Holding time duration: 04:47 (mm:ss)
Tmin and Tmax during holding phase: 135.1 / 135.6 °C
pmin and pmax during holding phase: 313.3 / 315.0 kPa
Procex duration: 01:23:13 (hh:mm:ss)
NCG fraction (gas to condensate): 0.17 % (min) - 0.38 % (max)
T(heor) during holding phase: 135.2 °C

Steelco Steam Sterilization NCG Sensor

Example of NCG sensor protocols

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How does the NCG sensor work?

The NCG sensor is hermetically linked to the chamber of the steam sterilizer. The operating principle is based on the heat transfer of condensing steam to the inside of the sensor.

After the sterilization process has started, the space within the sensor is filled with a mixture of steam and air of the sterilization chamber. The steam condenses against the inner wall of the sensor. This releases heat, which is dissipated by the sensor. The amount of heat dissipated per second is measured by the sensor. If there is no air in the steam, the steam condenses at the top of the sensor. If air is present, the steam does not condense all the way to the top of the sensor, so less heat has to be removed.

The more air present in the steam, the less heat is dissipated.

There is thus a direct relationship between the amount of air in the steam in the sterilizer chamber and the output signal of the NCG sensor. The NCGs are measured directly in this way.

The heat flux will be large (fast heat up) when there are only few NCGs present. The heat flux will be small when there are more NCGs present. This is caused by the lower heat transfer of the NCG’s. The measuring system also provides pdf protocols that can be used to evaluate the processes and release cycles.

Additional information:

Detailed information about the operation, measurements and reported data can be provided by your Steelco representative.
**Does the NCG sensor produce protocols of the measurements?**

Yes, the controller of the sensor collects all data and then sends it to a computer (laptop or PC) where the data is processed and protocols can be printed or stored online.

There are three protocol results provide:

- **A green Pass:**
  it is guaranteed that criteria in the EN285:2015 are met.

- **An orange Pass:**
  the criteria in EN285:2015 are met but within the accuracies allowed by the EN285:2015.

- **A red Fail:**
  the criteria in EN285:2015 are guaranteed NOT met.

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**Additional information:**

Relationship between the criteria specified within EN285:2015 and the measuring results of the NCG sensor.
Steelco Steam Sterilization NCG Sensor

**Does the NCG sensor take into account the pressure of the steam?**

Although time, temperature and composition of the steam are essential parameters of steam sterilization, the NCG sensor is also equipped with a pressure sensor. This is used to identify the start and end of a cycle.

**Can the NCG sensor replace current and frequent tests?**

Yes, because it complies with EN 285:2015 clause 8.1 for daily steam penetration testing and EN 285:2015 clause 8.2.3 for routine vacuum testing, it can replace both tests.

When the daily steam penetration test and periodically performed air leakage test are no longer performed, this will result in less test cycles. This results in a reduction of energy and water consumption, time, use of staff and prolong the lifespan of the sterilizer.

**Additional information:**

**Does the NCG sensor measure the physical steam composition in the chamber?**

Yes, it complies with EN 285:2015 clauses 13.3.1, 13.3.2 and 13.3.3, and therefore measures physical steam composition in the location that really matters; in the sterilizer chamber in every process. Instead of the steam feed to the sterilizer chamber for example once a year during Performance Qualification.

**What is the relation to the Steelco 4D<sup>IR</sup> sensor?**

Knowing the actual physical steam composition in the sterilizer chamber, the next critical part of a sterilization process is delivering the correct steam penetration in every surgical instrument in the load.

The design and composition of surgical instruments has dramatically changed over the last decades. Coming from porous loads such as textile packs (the original Bowie and Dick test) and reasonably simple instruments to very complex surgical instruments used in laparoscopic and robotic surgery.

Based upon the loads of today, Steelco offers the 4D<sup>IR</sup> Sensor that can monitor and measure the steam penetration and density of the steam in narrow channels.

Although both sensors can be used independently in a Steelco sterilizer, the combination of both will give the maximum security and safety of every sterilization process. The sensors complement each other, ensuring that the steam sterilization conditions as specified in the EN285:2015 are met.

The NCG sensor can also be used for the automatic calibration of the 4D<sup>IR</sup> sensor. NCG sensor available is available as service tool for validation and maintenance purposes.

For more detailed information on the 4D<sup>IR</sup> sensor please read the dedicated 4D<sup>IR</sup> brochure.

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**Additional information:**

**Where are those sensors placed in the sterilizer?**

They are placed so close to the chamber to be considered part of the chamber itself and subject to any phenomenon that happens inside of it.

4D sensor measures steam quality and penetration in the load and in the "worst case" of packed hollow instruments.

NCG sensor replaces the steam sampling point and measures in real time the NCGs concentration in the chamber.

Additional information:

What are the true benefits of using Steelco steam sterilization sensors?

The sensors comply not only with the current standards but supersede them. They are based upon scientific peer-reviewed research and real thermodynamic principles.

Data collection is performed in every cycle and provides all relevant information; time, temperature, air removal, amount of NCGs, quality of the steam, and steam penetration in the actual load.

The output and protocols are measured data that can be logged and stored. This is in comparison to chemical and biological tests.

With this information provided, daily steam penetration test and periodically air removal test cycles are no longer needed.

Verification of sterilization cycles with biological and/or chemical process indicators can be left out. This provides a significant cost saving for the CSSD/Hospital.

Depending on the application of the process indicators, which can differ per region, a cost saving of around € 20,000 per year is possible.

With no individual test cycles performed, the water and energy consumption is reduced with an average of around 12% per sterilizer/year (250 work days, 8 cycles a day).

This is a huge contribution to the sustainability of the CSSD and of the environment.

<table>
<thead>
<tr>
<th>TEST: current practice</th>
<th>STEAM QUALITY</th>
<th>STEAM PENETRATION</th>
<th>STEAM PENETRATION IN HOLLOW INSTRUMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>According to EN 285</td>
<td>frequently*</td>
<td>daily</td>
<td>no previous technical solution available</td>
</tr>
<tr>
<td>Measuring interval</td>
<td>sporadic</td>
<td>1 at day start</td>
<td>not existing</td>
</tr>
<tr>
<td>Cycle type</td>
<td>external</td>
<td>empty chamber</td>
<td>not existing</td>
</tr>
</tbody>
</table>

*Depending on local regulations. Often done only once in the sterilizer lifetime during installation and commissioning or on a yearly basis.

<table>
<thead>
<tr>
<th>TEST: Steelco sensors</th>
<th>NCG SENSOR</th>
<th>NCG SENSOR &amp; 4D* SENSOR</th>
<th>4D* SENSOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Steelco sensors</td>
<td>each cycle</td>
<td>each cycle</td>
<td>each cycle</td>
</tr>
<tr>
<td>Measuring interval</td>
<td>continuous</td>
<td>continuous</td>
<td>continuous</td>
</tr>
<tr>
<td>Cycle type</td>
<td>all test &amp; production cycles with load</td>
<td>all test &amp; production cycles with load</td>
<td>all test &amp; production cycles with load</td>
</tr>
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</table>
What are the benefits for me when I use the NCG sensor?

Increased patient safety due to the fact that every sterilization process is monitored for the amount of NCGs.

Staff safety because the measurements are automatic and no handling of hot measuring devices that must be placed and removed from the chamber.

Increases sustainability because no separate test cycles are needed. All relevant parameters are monitored during every sterilization process.

Reduces use of resources, such as daily tests (Bowie and Dick tests) as well as chemical or biological indicators, and time needed for staff to run test cycles and process the results.

Makes steam sterilization easy to understand, validate and monitor. Gives a clear overview of the sterilization conditions in the chamber and interpretation of the measured values.

Can be used for daily calibration of the Steelco 4D IR sensor. Together with the 4D IR sensor (measuring the steam penetration within the actual load and the lumen of a medical device) the NCG sensor (quantifying the steam quality inside the chamber) provides the maximum patient safety possible.
In which devices of the Steelco sterilizers range is it possible to use the NCG sensor?

In general the NCG sensor is compatible with any sterilizer provided with a sterilization chamber connection port for steam quality testing as defined in the EN 285 standard.

Both the range of Steelco sterilizers VS and VS G2 series are compatible with the NCG sensor including those already installed at customer sites prior to the availability of this new device.

Always ask Steelco for additional details on integration of software and traceability functionality. Also check on the smaller size sterilizers (i.e. 1 and 2 STUs capacity) that there is sufficient space for fitting the sensor.

Is there any other possible application of the the NCG sensor apart from on a Steelco steam sterilizer?

As the measurements of the NCG sensor is independent from the sterilizer controls, it can be compatible with any sterilizer brand fitted with a steam quality testing port as defined in the EN 285 standard.

The NCG sensor can moreover be used as an independent testing device for checking the presence of NCGs in steam for performance validation/re-validation purposes.