LIGHTHOUSE
WORLDWIDE SOLUTIONS

**Lighthouse Worldwide Solutions
Master Presentation**

R&D / Headquarters / Manufacturing

Medford, OR

Fremont, CA

Medford, OR

★ **Manufacturing**
★ **Service & Repair Center**
★ **Central Calibration Lab**
★ **RMA Center**

Fremont, CA

★ **R&D**
★ **Engineering**
★ **Pilot Production**
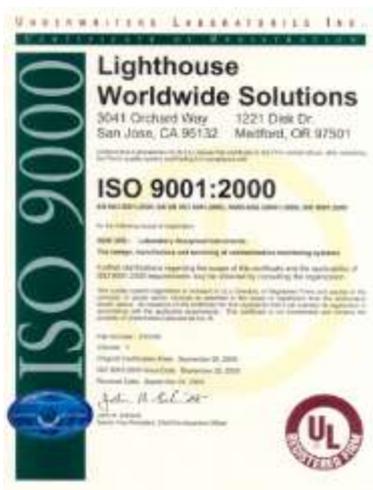★ **Executive Management**

New Headquarters: Silicon Valley

Lighthouse Focus on Quality
ISO 9001:2000 Facilities

United States:
Medford, OR
San Jose, CA

The Netherlands:
Alphen

Singapore

Thailand

5 Lighthouse Locations are ISO 9000 Registered

Lighthouse Worldwide Solutions

★ **Pharmaceutical Capabilities:**

  ★ **Particle counters and facility monitoring systems for meeting cGMP monitoring regulations**

    ★ **21 CFR Part 210 & 211**

    ★ **21 CFR Part 11**

    ★ **EU GMP Annex 1**

    ★ **PIC/S Annex 1**

    ★ **WHO Guidelines**

    ★ **USP 788/797**

  ★ **Systems designed for compliance**

  ★ **Project management services**

  ★ **Installation services**

  ★ **Validation services**

  ★ **Service, repair, retrofit of monitoring systems**

  ★ **Calibration per ISO 21501 standards**

  ★ **Contamination control consulting and training**

Monitoring Solutions

General Monitoring

✓ Air Particle

✓ Liquid Particle

✓ Temperature

✓ Humidity

✓ Differential Pressure

✓ Electrostatic Charge

✓ Air Velocity

✓ TOC

Specific Applications

✓ Current on FFU's

✓ Chillers/Refrigerators

✓ Door Switches

✓ Oven Temp

✓ Dry Box Humidity

✓ Gas Purity

✓ Incubators

✓ Large LCD Displays

Lighthouse Systems Experience

★ **Lighthouse experience in FMS system installation, particle counter integration and software**

★ **Over 200 FMS system installations worldwide**

★ **Lighthouse is the number one shipper of remote particle counters (numbers exceeding 900 units / month)**

Pharmaceutical Customers

PharmaForce

Pfizer

関東化学株式会社
Qca
KANTO KAGAKU

Abgenix

Lilly

Organogenesis Inc.
Breakthrough Products in Tissue Engineering

LOURDES

Roche

S Boston Scientific

Germfree Laboratories, Inc.

Medtronic
When Life Depends on Medical Technology

BAYER Bayer

stryker® Ireland Ltd.
INSTRUMENTS Division

intervet

Baxter

AMGEN®

Amersham

Agilent Technologies

Ferrer grupo

AstraZeneca

BPL
Bio Products Laboratory

AMYLIN®

NIBSC National Institute for Biological Standards and Control

Lighthouse Pharma Customers (System)

Large multi-building Pharma system which consists of particles counters and environmental sensors. These sensors are integrated to the FMS software with alarm beacons.

- ★ Baxter System
- ★ ROCHE
- ★ Sandoz
- ★ Bimagen
- ★ Beta Plus Pharma
- ★ Budelpack NV
- ★ Galapagos NV
- ★ Helvoet Pharma Belgium NV
- ★ Mediline NV
- ★ Salvamed
- ★ Novo Nordisk
- ★ Styker Howmedica –system

- ★ West Pharmaceuticals
- ★ Hospira / Abbott
- ★ GE Healthcare – system
- ★ Kabi Fresenius
- ★ Biogalenica
- ★ Favea
- ★ Vericore
- ★ Jugoremedia
- ★ Octapharma
- ★ Q- Med
- ★ Alcomed BV

Lighthouse Pharma Customers (System) – Cont'd

- ★ Crucell
- ★ Dutch Veterian Institute
- ★ Fresenius Hemocare BV
- ★ Mallinckodt Medical/ Tyco
- ★ Microclean B.V
- ★ Nelipak / Seal Air
- ★ Sandoz
- ★ Schenker International
- ★ TNO –Dimes
- ★ ACE Pharmaceuticals
- ★ Allergy Therapeutics – system
- ★ Aston University (Mayne-Parma)
- ★ Astra Zeneca – system
- ★ Baxter system
- ★ Glan Clywdd Hospital
- ★ Medtronic

- ★ Glaxo Smith Kline – system
- ★ NIBSC Stem Cell Bank
- ★ Pfizer-system
- ★ University College London system
- ★ Vericore (Novartis) –system
- ★ Astra Zeneca – system
- ★ Bassaire
- ★ IBA Molecular
- ★ Amgen
- ★ Chiron
- ★ Organogenisis
- ★ Pharmaforce
- ★ Cell Genesys
- ★ McGuff Pharma
- ★ MDS Nordion

Software

Easy to Use
Compliant

LMS Standard Software Capabilities

- **Designed for 21 CFR Part 11 compliance**

- **Full life cycle documentation per GAMP 5**

- **Real-time data collection**

- **Historical data review**

- **Multi level maps**

- **Reports**

- **Thin Client data access (depending on package)**

- **Complete failover solutions (depending on package)**

- **Supports user administration via MS Windows domain**
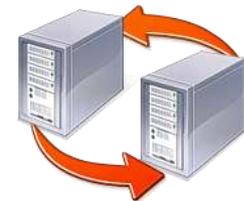
21 CFR Part 11 Compliance

Software Security

★ **Unique name**

★ **Unique password**

★ **Password aging**

★ **Auto logout**

★ **Inactivity logout**

★ **Failed logon**

★ **Encrypted database**

Identification	User Methods	General	Security	Configuration ViewStation	Contact Information

Enabled ☑

Minimum Password Length `6` ⇅ Characters

Minimum Password Strength `Very Strong ▾`

Allowed Failed Logons `5`

Password Dictionary Size `0`

Must Have Password ☑

Can Change Password ☑

Password Expires After `0` `...`

Inactivity Logout `4H` `...`

Example of Facility Map

★ **Unique map for each building or room**

★ **Changes state based upon condition**
  -normal
  -alarm
  -warning
  -fault

★ **Supports internet cameras**

★ **Icons for each type of sensor**

Example of Real-time Screen Grid

★**Multiple views**

★**Grid view**

★**View sensor data In real-time**

★**Status displayed in color**

★**Green = OK**
★**Red = Alarm**
★**Yellow = Warning**
★**Blue = Fault**

Data Charts

Date Range:	2009-02-20 11:37:04 - 2009-02-20 11:47:04		
Duration:	0 hours, 10 minutes		
Date Printed:	2009-02-20 11:47:13		
DATE	TIME	LwsMacro_Cycle000_Value	LwsMacro_Cycle001_Value
02/20/2009	11:37:05	1452.870	1121.750
02/20/2009	11:38:09	1254.260	1311.410
02/20/2009	11:39:05	1384.640	1315.580
02/20/2009	11:40:05	212.632	249.190
02/20/2009	11:41:07	350.871	254.967
02/20/2009	11:42:07	279.925	252.641
02/20/2009	11:43:07	790.005	777.462
02/20/2009	11:44:07	633.949	858.654
02/20/2009	11:45:07	784.448	612.003
02/20/2009	11:46:07	1287.470	1498.710
	COUNT	10	10
	SUM	8431.070	8252.367
	AVG	843.107	825.237
	MAX	1452.870	1498.710
	MIN	212.632	249.190

★ **Copy and paste**

★ **Color status**

★ **User defined status**

★ **Selectable duration**

★ **Rolling charts**

★ **Statistics**
  - ★ **Count**
  - ★ **Sum**
  - ★ **Avg**
  - ★ **Max**
  - ★ **Min**

Reports

★ **Customizable**

★ **Summary of data**

★ **User defined**

★ **Std reports available**

Email Alarming

Choose a single person or group of people

User can choose what status will trigger the alarm.

Main Screen

Multi-level Maps
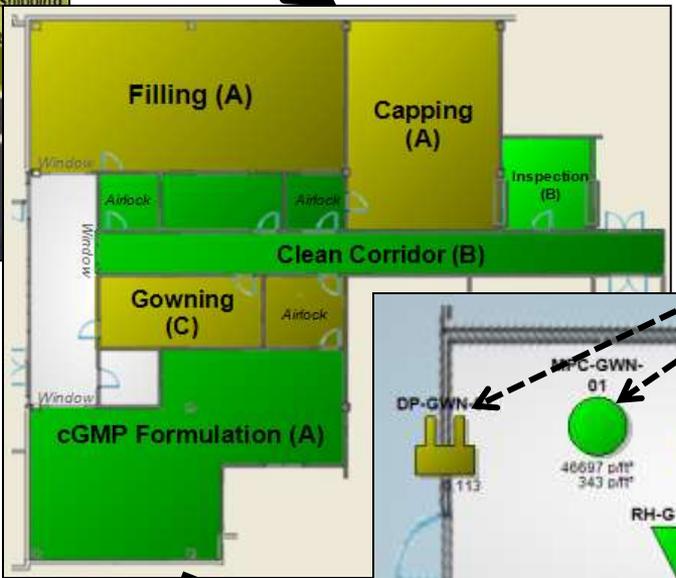
Unique sensor shapes

Drill-down maps allow you to see an overview of the facility and then status of a specific room

From Map to Graph
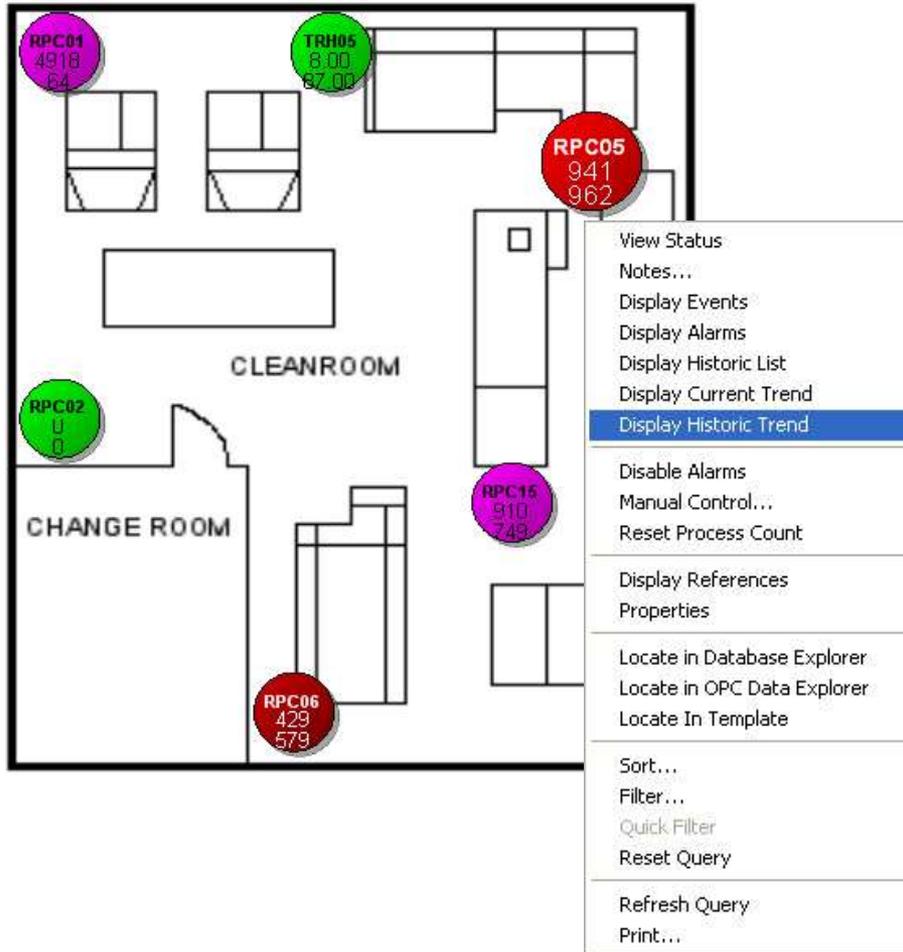
Simple mouse click navigation to the data you want to see…
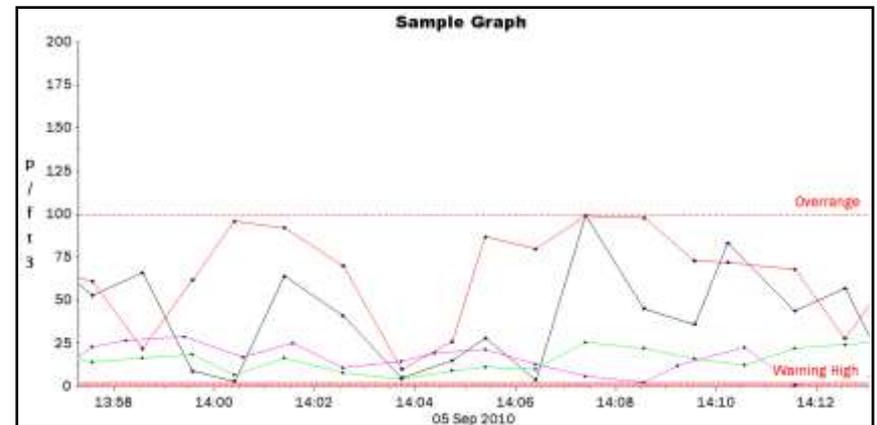
List Screen

View All Sensors Status

★ **Real Time Color Status**

★ **Real Time Data Status**

    ★Location Name

    ★Values

    ★Date and Time

★Sort by Status

Click n Go

Acknowledge an alarm

Display a trend

Disable / enable alarms

Configure

Locate a sensor

Map	List	Grid	Trends	Reports

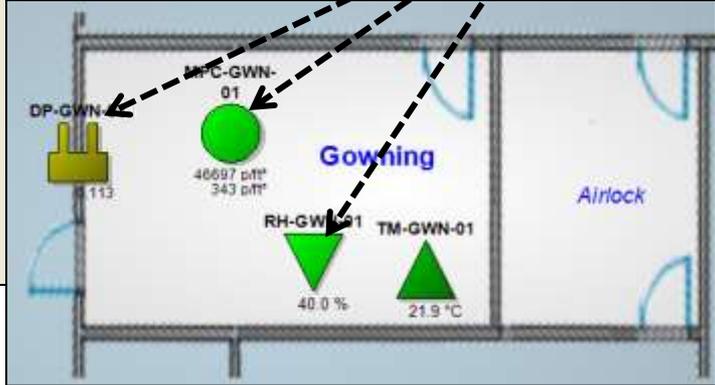| Point	Value	Timestamp
DP-LBL-01	0.150 "H2O	4/30/2011 5:18:36.705 PM
RH-SHIP-01	41.3 %	4/30/2011 5:18:36.505 PM
TM-GWN-01	23.1 °C	4/30/2011 5:18:36.505 PM
DP-GWN-01	0.113 "H2O	4/30/2011 5:18:36.505 PM
DP-PREP-01	0.020 "H2O	4/30/2011 5:18:36.405 PM
TM-		
DP-CAP-01	0.050	
RPC-FRM-02 0.5	71	
Test1	48.	
MPC-GWN-01 0.5	47022	
MPC-PREP-01 0.5	42977	
RH-CAP-01	40.	
RH-SHIP-02	40.	
RH-STOR-01	40.0 %	4/30/2011 5:18:36.005 PM
RH-CORR-01	37.5 %	4/30/2011 5:18:36.005 PM
RH-FILL-01	37.5 %	4/30/2011 5:18:36.005 PM
RH-GWN-01	37.5 %	4/30/2011 5:18:36.005 PM

Context menu:
DP-PREP-01 ▸
- Acknowledge Alarms
- Display...
- Trends...
- Disable Alarms
- Enable Alarms
- Configure...
- Locate...

SPC

★ **SPC calculations**

   ★ **Min**

   ★ **Max**

   ★ **Average**

   ★ **Standard deviation**

   ★ **X-Bar**

   ★ **R-Bar**

★ **Modifiable parameters**

   ★ **Sigma**

   ★ **Warning count**

   ★ **Alarm count**

   ★ **Sample group size**

Calculation:	Mean

C-Chart
Lower Control Limit (LCL)
Lower Warning Limit
Mean
P-Chart
Standard Deviation (Sigma)
Summation
Upper Control Limit (UCL)
Upper Warning Limit
Variance
Process Cp
Process CpL
Process CpU
Process Cpk
Process CR

Calculation:	0
Calculation:	0

Drop down selection menu
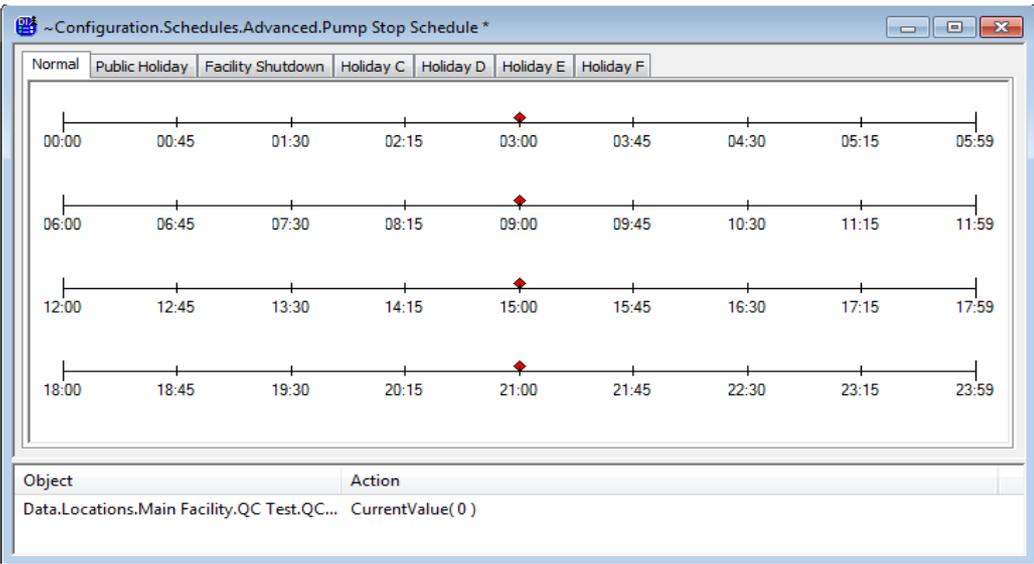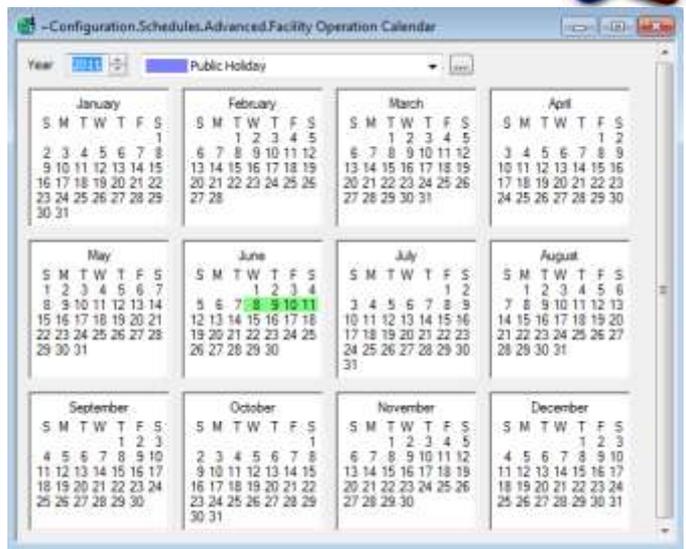
Click n Go

Schedules

★ **Setup a scheduled event based on date and time.**

 ★ **Turn on / off a pump**

 ★ **Automatically change alarm limits**

 ★ **Trigger sampling recipes**

 ★ **Print reports**

 ★ **Stop recording data**

Status Screen

View all sensors status

★ **Real-time color status**

★ **Real-time data status**

   ★ **Location name**

   ★ **Values**

   ★ **Date and time**

★ **Current / historical graphs**

★ **Alarm acknowledgment**

Map	List	Grid	Trends	Reports	Events	Process

RPC01	RPC02	RPC05	RPC06	RPC07
4918 CH 0.5µ	0 CH 0.5µ	522 CH 0.3µ	184 CH 0.3µ	367 p/ft³
64 CH 5.0µ	0 CH 5.0µ	718 CH 0.5µ	160 CH 0.5µ	858 p/ft³
7/16/2010 3:09:39.379 PM	7/19/2010 7:22:59.421 PM	7/25/2010 8:56:03.968 PM	7/25/2010 8:56:03.968 PM	7/25/2010 8:56:03.999 PM
RPC08	RPC09	RPC10	RPC11	RPC12
1334 p/ft³	801 p/ft³	268 p/ft³	1234 p/ft³	701 p/ft³
496 p/ft³	1075 p/ft³	1272 p/ft³	910 p/ft³	548 p/ft³
7/25/2010 8:56:03.999 PM	7/25/2010 8:56:13.999 PM	7/25/2010 8:56:14.030 PM	7/25/2010 8:56:14.030 PM	7/25/2010 8:56:14.030 PM
RPC13	RPC14	TRH05		
168 p/ft³	1251 p/ft³	66.00 °C		
186 p/ft³	884 p/ft³	48.00 %		
7/25/2010 8:56:14.030 PM	7/25/2010 8:56:04.062 PM	7/25/2010 8:56:05.077 P		

Acknowledge Alarms

Display…

Trends…

Disable Alarms
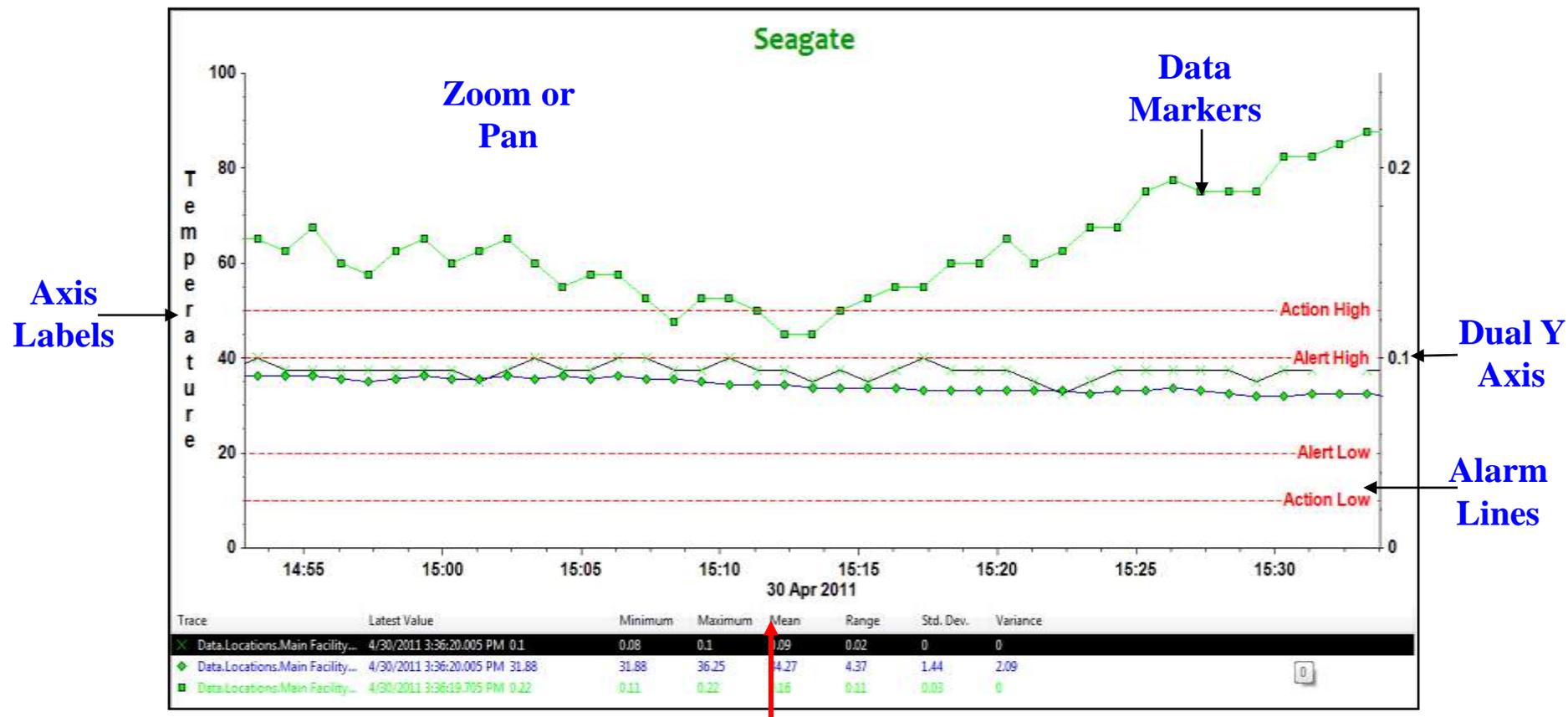
Enable Alarms

Configure…

Locate…

Mouse click menu selection simplifies use…

Click n Go

Graphs: Simplified Functionality

Rolling Statistics: Min, Max, Mean, Range, Std. Dev. and Variance

Calibration Tracking

★ **Calibration dates are tracked in the system**

★ **Users are notified when a date is coming due**

Report Function

* **Conformance report**
  * **Raw data by channel size**
  * **Color-coded**
  * **Summary of events**
    * **★ # of Measurements**
    * **★ # of Warnings**
    * **★ # of Alarms**
    * **★ Min**
    * **★ Max**
    * **★ Average**
    * **★ Mean**
    * **★ Standard deviation**
  * **Graphs of selected points**
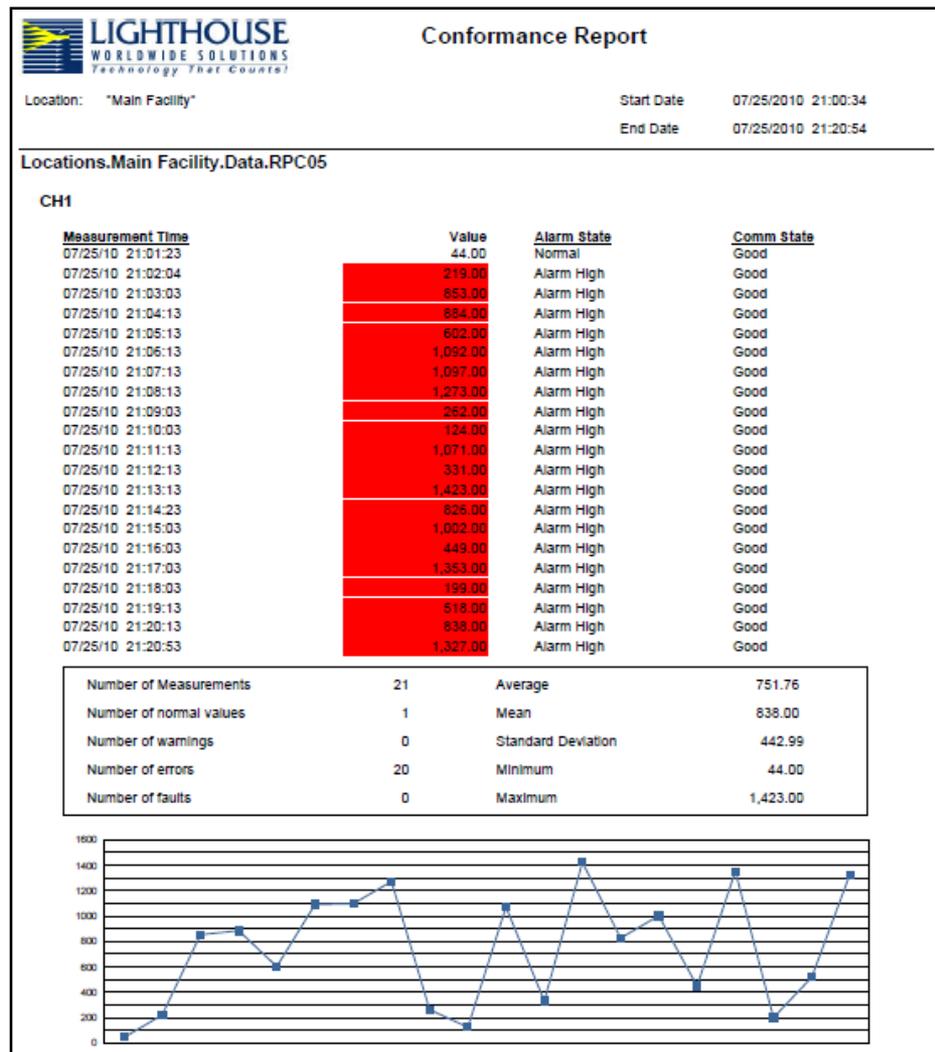
Simplified Operation
Lighthouse has focused on simplifying system configuration and setup

Simplified Operation

★ The system incorporates several features that simplify configuration, reduce training requirements and reduce operator configuration errors.

★ Templates

★ Modules

★ Recipes

Templates

★ **Templates – Templates allow us to specify which settings are common for all sensors (and the values for those settings), and which settings can be changed on a sensor-by-sensor basis.**

For example, all particle counters have a minimum value of 0 and no specified maximum value, so in the particle counter template, those values are fixed.

Modules

★ **A module is a pre-configured group of sensors that can be imported into the system.**

★ **Reduces configuration time.**

★ **Reduces user error.**

★ **Simplifies the adding of sensors.**
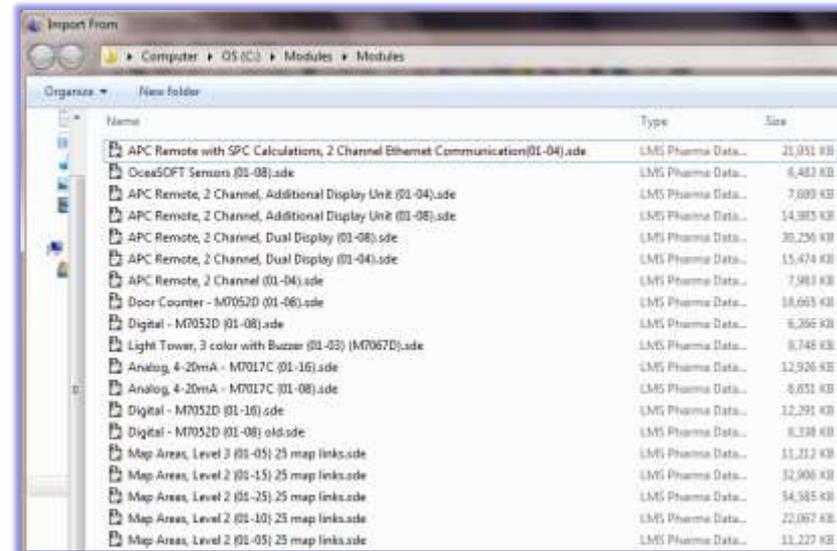
Recipes

★Recipes allow us, for the settings which *can* be changed, to create groups of settings, and select for each sensor which group of settings to use.

For example, particle counters may be used in areas of different ISO classes, and in each ISO class, the alarm limits are different. Having a recipe for ISO class 5, another recipe for ISO class 6, and another recipe for ISO class 7 makes it easy to specify the alarm limits for different particle counters, without having to explicitly set the alarm limits for each sensor. If the alarm limit specification for a given area changes later, the values only need to be changed in the recipe, and all particle counters tied to that recipe will automatically reflect the change.

Recipe parameters
- Alarm limits
- Sample time
- Auto-trend intervals
- etc…
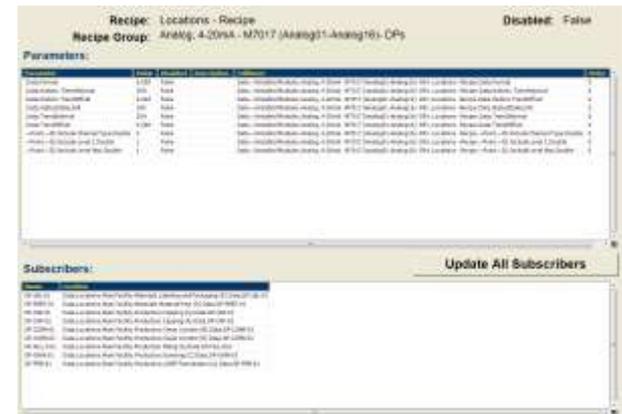
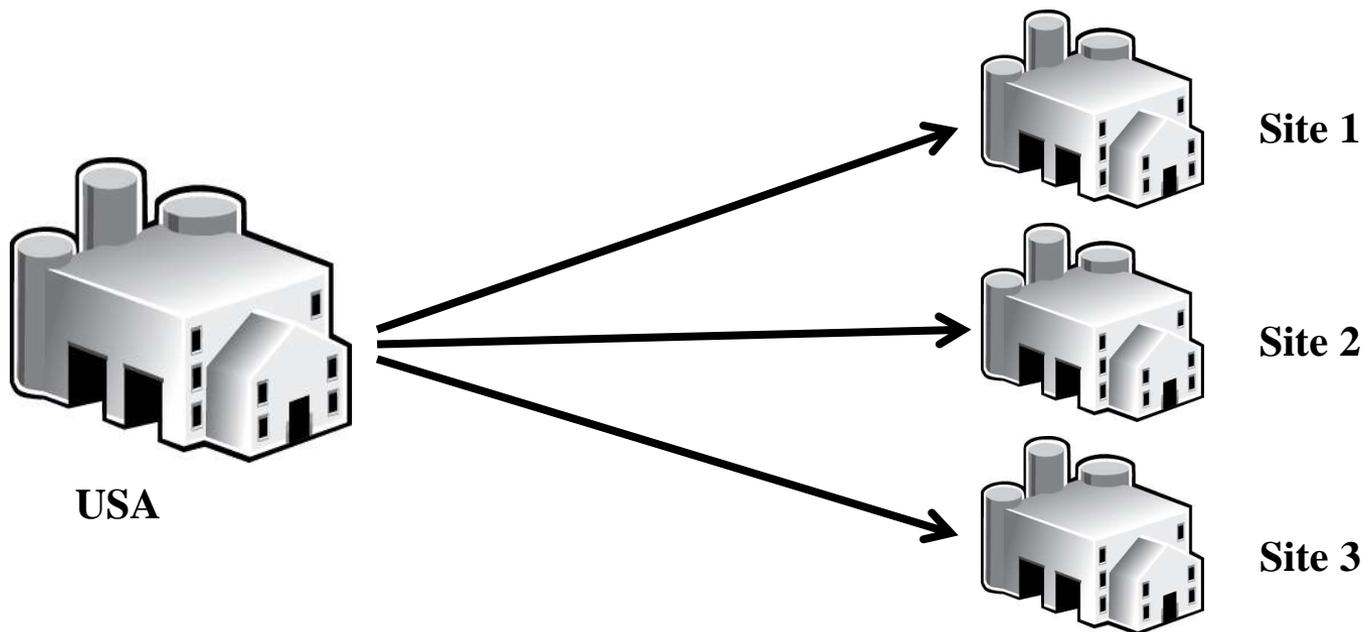# Simplified Deployment

★ **Templates and Recipes allow for easy and consistent deployment of monitoring changes across multiple sites.**

★ **Export** ⟹ **e-mail** ⟹ **Import**

★ **Remote desktop**

USA

Site 1

Site 2

Site 3

Alarming

The Lighthouse monitoring system alarm capabilities were designed with ultimate flexibility in mind.

Alarm Triggers

Each sensor can be setup to have four basic alarm triggers.

Conditional Alarming

LMS has a conditional alarming feature. This features allows the user to customize alarm triggering conditions that match their process concerns.   For example:

★ If a particle sample location is in alarm for a set amount of consecutive times then trigger an alarm.

★ We can alarm based on SPC rules.

★ We can vary alarm limits based on time and date.

Alarming

Alarm Notification

★ Light sticks (per room or central)

★ Buzzers

★ Text messages

★ E-mail alarm notification

Real-time viewing of alarms and warning conditions

★ Maps

★ Data tables

★ Reports

★ Grid view

Alarm

Manual Data Input: Example

★ **Input**
- ★ **Date**
- ★ **Time**
- ★ **Serial Number**
- ★ **Sample Location**
- ★ **Description**
- ★ **Calibration date**
- ★ **Individual channel size data**

★ **This can be used for any type of data.**
- ★ **Particle**
- ★ **Temperature/Humidity**
- ★ **Differential Pressure**
- ★ **Etc…**

Manual Particle Counter Data Entry

|	
Date and Time	5/24/2010 2:04:10.893 PM
Serial Number	081231042
Calibration Date	9/1/2012 2:08:15.272 PM
Location	Room B301
Description	Handheld Particle Counter

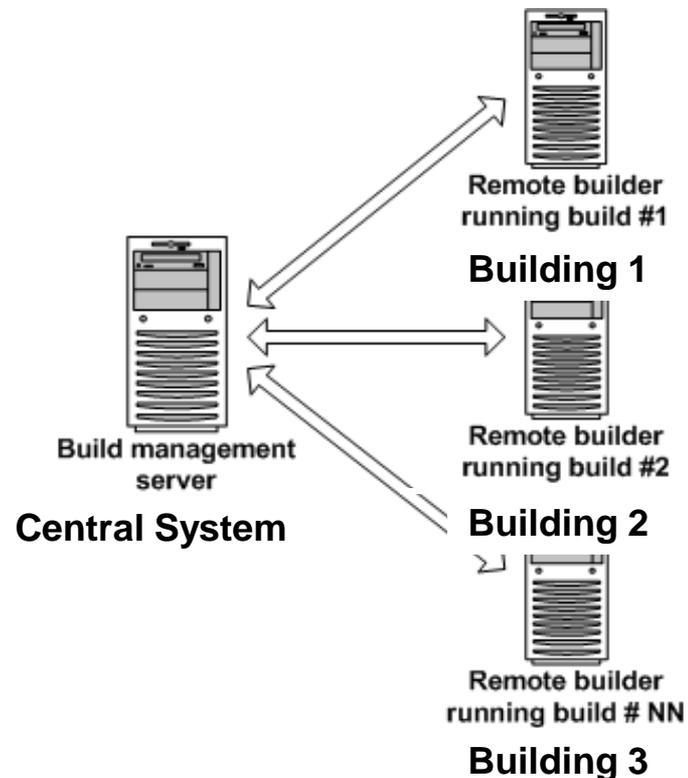| Count Mode	CH / Density	Counts
Cumulative	CH1 0.3µ	15013
	CH2 0.5µ	3001
	CH3 1.0µ	103
	CH4 3.0µ	40
	CH5 5.0µ	12
	CH6 10.0µ	2

Insert Record

Redundancy

★**Redundant data acquisition (failover)**

★**Redundant clients**

★**Automatic recovery (fail-back)**

    ★**No loss of existing calculations, summations or processes**

★**No operator intervention required**

★**Mirrored historical data**

LAN

Optional
Redundant
PC

View
Station

View
Station

Optional
Redundant
Client
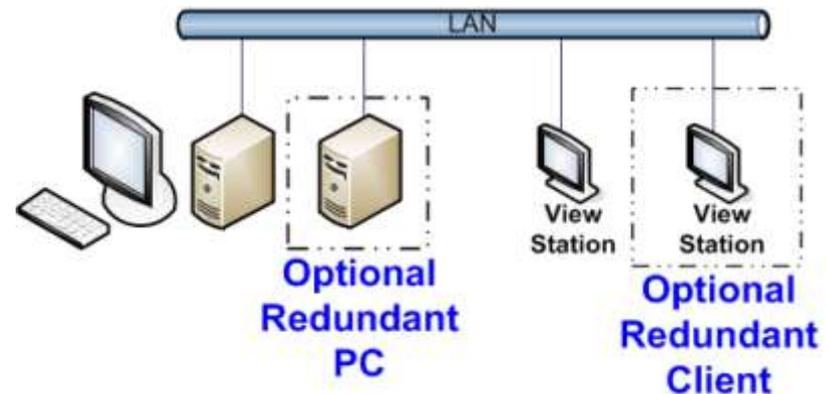
Ultimate in Scalability

The Lighthouse Pharmaceutical Monitoring System is designed to scale from a single point to thousands of points and still maintain the same look and feel.
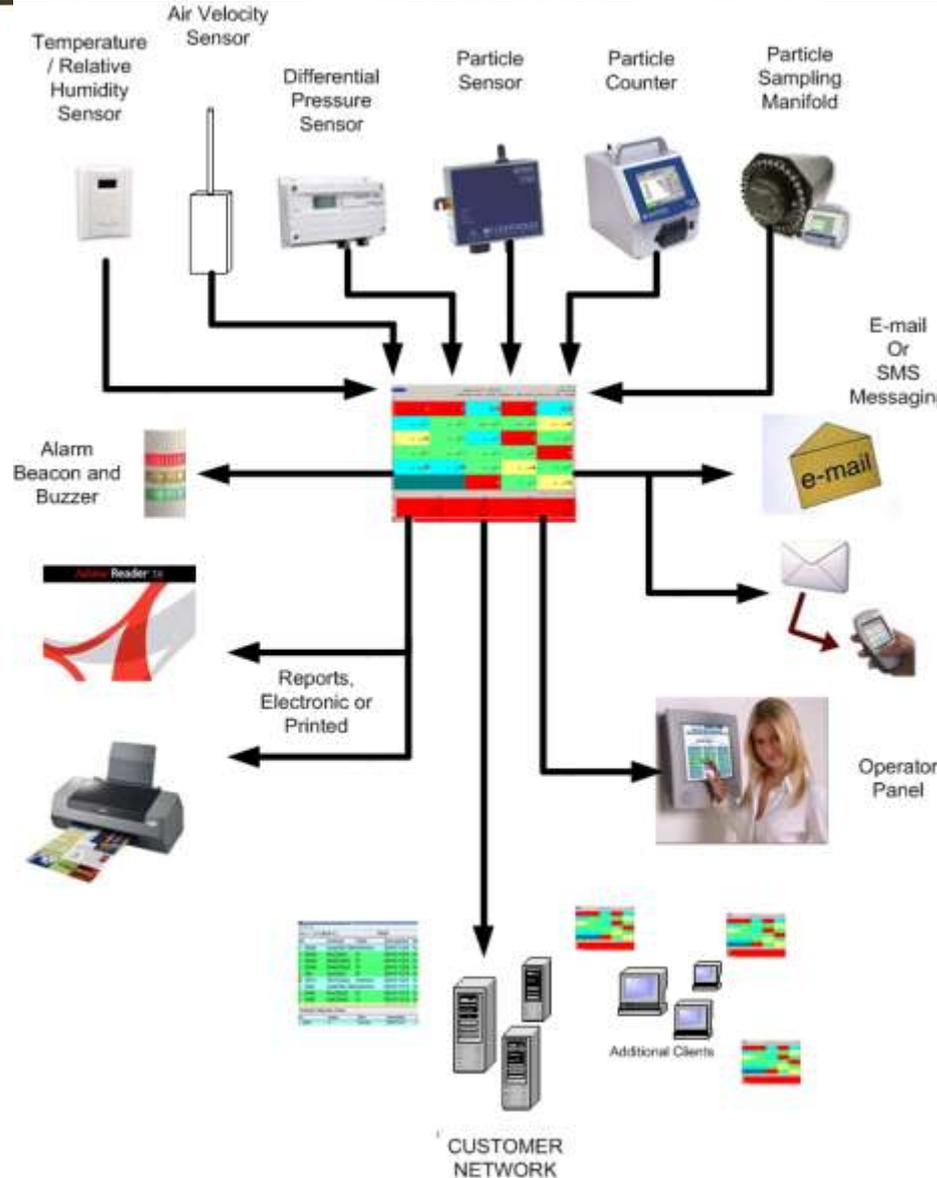

Remote builder running build #1

Building 1

Build management server

Central System

Remote builder running build #2

Building 2

Remote builder running build # NN

Building 3

Connectivity

★ **The Lighthouse Monitoring System is designed to meet all your monitoring needs.**

★ **Connectivity:**
  - ★ **4 – 20 mA**
  - ★ **MODBUS**
  - ★ **Ethernet**
  - ★ **Digital input**
  - ★ **Digital output**
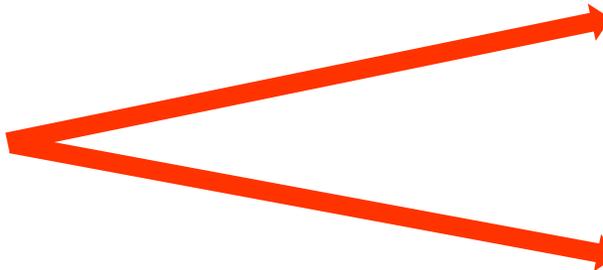 - ★ **Thermocouple**
  - ★ **RTD**

Connectivity

- ★ **The Lighthouse Monitoring System can be can send and or receive data from other types of building automation, SCADA or control based systems.**

- ★ **Common interface between systems are:**
    - ★ **OPC**
    - ★ **MODBUS TCP or MODBUS ASCII**
    - ★ **Profibus**
    - ★ **Device Net**

Summary

⋆ **64 Bit Architecture**

⋆ **Runs on Multiple Windows Platforms**

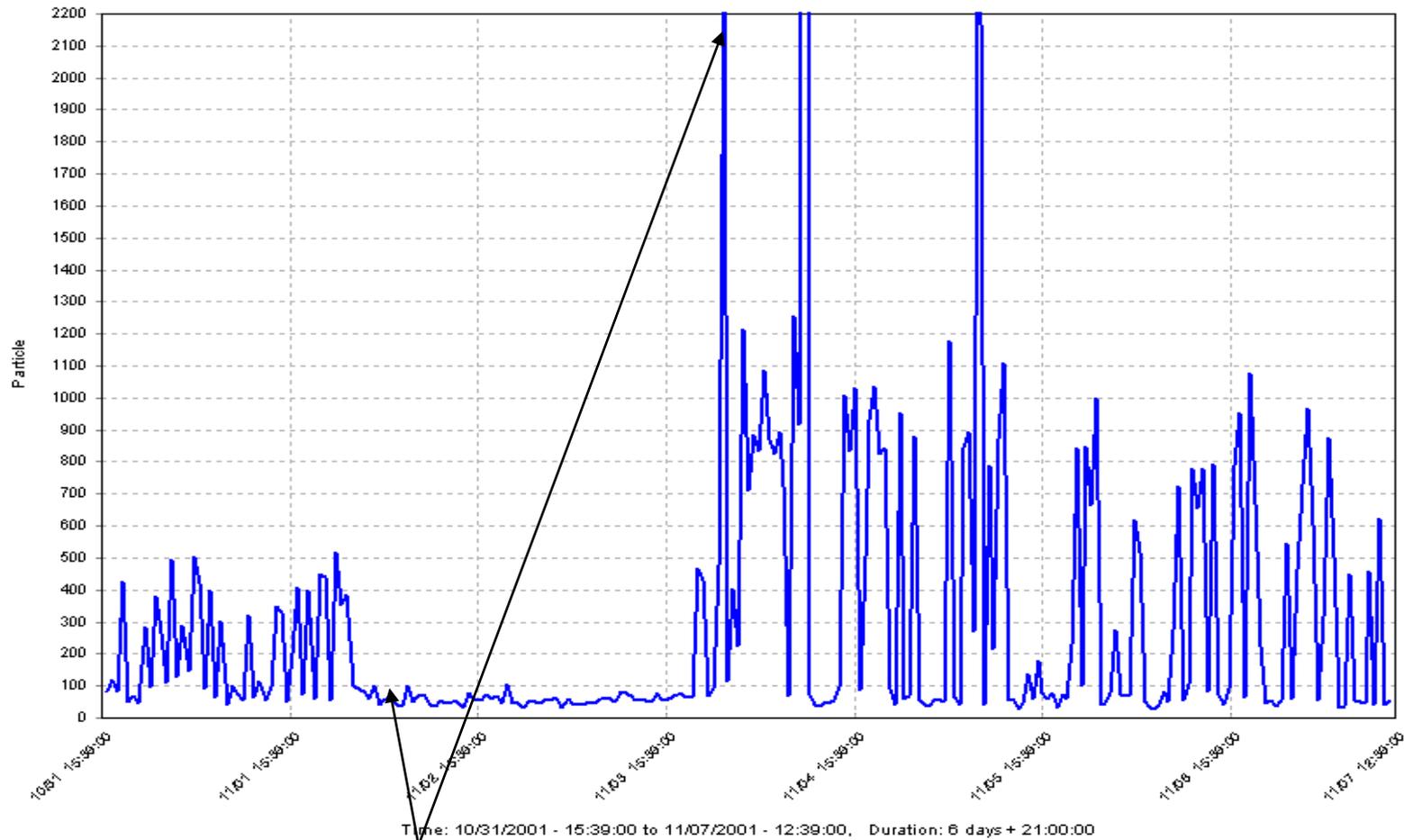⋆ **Win 7, Server 2003, Server 2008, Win XP**

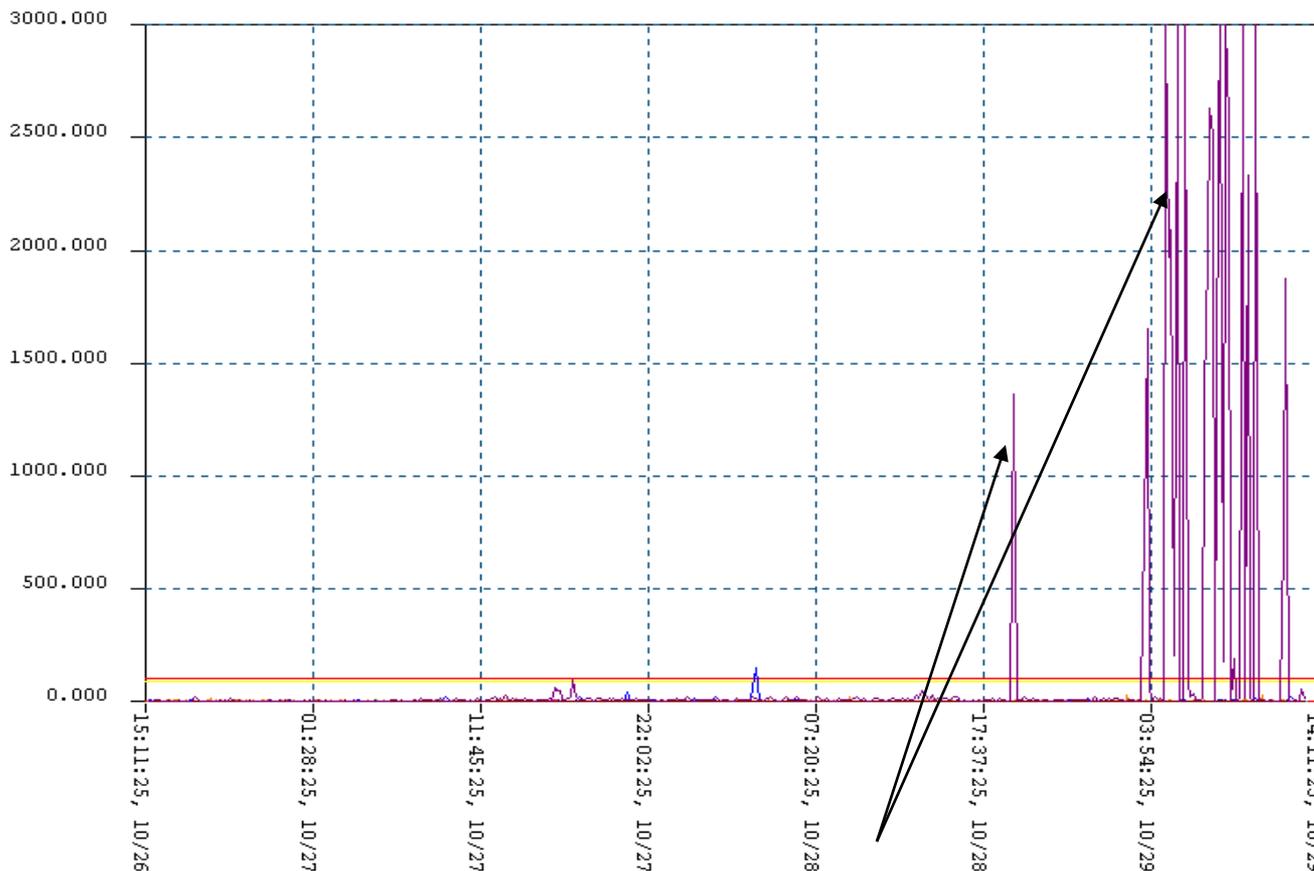⋆ **Supports Virtual Machine (VMware)**

Problems Identified

Major shifts in particle concentration were identified using the Lighthouse Monitoring System
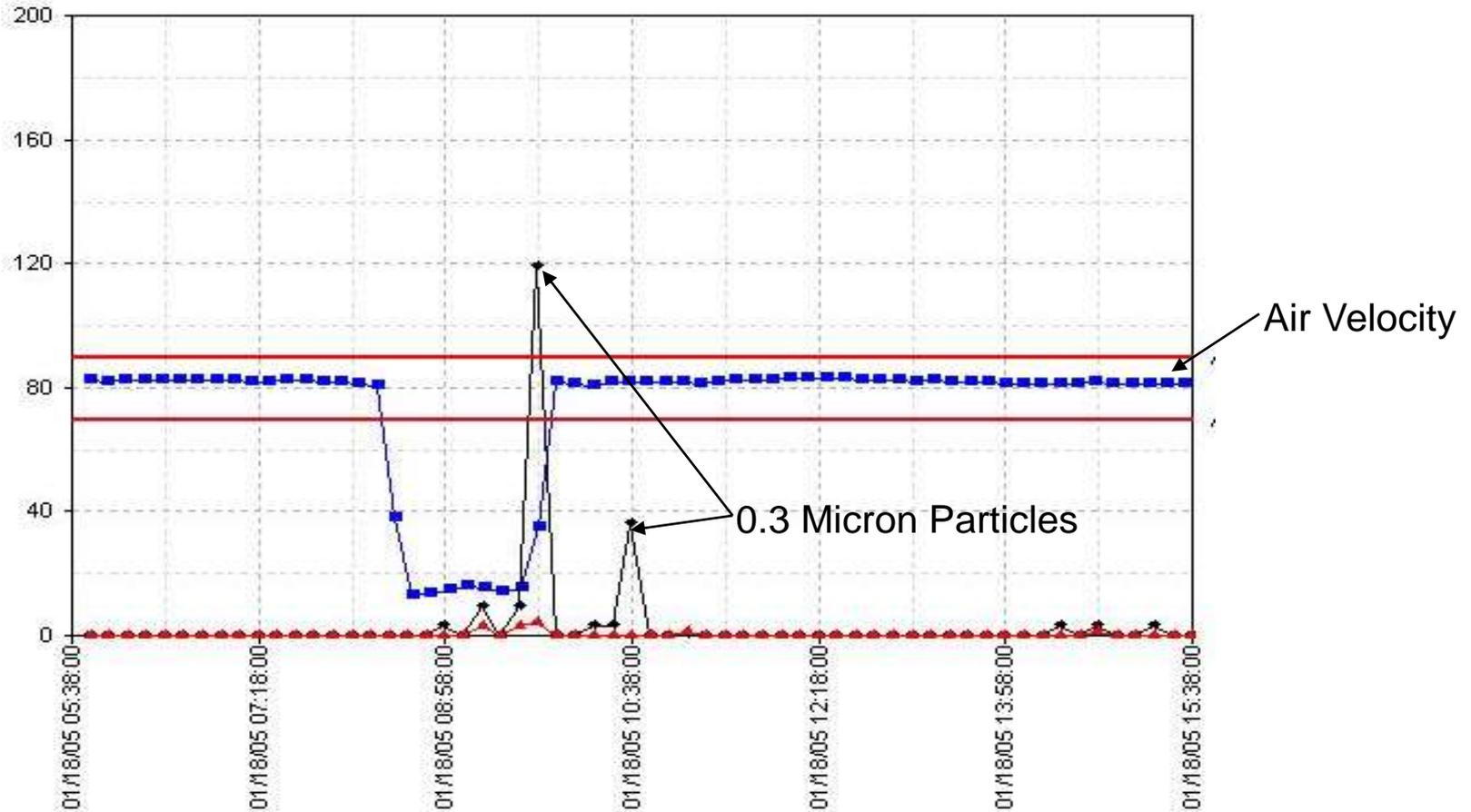
Parti-100@0.3, ,   72:00 hrs, 10/26/2001-10/29/2001

A pass though door was left open and allowed air from outside the cleanroom area to enter into a class 100 area. The issue was identified by the customer's Lighthouse System and then corrected

Air Velocity and Particle Data

Air Velocity

0.3 Micron Particles

A change in air velocity inside of this equipment had an effect on particle count concentration inside the equipment
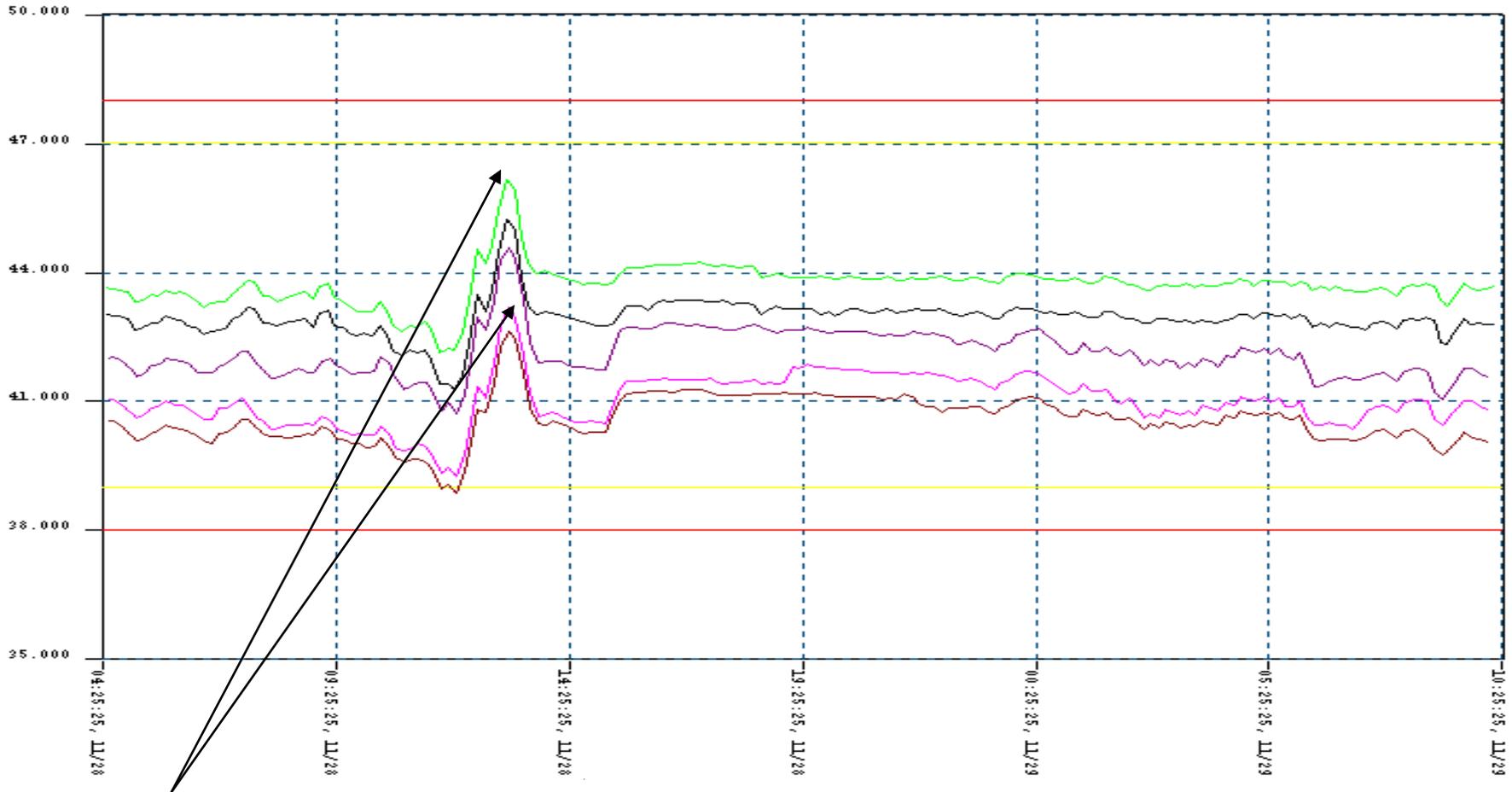
The Humidity Control System was accidentally reset to increase the humidity levels in the cleanroom. Their Lighthouse system identified the problem and corrective action was taken
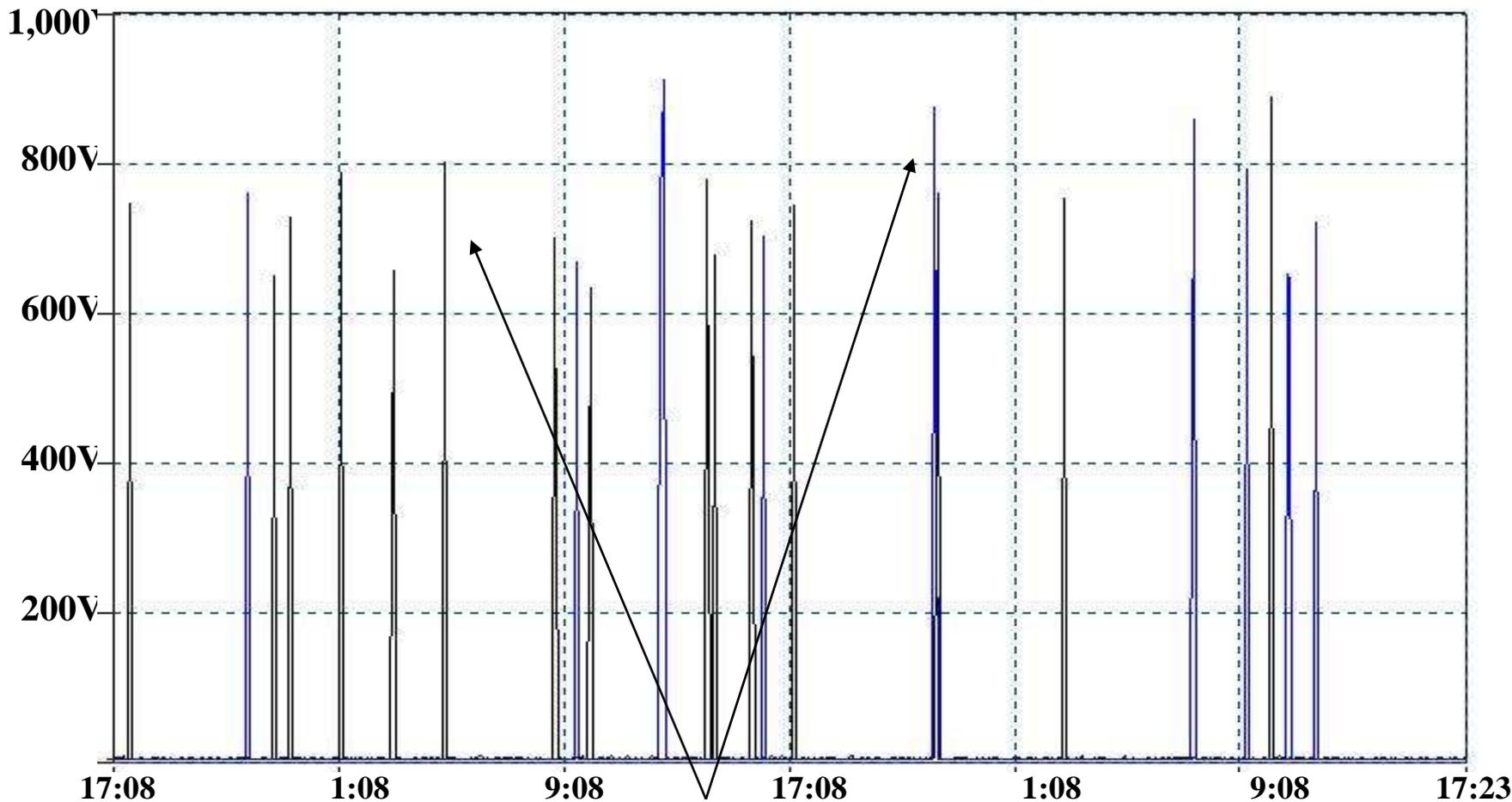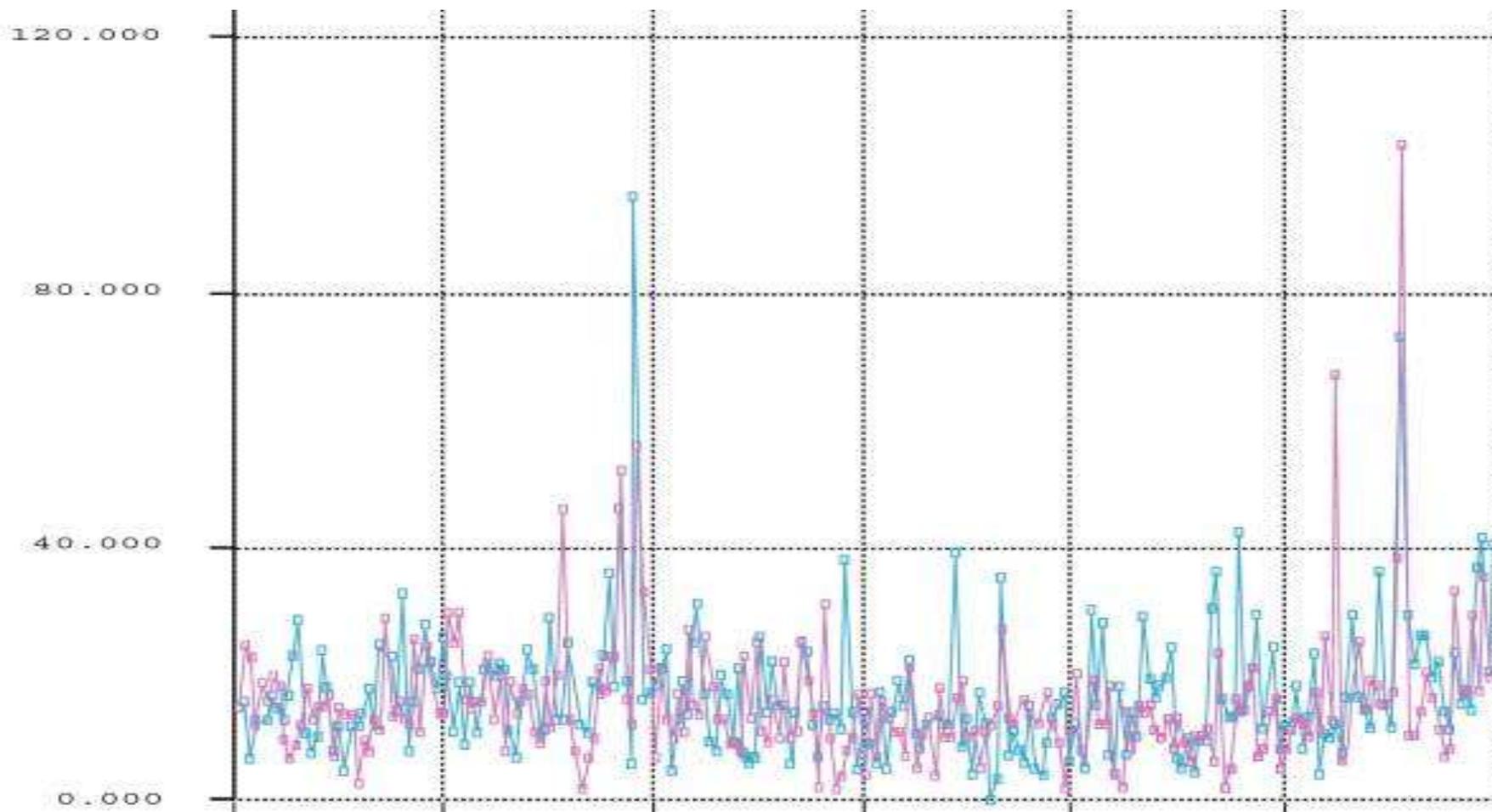
ESD Events where identified in two separate Steppers utilizing the Lighthouse ESD Monitoring System
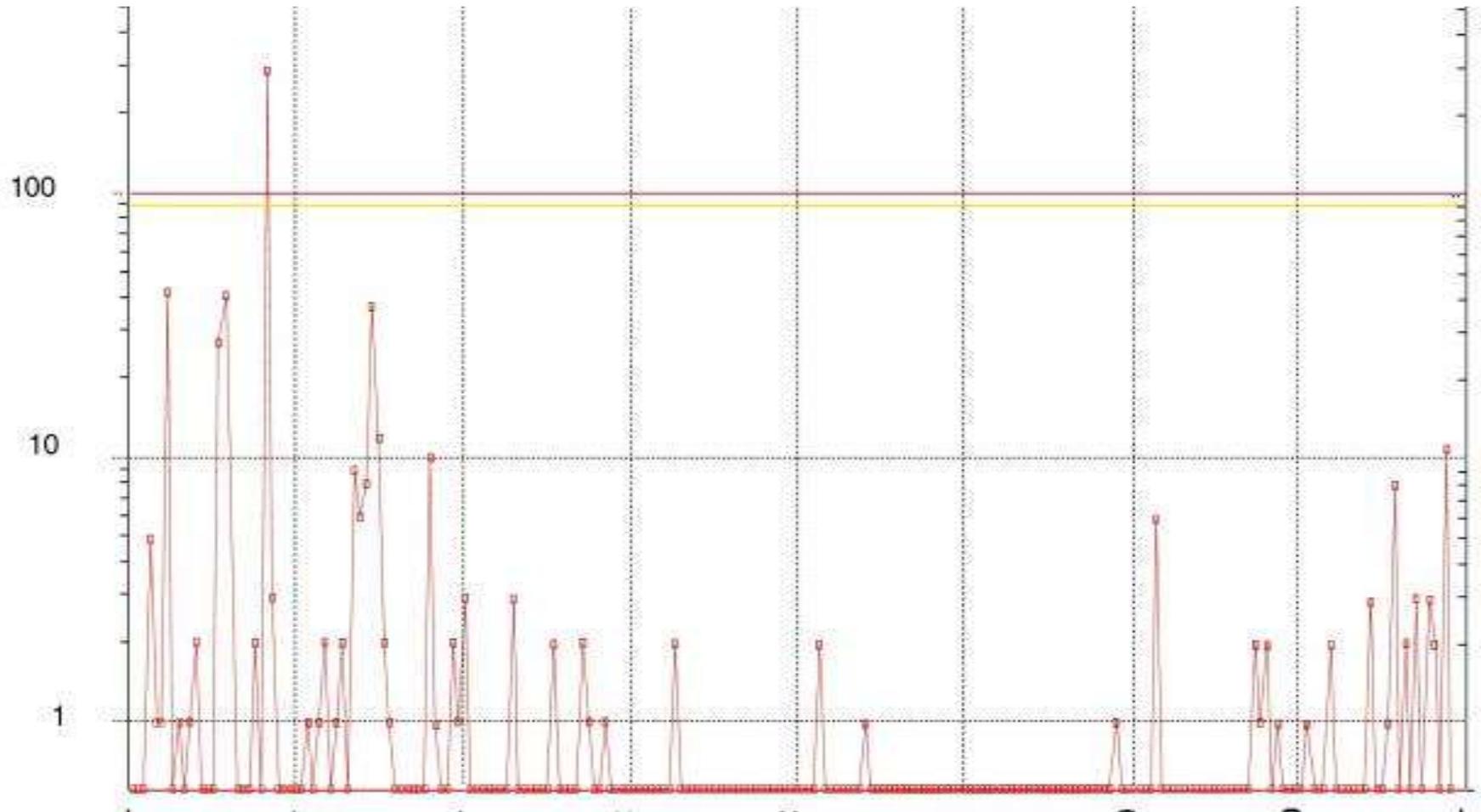
Particle Count Data

Particle counts in a 300MM etch tool
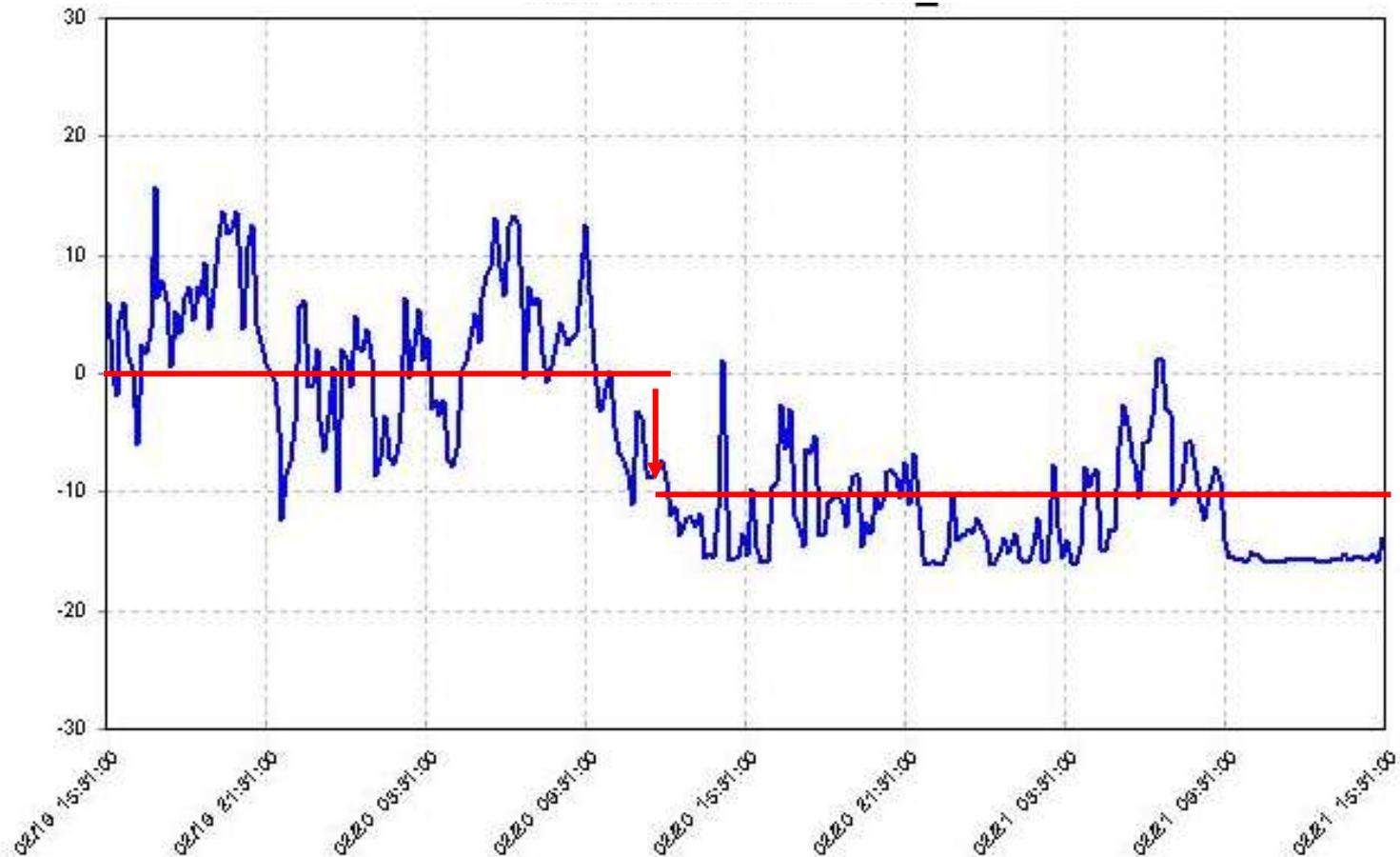
Particle Count Data

Particle counts in a 300MM sorter tool

Differential Pressure

Major shifts in differential pressure between two rooms

Thank You