

Establishing metrology standards in microfluidic devices: project impact and future work

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EMPIR PROJECT 20NRM02 MFMET

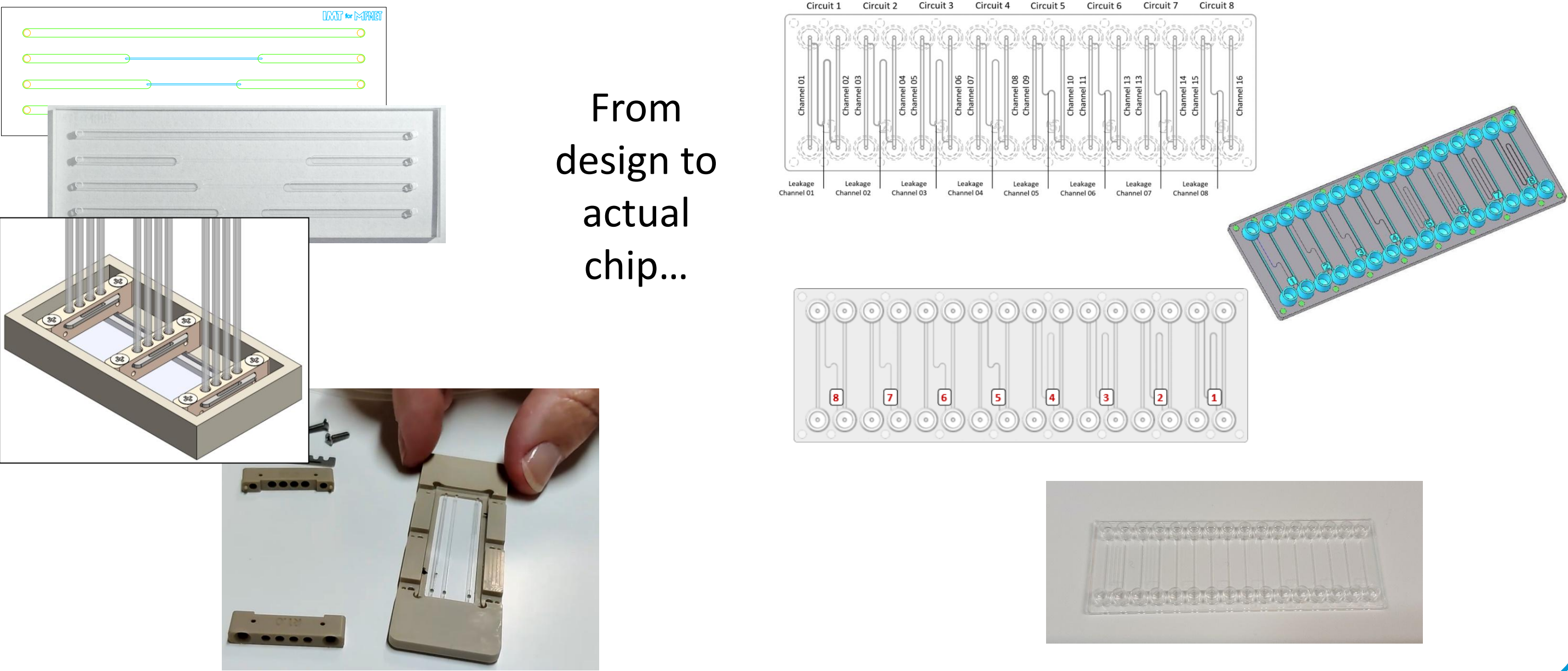
Widespread adoption depends on standards for qualification and characterization, ensuring component compatibility and enhancing reproducibility across suppliers. This project developed measurement protocols for key microfluidic quantities, including:

DIMENSIONS **INTERNAL VOLUME** **HYDRAULIC RESISTANCE**
SURFACE ROUGHNESS **LIQUID PROPERTIES**

Using various chips created during the project, MFMET aimed to promote globally accepted standards to support industry (healthcare and pharmaceuticals) and academia.

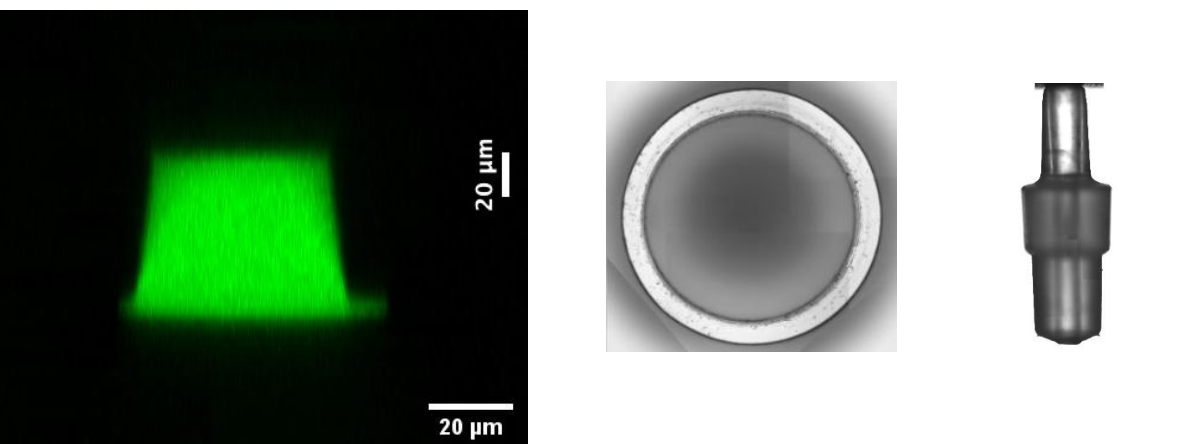
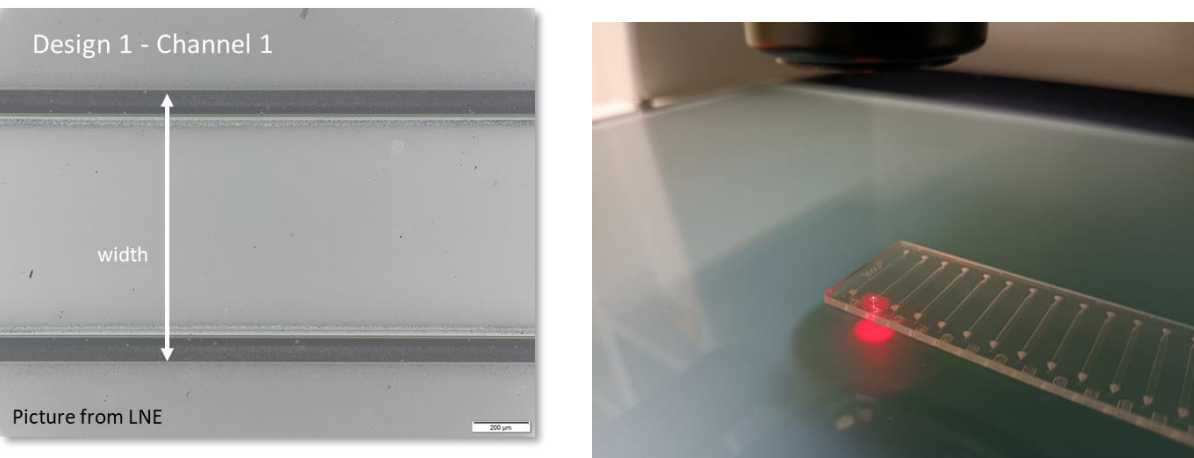
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TRANSFER STANDARD MICROFLUIDIC CHIPS DEVELOPED



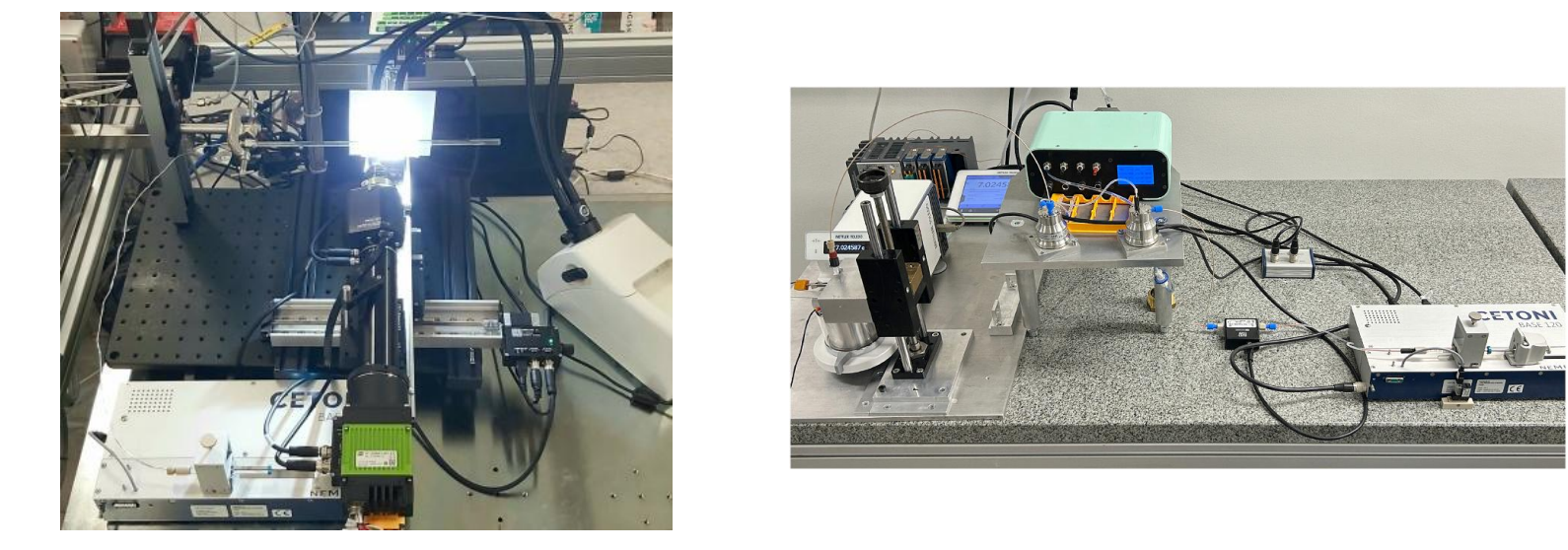
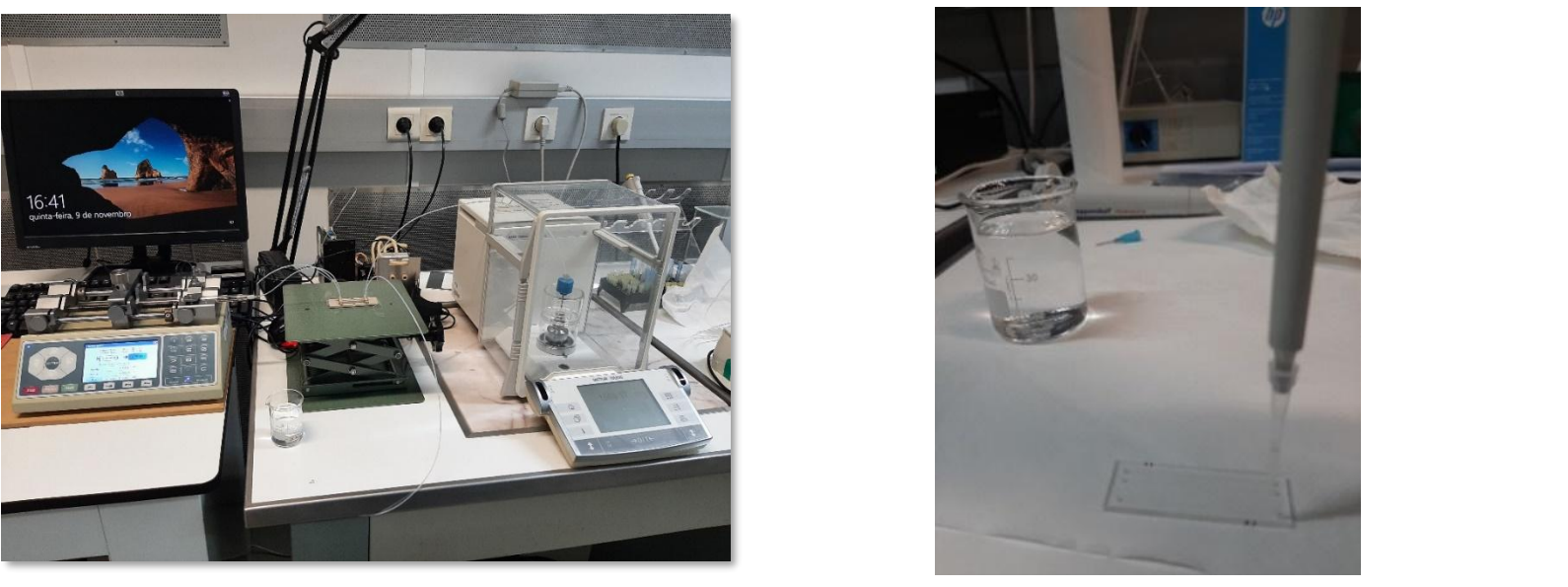
MEASUREMENTS PERFORMED

Dimensional



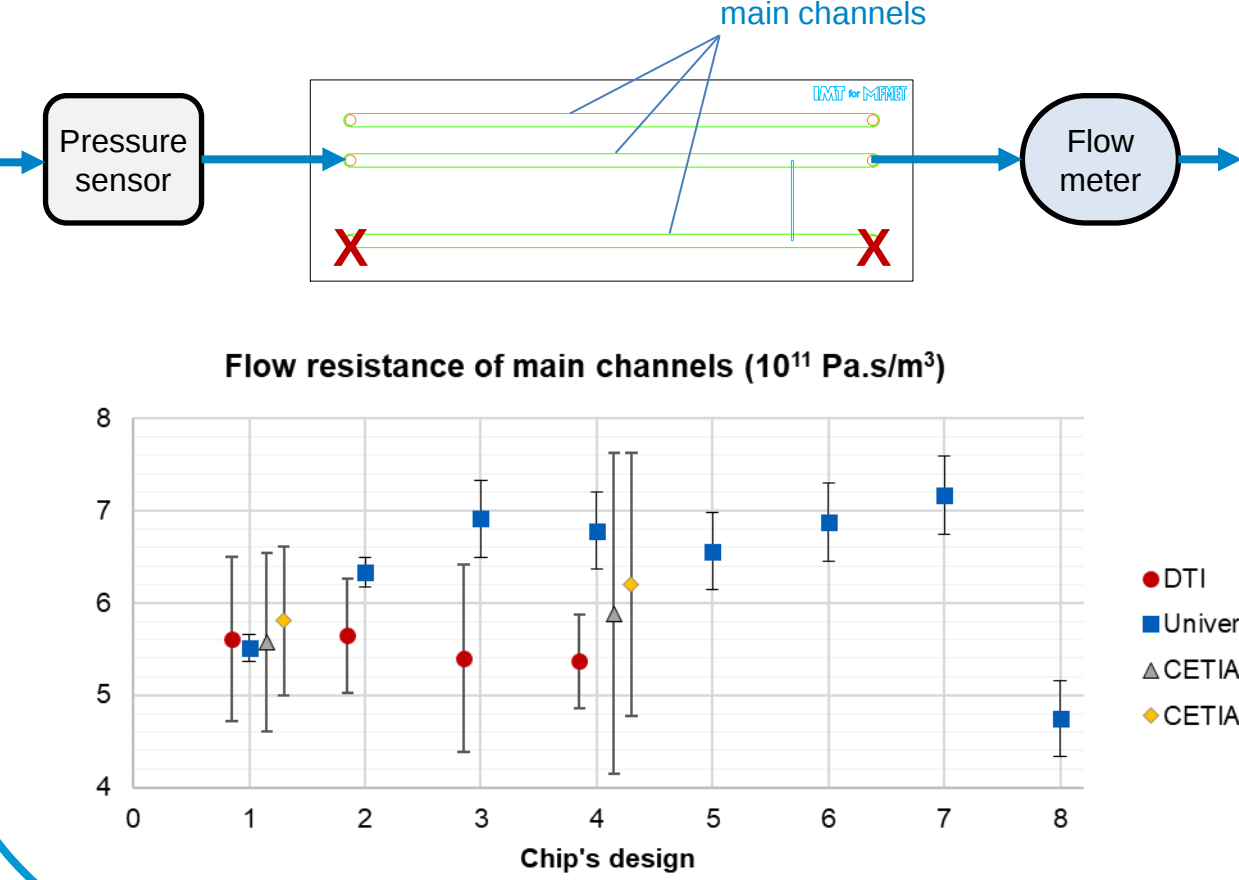
Measurand	Measurand estimation [mm]	Uncertainty [mm]
External large diameter	2.78	0.18
Inner diameter	2.843	0.019

Flow and volume

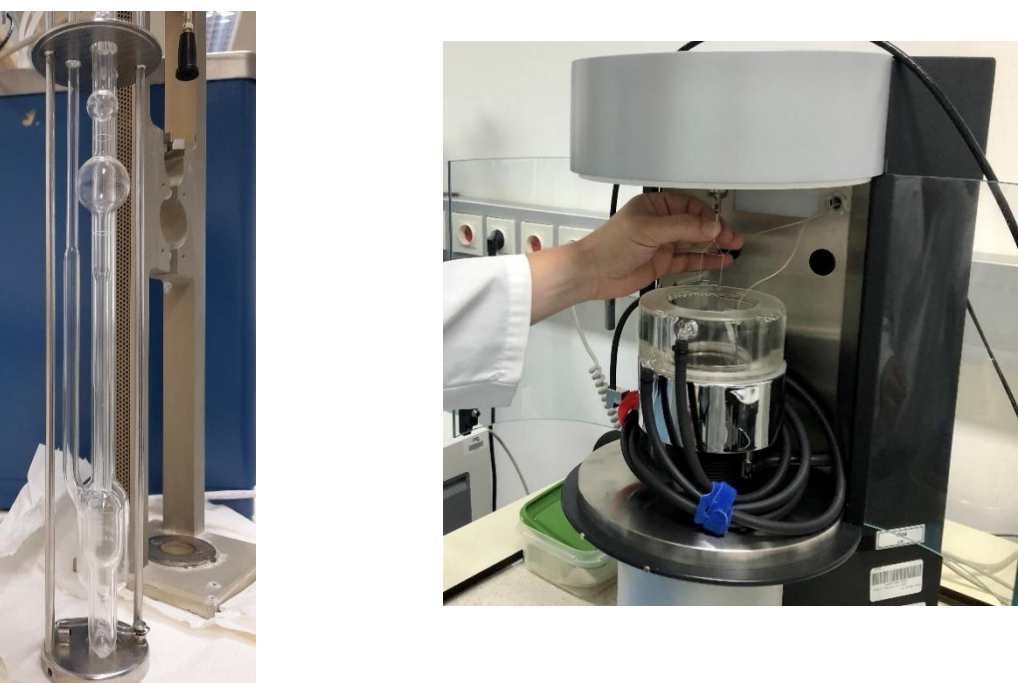


Chip	Nominal Flow [mL/h]	Measured Flow [mL/h]	Error [%]	U [%]	Variation with and without chip [%]
Glass 1_1 Channel 1	0.01	0.0099	1.00	3.98	-0.92
	0.1	0.1014	-1.40	2.98	-1.49
	1	1.0124	-1.24	2.29	-0.88
Glass 1_2 Channel 2	0.01	0.0097	3.00	3.84	1.12
	0.1	0.104	-4.00	5.21	-4.09
	1	1.0047	-0.47	3.53	-0.11
Glass 2_1 Channel 2	0.01	0.0025	-75.00	10.87	74.52
	0.1	0.103	-3.00	7.02	-3.09
	1	1.0047	-0.47	3.53	-0.11
Glass 2_3 Channel 3	0.01	0.0097	3.00	3.74	1.12
	0.1	0.1029	-2.90	6.65	-2.99
	1	1.002	-0.20	1.95	0.16
Glass 4_1 Channel 2	0.01	0.0108	-8.00	2.53	-10.09
	0.1	0.1024	-2.40	3.35	-2.49
	1	1.0004	-0.04	2.05	0.31
Glass 4_3 Channel 3	0.01	0.0092	8.00	4.80	6.22
	0.1	0.1019	-1.90	3.79	-1.99
	1	1.003	-0.30	1.93	0.06

Flow resistivity



Liquid proprieties



	Water	PBS	SBF	U
Density, ρ / (kg/m ³) at 20 °C	998.203	1005.225	1007.523	0.033

IMPACT ON STANDARDIZATION

Contributions to ISO/TC 48/WG 3 Microfluidic Devices

- ISO 22916:2022 – Microfluidic devices – Interoperability requirements for dimensions, connections and initial device classification
- ISO 10991:2023 Microfluidics – Vocabulary
- ISO/TS 6417 Microfluidic pumps — Symbols and performance communication

Contributions to ISO/TC 48/WG 5 Liquid Handling Devices - Automatic the development

- ISO 23783- 1, 2 and 3:2022
- ISO/TR 6037:2024 - Automated liquid handling systems – Uncertainty of the measurement procedures

Contributions to CEN/CENELEC Focus Group on Organ-on-Chip

- Focus Group Organ-on-Chip Standardization Roadmap

PUBLICATIONS



- Daugbjerg, T.S. *et al.* (2025) Measurement of wettability and surface roughness for metrology and quality control in microfluidics, *Int. J. Metrol. Qual. Eng.* 16(2), 13 pp.
- Kaal, J. *et al.* (2025) Comparison of Measurement Protocols for Internal Channels of Transparent Microfluidic Devices, *Metrology* 5(4), 20 pp.
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- Batista, E. *et al.* (2024) The Importance of Dimensional Traceability in Microfluidic Systems, *Metrology*, 4(2):240-253
- Gil, J.F. *et al.* (2023) Cancer Models on Chip: Paving the Way to Large-Scale Trial Applications, *Advanced Materials*, 35: 2300692
- Lima, J. *et al.* (2024) Determining Liquid Properties for Application in Microfluidic Devices, *TQM Journal*, 15:147-165
- van Heeren, H. *et al.* (2022) Metrology challenges for microfluidics, *CMM Magazine*, 15, 20-25
- Silverio, V. *et al.* (2022) Overcoming technological barriers in microfluidics: Leakage testing, *Frontiers in Bioengineering and Biotechnology*, 10, 17 pp.

EPM PROJECT 24NRM03 MFMET II

Supported by EURAMET and the European Partnership on Metrology (EPM), MFMET II is a collaborative effort to bridge gaps in the microfluidics supply chain, including organ-on-chip applications, with the following objectives:

- Develop protocols and guidelines for microfluidic device validation and characterization
- Support ISO standards (ISO/TC 48/WG 3 and ISO/TC 276/SC 2)
- Enable scalable, cost-effective manufacturing of harmonized, reproducible microfluidic devices and microphysiological systems

Collaborators: 19 partners from national metrology institutes, academia, and industry, led by IPQ. Chief stakeholder, the Microfluidics Association.

WP6 Management and coordination

Elsa Batista
IPQ

WP1

Thomas Daugbjerg
DANISH TECHNOLOGICAL INSTITUTE

Standard procedures to assess and characterize metrological quantities in microfluidics

WP2

Vania Silverio
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Protocols for the integration of elements and material characterization in microfluidic devices

WP3

Oliver Bükér
RI SE

General standards and guidelines for quality control and validation of microfluidic systems

WP4

Kevin Romieu
CETIAT

Setups for performance evaluation of integrated microfluidic devices

WP5 Creating impact

Elsa Batista
IPQ

SUMMARY

While microfluidics and nanotechnology have enabled portable mini-labs, establishing standardised performance assessments remains a challenge. Efforts toward harmonisation are underway, but comprehensive regulations for qualifying entire microfluidic systems are still needed. Progress in Organ-on-a-Chip (OoC) technology is driven by the goal to replace animal testing, supported by the FDA Modernization Act 2.0. However, companies currently lack standardised methods for validating manufacturing, performance, and safety.

The EPM MFMET II project aims to develop protocols and guidelines to support these standardisation efforts, aligning with ISO/TC 48/WG 3 and ISO/TC 276/SC 2.

Looking ahead, standardised calibration methods, innovative measurement techniques, and collaborative research will be key to shaping the future of microfluidics and OoC technology.

The project (20NRM02 MFMET) has received funding from the EMPIR programme co-financed by the Participating States and from the European Union's Horizon 2020 research and innovation programme.

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