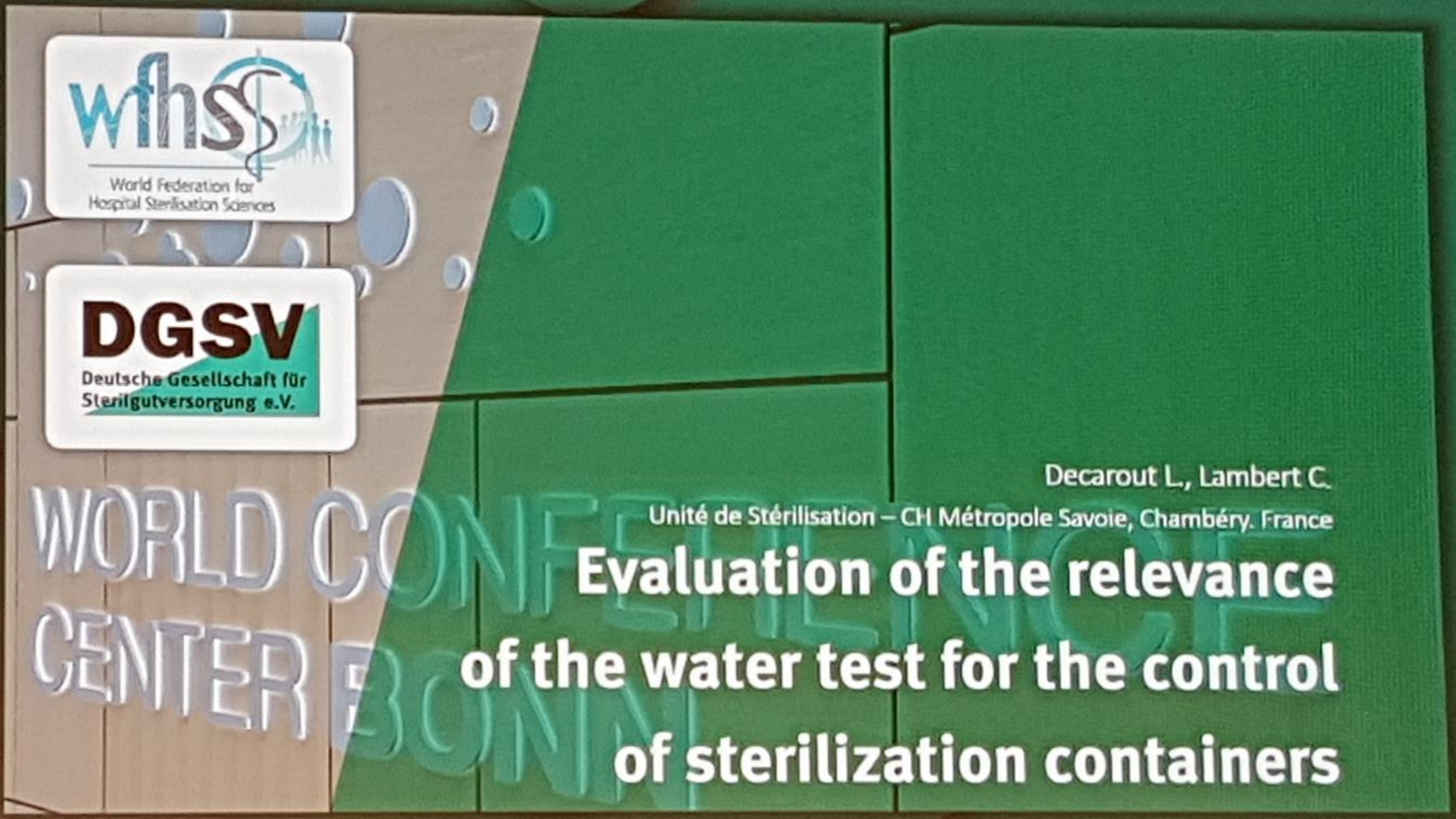


Decarout L., Lambert C.
Unité de Stérilisation – CH Métropole Savoie, Chambéry. France

Evaluation of the relevance of the water test for the control of sterilization containers

Concept of the SBS

- **Container** = reusable Sterile Barrier System (EN 11607-1)

- **ISO 11607-1** : after forming the sterile barrier system, the closures must constitute a barrier against micro-organisms.

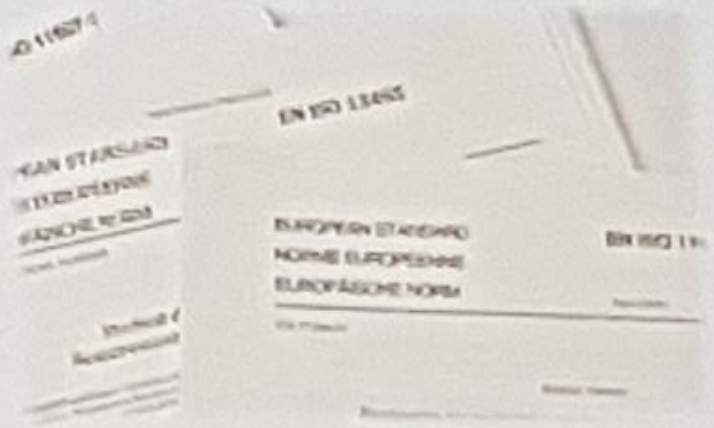
- **SBS integrity** = preservation of the sterile state

Container checks

- Mandatory functional tests in France

Before sterilization, each reusable container is visually inspected, and its suitability for operation is verified according to the manufacturer's recommendations. (1)

(1) Bonnes pratiques de pharmacie Hospitalière. Arrêté du 22 juin 2001

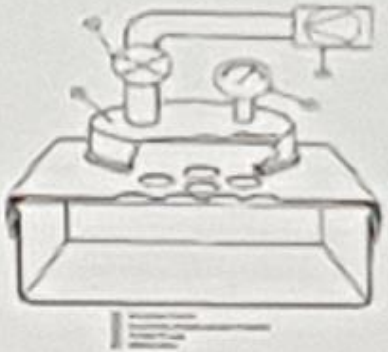


- EN ISO 11607-1 requirements

Acceptance criteria must be established for the inspection prior to each reuse.

Container performance controls

- Ultrasound test
- Vacuum cloche
- Visual checks



EN 868-1 (1997) : vacuum test

The water test

- **Objective**: evaluation of the watertightness of the container/lid junction

≥ 1 leak: test +

no leak: test -

(1) PDS 98-053 Test protocol to be performed on reusable sterile barrier systems (containers) to assess the watertightness of the container/lid closure (2014)

Relevance of the water test

- The water Test is not recognized by container manufacturers

- **National survey**: containers with positive leak test
  - France : 29% [3]
  - Switzerland : 17% [4]

(3) Validation des emballages en stérilisation centrale hospitalière – Atelier des Journées nationales d'études sur la stérilisation. Marseille 2013 – B. Valence et J. Molina

4) Cavin F. Analyse de risque inclus aux contrôles d'étanchéité des joints des conteneurs dans plusieurs établissements suisses. 16èmes congrès WFHSS; 2015; Lille

Does the water Test have a predictive character for an integrity breach of the SBS?

Permeability of the microbial barrier

- Gas exchange through the SBS:
  - Gas contraction during cooling

  - Pressure variations (atmospheric pressure, overpressure, elevation variation ...)

- Preliminary tests
  - Volume changes during cooling (exit autoclave)
  - Impact of pressure changes

- **Relevance of the water test for the control of sterilization containers**

Material & methods

- 15 containers 30x30 x11 cm
  - 5 with a positive leak test (F+)
  - 5 with a negative leak test (F-)
  - 5 Positive control without filter (T+)

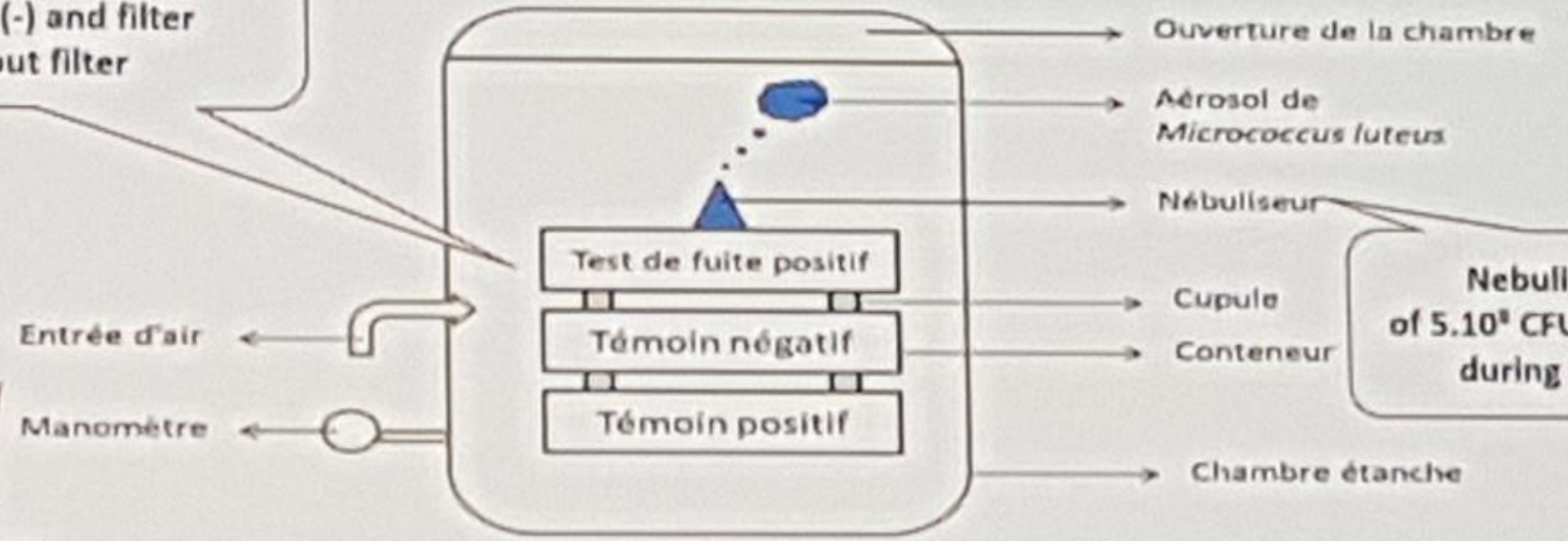
- PP trays/TSA agar/bottom of the containers
- Sterilisation at 125°C/ 20 min.
- Cooling in unloading zone (EN 14664-1:ISO 8)
- Containers placed in aerosol chamber

Material & methods (2)

- Self-contained ultrasonic nebulizer
- Suspension of *Micrococcus luteus* (5.10^8 UFC)
- 3 pressures (25, 50, 75 mbar)
- **3 containers per series**: 1 container F^+, 1 container F^-, 1 container T^+
- Exposure to overpressure for 30 min. in sealed chamber
- **15 series of 3 containers/pressure**
- Protective packaging before transport to the bacteriology laboratory

Materiel & methods (3)

15 sets of 3 containers:
F + = water test (+) and filter
F-= water test (-) and filter
T += without filter



Nebulization
of 5.10^8 CFU *M. Luteus*
during 20 min

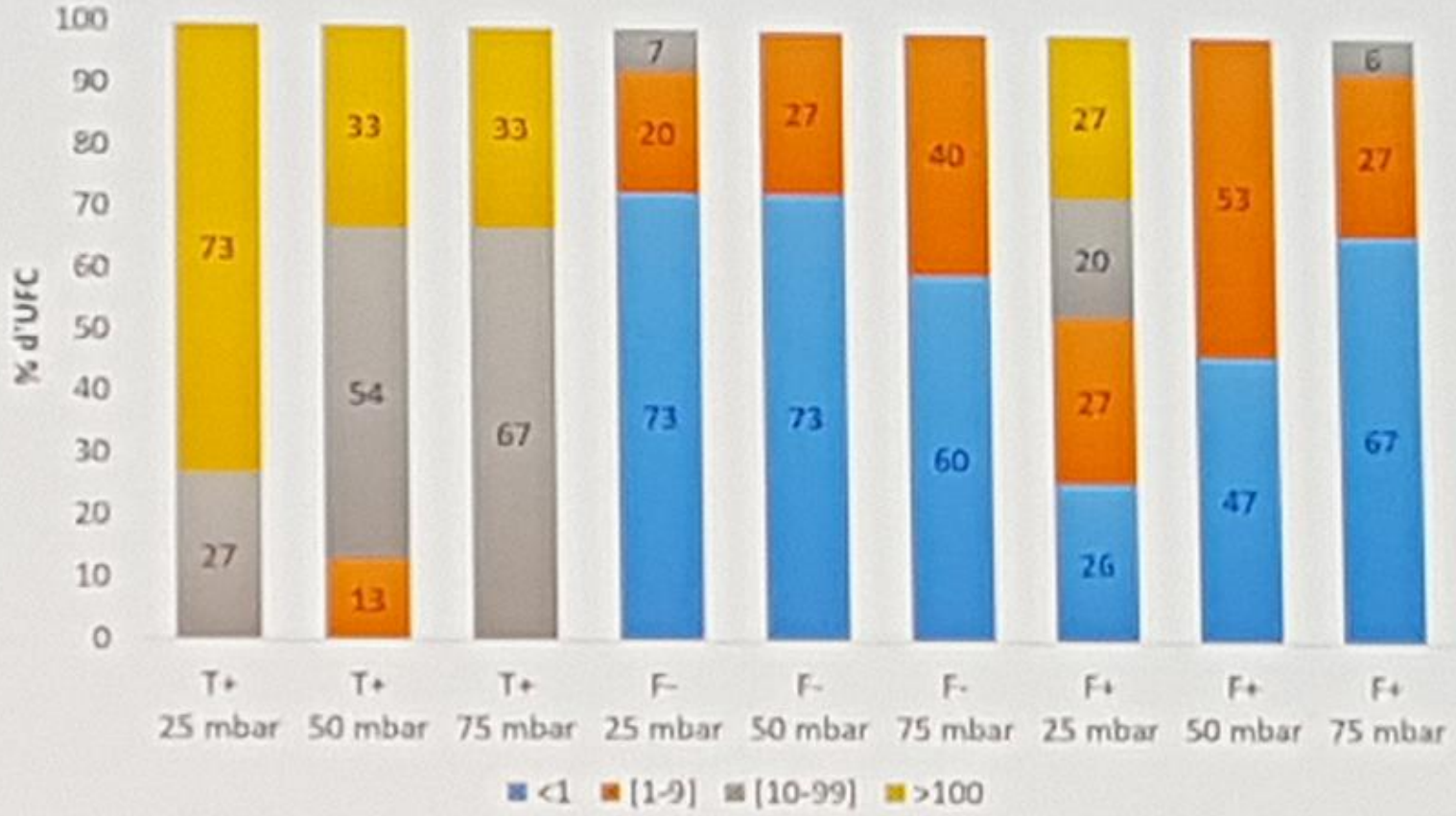
3 pressure:
25, 50 and 75 mbar
overpressure 30 min

Material & methods (4)

- Aseptic opening of containers
- Packaging of trays under laminar flow

- Incubation at 37°C for 5 days

Results



Distribution of CFU/containers/pressure

T+ : positive control

F+ : positive leak test

F- : negative leak test

Results : determination of log reduction value

Determination of log reduction value (LRV):
$LRV = \log CFU_0 - \log CFU_1$

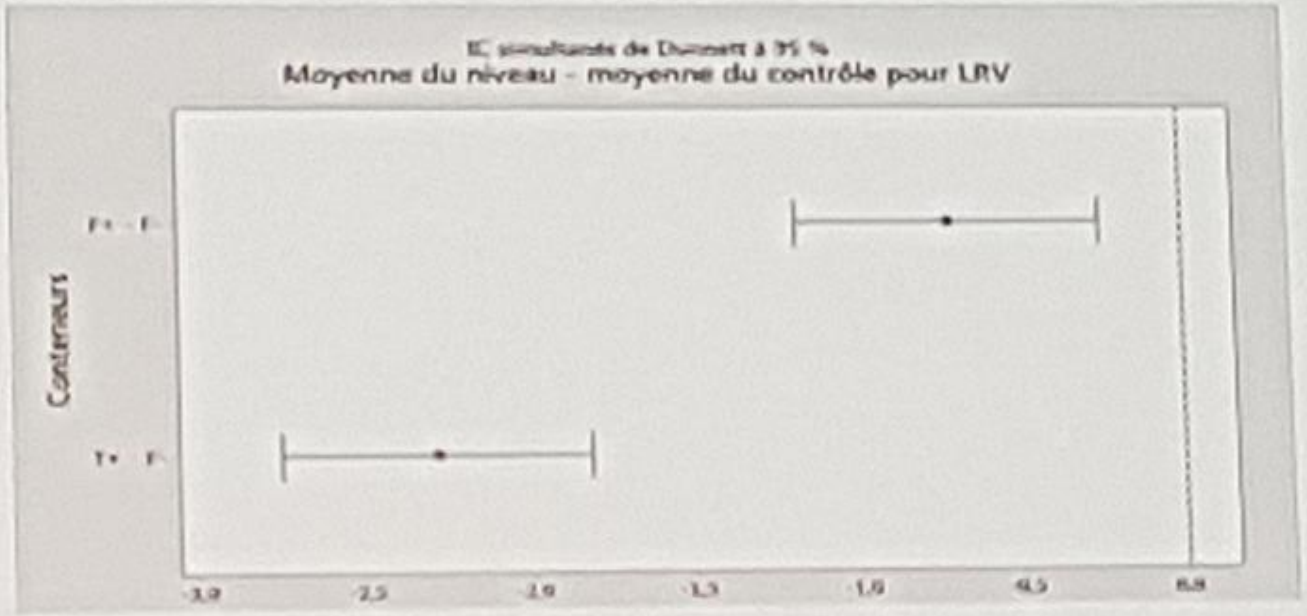
Sterility Assurance Level = LRV ≥ 6
Using the same containers → LRV_{mean}

	Type contenant	Pression (relatif)	$LRV_{moyenne}$
T1+	T+	25	3,39299769
F1+	F+	25	3,89573862
F1-	F-	25	5,51830839
T2+	T+	25	3,99752207
F2+	F+	25	4,28467999
F2-	F-	25	4,87054405
T3+	T+	25	3,52134567
F3+	F+	25	5,34152134
F3-	F-	25	6,7934543
T4+	T+	25	3,39233701
F4+	F+	25	3,75675486
F4-	F-	25	6,29979445
T5+	T+	25	3,37396797
F5+	F+	25	4,37900185
F5-	F-	25	5,91830839

T1+	T+	50	4,10323925
F1+	F+	50	5,74166619
F1-	F-	50	5,89630564
T2+	T+	50	3,88242412
F2+	F+	50	5,57898855
F2-	F-	50	5,73193596
T3+	T+	50	4,10323925
F3+	F+	50	6,14687132
F3-	F-	50	6,25832373
T4+	T+	50	4,28447965
F4+	F+	50	5,52693855
F4-	F-	50	6,58790818
T5+	T+	50	4,45160587
F5+	F+	50	6,74682896
F5-	F-	50	7,10902213
T1+	T+	75	4,32170488
F1+	F+	75	5,90768056
F1-	F-	75	5,90768056
T2+	T+	75	4,20848772
F2+	F+	75	5,39529855
F2-	F-	75	6,26529125
T3+	T+	75	4,19387805
F3+	F+	75	6,60866252
F3-	F-	75	7,2502129
T4+	T+	75	4,2502289
F4+	F+	75	6,14163861
F4-	F-	75	6,75652254
T5+	T+	75	4,94628948
F5+	F+	75	7,04135817
F5-	F-	75	6,75652254

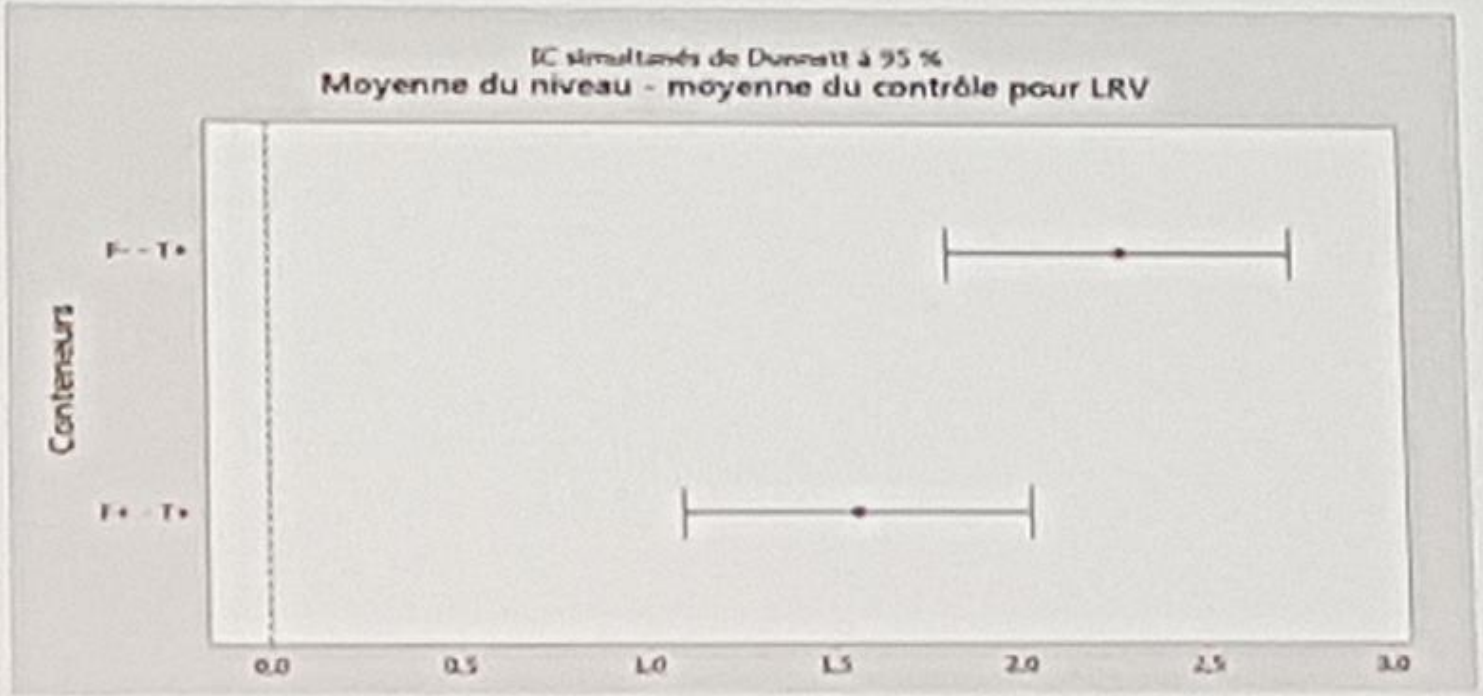
Results : group comparison

Statistically significant difference between negative water test containers (f-) and positive (f +) containers (P-value = 0.002).



Results : group comparison

Statistically significant difference between T + positive control and F + groups (P-value = 0.002) as well as T + positive control and F-group



Discussion

- Relevance of maintenance
  - Reduction in leakage rate from 58% to 15% after maintenance [5]
- Results in % : insufficient for demonstate filtering barrier
  - 99,9999% of barrier = 100 micro-organisms if bioburden is 10^6
- Bioburden of 10^8 *Micrococcus luteus* too high?
  - Exposure of 30 min. vs. storage for 6 months
  - Containers vs. wrapped trays: 87% contaminated vs. 0% [6]

(5) C. Lambert. Contrôle de performance des conteneurs : Intérêt du test à l'eau. JIFS 2014.

(6) Harry L. Shaffer. Sterility maintenance study : dynamic evaluation of sterilized containers and wrapped instrument trays to prevent bacterial ingress. AJIC

Discussion

- Are visual controls sufficient?
  - 76% containers that passed the visual inspection leak [2]
  - Depends on operator

- Using the leak test
  - Not feasible before each assembly of a tray
  - Periodic inspection necessary (periodicity to be defined according to QMS sterilization unit)
  - Provider: after maintenance
- In case of a positive test?
  - Removal of container from the reprocessing
  - Curative maintenance
  - Use fold inside container (SBS)

Conclusions

- **Overpressure promotes the penetration of microorganisms**: impact for facilities located at different altitudes
- **Particle control is required in the unloading area of sterilizers** (ISO 8 recommended)
- **Transport of sterile sets after cooling** protects from recontamination
- **Visual controls**: necessary but insufficient to evaluate container performance
- **Water Test**: highlights the lack of sealing of the microbial barrier!

Take Home Message

The choice and use of an SBS are only a matter of Strong Common Sense (Solide Bon Sens in French).

Act or play ostrich ?

Thank you for your kindly attention

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