



**LIGHTHOUSE**  
WORLDWIDE SOLUTIONS

## **Lighthouse Worldwide Solutions Master Presentation**



# R&D / Headquarters / Manufacturing



## 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





## **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**
- ★ **Organogenesis**
- ★ **Pharmaforce**
- ★ **Cell Genesys**
- ★ **McGuff Pharma**
- ★ **MDS Nordion**



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# Products



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# Lighthouse Family of Products



*World's Number One Particle Counters!*



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# Remote Particle Counters



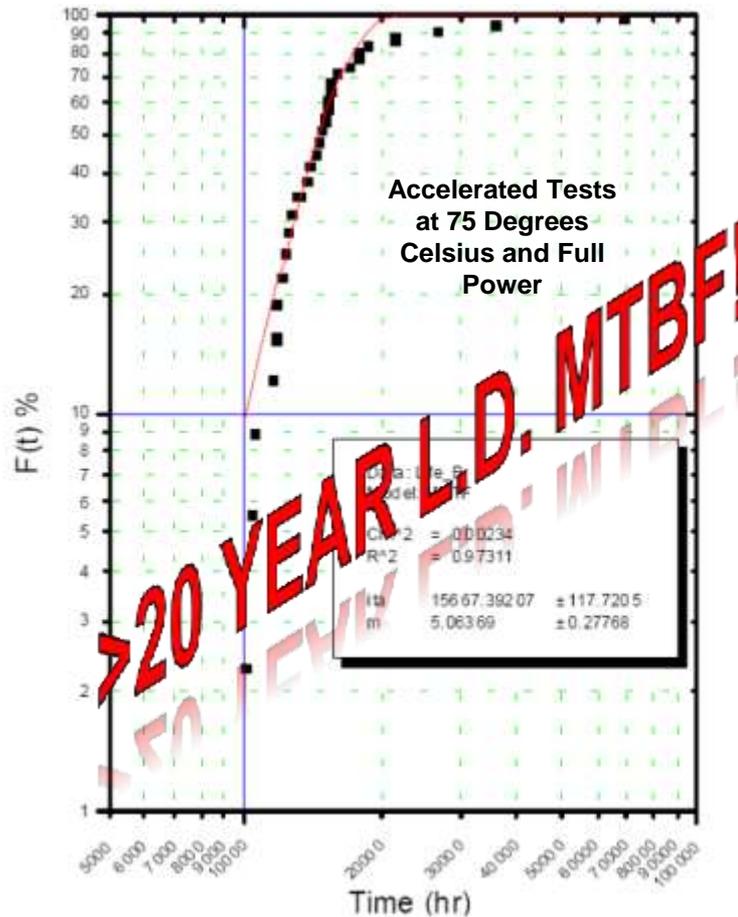
# Remote Particle Counters



- ★ Largest selection of remote particles counters available
- ★ Variety of outputs
  - ★ Modbus ASCII
  - ★ 4-20mA
  - ★ RS-485 (Met One Protocol)
  - ★ Ethernet
- ★ Sensitivity from 0.1 $\mu$ M
- ★ Flow-rates 0.1 CFM, 1.0 CFM
- ★ (4) Series includes flow sensor
- ★ Remote vacuum or self-contained pump units
- ★ Temp / RH probe options
- ★ Hydrogen peroxide resistant



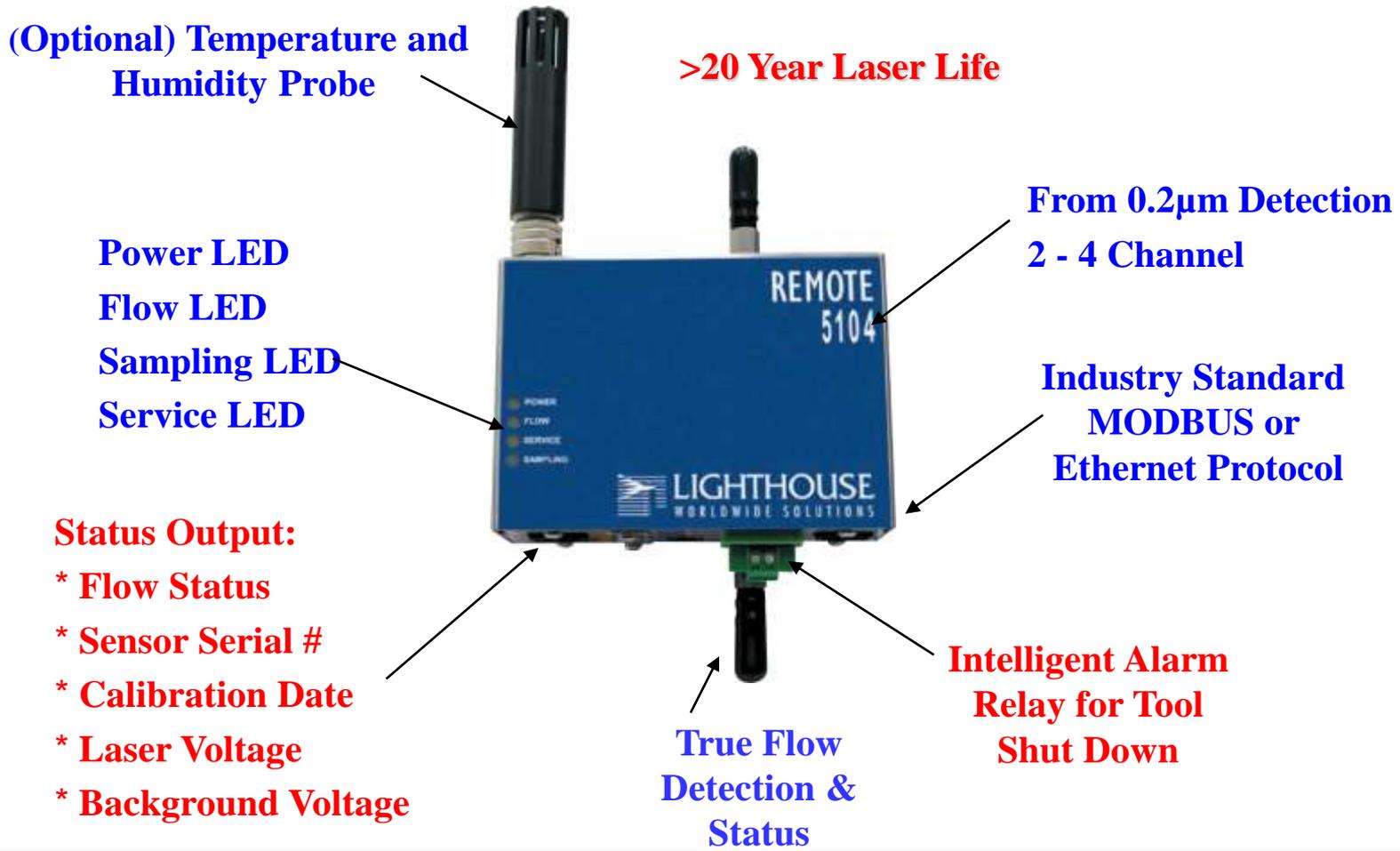
# ELITE Sensor Technology



- ★ Extreme Lifetime Infrared Technology Emitter (ELITE) higher power Laser Diode
- ★ Optical communications grade Laser Diode
- ★ Packaged and tested for Lighthouse products
- ★ Accelerated tests performed to verify lifetime
- ★ Extends lifetime of Laser Diode based products to an estimated **20-50** years based upon accelerated test results on all products



# REMOTE X104 ELITE Sensor





# REMOTE X104 ELITE Sensor

## Self-diagnostics

The Lighthouse Remote 4 Series particle counter has the most complete self diagnostics of any sensor on the market today.

**Self-diagnostics help to ensure data accuracy and reliability.**

**Self-diagnostics include:**

- \* Laser voltage
- \* Laser background voltage
- \* Laser Diode failure
- \* Photo amp failure
- \* Photo Diode failure
- \* Flow status





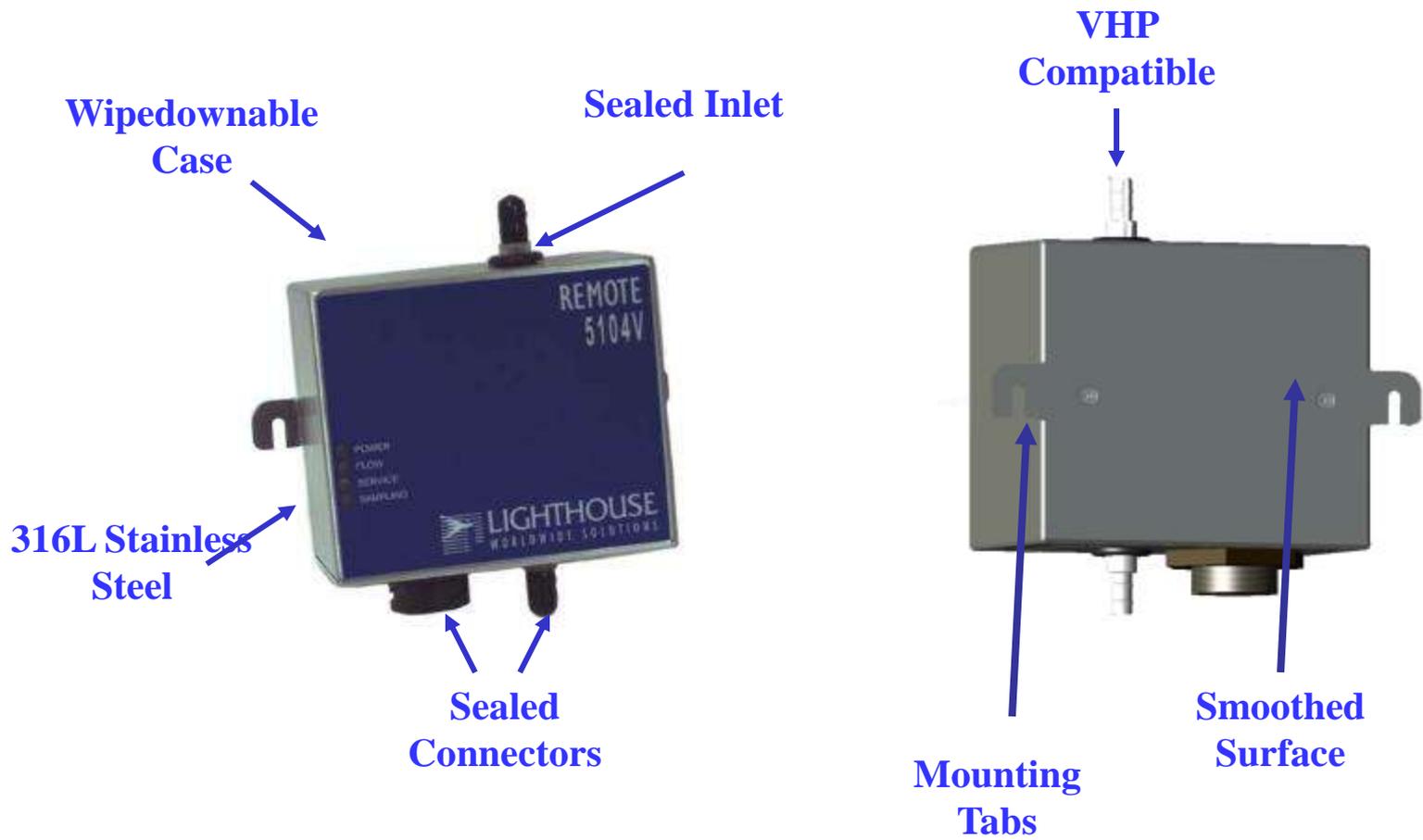
## Remote 5104V



- ★ VHP, IPA, LpH, Vesphene and Spor-Klenz compatible
- ★ Class 1 Division 2 Rating
- ★ Built-in flow monitoring
- ★ 0.5 - 5.0  $\mu\text{m}$
- ★ 1.0 cfm (28.3 LPM) flow rate
- ★ Designed for ISO21501-4 compliance
- ★ Small size
- ★ Stainless steel, wash down resistant / splash-tight enclosure
- ★ 20 year laser life



# Remote 5104V



**VHP, IPA, LpH, Vesphene and Spor-Klenz Compatible**



## Remote 5104PN & 5102PN



- ★ Remote 5104PN: Modbus
- ★ Remote 5102PN: 4-20mA
- ★ 1.0 CFM (28.3 LPM) flow rate
- ★ Built-in pump
- ★ Filter pump exhaust
- ★ Pump start / stop via software (5104PN)
- ★ Stainless steel construction
- ★ Wipe-down enclosure
- ★ 90-240 VAC Power (50/60Hz)



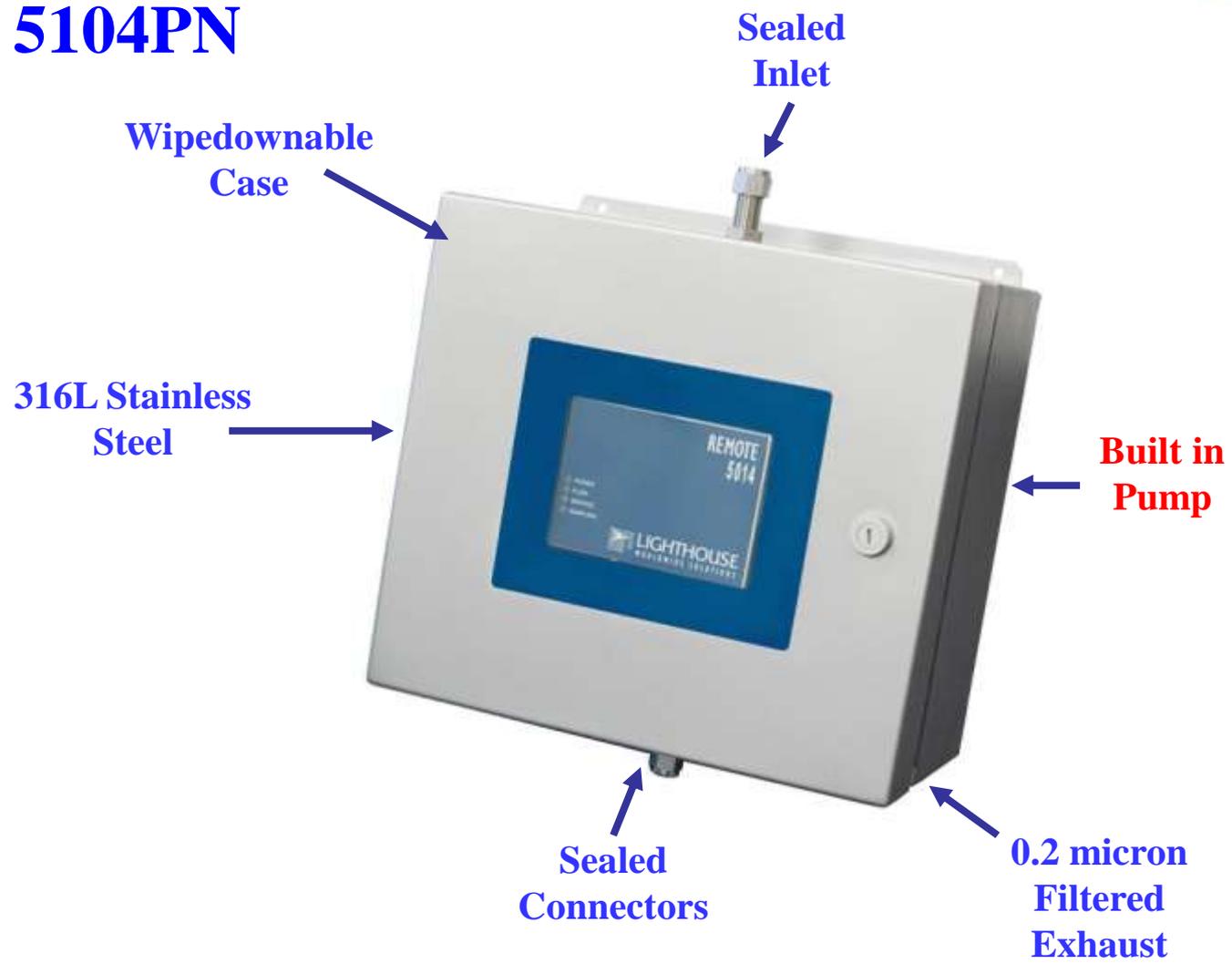
## Remote 5104PN



- ★ Channel sizes: 0.5 - 5.0 $\mu$ m
- ★ 1.0 cfm (28.3 LPM) flow rate
- ★ Internal vacuum pump with flow control
- ★ Designed for ISO21501-4 compliance
- ★ NEMA style stainless steel enclosure
- ★ LED status indicators
- ★ VHP, IPA, LpH, Vesphene and Spor-Klenz compatible
- ★ 20 year laser life



# Remote 5104PN

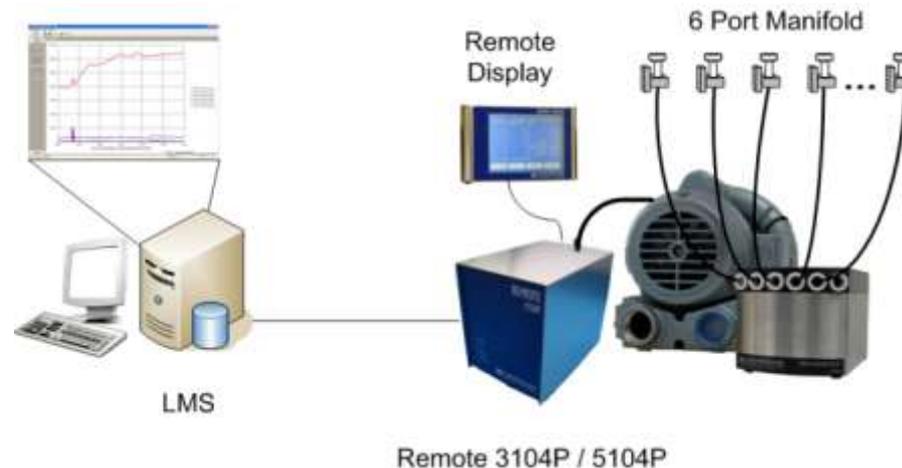


**VHP, IPA, LpH, Vesphene and Spor-Klenz Compatible**



## Remote 5104P & 3104P

- ★ Remote particle counter w/pump
- ★ Supports remote display
- ★ Interface: USB, RS-485 or Ethernet
- ★ HEPA filter cooling fan exhaust and pump exhaust
- ★ Interface with manifold
  - ★ 32 Port
  - ★ 6 Port
- ★ Reduced cost for manifold systems





## Remote 50104H (Remote Boulder Counter)

- ★ Remote 50104H (remote Boulder Counter for hazardous environments Class 1 Division 2)  
(Five-Zero-One-Zero-Four H)
- ★ 5 to 100 $\mu$ m remote particle counter
- ★ 1.0 CFM with flow monitoring
- ★ 4 channels
- ★ For use in Auto Manufacturing, Aerospace and other industrial applications





# Portable Cart System

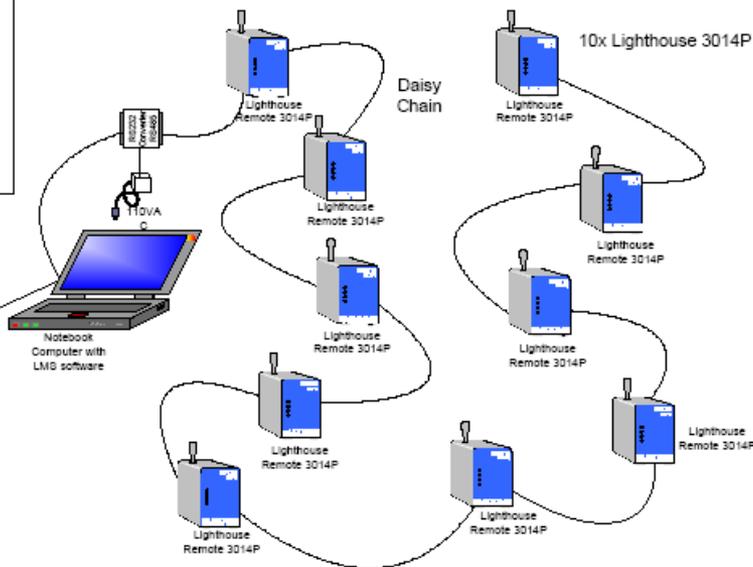
## Portable Characterization System:

### Notebook Computer

- LMSNet Software
- Capable of connection to existing LMS Network system
- Portable (Can run off UPS)

### 3014P APC Multiplexor

- Analog Inputs for Temperature, Air Velocity, & Humidity.
- 3000 Record Data Buffer
- Built-in Vacuum Pump with filtered exhaust.
- Daisy Chain Data Cable & Power Configuration.
- Portable (Can run off UPS)



- ★ Real time monitoring of multiple locations
- ★ Troubleshoot the process
- ★ Identify particle sources quickly
- ★ Characterize the process
- ★ Qualify the equipment

Drawn By:	Raymond Thomas	Customer:	Seagate International Technology
Date:	February 20, 2006	Description:	LMS Mini System - 3014P
Project:	Portable Characterization System - LMS Mini Monitoring System		



# Portable Cart System





# Manifolds



## Universal Manifold

32 sample locations

1.0 cfm

Works with Lighthouse and Met One particle counters



## Mini-Manifold

6 sample locations

0.1 cfm

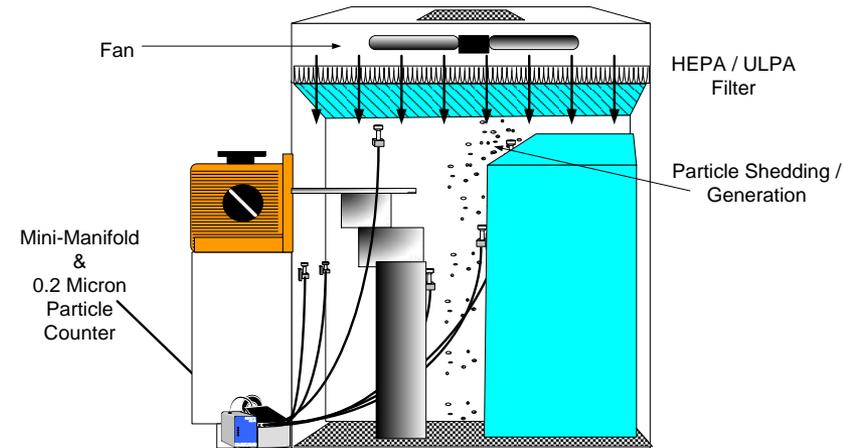
4 analog inputs



## Mini-Manifold+

6 sample locations

1.0 cfm



Mini-Environment Monitoring  
With Mini-Manifold & Single  
Particle Counter



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# Online Remote Viable Sampling



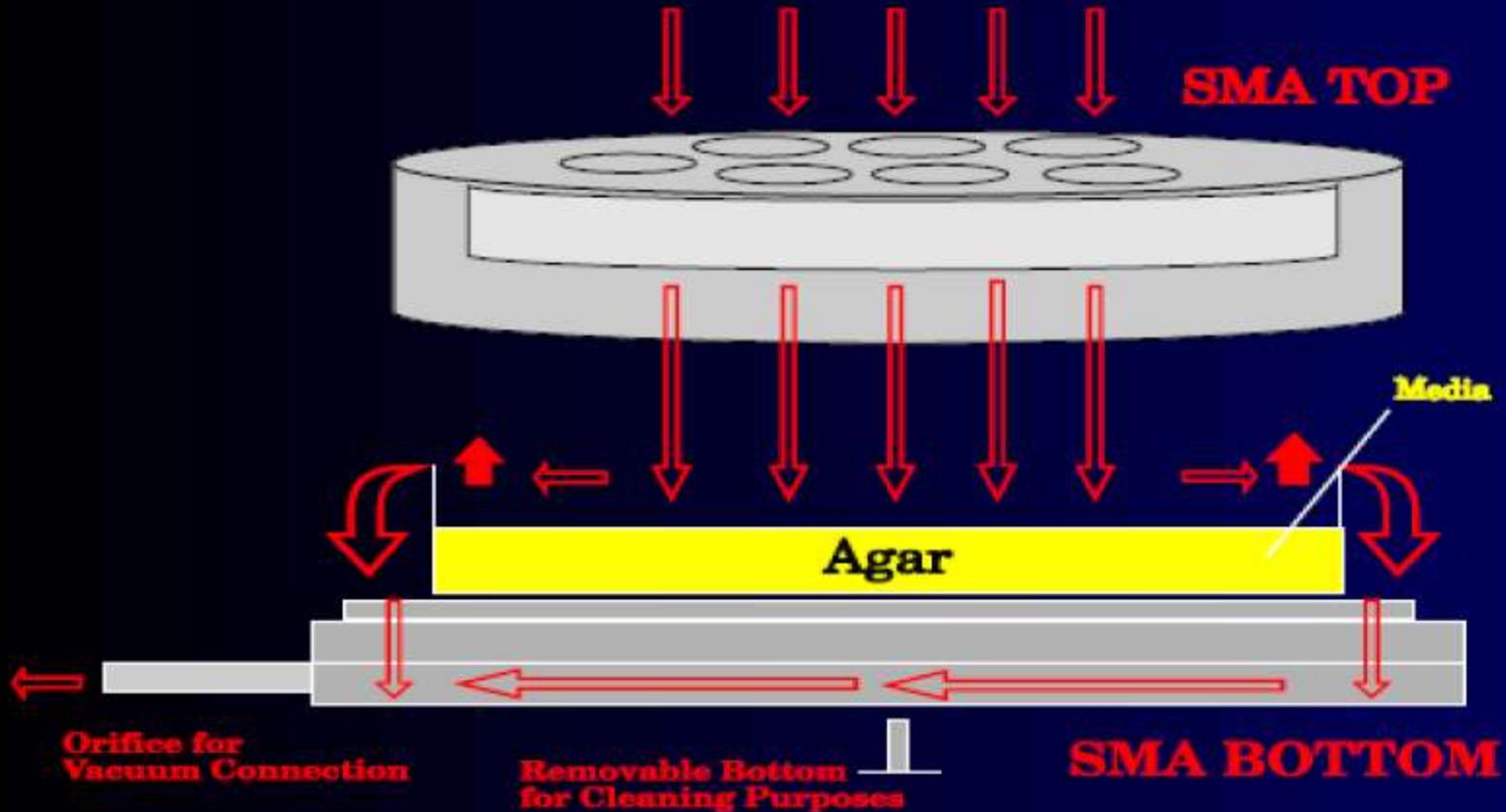
## Active Air Samplers

Similar to sieve impactor; cover contains uniformly spaced orifices; vacuum draws in air which is impacted on agar plate



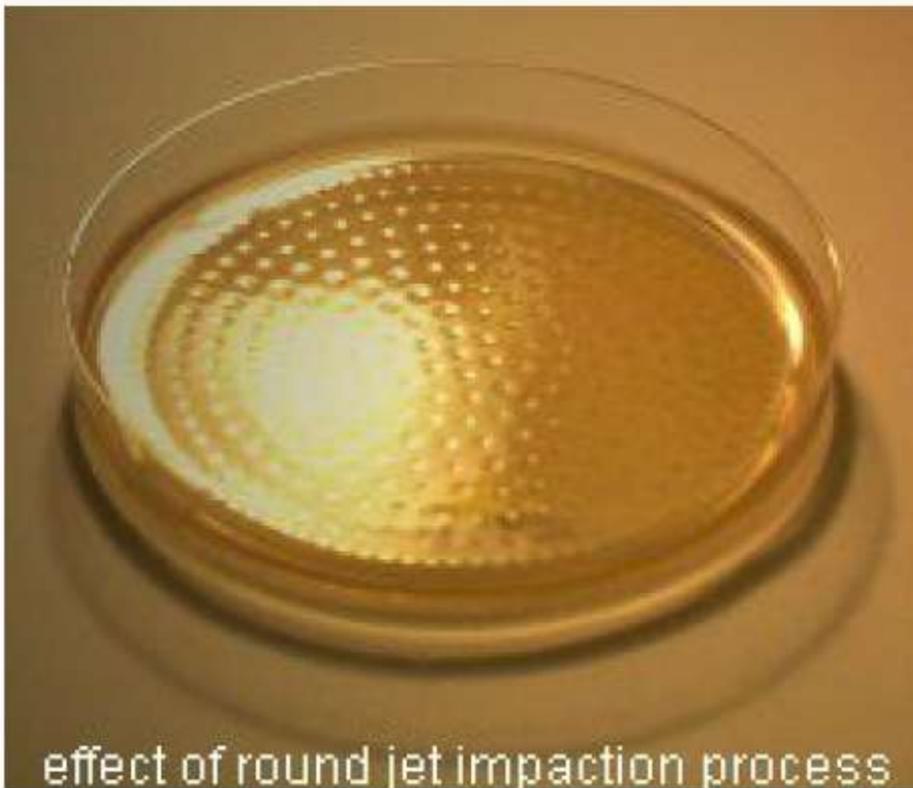


# Principle of Operation

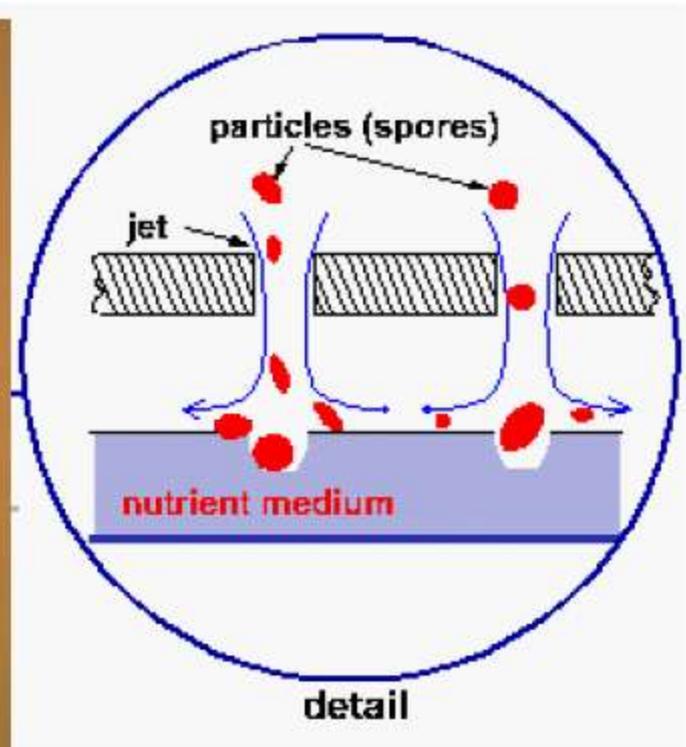




## Impaction on Media Plate



effect of round jet impaction process





## Remote Viable Sampling Systems

- ★ Remote SMA
- ★ Allows for not violating Grade A conditions for sampling
- ★ SMA is in Grade B environment: with tube to Isokinetic probe for Grade A sampling





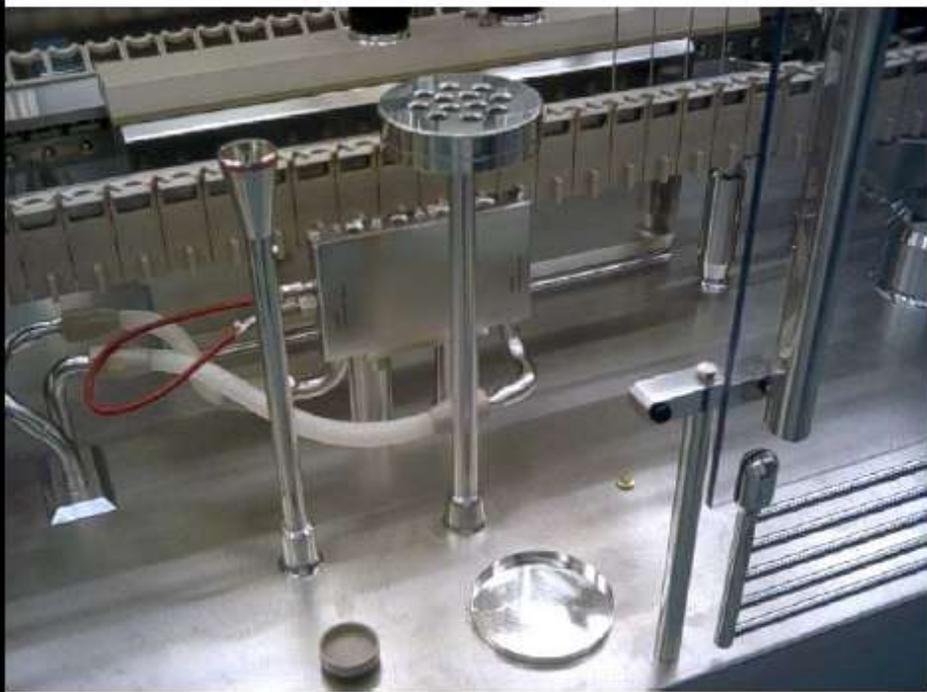
## Active Air Samplers

- ★ Provides for starting and sampling from inside the room



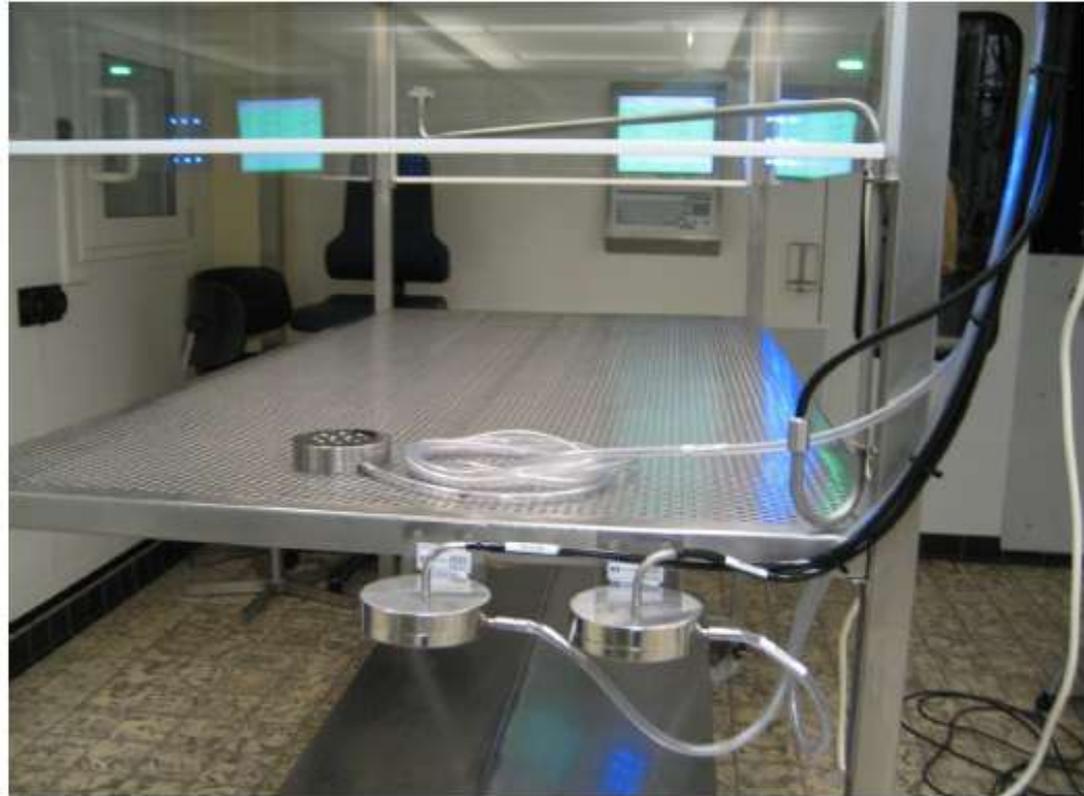


# Active Air Samplers





## Lighthouse Installation Pictures





## Lighthouse Installation Pictures



**Viabile Sampling**



## Lighthouse Installation Pictures

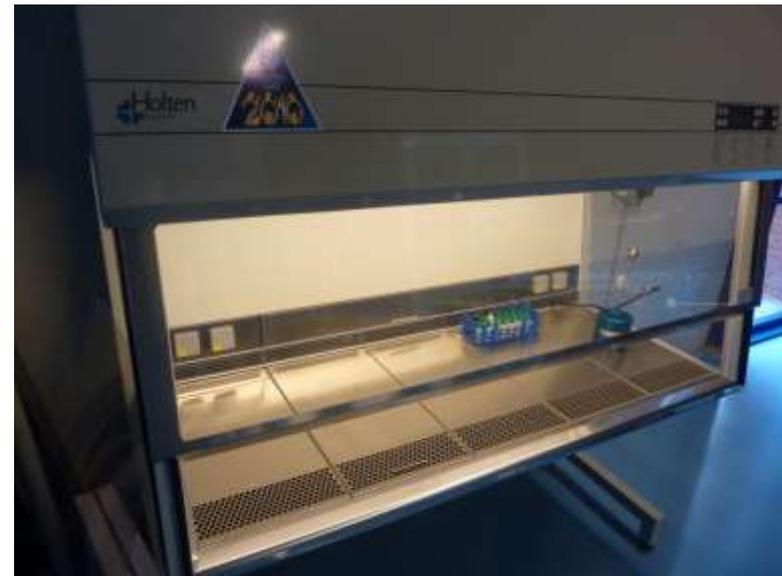


**Viability Sampling**



# Remote Viable Sampling Systems

- ★ Remote microbial sampling system
- ★ Utilizing microbial agar impactors
- ★ Controlled via FMS monitoring computer system
- ★ Internal pump or external





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# Combined Online Viable and Non-Viable Sampling



## Remote Viable / Non Viable Sampling Systems

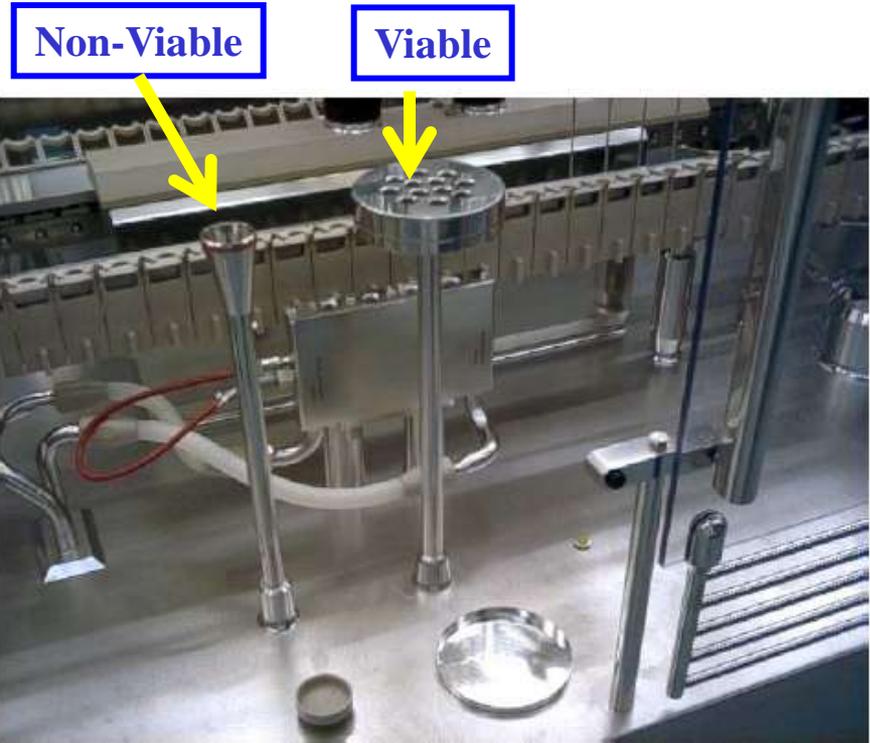
- ★ Combined viable and non-viable sampling
- ★ 1.0 cfm flow rate
- ★ Particle sampling at 0.5 and 5.0 micron
- ★ Controlled locally or via software
- ★ Internal or external vacuum





# Remote Viable/Non Viable Sampling Systems

- ★ Individually Controlled
- ★ Regulated Flow





# Installation



**Viable**

**Particle**



**Combined  
Viable / Non-  
Viable  
Sampling**



# SMA Control Interface: Example

- ★ Duration will allow the user to click on the text box and select one of the preset sample times for the individual SMA.
  - ★ Time remaining will show how much time is left for the sample.
  - ★ Air flow will show the flow rate of the sample taking place.
  - ★ Start will start the sampling process.
  - ★ Reset will reset the time remaining to the preset sample time selected.
- ★ Start / stop require password entry





# SMA Control Interface: Example

★ Manual data can be integrated into an existing record.

## ★ Input

- ★ Date
- ★ Start/Stop Time
- ★ Description
- ★ Flow Rate
- ★ Volume
- ★ CFU

**Manual CFU Data Entry**

Date	<input type="text" value="5/24/2010 9:36:44.497 AM"/>
Start_Stop Time	<input type="text" value="5/24/2010 9:37:28.325 AM"/>
Description	<input type="text"/>
Flowrate	<input type="text" value="0"/>
Volume	<input type="text" value="0"/>
CFU	<input type="text" value="0"/>



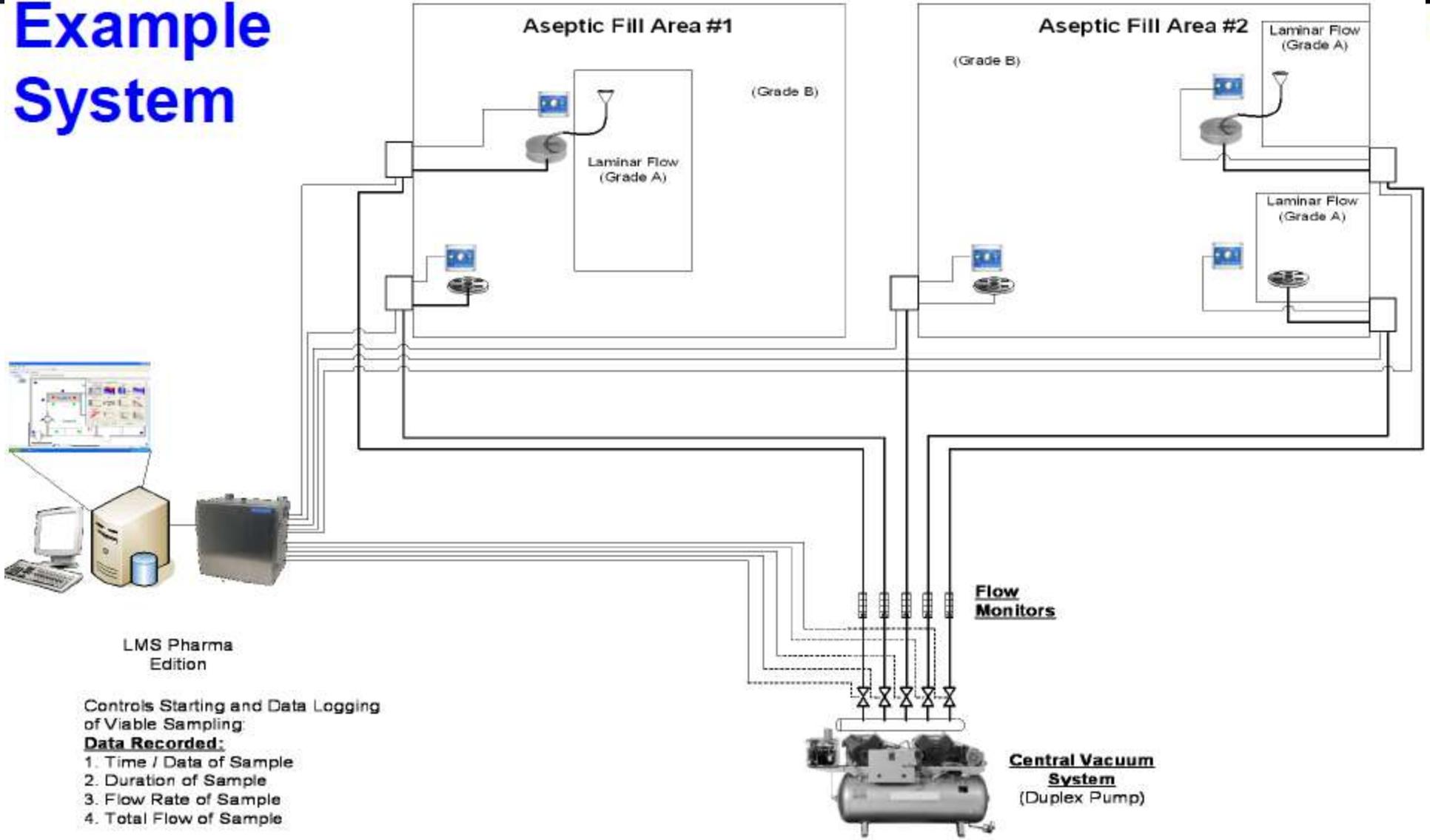
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# Online Monitoring Systems



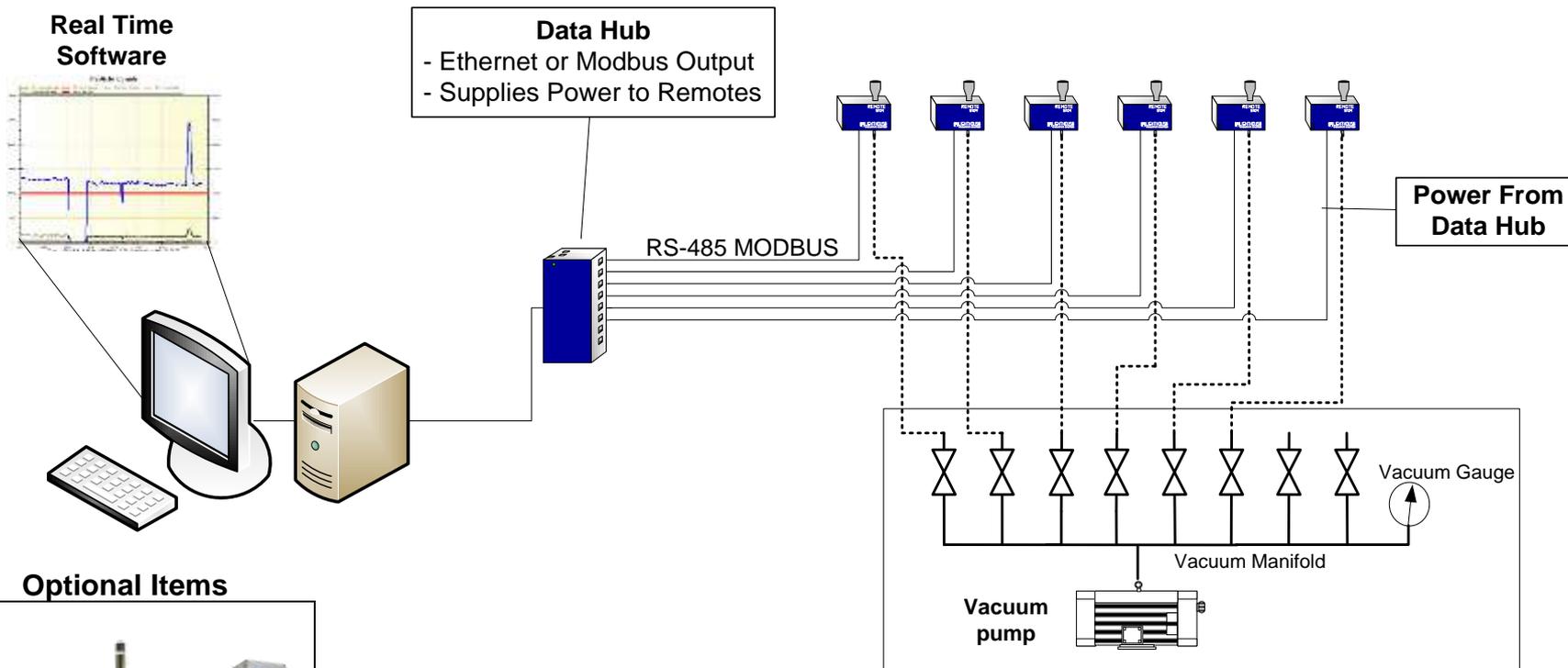
# Example System



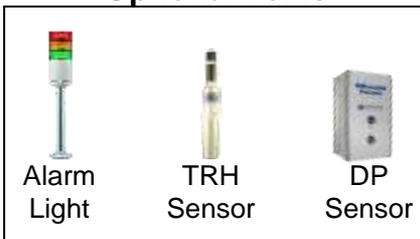


# Online Systems – Star Configuration

## 6 Real Time Particle Counters with External Vacuum Pump



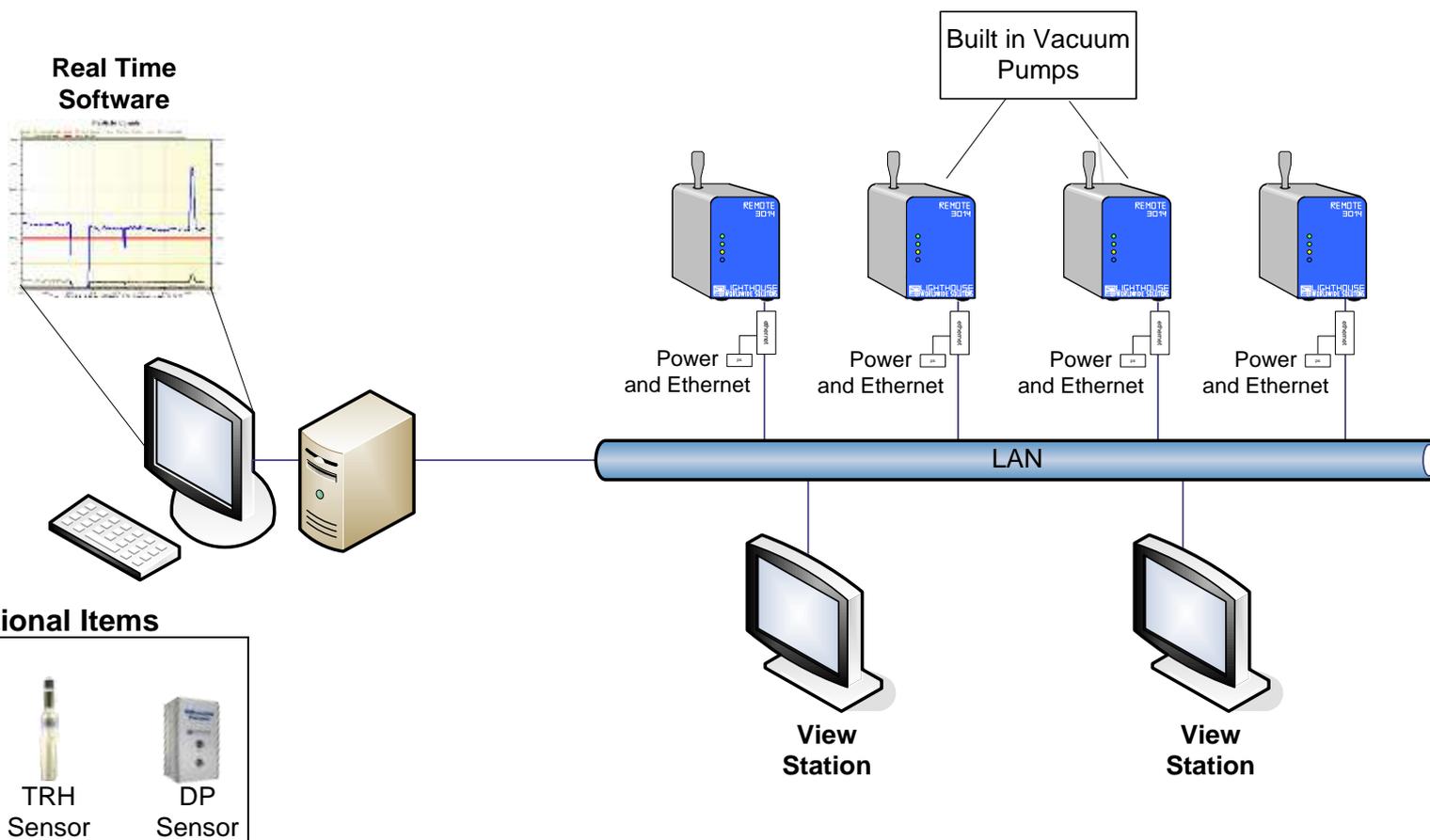
### Optional Items





# Online Systems- Network Configuration

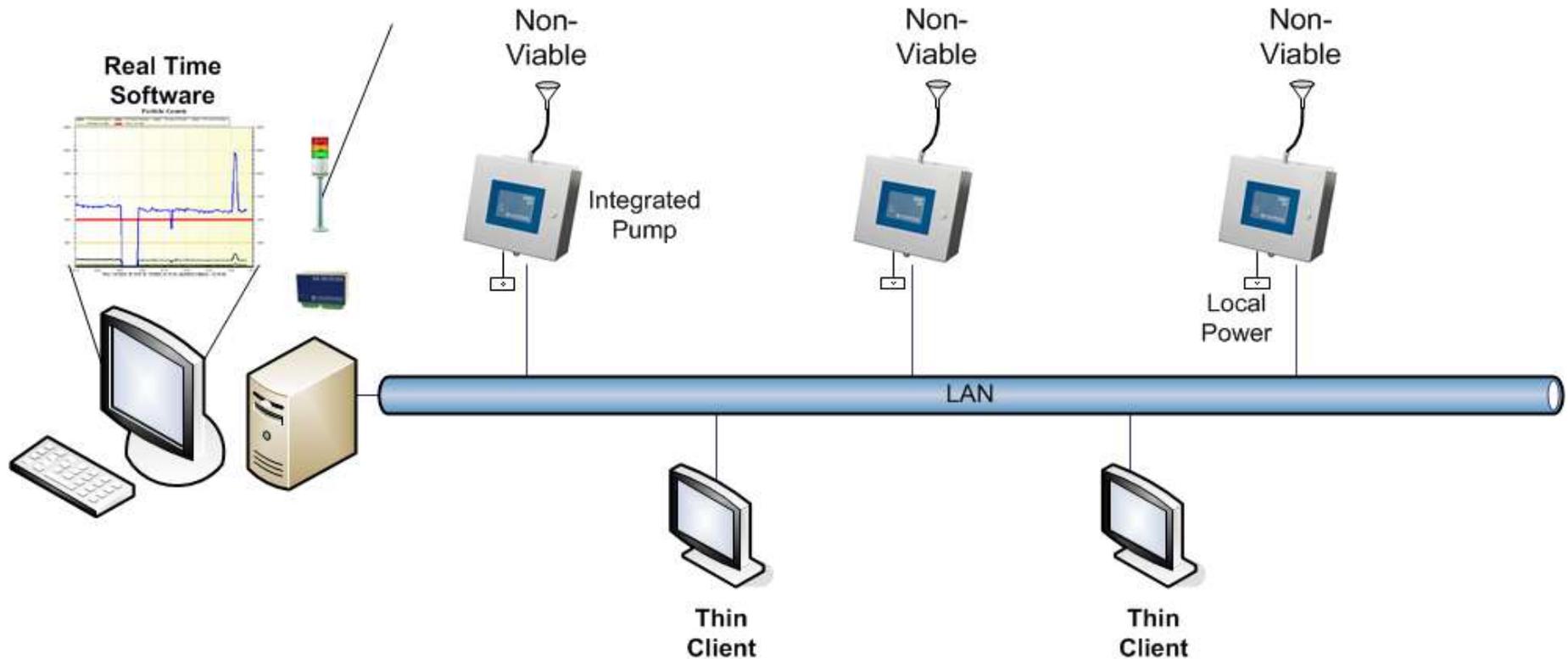
## 4 Real Time Particle Counters with Built in Vacuum Pump Over Ethernet





# Online Systems- Network Configuration

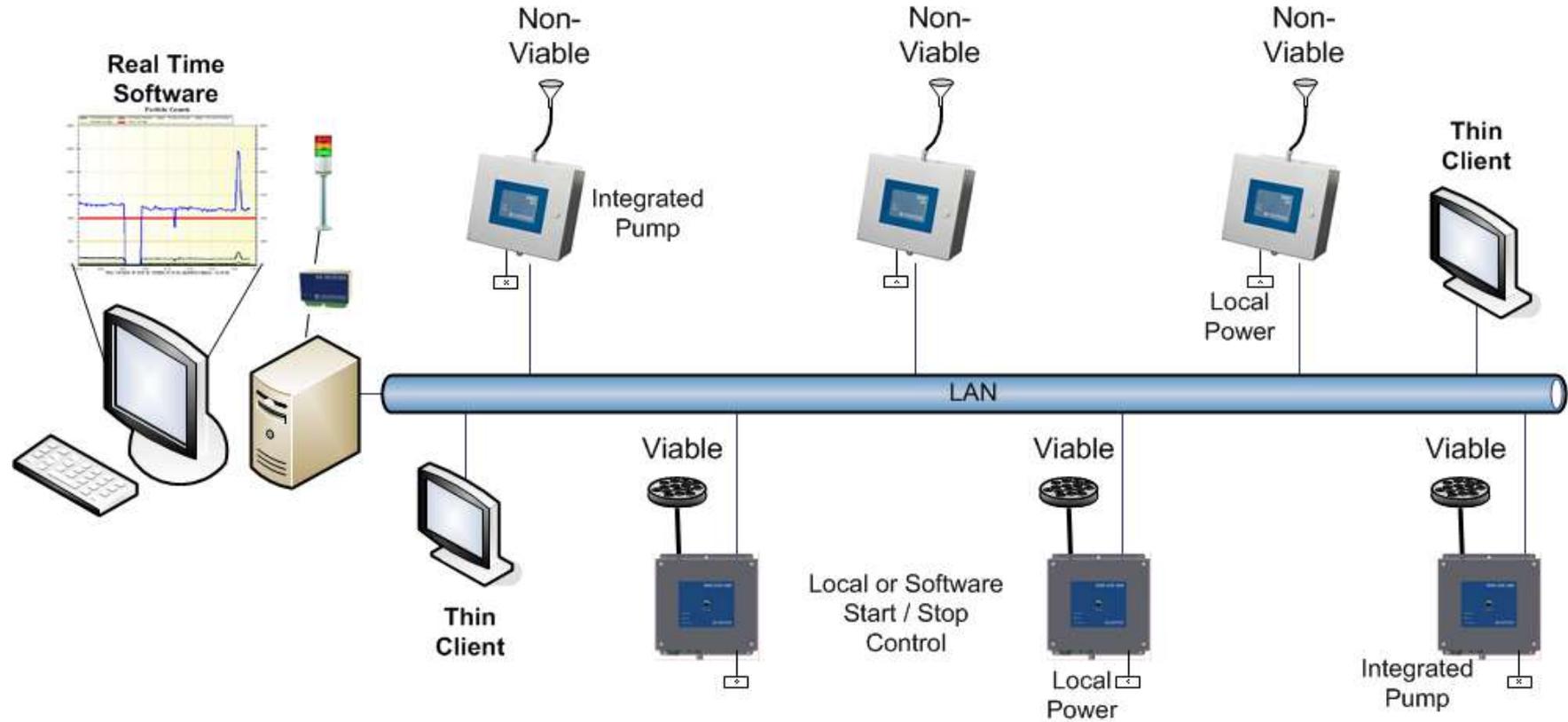
## 3 Real Time Particle Counters with Built in Vacuum Pump Over Ethernet





# Online Systems- Network Configuration

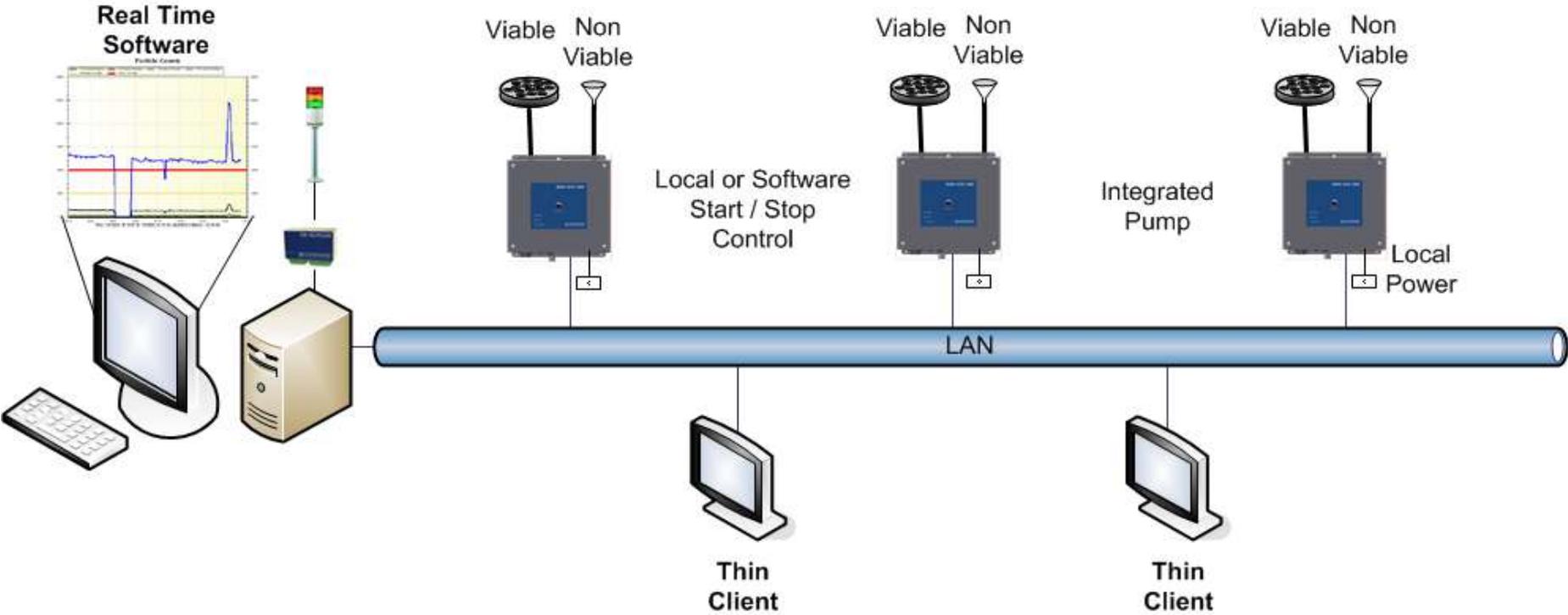
## 3 Real Time Particle Counters and Viable Samplers with Built in Vacuum Pump Over Ethernet





# Online Systems- Network Configuration

## 3 Real Time Particle Counters and Viable Samplers with Built in Vacuum Pump Over Ethernet



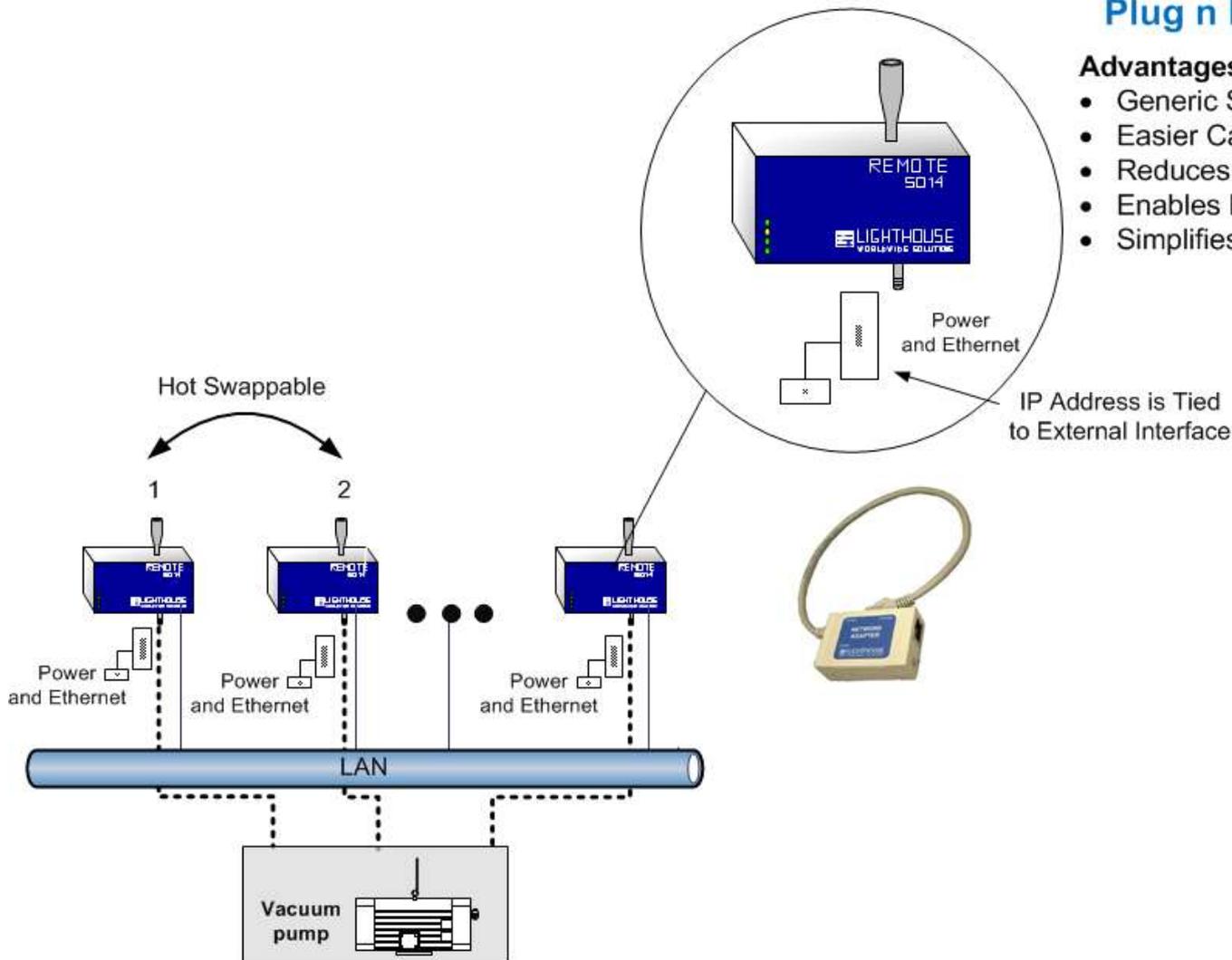


# Plug and Play

## Plug n Play Technology

### Advantages

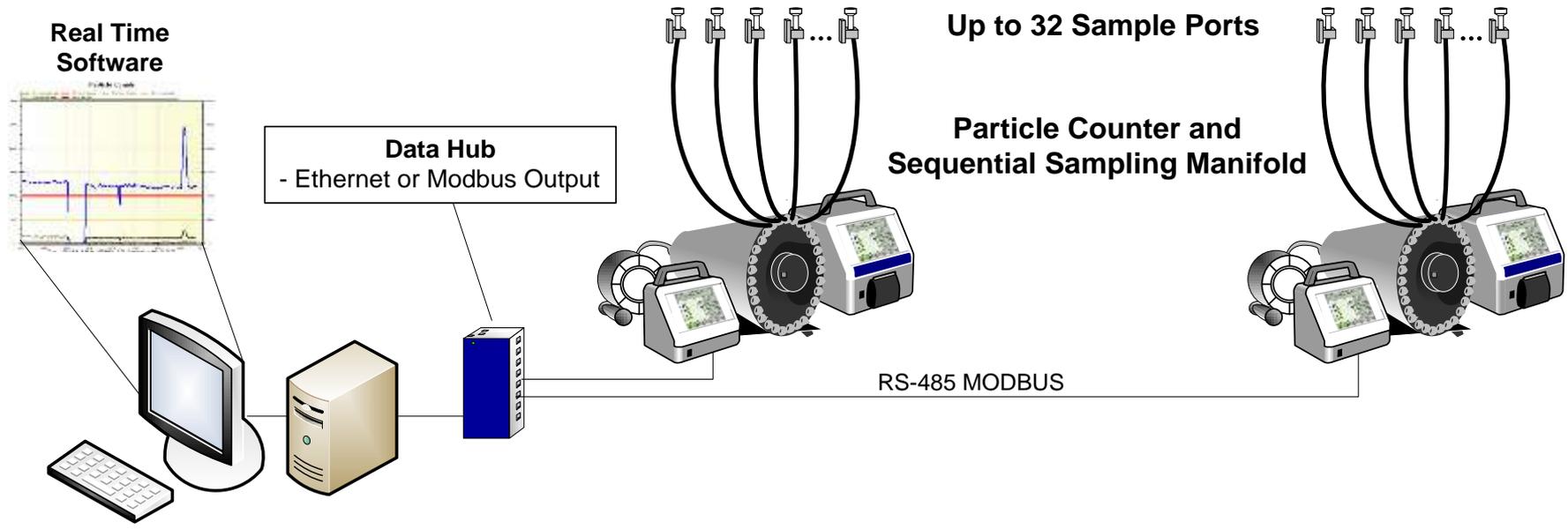
- Generic Sensor Addressing
- Easier Calibration Management
- Reduces Operator Error
- Enables Easy Hot Swapping
- Simplifies Trouble Shooting





# Online Manifold Systems

## Manifold Sampling System

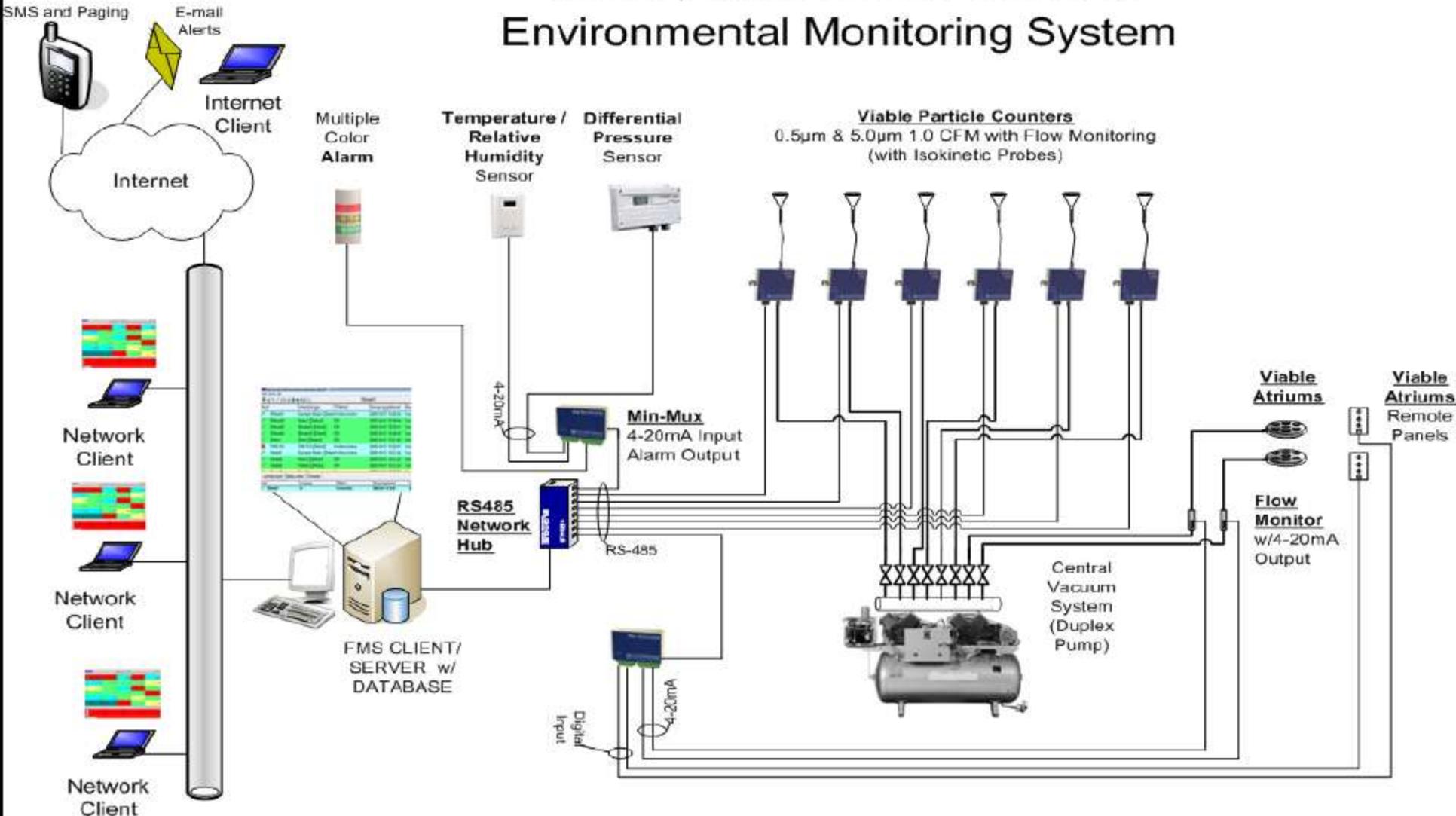


### Optional Items

		
Alarm Light	TRH Sensor	DP Sensor

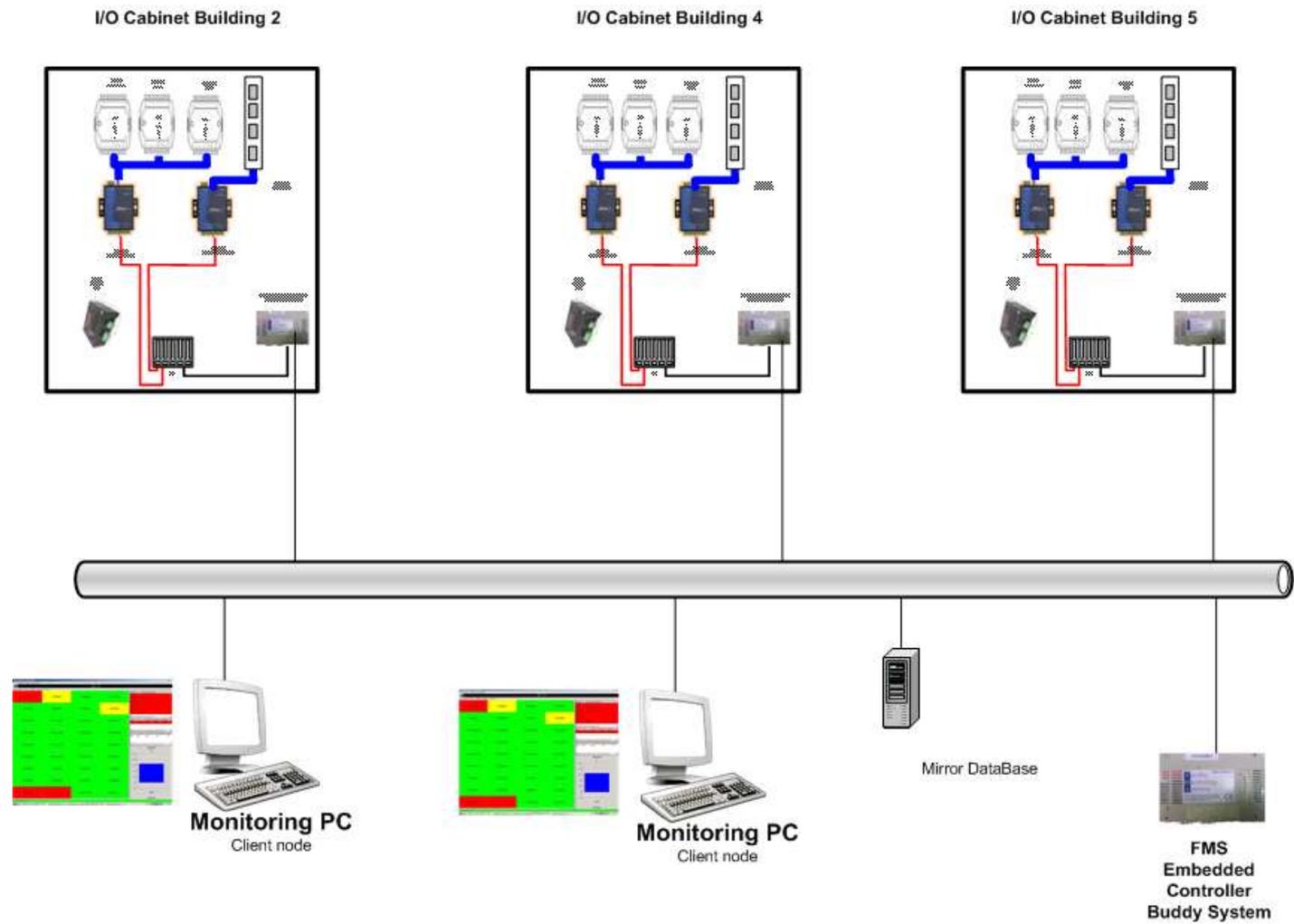


## Viab / Non-Viab Particle & Environmental Monitoring System





# Online System with Server





**Thank You**