



FMS technology to optimize and monitor nitrogen purge performance on a vial filling line

René Peeters
Manufacturing Technology Department Oss

Lighthouse Instruments Symposium Brussel 13th June 2007



Agenda

- Introduction
- Operation Standard Filling and Purge system
- Step 1: Overlay System
- Step 2: Position Post Purge Needle
- Step 3: Extended needle holder
- Step 4: Automatic rejection
- Summary and Conclusion

Introduction (1)

Goal of project:

- Optimization of Nitrogen purge system on the Bausch en Stroebel (B&S) vial filling line to achieve controlled low oxygen levels in the headspace of a vial.

Start situation:

- Nitrogen purge system is not qualified.
- Oxygen levels are high compared to the ampoule process
- Oxygen concentrations are not controlled, no procedure during machine stop

Proposed situation

- Qualified nitrogen purge system
- Low oxygen levels
- Controlled oxygen levels even during machine stop



Introduction (2)

Conditions

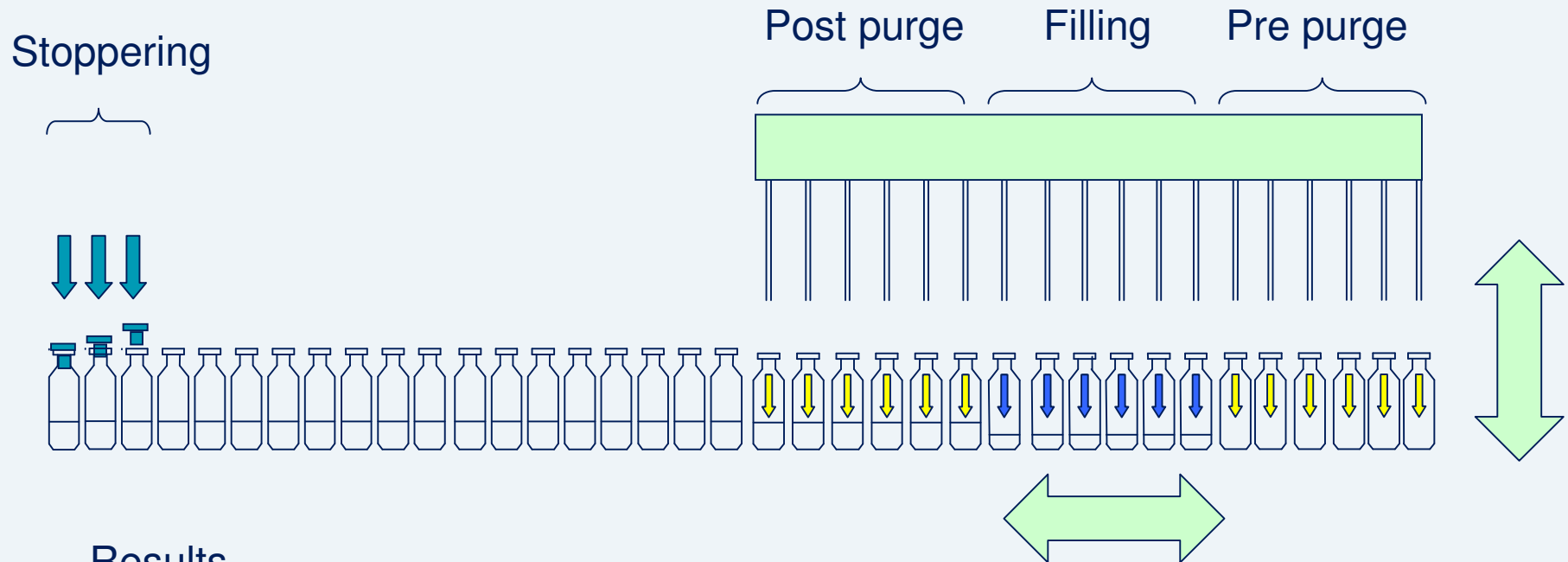
- No major investment on filling line
- Limited availability filling line

Test set-up

- At line FMS technology to measure oxygen contents in the headspace of a vial



Standard Filling Purge System



Results

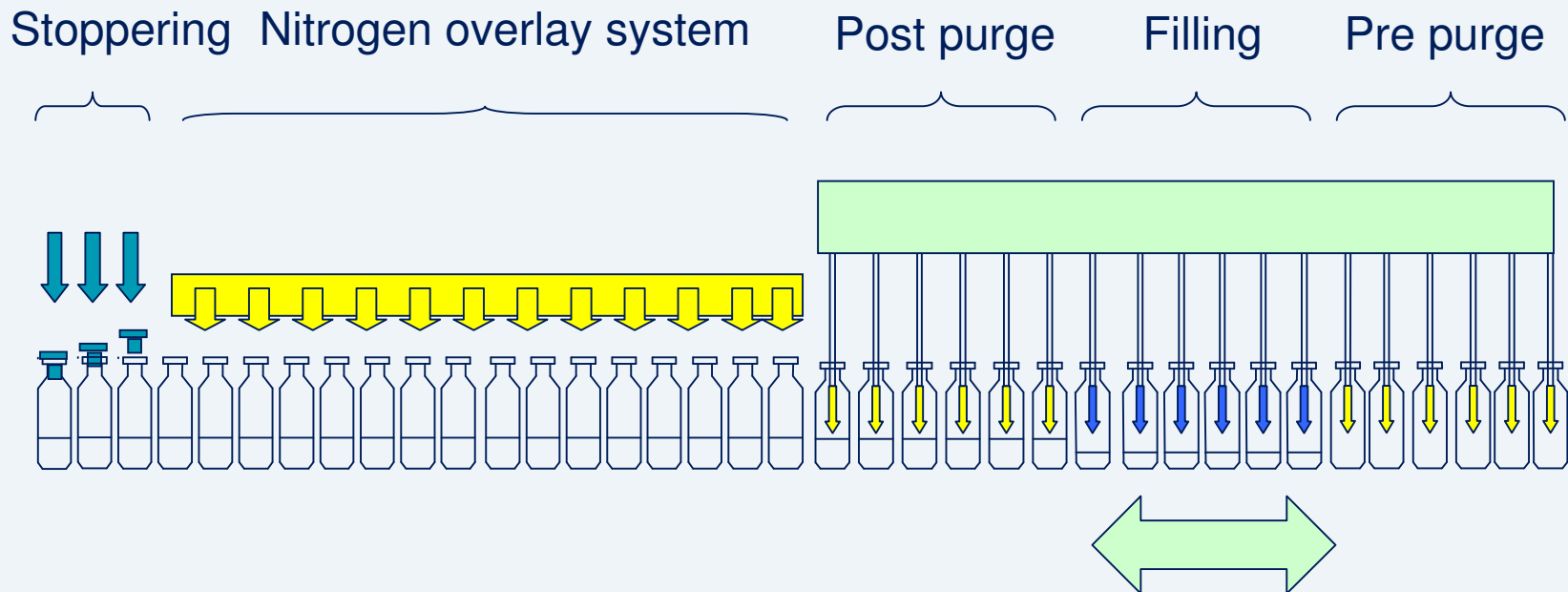
- Oxygen levels at maximum filling speed: 5%
- During machine stop oxygen levels increase fast to ambient conditions

Test 1: Overlay system (1)

Nitrogen blanket

- Controlled conditions during transport of vials after post purge and before stoppering
- Controlled condition during machine stop

Test 1: Overlay system (2)



Results

- Oxygen levels at maximum filling speed: ~ 7% (without overlay ~ 5%)
- Increased oxygen levels after a machine stop of 10 minutes 8-12%.

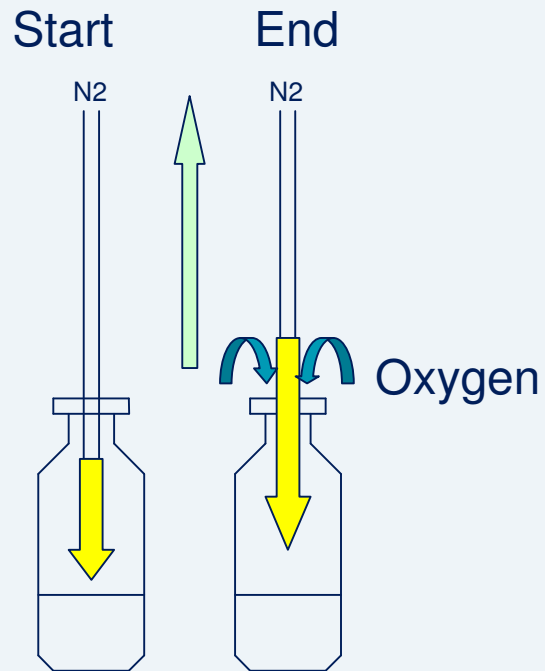
Conclusion

- Overlay system doesn't fulfil our requirements



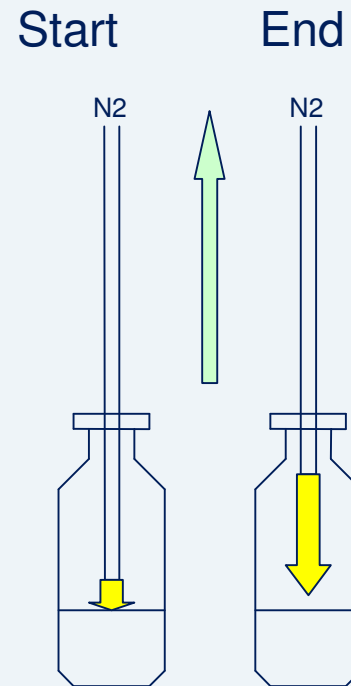
Test 2: Position Post Purge Needle

Purge needle position



Oxygen level of ~ 5 %*

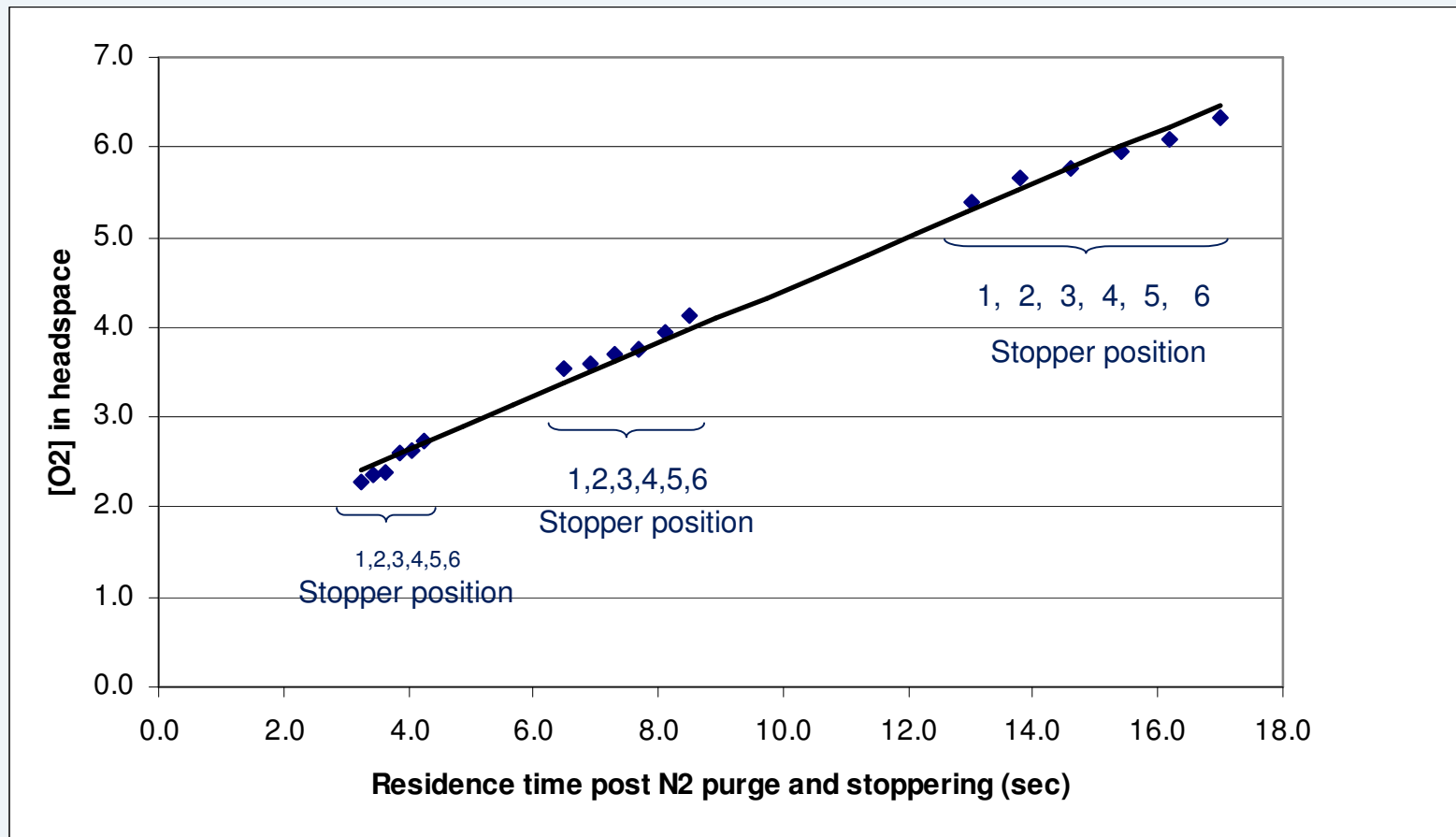
Optimized purge needle position



Oxygen level of 2-3 %*

*measured after stoppering at maximum filling speed

Test 3: Extended needle holder (1)

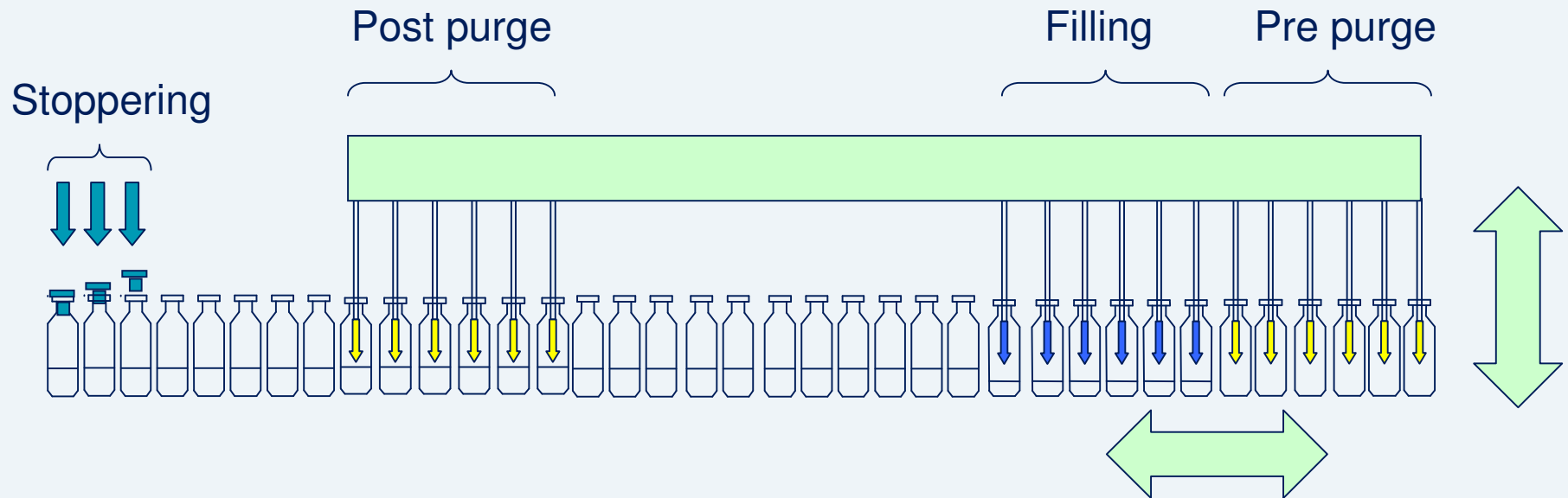


Test 3: Extended needle holder (2)

Advantages:

- A reduction of time before the stopper results in a decrease in oxygen level
- Less vials need to be rejected when the filling line stops

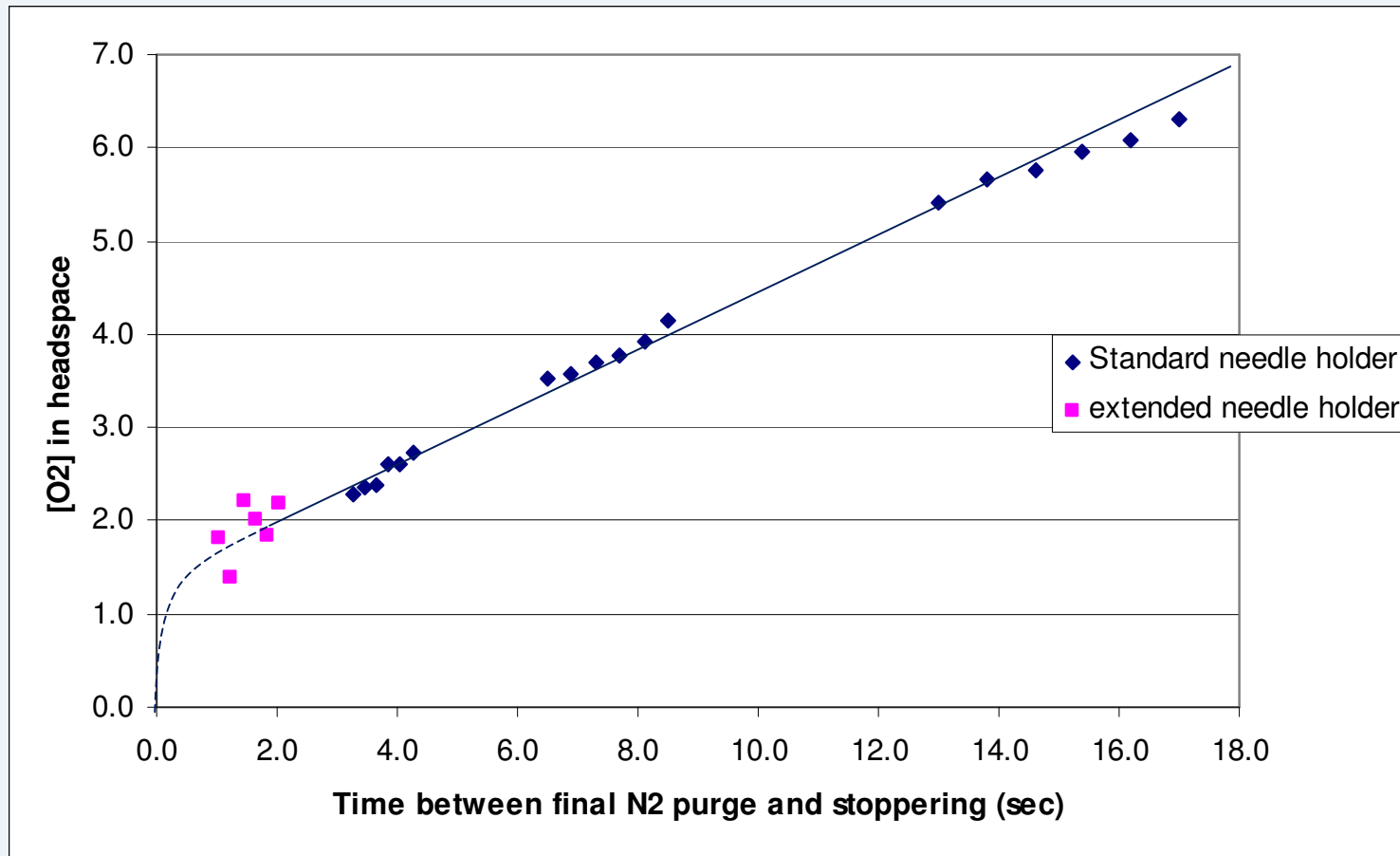
Test 3: Extended needle holder (3)



Results

- Oxygen levels at maximum filling speed: ~ 2%
- Number of vials that need to be rejected after machine stop is minimized

Test 3: Extended needle holder (4)



Test 4: Automatic rejection of vials

- The B&S software was adjusted, so that after a machine stop a fixed number of vials will be rejected.
- This system was qualified with help of FMS technology

Summary and Conclusions

- Optimization of the oxygen concentration in a vial with help of FMS technology is quick and accurate.
- The optimized filling process achieves controlled levels of oxygen, around 2%. To achieve lower values major investments are required.

- Questions?