

**Applied Sciences Group, Inc. - Cardiac Monitoring System  
White Paper  
February 24, 2009**

**Overview**

Applied Sciences Group is under contract to develop a Cardiac Monitoring System (CMS) using a dual balloon esophageal catheter to measure cardiac performance. A medically trained operator inserts the catheter through the nose into the esophagus, and uses an Electronics Unit (EU) attached to the catheter to position and inflate the balloons behind the left atrium and aorta. Pressure, audio and ECG measurements are taken and physiological parameters are derived from them.

The project was a group effort between four corporate teams with specific skill sets to contribute to the product development process. Although the teams were separated geographically, coordination of many of the tasks was completed with little difficulty and in a timely manner.

Applied Sciences Group, Inc. (ASG) was responsible for the daily planning and software management of the project. The assigned project manager coordinated the technical efforts, provided the systems engineering inputs, initiated staffing requests and provided regular and timely communications between the teams. The engineering team contributed to the requirements specification and risk analysis, and provided the software architecture design as well as the detailed software design, coding and documentation. ASG was also responsible for quality control oversight that included support on FDA regulatory issues: including identification and implementation of appropriate standards and formal compliance testing.

The CMS relies on significant mathematical analysis and to isolate the signals of interest from interference due to respiration, peristalsis and other contributions to pressure noise. ASG was responsible for the development and tuning of all algorithms to accommodate a broad range of patient physique and size, and to provide reliable, accurate results.

ASG also provided guidance to overall system design and led the design of the user interface.

As a part of the overall development, ASG employed a controlled methodology to establish a verification plan and validation procedures to demonstrate that the design met the defined requirements. This process, consistent with FDA regulatory requirements, is intended to provide quality software development across all projects.