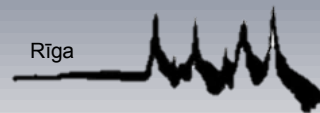


Where is a challenge for process challenge devices?

Gints Cīrulis(Latvia)

Gundars Lācis(Latvia), Roberts Linčiks(Latvia)



Presentation Outline

- ✓ Background
- ✓ Study Objectives
- ✓ Methods
- ✓ Results
- ✓ Recommendations
- ✓ Acknowledgements

Hollow load



The Study

Research Goals and Objectives

- ✓ To create Validation routine for Hollow load.
- ✓ Find best reference/test tools or materials.

Research Methodology

- ✓ Statistical data analyse of sterilization log files.
- ✓ Review of Existing standarts, publications and IFU's.
- ✓ Bench tests of hollow instruments and PCD's.

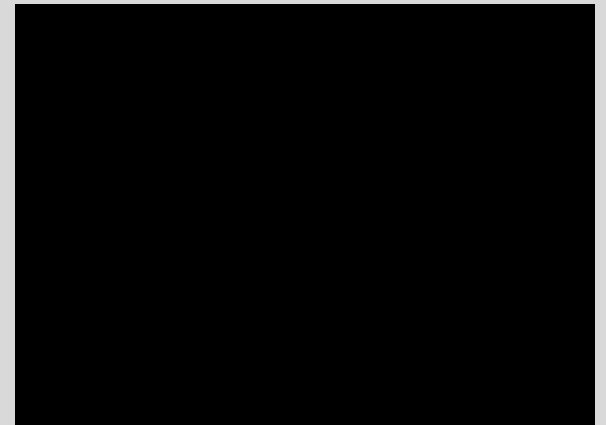
Vacuum assisted Air removal

Air removal is claimed as most difficult part of Hollow load sterilization process – is it true?

Vacuum is space that is devoid of matter.

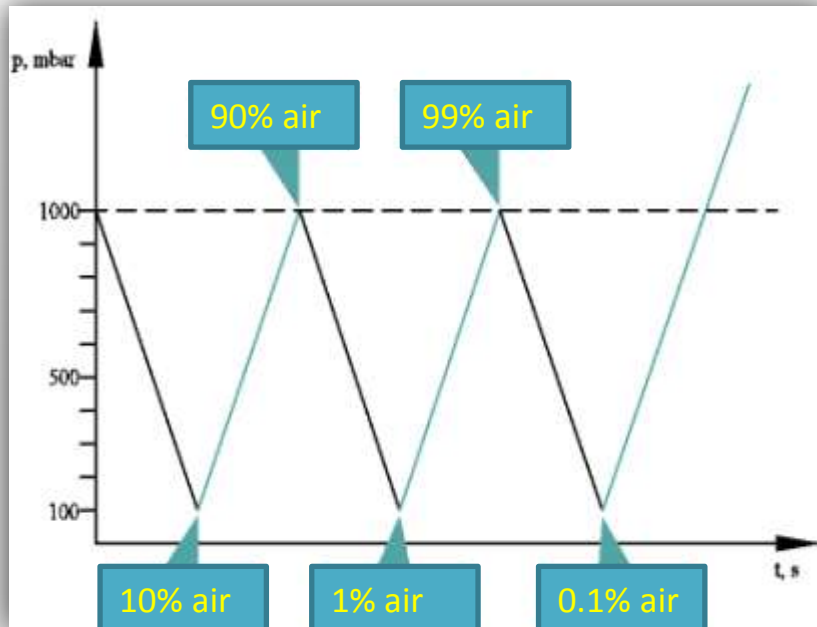
(www.wikipedia.org)

Bench test with 30m long tube!





Non Condensable Gases

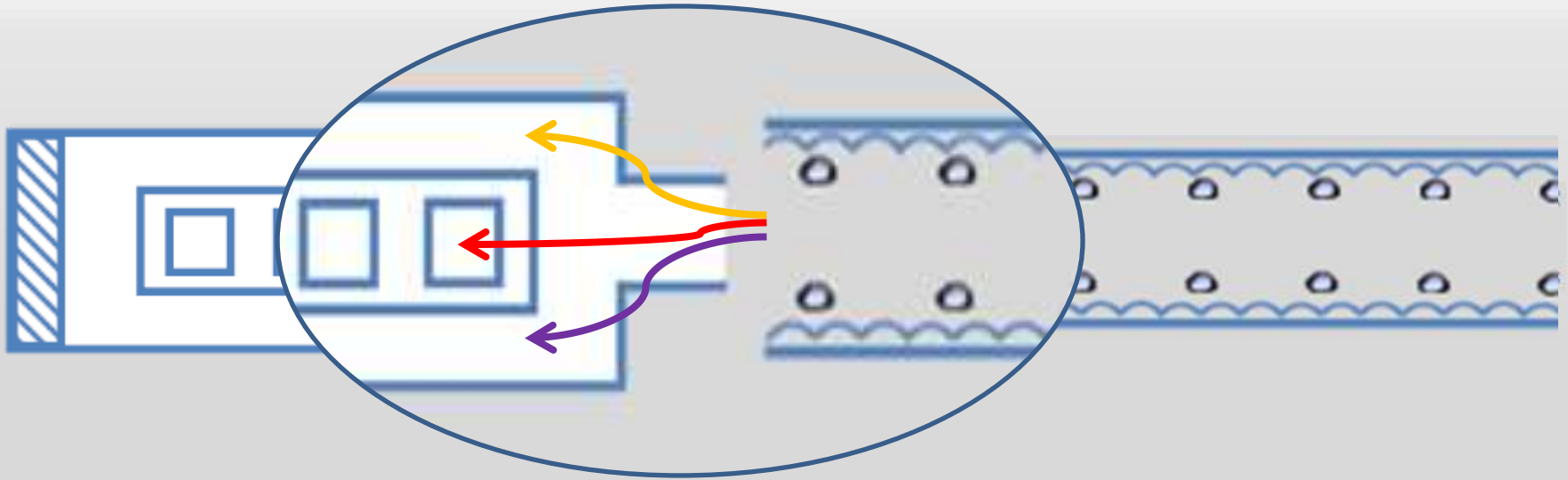


There is already up to 3,5% of NCG's in supply steam. It is not possible to get lower concentration than this.

Increased concentration due to release of NCG's while heated.

$$\text{NCG}_{\text{Total}} = \text{NCG}_{\text{VAC}} + \text{NCG}_{\text{Steam}} + \text{NCG}_{\text{Heating}} + (\text{NCG}_{\text{Air leak}})$$

Heating of PCD (Helix type)

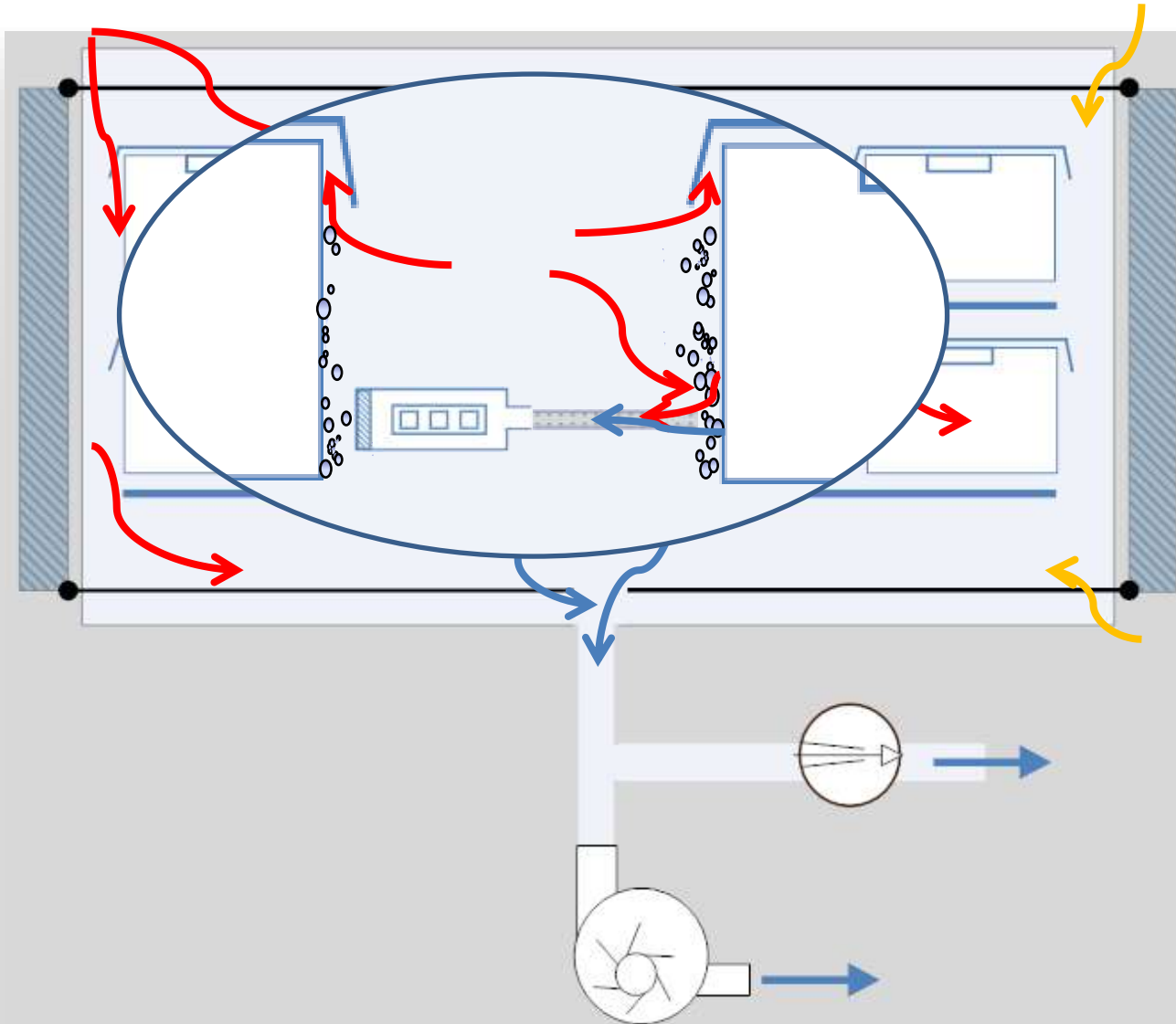


- NCG
- Steam
- Condensate

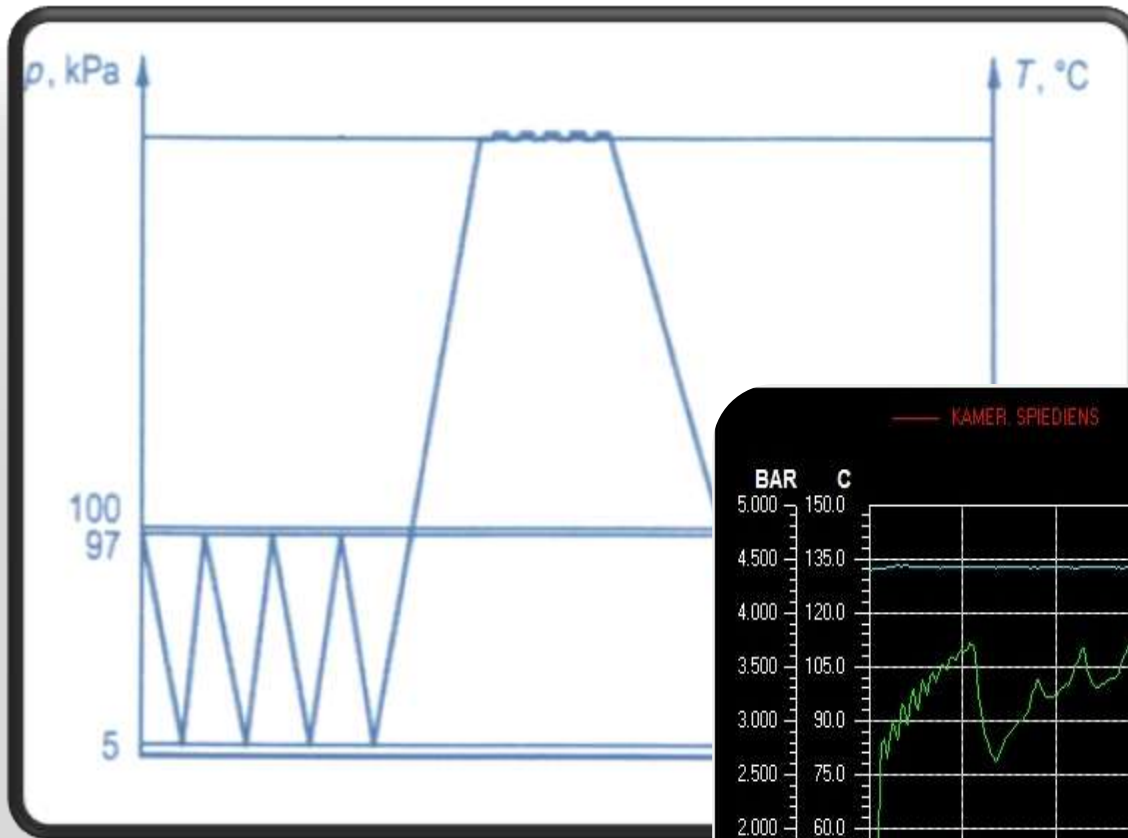
Steam, NCG's and condensate movement in the tube with one end closed



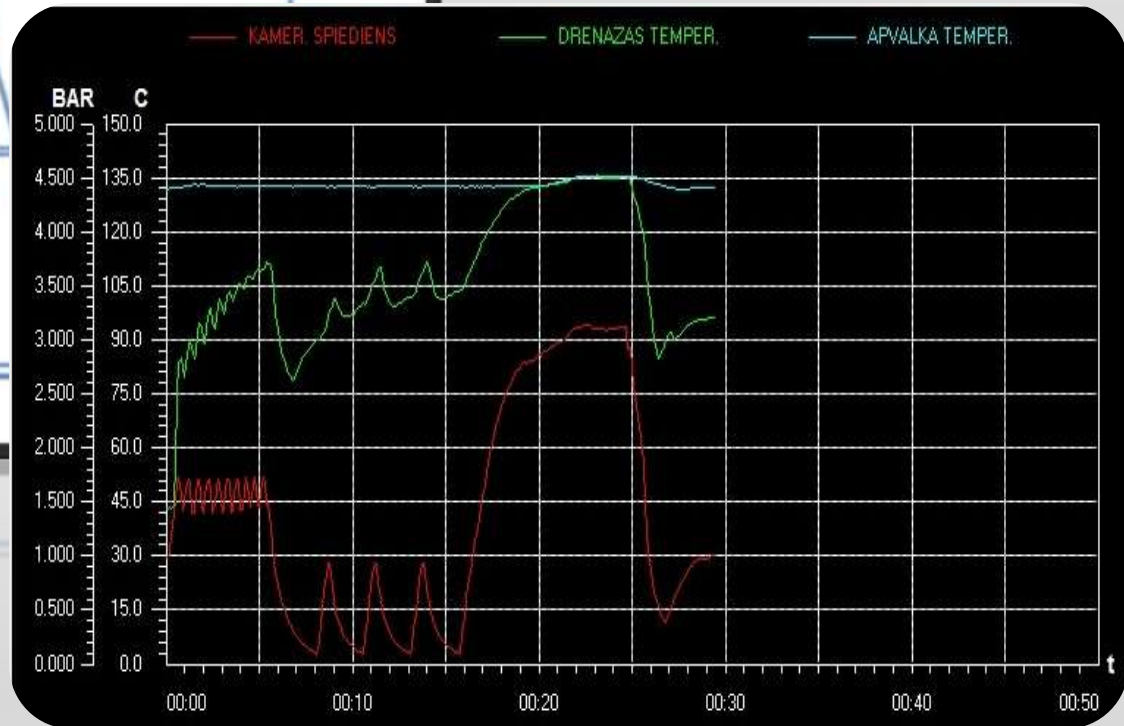
Zoom in Heating of the load



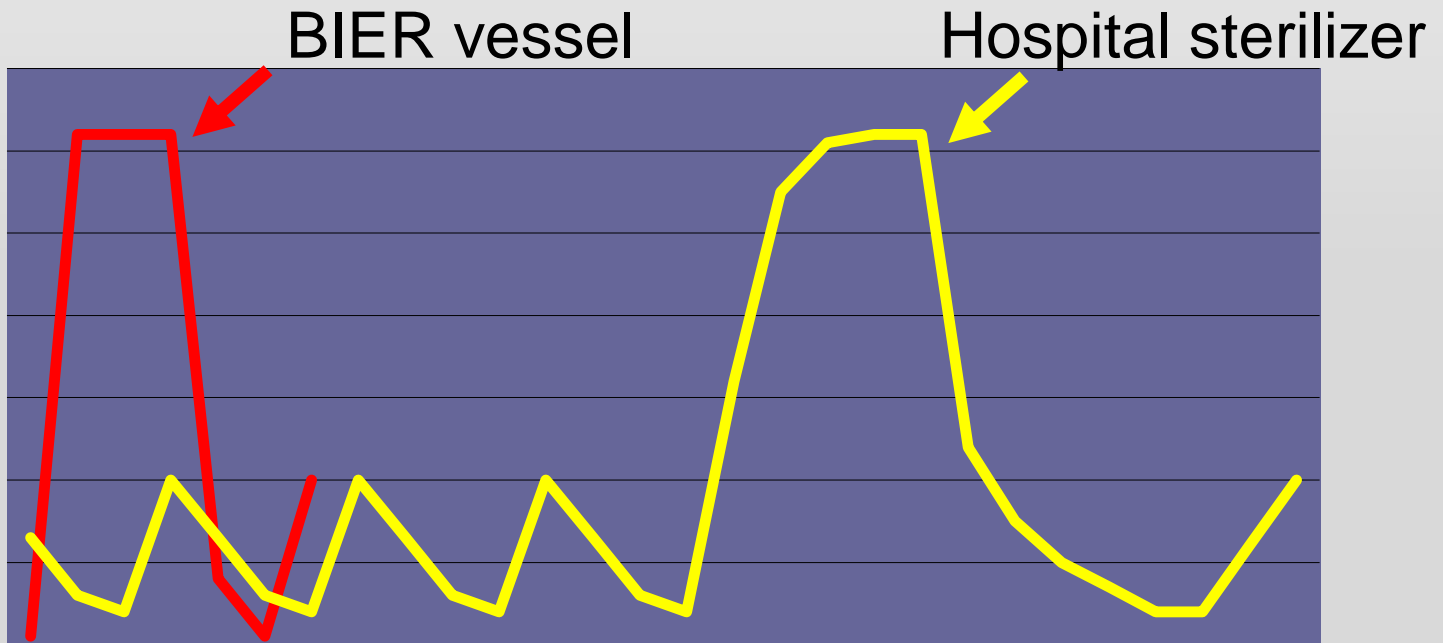
Pre-heating to reduce NCG_{Heating}



According to EN 867-4



Theory and “Reality”



Results

- ✓ Air removal is NOT the biggest issue.
- ✓ It is critical to reduce NCG_{Heating} component.
- ✓ Some of Commercially available PCD's will FAIL if Dry saturated Steam is used.

Recommendations

- ✓ Modify your sterilization cycle to fit load configuration.
- ✓ Be cautious using PCD's (Helix type) as reference test system – it may lead to incorrect result.
- ✓ If PCD's (Helix type) are used then:
 - a) Replace original CI with class 6 indicator that you trust.
 - b) Use PCD's at right Process Challenge Location.
 - c) Pay attention to steam entrance of the PCD's.
 - d) Pay attention to PCD's mass and its correlation to weight of the load.

Recommendations

- ✓ Do not adapt work routines to existing products on the market – do vice versa.
- ✓ Use combination of tubing set and BI's ($\log 10^6$) for hollow instrument simulation.
- ✓ Use class 6 indicator what is calibrated for longer plateau than set for tested sterilization cycle.
- ✓ Log every step of Validation process and keep your records safe.

Acknowledgements

- ✓ **RĪGAS AUSTRUMU KLĪNISKĀ UNIVERSITĀTES SLIMNĪCA** for provided facilities
- ✓ **Roberts Linčiks**, AB MEDICAL GROUP RIGA (validation engineer)
- ✓ **Martiņš Barons**, AB MEDICAL GROUP RIGA (validation engineer)
- ✓ **Prof. Yuri Dekhtyar**, Riga Technical University (help with theoretical and scientific issues)
- ✓ **Albert BROWNE** Company for provided test lab facilities

