

Dario Case Study

Customer Challenge

A leading global digital health company, headquartered in Israel, wanted to produce an IVD device for people with diabetes looking for a convenient health management solution. The client was looking for a medical device company that could produce a device prototype within three and a half months. The company had worked to design a model of a pocket glucose monitor that would work with smartphones to record a blood sugar log and allow the user to access their past test results via a digital menu on an app. The product, the Dario™ Blood Glucose Monitoring System, would be one of the first personalized smart meters on the market at that time. Even though Via Biomedical does not usually offer electromechanical manufacturing, Via's engineers decided to tackle the project head on.

The internationally-based client had obtained funding to work on their project but needed additional funding to move their concept closer to market introduction. The client already had promotional material and an app created for the device. The challenge was to create a working prototype by the end of the year, which was the client's deadline for presenting a working model to obtain continued medical device funding. The client came to Via Biomedical in mid-September. With three and a half months left to finish the project, Via Biomedical engineers sat down to plan within the timeline.

Via Solution

Via communicated with the client over the phone, email, and conference calls, as well as at Via Biomedical offices during monthly client visits. Via coordinated tasks in parallel, prepared with multiple backup plans so that no time would be wasted.

The first month of the project involved redesigning the client's original model, which had problems with device manufacturability. The client envisioned a compact medical device that would hold test strip cartons and a covered lancet. They wanted a seamless aesthetic design with laser markings and printed symbols.

Via designed plastic, metal, and silicone parts, some of which were sourced through contract manufacturing services and vendor coordination. Via asked their vendors to create twenty-eight molds in six weeks. Via Biomedical interfaced with over 20 subcontractors including

- Plastic injection molding companies
- Pad printing and packaging providers
- Silicone manufacturers
- Machinists
- Sonic welders
- Electronics engineers
- Lancet suppliers

Back at Via Biomedical, sales and engineering personnel worked together to assemble parts and direct the suppliers and subcontractors.

When designing the dimensions of the Dario™ Smart Glucose Meter, Via had to redesign the injection molded plastic parts. This involved adding draft angles, adding for shrinkage, and changing assembly techniques as the project evolved; some of the original parts were geometrically un-moldable. The



customer was looking for a working prototype with a “commercial look,” so printed parts could not be used.

In addition to design, Via worked to create a quality container that would hold and dispense test strips for the user while sealing out moisture. Via built an environmentally controlled dry room at the Via Biomedical labs for dry assembly, at no cost to the client. This climate-controlled room allowed engineers to count and transfer test strips into their individual cartons without damaging the test strip components.

After many long hours put in over the holidays, Via’s engineers began testing a compact model. Via’s team tested the cock and release of the spring-loaded lancet to the client’s specifications. Other aspects of testing included checking to make sure the dongle would release from the actual device, fit and work with a smartphone, and snap back on to the monitor. To accommodate the client’s timeline, Via’s team often worked late nights and brought their work home with them.

Resolution

Finally, on December 31 around midnight, Via glued the last piece of the working prototype together. The client’s president had been in the U.S. and was set to leave that morning at 5 AM. Instead of waiting to ship the prototype to the client, Via’s engineers drove to the client’s hotel to deliver the product in time for the president to personally bring it back to their headquarters. The client left on a plane with the confidence that their company would receive their next round of funding because they had a working prototype finished by their deadline.

Following the device completion, Via Biomedical provided the client with the information and paperwork for them to obtain CE compliance. Throughout the project, Via kept to the client’s specifications so that compliance testing and inspection was successful. Via Biomedical designed custom packaging for the Dario™ Blood Glucose Monitoring System.

The Dario™ Blood Glucose Monitoring System is commercially available in the U.S., Canada, United Kingdom, Germany, Italy, Netherlands, and Australia. This pocket glucose monitor requires no cables or batteries. It automatically records blood sugar log measurements and provides an analysis viewable on a smartphone. The app allows the user to track carbs, physical activity, and medication intake, as well as share the information with family members or physicians. Complete with a spring-loaded system that holds blood glucose lancets, the all-in-one glucose meter comes with a replaceable test strip carton that is attached to the device. The dongle, also designed to be stored on the monitor, can be snapped off to connect directly to a smartphone. The dongle holds a port to insert the test strips in for a blood sugar reading.

Since submitting the early version of the Dario™ Blood Glucose Monitoring System, Via Biomedical has used their project management skills for countless other manufacturing challenges. Via Biomedical’s team continues to go above and beyond to meet their clients’ timelines, budgets, and specifications.

[Contact us](#) to learn how Via Biomedical can design, develop, and manufacture medical OEMs and turn your device design into a working product.