

4th Newsletter

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EMPIR



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Welcome

I welcome you with great pleasure to our 4th 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, the focus was on the comparison of the new developed calibration facilities and on the characterization of several drug delivery devices.

Due to the restrictions that caused significant difficulties in performing laboratory work and test measurements, the project requested a 6 month extension and will now end in December 2022. Also, a new partner has joined our consortium, the University of Strathclyde in Glasgow.

Because the theme for World Metrology Day 2021 is Measurement for Health our project has developed several documents and a video that are available on our website, which celebrate this event.

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.

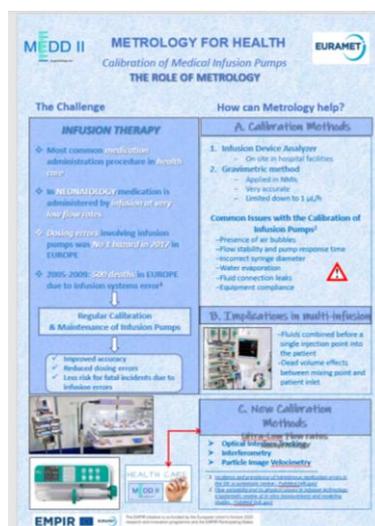


Elsa Batista

Coordinator of project MeDDII

News and facts

- A new partner joined our consortium, the University of Strathclyde in Glasgow;
- The reports for M18 were approved by EMPIR MSU;
- The project MeDDII has developed a Guide and a Flyer on Calibration of Medical Infusion Pumps, the links can be found below and, in our webpage, www.drugmetrology.com



https://drugmetrology.com/wp-content/uploads/2021/05/Flyer-MetrologyDay_Infusion-Pumps_v2.pptx

https://drugmetrology.com/wp-content/uploads/2021/05/MeDD_II_Calibration-Guide-Infusion-Pumps_05_2021.pdf

- A movie on Traceability of infusion pumps was also developed and is available on our webpage to help the understanding of the importance of Metrology in medical devices accuracy;

<https://youtu.be/Fws7J1Lu2XQ>

- The 14th Workshop on "Low Liquid Flows in Medical Technology" organized by TH Lübeck and MeDDII partners will be held on the 15th of September so please save the date. Details and registration can be found here:

<https://www.th-luebeck.de/msgt/aktuelles/workshops/mikrofluidik-workshop-2021/>

Highlights from the work packages

During this last six months the project has been focused on performing the comparison between the new developed microflow facilities and characterization tests.

Under **WP1 – Development of metrology infrastructure for ultra-low flow rates**, a comparison with the aim of validating the measurement methods for static and dynamic tests, with 10 partners participating, has been engaged. Three transfer standards were chosen, mainly, a thermal flow meter L01 from Bronkhorst (1500 nL/min to 20 nL/min), a thermal flow meter SLG-0075 (1500 nL/min to 20 nL/min) from Sensirion AG, and a Cetoni syringe pump (100 nL/min to 5 nL/min). The tests are almost concluded and the report is expected to be ready by the end of September 2021.

Under **WP 2 – In-line measurement of the physical and thermodynamic proprieties of single and multicomponent liquids**, tests with saline solutions, glucose solutions (various concentrations) and mixtures of them are now being performed.

In **WP3 – Development of microchip pump and calibration procedures**, the characterization of several drug delivery devices is almost finalized. The results will be analysed and a EURAMET calibration guide will be developed. Also, a physical prototype of a microfluidic pump by INESC-MN is under the validation stage and will be ready by August 2021.

Finally, in **WP 4 – Design and characterization of a multi-infusion system**, the work has been delayed due to the covid restrictions, but it is now restarting.

Dissemination of work

MeDDII participants are actively engaged with the impact on **standardization** namely ISO 8655 and ISO 23783 from ISO/TC 48, IEC60601-2-24 from TC62/SC62D/MT23, and TIR 101 from AAMI.

Five **presentations** were delivered and are available in our webpage:

- 1) “The effect of drugs rheological properties in the flow accuracy and uncertainty of infusion systems in the microflow range” at ESR 2021: European Society of Rheology and Nordic Rheology Society 2021 by Andreia Furtado et al (IPQ);
- 2) “Flow control system for organ-on-a-chip application” by Joost Lötters (Bronkhorst High-Tech) HLS 2021 workshop: Healthcare & Life Science & Entrepreneurship Workshop;
- 3) “Development of calibration procedures for drug delivery devices” by Anders Niemann (DTI) at HLS 2021 workshop: Healthcare & Life Science & Entrepreneurship Workshop;
- 4) “Multi-infusion setups and its influence in the flow rate accuracy” by Annemoon Timmerman, UMCU, Netherlands at IPQ Metrology Day, Portugal;
- 5) “Traceability and accuracy in infusion medical devices” by Elsa Batista (IPQ) at HMD Metrology Day, Croatia.

Other information

The EU has revised the legal framework of the current 3 directives to reflect progress over the last 20 years. Adopted in May 2017, the Regulation (EU) 2017/745 on Medical Devices will be applicable within the EU with **new rules**. To ensure a smooth transition from the Directives to the Regulations and to avoid market disruption several transitional provisions are in place until 2025. Since 26 May 2021 the new regulation presents a series of extremely important improvements to ensure safety of medical devices with measuring function to. More information available at https://ec.europa.eu/health/md_newregulations/overview_en

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