



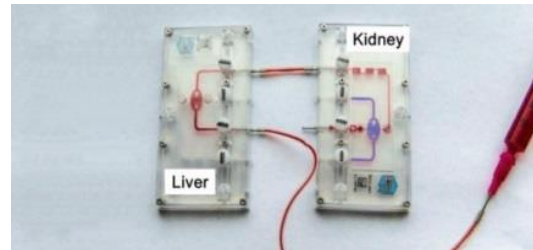
Metrology for Drug Delivery II: a new joint research project for metrology in healthcare

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Resume

- ✓ Project description
- ✓ Consortium
- ✓ Overview
- ✓ Needs and motivation
- ✓ Work packages
- ✓ Impact



EMPIR – MeDDII – 18HLT08

Call: 2018 Health

JRP name: Metrology for drug delivery

JRP reference: 18HLT08 MeDDII

Total budget: ~ 1,7 M€

Total labour: ~200 MM

Duration: 36 months

Start date: June 2019

Coordinating Organisation: IPQ

Partners - 9 NMIs/DIs, 4 universities, 2 manufacturers. 11 countries

Collaborators - 30



Consortium



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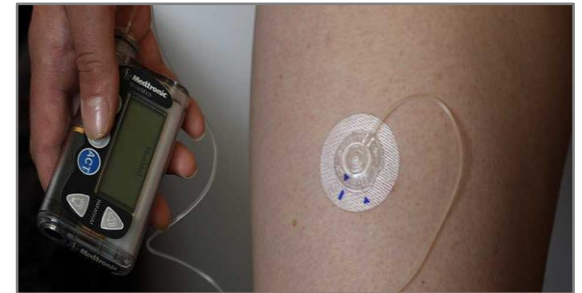
Microsystems and Nanotechnologies



Overview

This project aims to characterize and improve dosing accuracy of existing drug delivery devices and multi infusion systems and enable traceable measurements of their volume, flow rate, pressure and inline sensing operation at very low infusion rates:

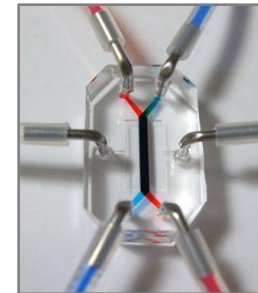
- ✓ by the development of **new calibration methods**
- ✓ by **expanding the existing metrological infrastructure**



Overview

Additionally this project will investigate:

- the effects of **fast transient flows** on dosing response
- the **physical properties** of liquid mixtures used in infusion
- the **occlusion phenomena** in multi-infusion systems
- development of a new micropump



Needs and motivation



- **Infusion therapy** → Main form of therapy in health care.
- **Deviations** in medication dose into the patient bloodstream have **dramatic effects**.
- Wide range of applications (vasoactive drugs, multi-infusion therapy, pre-term babies therapy, organ-on-a-chip technology, etc.).

Validated metrological infrastructure for traceable measurement and calibration

- volume
- ultra-low flow rates (< 100 nL.min⁻¹)
- pressure
- fast changing flow rate
- physical properties of mixtures
- occlusion phenomena

Crucial for patient safety and to advances in:

- ✓ microfluidics and organ-on-a-chip faithful reproduction of multi-organ functions
- ✓ reproducibility and accuracy of multi-infusion therapies
- ✓ reliability of drug delivery devices

Work Packages

WP1 OBJECTIVE 1

Development of metrology infrastructure for ultra-low flow rates



- Upgrade existing flow facilities and/or develop new techniques for measurement of **flow rates down to 5 nL.min⁻¹** for steady and fast transient flows.
- Establish robust and realistic **uncertainty budgets**. Target uncertainties at 1 % ($k = 2$) for steady flows and 2 % ($k = 2$) for fast transient flows.
- **Validate primary standards**, needed for the characterization of drug delivery devices and multi infusion systems.

Work Packages

WP2 OBJECTIVE 2



In-line measurement of physical and thermodynamic properties

- Upgrade the existing flow facilities of the participant NMIs in order to enable **traceable inline measurement** of the dynamic viscosity of Newtonian liquids, as a function of the flow rate and pressure difference, with a target uncertainty value of 2 % ($k=2$).
- Characterize flow devices for in-line measurements of **physical and thermodynamic properties**. These properties are needed to determine the proportion of components of a mixture of liquids.

Work Packages

WP3 OBJECTIVE 3

Development of a microchip pump and new calibration procedures of existing medical devices



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- **Identify the metrology infrastructure** for drug delivery devices and multi infusion systems.
- Develop and validate **calibration procedures** for drug delivery devices and on-chip flow micropump demonstrator.
- Fabricate and characterize a novel on-chip flow micropump as a **transfer standard**.

Work Packages

WP4 OBJECTIVE 4

Design and characterization of a multi-infusion system



UMC Utrecht

- Develop **multi-infusion setups** to investigate mixing and drug concentration at the patient's point of medication entry.
- Extend and validate a **predictive model** for multi-infusions.
- Develop a **Best Practice Guide** providing methodologies to build/assemble/use multi-infusion set-ups to guarantee the most effective dosing of drugs and fluids to the patient.

IMPACT

NEW GUIDANCE DOCUMENTS



- Draft **new calibration procedures and guides** of drug delivery devices and multi infusion systems

INPUT FOR THE REVISION OF REFERENCE DOCUMENTS

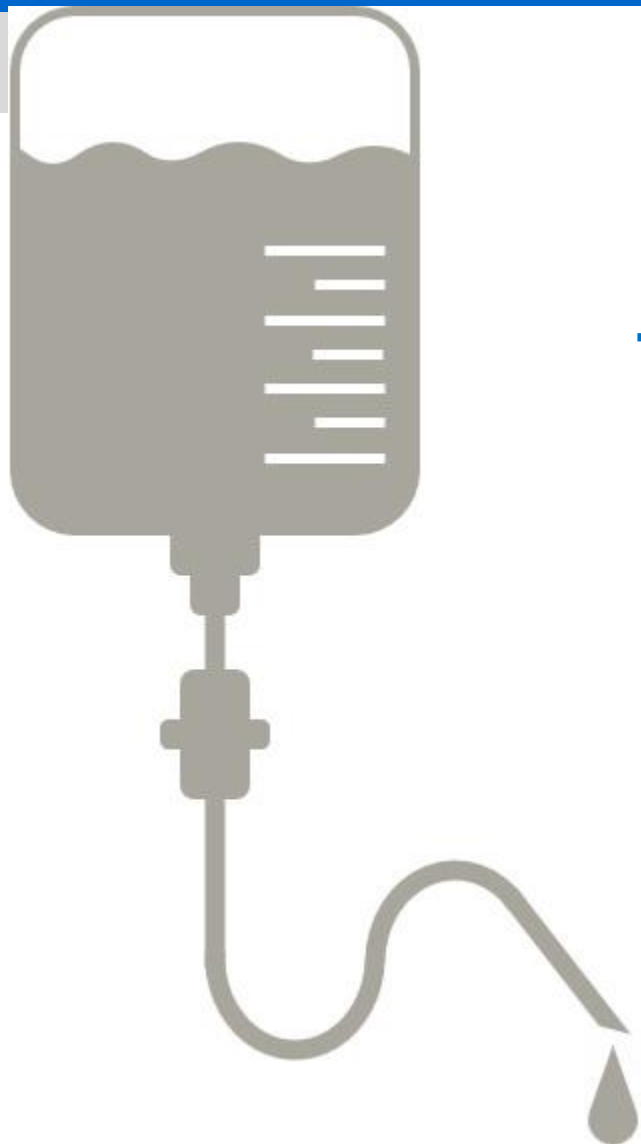
- Promote **Knowledge transfer and exchange** with International Standards Committees.
 - ISO 60601-2-24
 - ISO 7886-2
 - New OIML documents
 - ISO 8655-9



IMPACT

- ❑ Understand the behaviour of multi-infusion systems and **increase user knowledge** to prevent drug dosing errors.
- ❑ Develop **new traceable calibration methods** for infusion flow rates as low as $5 \text{ nL}\cdot\text{min}^{-1}$

Kick off meeting 1 and 2 of July 2019



THANK YOU

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