Instituto Português da Qualidade

EURAMET

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MEDD
Drugmetrology.com

Assessment of Several Drug Delivery Devices

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Resume

1. Introduction
2. Types of drug delivery devices
3. MeDD – Work Package 3 (assessment of drug delivery devices)
4. Different setups, instruments and accessories
5. Results
6. Conclusions

Introduction

- Drug delivery devices or infusion instruments are widely used in clinical environment. Their main function is to provide drug therapy, nutrition and hydration intravenously to patients.
- It is known that the dosage of infused pharmaceuticals is subject to uncertainties that may compromise the patient treatment.

Introduction

Relevant questions in therapeutics:

- Volume and flow rate
- Interference by using multiple pumps
- Administration lines
- Individual variables like density and viscosity of the used drug
- Interference between different drugs
- Human error

Types of Drug Delivery Devices

There are several types of drug delivery devices. They are used according to the type of patient, type of drug and quantity to be administrated.

Syringe pumps

Used for delivery of small amount of liquid at low flow rate

Peristaltic pumps

Used for drug delivery at flow rates higher than 10 mL/h

MeDD - Work package 3

Main goal of WP3 – Assessment of drug delivery devices was to test how the compliance and start up delay depend on several physical parameters, drug delivery devices and accessories. The flow rate error and flow rate stability are also studied.

- accessories: infusion line, filter and check valve;
- pump types: syringe and peristaltic;
- syringe types: Omnifix and OPS;
- syringe volumes: 10 mL and 50 mL;
- operating conditions: viscosity,

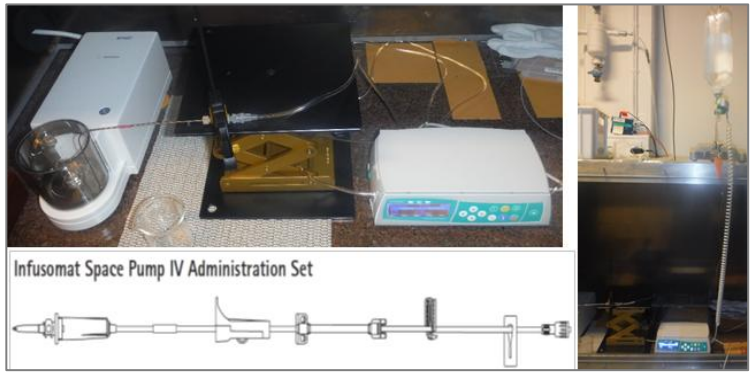
back pressure and temperature

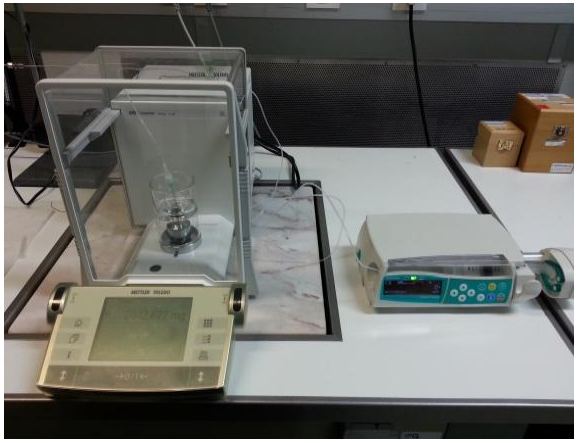
- Two different brands: Bbraun and Alaris

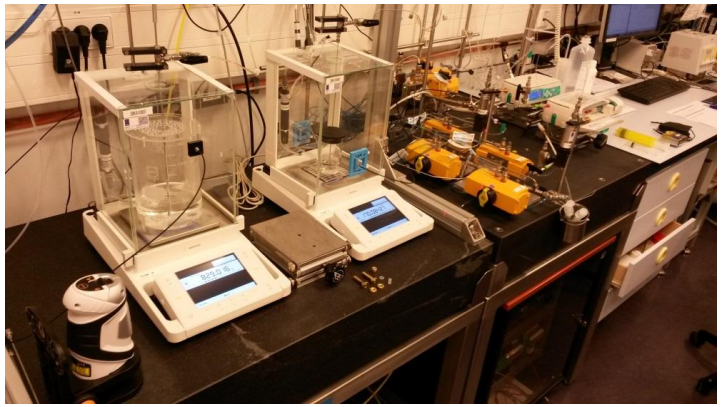
$$\varepsilon = 100\% \frac{q_{pump} - q_{actual}}{q_{actual}}$$

Different used setups

VSL, METAS, CETIAT, DTI and IPQ have performed measurements using the gravimetric method, based to IEC 60601-2-24, uncertainty information can be found in the paper - Primary Standards for measuring Flow Rates from 100 nL/min to 1 mL/min - Gravimetric Principle, to be published in Biomedical engineering magazine.







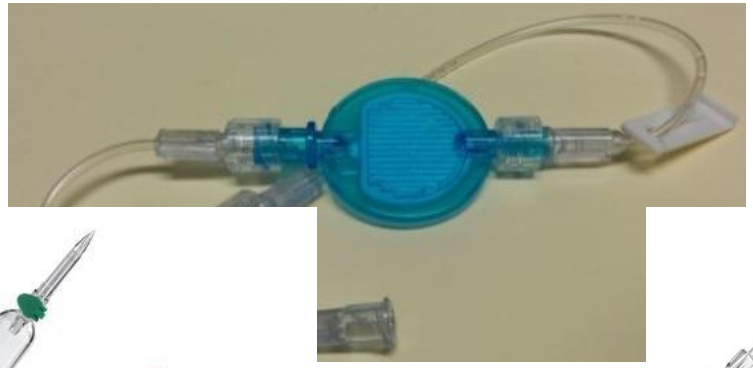
Tested Instruments

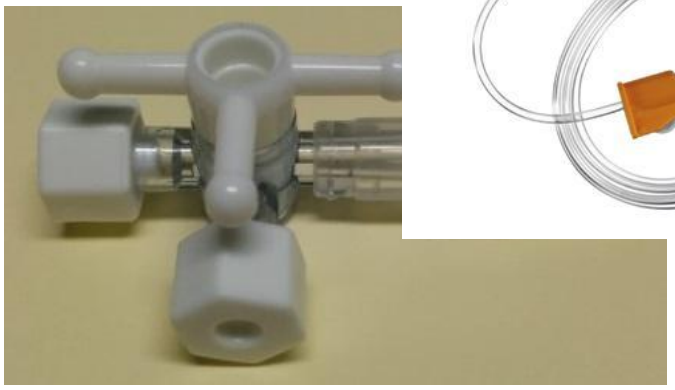
Perfusor®Space

Infusomat®Space

Alaris®pump

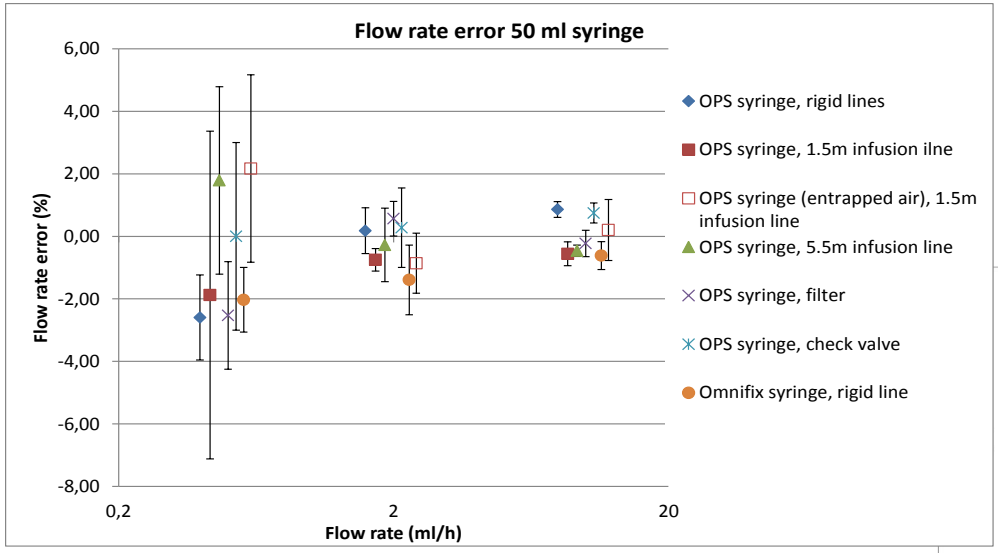
Accessories



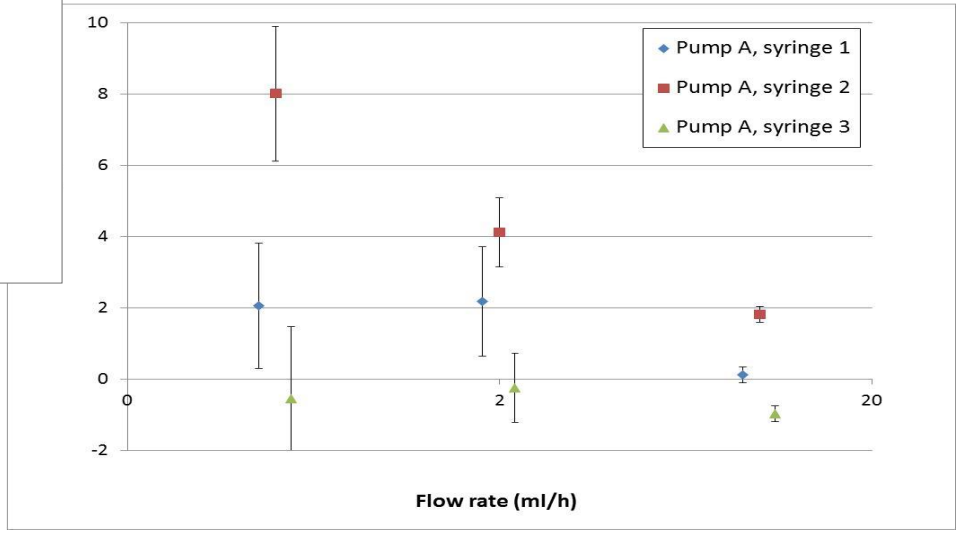


Results - Flow error determination – syringe pumps

BBraun

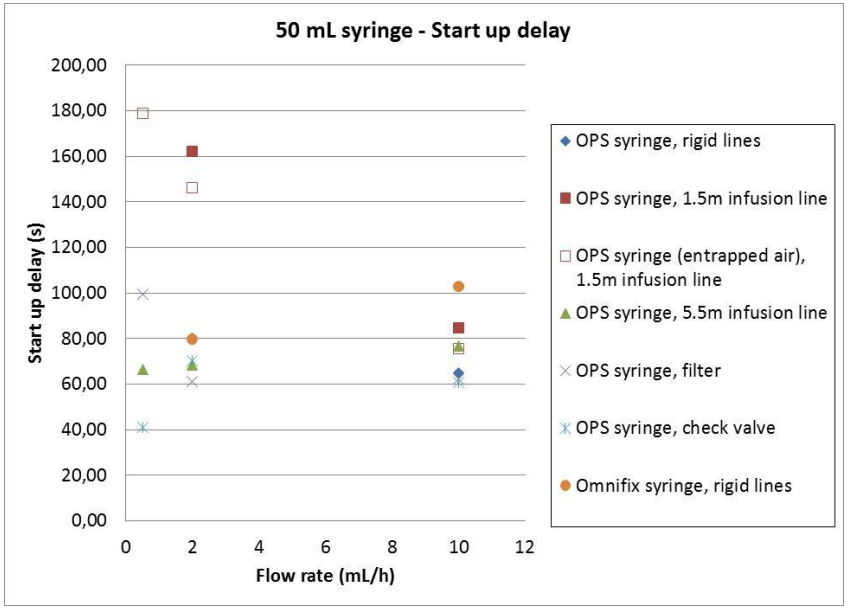


Alaris



Start up delay and accessories – syringe pumps

BBraun



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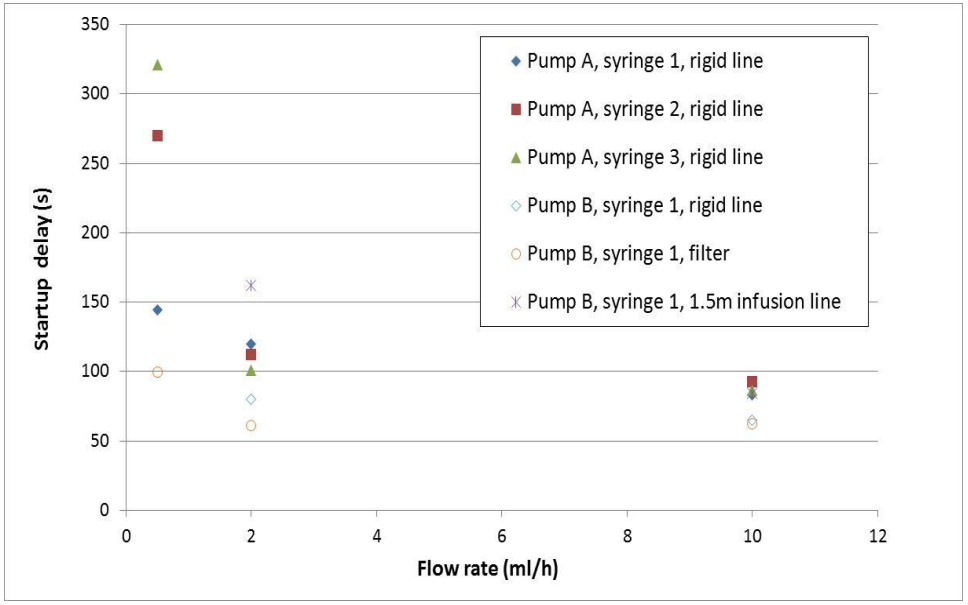
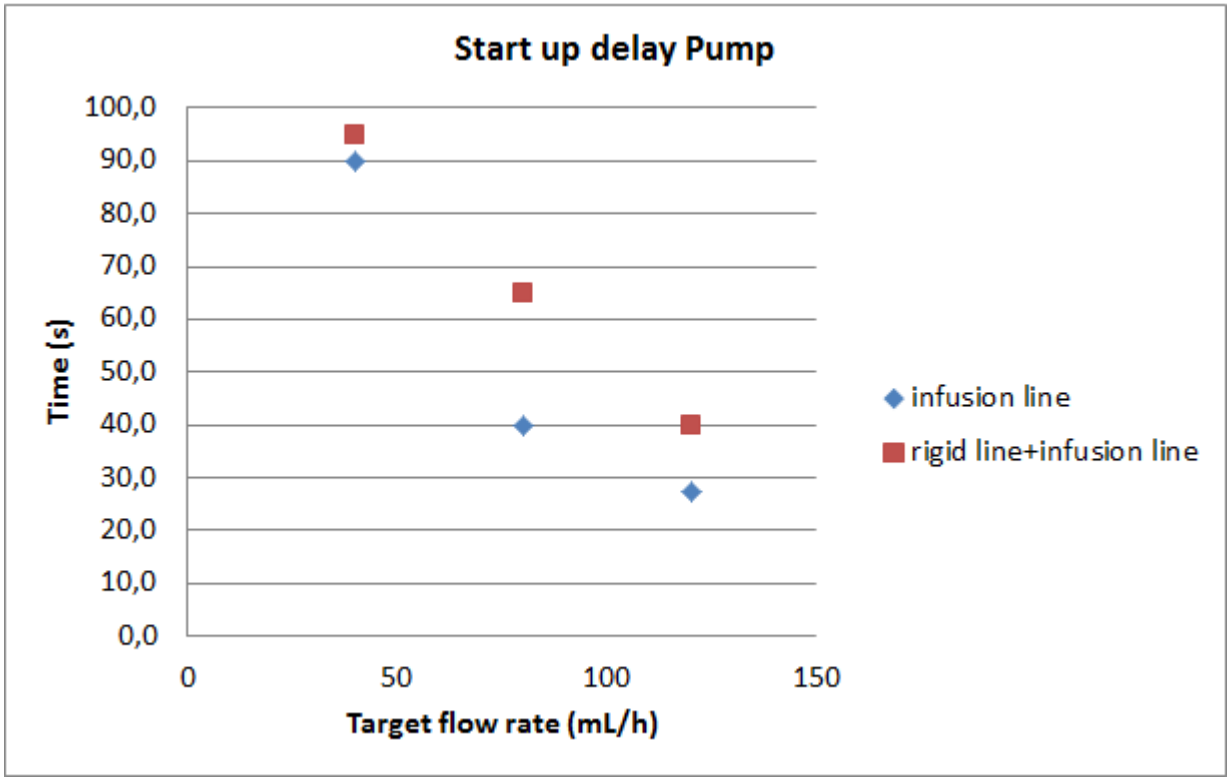


Start up delay– peristaltic pumps



Compliance based on occlusion measurements – syringe pumps

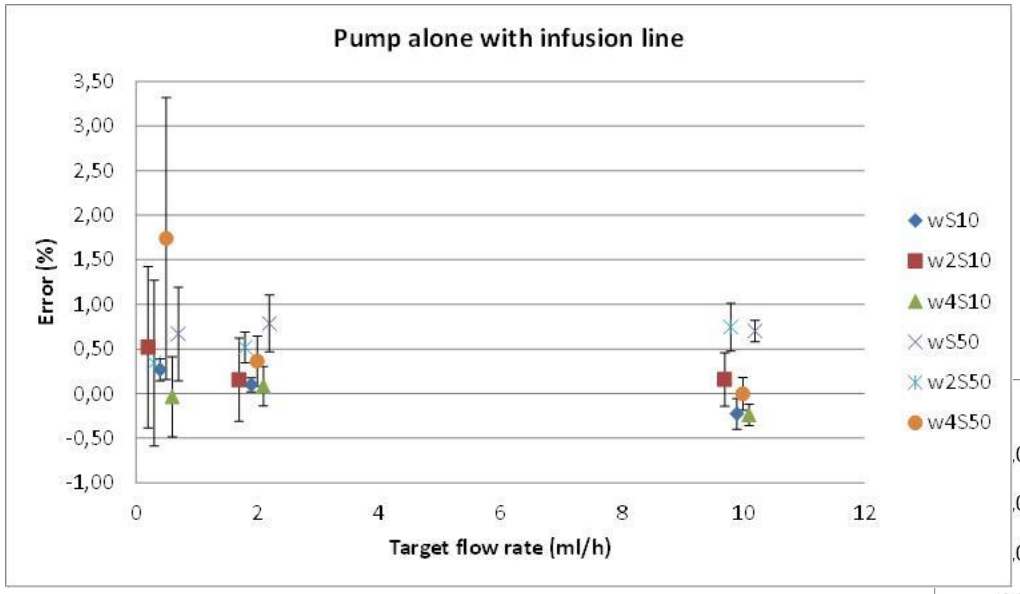
Scenario	10 ml syringe (ml/bar)	50 ml syringe (ml/bar)
rigid syringe	0.24	N/A
standard syringe	0.21	1.54
standard syringe, 1.5m infusion line	0.20	1.54
standard syringe, 1.5m infusion line, entrapped air	0.22	1.61
standard syringe, 5.5m infusion line	0.44	1.89
standard syringe, filter	0.52	2.10
standard syringe, check valve	0.22	1.54

$$C = \frac{\Delta V}{\Delta p}$$

ΔV is the volume increase due to an applied pressure increase Δp

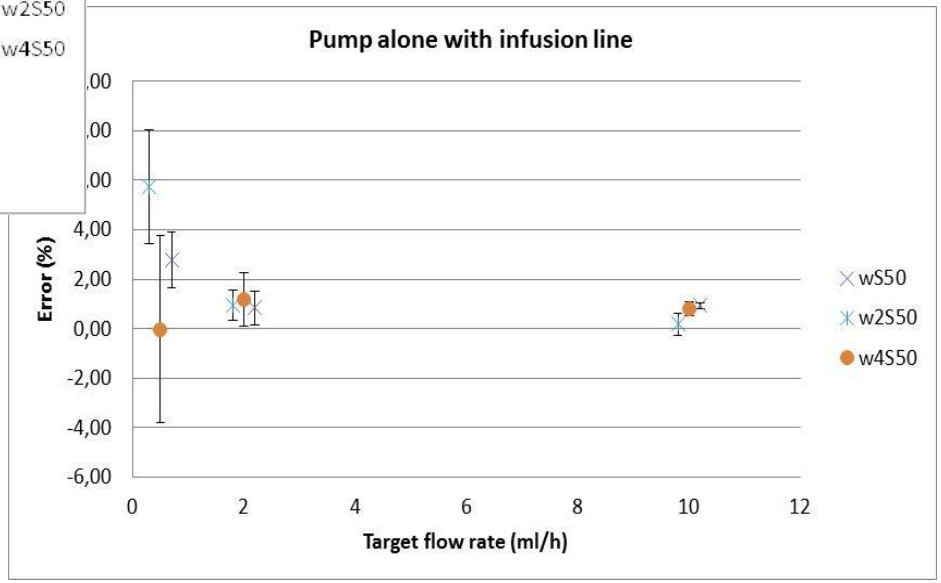
Impact of viscosity – syringe pumps

BBraun

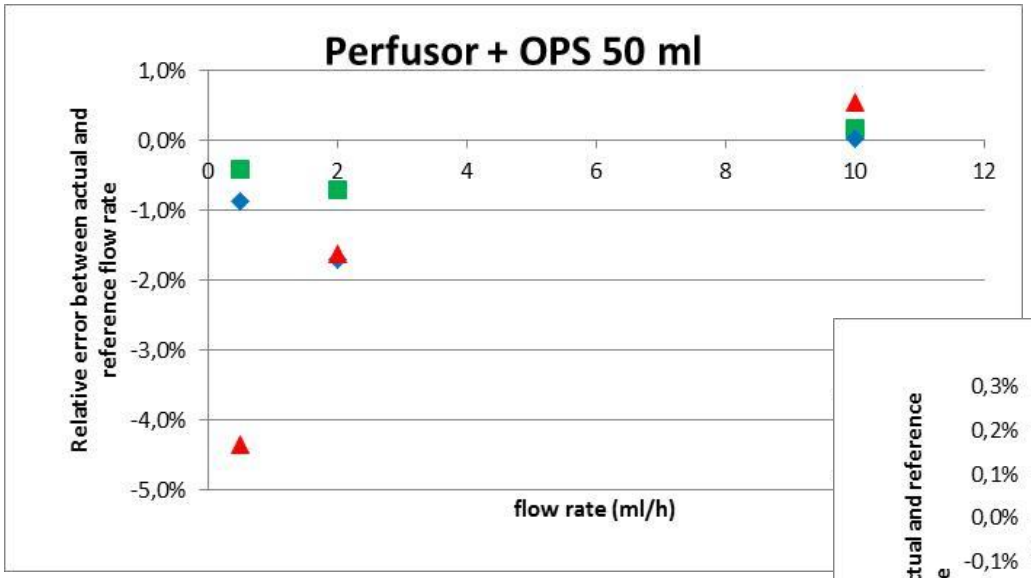


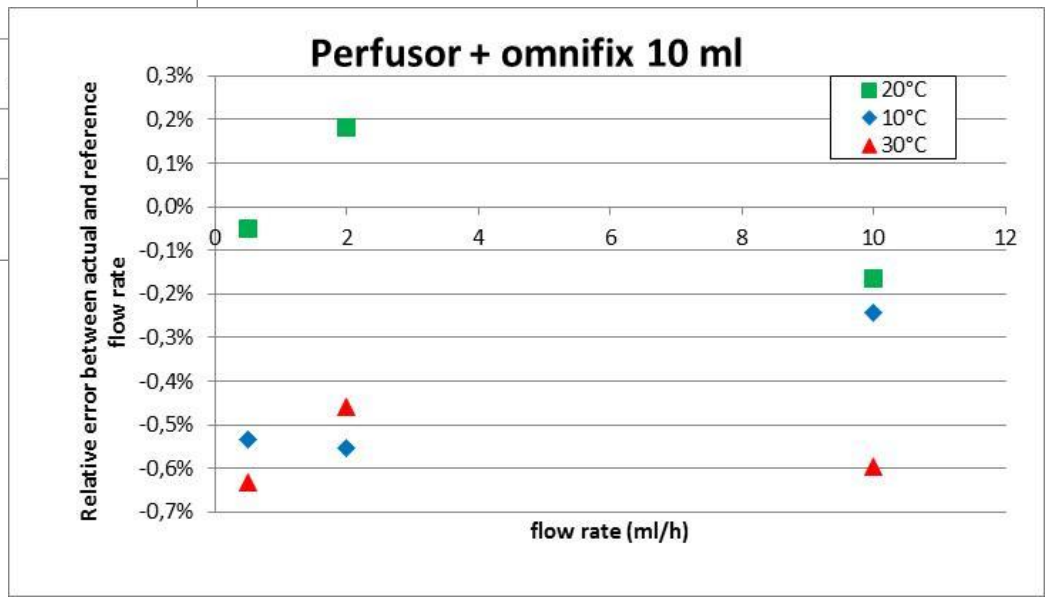
No dependence in viscosity

Alaris



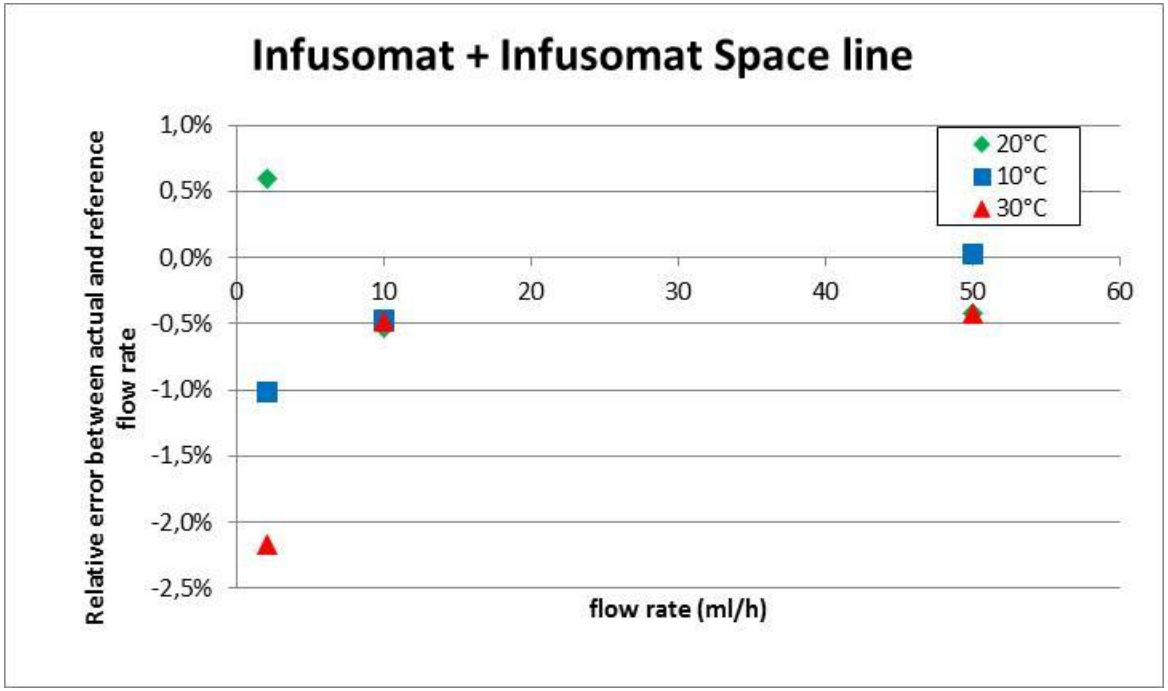
Impact of temperature – syringe pumps



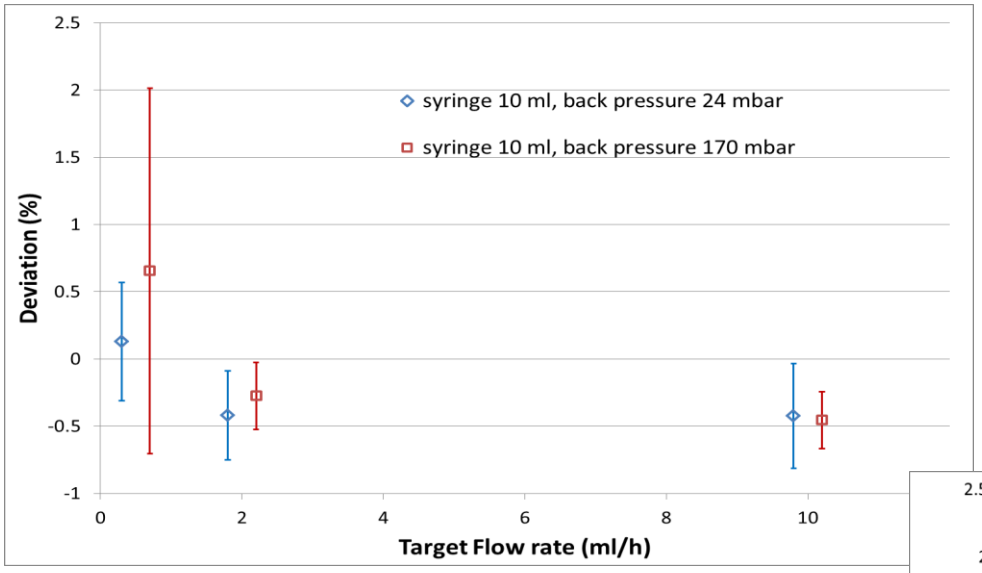


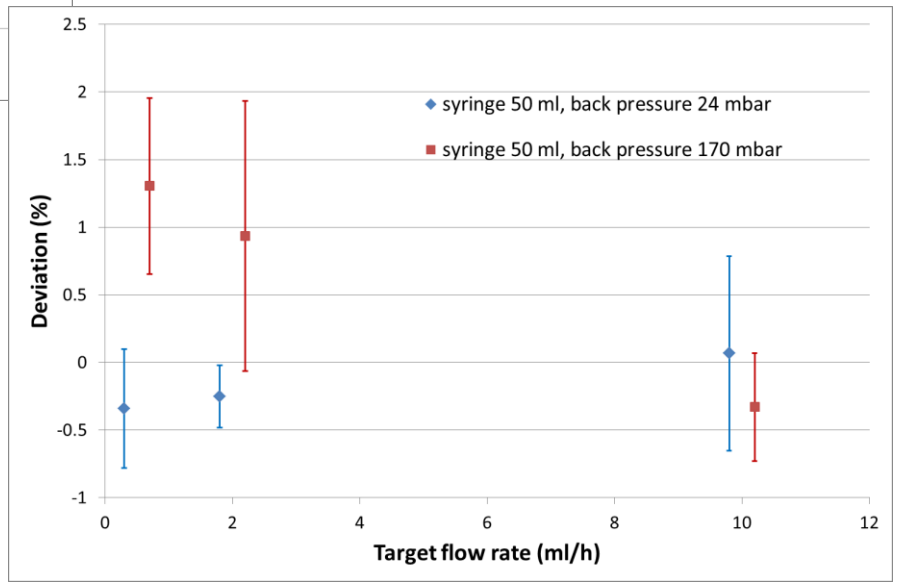
Larger errors with lower flow rates and change in temperature

Impact of temperature – infusion pumps



Back pressure - syringe pumps





No dependence in back pressure even for 50 mL since the discrepancy is within 2 %.

Major conclusions for the pumps tests

- The errors using the 50 mL syringe are always larger than the 10 mL syringe.
- There is no significant difference in errors when using solutions with different viscosity (2 times the water and 4 times the water).
- Temperature and back pressure have a more pronounced impact on the startup delay than the flow rate error
- The larger variation can be found at the lower range
- For the majority of the cases, the pumps performs within its claimed accuracy specifications of 2 % or 5 %

Thank you for your attention!!!!

Questions?

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