IV Simposio Nazionale

Centrale di Sterilizzazione e Sala Operatoria, processi trasversali: devono essere sicuri

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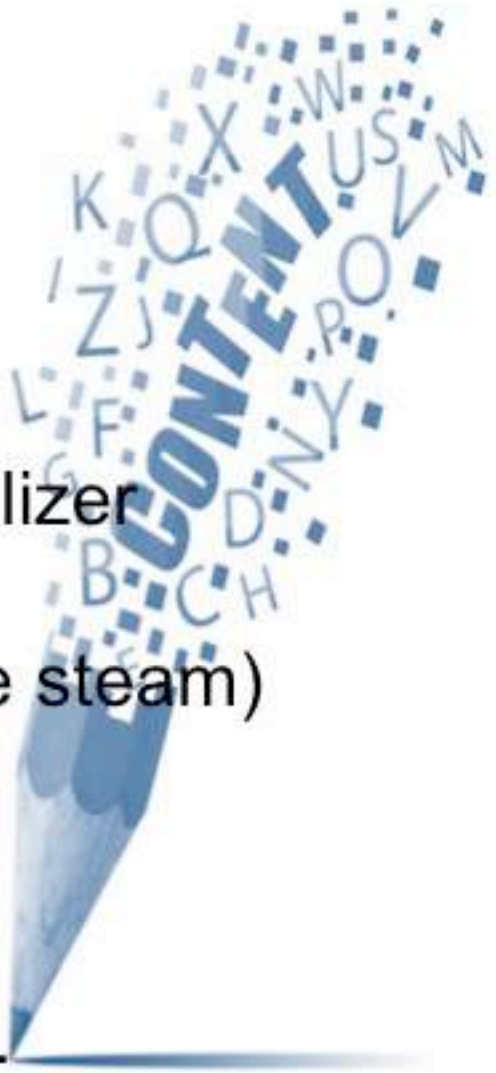
Sterilizzatore a vapore all'avanguardia

«State of the art steam sterilizer»

Andreas Schneider

Content

- Introduction
- Standards
- Sterilization process
- The main components of a steam sterilizer
- Chamber design
- Steam supply (ED, Converter or house steam)
- Built in test systems
  - Air detector
  - B-D Test
- EN 17665 part 3 (Application cycles)…



Introduction

Steam is still the safest, cheapest and simplest means of killing germs and does not leave residues on the surface that could endanger health.

Introduction

Steam sterilization is the oldest method that is still used to deactivate germs on objects (instruments, dressings, cloths, food, etc.). As early as the middle of the 19th century Louis Pasteur in Paris deactivated germs on nutrition solutions used for confirming the presence of microbes by boiling them (this is the origin of the expression "pasteurize"). This technique is still used in the food and beverage industries.

Louis Pasteur
1822 - 1895

First
Pasteurizer

Standards

EN 285:2006+A2:2009

Sterilization - Steam sterilizers - Large sterilizers

EN 13445

Unfired Pressure Vessels is a standard that provides rules for the design, fabrication, and inspection of pressure vessels

EN ISO 17665-1 to 3:2006

Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Standards

DIN EN 61010-1

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements

DIN EN 61010-2-040

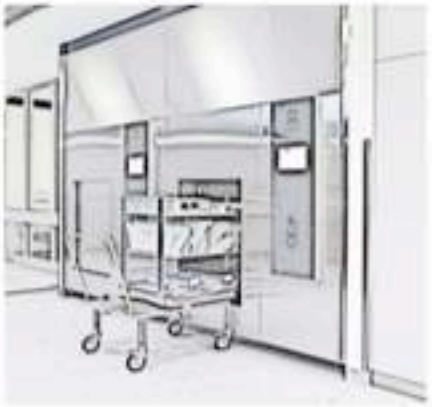
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

DIN EN 62304

Medical device software - Software life-cycle processes

Steam sterilization process

- Modern steam sterilizers must meet requirements such as short batch times and high safety with the effectiveness of their processes (sterilization safety).



- Vacuum processes are generally used for solid and porous sterilization goods in order to remove the air effectively from the sterilization goods before the actual steam sterilization.

Steam sterilization process

Conditions:

- When the sterilization chamber is closed, there is not only the sterilization goods but also air in the chamber.
- Air interferes with the heat transfer to the sterilization goods.
- To ensure safe sterilization, the air in the chamber must be removed.
- Various processes are used for this.

Steam sterilization process

The Fractional vacuum process:

- For around 20 years this has been the standard process for evacuation of the air from the chamber.

The air is evacuated in a range between - 100 and approx. 50 mbar in a multiple exchange process (3-5 times).

- A holding time between the fractionization stages is programmed in order to achieve an optimum pressure balance the chamber.

Steam sterilization process

- Evacuation of the sterilization chamber in multiple exchanges with steam inflows.
- Effect of saturated steam for a defined period at a defined temperature.

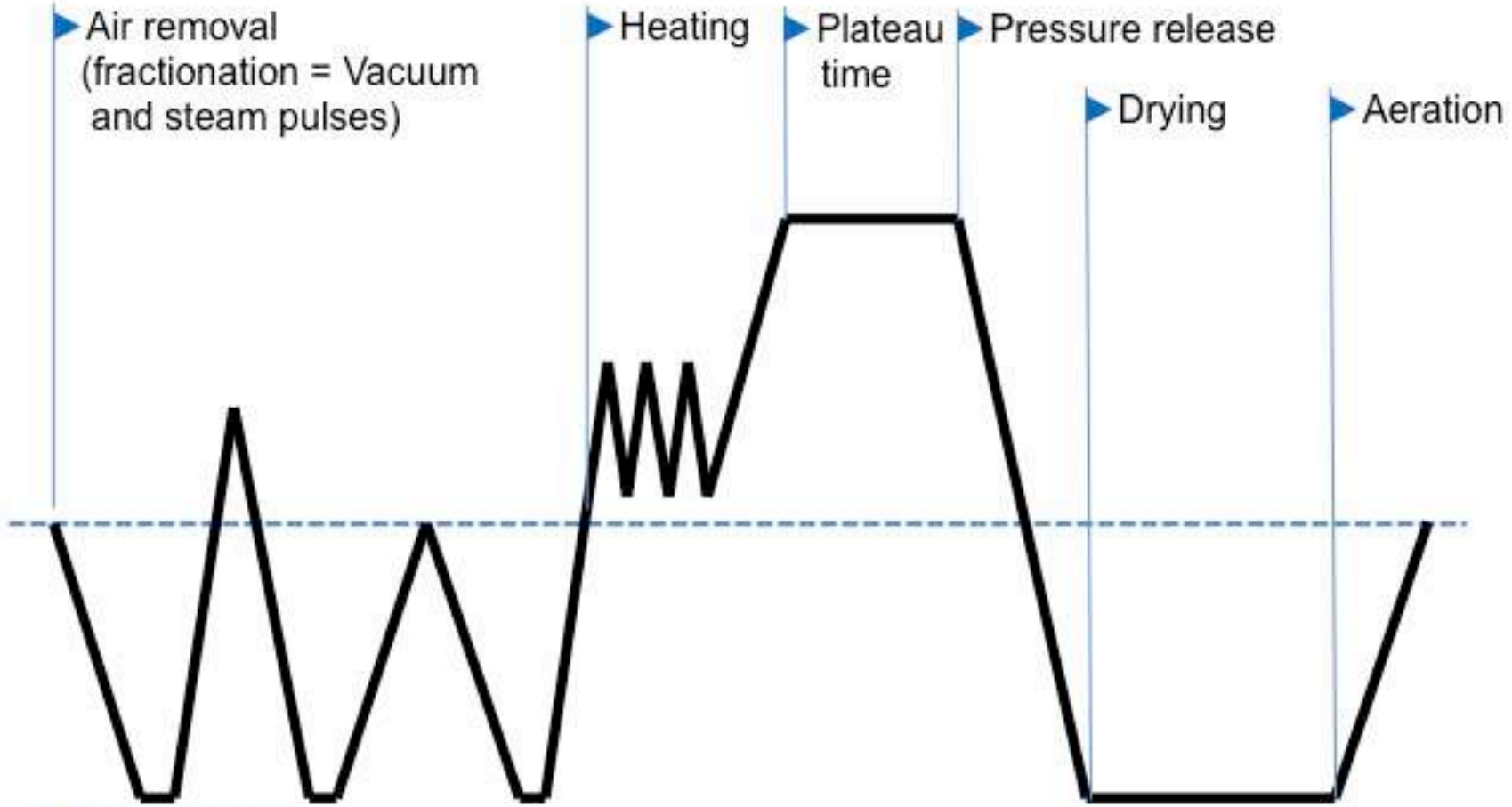
Sterilization temperature as per EN 285:

121 °C for 20 minutes - but min. 15 minutes

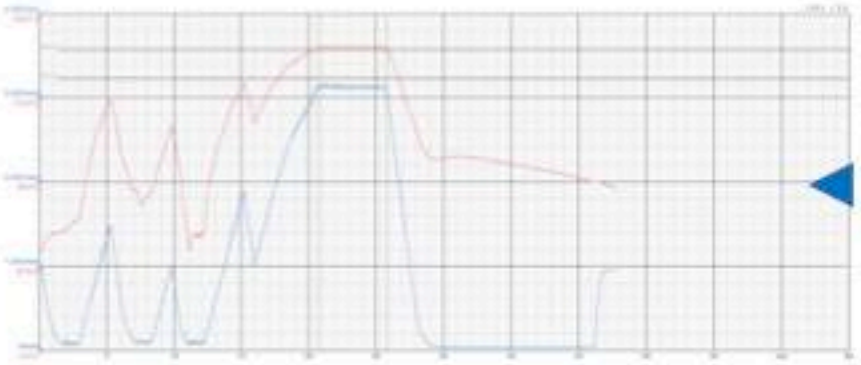
134 °C for 5 minutes - but min. 3 minutes

Steam sterilization process

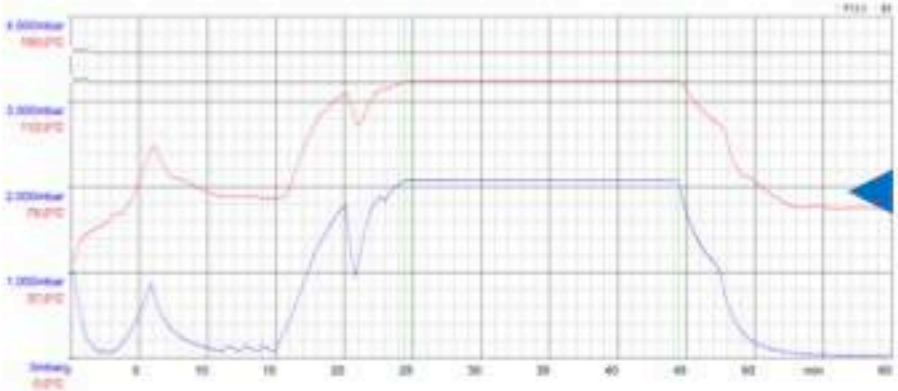
The Fractional vacuum process:



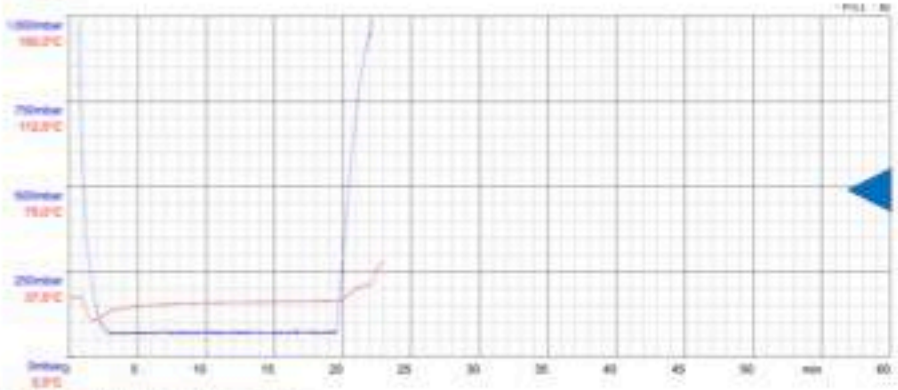
Steam sterilization process



Standard 134°C / 5 Min.



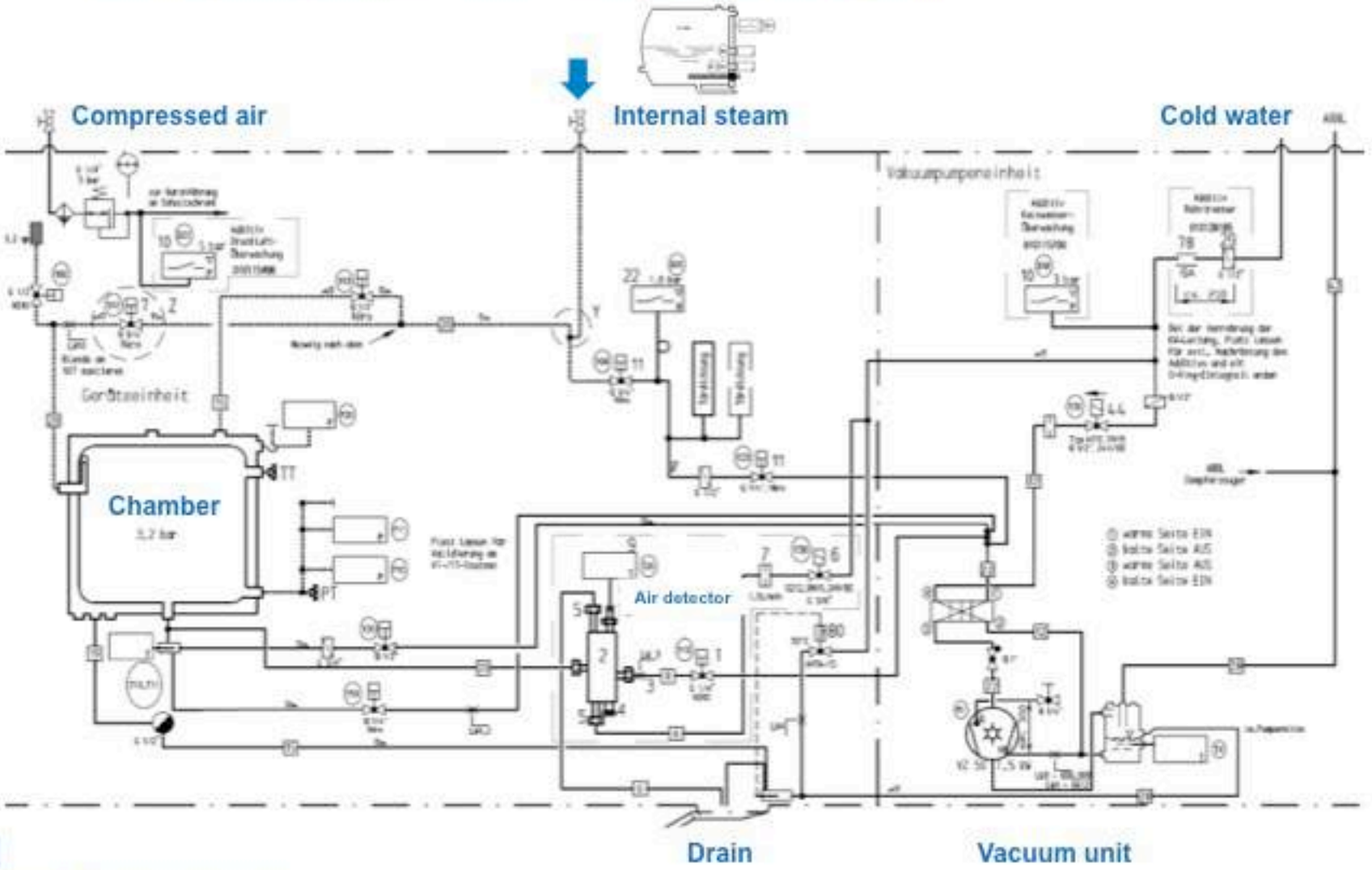
Standard 121°C / 20 Min.



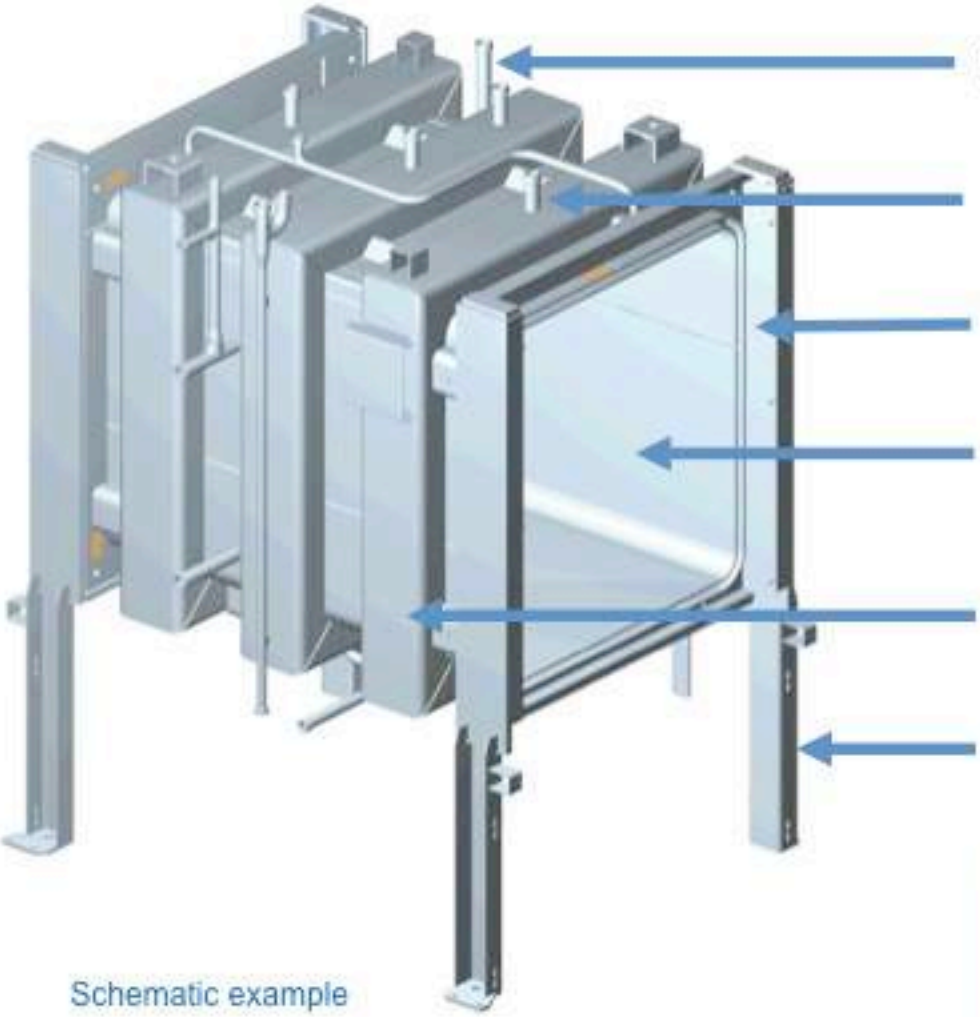
Vacuum Test

Main components

P&DU diagram / sterilizer pipe diagram



Chamber design



Schematic example

Separate steam inlet for the chamber

Separate steam inlet for the jacket

Nut for door seal steam activated

Chamber 316L (Pressure max 3.5 bar)
- Polished or electro polished

Heating jacket 316L

Frame with automatic door mechanism

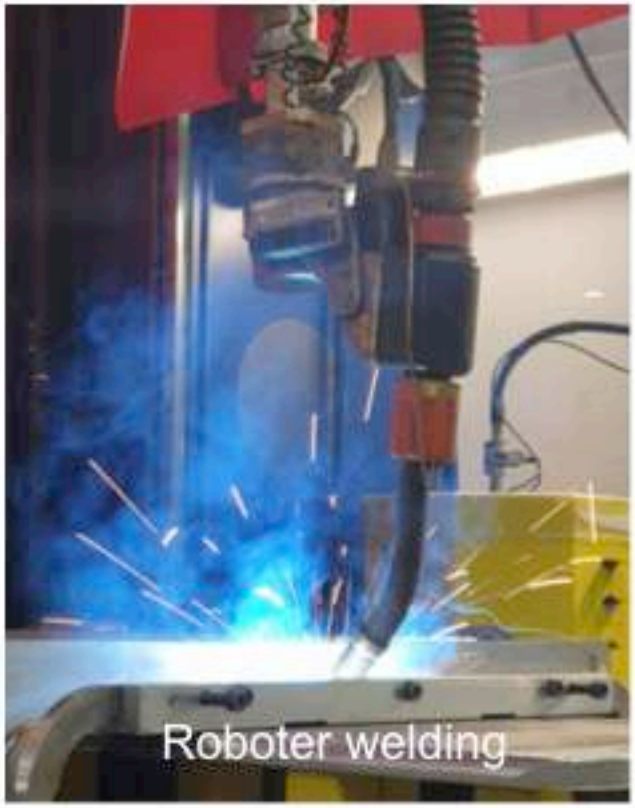
H-Type **V**-Type **P**-Type

Production & Quality

The heard of any steam sterilizer……..

……is the chamber – pressure vessel – which requires highest material, and welding quality.


Manual welding


Roboter welding

Production & Quality

The heard of any steam sterilizer……..

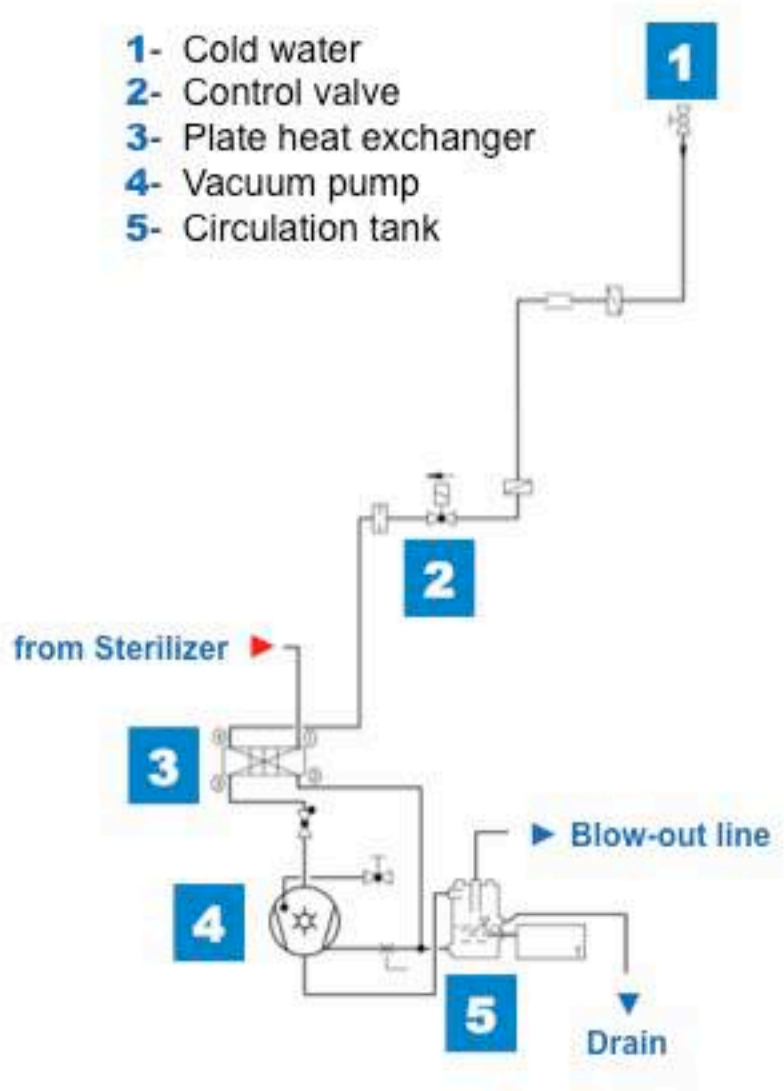
17

…..m welding lenght of a 8 StU chamber

Vacuum pump system

The powerful and low-noise two-stage vacuum pump provides fast air-removal from the chamber, thus reducing the cycle times.

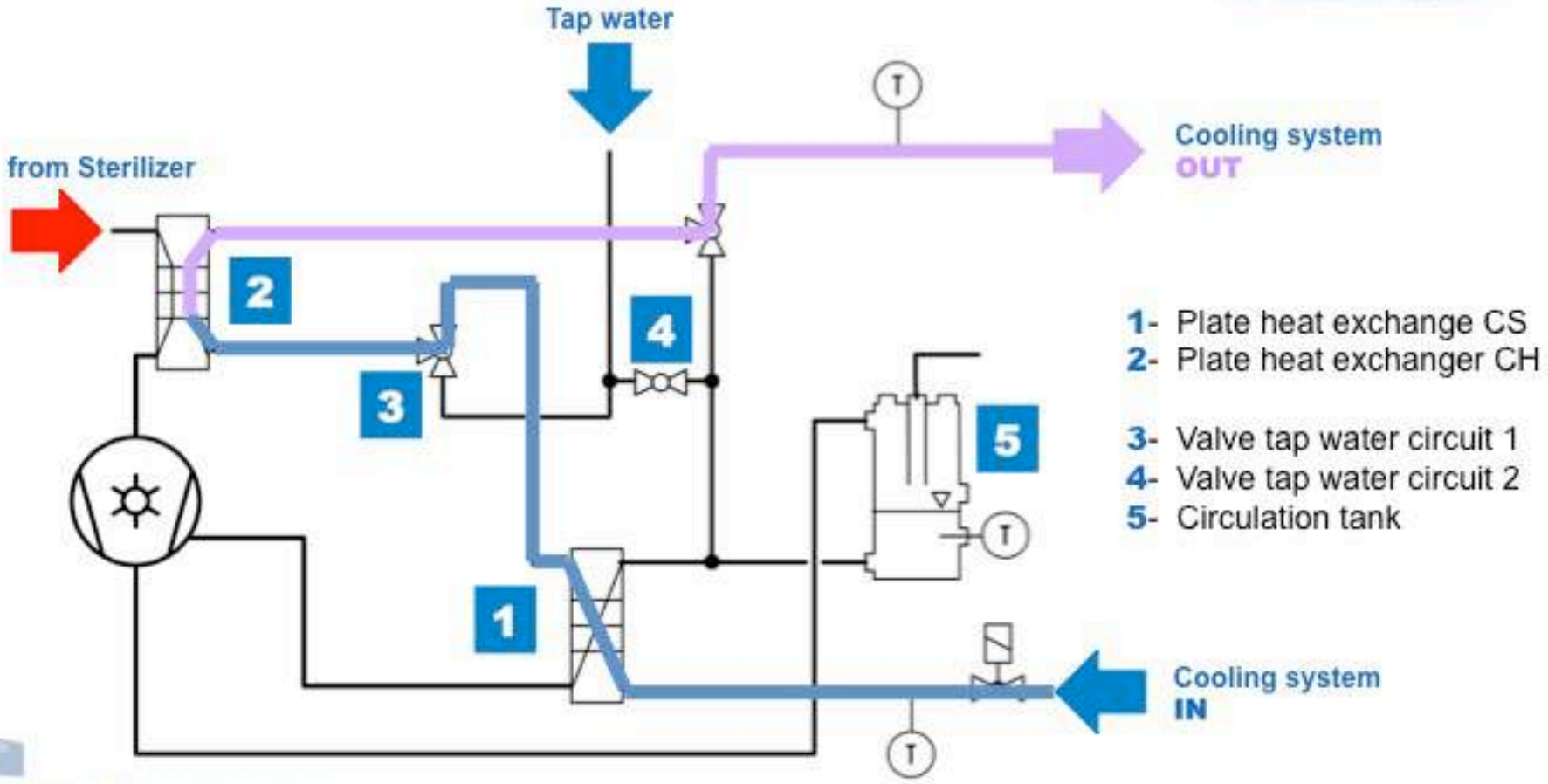
Special water saving systems helps reducing the water consumption.
The vacuum pump normally runs in a cost-effective circulation operation and fresh water is tapped only if necessary.



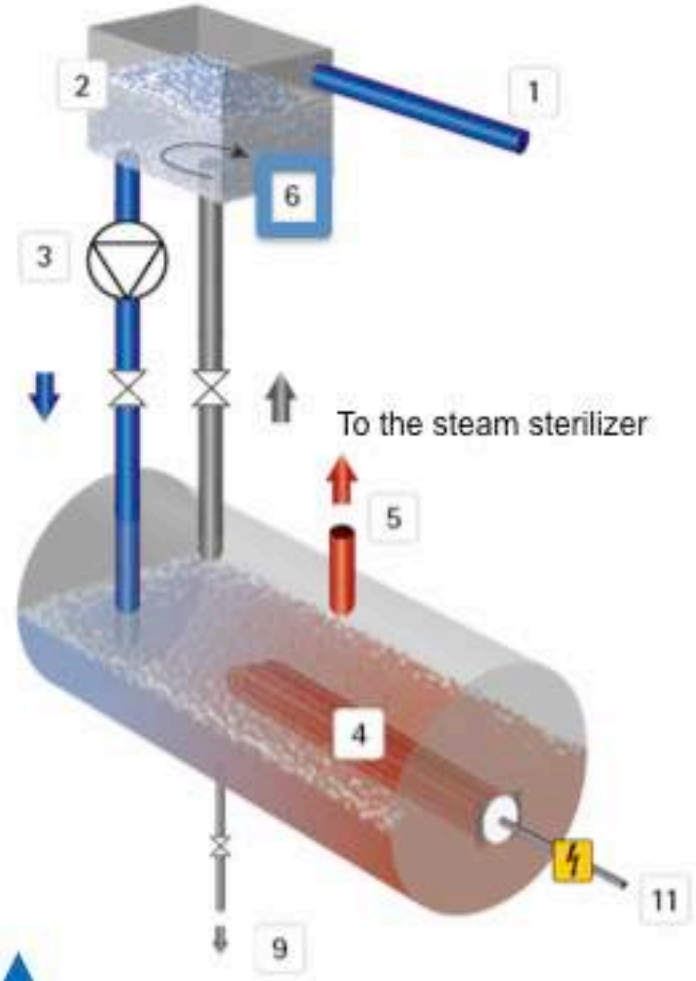
Vacuum pump system

Colling system for vacuum pump connected to the building site cooling system with high water saving potential:

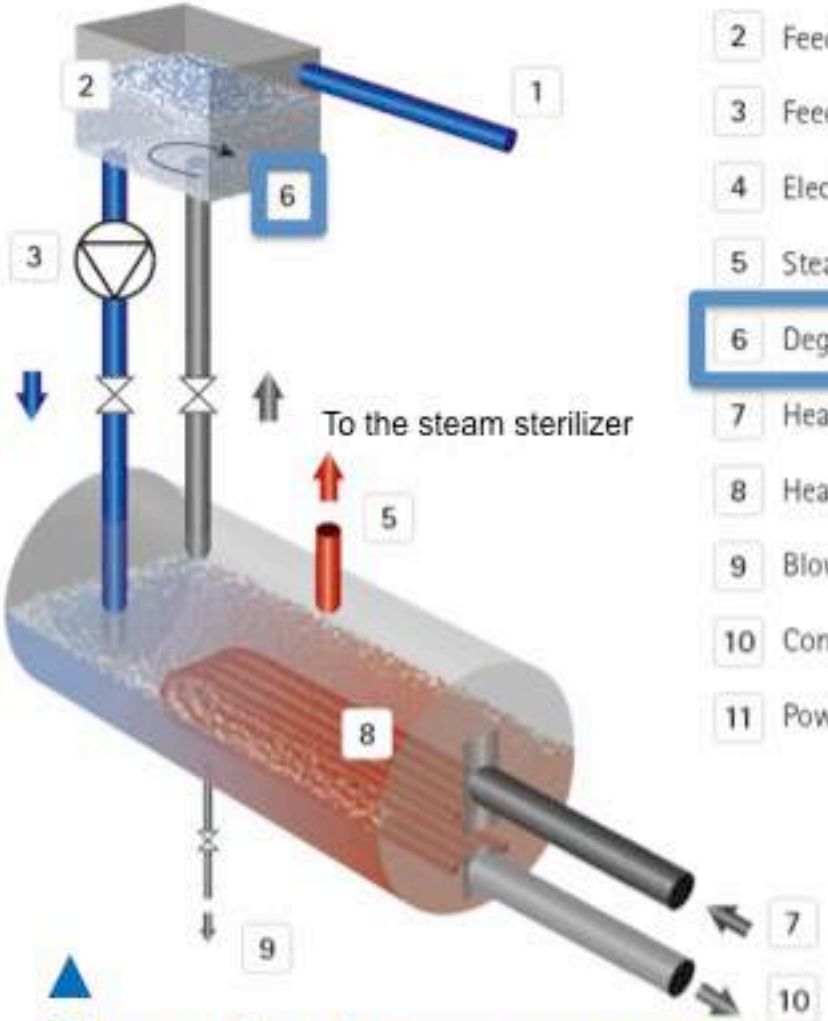
95%



Steam supply



Electric steam generator



Steam to steam generator

1 Deionized cold water
2 Feed water tank
3 Feed pump
4 Electrical heaters
5 Steam withdrawal
6 Degassing
7 Heat steam
8 Heating coils
9 Blow-down device
10 Condensate
11 Power supply

Steam supply

Steam quality conditions - for a save sterilization process

Steam supply

Inert gas - non-condensing gases (NCG)

As a result of the treatment of the feed water for the steam generator and also naturally there are gases in the water.

(oxygen, nitrogen, carbon dioxide)

Steam (water) quality

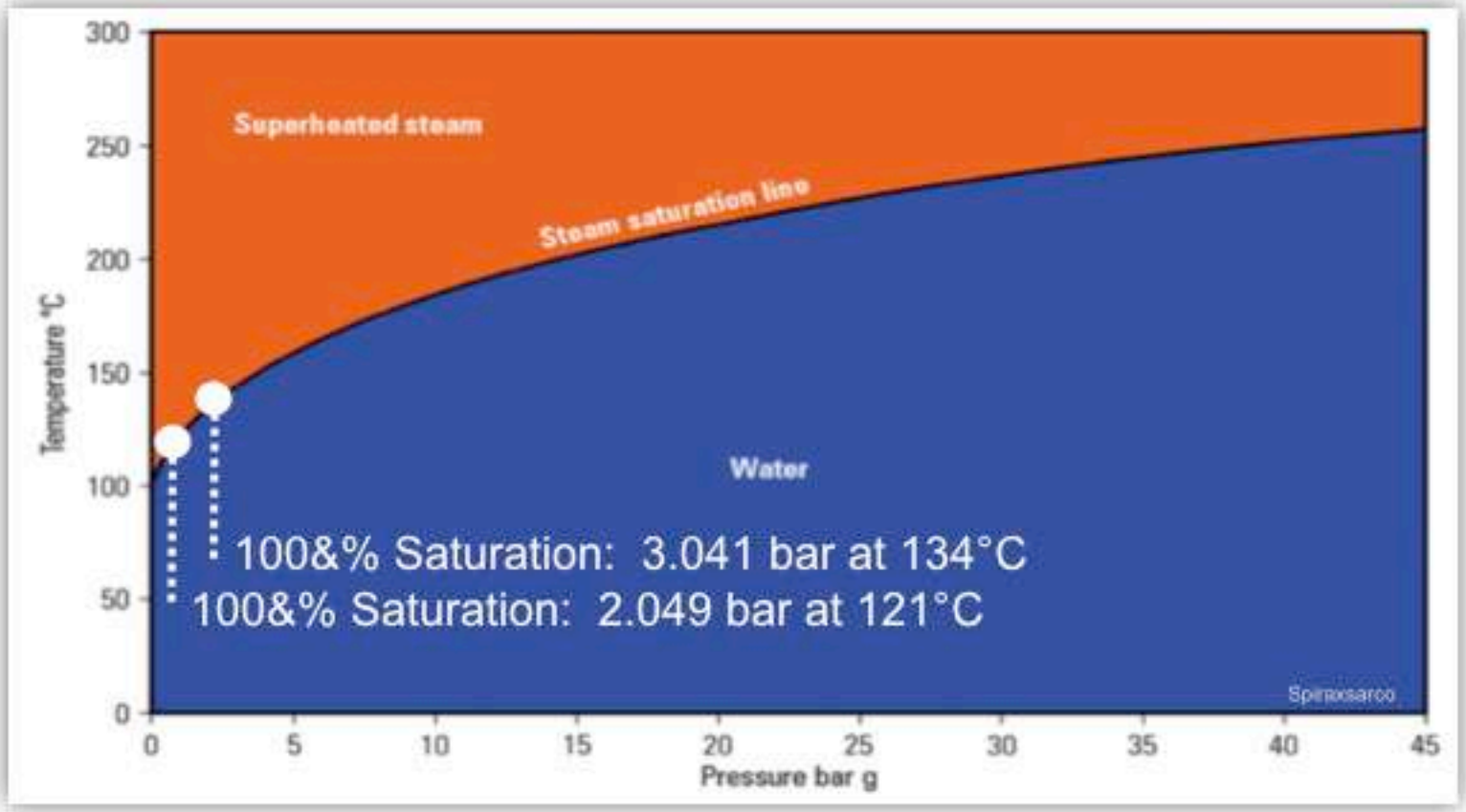
Inert gas - non-condensing gases (NCG)

If the content of inert gas is too high, the sterilization process may be affected.

Maximum volume concentration in steam should be 3.5 %
(gas in the liquid condensate)
(according to EN 285 – 13.3.2)

“ Daily test with steam penetration test or continuous monitoring during the sterilization process “.

Saturated steam



Saturated steam (a mixture of water and steam in absence of air) is in contrast to superheated, steam that is in equilibrium with heated water at the same pressure, i.e., it has not been heated past the boiling point for that pressure.

Steam (water) quality

100 % saturated steam conditions are the following:

- Optimum ratio between temperature and pressure
- Optimum heat transfer

There is still no guarantee for ideal chamber conditions without air inclusions.

There are several reasons for air inclusions in saturated steam or options for prevention:

- Inefficient air removal stage (evacuation phase)
- Air leak during evacuation
- Non-condensable gases in the steam supply

Built in test systems

A direct check of the sterilization

will destroy the product (sterility),

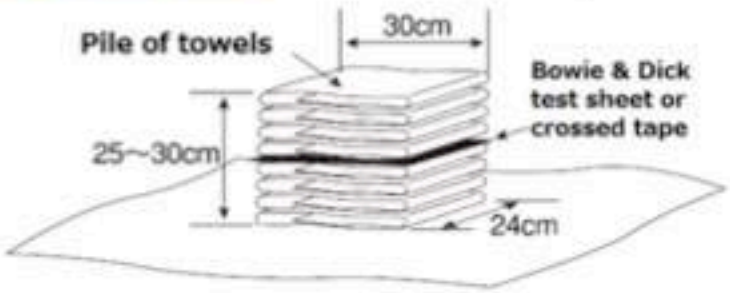
therefore a concept that enable indirect checks

is required.

Built in test systems

Sterilant (steam) delivery in porous load

- The **venting and steam penetration** of porous load (laundry stacks) has been paid much attention. (See DIN EN 285)
- The **Bowie-Dick test pack** was long regarded as a worst case.



- But difficulties during heating of laundry packets are seldom true transport problems, but can be attributed to **problems of the steam supply** of non-condensable gases or leaks.

Built in test systems

Air removal test system

Bowie-Dick Test pack conventional test systems as reference for all B-D tests according EN 285.

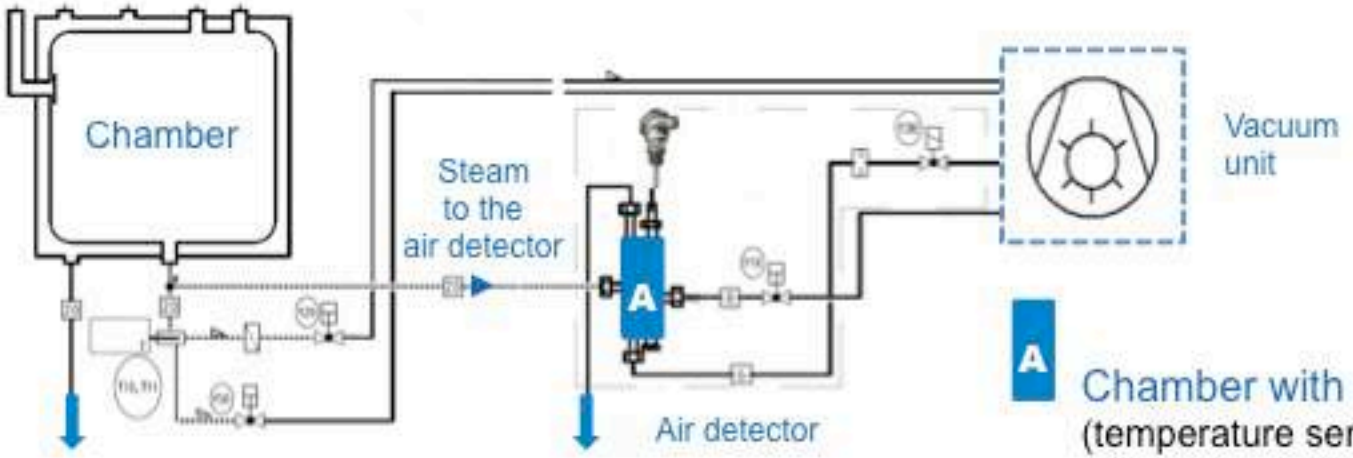
Other alternative B-D test systems	BDS-Test	Electronic	TwinTube	BD-Control	Helix	Integrated B-D Test Systems
	 gke	 Ebro	 BAG	 STERIS	 Browne	

Tests are carried out with **special B-D test cycle**

Built in test systems

Air detector as per EN 285

An **air detector** can be installed on a sterilizer and used to determine whether the non-condensing gases contained in the steam fed into the sterilizer and the air that remains after the air removal stage of the sterilization cycle are in sufficient volume to have a negative effect on the effectiveness of the sterilization process.



The tests are conducted with production cycles in "real time"

Built in test systems

Integrated B-D test and batch control

Hose

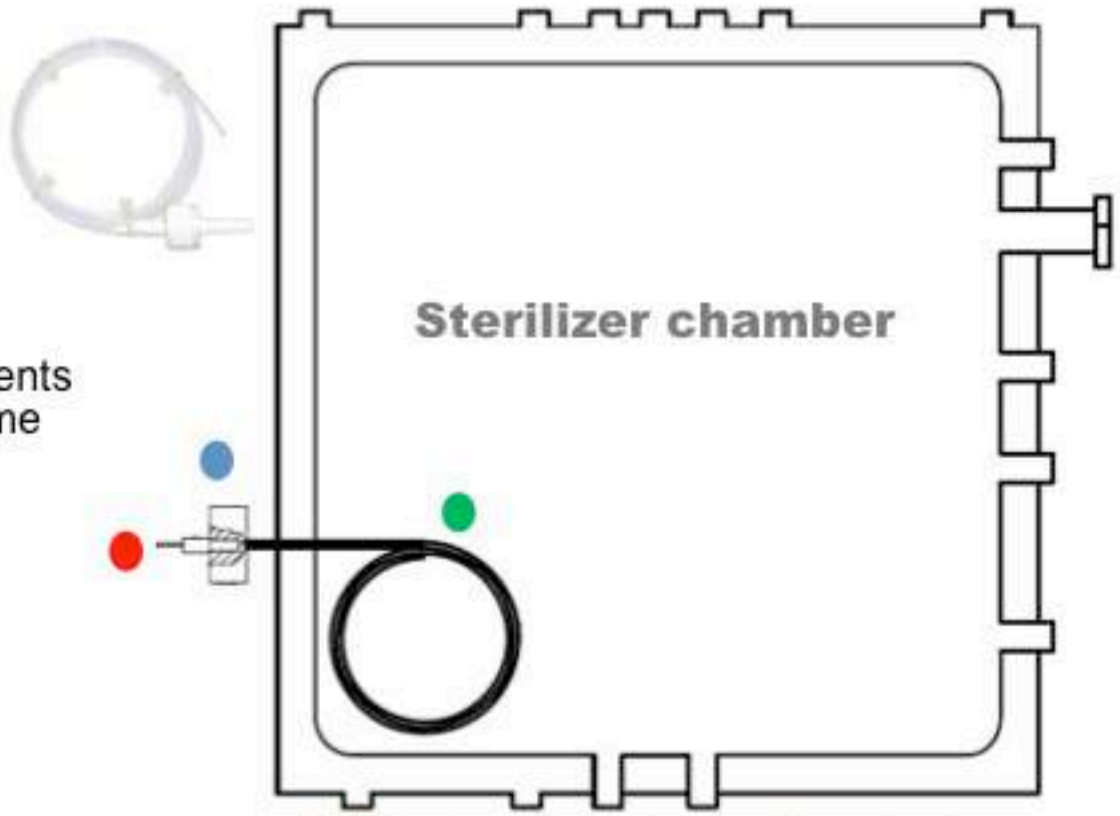
Similar to "Hollow A" to simulate the difficulty of steam penetration in porous loads.

Test bodies (PCD)

Special design to meet the requirements of the standard. Defined steam volume penetrating the hose.

Defined mass with a temperature sensor

Analysis of the temperature curve shows whether the result is good or bad. Correlation to chamber and theoretical temperature.



B-D test equipment in the Steri chamber

Built in test systems

Integrated B-D test and batch control

Simplification with an integrated B-D test with automatic evaluation and documentation:

Functional sequences:

1: Automatic program early start
2: Vacuum test (if necessary)
3: Preheat empty batch
4: B-D test (performance, evaluation, documentation)

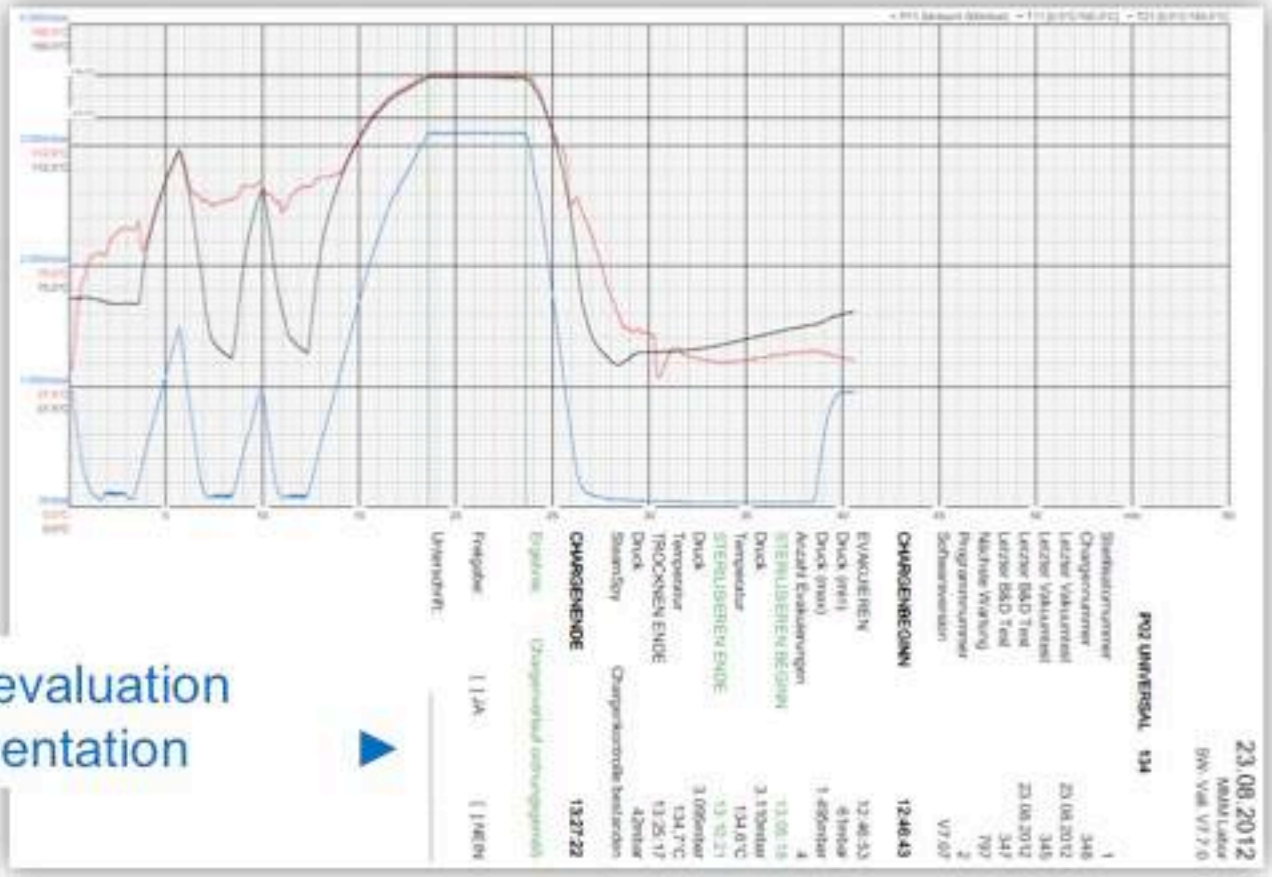
Hose in the chamber

“ The systems can also be used as batch control systems for every production cycle “.

PCD

Built in test systems

Integrated B-D test and batch control



Automatic evaluation and documentation ▶

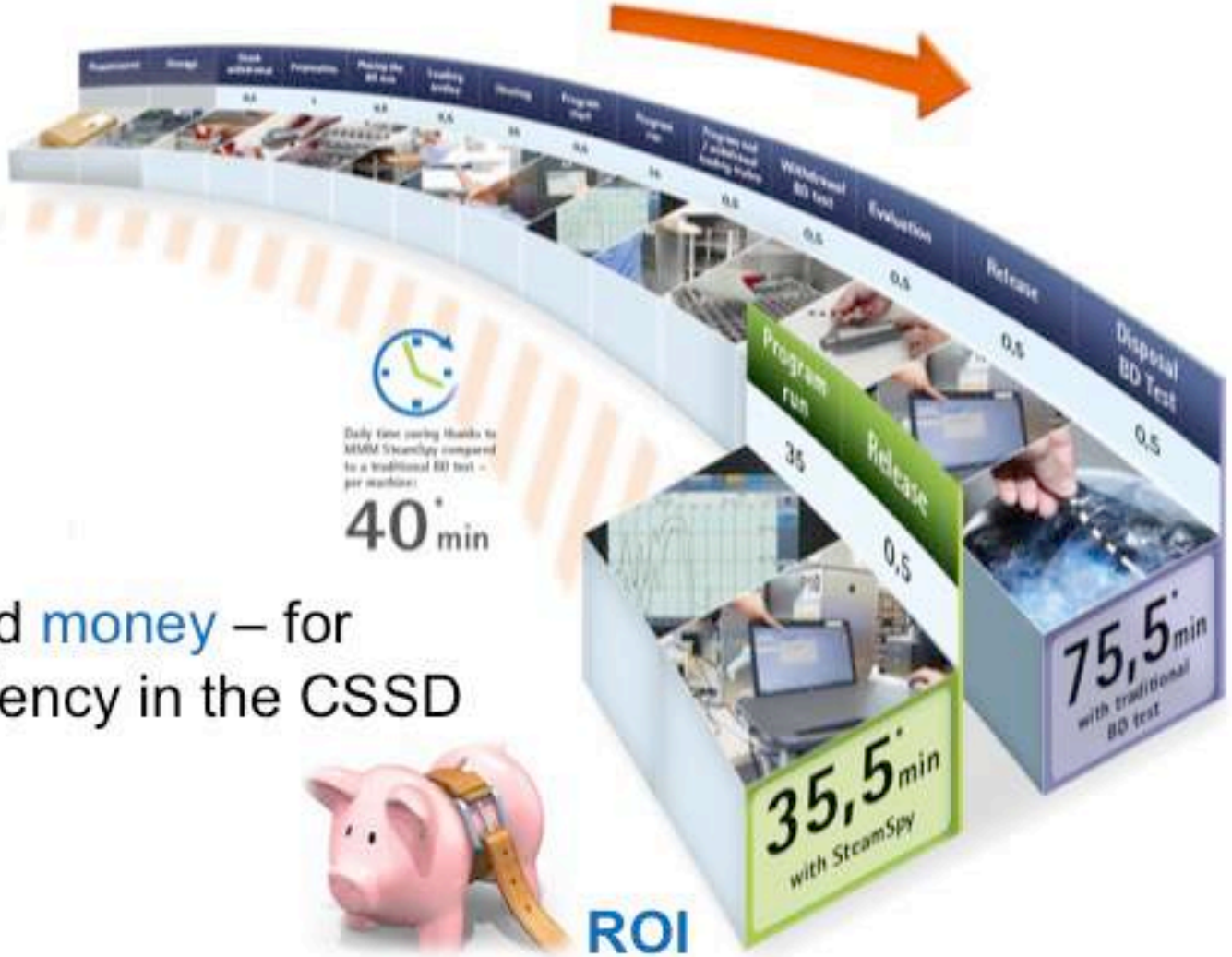
Built in test systems

Advantages of Integrated B-D test systems

- No double documentation, result of the B-D test is printed and archived on the batch protocol (paper less documentation)
- The result is available without delay at the end of the process
- The B-D test program can be added to the automatic warmup program. The sterilizer is ready for production at the end of the "Automatic warmup" procedure.
- Tests according to ISO-11140-4 are carried out with effectively production program

Built in test systems

Advantages of Integrated B-D test systems



Saves time and money – for increased efficiency in the CSSD

ROI

Built in test systems

All test systems need to comply with EN ISO 11140 – part 4 but respond very differently.

In summary, it can be said that, unlike conventional Bowie-Dick-Type Test packs, an **integrated system** not only recognizes faults reliably, but also shows if the Bowie-Dick cycle has been run in accordance with all relevant standards and in specifications.

EN 17665 - part 3

Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

Table 6 — Product families

MD	Attribute																Steam penetration resistance (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	*	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	*
1	x								x		x	x	x		x				x							
2	x								x					x	x					x						
3	x									x	x	x	x		x					x						
4	x									x				x	x						x					
5	x								x		x	x	x			x				x						

- MD product families
- Attributes (a, b, c, d)
- Steam penetration resistance (estimated)

EN 17665 - part 3

Sterilizing cycles according the application

The individual process stages were selected based on ISO/TS 17665-3.

The 4 most important factors for application-specific sterilization cycles:

EN 17665 - part 3

Sterilizing cycles according the application

High savings potential thanks application oriented sterilizing according EN 17665-3:

Final Conclusion

The ideal steam sterilization is the result of a physical processes that resulted in the killing of all viable microorganisms, i.e. bacteria, including bacterial spores, fungi and viruses.

Paperless documentation, parametric release as well as energy and resources saying systems

will effect the future design of a "state of the art" steam sterilizer.

“ This is it - Thanks for listening “