GEOMETRIXDESIGN
mechanical design solutions
through inventive engineering

Case Study: Point-of-Care Test Device for Detecting Infectious Bacteria

Client: Healthcare device manufacturer with technology for detection of microorganisms such as infectious bacteria, fungi, and molds

Client Problem: Develop a single platform point-of-care (POC) test device to screen, diagnose, and differentiate many commonly occurring vaginal infections through clinical swab sampling of bacterial vaginosis used to detect and measure the infections. This test device required a simple use sterile sampling and storage carrier for a set of swabs with insertion into a test unit for detection and measurement. Both the swab carrier and test unit would be disposables so a compact and low-cost design was required.

GEOMETRIXDESIGN Solution: Develop an injection molded polymeric design for a swab carrier and test unit that minimized the total number of assembled components, allowed for high-volume automated assembly, and was straight forward and intuitive to use by a clinician conducting an examination.

Design Details: Three swabs samples were required during an examination to conduct the diagnosis of the infections. The clinician was to place the three active swabs into a secure and sterile carrier for later insertion in a test unit for detection. A swab carrier was designed as single injection molded polypropylene component. A living hinge was designed along the edge between the upper and lower halves and snap closure was used along the opposite edge to provide a reliable and secure carrier. The three swabs were mounted into the carrier with snap grooves that attached to the shaft of the swabs. The swabs would slide along these snap grooves during insertion into the test unit. A window in the upper half of the carrier provided access to the swab handles for insertion into the test unit. A peel-a-way film cover was used to maintain sterility for later access through the window. A writable label for patient information was located on the carrier upper.

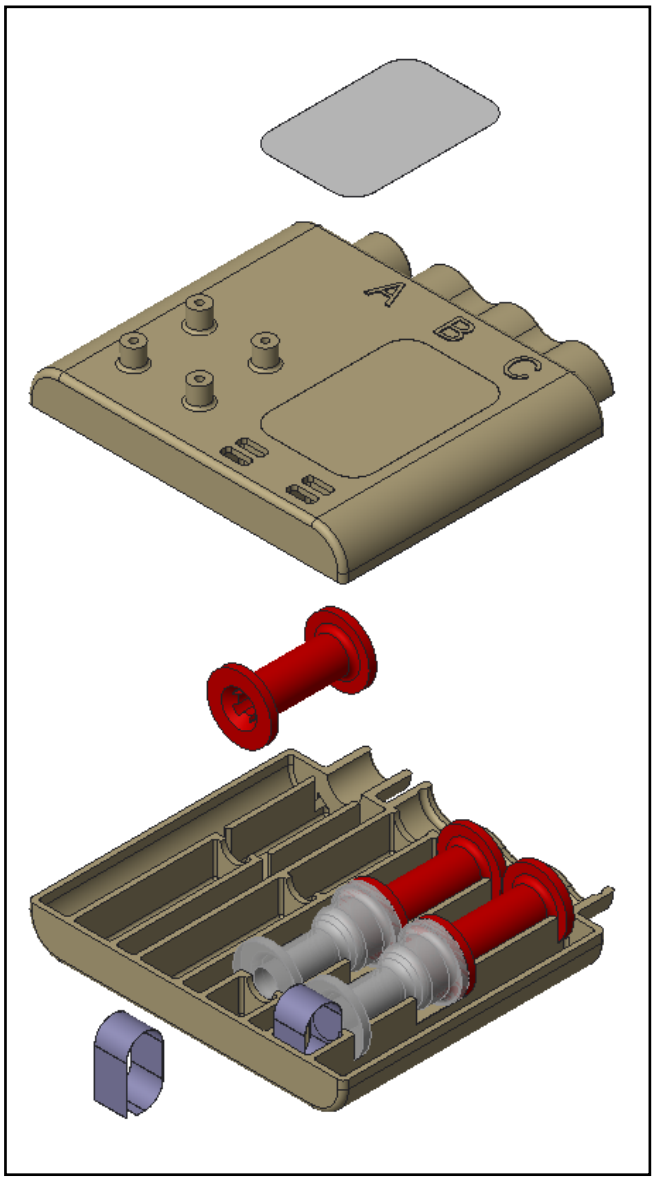
Assembly model of injection molded PP open swab carrier with living hinge and snap closure

Model of swab carrier with window and writable label

The test unit connects to a system for gas phase detection of the microorganism metabolites from the clinical sample to identify the infections. The basic function of the test unit is to extract the aqueous clinical samples from the three swabs and present them for process detection. Extraction of the clinical samples from the swabs consists of individually passing each swab through a split vane component that compresses the swab tip and collecting the samples for sensing. One test consists of measuring pH levels of the clinical samples.

The design of the test unit consisted of two injection molded polycarbonate

components that formed front and back halves of the test unit. Four separate chambers within the test unit were designed to mount the extraction and collection components from the swabs—a fourth swab was used for calibration of the sensing system. The front and back halves were ultrasonically welded together during assembly to form a liquid tight seal.

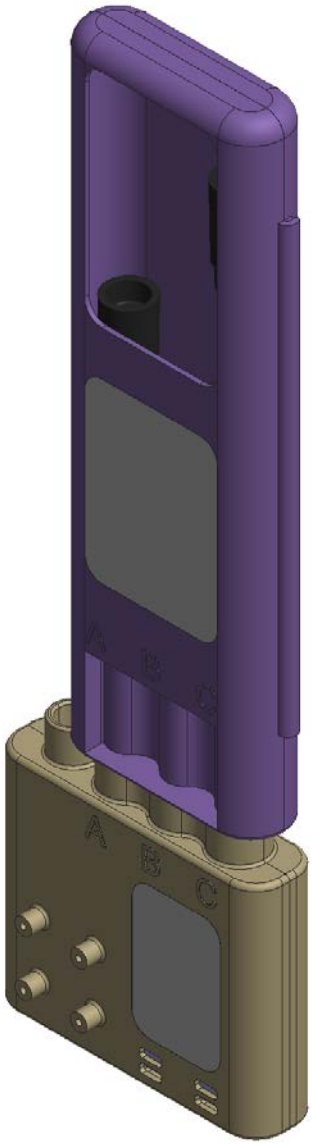


Exploded assembly model of test unit showing internal detection components

Access connections for the gaseous detection and viewing ports for the pH tests were designed on the front half of the test unit. A writeable label was provided for patient information.

During assembly, the extraction and collection components and two litmus samples were inserted into mounting features in the separate chambers of the back half. The front half would be placed onto the back half assembly. Ultrasonic welding was used to provide mechanical vibration at the interface of the polycarbonate component halves initiating melt at the surface interface resulting in a unified bond.

During test and detection, the swab carrier was inserted into the test unit. The peel-a-way cover was removed to access the swab handles through the window. Each swab was inserted into the test unit to extract the clinical samples. The three swabs are marked on both the swab carrier and test unit for safe and accurate testing. Upon test completion, both the swab carrier and test unit were disposed.



Model of the swab carrier inserted into the test unit during test detection

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