SensiNet Wireless in FDA 21 CFR Part 11 Compliant Systems
White Paper

Overview

Following the FDA regulations found in 21 CFR Part 11 and adhering to GxP guidelines are critical to your company's success. However, they are also time-consuming and expensive. Wireless Sensors's SensiNet sensor products are both easy to install and help ease the burdens of compliance by reducing the cost of collecting critical environmental data.

In this white paper you will find information on the following topics:
- How SensiNet fits into FDA 21 CFR Part 11 monitoring systems.
- What advantages SensiNet provides over traditional monitoring methods.
- How FDA 21 CFR Part 11 applies to SensiNet.
- How to validate SensiNet according to GxP.
- What other components are used in a complete monitoring system.
- How SensiNet is plug & play compatible with other system components.

SensiNet Makes Compliance Simpler

The first step in creating an FDA 21 CFR Part 11 compliant system is to gain access to the environmental data required by the FDA – without this data there are no Electronic Records to keep. Traditional methods of collecting this data have significant drawbacks:
- **Wired Systems** – Wired systems make use of sensors that are placed on laboratory equipment (e.g. refrigerators, incubators) that are then wired back to a central data collection point. These systems are costly and time consuming to install, difficult to maintain, and inflexible to changing equipment locations and physical environment.
- **Data Logging Systems** – Data logging systems make use of sensors that have the ability to buffer many readings at a time. To make the system work a lab technician must periodically download the data from the data loggers – a time consuming, tedious, and expensive process. In addition, if a data logger ceases to operate properly there is no way to learn of the failure until the next scheduled download which can lead to lost data.
- **Manual Systems** – In a manual system a lab technician is responsible for going from monitoring point to monitoring point, looking at a sensor read-out, and then writing down the measurement result. Manual data collection is time consuming, tedious, and expensive as well as highly error prone.

Wireless Sensors is the leading provider of high-security, high-reliability data collection systems based on cutting-edge wireless technology. The SensiNet product line of Smart Sensors, Mesh Routers, and Gateways is helping pharmaceutical and bio-medical companies, hospitals, and blood banks change the way that they meet FDA regulations.

SensiNet enables customers to collect the environmental data required by the FDA more easily without making FDA 21 CFR Part 11 compliance more difficult. In fact, most existing 21 CFR Part 11 monitoring systems are plug-and-play compatible with SensiNet.

By deploying SensiNet wireless sensor networks in combination with FDA 21 CFR Part 11 software systems customers realize several significant benefits over traditional methods:

- **Reduced Cost** – Monitoring systems that are based on SensiNet are inherently less costly to deploy and maintain then typical monitoring systems. With SensiNet there is no need to pull wiring through a facility, or pay lab technicians to take time-consuming and error-prone manual readings.
- **Speed and Ease of Installation** – Due to its wireless nature, SensiNet is extremely quick and easy to deploy. Most SensiNet based monitoring systems can be deployed in 1-3 days depending on size.
- **Simple Reconfiguration** – Unlike wired systems, SensiNet is easily reconfigured to deal with your changing environment. Smart Sensors move with equipment and continue to send data wherever they are located.
- **Simple Recalibration** – When it comes time to calibrate your environmental sensors SensiNet makes the process painless. Smart Sensors are simple to calibrate in place or in a metrology lab. Wireless Sensors even offers an A2LA accredited calibration program.

FDA 21 CFR Part 11 and SensiNet

Wireless Sensors's SensiNet product line is a wireless data transport system that moves data from one location to another. As described below, it is nearly transparent to FDA 21 CFR Part 11. SensiNet can be deployed to collect environmental data without creating extra validation and documentation work.

Subpart B – Electronic Records
A key benefit of using SensiNet for collecting environmental data is that it does not store Electronic Records as defined by the FDA in 21 CFR Part 11. As a result, most the FDA regulations that govern the generation and storage of Electronic Records are not applicable to the SensiNet wireless sensor network.

As seen in Table 1, only two requirements of 21 CFR Part 11 Subpart B for Electronic Records apply to SensiNet:

- **Reading Validation** – SensiNet is required to validate that data collected by the wireless system is accurate, reliable, consistent, and unaltered.
- **Device Checks** – SensiNet is required to determine that data collected by the wireless system originates from a valid source (i.e. a SensiNet Smart Sensor).

However, other components of the SensiNet-based monitoring solution external to Wireless Sensors's products are subject to FDA 21 CFR Part 11 Subpart B – Electronic Records. These components are described in greater detail later in this document.

FDA 21 CFR Part 11 Subpart B - Electronic Records	Validation	Copies of Records	Protection of Records	Limiting Access	Audit Trails	Sequencing of Steps	Authority Checks	Device Checks	Operator Training	Document Control	Signature Manifestations	Signature/Record Linking
SensiNet												
Smart Sensors & Services Gateway	X							X				
Operating System												
Microsoft Windows Server 2003	X		X	X	X		X					
Monitoring Software												
Intellution iFix	X	X		X	X	X	X	X				
Iconics Genesis32	X	X		X	X	X	X	X				
CitectSCADA	X	X		X	X	X	X	X				
Enterprise Data Storage												
Microsoft SQL Server	X	X	X	X	X							
Oracle	X	X	X	X	X							
OSIsoft PI	X	X	X	X	X							
Alarming Package												
Win-911	X		X	X	X							
Iconics AlarmWorxMMX	X		X	X	X							
Electronic Signatures Package												
Adobe Acrobat											X	X
Customer Procedures												
Customer Procedures									X	X		

Table 1: FDA 21 CFR Part 11 Subpart B – Electronic Records applicability
to the components of a SensiNet-based wireless monitoring system.

Subpart C – Electronic Signatures
When transporting data, SensiNet does not make use of Electronic Signatures as defined by the FDA. For this reason none of the FDA regulations for Electronic Signatures are applicable to SensiNet as seen in Table 2.

As in the case of the Electronic Records regulations, other components of the SensiNet-based monitoring solution external to Wireless Sensors's products are subject to FDA 21 CFR Part 11 Subpart C – Electronic Signatures. These components are described in greater detail later in this document.

FDA 21 CFR Part 11 Subpart C - Electronic Signatures	Signature Uniqueness	Identity Verification	Signature Authentication	ID Code & Password Rotation	Loss Management	Unauthorized Access Detection	Device Testing
SensiNet							
Smart Sensors & Services Gateway							
Operating System							
Microsoft Windows Server 2003		X		X		X	
Monitoring Software							
Intellution iFix				X		X	
Iconics Genesis32				X		X	
CitectSCADA				X		X	
Enterprise Data Storage							
Microsoft SQL Server				X		X	
Oracle				X		X	
Alarming Package							
Win-911				X		X	
Iconics AlarmWorxMMX				X		X	
OSIsoft PI				X		X	
Electronic Signatures Package							
Adobe Acrobat	X		X				
Customer Procedures							
Customer Procedures		X				X	X

Table 2: FDA 21 CFR Part 11 Subpart C – Electronic Signatures applicability
to the components of a SensiNet-based wireless monitoring system.

It is important to note that although the majority of FDA 21 CFR Part 11 does not apply to SensiNet that does not mean that SensiNet is unnecessary to the monitoring system. To the contrary, SensiNet collects and provides all of the environmental data that is stored in Electronic Records and digitally signed using Electronic Signatures. SensiNet is the very core of the monitoring system and enables all of the other system components.

Validating SensiNet

As described above, most of the FDA regulations in 21 CFR Part 11 are not applicable to SensiNet. This makes validating SensiNet according to GxP straightforward.

For the purposes of validation SensiNet should be viewed as a data transportation black box – data goes in one side and comes out the other. When it comes time to validate SensiNet all that's needed is the following procedure:

- Select the Smart Sensor to be validated.
- Provide the Smart Sensor with a known input value.
- View the data value measured by the Smart Sensor in the monitoring software.
- Compare the results – if they match to within calibration tolerances then the point is validated.
- Continue to the next Smart Sensor.

Wireless Monitoring System Architecture – SensiNet Components

The SensiNet wireless sensor network is comprised of three main components described below.

SensiNet Smart Sensors
SensiNet Smart Sensors are wirelessly enabled environmental sensors that come in a variety of types:

- Temperature and Humidity Smart Sensors– for measuring ambient temperature and humidity
- Temperature Smart Sensors – for measuring temperature using RTD probes
- Current Smart Sensors – for measuring 4-20 mA current transducers
- Voltage Smart Sensors – for measuring 0-10 V voltage transducers
- Contact Closure Smart Sensors – for measuring contact closure points

Each of these Smart Sensors is a part of the SensiNet wireless network and can be used in conjunction with other Smart Sensors in the same network according to customer need. Users can configure Smart Sensors to sample and transmit sensor data at an interval of their choosing. Smart Sensors come standard in packaging designed for indoor office environments, but can also be configured with NEMA 4X packaging for wet environments.

SensiNet Mesh Routers
SensiNet Mesh Routers form the wireless backbone on which Smart Sensors transmit their data. Their sole purpose in the network is to route messages from Smart Sensors to SensiNet Services Gateways and back. They accomplish this by forming a wireless mesh network topology that has built in redundancy to protect against data loss. In addition, they extend the range of the network well beyond the transmission distance of any one device and enable sensing points that previously may have been impossible to measure.

SensiNet Services Gateway
Every SensiNet wireless sensor network is managed by a SensiNet Services Gateway – essentially an intelligent wireless access point. The Gateway is capable of supporting one network consisting of many Mesh Routers and Smart Sensors of varying types. For very large or physically separated environments, multiple gateways can be used to form redundant, overlapping or totally separate networks.

SensiNet Services Gateways collect data from Smart Sensors and make it available to external applications through a variety of interfaces including:

- OPC Data Access
- Modbus/TCP
- Web Services

When the components of SensiNet are combined they have the architecture shown in Figure 1.
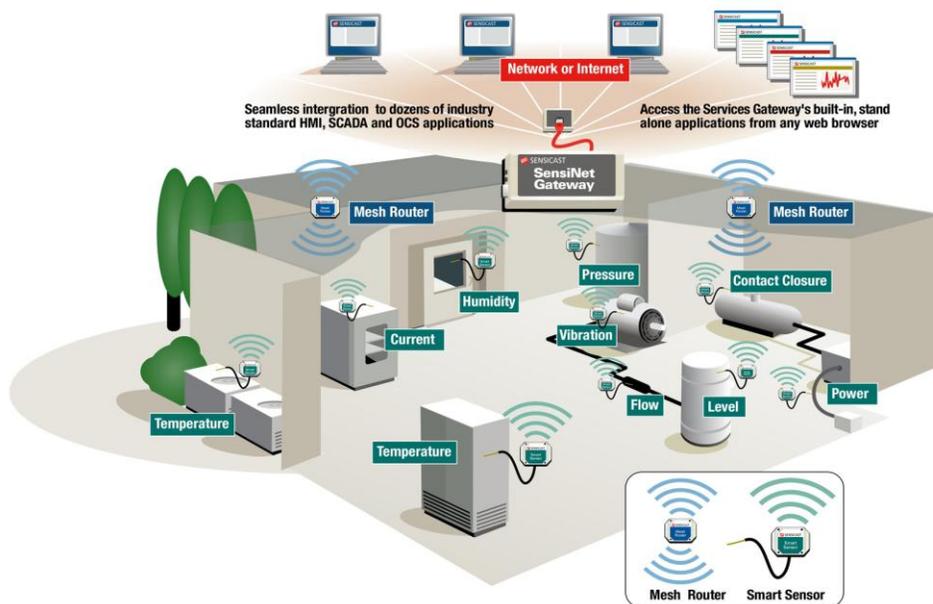

Figure 1: Architecture of a SensiNet wireless sensor network.

Wireless Monitoring System Architecture – External Components

SensiNet is at the heart of a wireless monitoring system that includes additional components not manufactured by Wireless Sensors. A typical FDA 21 CFR Part 11 compliant and validated system that is enabled by the Wireless Sensors wireless product line includes the following components:

Corporate Local Area Network (LAN)

Functions:	Provides TCP/IP between SensiNet Gateway and other components.
Integrates with:	SensiNet Gateway Operating System
Integrates through:	TCP/IP
Plug & Play with SensiNet:	Yes
Specific Examples:	N/A

Operating System (OS)

Functions: Hosts other software applications on monitoring system server.
Provides audit trails, limits system access, and verifies identities.
Archive and backup functionality.

Integrates with: Corporate LAN

Integrates through: TCP/IP with LAN
N/A for all others

Plug & Play with SensiNet: N/A

Specific Examples:

Microsoft Windows Server 2003
www.microsoft.com

Monitoring Software

Functions: Primary user interface to SensiNet-based wireless monitoring system.
Receives data collected by SensiNet.
Validates proper system input.
Manages usernames and passwords.
Provides audit trails, limits system access, and verifies identities.

Integrates with: Operating System
SensiNet Gateway
Enterprise Data Storage
Alarming Package
Electronic Signature Package

Integrates through: OPC Data Access
OPC Alarms & Events
Modbus/TCP
Web Services

Plug & Play with SensiNet: Yes

Specific Examples:

Intellution iFix

Iconics Genesis32

CitectSCADA

Wireless Sensors, LLC
75 Rochester Ave
Portsmouth, NH 03840
888.928.4362
www.WirelessSensors.com

Enterprise Data Storage

Functions: Secure data warehouse for Electronic Record retention period.
                                      Limits access, protects and copies records, creates audit trail.

Integrates with: Monitoring Software
                                      SensiNet Gateway

Integrates through: OPC Data Access
                                      OPC Alarms and Events
                                      ODBC

Plug & Play with SensiNet: Yes

Specific Examples:

Microsoft SQL Server

Oracle

OSIsoft PI

Alarming Package

Functions: Generates email, SMS, and phone messages based on alarm conditions.
                                      Allows alarm acknowledgment and management.

Integrates with: Monitoring Software

Integrates through: OPC Data Access
                                      OPC Alarms & Events

Plug & Play with SensiNet: N/A

Specific Examples:

Win-911

Iconics AlarmWorx32 MMX

Wireless Sensors, LLC
75 Rochester Ave
Portsmouth, NH 03840
888.928.4362
www.WirelessSensors.com

Electronic Signatures Package

Functions:	Digitally signs documents to support Electronic Signatures.
Integrates with:	Monitoring Software
Integrates through:	Adobe PDF Distiller
Plug & Play with SensiNet:	N/A
Specific Examples:	

Adobe Acrobat
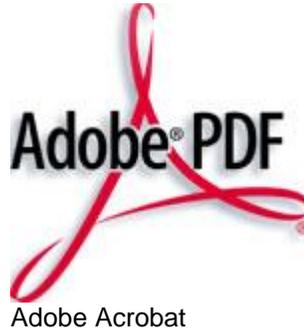
Summary

Wireless Sensors's SensiNet wireless sensor network collects environmental data from your laboratory and manufacturing equipment without the costs and shortcomings of traditional monitoring methods. SensiNet is nearly transparent to FDA 21 CFR Part 11 and is plug & play compatible with most existing monitoring systems. As a result, SensiNet can be deployed both in new and legacy applications without any special engineering, or additional validation and documentation work.

The SensiNet wireless sensor network makes complying with FDA 21 CFR Part 11 and GxP easier for your company by reducing the cost of collecting data while providing high reliability and increased monitoring system flexibility.