

6th Newsletter

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EMPIR



The EMPIR initiative is co-funded by the European Union's Horizon 2020 research and innovation programme and the EMPIR Participating States

Welcome

I welcome you with great pleasure to our 6th MeDDII newsletter. We take this opportunity to provide a status update of the project and inform you about news, achievements and the results of our work.

In the last six months several tasks were concluded, mainly: the comparison of the newly developed calibration facilities, the microfluidic pump development and the analysis of the results for the characterization of several drug delivery devices. Also, the validation of the in-line measurements of non-Newtonian fluids were performed. The testing of the prototypes of the mobile multi-infusion setup build has been initiated. The predictive model of multi-infusion was extended to multiple flows and air bubbles and different viscosities.

Our fifth project meeting was held in a hybrid format (online and at RISE (Sweden)) in May 2022 with 26 participants.

The partners were also involved in several dissemination activities, mainly a training course on Metrology for drug delivery for medical staff was conducted at IPQ. A report on “Drug Delivery Devices safety and use – the role of the medical devices regulation” was developed and published on our project webpage.

Our webpage was updated, mainly a new document page was added, and the standards page was updated.

I hope you will find valuable information in this newsletter. We are keen to keep in contact with you as key stakeholders or as someone generally interested in this work and welcome you into our project community.

Thank you for following our project!!!!

Elsa Batista

Coordinator of project MeDDII

News and facts

- The fifth meeting of the MeDDII project was in a hybrid format (online and at RISE (Sweden)) on 3rd and 4th of May 2022. All partners involved in the project participated, along with some members of our advisory board.

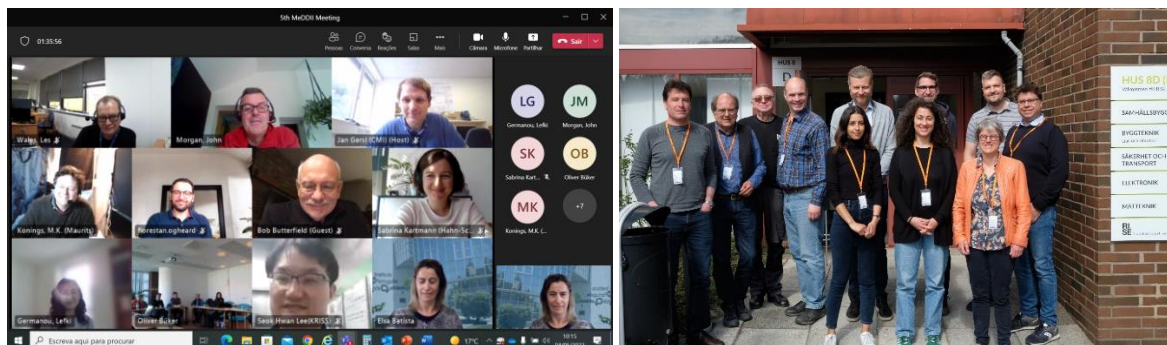


Figure 1 - MeDD II team and advisory board in the meeting online

- A training course on Metrology for drug delivery was held online on the 21st of June by IPQ in Portuguese. More than 50 participants from the medical field attended the training course. This event addressed among other issues the best practices of use of medical devices, the legal and normative documents and the calibration procedures of drug delivery devices. Presentations were given by Elsa Batista and Maria do Céu Ferreira and will be available on our webpage. A discussion forum was held at the end of the presentations.

The video of the training course can be found in <https://youtu.be/9LdZzplbXow>

The same online training course will be given in English by NEL and in French by CETIAT in September 2022.

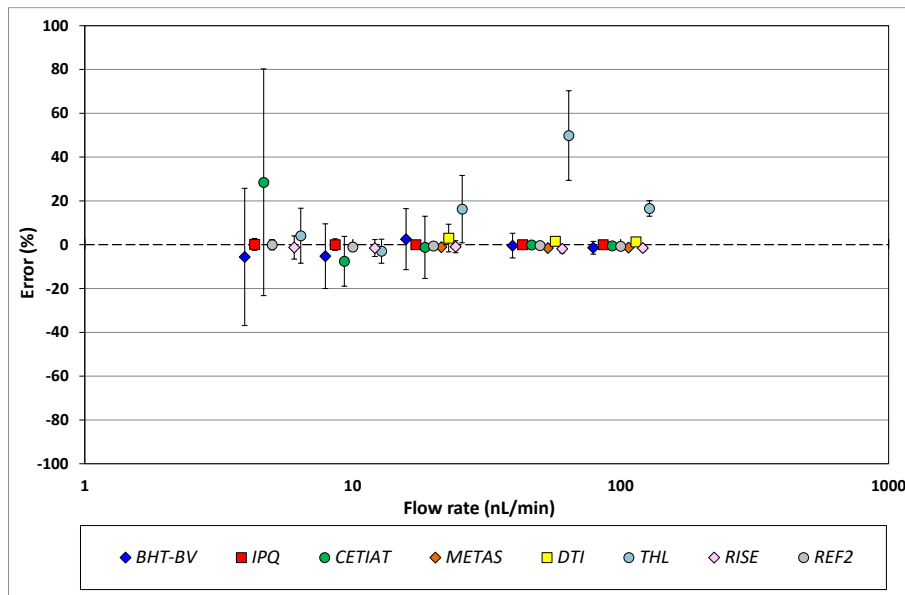
UMC Utrecht will provide a workshop on drug delivery for medical personnel at ESICM Lives on October 22-26, 2022, Paris.

- A report on “Drug Delivery Devices safety and use – the role of the medical devices regulation” was developed by the consortium partners and will be sent to the regulators of each country partner and to the EU. The document is available on our [webpage](#).
- The reports for M30 were approved by EMPIR MSU.

Highlights from the work packages

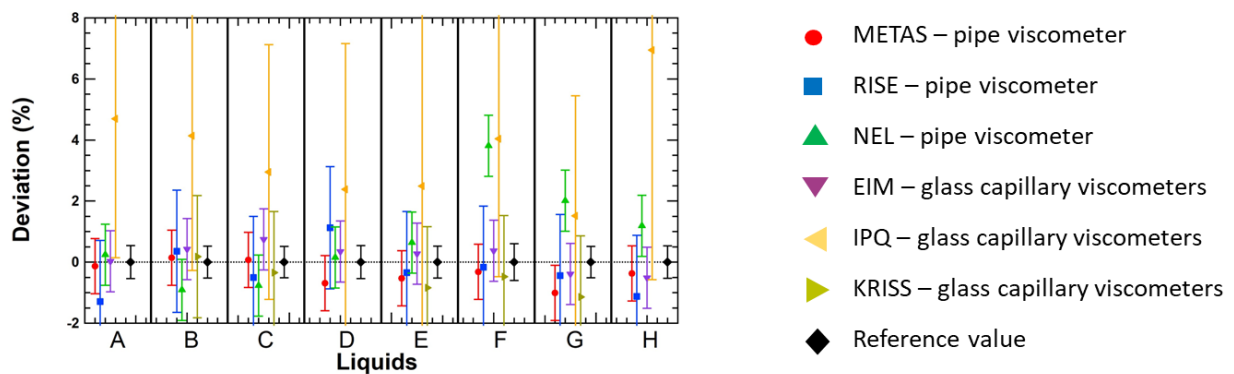
During this last six months the project has been focused on data analysis of the comparison results between the new developed micro and nanoflow facilities and the results of the drug delivery devices characterization tests.

Under **WP1 – Development of metrology infrastructure for ultra-low flow rates**, the report of the comparison with the aim of validating the measurement methods for static and dynamic tests was published in the EURAMET webpage [under project 1508](#). **90% of the results were satisfactory (En<1)**.



Under **WP 2 – In-line measurement of the physical and thermodynamic proprieties of single and multicomponent liquids**: The primary standards for in-line measurements of dynamic viscosities have been developed at RISE, NEL and METAS. Calibrations of the dynamic viscosity of reference oils with traceable densities and viscosities measurements were used for the validation of the stated uncertainties of the pipe viscometers.

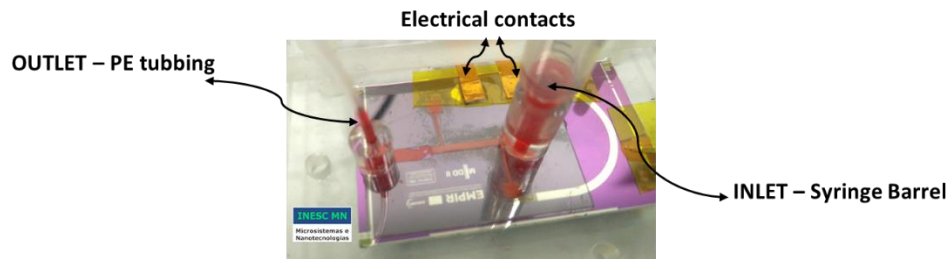
Additionally, eight different liquids used in medical applications have been measured by pipe viscometers, glass capillary viscometers (commercially available instruments) or rotational viscometers. These measurements underline the validity of the stated uncertainties and the measurement procedure of the newly developed pipe viscometers.



- Liquid A: Saline solution of 0.9 %wt NaCl
- Liquid B: Glucose solution 10 %wt
- Liquid C: Glucose solution 20 %wt
- Liquid D: solution of NaCl 0.22 %wt and Glucose 2.75 %wt
- Liquid E: solution of NaCl 0.22 %wt and Glucose 5.55 %wt
- Liquid F: solution of NaCl 0.45 %wt and Glucose 5.54 %wt
- Liquid G: solution of Glycerol 52.0 %wt
- Liquid H: solution of Glycerol 58.8 %wt

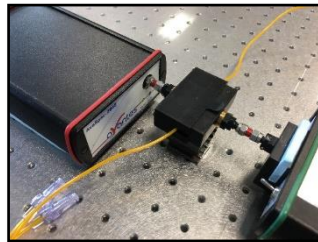
In **WP3 – Development of microchip pump and calibration procedures**, the results of the characterization of several drug delivery devices were concluded and a EURAMET calibration guide is expected to be ready in September 2022. Also, a physical prototype of a microfluidic pump by INESC-

MN was concluded and deliverable D5 was published on the website of the project and on the Zenodo platform.



Finally, in **WP 4 – Design and characterization of a multi-infusion system**, multi-infusion setups were built in Lübeck and in Utrecht. A mobile setup was built by UMC Utrecht with the aid of BHT which includes a mass flow sensor and two pressure sensors connected inline. Concurrently, an optical setup using a spectrometer and mass balance or mass flow meter, representative for clinical practice was built. The testing of the prototypes has been initiated.

The predictive model of multi-infusion was extended to multiple flows and air bubbles and different viscosities. Replicas of the setup are being sent to NEL and METAS. A measurement plan for validation has been drafted.



Dissemination of work

MeDD II participants are actively engaged with the impact on **standardization** namely ISO 8655-9 that was published in April 2022, ISO/DIS 23783-1,2 and 3, ISO/DIS 22916 and ISO/AWI TS 6417 from ISO/TC 48, ISO 15189 from ISO/TC 212 and TIR 111 from AAMI published in November 2021.

A special issue of the journal Biomedical Engineering, to be published by deGruyter, Berlin, Germany, in September 2022, will contain more than ten contributions of the MeDDII - group and is currently in preparation. <https://www.degruyter.com/journal/key/bmte/html?lang=de>

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