What is the place for Hydrogen peroxide plasma sterilisation in hospital sterile supply?

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Background

- Growing interest in easy-to-operate sterilisers for complex medical devices (MD)
- Simplicity and reliability claimed for Sterrad™ hydrogen peroxide vapour (HPV) sterilisers
- Conflicting results from different investigator teams
- German/Austrian multicenter study warranted restrictions for HPV-steriliser use in clinical settings

Study protocol (1): authors

- Three STERRAD 100S sterilisers tested in parallel with the same protocol in Vienna/A (two centres [1, 2]) and Schwerin/Ge [3]

[1] KOLLER W, Clin.Div. Hospital Hygiene, Medical University Vienna, Austria

2 GETREUER H, Dept. for Hospital affairs, Vienna County, Austria

3 WERNER H P, Hyg-Cen, Schwerin, and KRAMER A, Dept. Hygiene and Environmental Medicine, Ernst-Moritz-Arndt University, Greifswald, Germany

Study protocol (2): micro lab

- 10^7/ml suspension of G. stearothermophilus dried onto carriers and exposed to HPV sterilisation cycle
- Spore recovery from carriers by vortexing in CSB and plating in serial dilutions on CSA
- Spore killing effect expressed as log reduction calculated from exposed and unexposed carriers
- Each variation tested in triplicate

Study protocol (3): variables

- Spore suspension media
- Carrier types
- Carrier wrapping
- Steriliser load size
- Steriliser cycle length
- Carrier position in steriliser chamber

Legends to figures (1)

LOG-REDuctions as calculated after HPV exposure in Sterrad

(LOG-RED = log cfu_{before} - log cfu_{after})

SAL 10^{-6}

= sterility assurance level

LABoratories/ Investigators (city):

- koller (Vienna)
- werner/Kramer (Schwerin/Greifswald)
- getreuer (Vienna)

Legends to figures (2)

SPORe SUSPensions:

G.stearothermophilus-spores (~10^6/carrier) in:

napep isotonic saline + peptone

adest dest. water

Legends to figures (3)

EXPOSition of spores: carriers/devices
(wrap- and *carrier-type*):

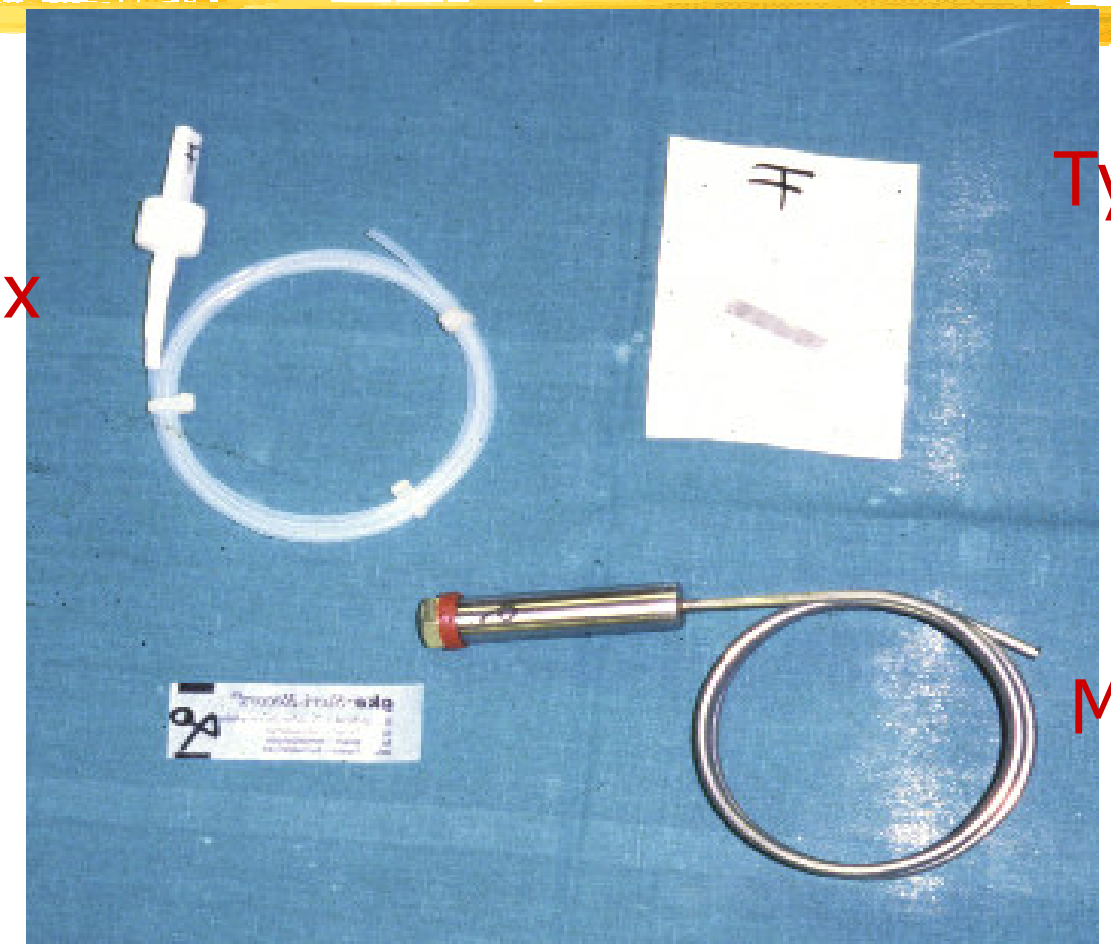
PEhelix polyethylene-helix *(fine mesh metal)*

Methelix metal-helix *(fine mesh metal)*

Tyvekfol Tyvek-wrap *(fine mesh metal)*

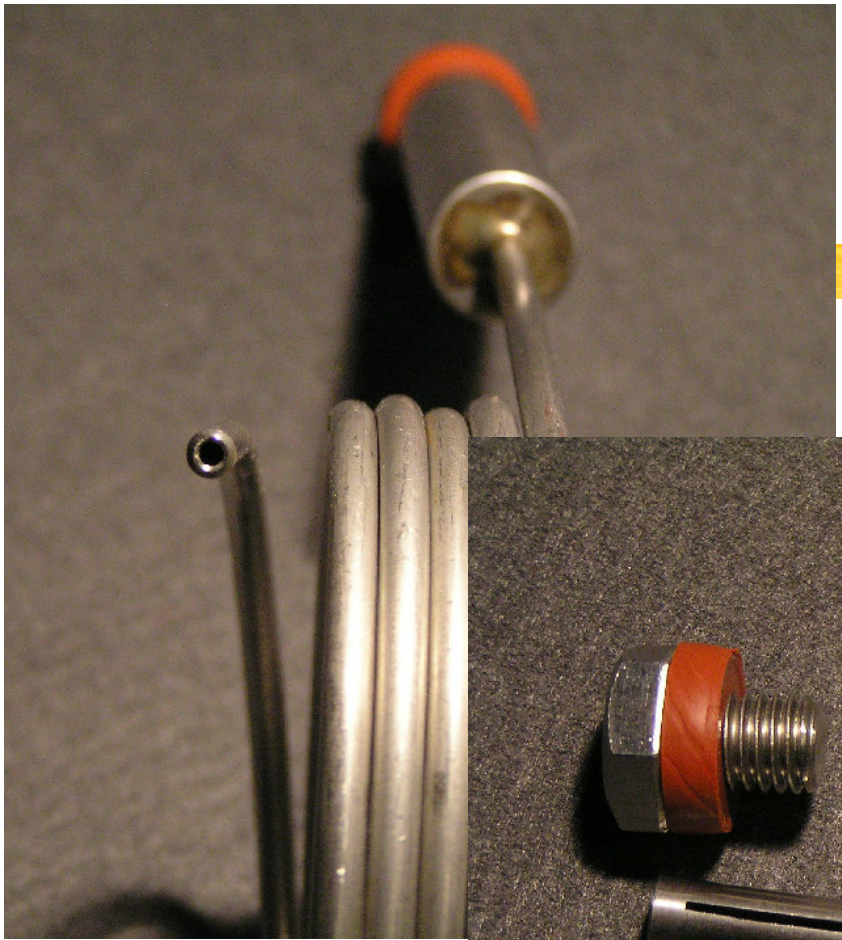
Wraps for fine mesh metal spore-carriers

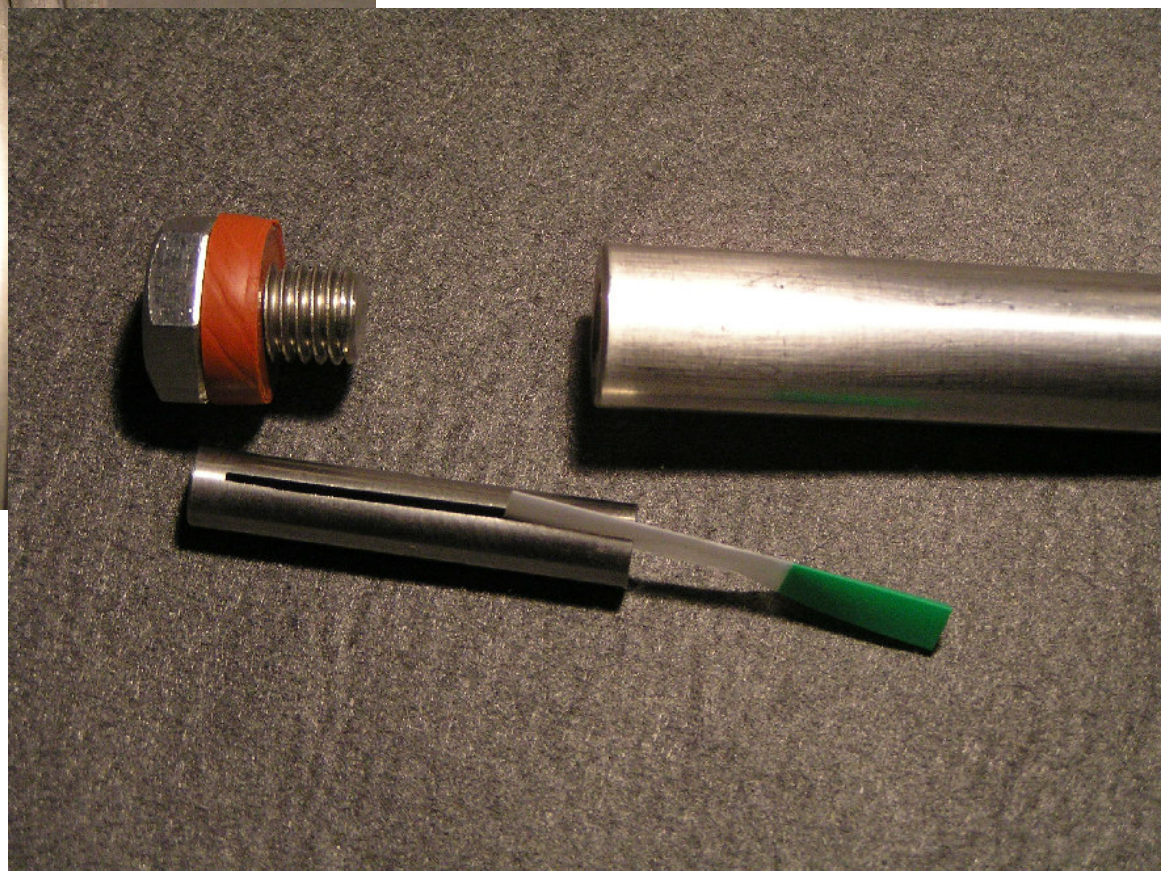
PEhelix



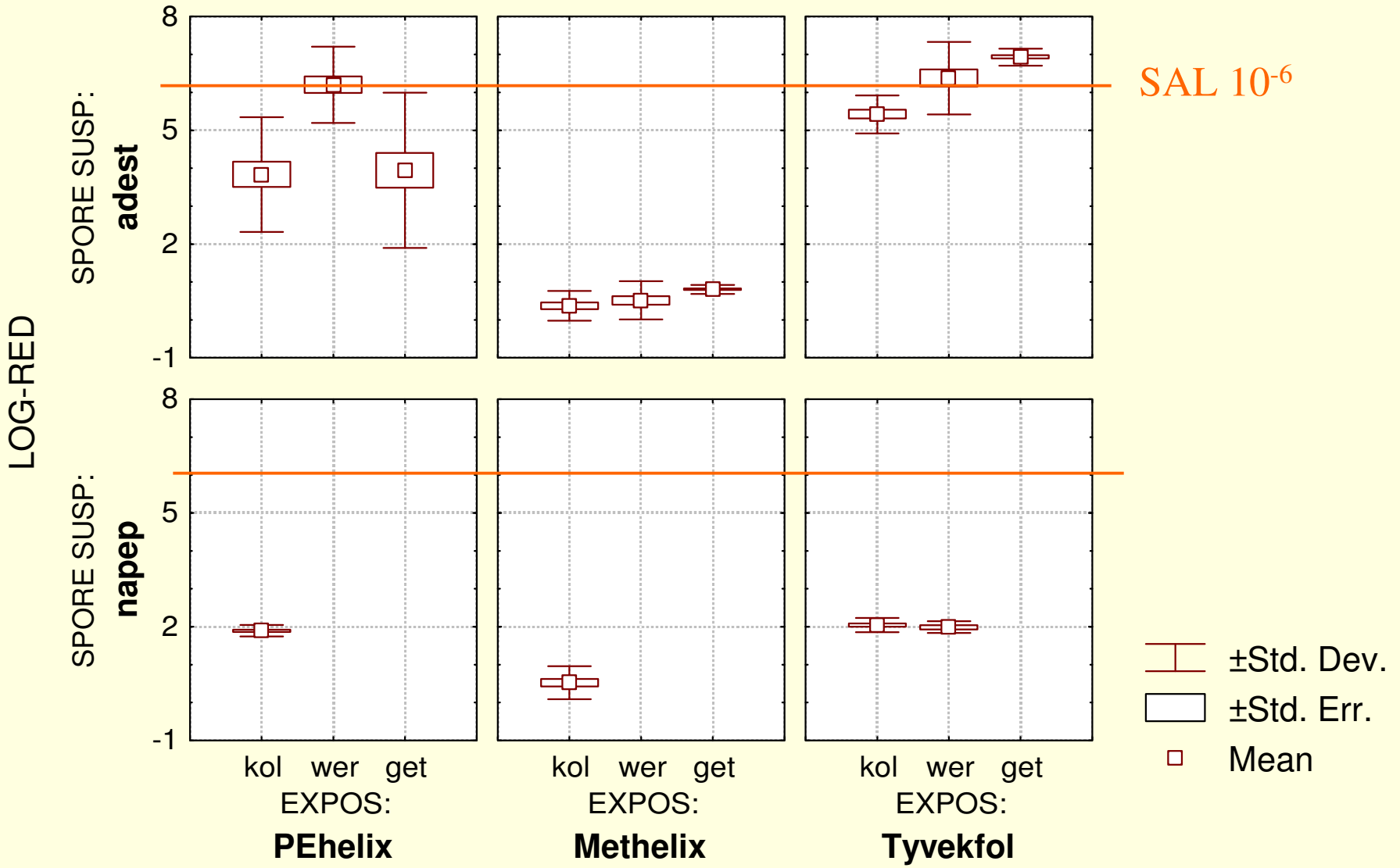
Tyvekfol

Methelix

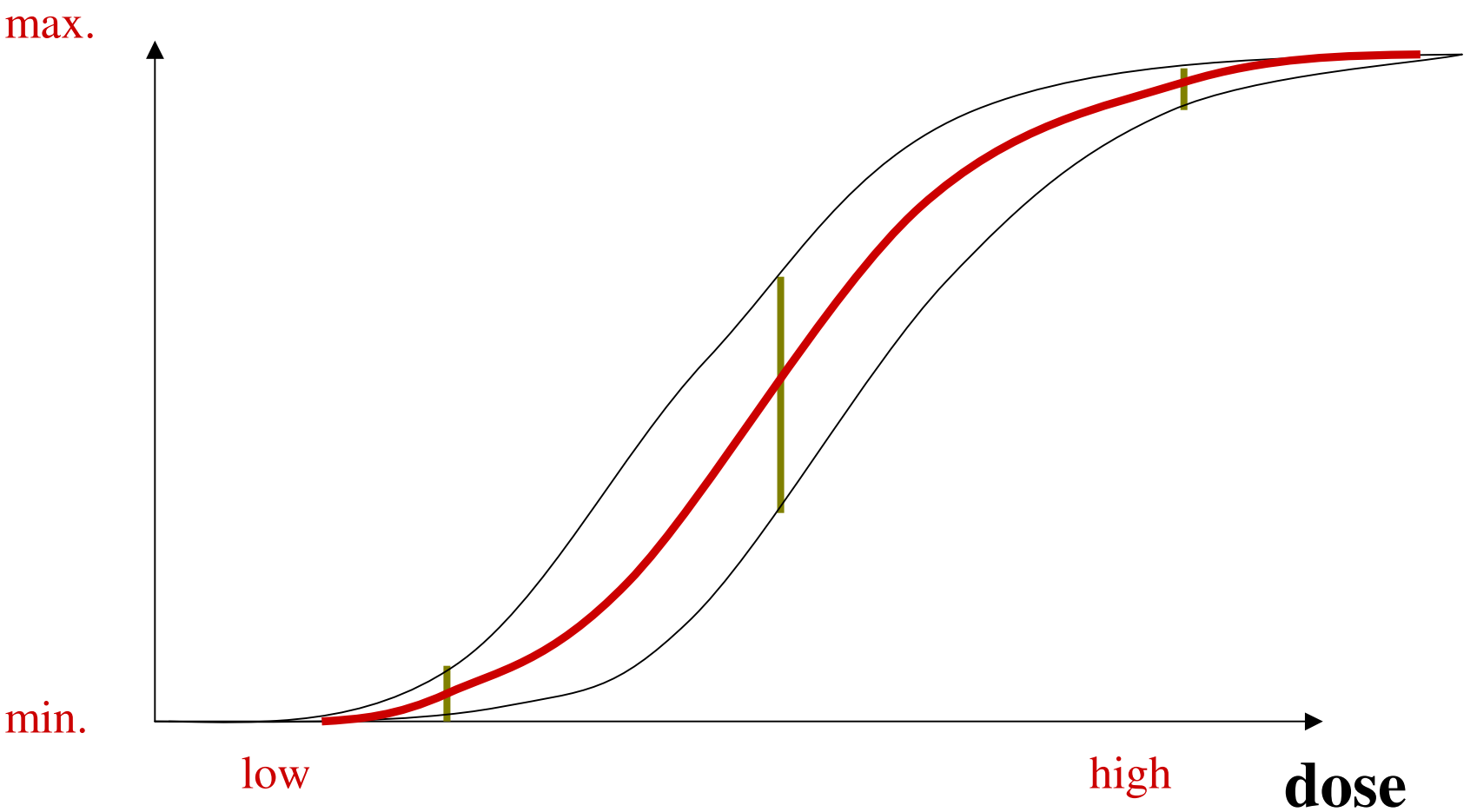




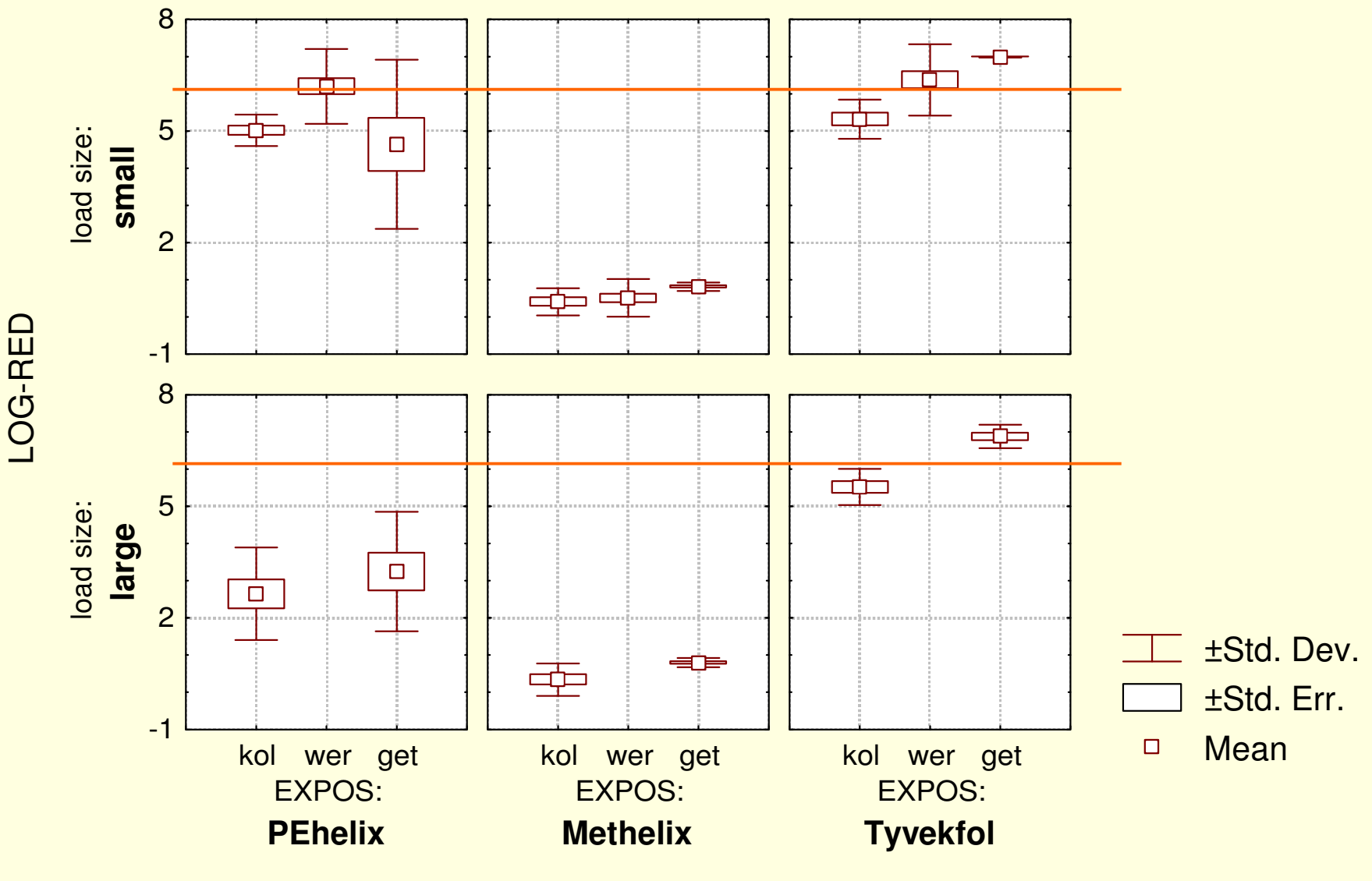
Var's: **spore suspensions** and **carriers/expositions**



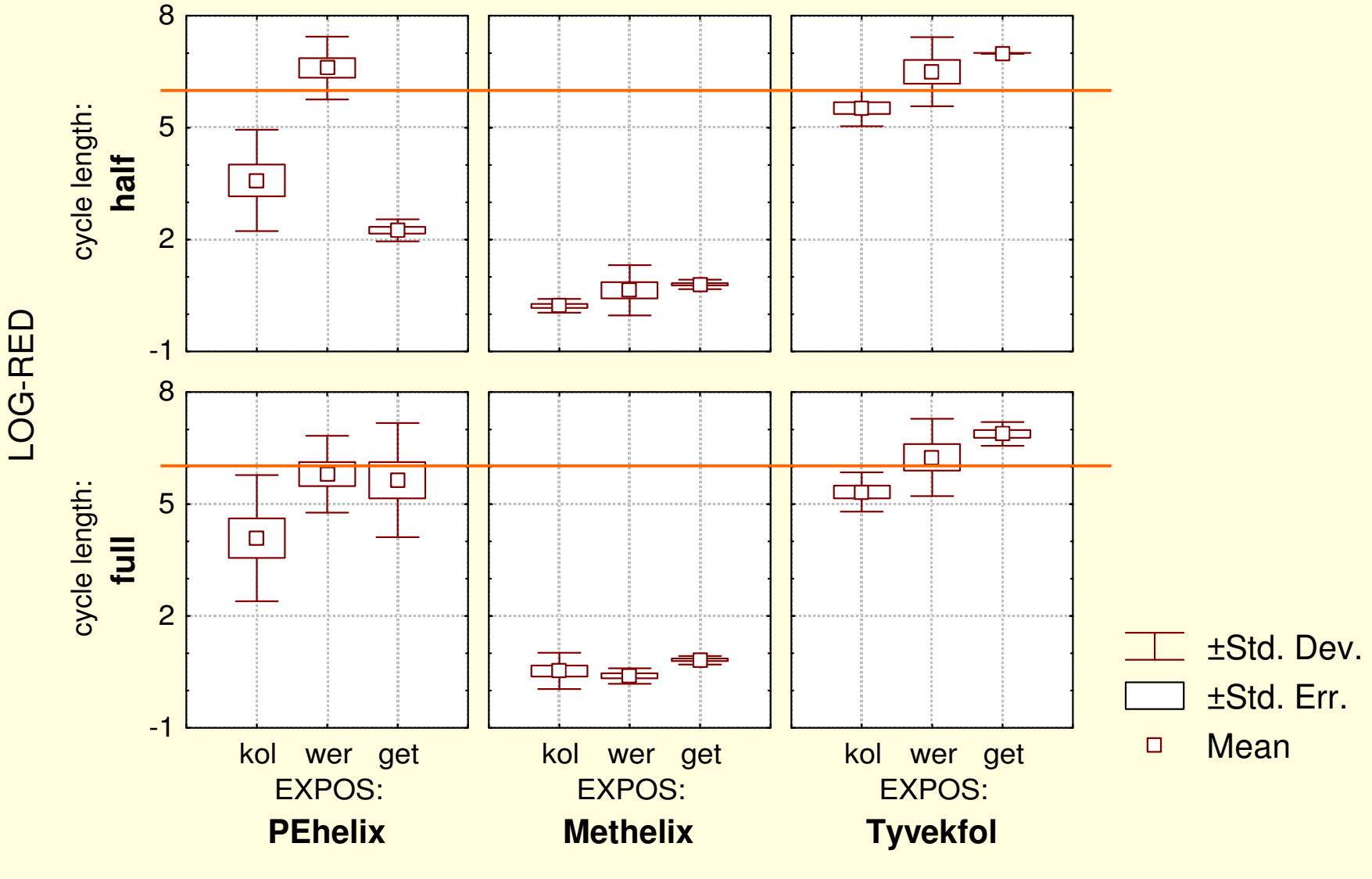
General effect of position in dose/response curves on variances



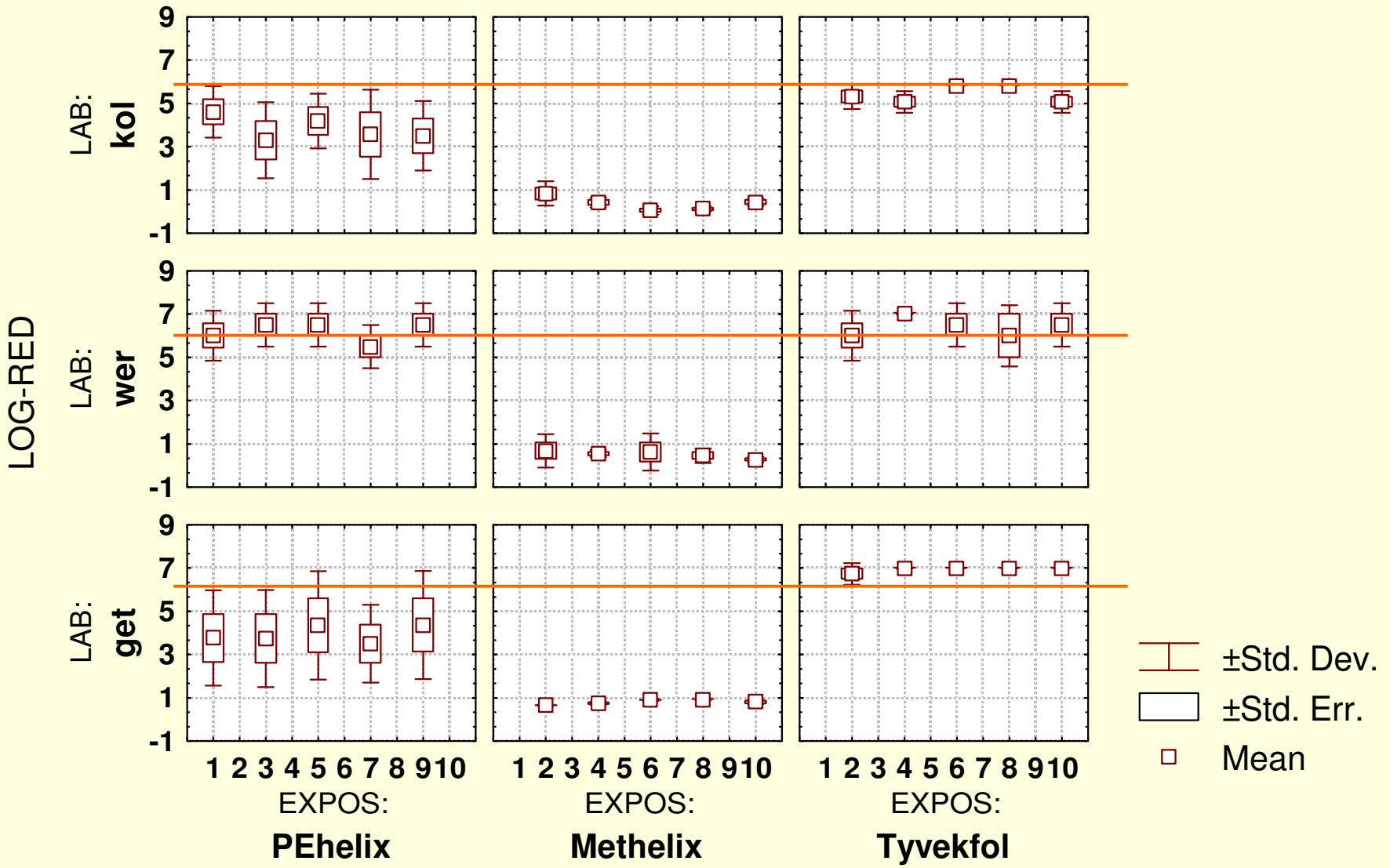
Effect of **steriliser load size** (spore suspension adest)



Effect of **cycle length** (spore suspension adest)



Effect of **spore carrier position** in steriliser (spore susp adest)



Conclusions from study 2000

Sterrad™ 100S only acceptable with significant limitations:

- Absence of any organic or crystalline mini-residues on surfaces
- Absence of long fine bore channels esp. in metallic structures
- Steriliser load below critical limit
- Absence of cotton/cellulose and other organic components in MD and wrap

Control and documentation of critical process parameters urged!

2007 status

New generation of STERRAD 100-S, NX and 200 systems equipped with process control and documentation tools which allow validation.

In October 2006, a **limited approval was issued by the Austrian ministry of health (AMH)** for these STERRAD products. AMH **Limitations** for Sterrad™ use in human medicine comprise:

- Compliance with EN ISO 14937:2000 mandatory for use in medical settings (notably documentation and control of all relevant process parameters with suitable and calibrated instruments)
- optimised and validated precleaning mandatory

Limitations (cont.)

- exclusion of any MD which can be autoclaved
- exclusion of (invasive) MD equipped with hardly accessible fine bores, joints, seams, grooves, lamellae or grills
- STERRAD not accepted as alternative to EO- or LTF-sterilisation unless suitability of and compatibility with MD in the given clinical setting proven and on site validation successfully performed
- Specialised instrument wraps (Tyvec) and sealing equipment as recommended by mfct. to be used in any case.

Recommendations

- New STERRAD 100-S, NX and 200 systems recommended for MD which
  - require sterilisation and
  - are not intended for invasive use and
  - do not require special manipulations in the process steps preceding sterilisation

  = exclusively for highly specialised procedures and equipment !
- Specialised instrument wraps (Tyvec) and sealing equipment must be budgeted when comparing with other LT sterilising systems

Conclusions

- HPV can act sporocidal at moderate temperatures (40 - 60℃) when high level cleanness and uninhibited access of HPV is guaranteed.
- New STERRAD 100-S, NX and 200 systems are equipped with process control and documentation tools which allow validated sterilising processes,
- approved by the Austrian ministry of health as niche products for sterilisation of highly selected MDs under strictly controlled conditions (EN ISO 14937:2000).
- Specialised instrument wraps (Tyvec) and sealing equipment are required.