



## Continuous Blood Glucose Monitoring Device

### MPR Develops Automated Diagnostic Device for Blood Glucose Monitoring

#### Practice Areas

- Medical Devices
- Diagnostics
- Laboratory Instruments
- Analytical Instruments
- Biotechnology
- Pharmaceuticals

#### Product Types

- Durables
- Disposables
- Packaging

#### Service Areas

- Research and Development
- Voice of the Customer
- Conceptualization
- Proof-of-Concept
- Detailed Engineering
- Industrial Design
- Design for Manufacturing
- Supply Chain
- Regulatory
- Intellectual Property
- Scale-Up
- Fundraising
- Device Certification

#### CHALLENGE

An MPR client desired a medical device capable of automated glucose monitoring using a conventional in-line intravascular (IV) catheter. The device was to be designed specifically for patients undergoing intensive insulin therapy in critical and intensive care units. It was required that the monitoring system would automatically sample the patient's blood, test the blood for glucose levels, and reinfuse the blood into the patient, ensuring the entire fluid pathway was kept clean for extended periods of time (up to four days). In addition, the device was required to operate in an automatic unattended fashion and report any abnormal readings.

#### SOLUTION

MPR developed a unique automated instrument based on technology in commercially available glucose meters to meet the requirements of the client's device. The durable instrument utilizes a syringe pump and a variety of sensors, including an Air-In-Line sensor and Blood-Saline sensor, and actuators to control the system and ensure correct positioning between the durable and disposable units. A custom RFID antenna is also integrated into the device to maximize patient safety. A graphical LCD, membrane keyboard, and jog wheel enable easy setup and alarm management, and an external interface to popular infusion pumps is also provided so that a single IV line can be used with the glucose monitoring device and existing infusion pumps. The durable is also designed for quick loading of the disposable kit. MPR performed all aspects of the work including industrial design, custom circuit boards, graphical display, software design, and full-system verification and validation testing.

#### RESULTS

The resulting diagnostic system is an easy to use solution and provides for unattended operation for as long as the IV set is in use, providing real-time glucose readings to improve treatment. Consumable portions of the device may also be changed without disrupting other operations, including IV tubing priming. The intuitive software interface is best-in-class as compared with similar devices (infusion pumps) and enables clinicians to setup the device quickly and obtain automated glucose readings as frequently as 15 minute-intervals with trending of past readings available. Patient conditions requiring attention are clearly indicated through visual and audible alerts and alarms. .

#### TIMELINE 9 Months














## Diagnostic Disposable Development

### MPR Designs Innovative Disposable Kit for Blood Glucose Testing

#### Practice Areas

-  Medical Devices
-  Diagnostics
-  Laboratory Instruments
-  Analytical Instruments
-  Biotechnology
-  Pharmaceuticals

#### Product Types

-  Durables
-  Disposables
-  Packaging

#### Service Areas

-  Research and Development
-  Voice of the Customer
-  Conceptualization
-  Proof-of-Concept
-  Detailed Engineering
-  Industrial Design
-  Design for Manufacturing
-  Supply Chain
-  Regulatory
-  Intellectual Property
-  Scale-Up
-  Fundraising
-  Device Certification

#### CHALLENGE

An MPR client develops bedside diagnostic analyzers to monitor blood characteristics in critically-ill patients. A new continuous blood glucose monitor developed by MPR required the design of a disposable system that would allow for the sterile sampling, evaluation of blood, and reinfusion of blood into the patient. The core technology was specified by the client and consisted of commercially-available glucose test strips. It was also desirable to minimize the amount of blood used for each glucose reading to the order of 10 microliters. Blood drop sizes in this range are very challenging and required special attention to the consumable design.

#### SOLUTION

In addition to the durable diagnostic device, MPR developed a consumable kit consisting of an IV tubing set and test strip cartridge. The IV tubing kit housed a syringe, tubing, valves, and dispense nozzle, in addition to an integrated disposable pressure sensor. The test strip cartridge contained the test strips and sterile barrier. RFID technology was also integrated into the consumable for lot traceability and patient safety. The consumable kit optimized nozzle design, an intermediate transfer well, and test strip cartridge design. Geometries and surface treatments were utilized to significantly reduce the amount of blood required for testing as it traveled from the nozzle - to transfer well - to test strip. The consumable was tightly integrated with the durable instrument to provide a click-in loading approach that allowed for a variety of components to be simultaneously inserted into their corresponding durable interfaces.

#### RESULTS

MPR successfully developed a low-cost disposable test cartridge integrating the use of the client's commercial test strip selection, in addition to the IV set, with a loading time of less than one minute. The separate test strip cartridge enables quick replacement of test strips without affecting other operations of the device. Development of the disposable kit was taken from concept to operational device in less than 9 months.

#### TIMELINE 9 Months

