

New methods to monitor steam penetration into complex medical devices (MD) using Medical Device Simulators (MDS) and Batch Monitoring Systems (BMS)

VSZ Workshop Mechelen, October 16, 2008

Agenda

- 1. Consequences of non-condensable gases (NCG) in steam sterilization processes**
- 2. Limitations of traditional biological and chemical indicators**
- 3. Type tests to prove sterilizer specifications**
- 4. Traditional batch monitoring testing the sterilizer**
- 5. Concept of MDS and BMS**
- 6. Using MDS and BMS**

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Services:

Design, Validation and Monitoring of dry heat, steam, ethylenoxide, formaldehyde and hydrogen peroxide sterilization processes

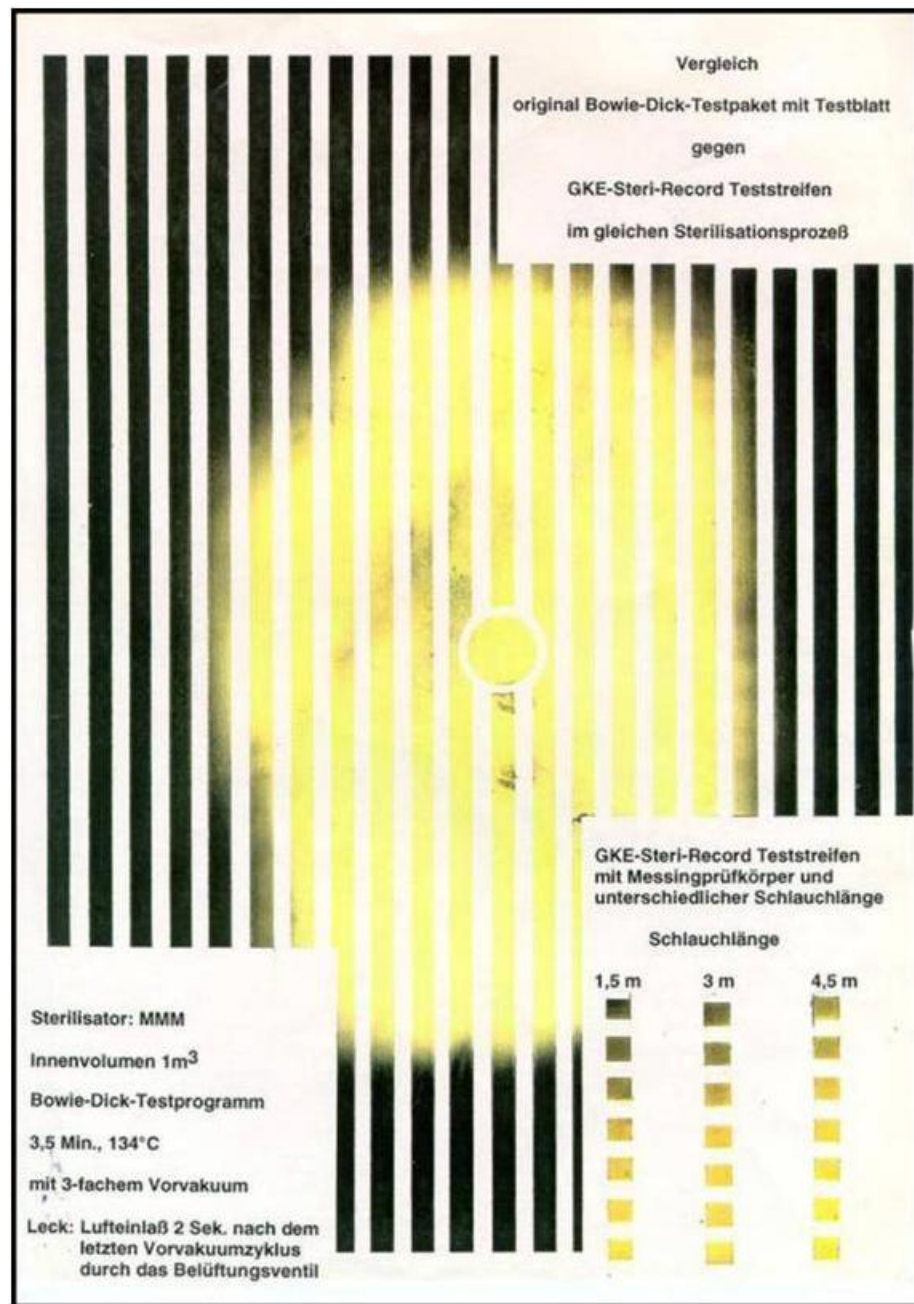
Production and distribution of:

Sterilization monitoring and documentation materials
Biological and chemical indicators with process challenge device (PCD) systems
Documentation labels



gke Steri-Record® Bowie-Dick Test Sheet for Steam-Sterilization

GKE - Steri-Record® Bowie-Dick-Testbogen für die Dampfsterilisation			
für Testprogramme mit fraktioniertem Vakuum von 134°C und einer Haltezeit von 3 - 3,5 min			
			Testbedingungen :
			Steri-Nr.:
			Test-Datum:
GKE - Steri-Record®	GKE - Steri-Record®	GKE - Steri-Record®	Uhrzeit:
			Anzahl der zuvor durchgeführten
			Leerchargen 1 2 3
Steri-Record®	GKE - Steri-Record®	GKE - Steri-Record®	Testversuche : 1 2 3
			Freigabe : ja nein
GKE - Steri-Record®	GKE - Steri-Record®	GKE -	Mitarbeiter-Kürzel :
			Unterschrift :
GKE - Steri-Record®	GKE - Steri-Record®	GKE - Steri-Record®	GKE - Steri-Record®
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Temperature and time parameters to achieve overkill for the steam sterilization process according to EN 554

Temperature [°C]	Sterilization time [min]*	Equilibration time [min]**	F _{0 121°C} [min]	Remarks
121	15	<0,5	15	Those conditions are only valid in presence of steam but not in presence of dry heat.
134	3	<0,5	ca. 60	

Dry heat and superheated steam sterilization process (incl. non-polar solvents and oils)

Temperature [°C]	Sterilization time [min]*	Equilibration time [min]	Remarks
160	120	10 – 50	The temperature-come-up-time changes depending on the heat capacity of the goods and the insulation of the pack.
180	30	10 - 30	

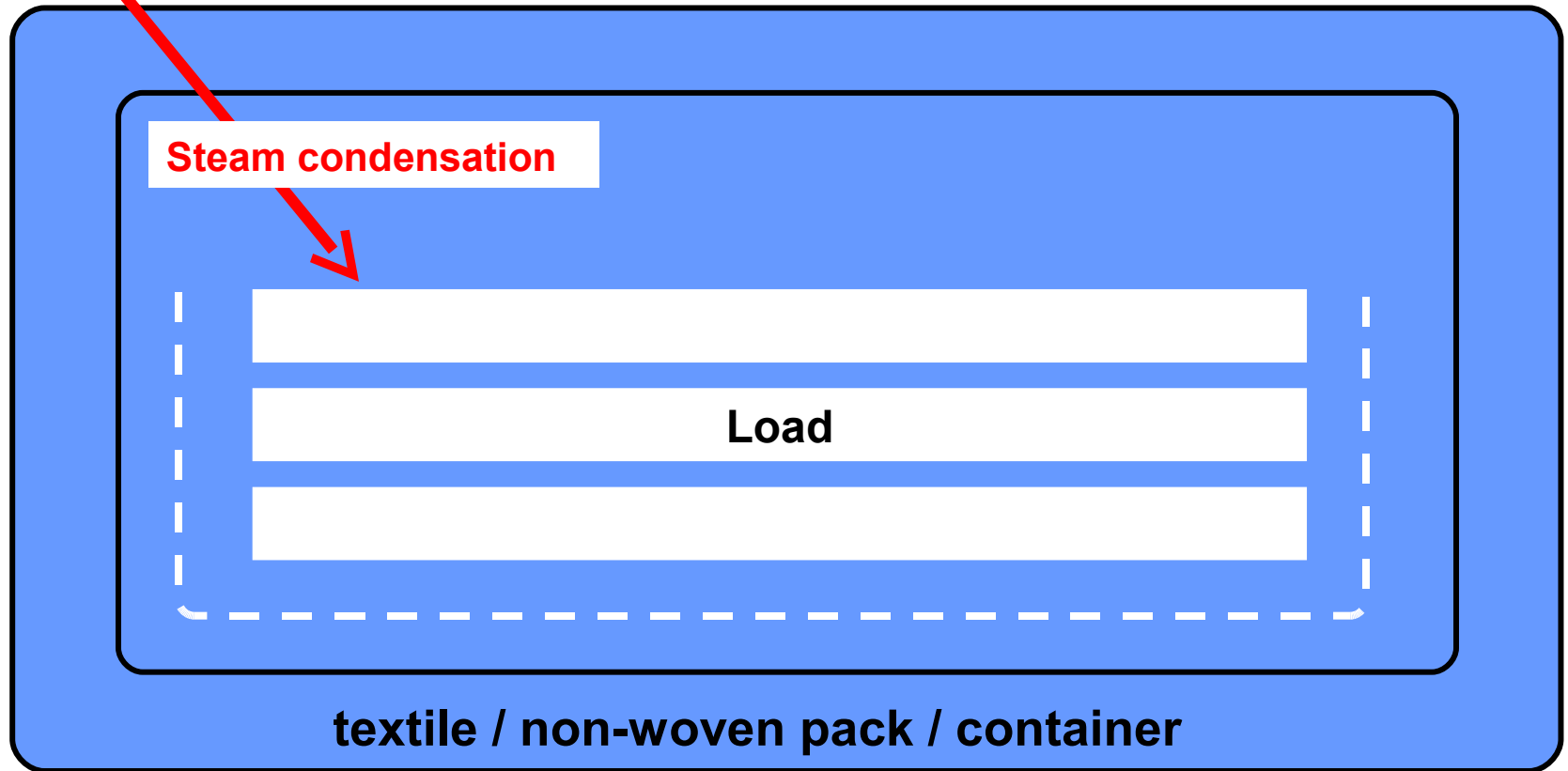
* Sterilization time after reaching the temperature of the goods on the surface and in hollows

** If complete air removal is achieved

Steam consumption

Steam

about 350 – 400 l/10 kg load



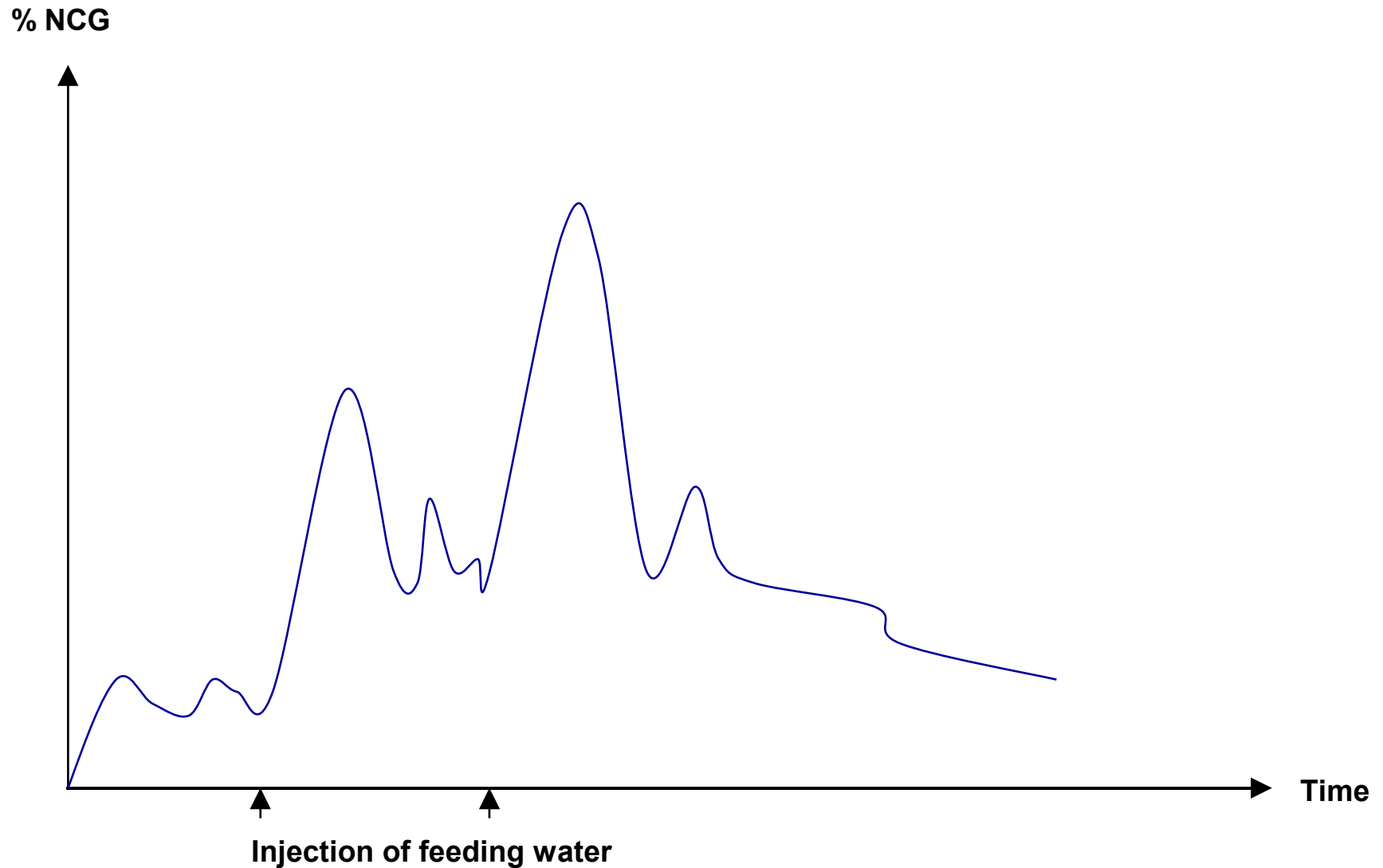
Potential risks during a fractionated vacuum steam sterilization process

1. Unsatisfactory air removal during the fractionated vacuum cycle (remaining air in the sterilization chamber)
2. Leakages on door seals, valves and other devices (air returns into the chamber after the last vacuum cycle)
3. Air transfer through the door seal, if the sealing is pneumatically actuated (if steam is used to pressurize, the sealing problem does not occur)
4. Non-condensable gases are introduced together with steam (malfunction which is usually undetected during the sterilization cycle) After sterilizer and eventually steam generator are switched off, non-condensable gases develop in the pipes between steam generator and sterilizer and in the steam generator, and get into the sterilizer after starting again.

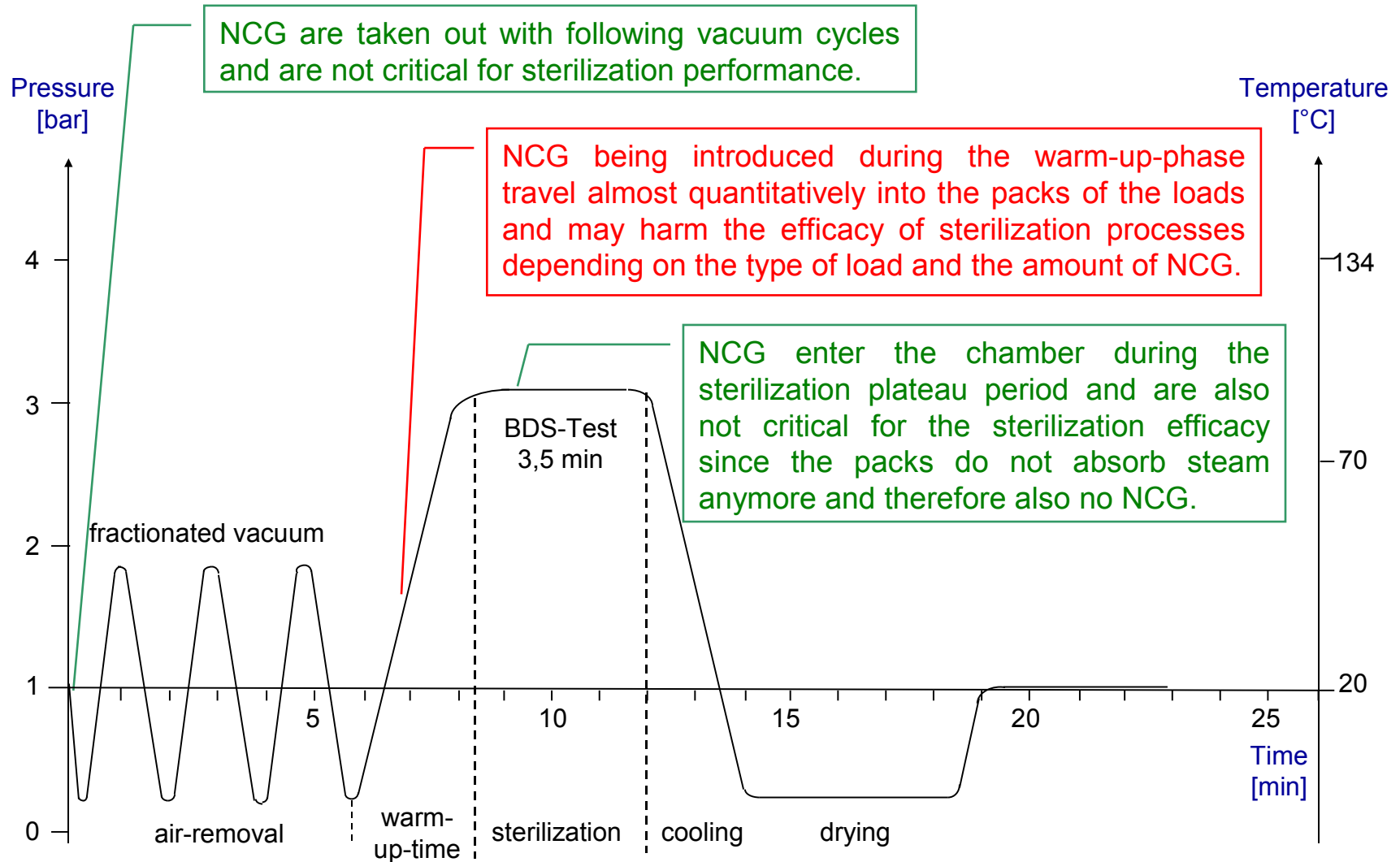
Non-condensable gases (NCG) in steam

Type of gas	Origin	Effect	Elimination
air ca. 80% N ₂ 20% O ₂	dissolved air in water (ca. 25 ml air per 1 l water)	The produced amount of air depends on the supply of injected water in the steam vessel. (air peaks after water injection)	Degasing of the injected water by heating up to 90°C – 105°C before injecting into the steam vessel
air ca. 80% N ₂ 20% O ₂	In steam boilers and steam pipes before start-up	When not in operation steam boilers and steam pipes fill up with air	During start-up steam pipes need to be purged by a warm-up cycle to remove the air.
carbon dioxide CO ₂	water containing hydrogen-carbonates	During the heating process, CO ₂ and carbonate salt (white covering) are formed $\text{Ca}(\text{HCO}_3)_2 \rightarrow \text{CaCO}_3 \downarrow + \text{CO}_2 \uparrow + \text{H}_2\text{O}$ (NCG peaks depending on the amount of water injection)	Degasing or de-mineralization by Ion-exchange or possibly together with Reversed Osmosis (RO) RO alone is <u>not</u> sufficient !
hydrogen H ₂	corrosion of metals	permanent small amounts of NCG and of flying rust in iron pipes (seldom)	Adjust pH-value > 7 in buffer solutions Remove chloride and other chelate complexing agents from feeding water
Superheated steam	pressure reduction in steam pipes	The superheated steam is unable to condensate until it is reaching its condensation point.	Install cooling line after pressure reduction.
	Hydratization of porous goods (heat generation by taking up water)		Don't dry porous goods with dry heat before the sterilization. Conditioning in normal humidity is required or moisten the goods before sterilization

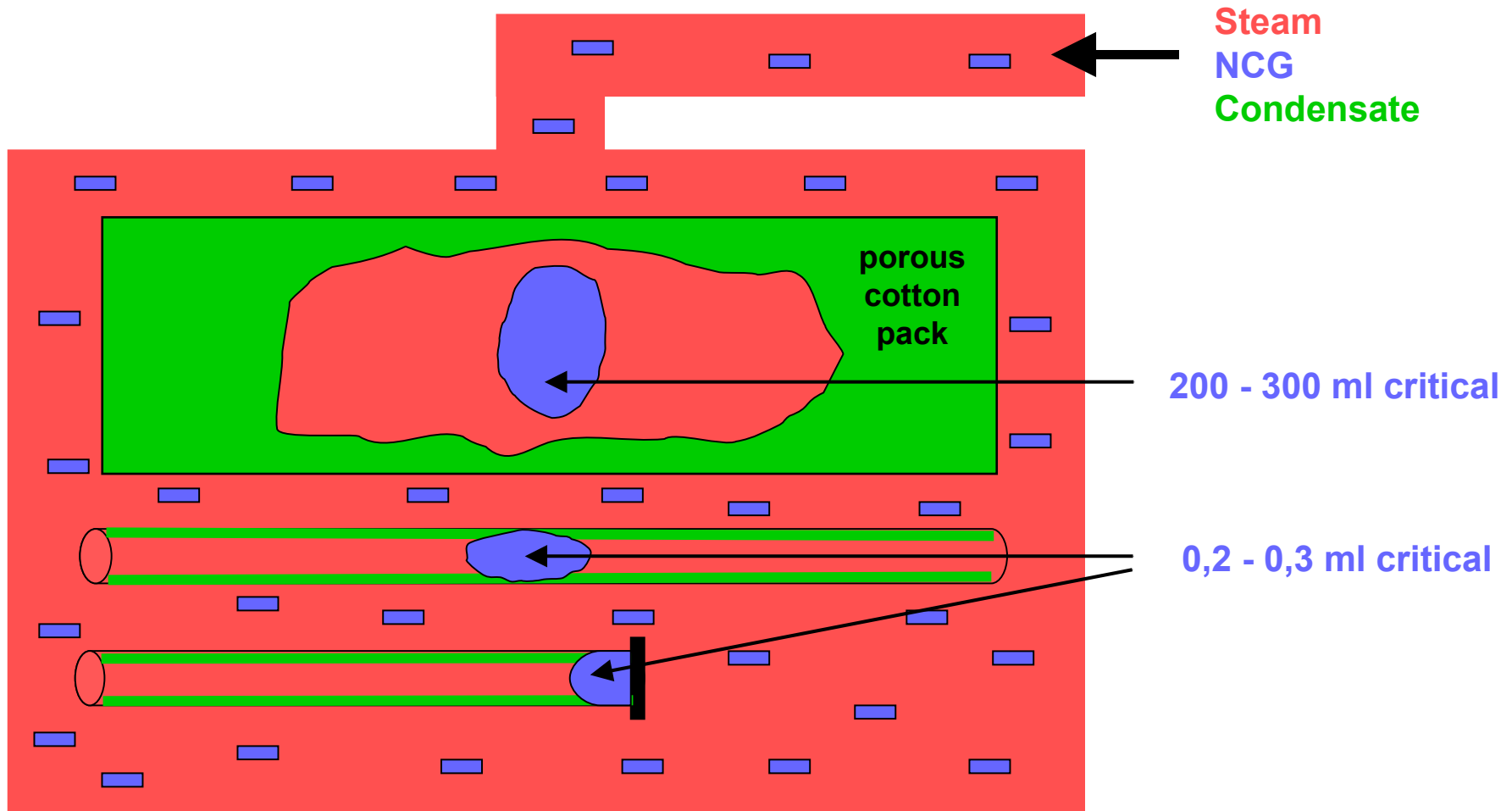
Analysis of non-condensable gases (NCG) in steam pipes



Influence of time if non-condensable gases (NCG) entering the steam sterilization process cause a risk



Comparison of separations of non-condensable gases (NCG) in porous loads and hollow instruments



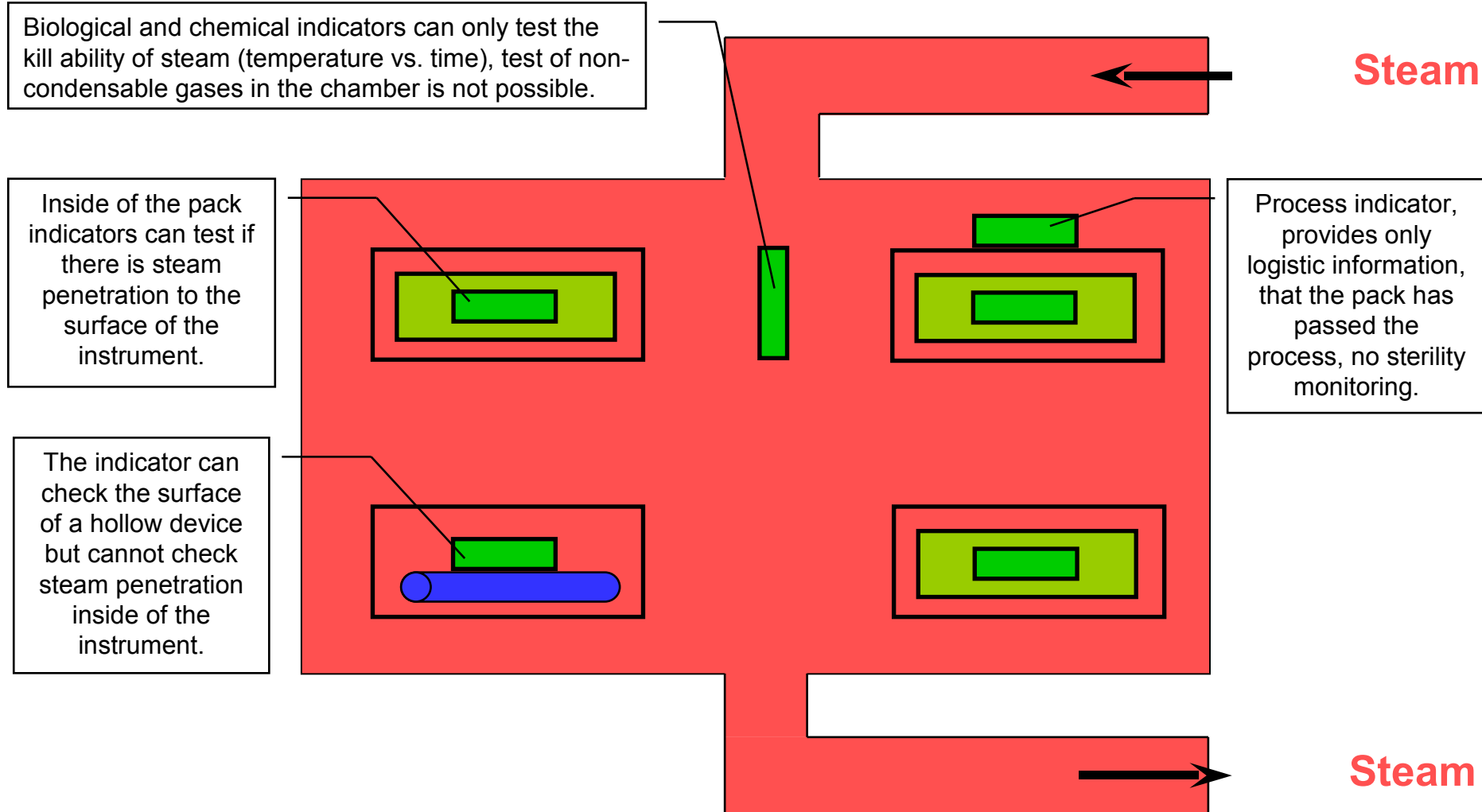
Ratio of the critical NCG amounts:
porous : hollow $\approx 1.000 : 1$

Different types of the Bowie-Dick-Test Comparison Europe - USA

Country	Standard	Size [cm]	Weight [kg]	BD-Test-program inside the sterilizer	Required method of simulation test		
					Standard for test	name	Test method
Europe	EN 285, part 17	25 x 35 x 20	7 kg \pm 2%	134°C, 3.5 min or 121°C, 15 min	EN 867-4 = EN-ISO 11140-4	Steam penetration test	- Air removal - Leaks - Non-condensable gases
USA	AAMI	ca. 24 x 35 x 29	4 kg \pm 200g (\pm 5%)	132°C, 3 min	ISO 11140-5	Air removal test	- Air removal

The American test package has approximately 1/2 of the weight of the European test package and is therefore less sensitive in testing the air removal and steam penetration.



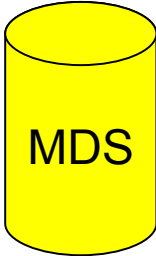
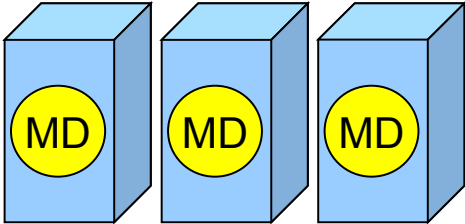

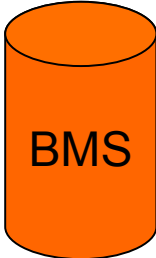
Limitations of biological and chemical indicators at different positions in steam sterilization cycles



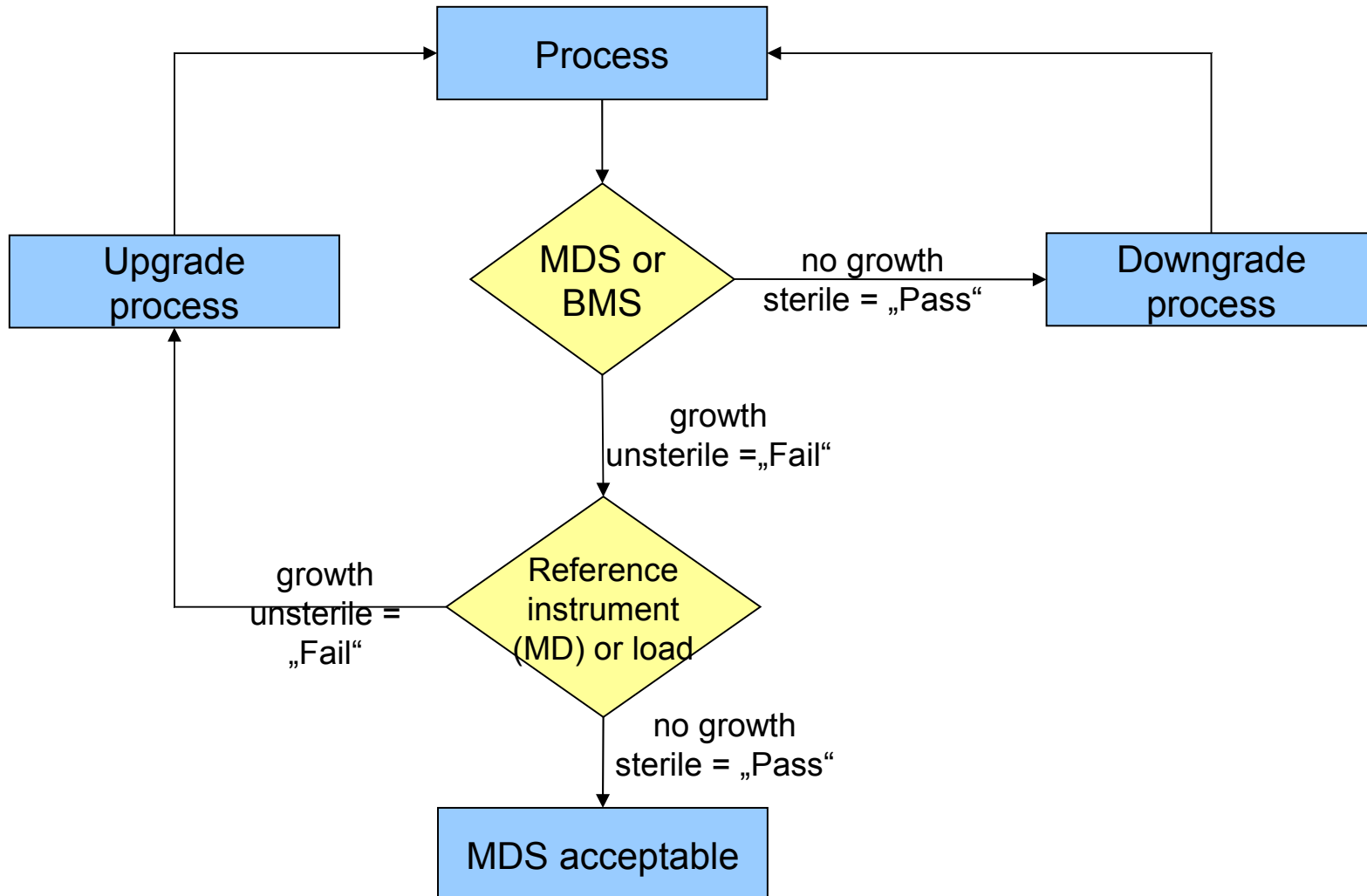
**Helix-PCD® according to EN 867-5 Hollow A
for validation and batch monitoring**



Process Challenge Devices (PCDs) for different applications

Reference	is simulated by	Process Challenge Device
Medical Device 		Medical Device Simulator 
Batch  Defined Load Configuration		Batch Monitoring System 

Test method to check if a Medical Device Simulator (MDS) or Batch Monitoring System (BMS) is equivalent to a Medical Device (MD) or load



Class 2 indicators for type tests, MDS¹ and BMS²

MDS or BMS test-system are used to monitor sterility of a medical instrument or load in sterilization processes:



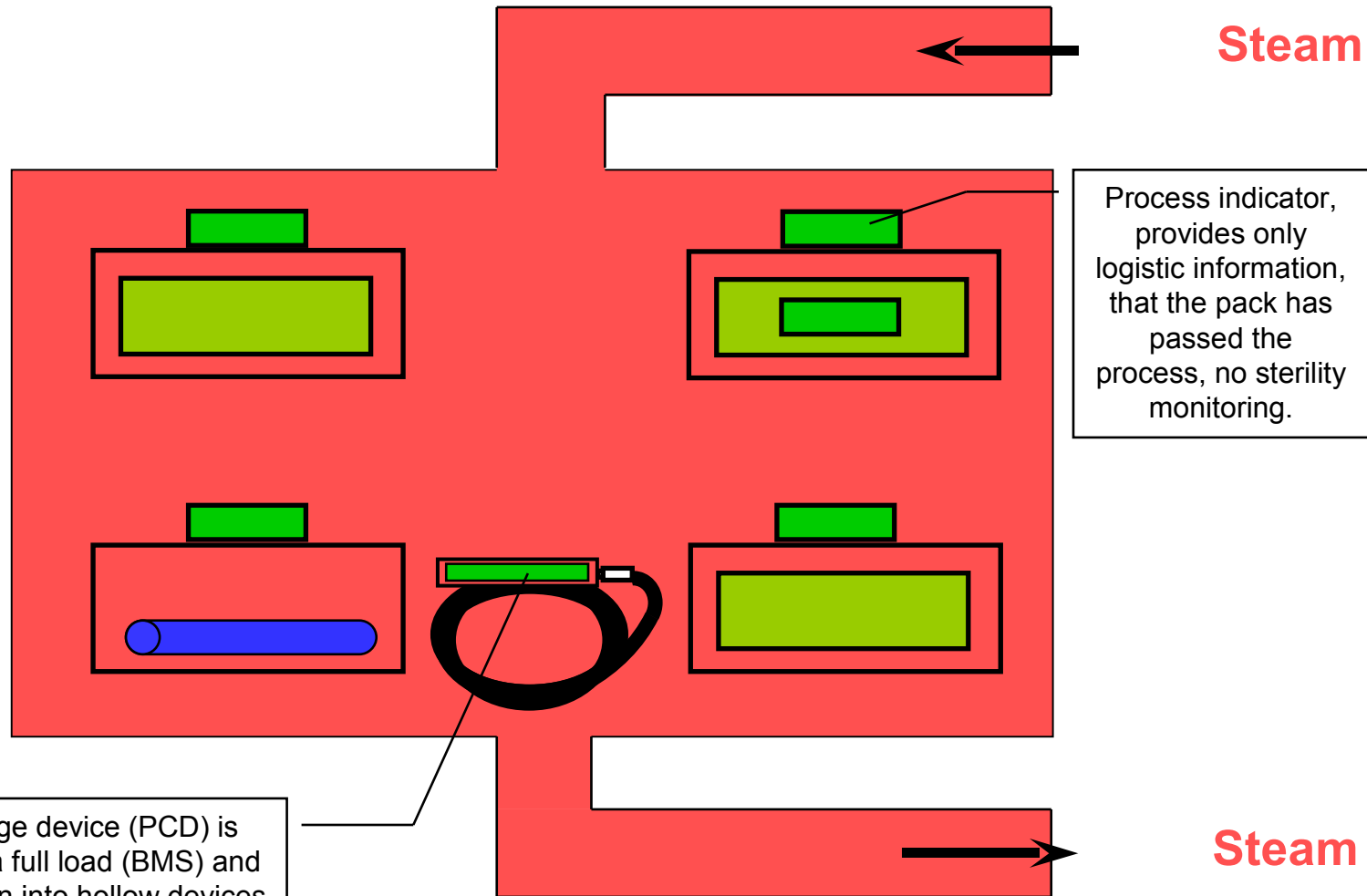
An indicator is an object in its final form in which it is intended to be used.

(Definition in EN-ISO 11140-1 for class 2 indicators)

¹ MDS = Medical Device Simulator

² BMS = Batch Monitoring System

Use of a batch monitoring system (BMS)



Air removal – steam penetration of:

- Sterilizer capability

- Type Test

- Load configuration necessity

- Batch Monitoring System (BMS)

Increased air removal – steam
penetration

EU Sterilizer, EN 285

EU BD-Test pack, 7 kg (Type test)

USA Sterilizer

AAMI-BD-Test pack, 4 kg (Type test)

Solid Load

Porous Load

Hollow Load

Batch Monitoring System (BMS) for Load 1

Solid Load

Porous Load

Hollow Load

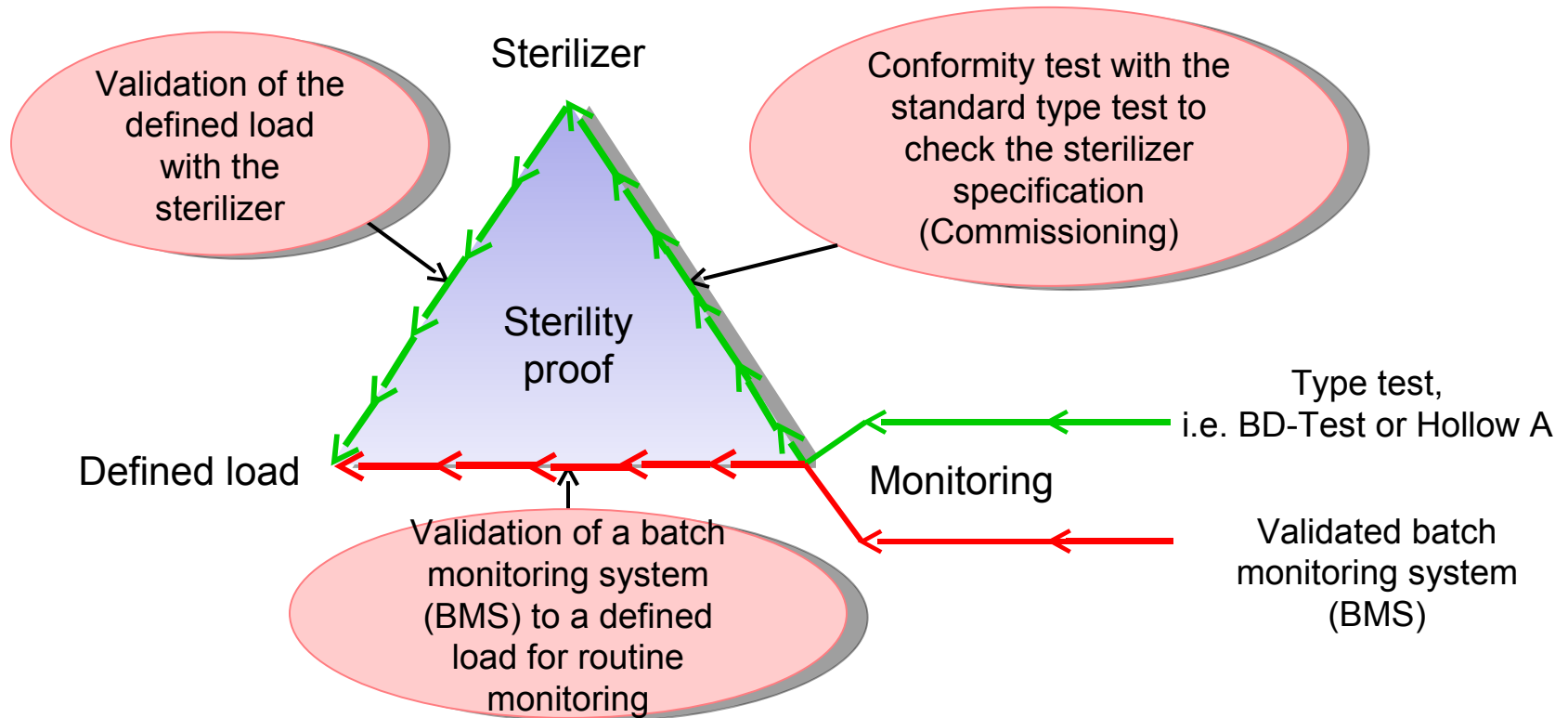
Batch Monitoring System (BMS) for Load 2

Hollow load test

Load Configuration
1

Load
Configu-
ration 2

Conceptual approaches for routine monitoring with a batch monitoring system (BMS)



- ← Commissioning + Performance Qualification = Validation of a process.
After validation the process is secured using a type test for routine monitoring to check the sterilizer.
- ← Routine monitoring with a batch monitoring system (BMS) that is validated against a defined load, without a performance test of the sterilizer.





Historical monitoring concept:

Checking steam penetration specifications of a sterilizer with a type test

- large sterilizers EN 285 with the 7 kg BD-Test pack
- small sterilizers EN 13060 type B with helix test (EN 867-5)

Assumption:

If the sterilizer works according to the specifications, all goods come out sterile.

This concept is wrong:

Depending on the penetration requirements of the load the steam penetration may be sufficient, correct or not sufficient.

Suggested monitoring concept:

Defining the steam penetration requirements of a load by designing a batch monitoring system (BMS) checking the steam penetration requirements of the load

If the BMS is validated according to the load, the necessary steam penetration is checked, independent from the specification of the sterilizer.

The sterilizer does not require defined standard specifications but must work reproducible and must pass the BMS.

Depending on the requirements of the load configuration alternatively inexpensive sterilizers like type N or S or sterilizers according EN 285 may be used or sterilizers with higher penetration characteristics may be required.