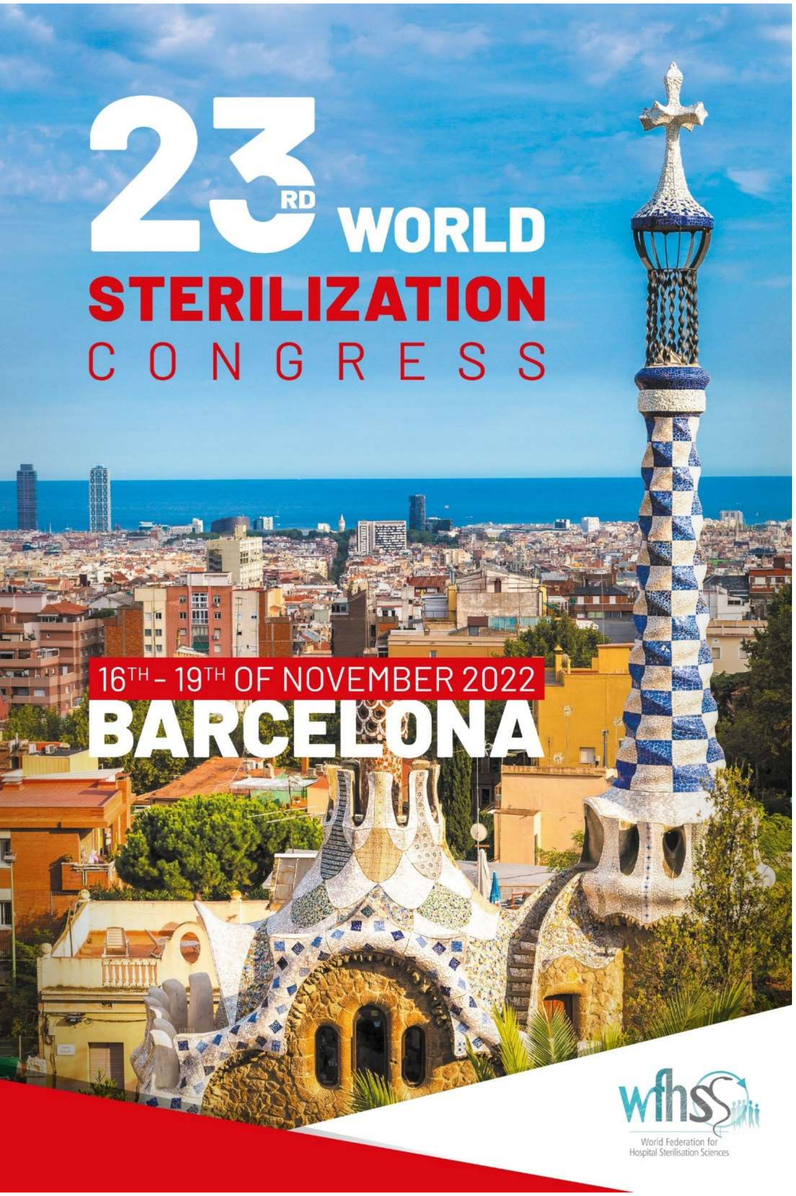


World Federation for Hospital Sterilisation Sciences

Performance evaluation of chemical, biological and physical indicators in the process of sterilization under the effect of non-condensable gases

Sandoval Barbosa Rodrigues
Technical Director at CisaBrasile ltda

Steam Supply to the Sterilizer Chamber

CONTAMINANTS IN FEED WATER
Annex B

CONTAMINANTS IN STEAM
Table 4

DRYNESS VALUE
> 95 %   95 % EN 285 97 % AAMI ST 79

SUPERHEAT
< 25 K

PRESSURE FLUCTUATION
< 10 %

NON-CONDENSABLE GASES
< 3,5 % V/V

EN 285 (2015)

What are Non-Condensable Gases (NCG)?

NCG are defined as gases that cannot be liquefied in the pressure and temperature range used during the saturated steam sterilization process.

(EN 285, 2015)

N_2 O_2 CO_2

NCG competes with steam for space in the inner chamber.
The presence of NCG constitutes a potential failure (thermal insulator) and compromises thermocoagulation and protein denaturation

Sources of NCG

Feed water for steam generation

NCG dissolved in the water (CO_2 O_2)

Water supply failures

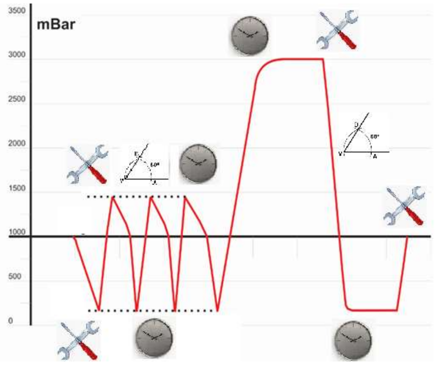
Contaminants
Colligative properties
When heated become NCG

Degasser can be installed before the water supply to the steam generator

The amount of NCG in the chamber may be higher than in the steam supply.

Inefficiency in the air removal stage

Failure of the pressure measurement system

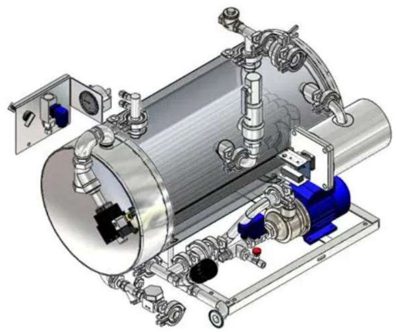


Inadequate **programming** of the conditioning phase

Vacuum pump performance

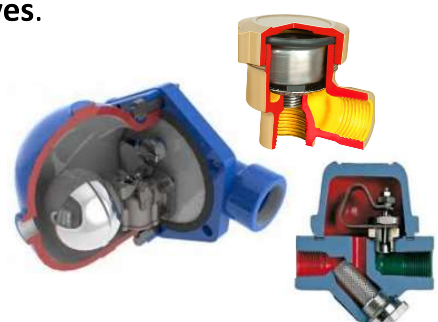
Sources of NCG

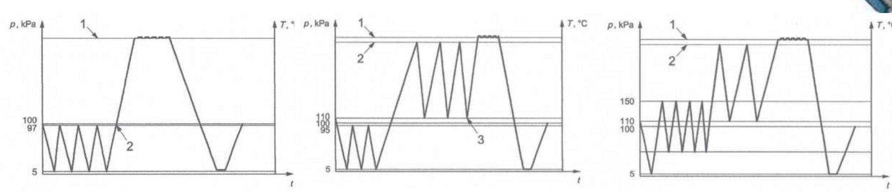
Sterilizer Design



When the steam is cooled, the volume decreases in such a way that there is formation of a vacum in the generator and its pipelines.
It is not convenient to use vacuum break valves.

There are different **models of trap valves** for condensate removal that allow or not to remove air.





Among autoclave manufacturers, there are **different methods for removing air** in the conditioning phase,

NCG from the Load

Indiscriminate use of the **sterile barrier system**

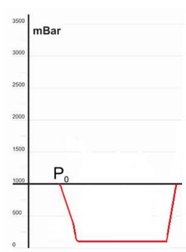
Presence of **volatile chemical agents** from the process fabric washing

Load
Hollow and Porous

Sources of NCG

Chamber Leakage

Corrosion perforations or loose connections, which can commonly occur due to vibration, resulting from the operation from the autoclave. Both can allow air to enter when the autoclave is in a vacuum;



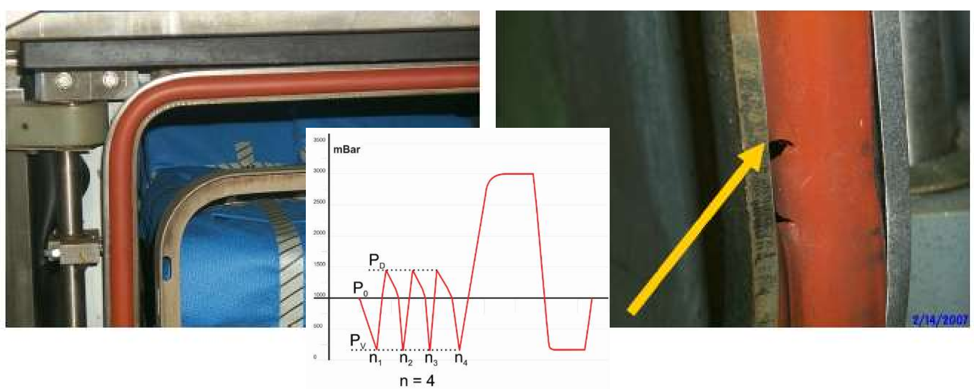
Door Seal Problems

Preventive maintenance failure

Use of gaskets with hardness different from that specified by the manufacturer,

Mechanical failure in the gasket channel

Failure to adjust the pressure of the gasket pressurized by compressed air



Literature Review

- **2022** KOSTER, René; RALPH, AC van; WEZEL, Josephus PCM van. Parametric release with measurements of steam sterilisation parameters: temperature, steam composition and time. aseptica, p. 41. 2022
- **2021** RODRIGUES, S. B. et al. Performance evaluation of chemical, biological and physical indicators in the process of sterilization under the **effect of non-condensable gases**. Journal of Hospital Infection, v. 108, p. 1-6, 2021.
- **2005** KAISER, U. **Effects of Non-Condensable** Gases (NCGs) on Steam Sterilisation Processes. Central Service, v. 13, p. 48-50, 2005.
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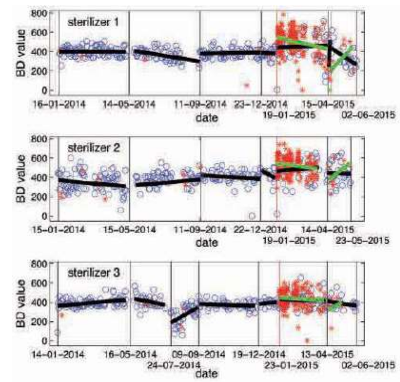
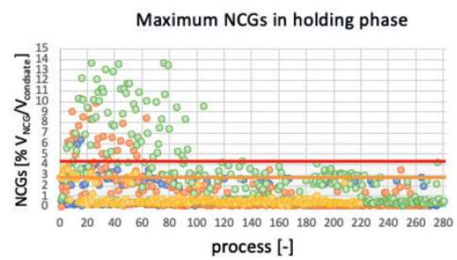
- **1873** REYNOLDS O., On the **condensation of mixture of air and steam** upon cold surfaces, Proc. Roy. SOC. 144 (1873) Desafio dos GNC na Indústria (Aquecimento ou Resfriamento)



Monitoring of the sterilization process must be carried out in each cycle

Failures with NCG don't just occur on the first cycle of the day

(Josephus PCM van, 2016)



Similar sterilizers (Validated), showed different NCG results.

(Koster et al, 2022)

Each Steam Sterilization Process is a UNIQUE Event!

EN 285 (2015) 8.1 Steam Penetration

There are many adverse events in the process !

Literature Review

Among the causes of wet material, operational failures in the assembly of loads, malfunctions of the sterilizer, steam quality related to low saturation title, variations in steam demand and also the NCGs are pointed out. BASU (2016)

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Specialists' opinion regarding factors related to wet loads after steam sterilization

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SUMMARY

Background: Episodes of wet loads after steam sterilization are frequent; however, the factors related to these events are still unclear.
Aim: To evaluate the strength of relationship of factors related to wet loads after steam sterilization.
Methods: By adapting the Delphi technique, steam sterilization specialists assigned a score for the relation strength of a list of 37 factors (f.01—37) related to wet load, grouped into: cycle parameters, sterilizer, steam, load, and environment. Sixty-seven specialists distributed on five continents participated in all phases of this study.
Findings: Certain factors related to wet loads are better established, such as vacuum depth in the drying phase, whereas others are still controversial, such as those related to the environment. The factor that obtained the highest average score was the vacuum depth in the drying phase (f.12), with a value of 4.28, and the lowest score of 2.66 was obtained in the delay time when the set reaches the value of vacuum or steam in the conditioning phase (f.05).
Conclusion: Specialists' opinions diverge in most of the factors related to the occurrence of wet loads. The results obtained will enable further research and the establishment of normative requirements.

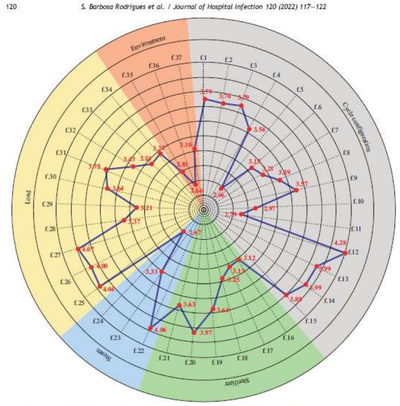
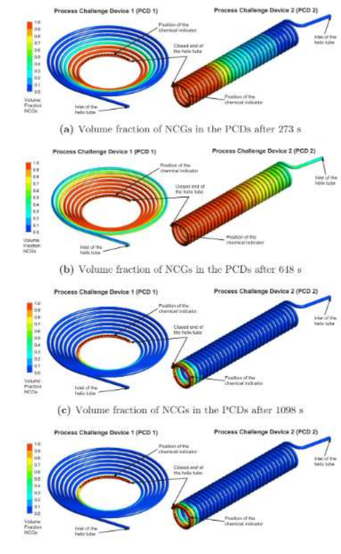
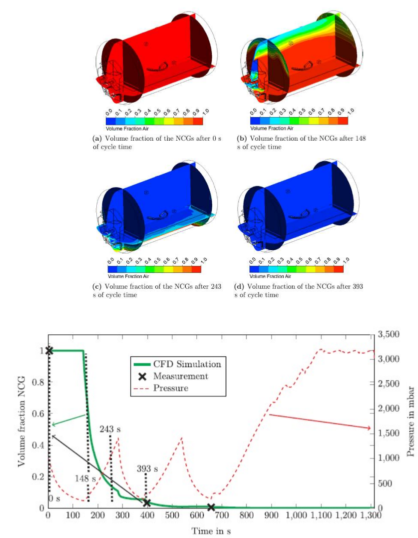


Figure 1. Distribution of average scores of the strength of the relation of factors associated with wet load episodes in steam sterilization, according to group.

RODRIGUES (2022)





Some interesting computer simulation methods are being used to investigate steam penetration.

FEURHUBER (2019)

The danger related to NCG has been underestimated. The best IQ and IB on the market do not signal the presence of a **NCG** content of up to 10%. KAISER U. (2005)

Effective removal of air from lumens, porous loads and other complex shapes including interior spaces **is difficult**. (ABNT ISO 17665-2, 2013)

Low levels of NCGs in the steam supplied to sterilizers **can significantly affect** sterilizer performance and process effectiveness. HTM0101 (2016)

Application of risk management

ISO 14971:2019 Medical devices - Application of risk management

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Performance evaluation of chemical, biological and physical indicators in the process of sterilization under the effect of non-condensable gases

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Air detector

SUMMARY

Background: The risk concerning the presence of non-condensable gases (NCGs) has already been demonstrated, but routine monitoring still requires further research to be implemented in each sterilization cycle.

Aim: Performance evaluation of the physical, chemical and biological indicators used in monitoring in comparison with a sterilizer integrated detector for NCG in the Sterilization Process.

Methods: Chemical indicators (type 2 Bowie–Dick test, type 5 and type 6 models), self-contained biological indicators and physical indicators (temperature, pressure, thermal qualification and a patented integrated air detector) were used to monitor the steam sterilization process in two situations of controlled failure: chamber leakage and door seal failure. This controlled failure was obtained by the presence of a known amount of air: 0–30 L/min for chamber leakage and 0–30% for the door seal failure. Evaluation tests were carried out with and without the use of process challenge devices (PCDs).

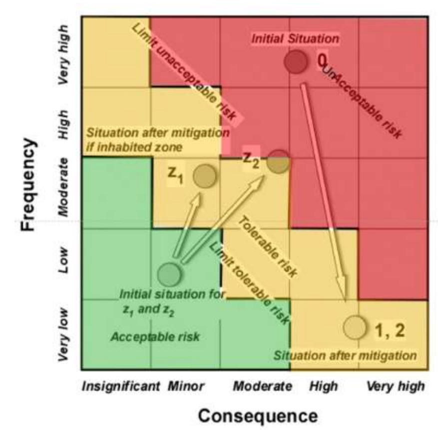
Findings: In both studies, the Bowie-Dick Test showed different results, according to the manufacturer. The biological, physical or chemical indicators without a PCD were unable to detect small volumes of NCGs in both simulations.

Conclusion: The integrated air detector can be considered an option for the detection of NCGs in each cycle.

To find a quantitative value of the risks related to the NCG in the sterilization process, the risk analysis was performed with the FMEA in order to ensure that the most representative causes are included in the study

$$\text{Risk} = \sum_{\text{All hazards}} \left(\int_{P_T=0}^{P_T=1} P_{(T|HS)} * \left(\sum_{\text{All EaR}} (P_{(S|HS)} * (A_{(ER|HS)} * V_{(ER|HS)})\right)\right)$$

The risks were mitigated so that there is no interference in the tests (e.g. Steam Quality Control, Leaks in the Systems)



We selected 2 of the risk with the highest residual value

Failures Caused Intentionally

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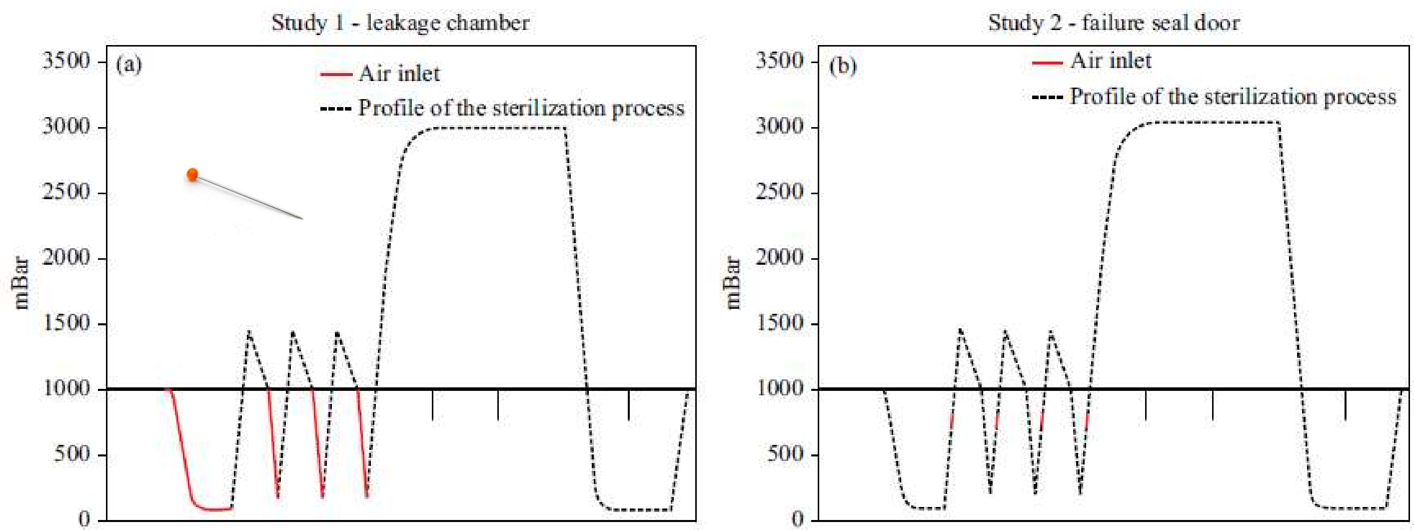


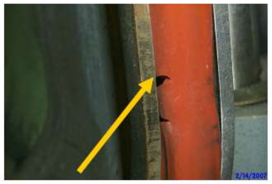


Figure 1. Pressure profile of failure studies that presented a higher risk of non-condensable gases in the sterilization process. (a) Representation of the air input simulation in study 1 for chamber leakage; the airflows were gradually increased for each flow study. (b) Representation of the air input simulation in study 2. For each studied percentage of air, a known volume of air was introduced into the chamber from 700 mbar, thus 3.5% represents 35 mbar of air introduced in 1000 mbar.

$$F = \int_{o}^{t} 10^{[(T-121,1)/Z]} dt \qquad \text{equation 1}$$

where dt is the time interval between two next measurements of T; T is the temperature of the sterilized product at time t; Z is the temperature coefficient, assumed to be equal to 10°C.

$$T = A + B(\ln P + C)^{-1} \qquad \text{equation 2}$$

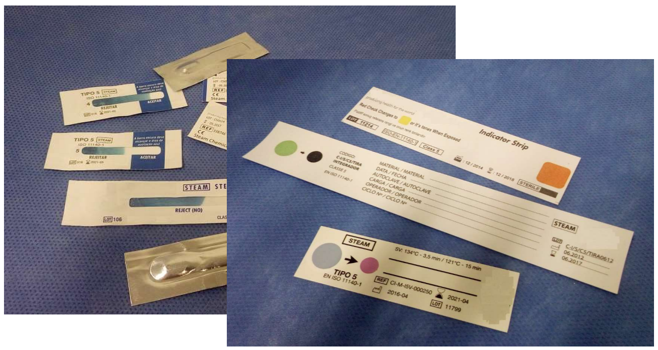
where T is the saturated steam temperature in Kelvin; P is the measured pressure in mega pascals, time averaged to result in a time constant between 1 s and 2,5 s; A is 42,677 6 K; B is -3892,70 K; C is -9,486 54.

23RD WORLD STERILIZATION CONGRESS

Indicators

CHEMICAL INDICATORS

Type 5 - 6



BIOLOGICAL INDICATORS

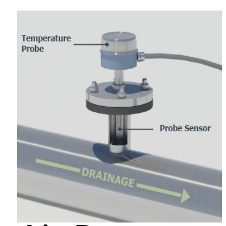
Geobacillus stearothermophilus

PHYSICAL INDICATORS

Thermal Qualification
(Penetration and distribution study)

$$T = A + B(\ln P + C)^{-1}$$

$$F = \int_{0}^{t} 10^{[(T-121{,}1)/Z]}\, dt$$



Air Detector

PROCESS CHALLENGE DEVICE (PCD)

Results

Study 1 - leakage chamber

Table I

Results of chemical, physical and biological indicators when subjected to simulated failure of chamber leakage (study 1)

Indicator	PCD	Air (L/min)							
		0	1	2	3	5	10	20	30
1 CI Type 2 Manufacturer A	Porous load – paper	Pass	Pass	Pass	Pass	Pass	Fail	Fail	Fail
CI Type 2 Manufacturer B	Porous load – paper	Pass	Fail	Fail	Fail	Fail	Fail	Fail	Fail
CI Type 5	CSTP	Pass	Pass	Pass	Pass	Fail	Fail	Fail	Fail
CI Type 5	Hollow load – stainless steel	Pass	Pass	Pass	Pass	Pass	Fail	Fail	Fail
CI Type 5	Hollow load – PTFE	Pass	Pass	Pass	Pass	Pass	Fail	Fail	Fail
CI Type 5	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
CI Type 6	CSTP	Pass	Pass	Pass	Pass	Fail	Fail	Fail	Fail
CI Type 6	Hollow load – stainless steel	Pass	Pass	Pass	Pass	Pass	Fail	Fail	Fail
CI Type 6	Hollow load – PTFE	Pass	Pass	Pass	Pass	Pass	Fail	Fail	Fail
CI Type 6	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
BI	CSTP	Pass	Pass	Pass	Pass	Fail	Fail	Fail	Fail
BI	Hollow load – stainless steel	Pass	Pass	Pass	Pass	Pass	Fail	Fail	Fail
BI	Hollow load – PTFE	Pass	Pass	Pass	Pass	Pass	Fail	Fail	Fail
BI	2 Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI temperature control	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI pressure control	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI F value (equation 1)	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
4 PI T value (equation 2)	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI leak test	Not applicable	Pass	Fail	Fail	Fail	Fail	Fail	Fail	Fail
PI thermal qualification	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI thermal qualification	CSTP	Pass	Fail	Fail	Fail	Fail	Fail	Fail	Fail
PI air detector	Not applicable	Pass	Fail	Fail	Fail	Fail	Fail	Fail	Fail

BI, biological indicator; CI, chemical indicator; CSTP, cotton standard test pack; PCD, process challenge device; PI, physical indicator.

Study 2 - failure seal door

Table II

Results of chemical, physical and biological indicators when subjected to simulated door seal failure (study 2)

Indicator	PCD	Air (%)							
		0	1.0	2.0	3.5	5.0	10.0	20.0	30.0
CI Type 2 Manufacturer A	Porous load – paper	Pass	Pass	Pass	Fail	Fail	Fail	Fail	Fail
CI Type 2 Manufacturer B	Porous load – paper	Pass	Pass	Fail	Fail	Fail	Fail	Fail	Fail
CI Type 5	CSTP	Pass	Pass	Pass	Pass	Fail	Fail	Fail	Fail
CI Type 5	Hollow load – stainless steel	Pass	Pass	Pass	Fail	Fail	Fail	Fail	Fail
CI Type 5	Hollow load – PTFE	Pass	Pass	Pass	Fail	Fail	Fail	Fail	Fail
CI Type 5	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
CI Type 6	CSTP	Pass	Pass	Fail	Fail	Fail	Fail	Fail	Fail
CI Type 6	Hollow load – stainless steel	Pass	Pass	Fail	Fail	Fail	Fail	Fail	Fail
CI Type 6	Hollow load – PTFE	Pass	Pass	Fail	Fail	Fail	Fail	Fail	Fail
CI Type 6	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
BI	CSTP	Pass	Pass	Pass	Fail	Fail	Fail	Fail	Fail
BI	Hollow load – stainless steel	Pass	Pass	Pass	Fail	Fail	Fail	Fail	Fail
BI	Hollow load – PTFE	Pass	Pass	Pass	Fail	Fail	Fail	Fail	Fail
3 BI	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI temperature control	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI pressure control	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Fail	Fail
PI F value (equation 1)	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI T value (equation 2)	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Fail	Fail
PI thermal qualification	Without PCD	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
PI thermal qualification	CSTP	Pass	Fail	Fail	Fail	Fail	Fail	Fail	Fail
PI air detector	Not applicable	Pass	Fail	Fail	Fail	Fail	Fail	Fail	Fail

BI, biological indicator; CI, chemical indicator; CSTP, cotton standard test pack; PCD, process challenge device; PI, physical indicator.

1 - The manufacturer of B&D Test can be determinant for an effective NCG control.

2 - Biological, physical or chemical indicators without a PCD are unable to detect small volumes of NCG.

3 - The pressure, temperature measurement and the theoretical calculations are not sufficient to monitor small volumes of NCG.

4 - The air detector, leak test and thermal qualification detected the simulated failure from the first air injection.

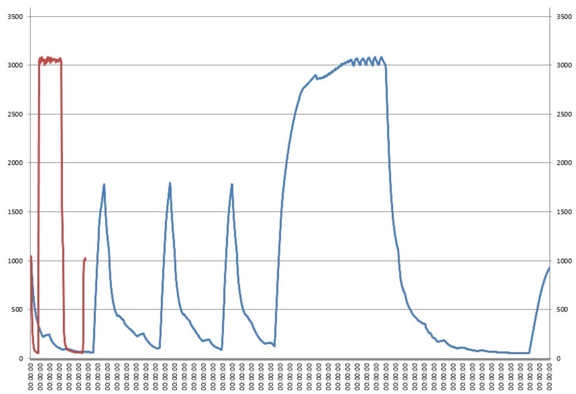
Discussion

Performance difference between chemical indicator manufacturers

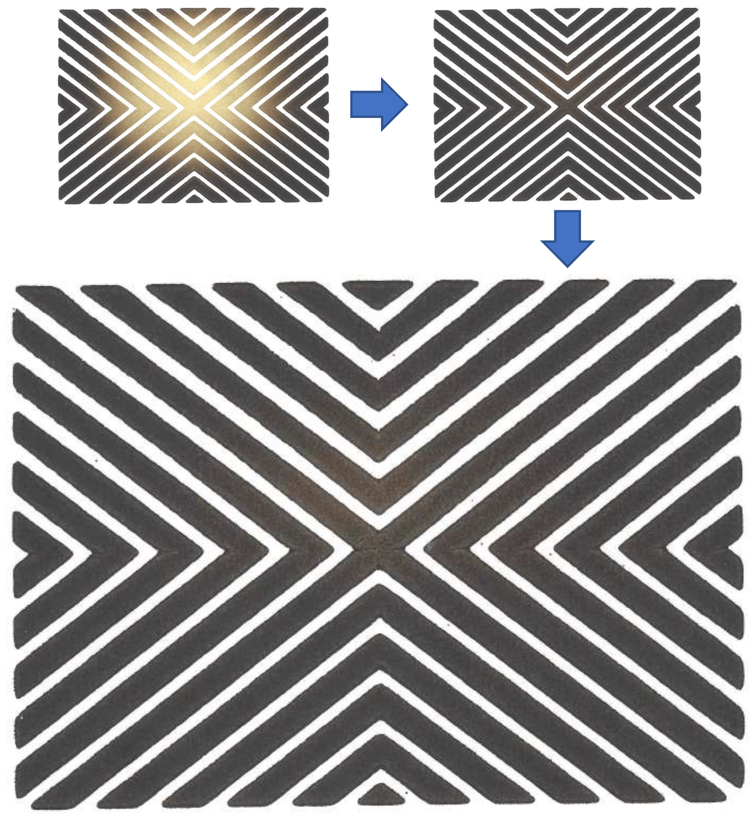
Six commercially available Type 6 CI tested against their stated values. Only **one** actually reached its reference color and showed a color change close to its SVs. (VAN DOORNMALEN, 2012)

Nine commercially produced alternative BDT packs were assessed for sensitivity towards residual air , just **four** detected residual air . (KIRK, 2012)

False positive results for BDT were obtained with come-up ramp time of 3 min (LARANJEIRA, 2020)



Pressure profile of one cycle of a B.I.E.R. (Red) versus the profile of a conventional cycle (Blue)



We need to discuss current technical standards and research additional methods for evaluating the CI used in CSSD

Discussion

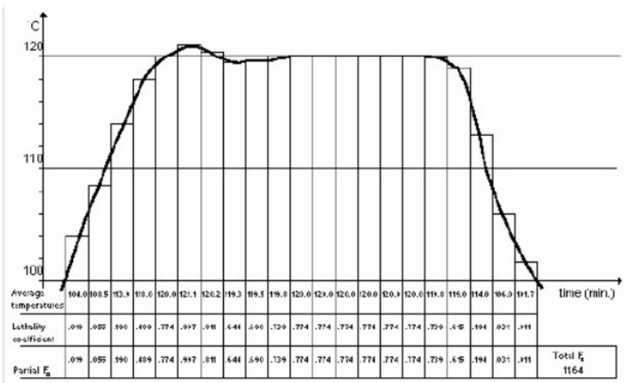
Without the use of a PCD, it was not possible to detect the NCG

Differences between the set point control temperature and the theoretical temperature calculated from the chamber pressure may not be adequate to detect the small volumes of air and prevent the penetration of steam.

(ISO 17665-2, 2009)

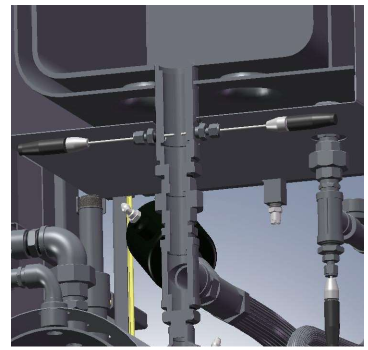
Although measurements of pressure and temperature may be sufficient to control a steam sterilization process, they are not sufficient to ensure that surface steam sterilization conditions are actually met for all types of loads

(VAN DOORNMALEN, 2014)



The greater the air injection, the greater the F0 value, giving a false impression of good sterilization. In fact, the value was higher due to the amount of air that delays reaching the temperature.

Pressure and temperature measurements **alone** cannot be used to determine the steam composition during a steam sterilization process

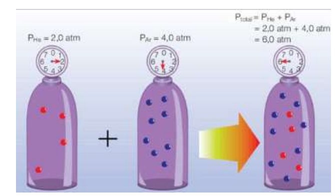


$$T = A + B(\ln P + C)^{-1}$$

$$F_0 = \int 10^{\frac{(T-121.1)}{10}} dt$$

Dalton's Law: The total pressure of a mixture of gases is the sum of the pressures that each gas.

$$P_T = P_A + P_B = \frac{n_A RT}{V} + \frac{n_B RT}{V}$$



Theoretical calculations based on pressure and temperature, CIs and BIs without the use of PCDs are not enough to monitor NCGs!!!

23RD WORLD STERILIZATION CONGRESS

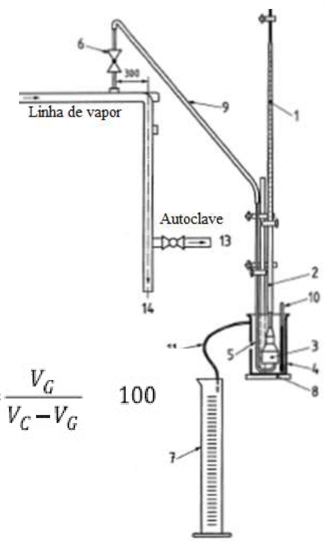
Discussion

Indicators for Control of NCG

All technologies have **advantages and disadvantages**!

VALIDATION / QUALIFICATION		ROUTINE CONTROLS			
NCG MEASUREMENT	THERMAL QUALIFICATION (PENETRATION STUDY)	LEAK TEST BDT	PCD HOLLOW LOAD POROUS LOAD	ELECTRONIC BDT	AIR DETECTOR (or other NGC meters)

NCG MEASUREMENT



$$C_{NCG} = \frac{V_G}{V_C - V_G} \quad 100$$

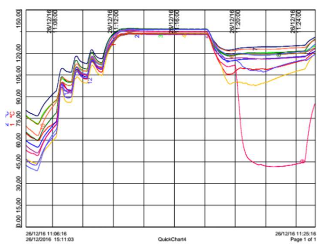
HTM0101, ISO17665, EN285

Method allows quantify (< 3,5 %)

Steam Source Measurement

Annual Frequency

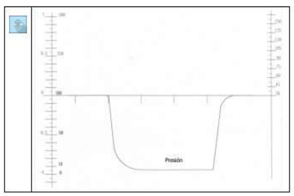
THERMAL QUALIFICATION (PENETRATION STUDY)

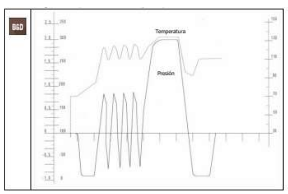


Allows you to understand the thermal profile at the critical load with its respective Packaging

Annual Frequency

LEAK TEST BDT





ISO17665, EN285

Does not monitor each load

PCD HOLLOW LOAD POROUS LOAD

Control Every Load

In addition to the NCG, it also controls the super heated steam

Subjectivity in interpretation

ELECTRONIC BDT

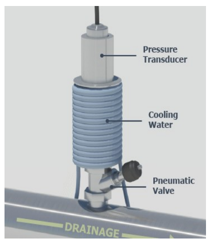
Friendly Environment

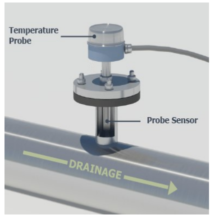
Theoretical equations that present quantitative data

Requires Cooling

Requires Calibration

AIR DETECTOR (or other NGC meters)





Control Every Load

Integrated Monitoring

Friendly Environment

Requires Calibration

Not designed to measure vapor composition

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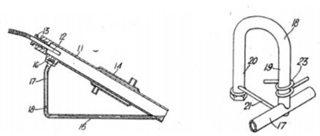
Air Detector

The value of 3.5% of NCGs was experimentally defined in the 1960s in relation to the sensitivity of air detectors commonly used in the UK

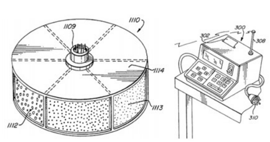
Simplistically, the performance of an air detector is to detect that a process fails with an induced leak of 10 mBar/minute or less, the temperature measured at the center of the test package is less than 2°C.

Dispositivos para detecção de ar em esterilizadores de vapor de Scoffield



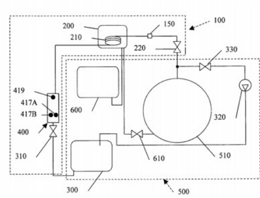
Fonte: Scoffield (1966)

Dispositivos para detecção de ar em esterilizadores de vapor de Colvin

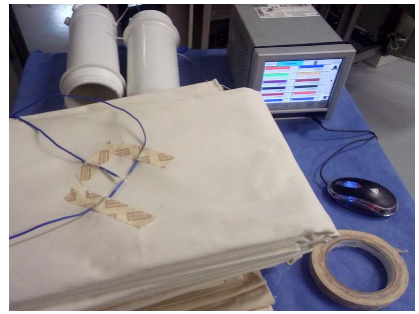


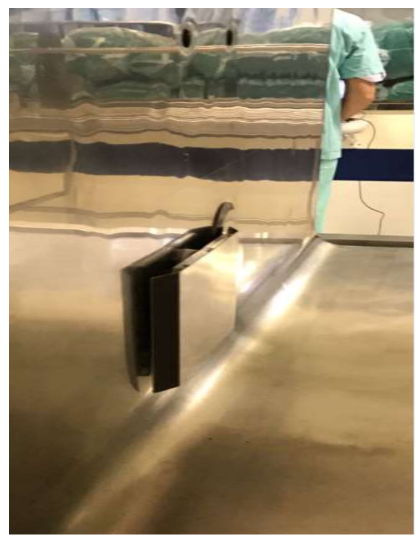
Fonte: Colvin (1995)

Dispositivos para detecção de ar em esterilizadores de vapor de Spendley



Fonte: Spendley (2009)





```
Autoclave Mod. CISA 6412
SN12345---

Inicio de Ciclo 11:53:59
                08/03/17
Operador:
Cisa

Numero de Ciclo        46
Teste Bowie & Dick
Esterilizacao  T=134.0°C
                t= 210seg

Aquecimento:    Eletrico

Acondicionamento      4 P
11:53   72.4°C  1010  mB

 1  Vacuo          150  mB
11:55   81.3°C     150  mB
 1  Vapor         1300  mB
11:55   91.8°C    1301  mB

 2  Vacuo          150  mB
11:56   56.1°C     150  mB
 2  Vapor         1300  mB
11:56   81.4°C    1300  mB

 3  Vacuo          150  mB
11:57   62.2°C     150  mB
 3  Vapor         1300  mB
11:57   83.1°C    1300  mB

 4  Vacuo          150  mB
11:59   56.7°C     150  mB
 4  Vapor         1300  mB
11:59   81.2°C    1301  mB

Aquecimento       134.0°C
11:59   81.2°C    1395  mB

Esterilizacao    210 seg
Hora   T.Cam.    P.Cam.
12:00  135.1°C   3104  mB
12:01  134.8°C   3098  mB
12:01  134.9°C   3091  mB
Secagem            1 min
12:02  134.8°C   3070  mB

Aeracao
12:04   52.3°C    114  mB

ALARME
12:02  134.8°C   3070  mB
DETECCAO DE AR

FASE DE ESTERILIZACAO
Tempo de Fase       68 seg
Temp.Max.Cam.      135.1°C
Temp.Min.Cam.      134.6°C
Temp.Max.Prod.     134.7°C
Temp.Min.Prod.     134.4°C
Temp.Max.AirDet.   133.7°C
Temp.Min.AirDet.   133.3°C
Pres.Max.Cam.     3127  mB
Pres.Min.Cam.     3049  mB
Dif.Max.Temp.        1.5°C
Dif.Min.Temp.        1.2°C

Tempo Total         11 min
F0 Total              43.4
F0 Air Detector       32.6
F0 Produto            39.6
CICLO FINALIZADO
IRREGULARMENTE
```

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Conclusion

The **thermal qualification** and the **air detector** were able to detect the presence of NCG in both studies, while the **leak test** only for the study of induced leakage

Physical indicators, BIs and CIs **without a PCD were unable to detect small volumes of NCGs** in both simulations

The BDT detected leaks in the chamber from 1 L/min, but **the performance was conditioned to the manufacturer**, even using products that meet the same technical standard.

It is necessary to **research methods to determine the steam composition**.

All indicators have advantages and disadvantages. Therefore, it is important that they are evaluated to mitigate the risks in their use

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Thank you very much for
your attention!

¡Muchas gracias por
su atención!

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