Colli-Pee™

Accuracy of the volume of first void urine, using a newly developed collection device

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Introduction

The objective of this study was to determine the accuracy of the collected volume of first void urine, using a newly developed device Colli-Pee™. The aim of this research project was twofold:

(i) determination of the accuracy and consistency of the collected urine volume, and

(ii) investigation of the dilution of that first void due to internal seepage within the device architecture.

Materials & Methods

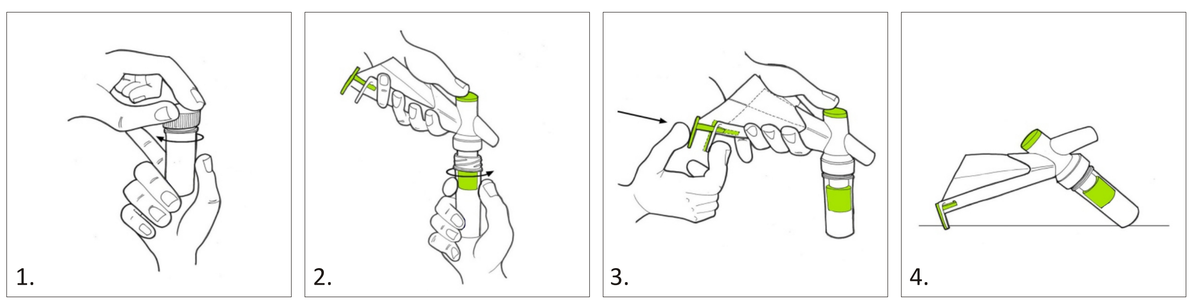
This study was conducted using three methods:

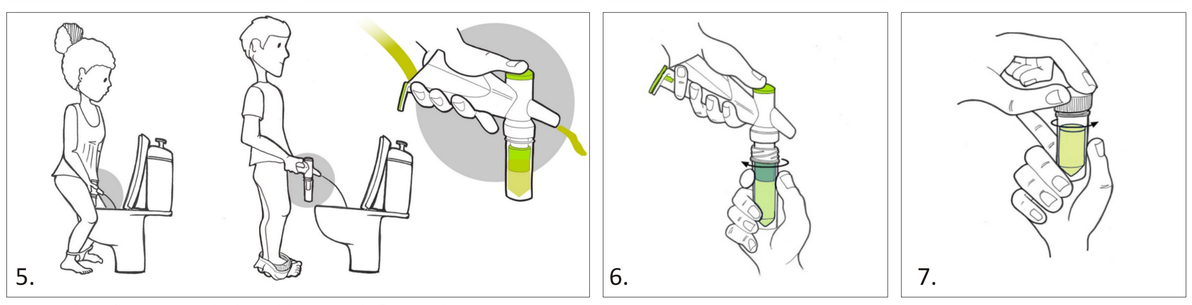
(i) a 3D CAD simulation model was built to run Computational Fluid Dynamics (CFD) simulations in order to verify the amount of dilution (mix of first void urine with midstream) that would occur;

(ii) mechanical flow tests to investigate the accuracy and consistency of the collected first void volume, for increasing volume flows and different lengths of time, i.e. volume flows of 25 ml/s and 40 ml/s were applied for 15 and 30 seconds (repeated ten times); and

(iii) assessment and inventory of collected volumes of first void urine using the Colli-Pee device as part of the BiR&D (Belgian Industrial Research & Development Fund) study in which 155 healthy volunteers participated to assess the usability of the device next to validation of accuracy and consistency of the device.

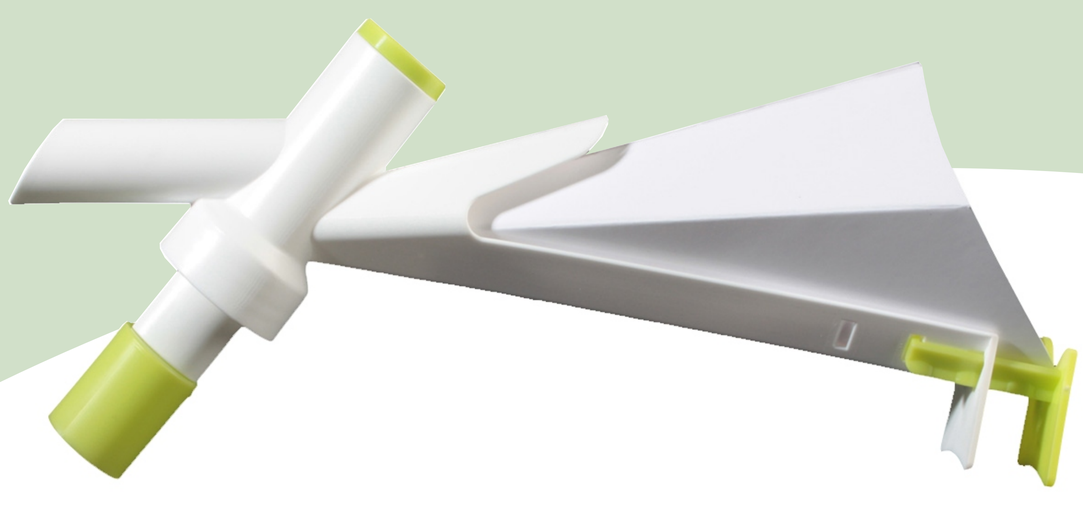
In the framework of an IWT innovation project, and in support of this study, different components and design variants were built using 3D printing and injection moulding in proto moulds. The best performing prototype was used for the mechanical flow tests, and compared with the CFD output.



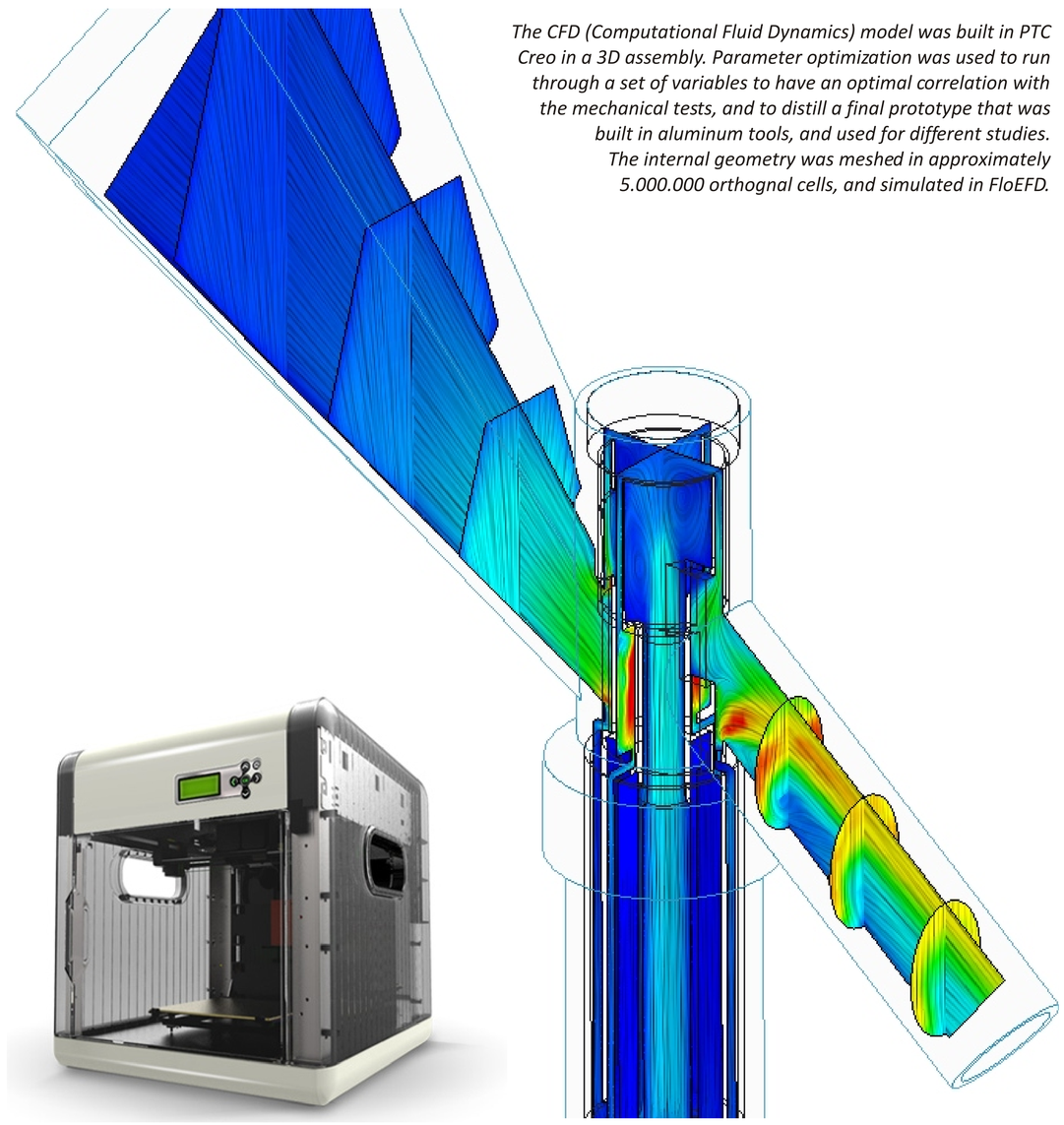


Instructions for use, as designed for the BiR&D study

Colli-Pee™ 3D prints and proto moulded parts for design variants and parameter optimization



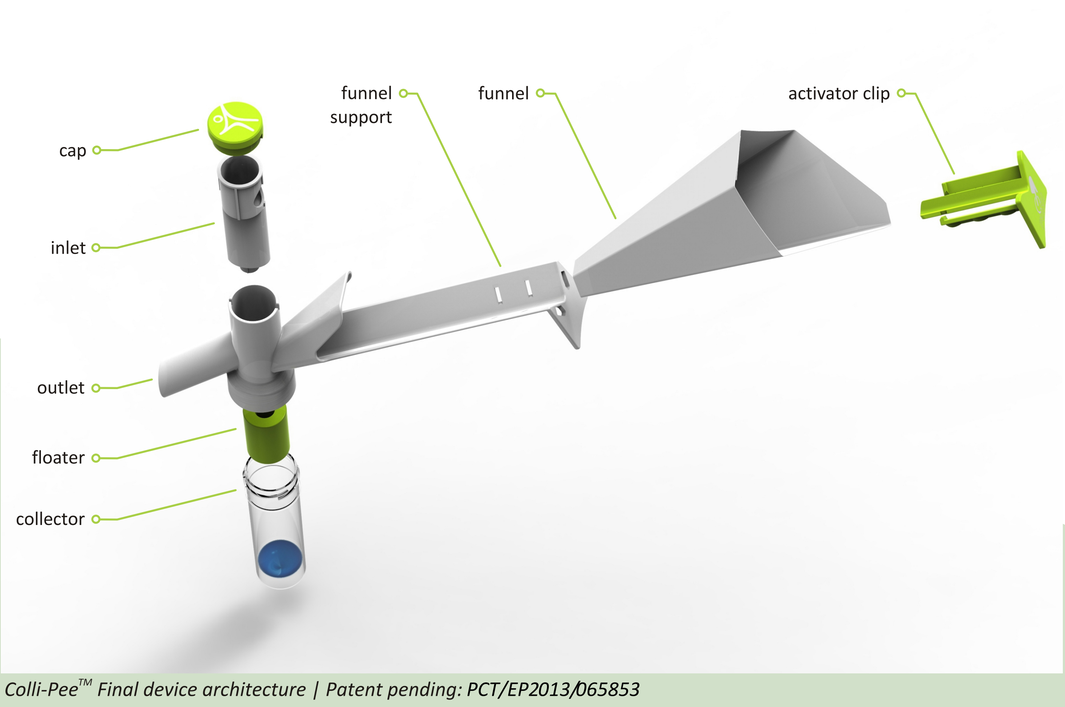
Colli-Pee™ prototype, built in proto-tools in polypropylene



The CFD (Computational Fluid Dynamics) model was built in PTC Creo in a 3D assembly. Parameter optimization was used to run through a set of variables to have an optimal correlation with the mechanical tests, and to distill a final prototype that was built in aluminum tools, and used for different studies. The internal geometry was meshed in approximately 5.000.000 orthognal cells, and simulated in FloEFD.

FDM 3D printer to build design variants

3D Computational Fluid Dynamics simulation model



Colli-Pee™ Final device architecture | Patent pending: PCT/EP2013/065853

Results

Both the BiR&D study and the mechanical flow tests showed a consistent captured volume of first void urine of **22ml +/- 2ml** (range 20-24ml). The accuracy of the captured first void volume proved to be – to some extent – sensitive to volume flow and flow time, but always within that 22ml +/- 2ml range. It appeared that a high volume flow and a long flow time would collect more urine (e.g. 24ml) than a low volume with a short flow time (e.g. 20ml).

The CFD simulations were set up to duplicate the mechanical flow tests and indicated that 0.5 – 0.8 ml midstream urine is mixed with the captured first void. Here too, a longer flow time will cause a slightly higher dilution than a short flow. It is believed that the higher collected volumes will therefore contain relatively more midstream urine (max 4%).

Conclusion

The Colli-Pee device is accurate and consistent in capturing first void urine. Additionally, at least **96%** of the captured fraction is **pure first void**. This research also demonstrated a limited dilution with midstream of first void urine. Insight was gained to mitigate this issue in new generations of the device.

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