

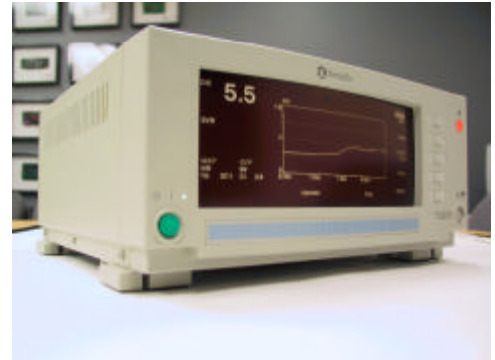
<b>Client</b>	InterFlo/Baxter Healthcare
<b>Project Name</b>	Vigilance Cardiac Output Monitor
<b>Industry</b>	Medical
<b>Location</b>	Plano, TX
<b>Class of</b>	1990
<b>Customer Type</b>	New

InterFlo/Baxter benefited from the Paragon Innovations approach of collaboration, innovation and efficiency to develop a device that improved physicians' ability to monitor cardiac patients' cardiac output. The project was completed ahead of schedule and is the first electrical medical device to secure FDA approval on its first submission, the direct result of Paragon's documentation process.

## OVERVIEW

For years, the accepted method of monitoring and measuring blood temperature in a patient with cardiac problems was to inject 10 to 20 cc's of freezing saline solution into the patient and then track the liquid. Doing so

was less than ideal, however, since the cardiac output reading so critical to the patient's care lacked the highest levels of accuracy, and also because the process of adding fluids complicated the patient's problem. To improve this process, InterFlo/Baxter sought to develop, design and manufacture a diagnostic device that combined the concepts of a thermo-dilution and revolutionary new catheter.



Paragon Innovations was retained to work collaboratively with a team of seven InterFlo/Baxter software and hardware development engineers who realized that quality was of the utmost importance in designing, developing and manufacturing a medical device. Paragon brought high standards of performance to the design and development process. And by contributing several innovative approaches – such as recommending and then implementing an extensive real-time diagnostic system – the company helped InterFlo/Baxter reduce costly development errors, accelerate its time-to-market, and eliminate the gap that often exists between designing a device and being able to manufacture it reliably and efficiently. Today, both the device and the process developed by Paragon are still hard at work, helping physicians obtain high-quality information for saving lives.

## RESULTS

- Produced the first electronic medical device to secure FDA approval on its first submission.
- Engaged in a collaborative approach to produce better problem resolutions, which helped deliver a high quality device while reducing design and development time.
- Developed a diagnostic system that allowed animal studies and human studies of the prototype to occur six to nine months ahead of normal schedules.
- Provided complete hardware and software documentation that became a standard procedure in other Baxter design and development projects.

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“  
...We ended up with a  
good solid design and  
innovative ways to  
implement solutions.”

Mike Quinn  
Vice President R&D

[www.paragoninnovations.com](http://www.paragoninnovations.com)



2100 10th Street, Suite 100  
Plano, Texas 75074

**972-265-6000**

#### **Prior Outsourcing Experience**

- None

#### **Services Provided**

- Architect RTOS system
- Software development
- Electronic design
- Power-on self-test design
- Diagnostics software / hardware platform
- Support for clinical trials
- Provided technical support

#### **Firsts for Client**

- First time that outsourced to Paragon

#### **Firsts for Paragon**

- First medical product development
- First DSP based product
- First multiprocessor design loaded from one CPU

#### **Features Suggested by Paragon**

- Head start on Functional Test Fixture for Engineering, Manufacturing, and clinical data replay
- Script processor based testing for manufacturing
- Extensive diagnostic software

#### **Target Production Size**

- Between 1000-5000 per year

#### **Hardware Features**

- TI 320C30 DSP, 80186, TI 340C10 Video processor
- Multiple 8051 processor
- Early SMT design
- Catheter connectivity

#### **Software Features**

- Power-on self test
- Extensive Diagnostics
- VRTX™ RTOS
- Factory acceptance test

#### **PCB Technology**

- Multiple boards including 10 x 12 inch, 8-layer board
- Allegro, 8/8 design rules layout package

#### **Primary Hardware Vendors**

- Texas Instruments

#### **Languages**

- C
- MATLAB
- 80186 and 8051 Assembly
- TI 340C10 Assembly and C