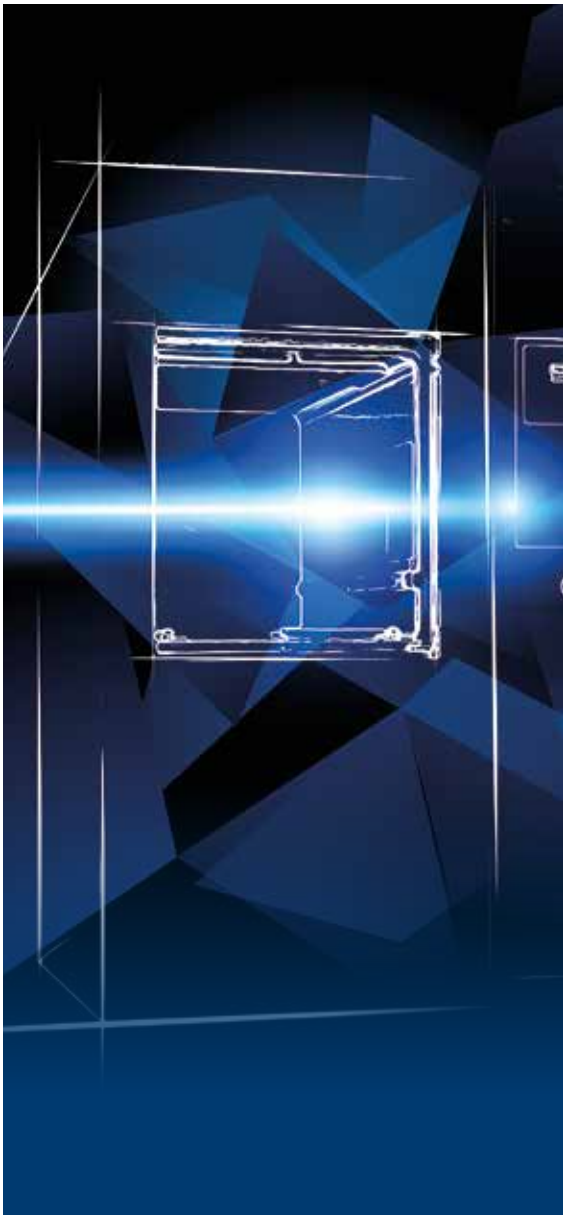
4D^IR SENSOR

monitoring steam saturation & penetration
of every sterilization load



Miele Group Member

4D^{IR} Sensor:

the importance of monitoring steam saturation & penetration of every sterilization load

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 within Miele organization in late 2017 has provided additional boost in technological development.
The 4D^{IR} sensor is breakthrough innovation in steam sterilization resulting in an impressive step forward in terms of safety of instrument reprocessing.

How this guide works

Questions and Answers.
To quickly get into the topic on how the 4D^{IR} sensor technology can improve sterilization process safety

i1 Scientific literature and additional comments

i2 Deep dives and related topics

Documents mentioned within i1 and i2 notes are publications available online.

Do we need to monitor steam condition during the sterilization process? In every load?

Yes, steam condition is one of the essential factors for a successful sterilization process!

- It is required by standards (e.g., EN 285:2015)
- It is required in every load (e.g., ISO 17665-1:2006 clause 10.1)

Temperature, holding time and…
...the **presence of steam**!

Current practice is to use the relationship between temperature and pressure to evaluate steam conditions - ideally 100 % saturated steam*. But this relationship is unreliable due to allowed tolerance and uncertain steam quality. Moreover **pressure is not mentioned in the standards as a sterilization parameter.**

State of the art is to measure sterilant conditions directly!

Some recent literature on the subject:

- ***The relation between the load, duration and steam penetration capacity of a surface steam sterilization process, a case study.***
  November 2018 PDA journal of pharmaceutical science and technology/PDA
- ***Case study: Correlation between the duration of a steam sterilisation process and the weight of the processed load.***
  September 2018, Zentralsterilisation - Central Service
- ***Following trends in steam sterilizer performance by quantitative monitoring of non-condensable gases.***
  August 2017, Journal of Hospital Infection 97(4)

EN 285:2015 clause 8.2.1.2.3 specifies that it is assumed that saturated steam is present when the calculation of the theoretical temperature is derived from pressure. But current standards allows for the presence of Non-Condensable Gases (up to 3,5 ml of Non-Condensable Gases from 100 ml condensate - EN285:2015, ISO 17665-1:2006 and the AAMI ST 79:2017).

Since traditional methods do not measure NCG during the process, therefore, the amount of water vapor present in a steam sterilizer cannot be be known.

- ***Measurement of only pressure and temperature are insufficient to monitor steam sterilization processes: A case study.***
  January 2014, Zentralsterilisation - Central Service, 4:250-253

So the 4D^{IR} sensor monitors the presence of the steam, correct?

Yes exactly. To date, the available references that could be measured as stated in standards for process control have been exclusively **temperature** and **contact time**... the 4D^{IR} sensor finally makes it possible to measure the last missing critical parameter: **the presence of the sufficient saturation of steam**.

- The control of the steam at **the end of a dead ended narrow channel**, enables the assessment of the capacity for correct **steam penetration, in real time and for each sterilization cycle!**

The 4D^{IR} sensor is currently **the only commercially available instrument that ensures the control of sterilization conditions** as required by regulations such as EN 285: 2015 and ISO 17665-1:2006 clause 10.1.

Additional information:

The calculation method of the theoretical temperature derived from pressure cannot provide reliable information and pressure is just and indication of steam saturation derived from a correlation table that doesn't represent the conditions within a sterilizer. ***A direct measurement is absolutely needed.*** *See for example the references [46] and [47] in the standards:*

- *[46]* **Release on the IAPWS Industrial Formulation 1997 for the Thermodynamic Properties of Water and Steam**.
  Erlangen, Germany, September 1997 (IAPWS-IF97) published in ASME International Steam Tables for Industrial Use, ASME Press, New York NY 10016, 2000, ISBN 0-7918-01543
- *[47]* ***Steam and Gas tables with computer equations.***
  Irvine TH. F., Liley, P.E Academic Press, 1984, the temperature and the Water Vapor Fraction (preferable the steam penetration) have to be measured in every load to ensure steam sterilization conditions in every process.

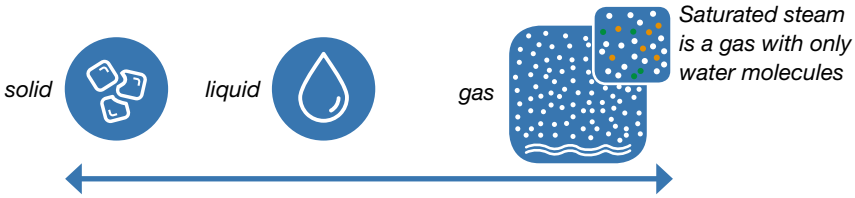
We can state that steam sterilization conditions are indirectly specified in the EN 285:2015

- *See for example:* **Steam sterilisation does not require saturated steam.**
  July 2017, The Journal of hospital infection, DOI: 10.1016/j.jhin.2017.07.011

Why is it called 4D^{IR} sensor?

4D^{IR} is the first of a new range of devices from Steelco allowing the monitoring of the sterilization process to... a new dimension.

Steam saturation is also the 4th parameter that needs to be monitored in the sterilization process together with time, temperature and pressure.



Definition of saturated steam EN 285:2015 clause 3.27: water vapour in a state of equilibrium between its liquid phase and its gas phase.

Already in 1959 the steam sterilization conditions where specified.

They can be summarized as:

Temperature [°C]	134	126	121
Time [min]	3	10	15

- ***Sterilisation by steam under increased pressure; a report to the Medical Research Council by the Working Party on Pressure-Steam Sterilisers***
  Lancet. 1959 Feb 28;1(7070):425-35.

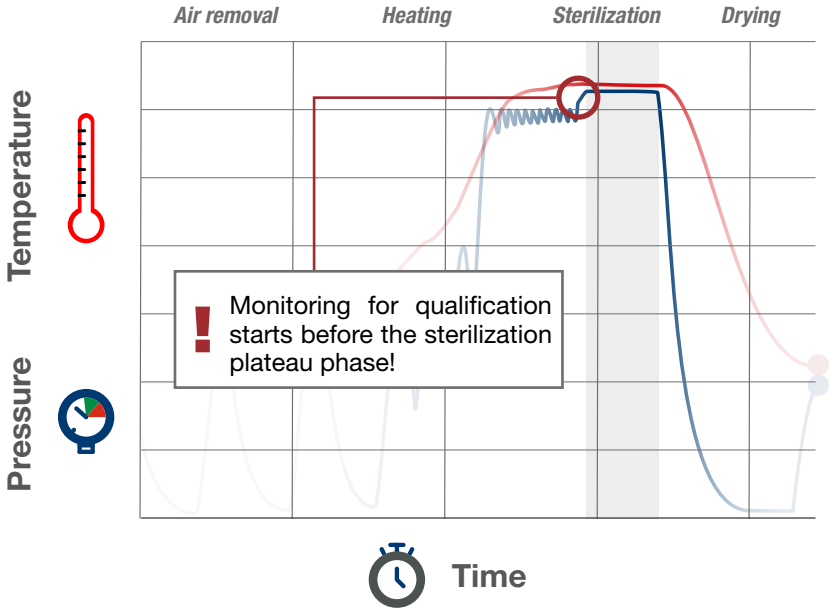
*In these values it is assumed that **a limited amount of NCGs may be present**.*

So, already in 1959 it was known that NCGs may be present in a steam sterilizer.

*Unfortunately, **the quantity of NCGs was not defined** because no measurement devices were present/available at that time.*

We definitely need to monitor steam saturation but also it's capacity to penetrate!

Exactly. the 4D^{IR} sensor is monitoring steam saturation continuously at the end of a dead end long hollow channel and, for cycle qualification, we measure from the beginning of the holding time of the sterilization phase and for its entire duration:



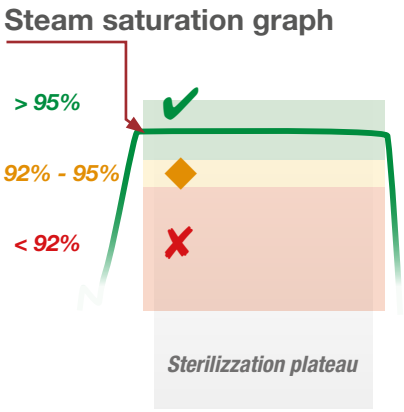
Additional information:

Only in 2013 was the first steam penetration measurement tool published:

- **Penetration of water vapour into narrow channels during steam sterilization processes.**
  February 2013, Journal of Physics D Applied Physics 46(6):065201, DOI: 10.1088/0022-3727/46/6/065201

What are the required conditions for steam that we have to refer to?

The parameter and its value can be derived from the standards, taking into consideration the accuracy required of the temperature and pressure probes. **The saturation of steam must be greater than 92 % at any point in the load.** This is the minimum value to maintain (and therefore to measure) **during the entire sterilization plateau!**



The areas for pass, pass with warning and fail are the result of the most recent studies!

The display and record of the Steelco sterilizers equipped with the 4D^{IR} Sensor indicate the degree of saturation. When the temperature has reached the sterilization temperature:

- **A pass** will be indicated when steam saturation is equal or higher than 95 %.
- **A pass with a 'warning'** will be indicated when steam saturation is equal or greater than 92 % but less than 95 %
- **A fail** will be indicated when steam saturation is less than 92 %

A pass with a warning alerts users that the sterilizer may need maintenance. but currently the sterilization conditions comply with the specifications in the standards.

The 4D^{IR} sensor makes it possible to measure steam penetration in devices with channels and cavities, for example:

- ***Steam penetration in thin-walled channels and helix shaped Process Challenge Devices.*** *December 2015 Zentralsterilisation - Central Service 6(6):429-433*

It is on the basis of this scientific evidence that Steelco has decided to integrate the 4D^{IR} infrared sensor in steam sterilizers.

What about the Bowie & Dick test? Can't it tell us steam penetration and presence of air!

The Bowie & Dick is a mechanical test to perform at the beginning of the day to test the removal of air and steam penetration in an empty chamber without a load.

The test was a big step forward in sterilization process monitoring, but it was more than 50 years ago (1963).

At that time there were very few channeled instruments and the packing was **mainly performed with linen** (often Huckaback towels) and the steam penetration mechanism in textiles **differs strongly from steam penetration in channels**.

From: Aorn JAORN journal , June 1981

Additional information:

Steam penetration mechanisms in a textile pack differ from steam penetration in channeled devices: in textile it is supported by capillary action working of the porous goods (absorption of water), while in hollow devices capillary is almost none (steam penetration is more related to convection, diffusion and condensation phenomena).

Some recent literature:

- **Case study: Correlation between the duration of a steam sterilisation process and the weight of the processed load**.
  September 2018. Zentralsterilisation - Central Service 26(4):225-230

I see there is a need for a more up-to-date approach!

Yes, a Bowie & Dick test doesn't provide the level of safety that you would like for **your sterilization process to be foolproof**:

- Is not **representative for a load that you'll sterilize in a sterilizer!**
- Doesn't provide data of **what happened during the "sterilization plateau of each cycle"** but what happend in an empty chamber at the beginning of the day.

moreover

- **Every sterilization cycle is a unique event!**
  What action should be taken when on Tuesday the Bowie & Dick test is a 'pass' and Wednesday is a 'fail'?
  Should all the processed loads between these two tests be 'recalled'? **Obviously yes!**

  These are **just some of the limitation of the current B&D test**!

For deeper understanding:

- ***The relation between the load, duration and steam penetration capacity of a surface steam sterilization process; a case study.***
  November 2018, PDA journal of pharmaceutical science and technology / PDA, DOI: 10.5731/pdajpst.2017.008490
- ***A case study of steam penetration monitoring indicates the necessity of Every Load Monitoring of steam sterilization processes.***
  Central Service, 5:320-325, 2016.

But CSSD staff have been used to trust indicators!

Yes, and they did it correctly but… **we mentioned the Bowie & Dick test just as an example** of a chemical indicator to highlight that the **requirements of the current standard** in general is simply **not challenging enough to prove sterilization conditions**.

To monitor steam penetration capacity, a more advanced and innovative technology is needed overcoming the limits of current tests, with additional future functionality possible to be developed.

Among the limits of the current tests I would like to stress the difficulty of interpreting results!

The color change of chemical indicators are often difficult to interpret and leave room for human error. Indicators are judged with human eyes and different light conditions. If placed in a pack or container, indicators are only seen once packs are opened in the OR, again with different lighting conditions.

Some parameters are judged by indirect measurement. Indicators are supposed to **change at a specific phase of the process**, but you are **unaware of events happened in the meantime**.

Same situation for BIs which are inoculated spores on a test strip in a vial. It is relatively easy to remove air from these vials and achieve contact with steam, with the spores dying relatively early during the plateau phase or even before, but **in hollow instruments we are interested in sterilization conditions during the complete plateau period at a most challenging location**.

Additional information:

Concerns have been raised regarding the quality and reliability of indicators from different manufacturers with some of these changing without the presence of steam or faster with higher temperature (once a chemical reaction is started it almost cannot be stopped).

As previously mentioned color interpretation may vary, see for example:

- ***Six commercially available Class 6 Chemical Indicators tested against their stated values.*** *January 2012 Zentralsterilisation - Central Service 6(6):400-404*

We are also disposing of a lot of paper and vials!

Yes, a topic that that is increasingly important!

The transportation, storage and disposal of indicators is not compatible with an environmentally green footprint.

Indicator materials have to be **transported, stored and retained after use under specific conditions**. This may influence the behavior characteristics of indicators and these conditions may be difficult to check by the user.

For a robust quality system it is necessary to know the transport and storage conditions of every indicator.

For deeper understanding:

A test cannot be better than the reference to which it is developed.

Standard specify that for CI (ISO 11140) and BI (ISO 11138) indicators a specific test vessel (sterilizer) has to be used for validating their performance as specified in the ISO 18472:2018

Even in the case of this dedicated pressure vessel, however, validation does not concentrate on measuring the steam but only the temperature and pressure of the sterilization chamber.

I have already heard about B&D electronic devices. Does the 4D^{IR} sensor compare to those devices?

Definitely NOT! **Electronic devices in the market have been focused in merely replacing the B&D test as a daily routine machine control** matching the performance of the original B&D textile test from the '60s, **without going beyond or providing any additional benefit in process safety!**

The parameters monitored are typically pressure and temperature, sometimes temperature only. Those parameters, even when analyzed together **with an algorythm referencing the original test (B&D towel test pack)** don't provide sufficient information on the steam conditions as required by the standard! (e.g., ISO 17665-1:2006 clause 10.1).

The 4D^{IR} sensor measures the presence of the sterilant itself!

Additional information:

Although the Bowie & Dick test was in the early 1960s an innovative test in the meantime, it appears that the test is difficult to standardize. For example, 5 Bowie & Dick tests out of 9 appear not to comply with standards:

- **An Evaluation of Nine Bowie & Dick Test Products Available in the United Kingdom.** *Published IDSc J Aug 2012*

Also, between Electronic Steam Penetration according the ISO 11140-4 it appears that large variations are noticed:

- ***A comparison of four commercially available electronic steam penetration tests according to ISO 11140 part 4***
  January 2011, Zentralsterilisation - Central Service 3(3):180-184

For deeper understanding:

The large variations in the different steam penetration tests, makes it doubtful whether they can comply with the ISO11140:2007. The way the Bowie & Dick is specified in the ISO 11140-4 is actually a Non Condensable Gas Measurement. This is demonstrated in the literature, e.g.;

- **Measuring non-condensable gases in steam**,
  November 2013, The Review of scientific instruments 84(11):115106. DOI: 10.1063/1.4829636

B&D portable electronic devices can't be shared between sterilizers combined within a highly automated CSSD.

For deeper understanding:

Current devices are not a steam penetration tests for channeled instruments.
The standards try to overcome this with the introduction of helix shaped test devices (EN 867-5:2001 and ISO 11140-6 draft).

The literature however demonstrates that these devices are not representative of channeled instruments, because the dimension of the device promotes steam penetration and is not representative of channels with a constant radius:

- ***Steam penetration in thin-walled channels and helix shaped Process Challenge Devices,***
  December 2015, Zentralsterilisation - Central Service 6(6):429-433
- ***Current reference devices for hollow instrument loads as defined in standards are not a valid steam penetration test.***
  January 2012, Zentralsterilisation - Central Service 4:256-260
- ***One set of requirements for steam penetration tests is enough.***
  January 2011, Zentralsterilisation - Central Service 5(5):365-366

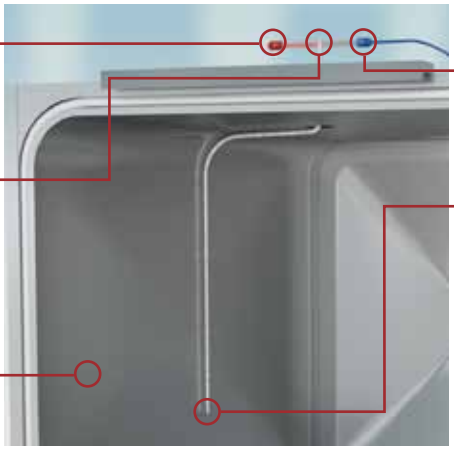
The standards contain warnings that the helix shaped devices do not represent medical devices: E.g. EN 285:2015 and EN 13060:2014, therefore the following note is included in the standards on several locations.

NOTE: The performance of the hollow load test as defined in EN 867–5 is under discussion within ISO/TC 198. Test data that has been generated and published shows variability in the performance of the hollow load test associated with variation of the rate of pressure change during the air removal stage of the cycle.

What additional benefits can the 4D^{IR} sensor provide?

Most of the benefits come from **continuously monitoring steam penetration** throughout each cycle, in addition:

- It is **a "self-testing" device** and has to detect a **"fail"** result during the daily warm up cycle and then a **"pass"** during the following steam penetration test cycle: **a unique automatic feature not available in any other chemical or biological indicator or digital device**.
- **Provides traceability** of the steam penetration by recording the 4D^{IR} sensor cycle data together with the other critical information parameters, **reducing handling time and potential human errors thus improving patient safety**.
- Provides information (acquired per sterilization cycle) to be used for actual load parametric release or for trouble shooting and process cycle development.
- **It guarantees savings in a short time.**



i1

i2 ***Additional information:*** *detailed information on the calculation of the return on investment can be provided by Steelco personnel or it's distributors*

I'm not an engineer so please keep it simple. How does the Steelco 4D^{IR} sensor work?

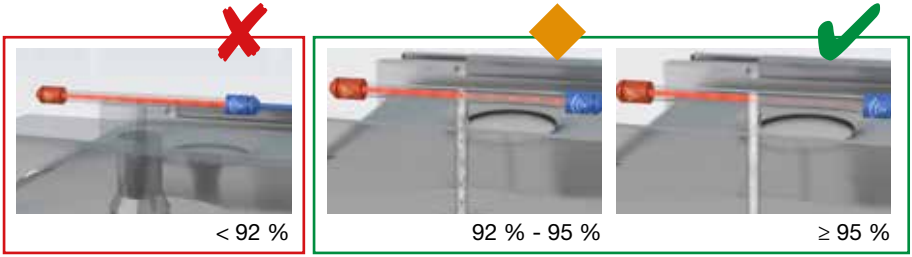
It measures steam saturation, the only parameter which can guarantee that sufficient steam is present in the sterilizer chamber and load and that there are no excessive residues of non-condensable gasses. **The measurement takes place at the close end of a long narrow channel** (70 cm) **to simulate a worst-case scenario** (140 cm) open ended instrument.

The working principle can be explained with **a simple comparison**:

A. When you stay in the direct sunlight, the UV light from the sun tans or even burns your skin.

B. When you stay in the same sunlight, but behind glass, you will get warm, but you will not be tanned or burned because the UV-B light is filtered out of the sunlight by the glass.

In the 4D^{IR} Sensor a similar phenomenon is used: the IR light can penetrate normal air but can't travel thought steam. The steam 'filters' the IR light, just like glass filters the UV light, so:



the **greater the absorption of IR light** by steam
the **higher the saturation of steam**

Steam presence and steam penetration are proven and monitored in real time during the sterilization plateau, every single second.

In depth: 4D^{IR} sensor represents the worst case condition for steam penetration in channelled instruments simulating everyday use
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