BLUE STAR

BLUE STAR INFOTECH

Health Sciences Practice

Analytical Instrumentation

Overview

- Over 10 years of experience in providing product development/support services to companies in:
  - Medical Electronics
  - Analytical Instrumentation

- Dedicated Health Sciences group focused on software development for Medical Devices, Analytical Instruments – **Current team strength of 110 engineers**

- Product Development mindset
  - Extensive experience working with equipment and software solution companies
  - Strong technical team with R&D bent of mind
  - In-house team of Image Processing experts
  - Robust eco-system comprising of Research Institutes, Hospitals and domain experts built over many years of active partnerships and collaboration
  - Availability of Research Scientists, Physicists, Mathematicians & Clinicians on need basis for project activities
  - In-house Tech-cell to incubate and imbibe new technologies

- Customers include:
  - Medical Electronics: Hitachi, Gamma Medica, MedicSight
  - Analytical Instrumentation: . Stratagene, Hycor

Blue Star Infotech Positioning

BSI

Hardware Communication & Control

Data Acquisition

Graphs & Charts

Data /Image Analysis

Reports Generation

Algorithms

Data Exports

Intuitive User Interface

PC Control Software

Embedded Software

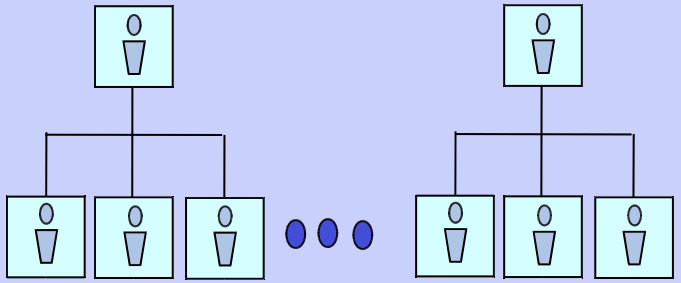
Data Acquisition
Image Re-construction
Communication Engine
Device Interfaces

Hardware

Health Sciences - Ecosystem

HEALTH SCIENCES PRACTICE

BSI Project Teams



RESEARCH INSTITUTES | **ACADEMIC COMMUNITIES** | **MEDICAL FRATERNITY**

- Image Processing
- Research Scientists, Lab Technicians
- Material Research Scientists, Metallurgists
- PACS, EMR, LIMS, SMEs

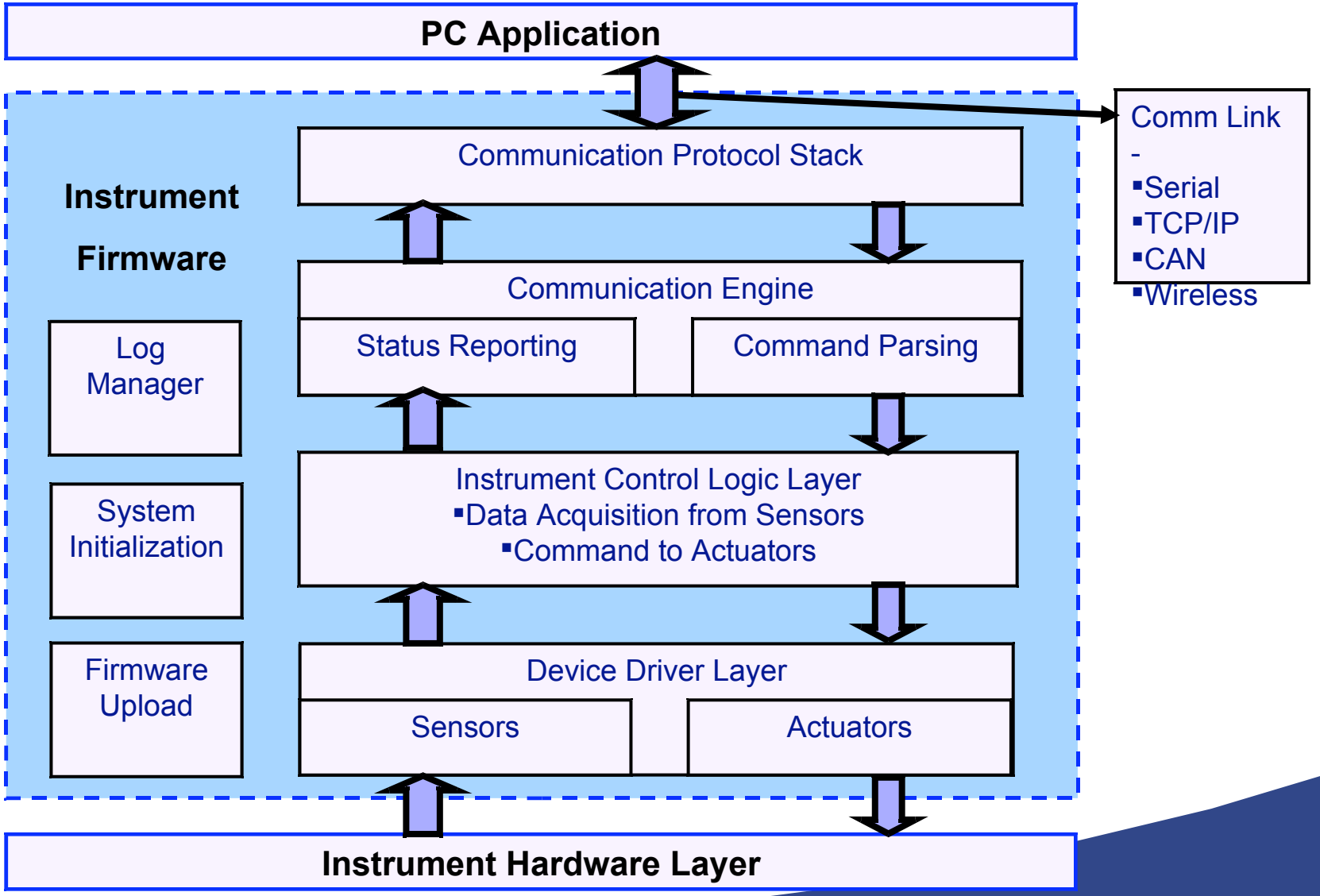
TECHNICAL TEAM | **DOMAIN CONSULTING GROUP**

BSI Experience in Devices and Analytical Instruments

Embedded Software for Equipments

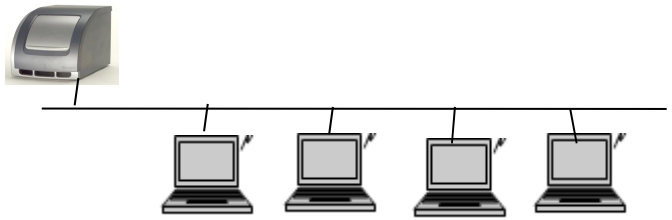
- **Instrument Computing**
  - **Real-time data acquisition from sensors like opto-circuits, photo meters, etc**
  - **Real-time command execution using actuators like relays, motors, alarms, etc**
- **Communication Engine development using either industry standard protocol or client-specific protocol over device interfaces like**
  - **RS-232 and RS-485**
  - **TCP/IP**
  - **CAN**
  - **USB**
- Application / Embedded Software
  - Development
  - Porting / Migration
  - Re-engineering
  - Sustenance
- Device Driver Development for
  - Sensors
  - Actuators

Typical Instrument Firmware Architecture



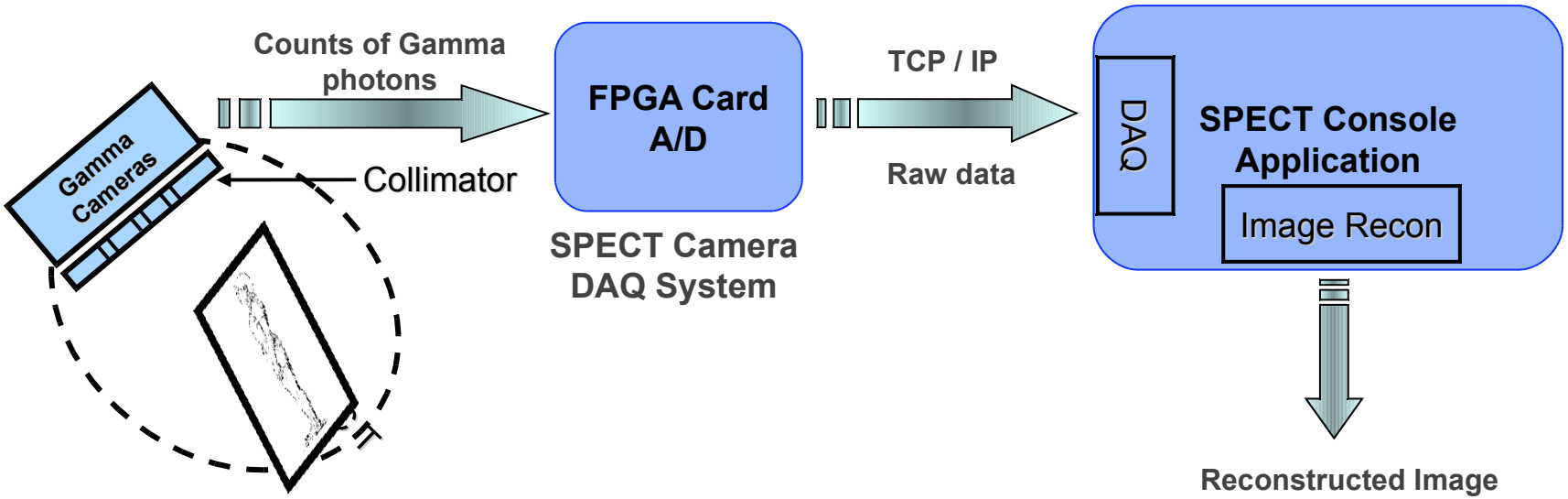
Equipment Control and communication

- **BSI has wide experience in equipment control & communication**
  - **Communication Protocols**
    - Serial Communication
    - TCP / IP Communication
    - Wireless Communication



  - **Equipment Control**
    - Instrument Discovery and Connection
    - Instrument Configuration
    - Instrument Qualification Test
    - Experiment Execution

E.g. Single Photon Emission Computed Tomography (SPECT)

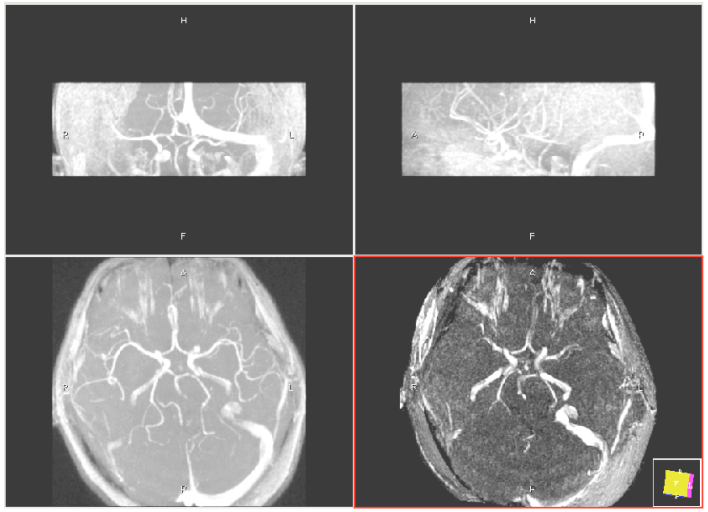


- SPECT data acquisition Process
  - Rotating Gamma Cameras around the subject
  - Detect hits of gamma radiations, the count of which is recorded
  - FPGA card based SPECT camera DAQ unit converts the count into raw digital data format
  - Data acquisition protocols are implemented in console application software
  - The data is then further processed for image reconstruction and the reconstructed image is rendered on UI

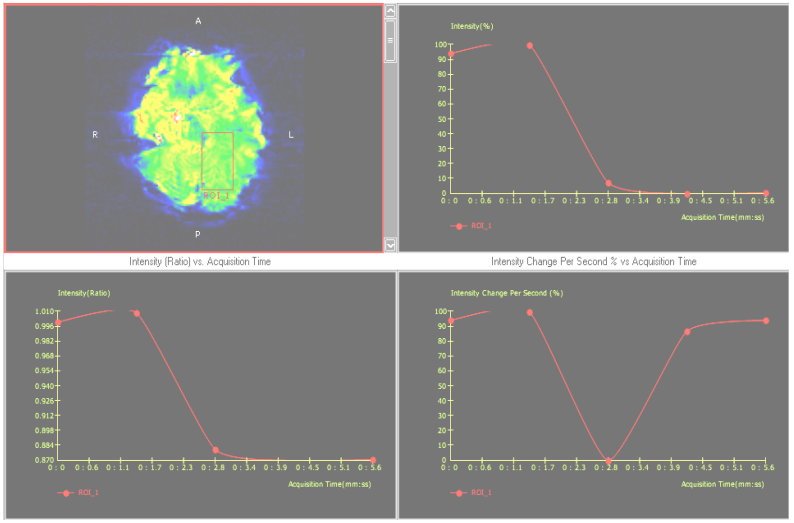
Image Analysis & Visualization

- BSI has extensively worked on Image Analysis and Visualization features like:
  - 2D and 3D Image Rendering
  - Framework for interactive drawing of 2D ROIs
  - Interactive image manipulation (Zoom, pan, rotate etc)
  - ROI based image processing
  - Statistical measurements (e.g Volume)

Image Rendering



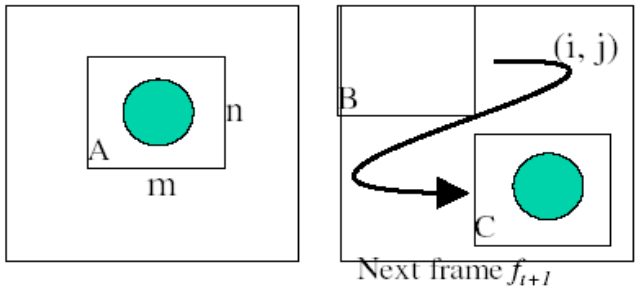
ROIs, Image Analysis on Images



Algorithms

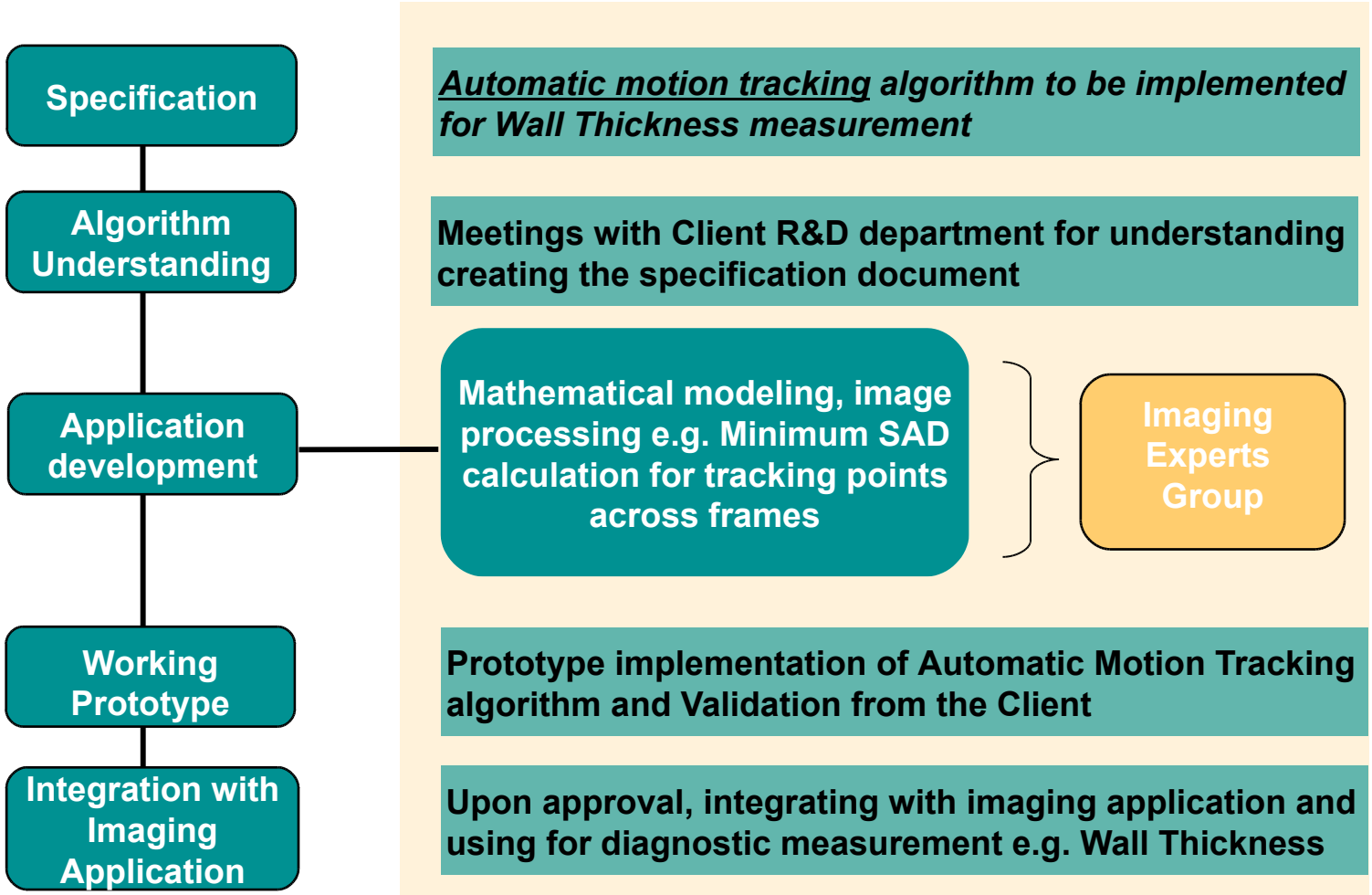
BSI has developed several Imaging Algorithms (2D/3D) for diagnostic imaging application

- **Complete development**
  - **Automatic Contour / Edge detection**
  - **Automatic Motion Tracking**
  - **Region Growing**
  - **Image Filtering**
  - **Statistical Analysis**



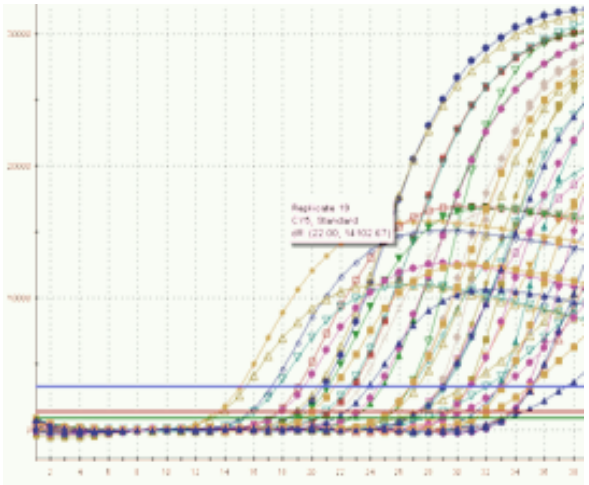
Motion tracking using block matching

Algorithm Development Process

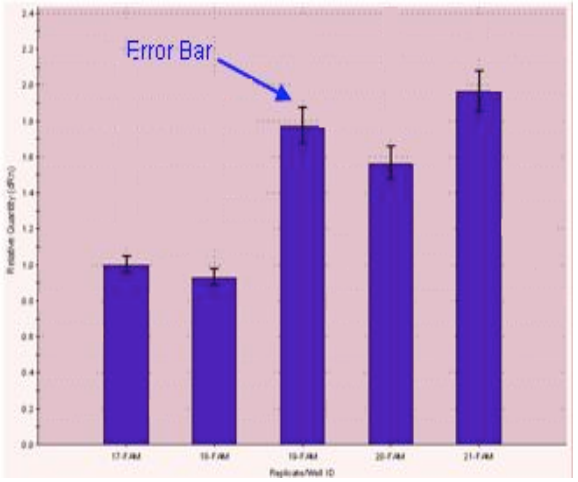


Graphs and Charts

Analyzed data is presented with some editable elements.



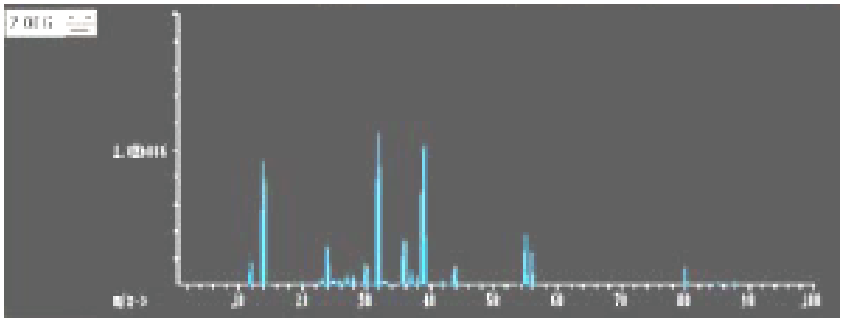
Data is presented with error information.



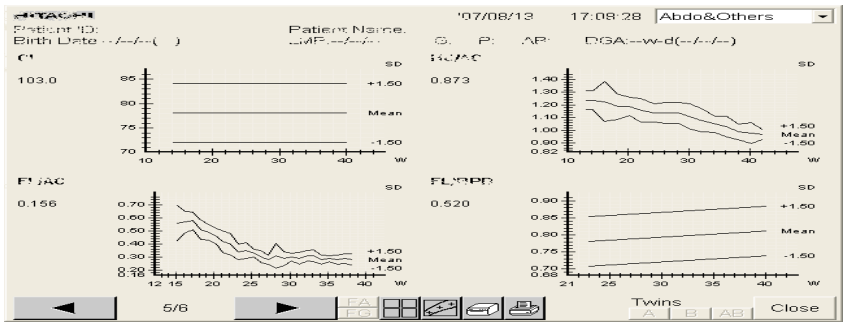
Reports Generation

Analyzed data can be reported in many ways.

Progressive analyzed data reported at run time.



Report with tiled graphs.



Report available with option of selecting fields.

Multi-page print and print preview for report.

Data Exports

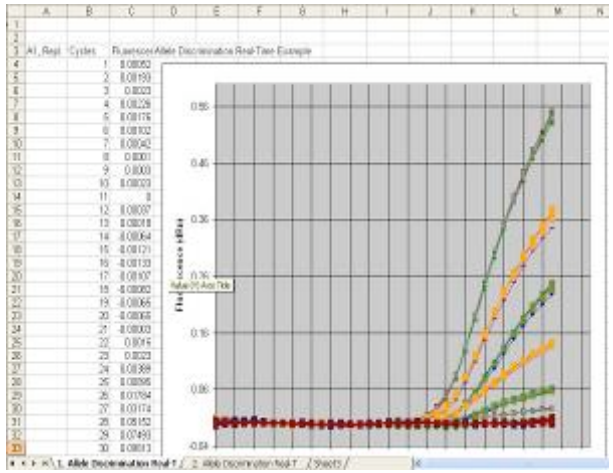
Data is exported to text file.

Text Report Data.txt - Notepad

File Edit Format View Help

Dye	Assay	Well Type	Replicate	Rn Last	dRn Last
ROX	ROX	Calibrator	17	1.000	0.000
FAM	FAM	Calibrator	17	3.742	2.997
ROX	ROX	Unknown 18	1.000	0.000	Ref
FAM	FAM	Unknown 18	3.733	2.978	0.1246
ROX	ROX	Unknown 19	1.000	0.000	Ref
FAM	FAM	Unknown 19	3.710	2.959	0.1246
ROX	ROX	Unknown 20	1.000	0.000	Ref
FAM	FAM	Unknown 20	3.673	2.916	0.1246
ROX	ROX	Unknown 21	1.000	0.000	Ref
FAM	FAM	Unknown 21	3.661	2.904	0.1246
ROX	ROX	Calibrator	23	1.000	0.000

Data is exported to excel in multiple sheets (with embedded graphs) .



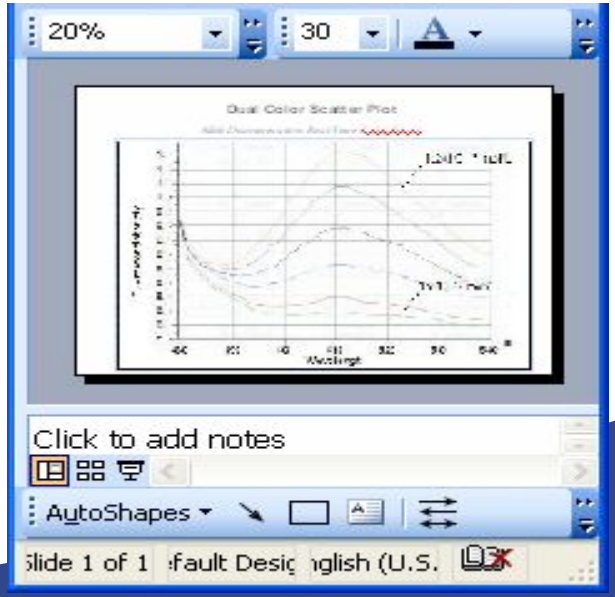
Data is exported to XML which can be viewed in explorer.

C:\Program Files\Stratagene\MxPro\Storage\Chart D...

Format	Name	Type	Date	Time
Format 2	Comparative Quantitation Separate Well Example.mxp	Comparative Quantitation	03 August 2007	12:02:59

1.00000	0	1.00000	0.01291	1.00000	0	1.00000	0.0122	1.00000	0	1.00000	0.01628	1.00000
2.00000	0	2.00000	0.00945	2.00000	0	2.00000	0.00702	2.00000	0	2.00000	0.01032	2.00000
3.00000	0	3.00000	0.00656	3.00000	0	3.00000	0.00411	3.00000	0	3.00000	0.00667	3.00000
4.00000	0	4.00000	0.00486	4.00000	0	4.00000	0.00347	4.00000	0	4.00000	0.00538	4.00000
5.00000	0	5.00000	0.00317	5.00000	0	5.00000	0.00259	5.00000	0	5.00000	0.00401	5.00000

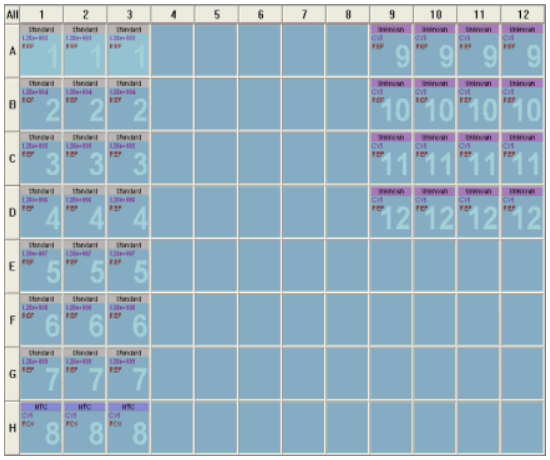
Data is exported to presentation slide (ppt file).



Intuitive Graphical User Interface

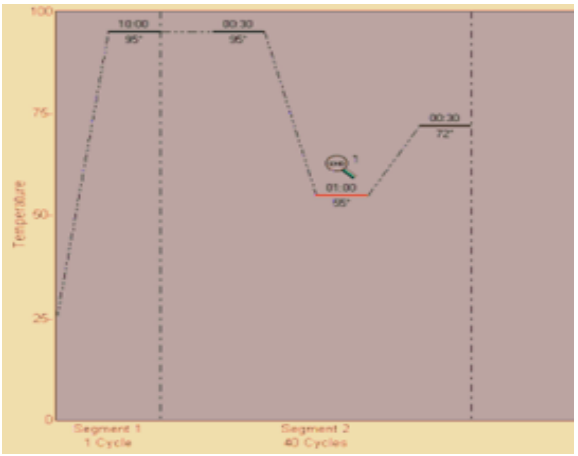
Hardware setup simulation:

User Interface simulates the actual hardware setup. In this case it is the Microplate setup.



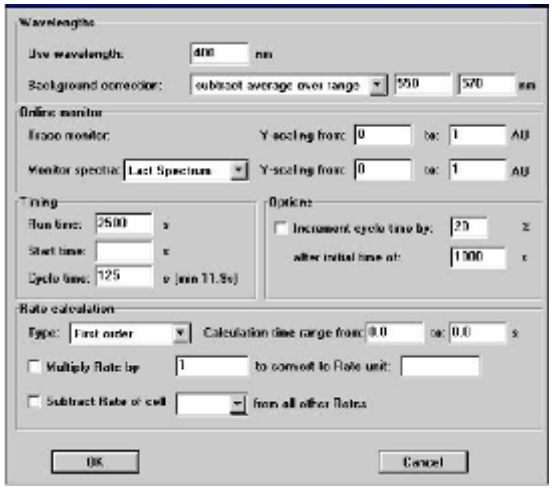
Graphical UI:

Various parameters of thermal profile e.g. Ramp, Plateau and Data Collection points are displayed and can be set using this graphical interface.



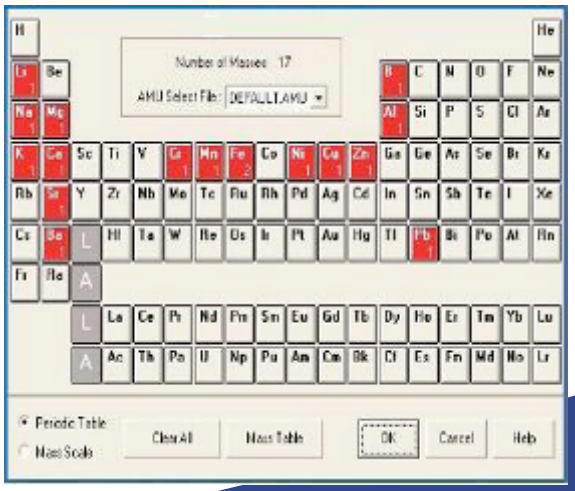
Parameter Setup:

The kinetic parameters required for a test can be setup using a simple and compact user interface.



Simulation of standard tables :

A structured Periodic Table UI enables easy selection of elements for analysis.



Regulatory Compliance - 21 CFR Part 11

- Secured access to application, User authentication and Auto logout.
- Traceability for every data exported from the application (includes printing and screen captures).
- Application data to be stored with delta changes. No application data can be destroyed.
- Audit trail (with date time stamp) for user activity involving change in application data.To be stored with application data.
- Secured data storage in database.

Service Offerings

- **Collaborative Product Development**
  - Equipment Software (Embedded) and PC Control Software for Analytical Instruments
  - Data Acquisition and Post processing
  - Visualization, Viewport tools
  - Algorithm Development
  - GUI Development and Usability Engineering
- **Maintenance and End-Of-Life Support**
- **Testing and Validation**
- **Re-engineering**
  - Re-engineering legacy systems using Commercial-Off-The-Shelf Hardware and Software technologies
  - Technology up-gradation and Migration
- **Performance optimization**
- **21CFR Part 11compliance**

Case Studies

Image Acquisition - SPECT

Client

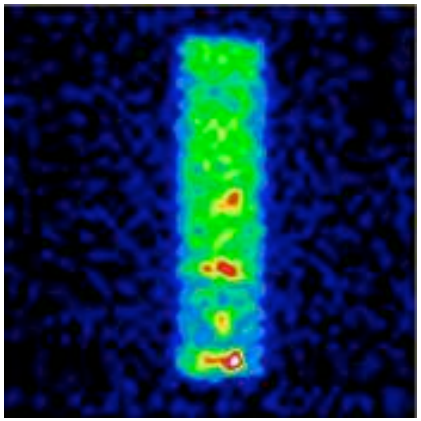
The client is one of the world's innovative manufacturers of next-generation imaging systems for both clinical and pre-clinical applications

The Need

- Development of a standalone image acquisition application (for SPECT Modality) that would display real time projection images.
- This also required implementation of various image acquisition protocols such as Static, Dynamic and Tomographic etc including the gating signal support.

BSI's Role

- A team of domain specialists and architects from BSI worked very closely with the client in the initial phases to gain complete understanding of the SPECT imaging concepts to formulate the software requirement specification in a very short time
- BSI used the SPECT image generation algorithm for acquisition and creation of the projection image. Also implemented the SPECT imaging protocols.
- Offered an effective solution for patient and study data storage and retrieval.



SPECT Projection Image

Technology

VC++, .NET

Benefits to the Client

- Implementation of a scalable & re-usable architecture with efficient Object Oriented design enabled the client to enhance the application with new features for patient data management and image reconstruction in a short timeframe.

2D and 3D Image Processing

Client

The client is one of the world's largest manufacturers & sellers of medical electronics equipment

The Need

- Development of a Modality console application consisting of various post-processing tasks such as Maximum Intensity Projection (MIP), Multi Planar Reformat (MPR), Volume Rendering (VR) and many others.
- All these tasks involved implementing various image processing algorithms operating on a plain (single) image (2D processing) / (3D processing).

BSI's Role

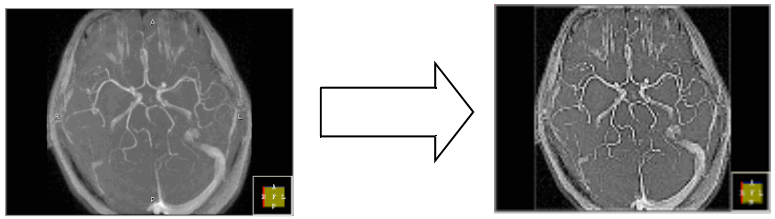
- 3D image processing algorithms implementation using Third Party Libraries
- Design of complex IAP pipelines (using IAP objects) and implementation of 3D functionalities such as MIP, MPR, VR (both parallel and perspective), Virtual Endoscopy and 3D filtering.
- Also involved in various 2D image processing tasks such as Addition/Subtraction of images, Perfusion, 2D Filtering tasks.

Technology

- .Net (VB .Net, C#, Managed C++)

Benefits to the Client

- Plug-in architecture allowed easy replacement of third party software components



Edge Enhancement Filter

Colour Tissue Tracking

Client

The client is one of the world's largest manufacturers & sellers of medical electronics equipment

The Need

- An application for creating a user-friendly display of strain and the torsion data using the latest and easily available display forms.
- Enhance the tracking techniques and fasten the data processing.

BSI's Role

- BSI designed a user-friendly MDI application with the following features:
  - Development of Motion Tracking algorithm
  - 4 different types of views
  - Saving the color view as motion files
  - ROIs comprising of two equidistant co-axial & similar shapes.
  - Manipulations of ROIs
  - Tracking of a large number of point-pairs on the frames of motion file and displaying the data analyzed in the color

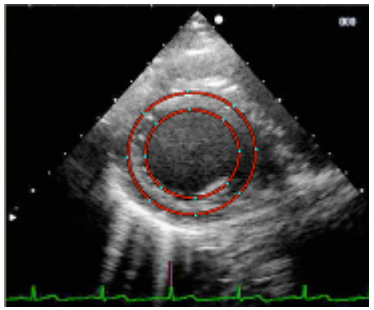


Fig (1) Marked ROI

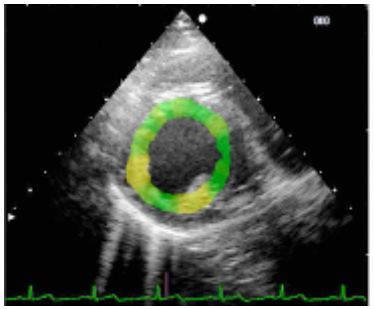


Fig (2) Color view

Technology

- VC++ 5.0/MFC

Benefits to the Client

- The re-usable components resulted in saving time and cost

Quantitative PCR Instrument System

Client

A worldwide leader in developing innovative products and technologies for life science research in fields spanning toxicology, genomics, proteomics. drug discovery, and molecular biology

The Need

- Enhancing the existing real-time Quantitative PCR instrument system.

BSI's Role

- Implementation of data processing algorithms. Some of the algorithms implemented were Baseline correction, Adaptive Thresholds, Threshold computation and Decomposition algorithm.
- Intuitive User Interface and Ingenious Custom Controls Development
- Enhancement of communication layer to communicate with new generation hardware.

Technology

- Visual C++. NET, MFC, Windows XP / 2000, QPCR Hardware, SQL Server 2005 express edition

Benefit to the Client

- The client was able to release the next generation system with rich enhancements in short time and cost effective manner.

Allergy Analyzer – Legacy Application Porting and Enhancement

The Client

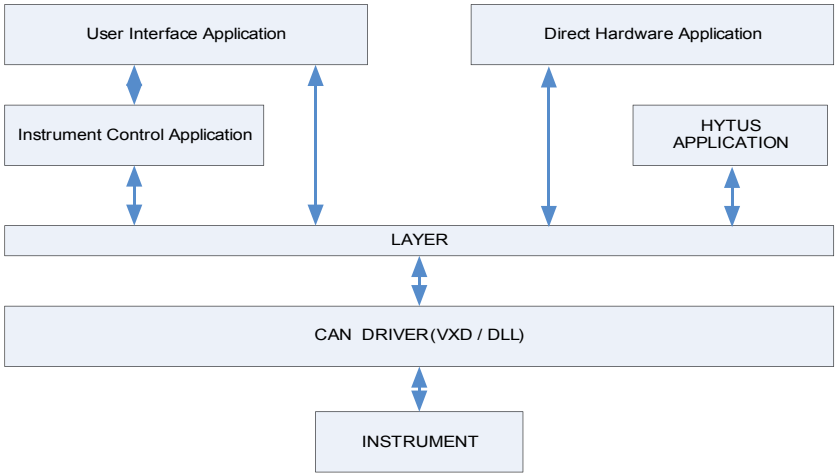
- USA based Bio-medical company providing allergy and immunity diagnostic instrument and re-agents

The Need

- To upgrade instrument software to run on Windows XP from existing Windows ME
- Migrate to USB-CAN interface replacing ISA-CAN interface
- Firmware download application re-write

BSI's Solution

- Modular software that can be utilized both with USB-CAN and ISA-CAN interface
- Feature enhancements
- Offshore development lab setup
- Enhanced GUI for the firmware download application



The Technology

- Delphi 2.0
- Windows XP and Windows ME
- ISA-CAN and USB-CAN libraries

21 CFR Part 11 compliance

Client

A worldwide leader in developing innovative products and technologies for life science research in fields spanning toxicology, genomics, proteomics. drug discovery, and molecular biology

The Need

Enhance the software of their flagship product to meet the FDA compliance - 21 CFR Part 11.

BSI's Role

- Software package for managing 21 CFR Part 11 functionalities. The main modules were Administrator module, Login module, Data encryption module, Database module, Audit trail, Export/Import module for backward compatibility with the earlier systems
- Integration of the new modules into the existing software
- Modifications to existing software for dependent modules like audit trail etc

Technology

- Visual C++. NET, MFC, Windows XP / 2000, QPCR Hardware, SQL Server 2005 express edition

Benefit to the Client

- The client was able to achieve increased acceptance for their flagship product and widen the market for it as well.

Thank You