

GE Sensing

Features

- RF Mesh Networking technology provides reliable real time process data. Uses global 2.4 GHz RF frequencies
- Provides 100% guarantee of validation data delivery
- Ability to store data as a logger if no RF network available
- Two-year battery performance based on average use
- Can operate stand-alone or with PC connected with data stored in RF Base Station
- Intuitive study set-up and extensive calculations simplify the validation and reporting process
- Best-in-class data analysis tools, including ability to graph and report in cycles and groups
- Report tool can process and create merged reports from RF ValProbe or ValProbe products
- Versions provide temperature to 0.1°C accuracy, RH to 2% RH, 4/20 mA, 0 to 10 V and dry contact switch inputs

The Kaye RF ValProbe integrates breakthrough RF Mesh technology with well-established thermal validation in situ loggers from GE Sensing.

The Kaye RF ValProbe system is intended for the validation and monitoring of environmental chambers and storage areas (i.e. stability chambers, freezers, refrigerators, warehouses, etc). The RF ValProbe system utilizes a 2.4 GHz RF Mesh network and multiple-redundant data storage to provide ultra-reliable and robust communications and storage of critical validation data. Additional safeguards guarantee data integrity, storage and compliance with regulatory requirements.

The RF ValProbe system is comprised of RF wireless loggers, a base station and software. The loggers provide high accuracy measurement of temperature, humidity, and any 4 to 20 mA or 0 to 10 V output.

The software provides ease of use by incorporating features such as self-configuring of the mesh network and automatic data collection. Extensive graphing, reporting and calculation capabilities minimize data analysis and provide regulatory-compliant reports.

Kaye RF ValProbe™

RF Thermal Validation System

Kaye Instruments has joined other GE high-technology sensing businesses under a new name—GE Sensing.



GE Sensing

SmartMesh® Technology

GE's mesh networking technology is proven in many harsh environment applications. Its implementation in the Kaye product line allows up to 100 nodes to be connected in a seamless, reliable and self forming mesh network. The mesh technology permits nodes to communicate with the base station and each other, correcting for weak RF links and automatically adjusting to dynamic RF environment, e.g. a forklift truck driving into a warehouse blocking a signal. Interference from WiFi and other existing industrial RF networks is removed due to the frequency hopping features. No special knowledge or expertise is required to install or operate the Kaye RF ValProbe.

RF Specifications & Certifications

RF 2.4 GHz SmartMesh Technology
 Max number wireless nodes: 100
 Range: approx 300 ft/100m from one node to another
 Each node can act as a repeater
 RF Type Approval Certifications in: US, Canada, EU. Other countries in progress, please contact factory for up to date country list

Data Redundancy

The RF SmartMesh Technology provides a very secure, reliable transmission; however there are circumstances where RF transmission is blocked, either by placement of a logger of some intermittent physical or radio-frequency blocking of the signal.

The loggers store up to 10,000 samples per sensor permitting the operation as a data logger if RF communication is not possible, e.g. one logger placed in a warehouse exhaust HVAC duct. The logger will resume transmitting data once it is in RF communication with the base station or other logger.

The base station provides data storage also, permitting the user to start a study then disconnect the PC. Data storage permits all data collected on all loggers to be stored in the base station until the PC is next connected.

Map	Motes	Data	Alarms	Network Statistics	Data
24 Hours		Daily	Lifetime		
Daily					
Date	Data Reliability (%)	Path Stability (%)			
08/04/2005	99.998	85.590			
08/05/2005	100.000	80.620			
08/06/2005	99.999	86.260			
08/07/2005	100.000	88.560			
08/08/2005	100.000	92.150			
08/09/2005	100.000	90.230			
08/10/2005	99.997	88.300			

Daily RF Transmission reliability statistics for a typical network

SmartMesh is a trademark of Dust Networks, Inc.

Secure Data

There are multiple levels of transactional and data security built into the RF ValProbe system.

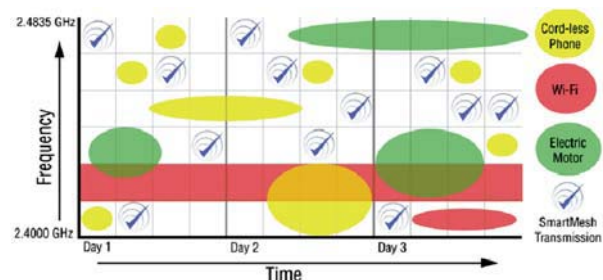
1. Only Kaye RF ValProbe nodes from GE Sensing are permitted to join a RF ValProbe network through the use of private keys and login registration information exchanged between the Base Station and RF ValProbe nodes at start-up.
2. All data transmitted on the network is protected using secure keys, preventing non-authorized base stations or nodes eavesdropping on the data or feeding non-authorized data into the network.
3. All data is timestamped, and identified by sending the logger's serial number. All data and meta data associated with a qualification study is stored in a single secure, tamperproof file.
4. DoS (Denial of Service) attacks are prevented by Message Integrity Codes.

Automatic Network Formation and Optimization

SmartMesh networks are self forming and self-optimizing. Every node can discover neighbors, measure RF signal strength, acquire synchronization and frequency hopping information, and establish best paths and links with neighbors. This ability to dynamically reconfigure is dictated by RF connectivity and/or network performance requirements.

Interference

The SmartMesh technology combines frequency hopping with TDMA (Time Division Multiple Access). In addition the mesh protocol permits the system to learn about the RF environment and dynamically adjust the network parameters to best fit the current situation.



The network provides an accurate time reference for the whole network, ensuring all loggers and the base station are time synchronized correctly. Each data sample is timestamped with this network time.

Coexistence with Other RF Systems

The RF ValProbe complies with the IEEE 802.15.4, the preeminent RF sensor network standard. Features like frequency hopping, listen-before-you-talk and channel blacklisting prevents other RF networks being affected by the RF ValProbe.

GE Sensing

Reports

The Kaye RF ValProbe software includes an intuitive, yet powerful reporting utility for generating Set-Up, Calibration, Qualification, Graph and Calibration Verification reports to document validation study results. Reports are generated from secure data files that can only be read by the system software. Upon study completion, process cycles to be analyzed are defined using the intuitive system graphic feature.

Qualification Reports present raw process data for individual sensors, statistical calculations selected during study set-up, and accumulated lethality for individual sensors.

Summary reports present study set-up details and post-study user comments, along with group interval and lethality calculations, as well as data for each group and cycle. Use of the Summary and Group Summary Reports can greatly reduce the need to export data for manipulation in Excel®.

Any action affecting user data can be permanently captured in a comprehensive audit trail, which can be automatically stored at a network location. System administrators can now have fully automated management of passwords, audit trails and data files across all validation groups.

Validator - Qualification Summary Report													
Study Name		Autoclave Test										Printed on: 10-Feb-2008 14:05:10 by Bob	
Group: 10													
Temperature Data(C)													
Logger SN	Heating Up				Ecozone				Cooling Down				Total
	Min	Max	Avg	AltH	Min	Max	Avg	AltH	Min	Max	Avg	AltH	
104A-T01	43.32	135.34	87.46	104.04	135.01	135.67	135.53	136.32	87.38	136.58	82.64	82.03	882.76
102A-T02	52.45	132.21	89.01	104.80	132.40	133.20	133.42	85.20	135.34	82.07	82.44	819.09	
103A-T03	54.21	133.47	89.89	107.19	133.25	133.75	134.48	137.82	84.69	136.59	81.68	80.32	880.00
104A-T04	52.64	133.02	88.28	106.76	134.84	133.68	133.04	136.02	85.02	136.02	82.04	84.83	880.00
105A-T05	58.19	132.27	87.42	102.72	133.03	133.52	135.23	88.29	85.84	135.78	82.25	83.86	815.56
106A-T06	53.71	135.00	87.92	105.04	133.05	133.25	133.11	89.70	84.69	135.31	81.69	82.59	882.64
107A-T07	49.77	135.11	87.25	101.28	134.80	134.38	134.14	87.89	81.27	135.50	81.81	79.72	883.89
108A-T08	54.88	133.00	88.25	106.72	133.98	133.50	133.25	89.24	85.02	135.02	81.71	84.83	880.00
109A-T09	55.29	133.04	87.66	99.94	134.91	133.18	133.07	89.29	87.40	135.53	83.80	80.91	885.53
110A-T10	54.54	132.64	88.46	99.49	134.85	133.15	133.00	89.13	85.81	135.53	82.07	82.68	842.21
111A-T11	57.87	133.58	89.14	100.39	134.85	133.19	133.10	88.47	84.40	135.31	82.76	81.58	846.82
112A-T12	46.48	134.63	88.46	98.00	134.87	133.03	132.99	89.28	87.02	135.00	83.06	80.56	883.68

Temperature Summary Data(C)													
Cycle Start	Heating Up				Ecozone				Cooling Down				Total
	Min	Max	Avg	AltH	Min	Max	Avg	AltH	Min	Max	Avg	AltH	
80-Dec-2005 09:04:42	43.32	135.34	87.46	104.04	135.01	135.67	135.53	136.32	87.38	136.58	82.64	82.03	882.76
113:44	52.45	132.21	89.01	104.80	132.40	133.20	133.42	85.20	135.34	82.07	82.44	819.09	
80-Dec-2005 09:28:02	54.21	133.47	89.89	107.19	133.25	133.75	134.48	137.82	84.69	136.59	81.68	80.32	880.00
124:47	52.64	133.02	88.28	106.76	134.84	133.68	133.04	136.02	85.02	136.02	82.04	84.83	880.00
80-Dec-2005 10:17:28	58.19	132.27	87.42	102.72	133.03	133.52	135.23	88.29	85.84	135.78	82.25	83.86	815.56
10:20	53.71	135.00	87.92	105.04	133.05	133.25	133.11	89.70	84.69	135.31	81.69	82.59	882.64
30:37	49.77	135.11	87.25	101.28	134.80	134.38	134.14	87.89	81.27	135.50	81.81	79.72	883.89
44:40	54.88	133.00	88.25	106.72	133.98	133.50	133.25	89.24	85.02	135.02	81.71	84.83	880.00
58:43	55.29	133.04	87.66	99.94	134.91	133.18	133.07	89.29	87.40	135.53	83.80	80.91	885.53
72:46	54.54	132.64	88.46	99.49	134.85	133.15	133.00	89.13	85.81	135.53	82.07	82.68	842.21
86:49	57.87	133.58	89.14	100.39	134.85	133.19	133.10	88.47	84.40	135.31	82.76	81.58	846.82
100:52	46.48	134.63	88.46	98.00	134.87	133.03	132.99	89.28	87.02	135.00	83.06	80.56	883.68

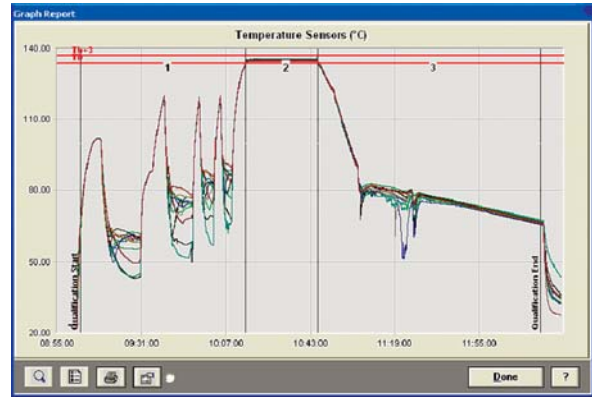
Summary Report

Data files can be merged from multiple RF ValProbe and ValProbe studies. Users can add unlimited cycles, separating qualification data into specific process phases, and create up to 25 groups with their own calculations and graphs during reporting.

Groups	Sensors
<ul style="list-style-type: none"> Bottom Shelf <ul style="list-style-type: none"> 109A-T09: Autoclave 09 110A-T10: Autoclave 10 111A-T11: Autoclave 11 112A-T12: Autoclave 12 Middle Shelf <ul style="list-style-type: none"> 105A-T05: Autoclave 05 106A-T06: Autoclave 06 107A-T07: Autoclave 07 108A-T08: Autoclave 08 Top Shelf <ul style="list-style-type: none"> 101A-T01: Autoclave 01 102A-T02: Autoclave 02 103A-T03: Autoclave 03 	<ul style="list-style-type: none"> T 103A-T03 Autoclave 0 T 104A-T04 Autoclave 0 T 108A-T08 Autoclave 0 T 101A-T01 Autoclave 0 T 102A-T02 Autoclave 0 T 105A-T05 Autoclave 0 T 107A-T07 Autoclave 0 T 106A-T06 Autoclave 0 T 111A-T11 Autoclave 1 T 110A-T10 Autoclave 1 T 109A-T09 Autoclave 0

Group Creation

A powerful graphing utility within the system software greatly simplifies process analysis and reporting. Sliding vertical axes enable the operator to flag and define process transition points, eliminating unnecessary reporting and streamlining the review process. The graph utility features increased flexibility for graph customization, including specifying X and Y axis ranges, background colors, line styles and labeled limit lines.



Graph report

Security, Passwords and Audit Trails

The Kaye RF ValProbe is specifically designed to enable compliance with FDA 21 CFR Part 11. All recorded data, including calibration offsets, set-up parameters, and administrative tasks are saved in secure, encrypted, tamperproof electronic records in a format accessible only through the system software.

All user inputs that could impact user data, for example starting a study or running a calibration, are protected via secure username/password logins, and are all logged in the secure audit trail database.

Identification Required

User ID:

Current Password:

Change Password

Login Request

The reporting software has been enhanced to enable easy review and printing of the audit trail based on dates, times and/or events, for example, the system administrator can select to review "all failed login attempts for the last 30 days." There is now also notification to the user and logged entries in the audit trail if files are tampered with or deleted from within Windows Explorer™.

GE Sensing

Specifications

Environmental

- Body: -22°C to 60°C, 0 to 95%RH non condensing
- External probe: -196°C to 200°C
- Logger dimensions: 190 mm x 127 mm x 45 mm
(7.5 in x 5 in x 1.75)
- Base station dimensions: 64 mm x 32 mm x 15 mm
(2.5 in x 1.25 in x 5 in)

Temperature

External Sensor

- 0.1°C, range 0°C to + 60°C
- 0.2°C, range -22°C to 0°C
- 0.5°C, range -80°C to -22°C
- 2.0°C, @ -196°C

Internal Sensor

- 1.0°C from 45°C to 60°C
- 0.5°C from 5°C to 45°C
- 1.0°C from -20°C to 5°C
- 0.6°C from 0°C to 45°C

RH

- 2% from 10°C to 90°C
- 5% from 0 to 10%, 90 to 100%
- 5% at 40°C, 75%RH
- Certificate states ICH Points

Auxiliary Inputs

- Contact: dry
- Voltage and current 0.5% FS

Battery Life (Varies ±10%)

1 min sample rate: 8000 hours

System Documentation

IQ/OQ Protocol

The Installation Qualification/Operational Qualification Protocol defines a set of procedures to ensure that the Kaye RF ValProbe system is properly installed and operated correctly, and is adequately documented and controlled according to cGMP requirements. The documents are provided in hard copy and on CD, allowing users to modify the documentation to suit specific organizational requirements.

Updates and addenda are available through the Kaye website.

Services

GE Sensing offers a full range of services for the pharmaceutical, biotech and medical device industries.

- Factory and on-site calibration
- Repair services and parts support
- Technical support
- Rentals
- Operator training
- System documentation IQ/OQ and protocol execution
- Equipment maintenance agreements

Our highly trained staff will support you, no matter where you are in the world. You can choose to send in your equipment to one of our Centers of Excellence or request dispatch field services to your location.

Validation Reference

The Kaye RF ValProbe system is supported with Design Qualification documentation. The Validation Reference Binder provides a comprehensive overview of the GE Quality Policy, description of ISO 9001 implementation and support procedures, and standards for the development, testing, and maintenance of hardware and software. Quality Control documents, Development procedures, Quality Assurance procedures, Release documents, and Quality Assurance test documentation are all included.

Ordering Information

X2558	RF ValProbe Base Station Includes USB Cable, PC Software and User Manual
X2570-12, -18, -36 X2570S-L	Logger with External Temperature Probe and internal RH Sensor No auxiliary inputs Specify 1 of 3 standard lengths; custom lengths available on request
X2571-12, -18, -36 X2571S-L	Logger with External Temperature Probe and internal RH Sensor Contact Switch and Voltage Input Auxiliary Input Specify 1 of 3 standard lengths; custom lengths available on request
X2572-12, -18, -36 X2572S-L	Logger with External Temperature Probe and internal RH Sensor Contact Switch and 4/20 Current Loop Auxiliary Input Specify 1 of 3 standard lengths; custom lengths available on request
X2563 X2564	Internal Temperature and RH Logger, Voltage and Contact Auxiliary Internal Temperature and RH Logger, 4/20 Current and Contact Auxiliary
X6030 X6035	RF ValProbe IQ/OQ Protocol RF ValProbe Validation Reference (DQ) Package

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