

Colli-Pee® - Development of an innovative and user-friendly urine collector

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INTRODUCTION

Urine as a sample type has great potential in disease detection. Urine sampling is easy, non-invasive and suitable for home collection.

In particular first-void/first-catch urine has shown great promise in screening and detection of sexually transmitted infections (STIs) including Human Papillomavirus (HPV)⁽¹⁾⁽²⁾⁽³⁾. First-void urine contains a significantly higher concentration of HPV DNA than subsequent fractions⁽¹⁾, as well as a higher *C. trachomatis* load for Chlamydia detection⁽⁴⁾. Urine has also shown potential to improve screening, detection and monitoring of cancers such as prostate⁽⁵⁾⁽⁶⁾ and cervical cancer⁽⁷⁾.

Collecting a urine sample with a standard urine cup has limitations and is often awkward, messy and inconvenient for the user. For this reason NovoSanis developed Colli-Pee, an innovative collection device that allows for standardized and volumetric collection of (first-void) urine.

To accommodate different applications, various Colli-Pee variants have been developed. The Colli-Pee platform can capture a range of volumes (4 mL up to 45 mL) and can be prefilled with different preservatives, allowing for longer stability and preservation of urine.

COLLI-PEE JOURNEY

In 2011, an initial concept of Colli-Pee, a device that would allow for volumetric collection of the first fraction of urine was designed and prototyped. Throughout 2012 and 2013, the design was further developed and optimized for injection moulding.

Alongside the development of Colli-Pee, in order to comply with the increasingly strict medical device regulations, NovoSanis (founded in March 2013) developed its own quality management system, including procedures for product development and quality assurance and control for Colli-Pee.

After the design was established and prototyped, verification and validation tests were performed to investigate the accuracy of volumetric collection, as well as the balance between practicality for the user and tightness of the tube-housing interface to prevent leakage.

In addition to functionality and performance testing, usability studies were performed to assess user acceptance of the device with regards to comfort and user-friendliness. In 2014, Colli-Pee (CP-2000) was first introduced into the market.

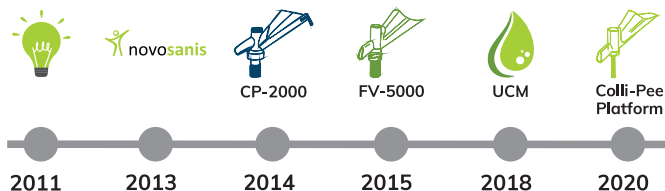
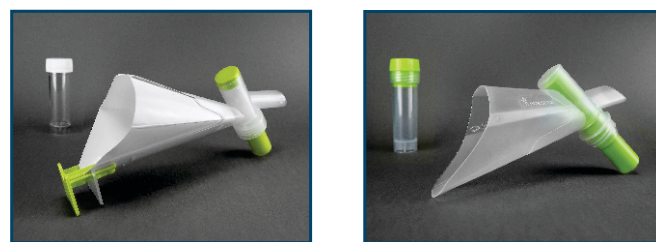


Figure 1: Schematic overview of Colli-Pee timelines.

After market introduction, thorough quality inspection and control tests were implemented to ensure every Colli-Pee going to a customer complied to our imposed quality standards.

Through testing and customer feedback, a second generation of Colli-Pee (FV-5000) was created, significantly reducing the number of components, making the device more straightforward to produce as well as easier to use. With this upgrade, chances of spillage during collection decreased and ease-of-use was rated higher (Figure 2). In June 2015, the device was CE-marked.



CP-2000

FV-5000

17% decrease in spillage
9% increase in ease-of-use
(up to 91% of users rating the device easy to use)

Figure 2: Picture of CP-2000 (left) and FV-5000 (right).

In March 2018, a new device was launched in the market: Colli-Pee containing Urine Conservation Medium (UCM) preservative. This allowed for home-use and collection, by preserving the urine sample during storage and transport. In October 2018, Colli-Pee with a transportation clip was further introduced. This clip squeezes the funnel of the housing to allow postal delivery of the device.

Over the years, through customer requests as well as potential market needs, continuous developments have been made to offer new applications in urine testing. In 2019, NovoSanis developed the Colli-Pee platform (Figure 4), adding two new volume variants of the Colli-Pee device. The new variants allow collection of both smaller and larger volumes urine (4 mL to 45 mL), compared to the original 20 mL. CE-marking of the new variants is targeted for 2020.

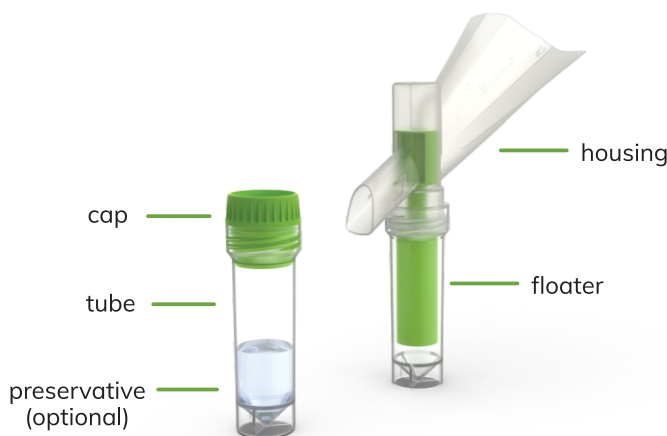


Figure 3: Visual representation of Colli-Pee components.

HOW IT WORKS

The Colli-Pee platform is designed to suit both men and women. The device consists of various components, including a housing, a moving floater, a collector tube, and a cap (Figure 3).

At first, the user urinates into the Colli-Pee housing – This can be done either by standing towards the toilet or in a sitting position. The funnel of the housing is designed to create a large surface area to easily guide urine into the device. This decreases the chances of spilling.



Figure 4: Visual representation of the Colli-Pee platform.

As urine is being collected, the device goes through three different phases:

- Phase 1 - First fraction of the urine is captured in the collector tube.
- Phase 2 - The increase in the urine level in the collector tube causes the floater to rise upwards.
- Phase 3 - The required volume is captured, activating the floater completely. The floater is now at its highest position, hereby closing the inlet flow in the collector tube. As a result, remaining urine flow is directed towards the outlet of the device and exits into the toilet.

This unique floater mechanism allows urine to be collected without interruption of flow. Additionally, this mechanism ensures that the device captures a standardized and volumetric first-void urine sample.

OTHER BENEFITS OF THE COLLI-PEE DESIGN

Given its unique design, Colli-Pee enables standardized sample collection, and allows users to independently collect urine at home with no/limited training.

Additionally, Colli-Pee collector tubes can be pre-filled with urine stabilization solutions for different urinary analytes, improving storage and transport of urine at ambient temperatures.

Another important feature of Colli-Pee Small Volumes is its compatibility with multiple tubes. This allows the device to accommodate tubes that fit the racks of different high-throughput automated machines, eventually improving lab automation by decreasing manual errors and costs.

As we continue to improve and further develop the Colli-Pee platform, there are challenges to address. Limiting the footprint by finding materials to reduce waste as well as increase recyclability of the device are some obstacles we aim to tackle.

Additionally, generating clinical evidence to increase acceptance in clinical practice by highlighting the benefits and need of a urine collection device, such as Colli-Pee, are necessary to compete with other more traditional testing methods.

For more information: www.novosanis.com

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