

**21<sup>ST</sup> **  
**WORLD  
STERILIZATION  
CONGRESS**



# ***Choice of a routine PCD instead of a BD test***

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**CICG, GENEVA,**  
**SWITZERLAND**



## Vapeur d'eau saturée

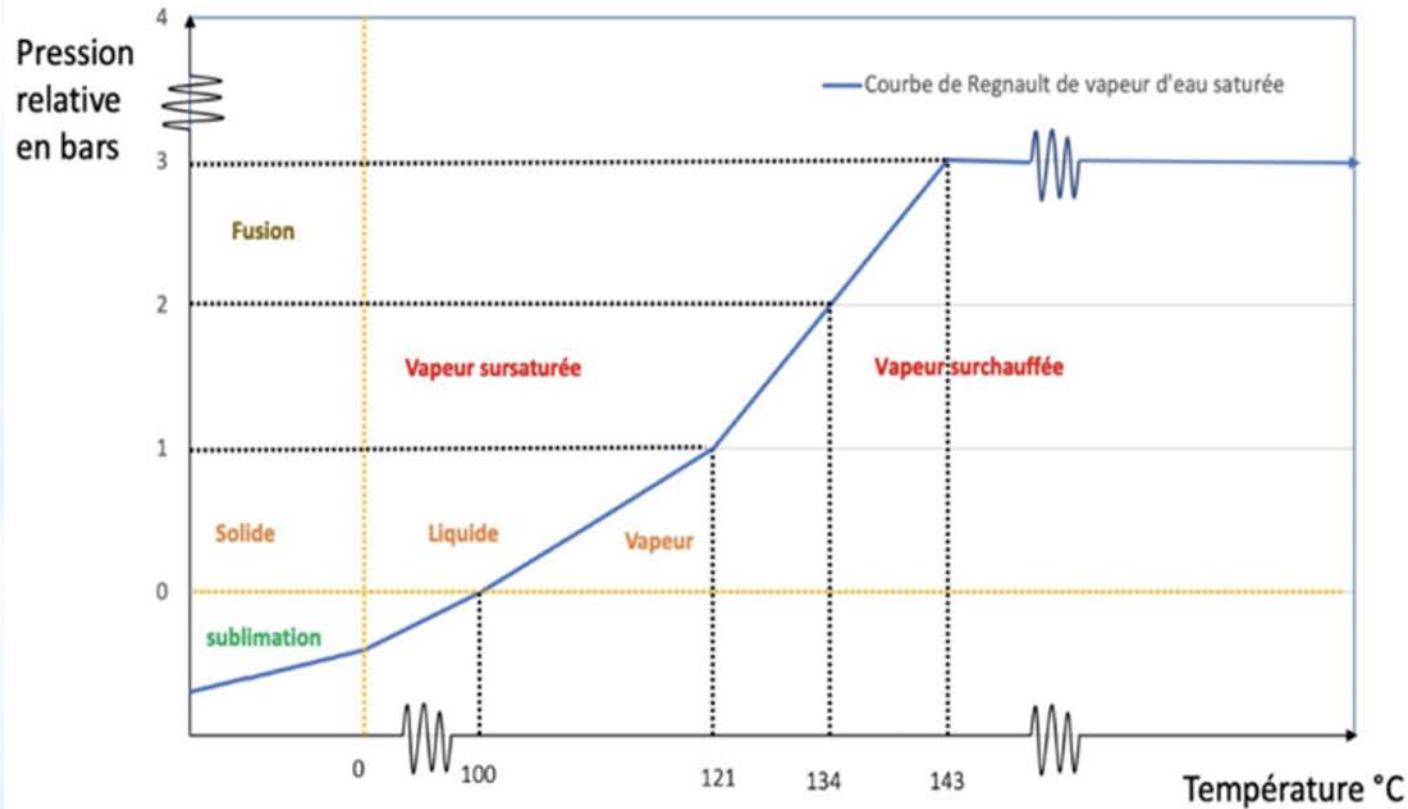


Table Regnault

Température °C	Pression relative bar
112	0,52
115	0,67
121	1,02
125	1,30
134	2,05
135	2,12
136	2,20
138	2,40

$$Fo = \Delta t \sum_{10}^{T-121,11} / 10$$

# Evolution of medical devices to be sterilized







**How to ensure the proper diffusion of saturated steam through the load?**

## French regulatory framework

*Good Hospital Pharmacy
   
 Practices (BPPH)*

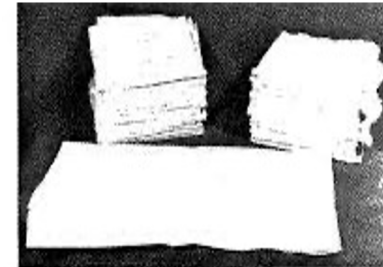


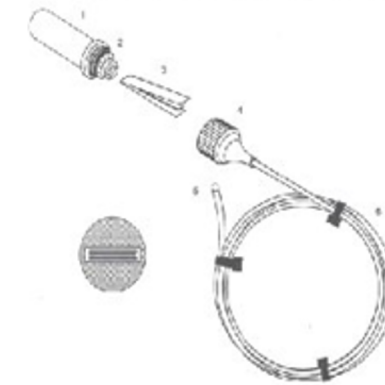
Fig. 1—General arrangement of original test, showing towels and tape before sterilisation.



**BD**

Penetration test of saturated steam through a **porous load**<sup>1</sup>

- ❑ Low representativeness
- ❑ Variable sensitivity<sup>2,3</sup>



**PCD**

Penetration test of saturated steam through a **hollow body**

- ❑ good representativeness
- ❑ Sensitivity to be determined

1. Bowie J.H., Kelsey J.C., Thompson G.R. The Bowie and Dick autoclave tape test. Lancet (1963), i, 586–587.

2. Brian Kirk, BSc, MSc, PhD, MRPharmS, FIHEEM, Senior Technical Service Specialist, (2012). An Evaluation of Nine Bowie and Dick Test Products Available in the United Kingdom, 3M Health Care, Loughborough UK.

3. Benoit F, Merger D, Hermsen R J and van Doornmalen J P C M, (2011). A comparison of four commercially available electronic steam penetration tests according to ISO 11140 part 4, Zentral Sterilisation, 3, 180-185.

Determine **which device is most sensitive** to a sterilization process defect under **conditions of use representative** of a routine load





# Equipment and methods

## BD



BD 3MTM test



StericlinTM Ready-to-Use BD  
paper test

## PCD



Sterisense® ELLABTM device



Goubanne® BVF ConseilTM



Helix StericlinTM Test  
test



BVF ConseilTM stainless steel helix



NanoVACQ® probe  
TMI ORIONTM



StericlinTM BD/PCD test



TMI™ PTFE Helix Test



Objective	1. Identify the worst case scenario			2. Determine the sensitivity of PCDs compared to BD tests	
	1. Determine the most restrictive packaging	2. Determine the minimum cycle	3. Determine the most restrictive composition	PCD	BD test
Packaging used	<ul style="list-style-type: none"> <li>- Non-woven paper</li> <li>- Plastic bag</li> <li>- ULTRA Bag</li> <li>- Containers</li> </ul>	<ul style="list-style-type: none"> <li>- Most restrictive packaging (pre determined)</li> </ul>	<ul style="list-style-type: none"> <li>- Most restrictive packaging (pre determined)</li> </ul>	<ul style="list-style-type: none"> <li>- Most restrictive packaging (pre determined)</li> </ul>	<ul style="list-style-type: none"> <li>- No packaging</li> </ul>
Cycles used	<ul style="list-style-type: none"> <li>- Container cycles 134°C-18min</li> </ul>	<ul style="list-style-type: none"> <li>- According to calibration</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum cycle (pre determined)</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum cycle (pre determined)</li> </ul>	<ul style="list-style-type: none"> <li>- BD Cycle</li> </ul>
Load composition	<ul style="list-style-type: none"> <li>- "standard" load according to the QP</li> </ul>	<ul style="list-style-type: none"> <li>- empty load</li> <li>- full load</li> <li>- full load of hollow instruments</li> </ul>	<ul style="list-style-type: none"> <li>- empty load</li> <li>- full load</li> <li>- full load of hollow instruments</li> </ul>	<ul style="list-style-type: none"> <li>- Most restrictive load (pre determined)</li> </ul>	<ul style="list-style-type: none"> <li>- empty load</li> </ul>
Method	<ul style="list-style-type: none"> <li>□ Comparison of measurements <i>Packaged PCDs / room probe</i></li> </ul>	<ul style="list-style-type: none"> <li>□ Cycle calibration <ul style="list-style-type: none"> <li>- Gradual increase of the number of pre-vacuum</li> <li>- Gradual increase of the vacuum threshold</li> </ul> </li> <li>□ Compliance of test devices (packaged PCDs/room sensor)</li> </ul>	<ul style="list-style-type: none"> <li>□ Compliance of test devices (packaged PCDs/room sensor)</li> <li>□ Comparison of measurements (packaged PCDs / room probe)</li> </ul>	<ul style="list-style-type: none"> <li>□ Creation of a leak during the cycle <ul style="list-style-type: none"> <li>- Leak at atmospheric pressure</li> <li>- Leak at sub-atmospheric pressure</li> </ul> </li> <li>□ Gradual increase in leakage rate <ul style="list-style-type: none"> <li>- Leak at atmospheric pressure</li> <li>- Leak at sub-atmospheric pressure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>□ Creation of a leak during the cycle <ul style="list-style-type: none"> <li>- Leak at atmospheric pressure</li> <li>- Leak at sub-atmospheric pressure</li> </ul> </li> <li>□ Gradual increase in leakage rate <ul style="list-style-type: none"> <li>- Leak at atmospheric pressure</li> <li>- Leak at sub-atmospheric pressure</li> </ul> </li> </ul>
				<ul style="list-style-type: none"> <li>□ Comparison of measurements</li> </ul>	

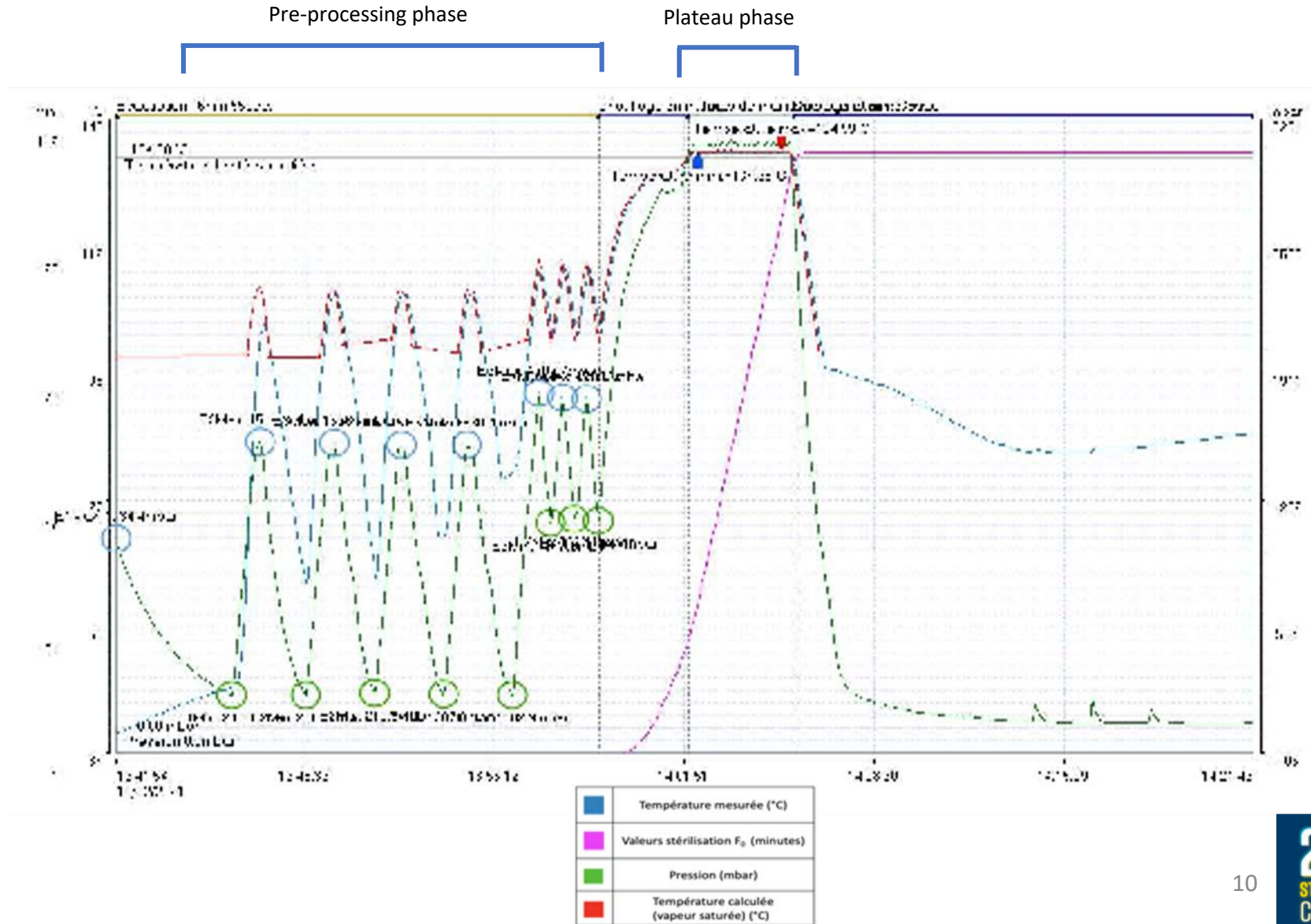
## Measures

Measuring temperature

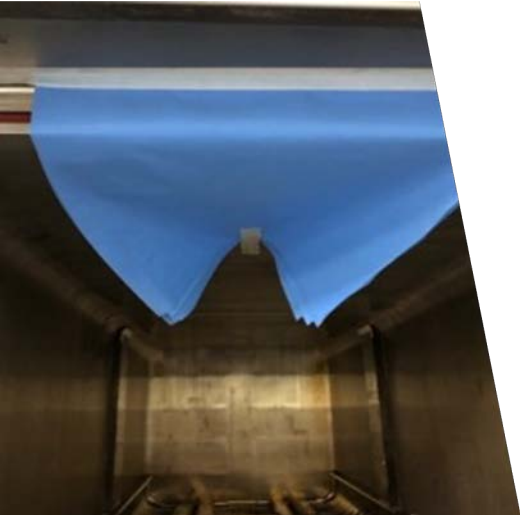
Measuring pressure

Sterilization value  $F_0$

Duration of the set



# Creation of a leak



□ Leak at atmospheric pressure



□ Leak at sub-atmospheric pressure

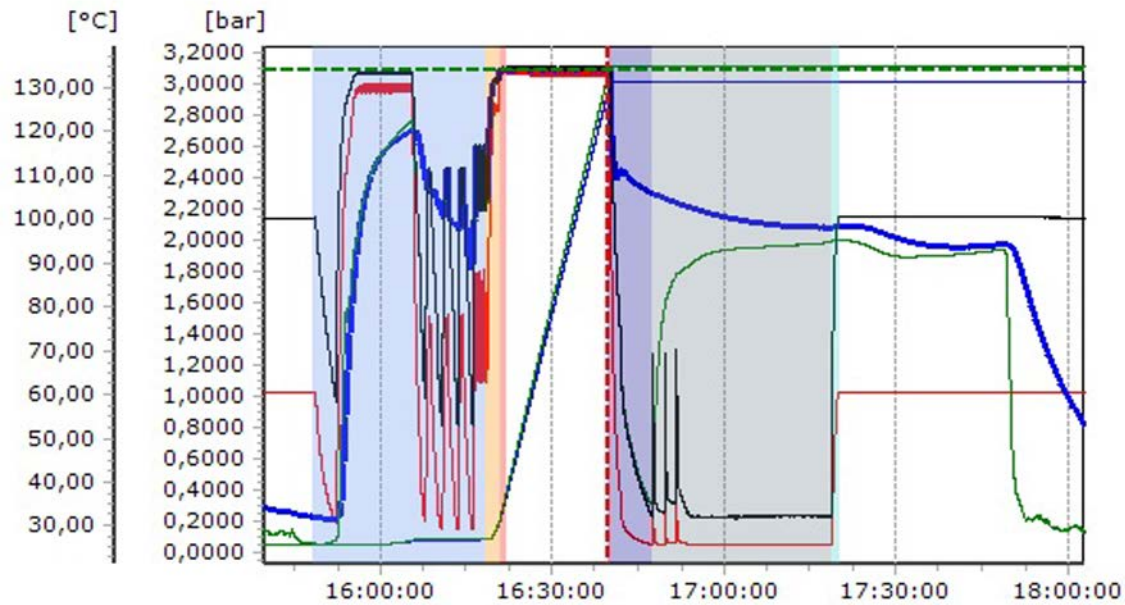




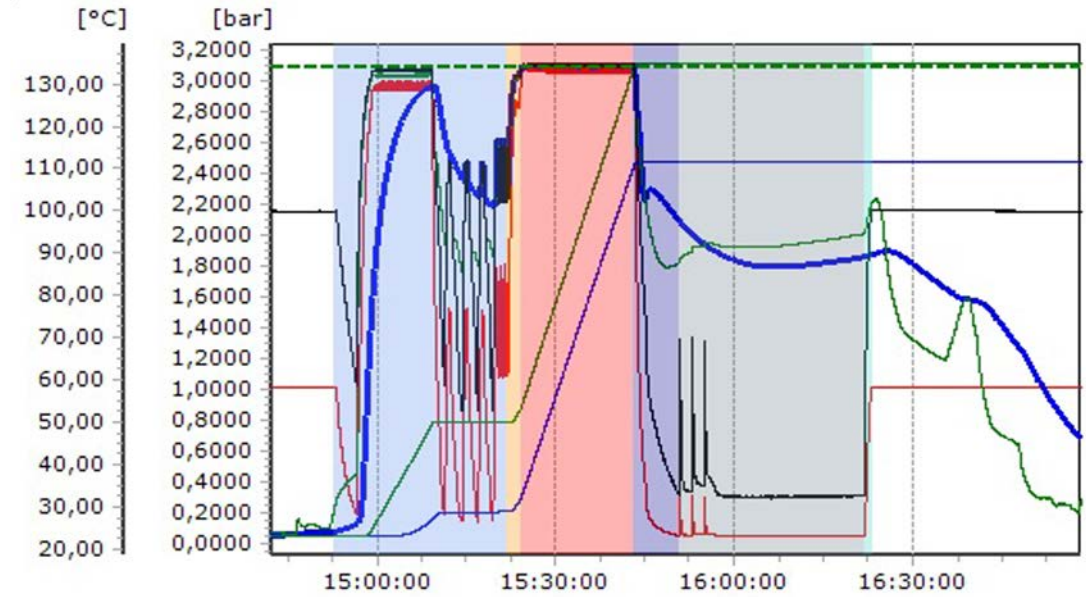
# Findings



- Temperature difference in pre-heating phase



Container packaging



Paper-plastic packaging

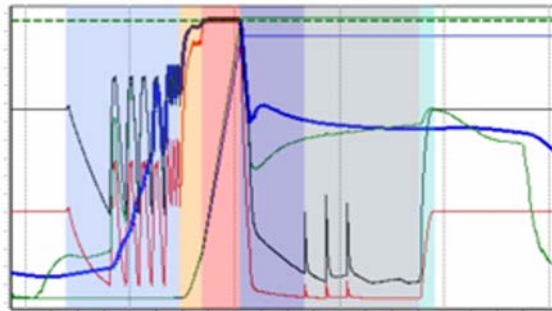
- Largest deviation of the sterilizing value F0

- ➔ **Cycle at 1 pre-vacuum 200 mbar + 3 pre-vacuum 150 mbar**
- ➔ **Cycle at 1 pre-vacuum 200 mbar + 3 pre-vacuum 100 mbar**
- ➔ **Cycle at 5 pre-vacuum 200 mbar**

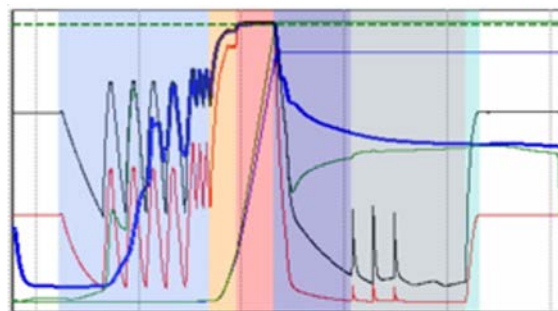


5 pré-vides à 200 mbar									
Dispositif d'épreuve	Charge vide			Charge pleine			Charge creuse		
	Δ Temps	Durée plateau	F <sub>0</sub>	Δ Temps	Durée plateau	F <sub>0</sub>	Δ Temps	Durée plateau	F <sub>0</sub>
Test Hélix en inox	00:00:00	00:03:35	107,42	00:00:00	00:03:35	111,76	00:00:00	00:03:35	108,7
Goubanne®	00:00:30	00:03:10	98,43	00:00:00	00:03:30	109,68	00:00:00	00:03:30	107,08
Test Hélix en PTFE	00:00:00	00:03:35	105,27	00:00:00	00:03:30	109,78	00:00:00	00:03:35	106,77
SteriSense®	00:00:00	00:03:36	99,5	00:00:00	00:03:38	103,66	00:00:00	00:03:36	96,4
Sonde ambiante		00:03:35	106,69		00:03:30		00:00:00	00:03:35	108,66
Test BD/PCD Stericlin	Conforme			Conforme			Conforme		

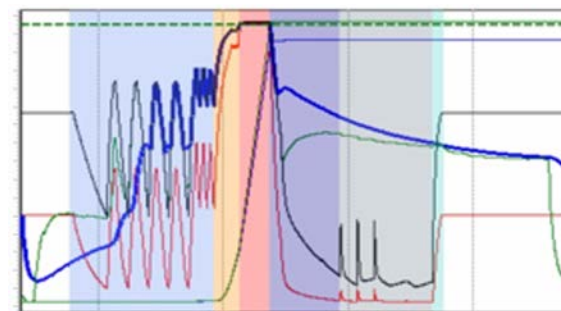
# Most restrictive load



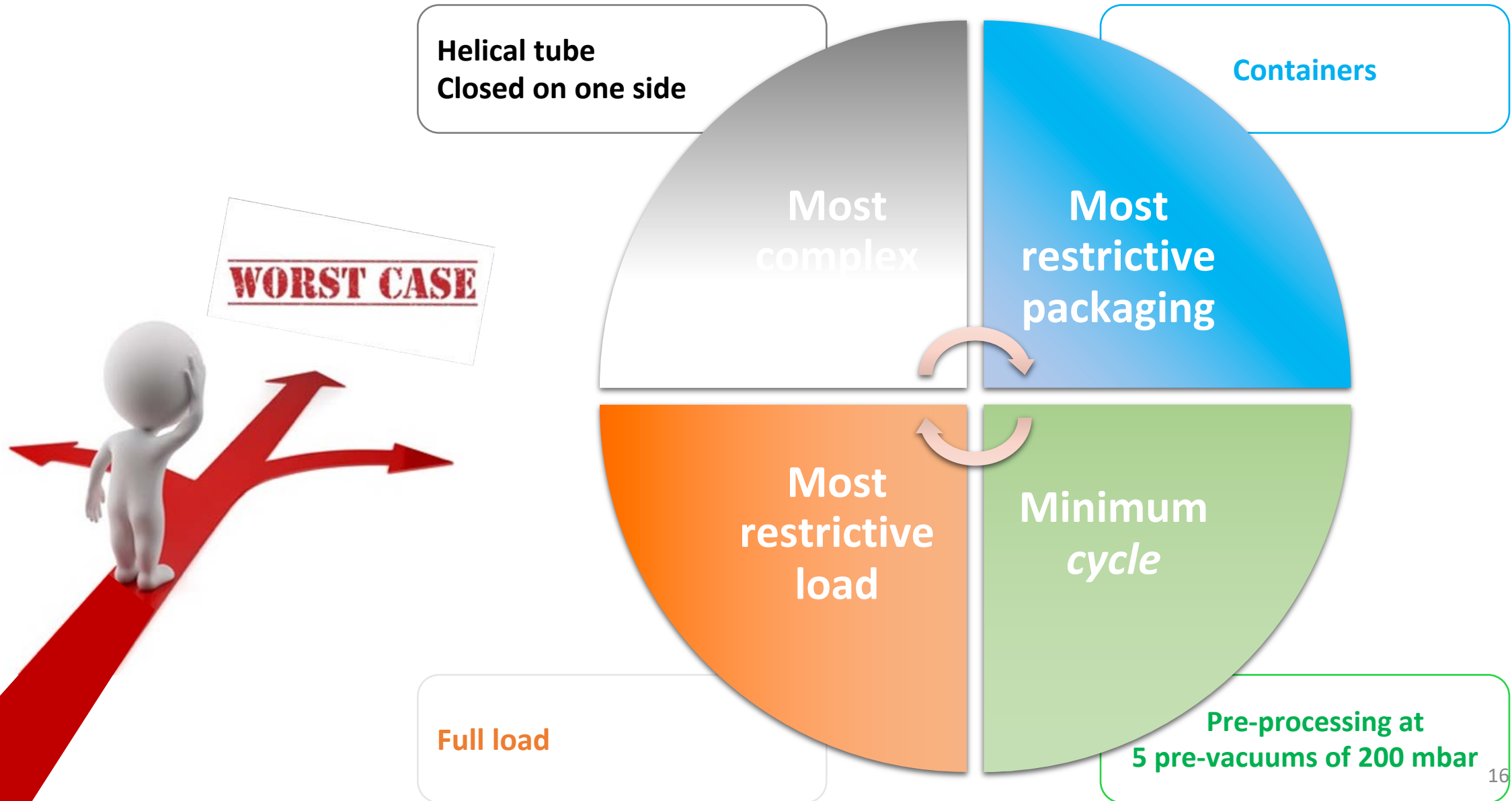
Empty load



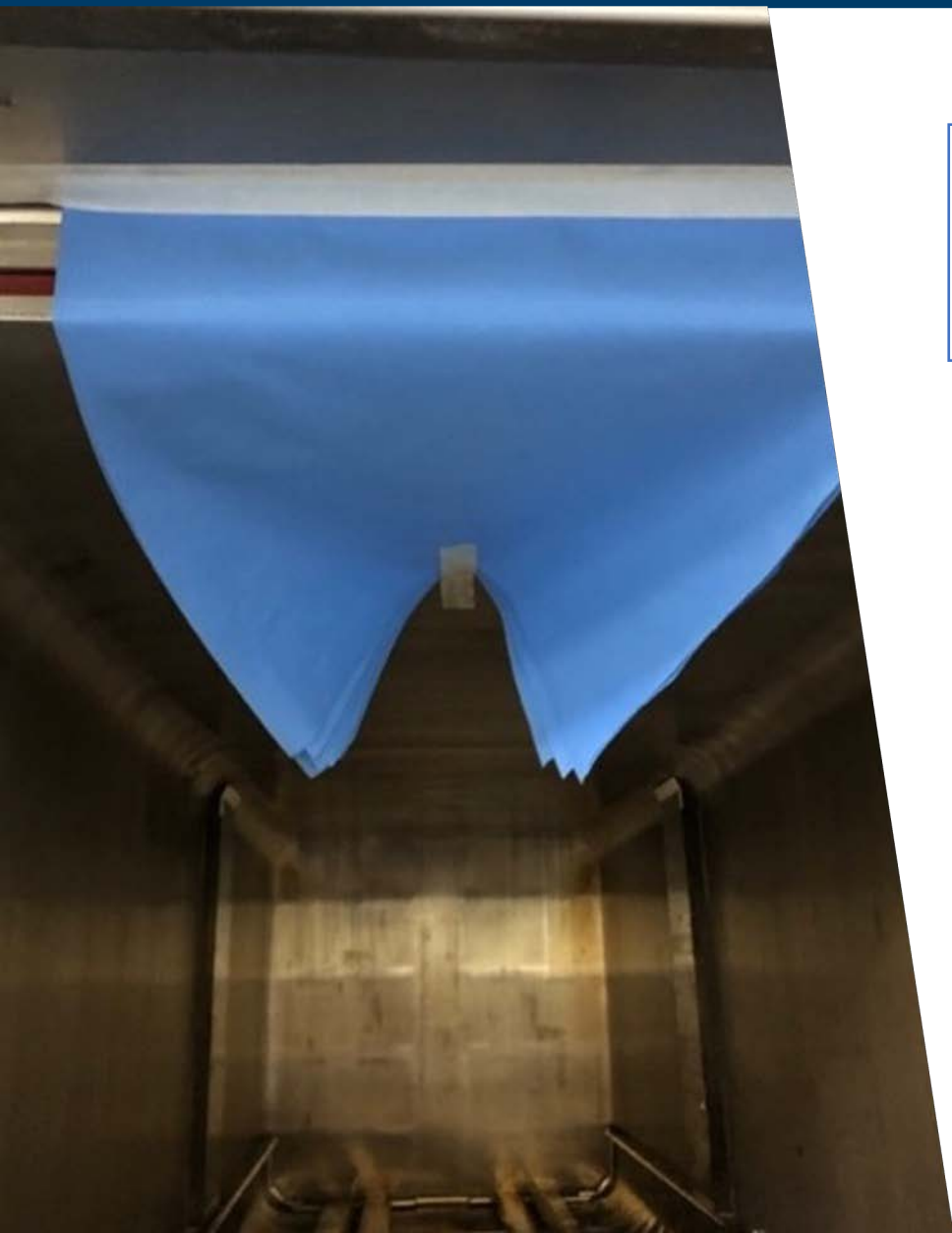
Hollow load



Full load







## 1 sheet

- Only Goubanne® detects the leak whatever the load
- No BD test detects the leak





## 20 mbar

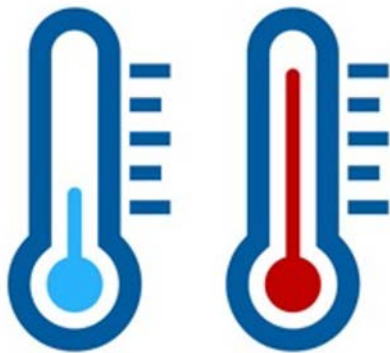
- Goubanne<sup>®</sup>, Sterisense<sup>®</sup> and Stericlin<sup>™</sup> BD/PCD tests detect a leak regardless of the load
- BD Cycle: 3M<sup>™</sup> BD Test and Stericlin<sup>™</sup> BD/PCD Test detect a leak





# Discussion

## PCDs: packaged or not, what is the difference?



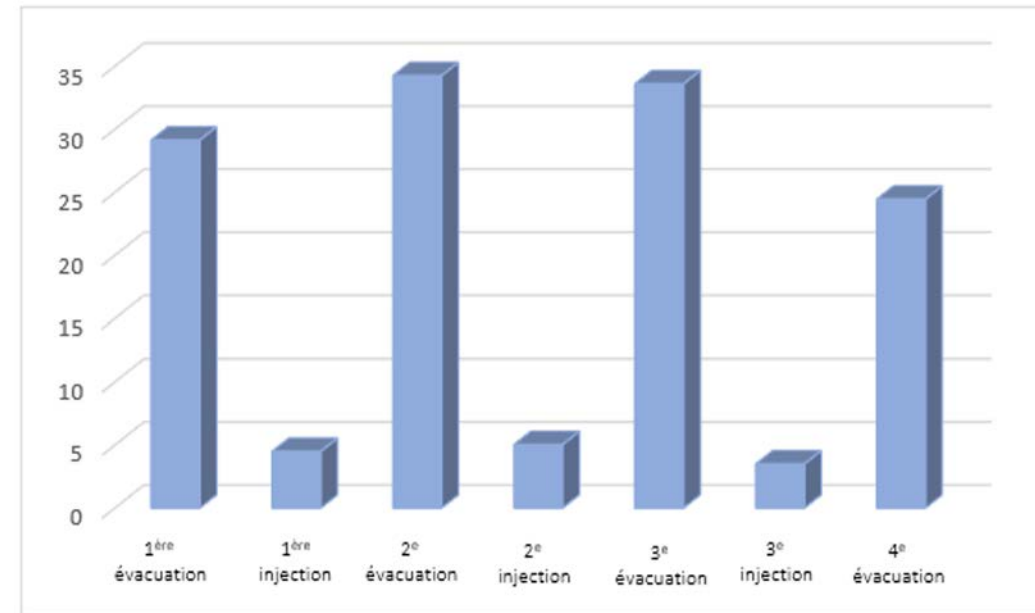
- ▶ During the pre-processing phase, some temperature differences between the packed test device and the ambient probe exceeded 50° C



*A packaged PCD is essential!*



## Be careful with the packaging of a hollow item!



Temperature differences measured between the helix test in paper-plastic bag packaging and the ambient probe during pre-processing



*Risk of blocking the opening with the waterproof part of the bag*

## Why does the Goubanne test systematically give incorrect results on empty cycles?

► Air extraction issue? Yes, but not only!



**Phenomenon of over-condensation**

- Influence of the material
- Influence of shape
- Influence of the ratio size of the hollow body / size of the packaging
- ???



- Sterisense® device packaged in a container
- Goubanne®



- Ready-to-use BD paper test



- ▶ Good sensitivity of the SteriGlin™ BD/PCD test
- ▶ Problem: colour change of indicators sometimes unclear



**The interpretation of the colour change is up to the reader**



- ▶ Degraded procedure?





## So? BD test or PCD?

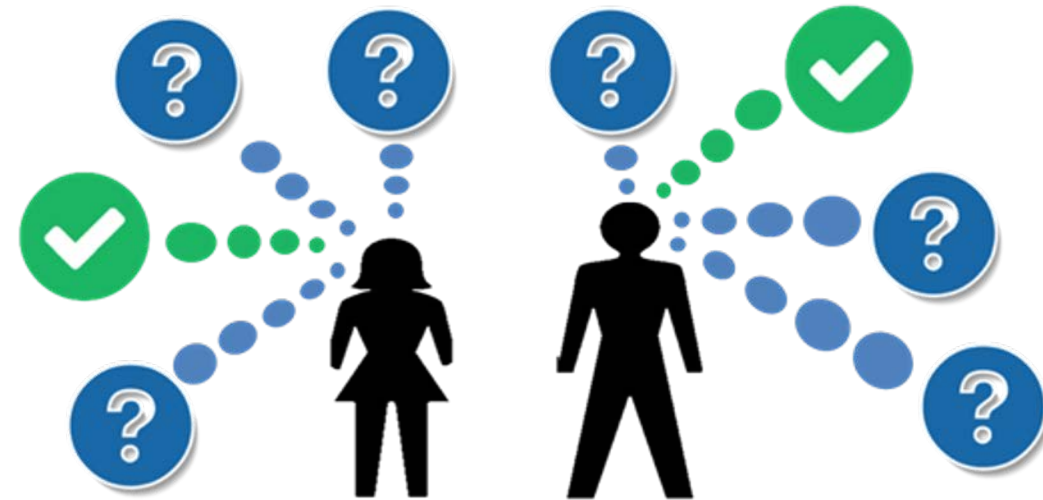
- ▶ PCD under worst case conditions more sensitive than BD tests
- ▶ PCDs representative of routinely sterilized MDs
- ▶ Allows control of steam penetration on all routine cycles, not just once a day

## BD test

- *the most commonly used in French health care institutions*
- *not very sensitive and not representative*

## PCD

- *good sensitivity: Goubanne<sup>®</sup> and Sterisense<sup>®</sup>*



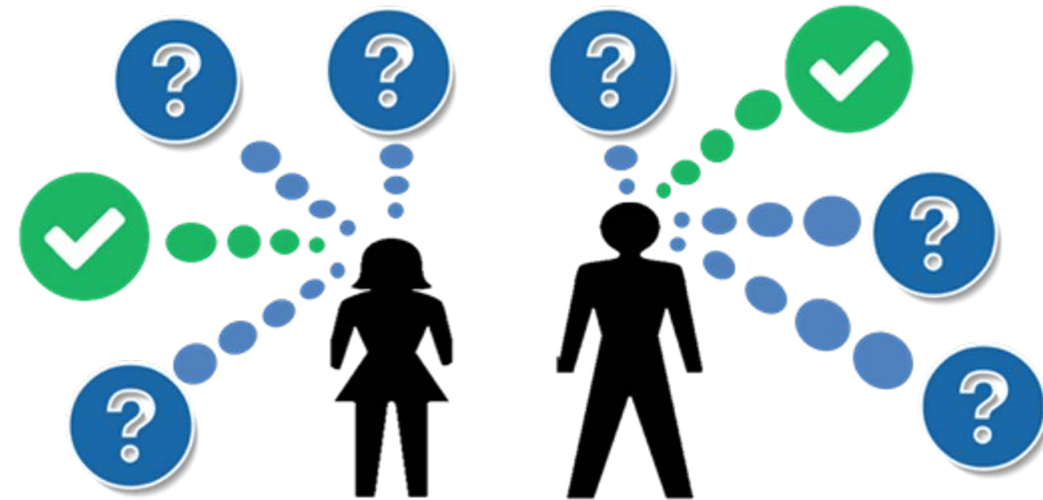
- ▶ **PCD as a substitute for BD**
- **Economic**
- **Secures the sterile RMD circuit**

PCD used in the worst  
sterilization conditions

Choosing the right PCD  
for your practice

PCD replaces the BD test  
AND an ambient probe

Qualification tool





- ▶ At the Rouen University Hospital:
  - ▶ The BD 3M™ test used routinely is a BD test capable of detecting most air leaks
  - ▶ To be tested on our routine cycles by CSSD operators



Thank you for your attention