# CAL-BAY SYSTEMS

Solutions for Test, Measurement & Automation

## Delivering global "Risk-Free" Test and Measurement Solutions for the Bio-Medical Industry

- Bio-Medical
- Biotechnology
- HASS / HALT testing

## Productivity Enhancing T&M Products

- FTS-200 Low Volume/High Mix Functional Test Solutions
- Test Data Management, Analysis and Report Generation

# CUSTOMER SOLUTIONS AND PRODUCT GUIDE

NATIONAL INSTRUMENTS
Select Alliance Partner

WWW.CALBAY.COM

# CONTENTS

# POWERPOINT PRESENTATIONS

Overview of Cal-Bay Systems

Test Solutions for Electronic Medical Devices

# CAL-BAY SYSTEMS CORPORATE OVERVIEW

- WHO IS CAL-BAY?
- WHERE IS CAL-BAY?
- CAL-BAY SERVICES
- WHY CHOOSE CAL-BAY?

1

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# WHO IS CAL-BAY?

- Cal-Bay Systems is quickly becoming the **largest, worldwide** solution provider for Test & Measurement systems, with operations in more than 10 cities.
  - Founded in 1992
  - Select Integrator of National Instruments (top 5 out of 700+ NI alliance partners)
  - Agilent Channel Partner
- Prize-winning projects and innovative products
  - Over 100 User Solutions
  - Web-based marketplaces like justTESTx.com
  - Platform products like the FTS-200 and IntraStage

2

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

## WHERE IS CAL-BAY?

3

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

## GLOBAL BRANCH OFFICES…

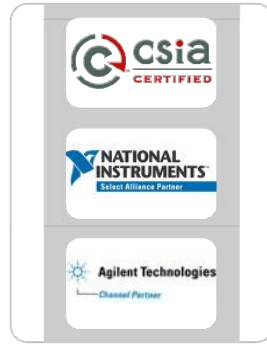
- Headquartered near San Francisco
  - Other California offices: San Diego, Irvine
- West Coast: Portland, Seattle, Arizona
- Rest of US: Texas, Virginia, Maryland
- Europe: UK, Spain
- Asia: Bangalore, India

4

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# CAL-BAY QUALIFICATIONS

- **CSIA Certified Member, audited in areas of:**
  - PROJECT MANAGEMENT
  - ENGINEERING PRACTICES
  - FINANCIAL MANAGEMENT
  - STANDARDS & QUALITY PROCEDURES
- Engineering Practices
  - RE-USABLE CODE & TECHNOLOGIES
  - SOURCE CODE CONTROL
  - INTELLECTUAL PROPERTY PROTECTION
  - ON-LINE BUG TRACKING



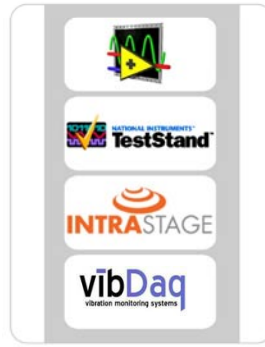



CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# SOFTWARE DEVELOPMENT

- Software Expertise:
  - LabVIEW
  - TestStand
  - Visual Basic / C / CVI
  - Test Data Management (IntraStage)
- Applications:
  - Low Volume / High Mix Functional Test
  - Automation with Instrument Drivers
  - Vibration Test & Monitoring
  - Windows-Based / Embedded / Real-Time
  - Motion, Vision, Industrial Control

LabVIEWexpert.com

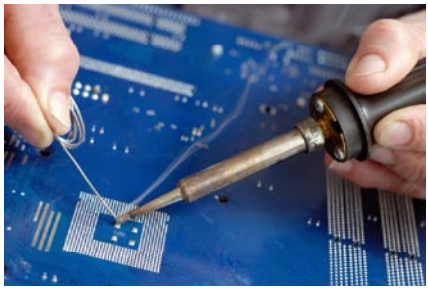





CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

## HARDWARE INTEGRATION

- Mechanical Design
  - Solid Modeling
  - Enclosures
- Electrical Design
  - PCA's
  - Custom Wiring Harnesses
  - Analog / Digital Design
  - Simulation
- Fabrication & Assembly
  - Order a complete test system as a single line item
  - Rigorous Configuration Management (CM) with online PLM





CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

## PROJECT MANAGEMENT

- Cal-Bay's Core Competence:
  - Project Management of Automated Test Systems
- The three constraints of Project Management
  - Cost
  - Schedule
  - Feature Set
- Best Practices
  - Spend proper time up-front on design and architecture
  - Break the project into managable components
  - Do "Build vs Buy" analysis on every component



CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

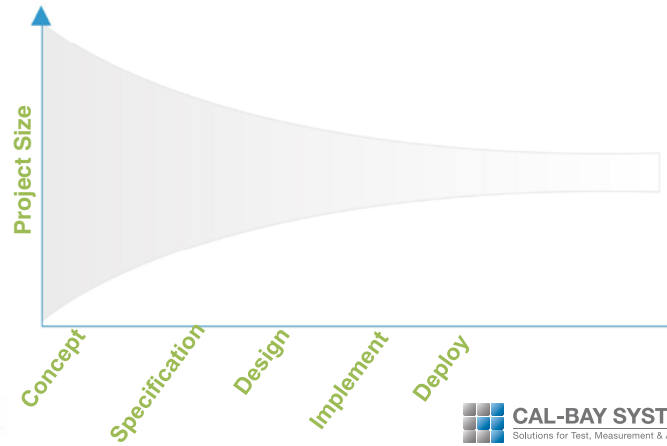
# TEST PROJECT PHASES

- SPECIFICATION
  - What the System MUST do (taking into account ALL stakeholders)
  - Interactions with DUT (Device Under Test)
  - Use Cases / Process; Initial User Manual / Screen Shots
  - Well-Formed Requirements (capable of Acceptance Test)
- DESIGN & DESIGN REVIEWS
  - Preliminary Design Review (PDR) and Critical Design Review (CDR)
  - Risks, Prototyping, and Risk Mitigation Processes
- IMPLEMENTATION
- VALIDATION AND ACCEPTANCE TEST
- DELIVERY

9

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# MAKE YOUR TEST PROJECT A SUCCESS BY UNDERSTANDING THE CONE OF UNCERTAINTY




10

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# WAYS TO ENGAGE WITH CAL-BAY…

- There is NO "One-Size-Fits-All"
  - Every client engagement is unique
- FIXED PRICE
  - With a "good spec", we can deliver "Turn-key" Systems
- TIME & MATERIALS
  - Without a detailed spec, we can place skilled engineers on-site
- HYBRID
  - T&M in early phases, followed by Fixed Price integration

11

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# CAL-BAY CLIENTS INCLUDE…

FUJITSU · Honeywell · KYOCERA · QUALCOMM · LOCKHEED MARTIN
Medtronic · LCS · NORTHROP GRUMMAN · Snap-on · XPO
Texas Instruments · Schlumberger · APPLIED MATERIALS · BOEING · St. Jude Medical
L3 communications · Panasonic · IBM · GOODRICH · Solar Turbines
Powerwave · GE · HITACHI Inspire the Next · BROADCOM · intel

12

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

## WHY OUR CLIENTS OUTSOURCE…

- Our clients are focused on improving the designs and profit margins of their products
  - Automated Test is a “necessary evil” to achieve this goal
    - In R/D, they use automated test for characterization
    - In Production, they need functional test systems & debug stations
    - They also need to support field test
- Our clients’ core competency is NOT automated test system development
  - In-house staff are often “lean”
  - Clients count on Cal-Bay to know latest technologies and best practices
  - Clients know that Cal-Bay can support them later, long after the initial project is finished

13

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

## TOP FIVE REASONS CLIENTS CHOOSE TO OUTSOURCE WITH CAL-BAY SYSTEMS

1. THE POWER OF TEAM
   - Cal-Bay has more certified LabVIEW and TestStand engineers than virtually any company in the world
2. OUR CORE COMPETENCY: AUTOMATED TEST
   - With world-class standards for Project Management
3. UNMATCHED TEST SYSTEM EXPERIENCE
   - Thousands of solutions integrated for hundreds of clients
4. A TRUSTED PARTNER
   - Financially stable; 16 years of growth; Solid Reputation
5. SIGNIFICANTLY LOWER RISK
   - A track record of staying on budget and on schedule

14

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# CAL-BAY SUMMARY

- TIME-TESTED AND PROVEN
  - 16-year track record
- OUR CORE COMPETENCY:
  - Project Management of Automated Test Systems
- Basically:
  - **Cal-Bay LOWERS the RISK of Automated Test Projects**
- Let's build an extraordinary solution together!

15

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Test Solutions for Electronic Medical Devices

1

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

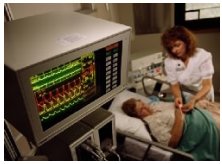
## Goals of Presentation:

- This presentation will address:
  - Specific test needs in Biomed/Biotech
  - Cal-Bay Systems experience in the market
  - Best Practices discovered and off-the-shelf tools
- Scope of this presentation:
  - Limited to electronic medical devices
  - Limited to Functional Test
  - Focused on R/D and Production environments

2

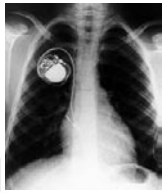
CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Medical Device Examples



Bedside Patient Monitor:
Measures ECG, NIBP, Sp02, Temperature

Ambulatory Monitor:
Measures pH, ECG, NIBP over extended time periods; battery powered



Implanted Devices
Heart Pacemakers, Defibrillators that help overcome organ failure

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Device Categories:

- Non-invasive Patient Monitoring
  - ECG, NIBP, Sp02, Temperature
- Implanted devices
  - Pacemakers, Defibrillators
- Wireless telemetry devices (in-body sensor)
  - Ambulatory PH, ECG, Temperature
- Human Body Simulation
  - Simulation of body responses to validate and calibrate medical instrumentation

4

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Functional Test Requirements

- On one hand, testing medical devices is similar to testing other electronic devices
  - There are a variety of analog and digital signals that need to be monitored
  - Fixtures need to be built to interface between instruments and the DUT (Device Under Test)
  - Test Software needs to be written and validated
  - Results need to be written to file or databases
  - Managers and engineers need reports from data
- These requirements are similar for all electronic test systems

5

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Unique to Biomedical Devices...

- On the other hand, testing biomedical devices **is very different** from other electronic devices
- There are often **Regulatory Issues**:
  - The system may require audits related to FDA regulations
  - This may involve validation of the test software, the instrumentation, and the operator process
- Biomedical Devices typically have longer life cycles
  - For example, while a cell phone can be obsolete and break down in two years...
  - An implanted device may need to last 20 years inside a human body

6

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Best Practices for Functional Test

- Use a flexible test rack with a mass interconnect
  - Same instrumentation, different DUTs (Low Volume / High Mix)
  - Different fixtures plug into the mass-interconnect
  - The DUT plugs into the fixture and not the instruments
- Use a scalable software architecture
  - Test Executive software which is standardized for all DUTs
  - Re-use GUIs, instrument drivers, result logging methodology, configuration methodology, report tools
  - Only the high-level test steps change
- Use a Self-Test Diagnostic Fixture (STDF)
  - This fixture and code lets you quickly “Test The Tester”
  - No need for “golden DUTs”





# Case Study: Automated Test for Patient Monitoring

# What is Patient Monitoring?

- Non-Invasive Instruments that measure basic vital signs
  - Pulse Rate
  - Blood Pressure
  - Blood Oxygen Concentration
  - Electro Cardiogram (ECG)
  - Temperature
  - Respiration
- Used by doctors, nurses and consumers

9

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Typical Problems with Testing

- Multiple products and variations of products to test
- Individual pod or module testing combined with final system (pre-delivery) test
- Difficulty sourcing one test solution as each module's test needs are extremely varied

Typical Pod Device

Typical Final System

10

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

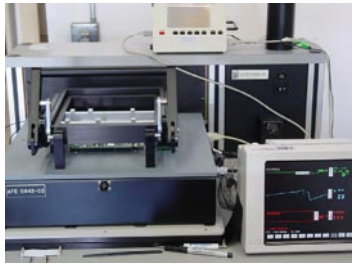
# Scenario: Bedside Patient Monitor Manufacturer Test System

## The Challenge

Replacing manual module test procedures with automated systems for the development and production test of combined patient monitoring products

## The Solution

Using LabVIEW as the common software platform and PXI-based instrumentation hardware, we simulated sensors to test the modules, and replicated the user interface. The results were faster test times and more repeatable and accurate results.





CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Typical test requirements for individual measurements



CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Pulse Rate and Blood Oxygen

- Both parameters are often measured with a Near Infrared (NIR) Sensor.
- Commonly called SpO2, the sensor often clips on the finger
- Typical test requirements
  - Sp02 sensor simulation LabVIEW control of SmartSat Simulator (by Clinical Dynamics)
  - Multiplexing between SmartSat and fingerclip sensors
  - Module calibration
  - Pass/ Fail module test

13

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Non-Invasive Blood Pressure (NIBP)

- Automated measurements
  - Use pumps and pressure sensors to replace manual squeeze bulb and pressure gauge
- Typical test requirements
  - Mechanical pump test (including over-pressure test)
  - Pressure sensor calibration (precise to 1 mm Hg)
  - Pass/ Fail module test

14

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Electrocardiogram (ECG)

- Measure action of heart muscles
- Typical test requirements
  - Simulation of ECG signals with AWG and custom signal conditioning
  - Analysis of module response
  - Pass/ Fail module analysis
  - Simulation Signal can be very small (microvolt waveforms)

15

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Solution: FTS-200 & IntraStage

- To solve the measurements, we used an FTS-200-PMET solution
  - Test Rack designed to handle these sensors and measurements
    - Agilent and NI instruments
    - Virginia Panels Mass Interconnect
  - Standard, Scalable Software Architecture
    - TestStand Test Executive
    - LabVIEW test steps
- To solve the test reporting needs, we chose IntraStage

16

CAL-BAY SYSTEMS, INC.
Solutions for Test, Measurement & Automation

# Cal-Bay Systems FTS-200x core Medical Device Tester

- One test rack designed to test multiple DUTs
  - Test Fixtures can be quickly swapped through use of a mass interconnect panel
- A typical facility will have several FTS-200 systems and multiple fixtures
  - By standardizing, all maintenance is identical (setup, self-test, calibration)
- PXI & LabVIEW lower tester cost
- FTS-200 & IntraStage lower NRE cost

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# FTS-200x Example "Flavors"

**FTS-200-IDT (Implanted Devices Tester)**
- Pacemaker
- Defib
- Micro pump
- Various wireless XDUCER
- Wireless telemetry
- Ambulatory pH, ECG, BP
- Human body sensors test

**FTS-200-PMET (Patient Monitoring Eqpt Tester)**
- SPO2
- NIBP
- ECG
- Emp-ETC

**FTS-200-HASS (Stress Testing)**
- Temperature
- Pressure
- Vibration
- Shock

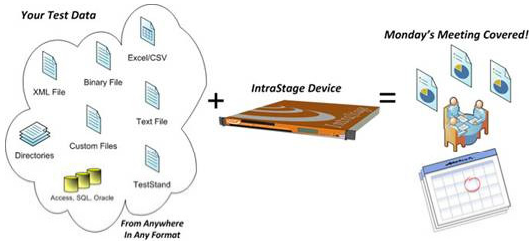
FTS-200x Core spec:
- Ruggedized mechanical enclosure
- High quality fixture interconnect
- Short cable lengths (provides low noise and leakage)
- Small footprint
- State of the art PC performance options
- High quality PXI based Modular Instrumentation
- Swing arm mounted monitor for ease of use
- Optional Light Tower
- System Self test using gold standard fixture (option)
  - Medical grade QA
  - Documented validation
  - FDA process capable

18

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Managing Your Test Data

- We have standardized on INTRASTAGE






CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Why IntraStage?

- IntraStage, Inc. offers products and services specifically for managing Test Data
  - Exclusive focus on this core competency
  - Test data from multiple ATE's is automatically pulled into this standardized database
  - Web-based reports are served up for engineers and managers
  - The ability to integrate with ERP systems and other enterprise databases is easily handled
- "Out of the box" solution for data storage and reporting



CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Cal-Bay Total Solution

- Custom design and build an FTS-200 system per each unique client's requirements
  - Once designed and validated, the solution becomes an orderable part (single line item) from Cal-Bay
- Architect and develop custom software leveraging LabVIEW & TestStand
- IntraStage for Test Data Management
- Design custom hardware fixtures
- Assist in regulatory audits of the system

21

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# Track Record of Success

- Cal-Bay Systems has delivered solutions to many of the top Medical Device Manufacturers
  - For both R/D and Production test environments
- Some of our customers include:

Medtronic

ST. JUDE MEDICAL

NELLCOR

SPACELABS Healthcare

22

CAL-BAY SYSTEMS
Solutions for Test, Measurement & Automation

# BIO-MEDICAL

LabVIEW Control System Assures
Artificial Heart Doesn't Skip a Beat

■

Medical Stent Production Test

■

Automating the Validation Process of
New Implantable Insulin Pump Designs

■

Success Story

# LabVIEW Control System Assures Artificial Heart Doesn't Skip a Beat

## The Challenge

Developing a closed-loop control system to test the reliability of blood pumps used in circulatory support systems. The control system was also used to develop new control algorithms subject to FDA review and was eventually used in functional validation trials on animals.

## The Solution

The multithreaded features of LabVIEW along with a PC-based data acquisition card enabled dependable control of four pumps for an extended period of time.


## Abstract

An implantable ventricular assist device (VAD) is a pneumatically controlled device (pump) used to assist a patient's ailing heart until a donor heart becomes available for a transplant. A closed-loop control system had to be developed for use during reliability testing of a new pump design and to enable the fine-tuning of a new control algorithm. A laboratory version of the system controlled eight pumps, uninterruptedly, for a period of over six months while a portable version of the same system was used in field validation trials on animals. The LabVIEW software running on a laptop controlled a VAD that assisted the natural heart rhythm of a test subject for a period of up to 45 consecutive days. The experiments conducted with this system provided critical data during the design verification and validation process for the new pump, thereby obtaining valuable information necessary for the FDA approval process. To date, Thoratec has received permission from the FDA to begin clinical trials on human subjects.


## Introduction

A pneumatic implantable ventricular assist device (VAD) system consists of three major components: a blood pump, two cannulae and an external drive console (Figure 1). The blood pump is connected to the heart with two connecting tube cannulae; one providing inflow and the other, outflow. The external drive console, provides alternating pulses of vacuum and pressure to fill and empty the blood pump. It also maintains control of the pump by using various control algorithms running on a micro-controller.

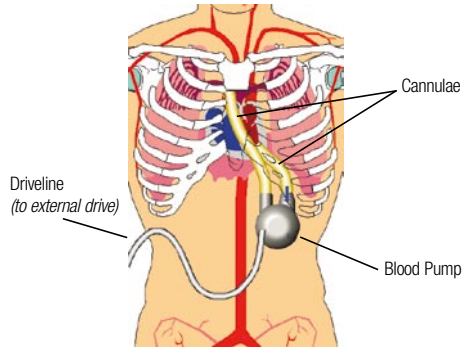



Figure 1. Implantable VAD system shows the assisting blood pump and the cannulae (external drive not shown)

An infrared proximity sensor mounted inside the pump (Figure 2) detects when the pump is filled with blood and sends a signal to the driver to initiate the empty cycle. In essence, the VAD is a closed loop control system with one analog input, the proximity sensor, and one digital output, the signal that triggers the console to empty or fill the pump. The fill/empty cycle of the pump runs at a rate of about one second, whereas the control loop

for the entire system runs at a rate of 4 milliseconds. Therefore, strict timing must be maintained by the console to ensure this artificial heart system doesn't skip a beat.

Figure 2. The new blood pump design required reliability testing in laboratory and field trials

Thoratec Corporation of Pleasanton, California is the world's leading manufacturer of VAD systems approved by the United States Food and Drug Administration (FDA). During the development of this new implantable VAD, Thoratec needed to test the reliability of the new device and to design new control algorithms that would later have to be programmed into a custom micro-controller circuit. In order to carry out these tasks, Thoratec Laboratories called upon Cal-Bay Systems, a system integrator and Alliance member in Northern California, to develop a control system using LabVIEW and National Instruments data acquisition hardware.

Maintaining consistent control of the pump during long-term bench testing and field animal studies was essential. The system had to be robust, yet flexible. Typically, in this type of application, an embedded real-time control system is used to maintain precise closed loop control. But in this particular application, because the pump fill/empty cycle was in the order of one second, the control loop could vary slightly without causing the pump to skip a beat. We decided to implement this system with a regular PC and off-the-shelf hardware and software. The use of a PC-based virtual instrumentation system provided huge cost savings and allowed us to get the system up and running in a matter of days, not months.

## The Hardware

After preliminary research and benchmarks were performed, we decided that one computer equipped with a National Instruments E-series data acquisition card would be used to control a bank of four pumps. Running two identical setups on Pentium III computers with Windows 98, we were able to maintain the 4 msec control loop cycle on eight separate pumps running in parallel without any problems.

We chose the PCI E-series card because it provided multiple functions such as digital and analog triggering for sampling the data and advanced counter/timer features for powering the proximity sensor. Later on, when the field validation testing was conducted, we switched to an equivalent DAQ card designed for a laptop and used the exact same software without modifications.

During actual running conditions, the proximity sensor is powered on for only a short period of time during each 4 ms cycle. This increases the lifetime of the sensor, but increases the complexity of the controller, which needs to supply a constant pulsing digital waveform (TTL) that turned the sensor on, triggered data sampling after a brief sensor "warm-up" period, and turned the sensor off every 4 ms cycle. When the design team wanted to implement this feature, we were able to deliver it easily thanks to the functionality of the E-series DAQ card. Using the general-purpose counters, we triggered the generation of two digital waveforms delayed in time. One was used to power the proximity sensor and the other was used to trigger the data acquisition shortly thereafter. The task of wiring the device was simplified by using the internal signal routing features of the DAQ card (PFI pins) to internally connect the output of the counter to the analog input start signal.

## The Software

The LabVIEW programming environment was the clear choice for this project due to its ease of use and flexibility. The main challenge for this system (Figure 3) was to implement the new control algorithms and maintain control of the pump at a closed loop rate of 4 msec. Considering the fact that the fill/empty cycle of the pump runs at a rate of about once a second, the pump control loop times could vary slightly without causing the pump to skip a beat. In order to maintain this tight loop control, we utilized the advanced LabVIEW features.

First, the data was collected based on a trigger event, it was then passed to a routine that performed linearization and differentiation, and finally it went on to an analysis routine which performed the algorithm that determined when a digital I/O line should go high or low. This entire cycle had to be done within 4 milliseconds or less.

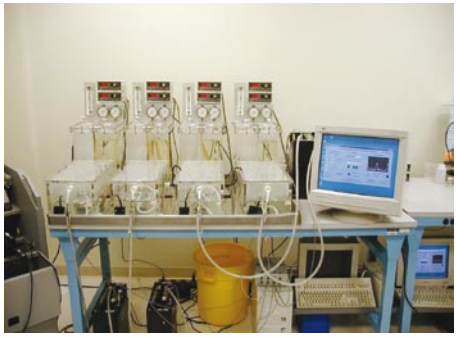


Figure 3. The control system ran four pumps uninterruptedly for a period of over six months.

The general requirements of the software were very simple, but they had to be implemented in a very efficient manner. The analysis VI was configured to run on a separate thread at normal priority. We experimented with different priorities, but concluded that running two separate threads, one for the main VI and one for the algorithm subVI was the most efficient.

Saving data to disk greatly affected the timing of the control loop. The users only needed to collect data for a few pump cycles and they could turn it on or off when needed. In order to collect data for a few cycles and not affect the loop timing, we first buffered the data in a queue and then saved it all at once at the end of the collection period. This prevented processor-intensive hard drive access from corrupting the collected data.

## Conclusion

This simple control and data acquisition system allowed Thoratec engineers to develop new control algorithms and to test the reliability of their new blood pump design. To date, all eight pumps have been operating for over six months, and the tests are ongoing. In addition, during field validation animal trials, this system controlled the pumps of two different test subjects for periods up to 45 consecutive days without interruption. Both the reliability testing bench system and the portable field test system proved to be stable and reliable. The studies done with this system provided valuable information for the FDA approval process. As a result of this and other studies, Thoratec received permission from the FDA to begin clinical trials on human subjects.

*Category: Biomedical, Design Validation, R&D/Lab Automation*

*Products Used: LabVIEW, PCI-MIO-16E-4, DAQCard-MIO-16E-4*

*by Sorin Grama, Cal-Bay Systems, Inc.*
*in collaboration with Jason R. Weidman, Lead R&D Engineer, Thoratec Corporation, Eric T. Lee, Ph.D., R&D Engineer, Thoratec Corporation*

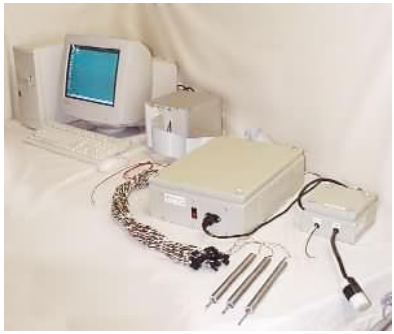
# Medical Stent Production Test

## The Challenge

Automating a high volume production test for a medical device manufacturer that analyzes properties of a medical stent (a device that is placed in an artery to support the arterial walls) and increases existing test throughput by a factor of 10.

## The Solution

Build an automated test system that tests 30 stents simultaneously by simulating the action of the medical device as it is inserted into the body, and measuring its expansion properties.



Production Test System for Medical Device Testing

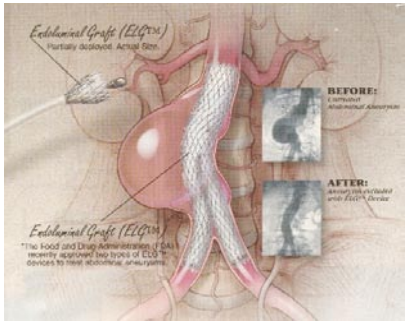

## Abstract

A stent is a spring-like device that is temperature sensitive. Compressed and supercooled, it is inserted into an artery, routed through the body and deployed at the point of an aneurysm, at which time it expands to its desired diameter and supports the walls of the artery. During production, it is necessary to ensure that the stents expand at the proper rate and to the proper size within extremely rigid specifications. Using LabVIEW, PXI, and SCXI, Cal-Bay Systems designed, developed, and implemented a fully automated, FDA approved test system for measuring and comparing the rate of expansion and the maximum expanded diameter of medical stents.


## Introduction

The world of medical treatment is improving every day. Medical research and development is expanding rapidly. Devices that get inserted into the body to assist or sustain are becoming more widely used. In the case of an aneurysm, the walls of an artery become weakened and are susceptible to breakage. A device that supports the walls of the artery in the area of the aneurysm could prove to be invaluable. But how would one get such a device into an artery (some arteries are the diameter of a silver dollar) without disturbing the sensitive area and possibly causing a premature rupture?

A device called a stent is used to prop open and support an artery that is weakened by an aneurysm. A stent is a spring that starts out very small, compressed and supercooled, and is inserted into an artery at a convenient location (usually the inner thigh). The stent is then routed through the artery and deployed at the point of the aneurysm at which time it expands to its desired diameter and supports the walls of the artery. It is necessary to ensure that the stents expand at the proper rate and to the proper size within extremely rigid specifications. A mistake could be life threatening.

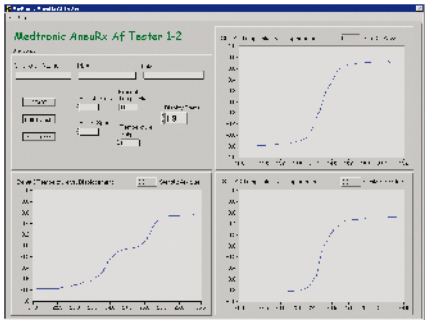



A stent (graft) inside an artery, supporting the arterial walls near an aneurysm

Cal-Bay Systems designed, developed, and implemented a fully automated test system, based on National Instruments PXI/SCXI hardware, for measuring and comparing the rate of expansion and the maximum expanded diameter of medical stents through a range of temperatures. This system replaced an older test system and provided a 10x increase in number of stents that are tested at one time.

## The System

Using LabVIEW and National Instruments PXI/SCXI data acquisition hardware, Cal-Bay designed a state of the art production test system. The system was designed to test the expansion of 30 stents at one time, using LVDT's (linear variable displacement transducers) to determine the diameter of the stents as they are heated from a supercooled state to normal body temperature.




LabVIEW main screen for test system

A PC running a LabVIEW application collects the data and graphs expansion vs. temperature in real time for each stent under test. The user is able to select up to three stents to view at one time. At the end of the test (when the test bath reaches body temperature), analysis is performed on the displacement curve to determine if the stents meet the desired specification. A report is generated for each test.

The software also controls the temperature of the test bath and a pneumatic valve that controls lowering the LVDT sensors onto the stents under test.

With the new test system 30 stents could be tested at one time, where only 3 stents were being tested simultaneously with the old system.

## FDA Validation

The software for this test fixture required FDA validation, and using LabVIEW, an application was written to test every input and every output of the system, complete documentation of calculations, expected results and actual results was provided to the FDA.

## Conclusion

Because of the success and popularity of medical stents in aiding aneurysm patients, and recent FDA approval, production of stents has skyrocketed. The automated test system developed by Cal-Bay Systems allows 30 stents to be tested at one time (an increase of 10x) and there are currently 5 production test systems in use.

*Category: Manufacturing Functional Test, Manufacturing, Biomedical*

*Products Used: LabVIEW, NI-DAQ, SCXI 1100 Analog Input Module, PXI-1010 PXI chassis integrated with SCXI, PXI-6025E Multifunction I/O Card*

*by Dave Weisberg, Cal-Bay Systems, Inc.*

# Automating the Validation Process of New Implantable Insulin Pump Designs

## The Challenge

Replacing tedious manual test procedures and visual inspections with automated systems for the validation of new mechanical and electrical designs of implantable insulin pumps.

## The Solution

image acquisition, motion control and data acquisition cards, we implemented three test systems to validate the new pump designs. The systems replaced existing manual procedures and set the stage for large-volume production testing.


## Abstract

An implantable ventricular assist device (VAD) is a pneumatically controlled device (pump) used to assist a patient's ailing heart until a donor heart becomes available for a transplant. A closed-loop control system had to be developed for use during reliability testing of a new pump design and to enable the fine-tuning of a new control algorithm. A laboratory version of the system controlled eight pumps, uninterruptedly, for a period of over six months while a portable version of the same system was used in field validation trials on animals. The LabVIEW software running on a laptop controlled a VAD that assisted the natural heart rhythm of a test subject for a period of up to 45 consecutive days. The experiments conducted with this system provided critical data during the design verification and validation process for the new pump, thereby obtaining valuable information necessary for the FDA approval process. To date, Thoratec has received permission from the FDA to begin clinical trials on human subjects.


## Introduction

All people, with or without diabetes, need insulin for two reasons: abackground amount of insulin for normal functions of the body without food and a burst of insulin "on demand" when food is eaten. People without diabetes can trust that their pancreas will produce this insulin for them. People with diabetes need to take insulin as similar as possible to the way their pancreas would produce it if it could. In contrast with insulin injection therapy, insulin pump therapy delivers the insulin in the way the body would deliver it. Various types of insulin pumps are available on the market and today more than 150,000 people from around the world are controlling their diabetes with pump therapy. Implantable insulin pumps (Figure 1), currently undergoing clinical trials in both the United States and Europe, are designed to deliver short, frequent pulses of insulin into the peritoneal cavity where it can be more rapidly and predictably absorbed. These new devices offer substantial advantages to diabetes patients who have difficulty maintaining consistent glucose control. Any new implantable pump designs must go through rigorous testing and validation processes to ensure consistent performance of the pumping mechanisms throughout the life of the device. Medtronic Minimed in Northridge, CA challenged Cal-Bay Systems with the task of automating three test procedures for a new implantable pump design.

Figure 1. Implantable insulin pump

The three test procedures are:

1. stroke volume test – a long-term study of how the pump performs under typical or accelerated lifecycle conditions.
2. valve leakage test – a measurement of the amount of fluid leaked by the pump under the extremes of normal operating conditions.
3. reservoir pressure-volume test – a measurement of the variation of reservoir pressure over the full range of reservoir volume.

## Stroke Volume Test

The long-term stroke volume tests system (Figure 2) was designed to measure the performance of the pump under typical operating conditions (37°C to simulate body temperature and continuous agitation to simulate body motion). Key parameters to be measured in tests lasting up to 24 months include the stroke volume of the pump (volume dispensed with each pulse), energy consumed and energy waveform characteristics.

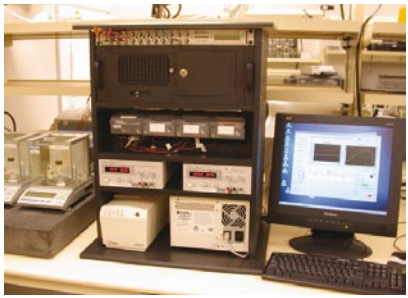


Figure 2. Stroke volume test system uses PXI and FieldPoint to collect data and control temperatures

To address these requirements we used a PXI system with a combination of data acquisition cards. The triggering and synchronization features of these cards were key features in this application. A digital output pulse from the PXI-6070 card is used to actuate eight pumps at the same time. The stimulus signal is delayed by a counter which generates a trigger signal that starts the acquisition shortly after the stimulus. The end of the pump cycle is signaled by a falling edge on another signal which triggers yet another set of measurement to be taken. These last measurements are used in determining the pump energy and thus its relative health. To maintain the units at body temperature we used a FieldPoint control system with temperature input modules and pulse-width modulation output modules. A software control loop running on the embedded PXI controller maintained the temperature at a constant level. To date, two of these systems have been build and used to run a variety of long-term tests.

## Valve Leakage Test

The valve leakage test is designed to measure the amount of fluid leaking back through a catheter into the pump and into the negative pressure reservoir. Negligible leakage occurs normally due to diffusion through the valve material and does not affect the safety of the patient, but larger amounts of leakage due to surface finish or mechanical alignment problems could lead to an under-delivery of insulin to the end of the catheter. Prior to automation, an operator would measure the movement of the meniscus in a small bore pipette using a small ruler. The problem with this approach is that the movement of the meniscus during the 15 minute test period is very small and so the operator required considerable experience to be able to detect liquid movement that could be measured.

We postulated that an image acquisition and processing system could perform this measurement faster and more reliably without operator intervention. To test this assumption we set up a simple prototype system that included an IMAQ PCI-1407 card, a camera with zoom lens and a backlighting system. We used NI IMAQ Vision to acquire and process images at regular intervals. The processing

is fairly simple: the program takes an initial snapshot of the setup and keeps it in memory. Subsequent images are compared with the initial image by using a subtraction algorithm, the result of which is proportional to the distance of travel. The valve leakage test system has proven to be an invaluable tool in the lab. It elegantly replaced the tedious and subjective visual inspection process and generates good quality data which requires no interpretation. To date, two of these valve leakage systems have been built and installed.

## Reservoir Pressure-Volume Test

The reservoir pressure-volume test is designed to measure the variation of reservoir pressure over the full range of reservoir volume. This simulates the normal operating cycle as insulin is removed from the reservoir while it is being dispensed from the pump. The test is carried out by filling the reservoir with water at 37°C, measuring the reservoir pressure, removing small amounts of fluid from the reservoir with a syringe whilst repeating the reservoir pressure measurements. Prior to automation, the test was performed manually by an operator who changed the syringe plunger position using a crankshaft while recording the measurements on a piece of paper.

Figure 3. Reservoir pressure-volume test system uses motor actuated syringes to vary the pressure

This process was another good candidate for automation (Figure 3). To move the pistons, we used stepper motors driven by NI motion control hardware and to actuate the valves we used one of the new industrial digital I/O cards. To measure the piston distance of travel we initially specified a set of high-precision linear variable displacement transducers (LVDTs) normally used for this type of measurement, however, after some thought we realized that the distance can be measured just as accurately using a rotary encoder on the stepper motor. This idea saved considerable development time and money. We designed the system to be capable of measuring and controlling up to 4 pumps independently of each other. The system completely automates a manual process and will be validated for use on production testing.

## Conclusion

All three system described here demonstrate the power of PC-based automation. Using a wide range of tools such as data acquisition, image acquisition and motion control cards we were able to completely automate three manual processes and thereby increase test coverage and prepare for eventual deployment in high volume manufacturing.

*Category: Biomedical*

*Products Used: LabVIEW 7.0, PXI-1042, 8-slot chassis with: PXI-8184 – embedded controller, PXI-6070 – data acquisition card, PXI-6025 – data acquisition card, PXI-6602 – counter/timer card, PXI-8420 – serial interface, FieldPoint system consisting of: FP-1000 – controller, FP-TC-120 – temperature module, FP-PWM-520 – pulse-width modulation module, IMAQ-1407 – image acquisition card, PCI-6527 – digital I/O card, PCI-7334 – 4-axis motion control card, NI-7604 – motion control driver*

*by Sorin Grama, Cal-Bay Systems, Inc.*
*David Hezzell, Consultant Engineer, Medtronic, Inc.*

# success story

**CLIENT:** **A Fortune 100 Biomedical Company** (a division of Johnson & Johnson) headquartered in Raritan, New Jersey

**INDUSTRY:** Pharmaceutical, Transfusion Medicine, and Clinical Laboratories

**PROBLEM:** To automate and standardize the visual, manual inspection of blood serumthereby eliminating inconsistent human judgment.

***The Hemolysis Blood Detection System, developed by Cal-Bay Systems, is at the root of this assessment in the automated laboratory environment.***

**Cal-Bay Systems** developed a highly flexible solution to detect hemolysis in blood sample serum after it is removed from a centrifuge: The Hemolysis Blood Detection System or HBDS. **Cal-Bay Systems** utilized its expertise in automated testing and data acquisition to automate and standardize the testing of hemolysis in human blood samples processed by the health care industry.

The HBDS fills a void in the processing of blood that normally requires a human judgment call ona sample based ona visual inspection of the blood serum. The HBDS passively examines samples in motion and makes a hemolysis judgment predicated on pre-determined user-defined parameters that are applied consistently to every sample processed. Consistent judgment of the presence of hemolysis ina sample is the result. The sample makes no physical contact with the HBDS; all analysis is performed optically as the specimens pass the HBDS sensors. The HBDS records all sample data for offline post processing using the HBDS Offline Playback Utility. This utility enables the operator to alter the hemolysis detection criteria and playback all processed blood samples to date using the changed criteria to see the results. Operators can also recall and export measurements to other Windows-based applications.

**Cal-Bay Systems** engineers designed the HBDS such that it will report hemolysis results to existing Laboratory Information Systems. This interface may be tailored to interface with other Information Systems if desired. However, the HBDS can also be operated as a stand alone lab appliance using a laptop computer.

The HBDS provides hardware and software redundancy. Two independent evaluations of each sample and the resulting conclusions are compared and reported to the Laboratory Information System. Alternatively, the HBDS provides the ability to automatically operate ina single processor mode if the second experiencesa hardware failure.

The Hemolysis Blood Detection System runs on Intel-based PCs and MS Windows 95/98/Me/2000. Hardware interfaces are customizable, supporting analog, digital, serial, and TCP/IP connections to existing LIMS and Automated Processing Lines.

# FTS-200 LOW VOLUME/HIGH MIX FUNCTIONAL TEST SOLUTIONS

FTS-200-IDT Implanted Device Functional Tester

FTS-200-PMET Patient Monitoring Equipment Test System

FTS-200-HASS Reliability Tester

# CalBay Systems FTS-200-IDT
# Implanted Device Functional Tester

***The FTS200IDT from CalBay Systems, provides a "RiskFree" Test Solution for manufacturers of implanted medical devices including:***

- Pacemakers
- Defibrillators
- Wireless telemetry devices
- Ambulatory recording devices
- Human body sensor simulation
- Surgical and treatment tools

***System Benefits:***

- FDA audited test solution
- "Gold standard" validation and calibration
- One tester for all product options
- Uses industry standard COTS products
- Built in Self Test Diagnostics

*The **FTS-200-IDT** has been designed to offer a single multiproduct test solution to companies designing, validating and testing medical devices. Based around high performance instrumentation hardware and Industry Standard software, the system is incredibly flexible and easy to use. It can be customised simply to your own specific needs, enabling you to obtain a customised solution to your test requirements for an off the shelf price.*

CalBay has supplied many leading medical device manufacturers with the FTS-200-IDT Test System, and has undergone extensive FDA and other regulatory body auditing. This level of understanding means that we can help you develop a test process that will make it easier to obtain FDA approval foryour medical device products.

The FTS-200-IDT Test System comes fully tested, documented and supported removing any risk you have by developing a test solution inhouse.

To find out how we can help you solve your Medial Device Test needs contact **sales@calbay.com** or visit **www.calbay.com**

# Cal Bay Systems FTS-200-PMET
# Patient Monitoring Equipment Test System

***One Functional Tester to test all of your Patient Monitoring product range***

- Designed for companies wanting to reuse their test system to test multiple Patient Monitoring modules in design validation and production
- Designed for testing Sp02, NIBP, ECG, Temp monitors and analyzers
- Reduced system cost: Built around industry standard LabVIEW and TestStand software tools lowering system cost
- Reduced test times: High performance PXI based measurement hardware improves test throughput
- Worldwide support: Installed, commissioned and supported by CalBay Systems

*The **FTS-200-PMET** Patient Monitoring Equipment test system from CalBay Systems has been designed to provide the ideal solution for companies producing stand alone or modular Patient Monitoring Equipment.*

Based around industry standard PXI hardware and configured using LabVIEW and TestStand, the FTS-200-PMET can be configured for your specific test requirements quickly and easily making it ideally suited to both design validation and production test. The heart of the system is the multi interconnect which is permanently connected to the system hardware allowing new test fixtures to be configured easily without the need for rewiring, enabling faster product change over between testing.

The easy to use, full function test system software provides the performance and flexibility required to test the most demanding of products. This increased flexibility means that the FTS-200-PMET is ideally suited for testing most patient monitoring products including:

• Sp02 analyzers • ECG Monitors • NIBP Monitors • Temperature Monitors

For further technical information or to find out if the FTS-200-PMET system is the test system to satisfy your company's test requirements, please contact your nearest CalBay office. Alternatively visit us at **www.calbay.com**

# Cal Bay Systems FTS-200-HASS
# **Reliability Tester**

### *Designed specifically for HASS Reliability testing*

- Monitors the health of 8 to 16 electronic devices in parallel when testing for failure due to vibration, shock and temperature
- Suited for testing any devices where high reliability is essential, including:
  - Defense electronics
  - Aerospace electronics
  - Telecomms Devices
  - High Reliability Audio/ Visual electronics
  - Computers and peripherals
- Significantly improves field MTBF, resulting in fewer field defects
- Individually controlled, fused and power for each DUT with integral current monitoring, along with Video and Audio signal monitoring for both analog and digital formats
- Worldwide support: Installed, commissioned and supported by CalBay Systems or your preferred local system integration partner

*The **FTS-200-HASS** Reliability functional test system from CalBay Systems has been designed to provide the ideal solution for companies performing vibration and shock testing on high reliability products.*

Based around industry standard COTS hardware and software , the FTS-200-HASS tester can be configured quickly and easily, providing a flexible solution for testing multiple batches of devices for potential failure in harsh environments. The multi interconnect adaptor is permanently connected to the system hardware allowing new device fixtures to be configured easily without the need for rewiring, enabling faster change over between batches.

The easy to use, full function software provides simple to use GUI's (Graphical User Interface) which enable control and monitoring of the devices under test throughout the duration of the test. The results of each test are stored in a database for reference. This data can be exported to any SQL database for further analysis or data storage.

For further technical information or to find out if the FTS-200-HASS Reliability Test System is the right functional test system to satisfy your company's HASS testing requirements, please contact your nearest CalBay office. Alternatively visit us at **www.calbay.com**

# TEST DATA MANAGEMENT, ANALYSIS AND REPORT GENERATION PRODUCTS

INTRASTAGE

# INTRASTAGE

ORGANIZING TEST DATA FOR A CHAOTIC WORLD

## SMOOTH

*IntraStage seamlessly organizes and stores your data to a centrally secure location while you work, play, or sleep.*

## CONSISTENT

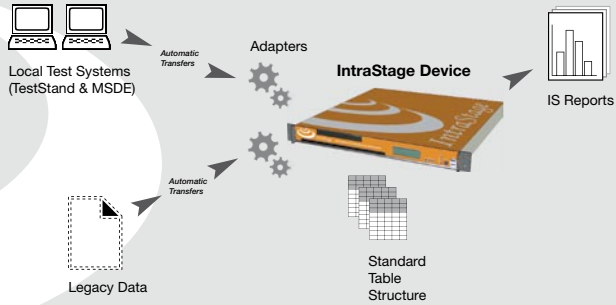
*Your whole organization can finally have a standard, consistent 'look and feel' for test data reports.*

## RESULTS

*You can make better decisions regarding process improvement or product reliability, having solid information at your fingertips.*

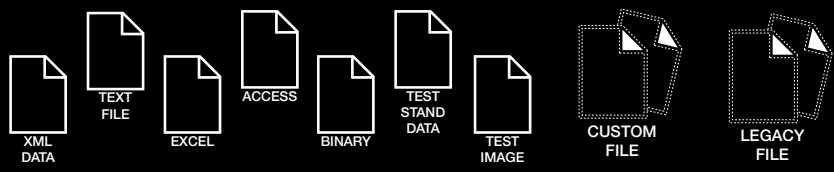
## OVERVIEW

IntraStage elegantly imports data from anywhere in your enterprise on the schedule you specify, into a central and secure location. This data is then immediately available to any user who has access to the IntraStage system.




## FILE TYPES

IntraStage can acquire data from just about any source. Whether it be from a well structured database or from a legacy tester outputting poorly structured text files, IntraStage will import this data on a schedule you specify.

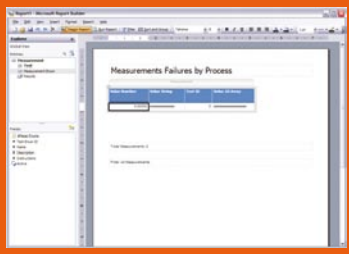


# WEB BASED REPORTING

Ease-of-use reports using a simple web browser to gain critical company information anytime. Unlimited client licenses allow companies to purchase this technology knowing the costs upfront.

# BUILD, SHARE AND SCHEDULE

IntraStage easily allows users to create their own reports, publish these reports for sharing with co-workers and schedule these reports (as well as the built-in reports) to their inbox or file share for their Monday morning meeting.




**R TYLER** *: TEST PROJECT ENGINEER - AEROSPACE*

*We had a requirement from our biggest client to operate an SPC regime for many products shipped to them. We compared many of the products on the market and found that IntraStage met our needs whilst still costing thousands less than other products. IntraStage is now used to automatically collect test results from many different test stations and provides us with multiple types of detailed reports on a regular basis.*

**TOM ARMES** *: FOUNDER*

*It is my firm belief that test data management should be no more difficult than managing music on my iPod™. I am consistently amazed that test data is strewn around most companies in some kind of known chaotic state ("because that's the way it has always been done").*

*This data disorder creates a serious lack of reliability, consistency, integrity and security with regards to any information attained. Building a product that eliminates these difficulties is the spirit behind the IntraStage device. With IntraStage, test data is now effortlessly gathered on the schedule specified and transformed and stored into useful information. The user is now empowered to create, share and schedule reports in a consistent and easy-to-use way. Companies can now make solid business decisions, based on reliable information straight from their Inbox.*

*So, go ahead and take off early on Friday! IntraStage will take care of your test data and email the critical report to you first thing Monday morning.*

# TECHNICAL SPECIFICATIONS

## BUILT ON INDUSTRY PROVEN TECHNOLOGIES:

- Hardware: Industry standard server hardware from Dell and HP that have a proven record of performance, scalability and reliability.
- Software: IntraStage software is built to run on Microsoft Windows Server technology, SQL Server, SharePoint and .NET.
- This combination of technologies creates an "out of the box experience" with a true "plug and play" feel.

**Contact us to find out how Cal-Bay Systems can help you develop a successful solution for your Test, Measurement and Automation needs.**


**Headquarters (West Coast US):**
Cal-Bay Systems Inc.
3070 Kerner Boulevard, Suite B
San Rafael
CA 94901
Tel: (415) 258 9400
Email: bsmith@calbay.com

**Headquarters (East Coast US):**
Cal-Bay Systems Inc.
5272 River Road
Suite 510
Bethesda, MD 20816
Tel: (800) 230 0029
Email: sseiden@calbay.com

**UK & Europe:**
Cal-Bay Systems Europe Ltd.
Suite 2
13 Fairlawn
Swindon
SN3 6ET
UK
Tel: +44(0)1793 538061
Email: ian@calbay.com