Colli-Pee™

Accuracy of a newly developed first void urine collection device

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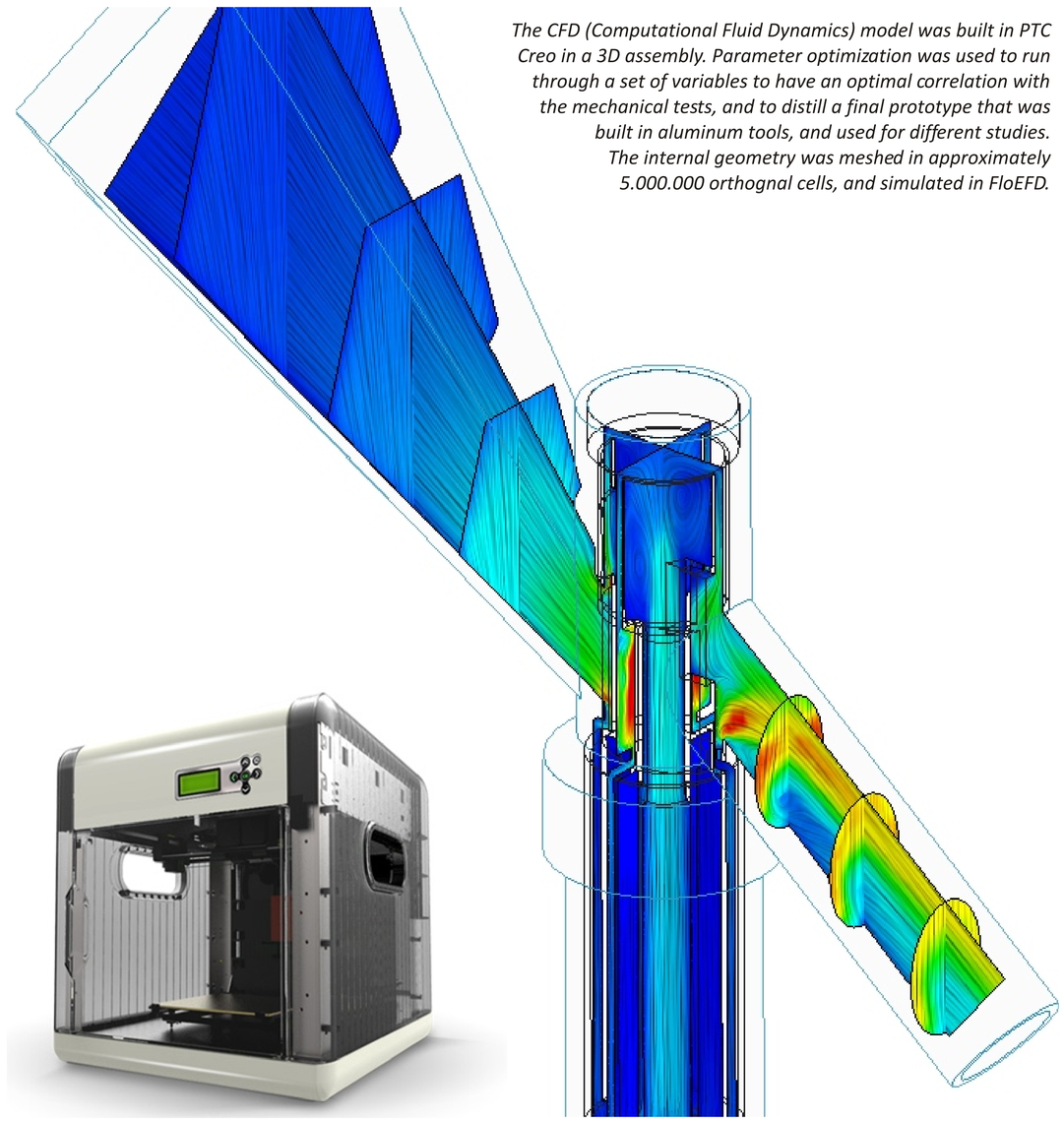
Introduction

The **objective** of this study was to determine the accuracy of the collected volume of first void urine, using a newly developed device FV-5000 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.



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.

Materials & Methods

This study was conducted using two methods:

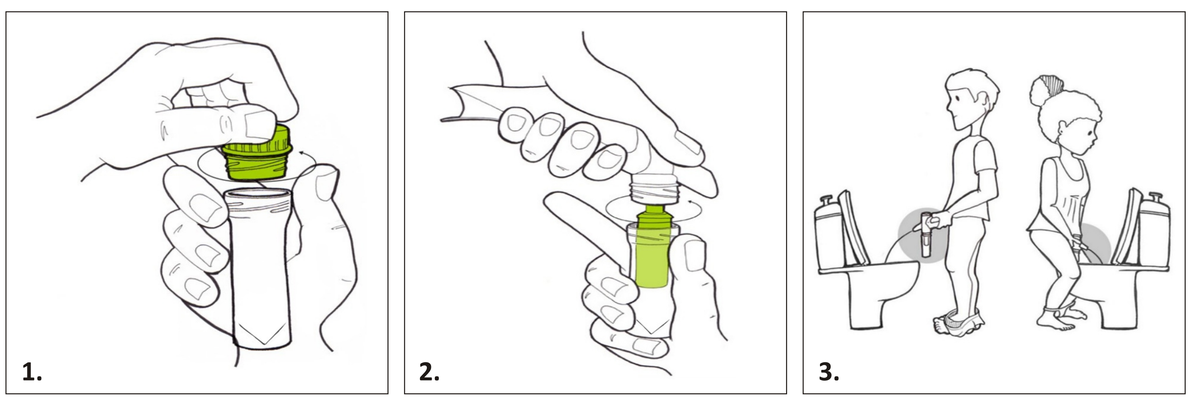
(i) a 3D CAD simulation model was built to run Computational Fluid Dynamics (CFD) simulations in order to verify the amount of dilution (mix of first void urine with midstream) that would occur;

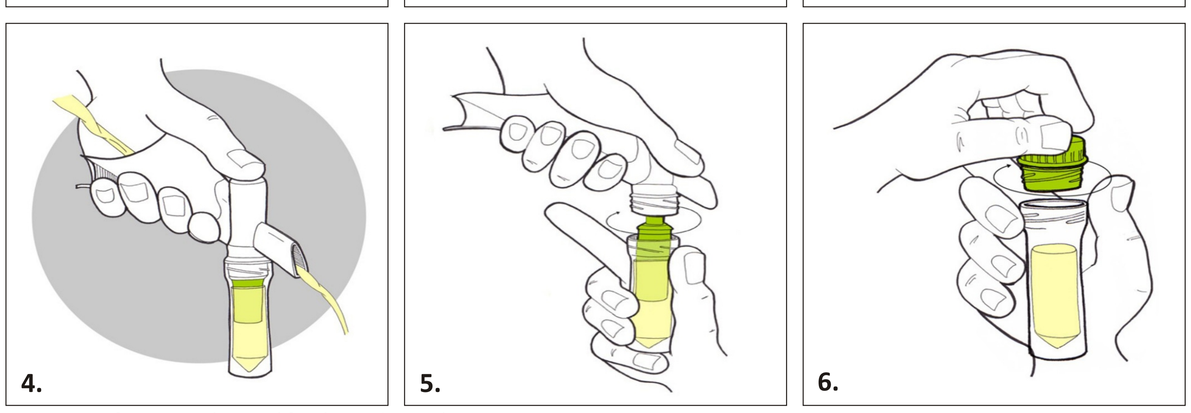
(ii) mechanical flow tests to investigate the accuracy and consistency of the collected first void volume, for increasing volume flows and different lengths of time, i.e. volume flows of 25 ml/s and 40 ml/s were applied for 15 and 30 seconds (repeated ten times); and

In the framework of an IWT (agency for Innovation by Science and Technology) 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.

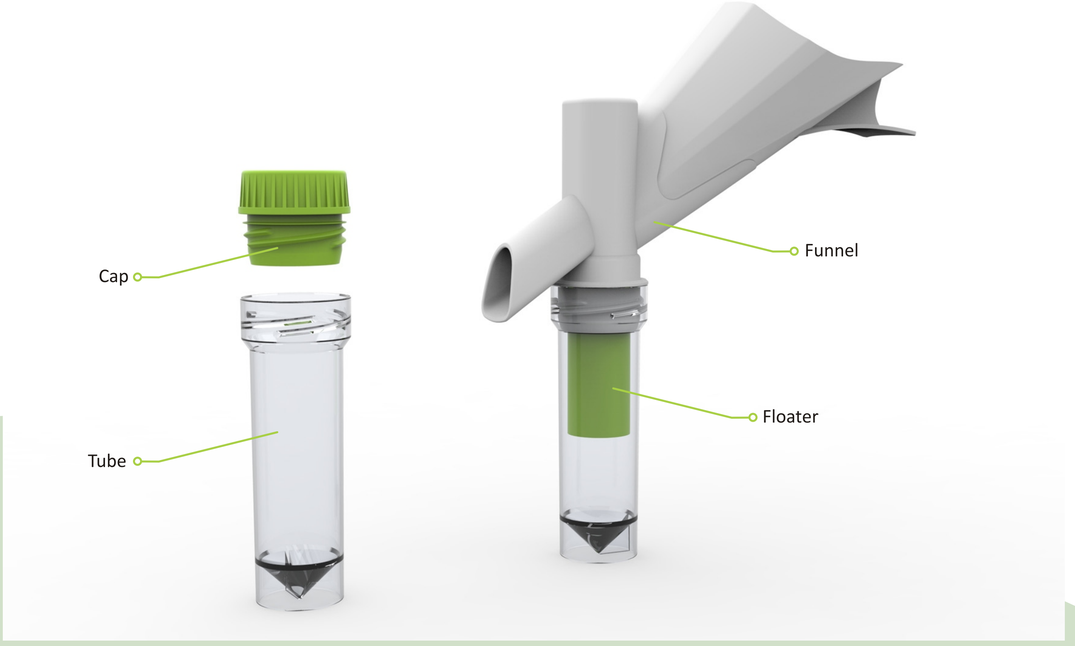
FDM 3D printer to build design variants

3D Computational Fluid Dynamics simulation model

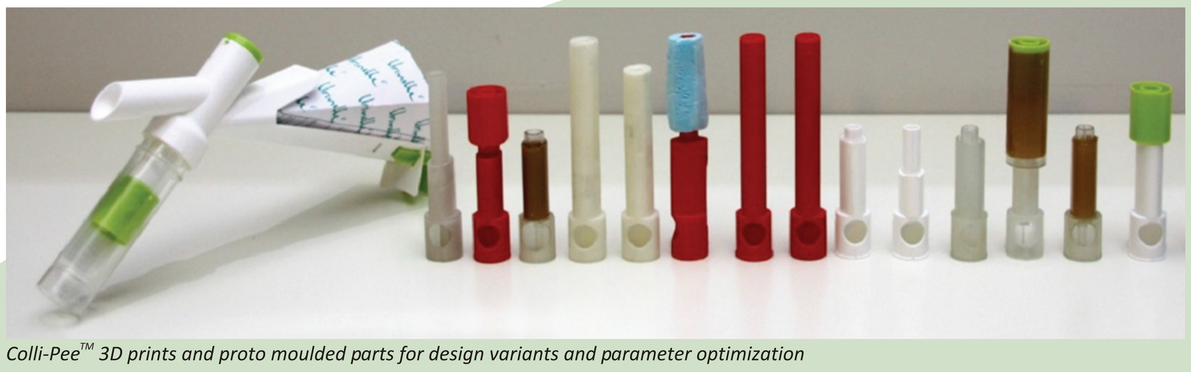




Instructions for use, as designed for the BiR&D study



Colli-Pee™ Final device architecture | Patent pending: PCT/EP2013/065853 | Patent granted NL 2011416



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

Colli-Pee™ FV-5000, injection moulded in polypropylene

Results

The mechanical flow tests showed a consistent captured volume of first void urine of **20ml +/- 1ml** . 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 20ml +/- 1ml range. It appeared that a high volume flow and a long flow time would collect more urine (e.g. 21ml) than a low volume with a short flow time (e.g. 19ml).

The CFD simulations were set up to duplicate the mechanical flow tests and indicated that 0.3 – 0.5 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 2.5%).

Conclusion

The Colli-Pee device is accurate and consistent in capturing first void urine. Additionally, at least **97.5%** of the captured fraction is **pure first void**. This research also demonstrated a limited dilution with midstream of first void urine. The insight that were gained to mitigate this issue, have now been implemented in the industrialized and CE-labled FV-5000 device.

*come and see us at **Booth 13** for more information*

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iwt agency for Innovation by Science and Technology

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