

# A Novel Microfluidic POC Device for Blood Collection and Preservation

## Summary

A healthcare customer tasked Gener8 with developing a medical device designed for the collection, stabilization, and transport of whole blood samples. The product had to provide a comfortable and convenient method of blood collection anytime and anywhere.

## Methods Employed

Following brainstorming sessions, several methods were explored to develop a device that would draw blood without pain. First, Gener8 integrated design, prototyping and fabrication of the consumable to allow testing of multiple concepts to accelerate development time. After testing several concepts, we settled on a design that incorporated a vacuum to draw a specific volume of blood based on air displacement with the push of a button that released the vacuum. Using a hydrogel adhesive, this created a suction on the skin to create a bulge. A second button was pressed that released a spring that pushes the lancets into the arm. The design incorporated a second spring that retracted the lancet from the arm and the blood was drawn into a second chamber where the sample wicked onto a matrix for stable storage and shipping. During the project, many material were tested, shelf life experiments were performed as well as FEA testing.

## At A Glance

### Customer

Biotech company

### Product

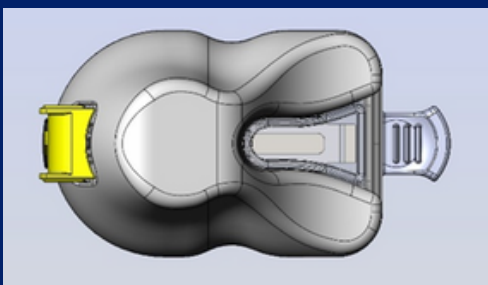
Painless blood collection and preservation device

### Services/ Market

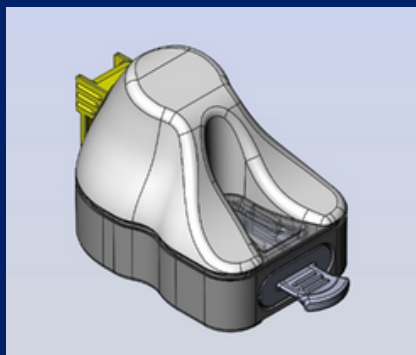
Healthcare

### Challenge

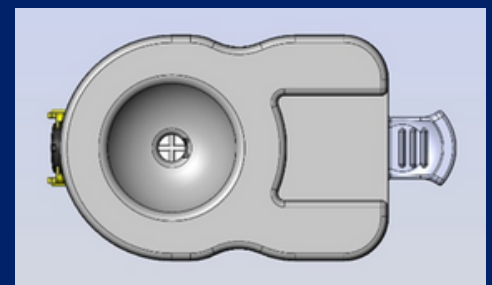
The primary challenge was to design and develop a system for high-volume manufacturing to painlessly draw >100  $\mu$ l of blood and deliver it to a stabilization matrix for room temperature transportation to a clinical lab for testing. A second challenge was in determining a suitable method to control the depth of tiny lancets to eliminate pain during the blood draw process. In addition, the device had to be capable of holding a vacuum for an extended shelf life represented a material science challenge due to vapor transmission.



Top view of final concept



Isometric view



Bottom view

## Solution

Gener8 met the customer's requirements in designing and developing a simple, easy to use, compact POC device that attached to the upper arm with a hydrogel adhesive and vacuum where the sample is taken with the push of a button and blood is stabilized within a removable cartridge. A transparent window on the device provided a visual indication to confirm sample collection. We also incorporated industrial design and a simple user interface to provide an intuitive and easy to use device. Gener8 manufactured and assembled more than 1,000 devices for use in clinical trials. The device received 510(k) clearance and was the winner of the 2020 Red dot product design award.



Top and side views of final design concept.

## Expertise Employed

- High-volume consumable development
- Industrial Design for manufacturability
- Project Management
- Fluidics and air movement
- Vacuum manifold
- Design of miniature molded button and spring mechanisms