

From a time- or event-related to a data-based shelf-life practice for sterilized items

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Topics

1. Time- and event-related concepts of shelf-life
2. Gas permeability of the packaging material
3. Barrier properties of the packaging against airborne microbes



4. Quantitative aspects of events compromising sterility
5. Implementation of a data-based shelf-life practice

1. Time- and event-related concepts of shelf life

Events compromising sterility*:

- punctures
 - tears
 - cuts or breaks on gaskets
 - loosened locks
 - broken seals
-
- type and configuration of packaging materials
 - exposure to airborne contaminants
 - storage conditions



*) AORN JOURNAL 2007:85;802-812

2. Consequences of the gas permeability of the packaging material

passage of steam,
ethylene oxide,



formaldehyde,
hydrogen
peroxide plasma
and

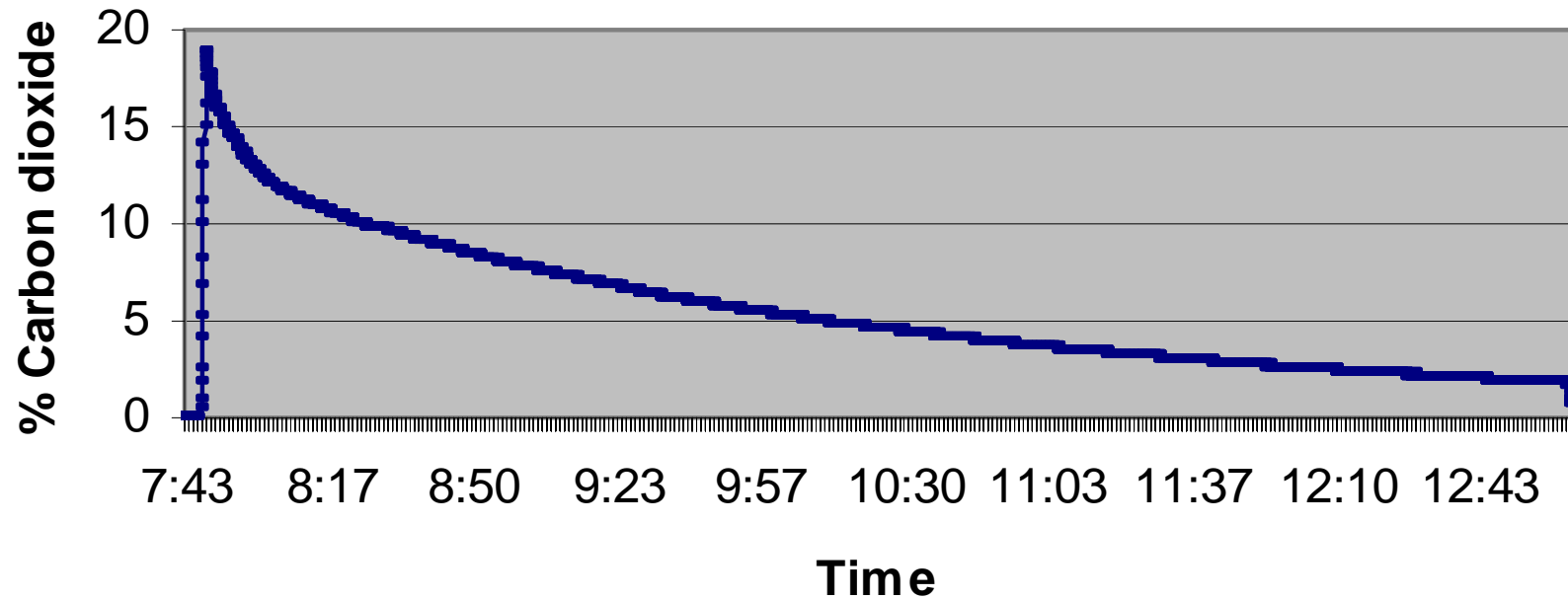


air



Gas permeability of packaging material

Decrease of carbon dioxide within a 6 L paper/film pouch during storage

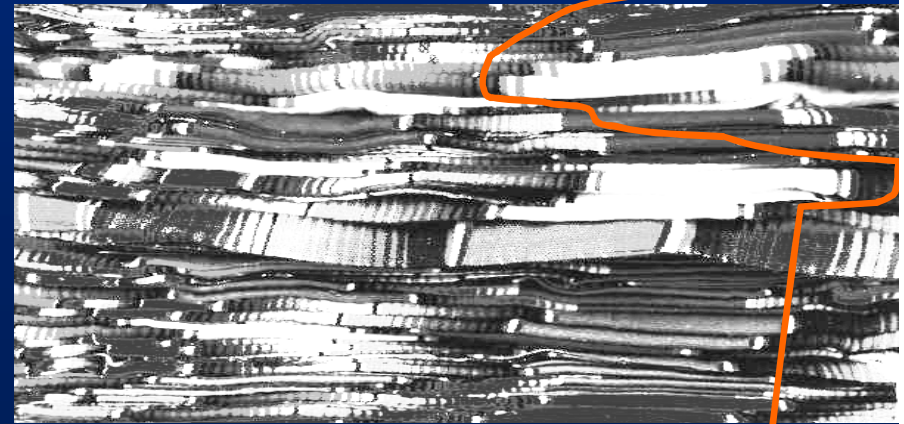


3. Barrier properties against airborne microbes

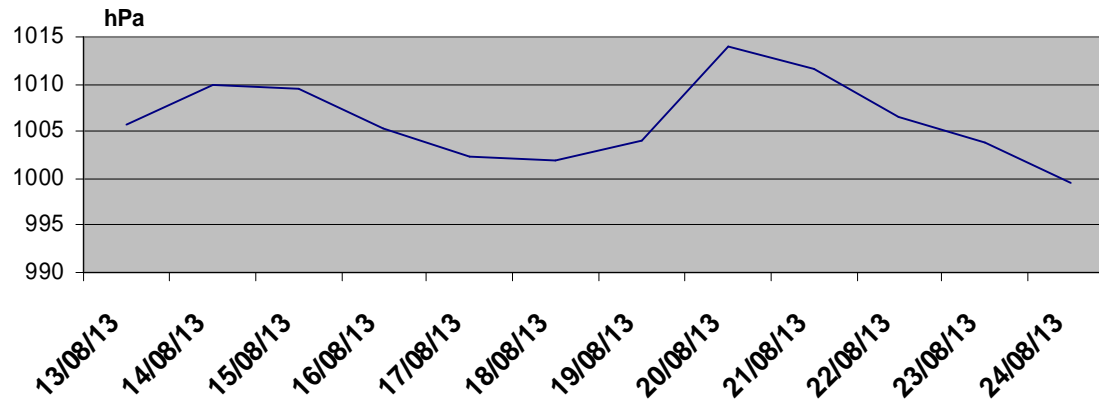
The International Standard

ISO 11607-1 :

"Evaluation of the microbial barrier properties of porous materials is typically conducted by challenging samples with an aerosol of bacterial spores or particulates ".*)



*) ISO 11607-1-2006: Packaging for terminally sterilized medical devices- Part 1: 5.2.3



Typical slope of atmospheric air pressure:
Frankfurt, August 2013

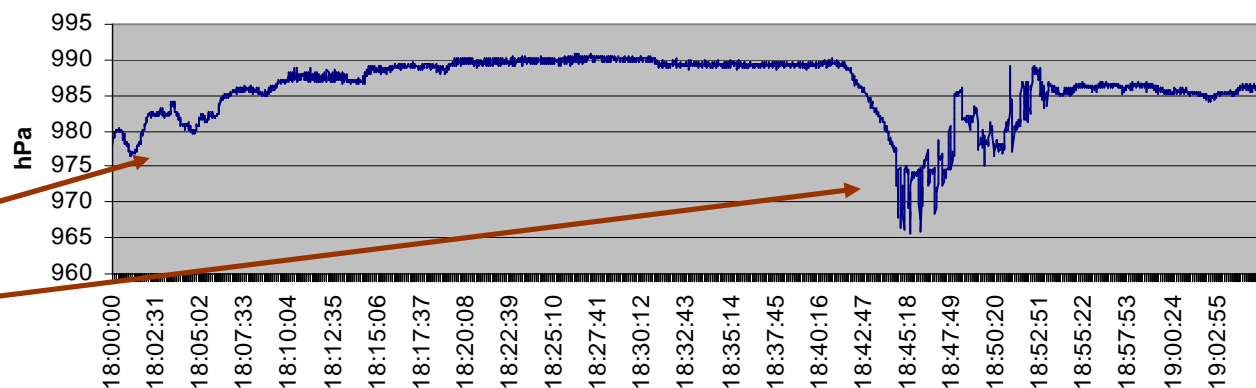
100 ml air flow into a 1 L-package is followed by:

temperature decrease (°C) **30**

reduction in altitude (m) **1000**

number of weather changes from low to high **6**
(17 hPa)

Atmospheric air pressure
Slope: 300 m of height
and transport through 9
railway tunnels



4. Quantitative aspects of events and barrier properties compromising sterility

Time control
module

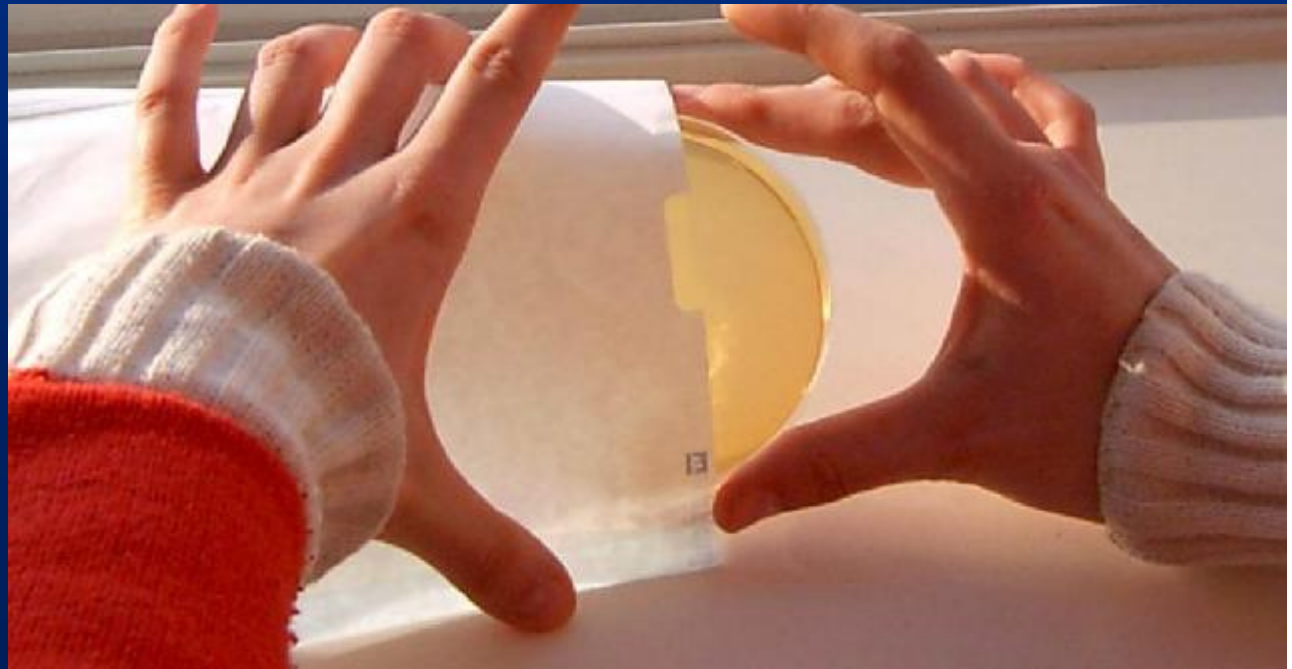


Vacuum pump

Pat No. US 8,053,210 B2



The samples are loaded with dishes filled with nutrient agar before sterilization



Calculation of the microbial penetration (%) and the filtration efficiency (%)

N_1 = Number of bacteria registered as colony forming units (CFU) on the dishes in the packaging

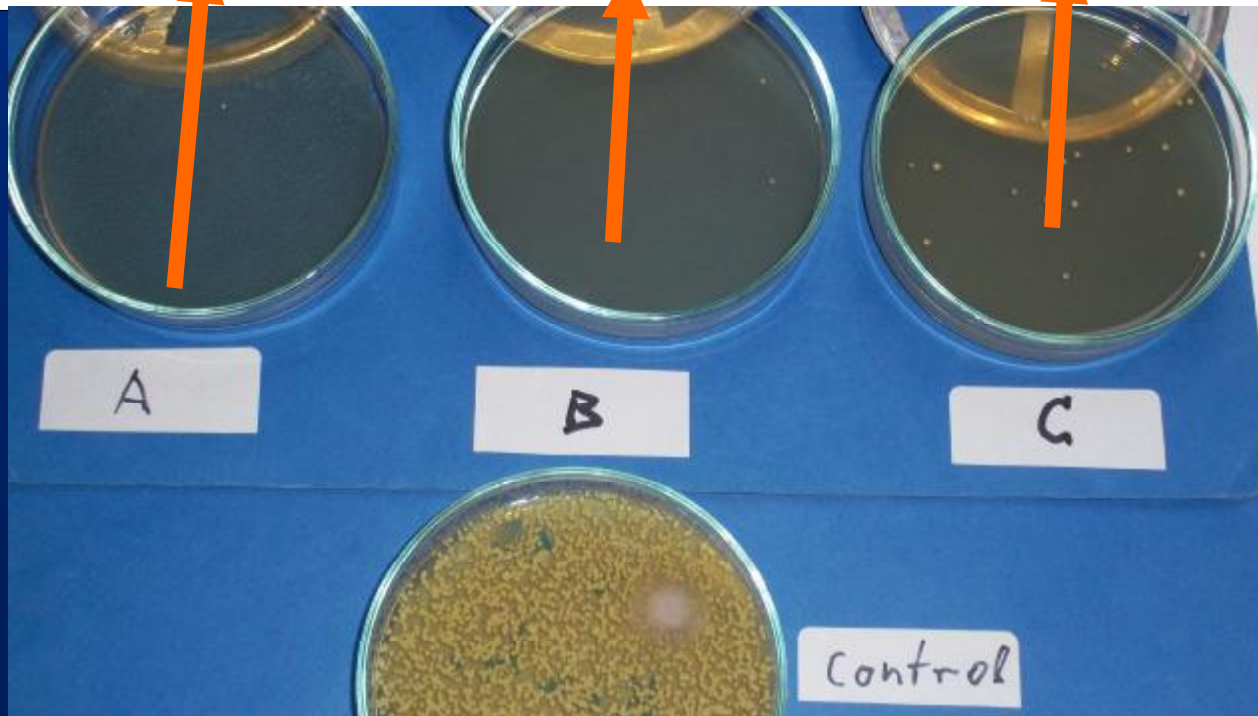
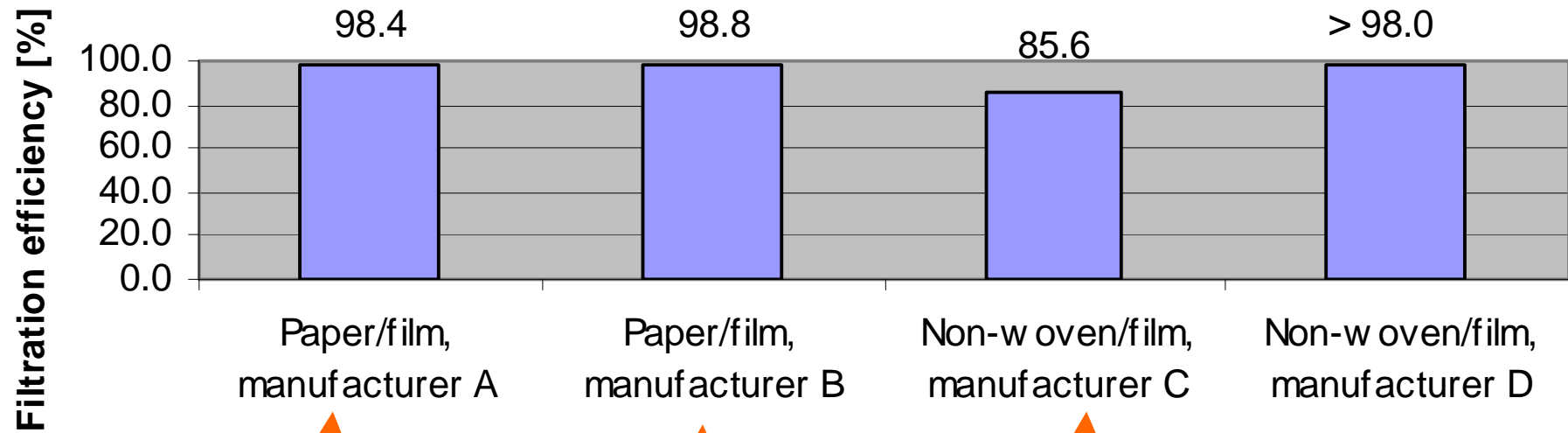
N_0 = Microbial challenge: number of bacteria in the air volume passing the packaging material

$$\text{Microbial penetration rate (\%)} = \left[\frac{N_1}{N_0} \right] \times 100$$

Filtration efficiency (%) =

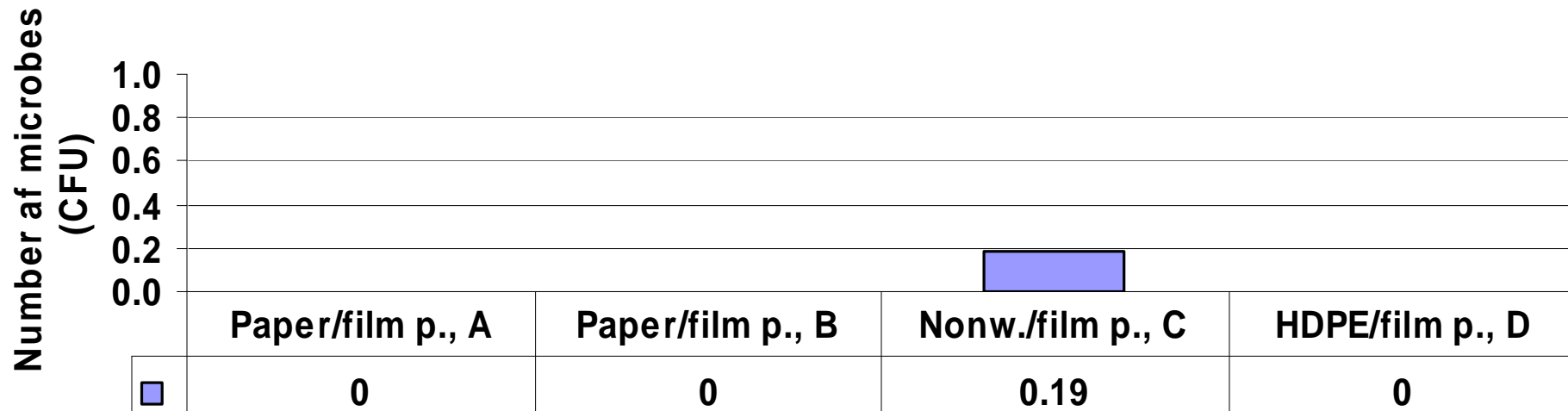
$$\text{Airborne microbial removal efficiency} = \left[1 - \frac{N_1}{N_0} \right] \times 100$$

Capacity of 4 types of pouches (15x15 cm) to remove airborne microbes (30 pouches per group)



Removal of airborne microbes by double wrapped pouches

Mean number of microbes entering the package
(double packaging, n=28)





ISO 11607-1:

“There is no universally accepted method of demonstrating microbial barrier properties ...”*)

*) ISO 11607-1, 5.2.3

Annex B

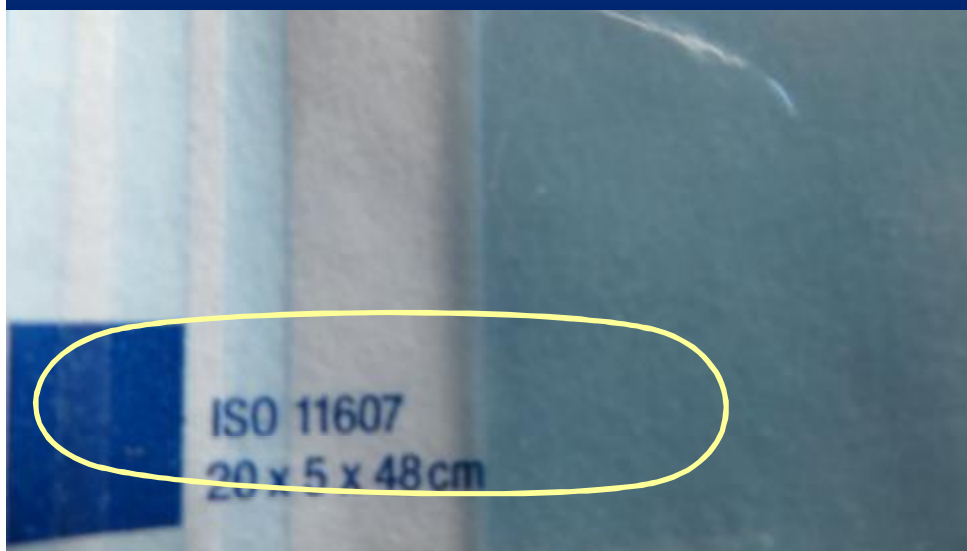
“Standardized test methods and procedures that may be used to demonstrate compliance with the requirements of this part of ISO 11607-1”

DIN 58953-6:2010: Mixture of 0.25g quartz powder (40-150 μm) and bacterial spores (2.5×10^5 CFU)

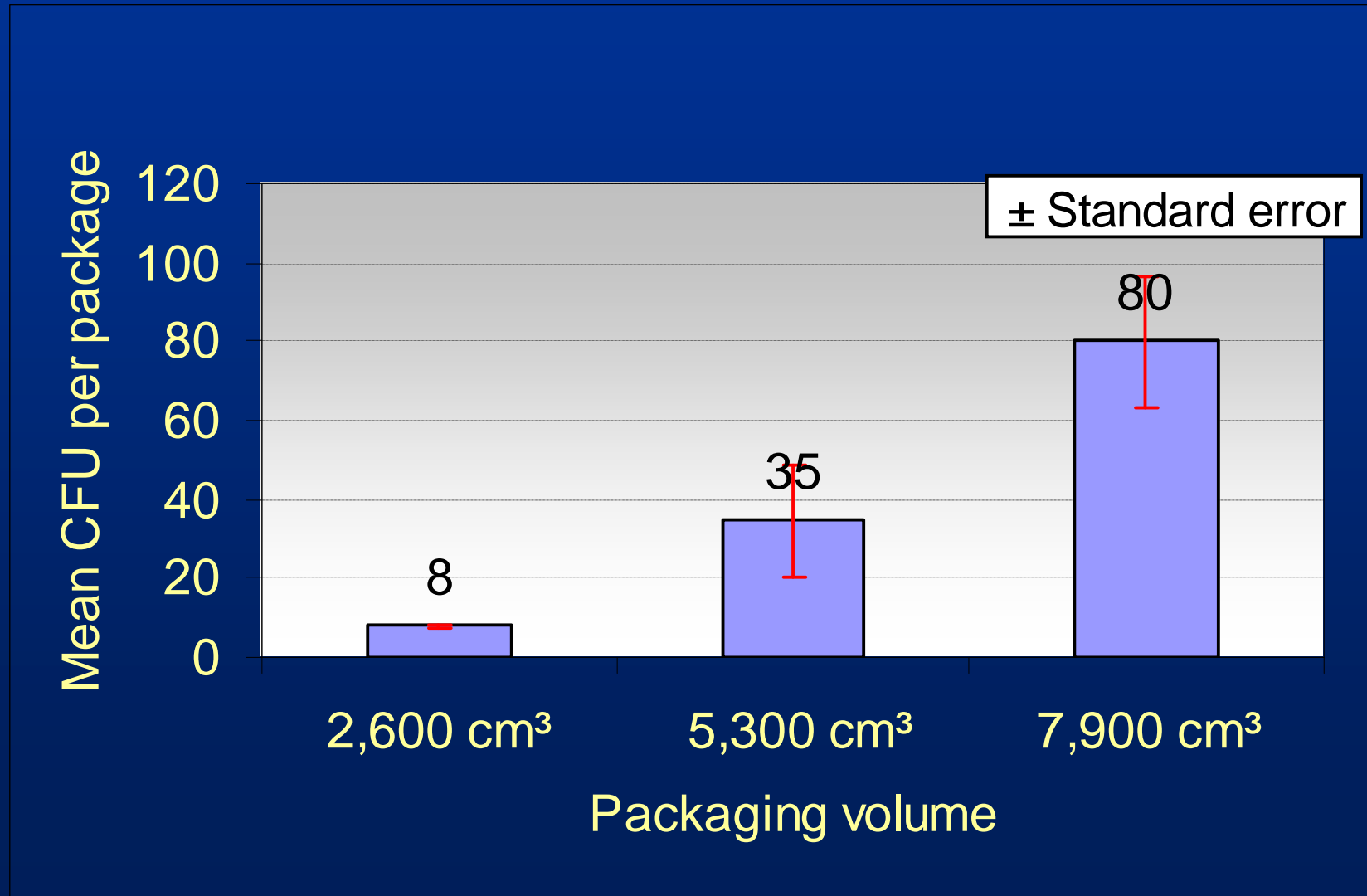


Inherent inconsistency between the statement in the body text and the tests listed in Annex B of ISO 11607

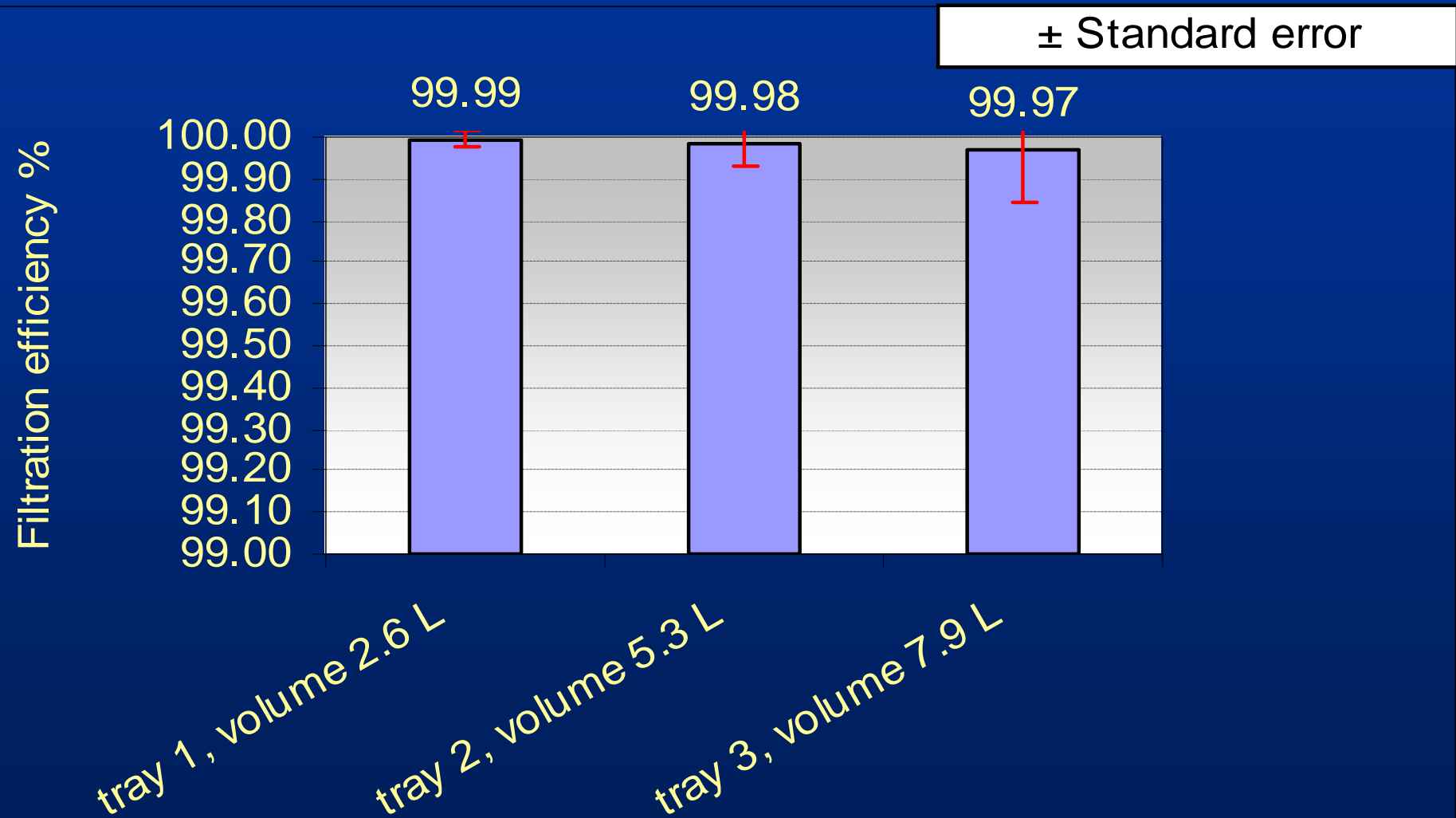
What do the labels stand for?



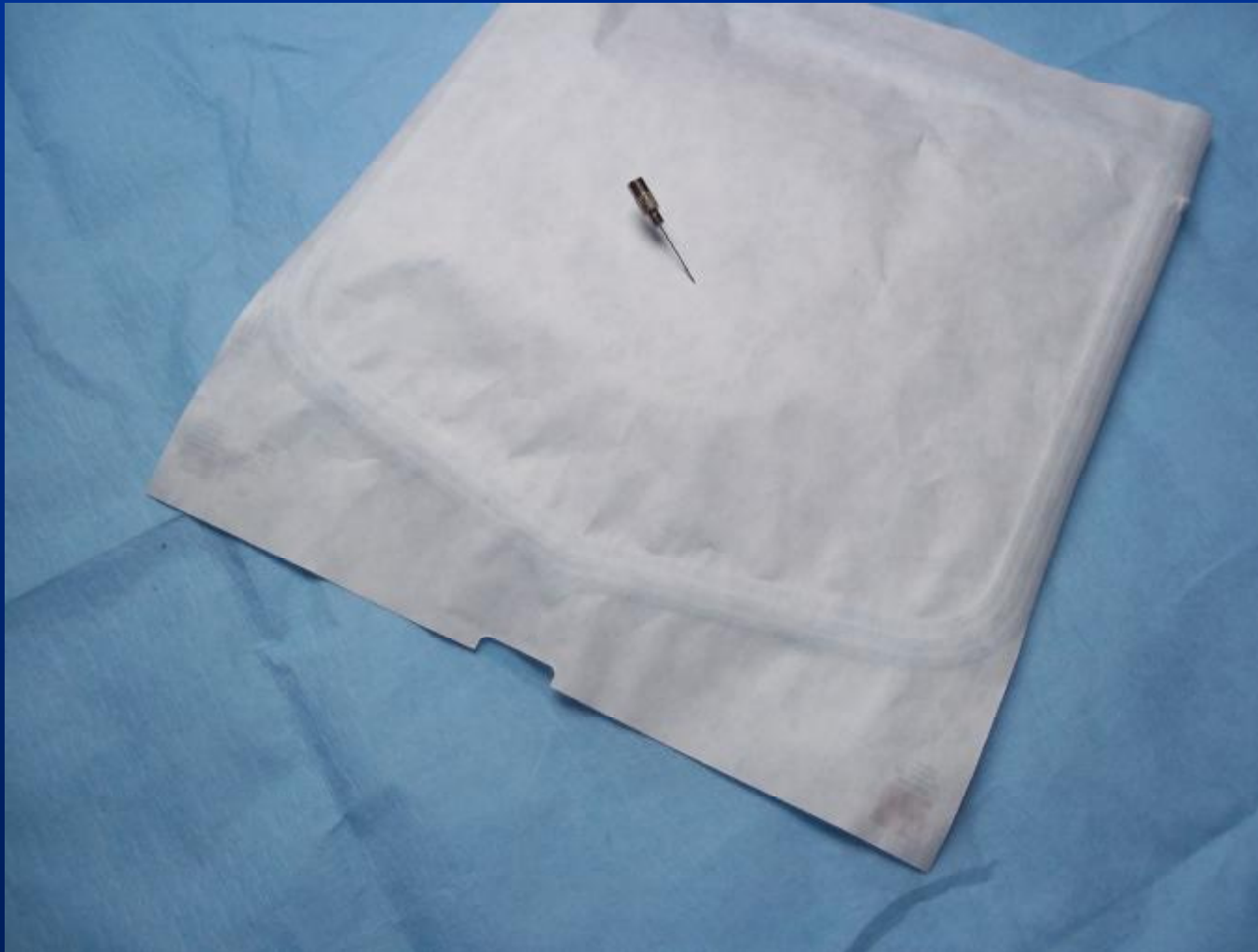
Passage of airborne microbes using pouches of different package volumes (51 pouches per group)



Filtration efficiencies (%) of the double wrapped trays

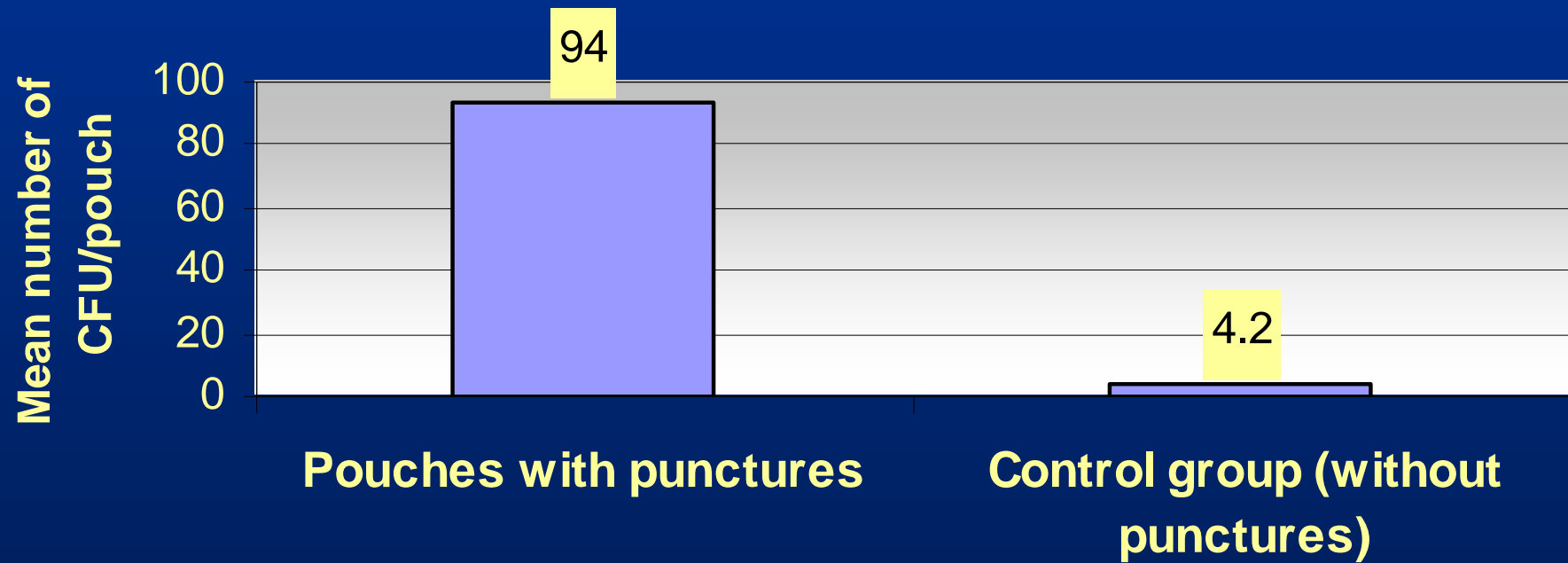


Punctures as events of compromising sterility



Effect of punctures on recontamination (25 pouches per group)

Effect of a 0.55 mm puncture on the microbial barrier



broken gasket

damage



On-site application of the exposure chamber in a clinical office room



Test conditions: 457 periodic air pressure changes of 200 hPa; airborne microbial concentration: 210 CFU/m³; 41 paper/film pouches; volume: 6900 cm³

4. Implementation of a data-based shelf-life practice for sterilized items

1. the filtration efficiency against airborne microbes,
2. control of the compatibility of storage conditions with the filtration efficiency of the packages,
3. confirmation that no visible defects of the packaging are observable.

Association of periOperative Registered Nurses (AORN):

“Health care organizations should determine the best methods and materials for packaging sterile items, based upon the anticipated storage, handling, and environmental events that may be encountered.”

Control of the compatibility of the airborne microbial challenge in the post-sterilization period with the filtration efficiency of the packages

10^{-6} = sterility assurance level (SAL)

$$N_0 \times \frac{100 - \text{Filtration efficiency (\%)}}{100} \leq 10^{-6}$$

or

$$N_0 \cdot \text{penetration rate} \leq 10^{-6}$$



Calculation of the compatibility of the airborne microbial barrier with storage conditions

packaging volume: 1 L

airborne microbial concentration: 100 CFU/m³

Exposure conditions	Air flow into the package (L)	Microbial challenge (CFU)
release from sterilizer $\Delta T = 40\text{ }^{\circ}\text{C}$	0.15	0.015
storage with $\Delta T = 1\text{ }^{\circ}\text{C}$ per day; 100 d	0.37	0.037
Total	0.52	0.052

$$0,052 \times \frac{100 - x}{100} = 10^{-6}$$

← required filtration eff.: 99.998 %

→ Start
Calculation of the microbiological challenge from transport and packaging
Input mask
Run program
Pore size and permeability for air
Exposure chamber techniques
Contact

Input mask for calculating the required barrier effectiveness of packaging of terminally sterilized products in dependence of changes in temperature, altitude and atmospheric pressure

Change the standard parameters in the grey fields according to your individual conditions. The results in the last section are again computed automatically for each change when leaving the field:

Microbiological challenge to the packaging by transport routes with different altitudes	Value:	Hint:
Volume of the packaging [cm ³]	2600	Value > 0
Atmospheric pressure [hPa]	1013	
Total of differences in altitudes [m]	0.1	Value > 0
Total number of air-borne microorganisms in colony forming units [cfu/m ³]	0.1	Value > 0

Microbiological challenge to the packaging by weather dependent atmospheric pressure changes	Value:	Hint:
Difference of atmospheric pressure change [hPa]	0.1	Value > 0
Atmospheric pressure [hPa]	1013	
Number of atmospheric pressure change	0.1	Value > 0

Number of changes in temperature	1	Value > 0
Initial temperature [°C]	60	
Difference of temperature [°C]	40	Value > 0
Total number of air-borne microorganisms as colony forming units [cfu/m ³]	100	Value > 0

Calculation of the minimal required barrier effectiveness of packaging for sterile medical devices on the basis of the entered data in terms of the logarithmic reduction value:	Required logarithmic reduction value [LRVrequ]	4.581
The required filtration efficiency in consideration of the entered condition of transport and storage is:	1 to	38074
The required filtration efficiency in % in consideration of the entered condition of transport and storage is:		99.997374

Reset form

www.microbiological-evaluation-of-sterile-barrier-systems.com/

Conclusion

The hospital sterile processing staff can introduce a data-based quality control program for assessment of the continued sterility up to the point of use. It includes:

- availability of data of filtration efficiency against airborne microbes,
- demonstration of the compatibility of storage conditions with the filtration efficiency of the packages,
- control of the relevant environmental factors,
- exclusion of visible failures of the packaging material.

Thank you for your attention