PARTICLE MEASURING SYSTEMS
www.pmeasuring.com
5475 Airport Boulevard, Boulder, Colorado 80301-2339
303.443.7100 1.800.238.1801 Fax: 303.546.7380
Customer Service Center 1.877.475.3317
Instrument Service 1.800.557.6363

Wireless Particle Monitoring of Pharmaceutical Cleanrooms

Introduction

Wireless technology has brought many innovative changes, enabling us to communicate in new ways. This article will explain how wireless technology can improve the way that particles are monitored within pharmaceutical cleanrooms, while meeting validation and calibration requirements.

Traditional Particle Monitoring Systems

A traditional particle monitoring system (Facility Monitoring System) is normally comprised of the following components:

- Particle sensors
- Environmental sensors(temperature, humidity, and differential pressure sensors)
- Vacuum pumps
- Computer
- Data collection software
- Communication cabinet with network switches, PLC type of device for collection of 4-20 mA signals from environmental sensors and triggering of alarm lamps, Power supply to particle and environmental sensors etc.

Installing a particle monitoring system requires large amounts of cable to supply the particle sensors with Ethernet communication, 24 V, and vacuum tubes. It can be difficult, time consuming, and costly to install all of the required cables and tubes. It can become impossible if there is a moving object, such as a cart, that is to be monitored.

Another problem with the existing “wired” method is when a communication failure between the particle sensors and the data collecting software occurs; the common particle sensors do not have a built-in memory to save collected data. This results in expensive production batches can being forfeited.

There is also a high demand for vacuum pumps to deliver correct and continuously airflow through the sensors for the collection of particle data. This normally requires an installation of up to 3 pumps with a control panel programmed to switch between pumps at pre-set intervals.

Wireless Particle Monitoring System

Lately, the Pharmaceutical industry has been looking towards new technologies to simplify installation while also improving the quality of the particle monitoring system.

In Scandinavia, a pharmaceutical company recently installed a wireless particle monitoring system. The core of the wireless system is built up around a particle sensor with a built-in pump and electronics that monitor and adjust the airflow to the desired one cubic foot / minute. It also has a built-in memory that saves data in case communication is lost. The stored data is then automatically transferred to the data collection software when communication is restored. This provides a very robust system.

Figure 1: Particle Sensor with built-in pump and wireless communication

Overview of a Wireless Particle Sensor Communication

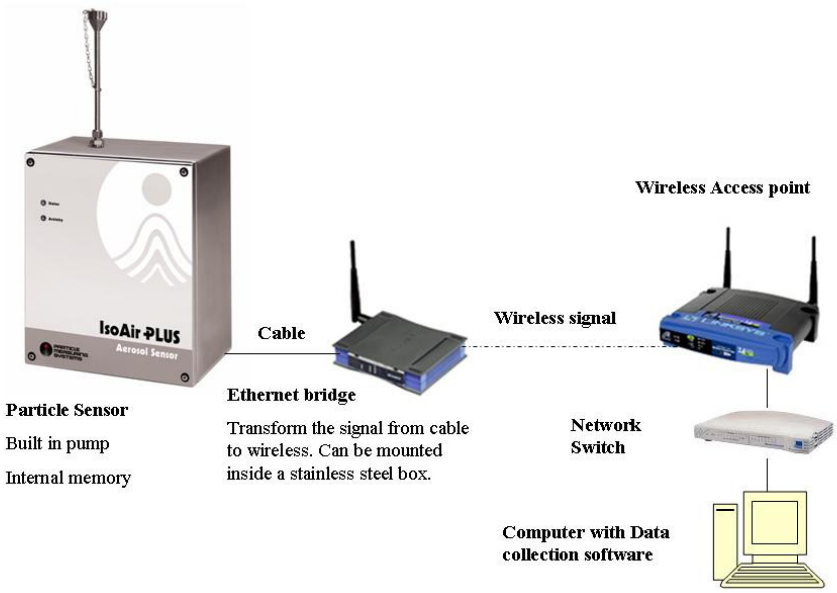

Figure 2: Overview of wireless particle sensor communication

Validation of a Wireless Particle Monitoring System

When considering a wireless system, concerns about validating the data arise. The following should be taken into account:

1. How do I verify that the facility is suitable for wireless communication?
2. What security do I need to set up within the wireless network?

3. How do I verify that the collected data is the correct one?

1. Verifying the facility

Before choosing to go wireless, a simulation of the system should be performed to verify that it is possible to get a good signal in the facility. This can be done by taking the particle sensor and put it on a cart down in the production clean room. Set up a laptop with the software that will be used to collect the particle data. Configure the sensor in the software so you can receive real-time data. Move the cart to the areas that will be monitored. In the other end of the room, a laptop can test that the data is being properly received and that no communication failures are detected.

Note: Although it is easier to test in non-production areas, it is essential to do the testing in a true-to-life setting. A production environment should be simulated as much as possible to verify if the signal is being interfered by other production equipment or personal.

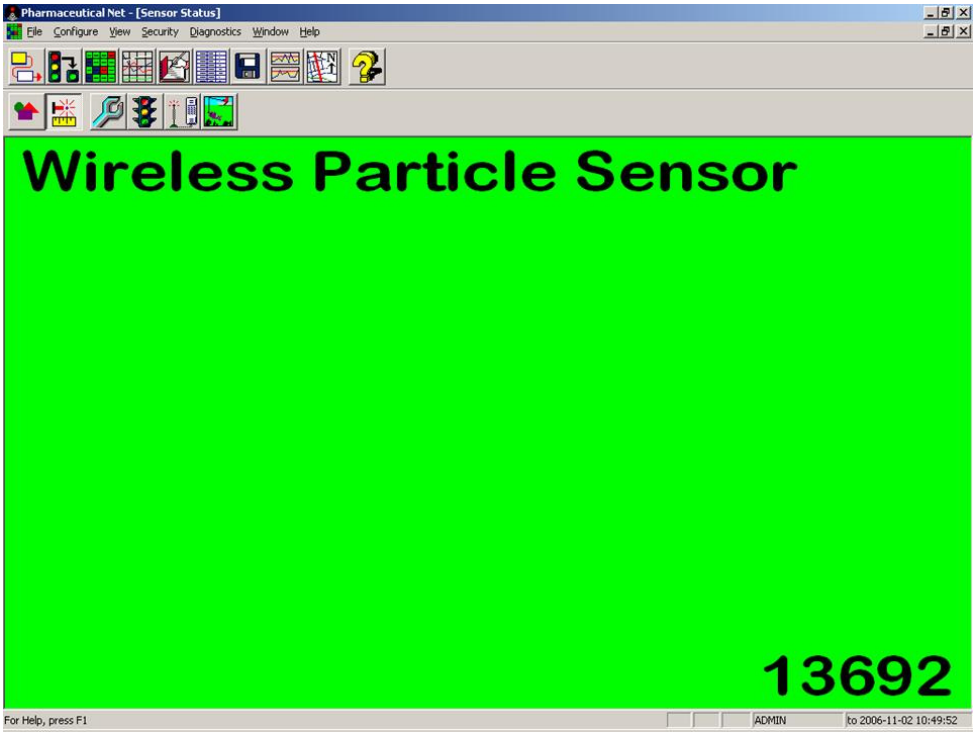

Figure 3: Wireless communication transfer of particle data to data collection software.

Within most wireless networks you can also verify the signal strength; a recommended level is 85-100%. If the signal is too weak, a second access point can be installed or high power antennas with extension cords mounted to pinpoint the sensors with a weaker signal.

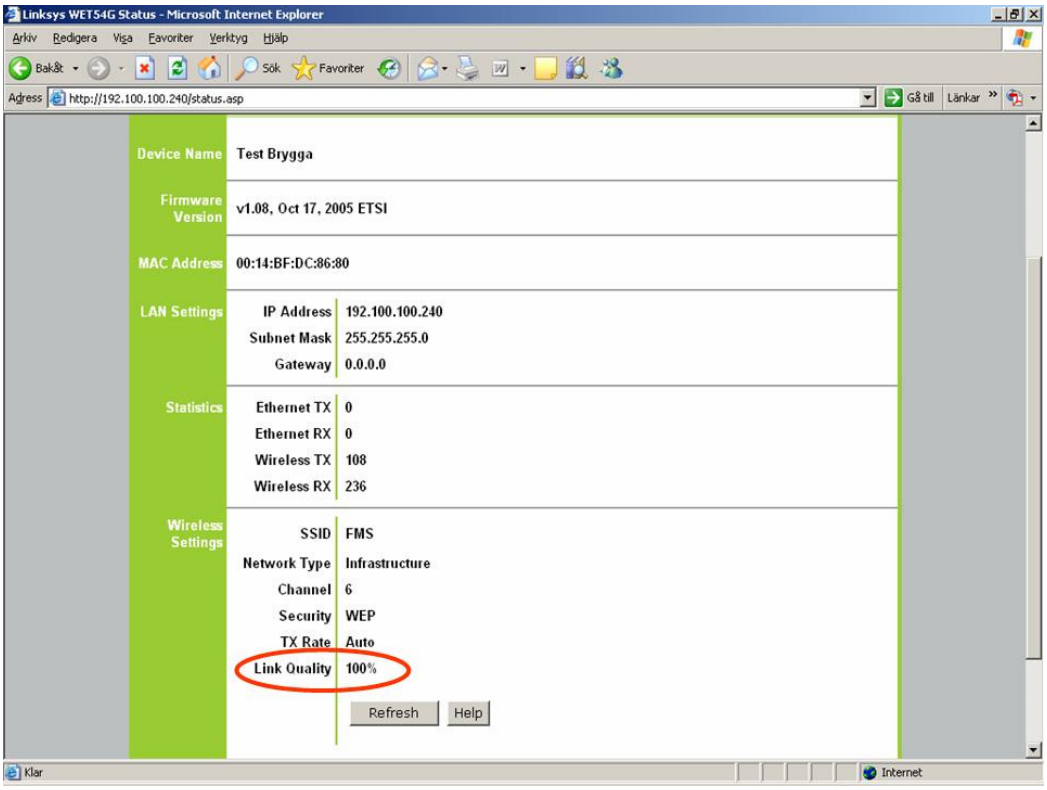

Figure 4: Test of signal strength (Link Quality).

2. Data security

As always with wireless data communication, the security of the network is imperative. If you install without adequate security, signals can be transferred through the walls to unsecured recipients.

There is a vast section of security systems to choose from. The most basic method requires a user ID and password to prevent any free surfers from using the wireless network. A more secure system involves setting the wireless network to only allow registered computers or sensors to communicate with the network; this is called “MAC address filter”. Each of the particle sensors has its own unique address that can be entered into the access point security authorization list.

Table 1: Example of configuration of wireless access point.

Menu Settings	Value
Network Setup	
Device Name	Wireless
Configuration Type	Static IP
IP Address	192.100.100.150
Subnet Mask	255.255.255.0
Default Gateway	0.0.0.0
AP-Mode	
Access Point	Enabled
Basic Wireless Settings	
Mode	Wireless-G Only
Network SSID	Particle
Channel	6

SSID Broadcast	Enabled
Security Settings	
Security Mode	WEP
Encryption	104/128-Bit(26 Hex digits)
Passphrase	Facility Monitoring System
Key 1	3D85D2F237D3FDD69F39668440
Wireless Mac Filter	
Access Restriction	Enabled
Permit PCs listed below to access the network	Enabled
Mac address 1	0016B646F2F8
Mac address 2	0016B646F2FA
Mac address 3	0016B646F2EE
Mac address 4	0016B646F2E8
Mac address 5	0016B646F2EA
Mac address 6	0016B646F440

3. Verifying the data

Any system is only as valuable as the data it provides, and so it is important to ensure that the correct data is being sent through the system. The best method to test this is to take a portable particle counter with a built-in printer and connect it to the wireless network via the built-in Ethernet communication connection. Data can be printed from the particle counter and compared with the data from the wireless collection method.

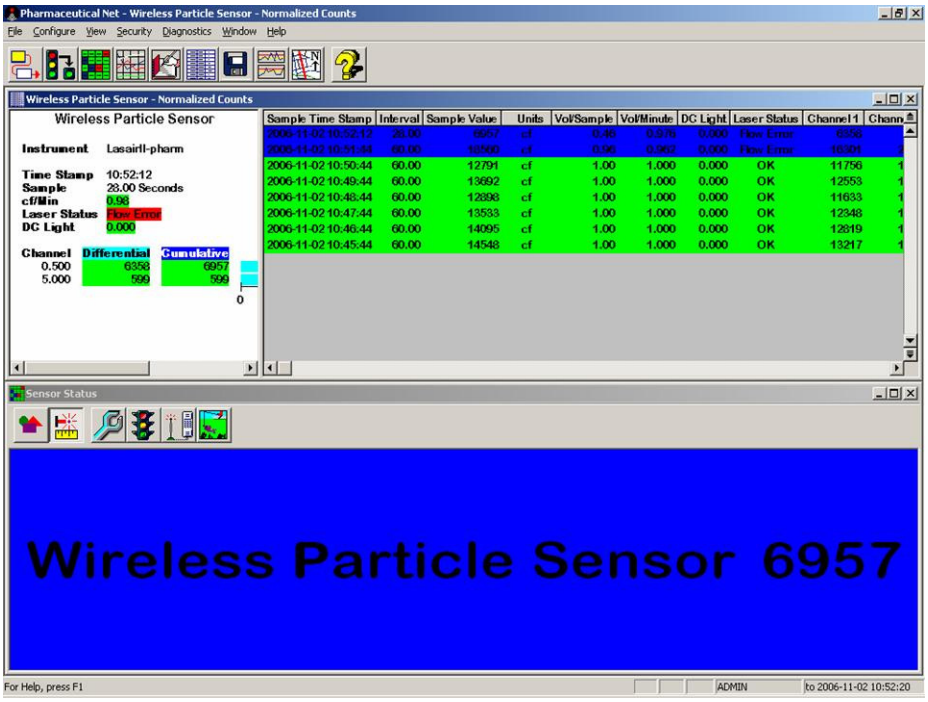

Figure 5: Flow error alarm from particle sensor registered in data collection software

The most critical item to verify is what occurs if there is a communication failure between the sensor and the software. Since the sensor has a built-in memory it will store all data if communications is lost and transfer it when communication is restored. A communications

failure can be simulated by disconnecting the Ethernet cable between the access point and the data collection software. The communication failure will register as a change in the colour on the display and no data will be logged. You could write down the time for the last registered sample for each sensor, reconnect the cable, then verify that all sensors received the historical data that was missing. This historical tabular can then be printed an attached as test result raw data.

You can also test the signal by blocking off the inlet of the sensor, forcing it to send a flow error signal to the software.

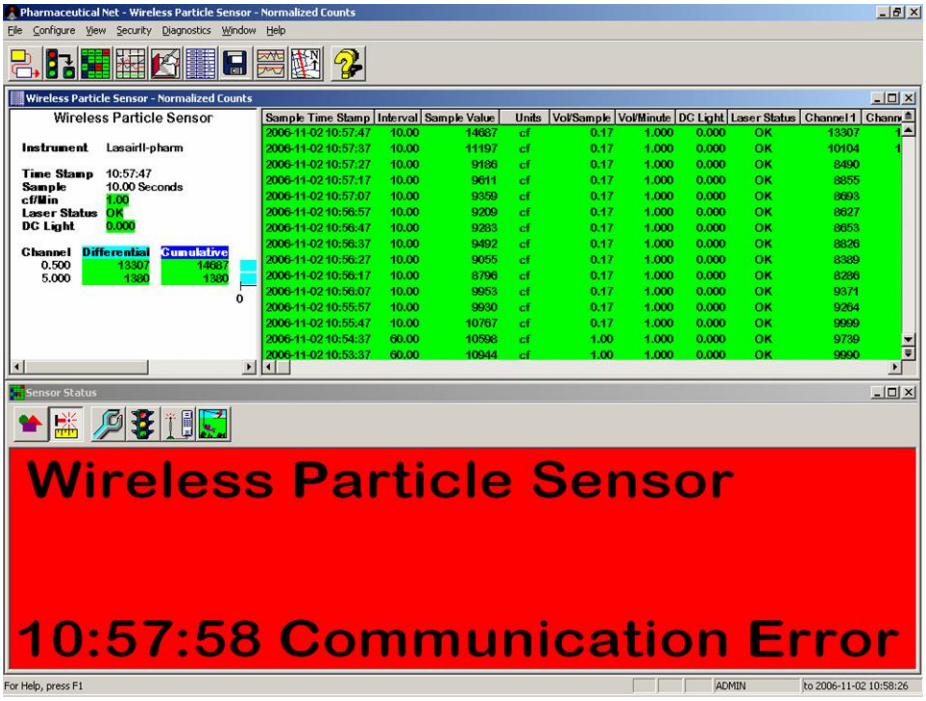

Figure 6: Communication failure registered in the data collection software.

Conclusion

Wireless technology has two main advantages. It ensures that critical data is not lost, and it is simpler to install. New security provisions ensure that the data is secure and can be validated.

Author

By Thomas Loof, Malvern Instruments Nordic