RF Thermal Validation System

Kaye RF ValProbe® II

High accuracy measurement of temperature and humidity

Kaye RF ValProbe II Simplified Real Time Validation

The Kaye RF ValProbe II integrates breakthrough RF Mesh technology with enhanced technology thermal validation in situ loggers.

The Kaye RF ValProbe II loggers operating range of -40°C to +60°C and temperature sensor range of -200°C to +200°C make them ideal for real-time RF validation and monitoring of environmental chambers, warehouses, freezers, refrigerators and steam-in-place (SIP) applications.

The RF ValProbe II 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 II 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 20mA or 0 to 10V output.

RF ValProbe's software enables support for 2-Channel and 5-Channel RF Temperature loggers for Validation.

The RF ValProbe II 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.

Features

- RF Mesh Networking technology provides reliable real time process data. Uses global 2.4 GHz RF frequencies

- Provides 100% data redundancy in both remote logger and base station in addition highly reliable RF network

- New State of Art Industrial design with integrated LCD Display

- Dual powered, logger runs on AC Power and/or Battery. Battery life greater than 1 year in typical use, using Standard 3.6V AA Primary Lithium batteries

- Additional options for redundancy data retrieval and backup using micro SD card and USB

- Emergency Battery backup for base station (30 min) for uninterrupted operation using 3.7V AA size Lithium rechargeable batteries

- Intuitive study set-up and extensive calculations Simplify the validation and reporting process

- Base Station connections for IRTD and Bath for Sensor Calibration or Verification

- Protective rubber boot with flexible stand for multiple monitoring configurations

- 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, ValProbe or Validator 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, 2-Channel and 5-Channel Temperature logger

- Up to 3 meter extension cable for RH sensor allows sensor to be placed inside the chamber and logger placed outside

- Temperature and pressure accuracy meets requirements for ISO-17665, EN554 and EN285 sterilization requirements

- Easy connection to Kaye Pressure transducer which is designed for harsh environment applications such as steam sterilizers and SIP systems

- Can be directly connected to 1.5 inch triclover flange via SmartGasket® or similar gasket design

Simplified Real Time Validation

SmartMesh® Technology

Mesh networking technology is proven in many harsh environment applications. Its implementation in the Kaye product line allows up to 40 loggers to be connected in a seamless, reliable and self-forming mesh network. The mesh technology permits loggers 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 2.4GHz SmartMesh Technology. Maximum number of wireless loggers: 40 with up to maximum 3 hops, Range: approximately 150ft/50m from one logger to another. Each logger 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.


Secure Data

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

1. Only Kaye RF ValProbe loggers 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 loggers at startup.

2. All data transmitted on the network is protected using secure keys, preventing non- authorized base stations or loggers 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 metadata associated with a qualification study is stored in a single secure, tamper proof 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 loggers 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.
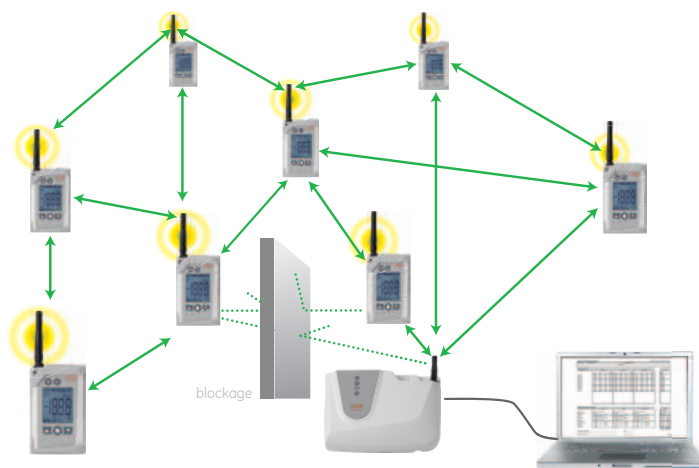
Interference

The technology combines SmartMesh® 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.
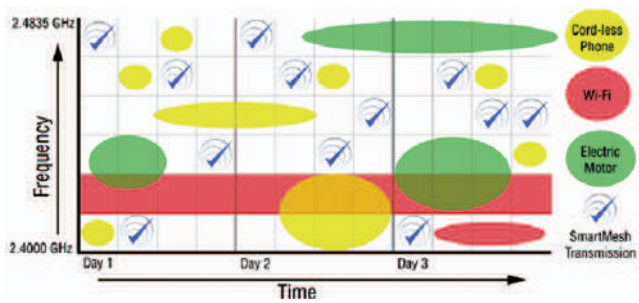
Coexistence with Other RF Systems

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.

Software Features

Historical graphing

Once a study has been started, user can connect his PC anytime to the base station and retrieve all the data from the base station on the real time graph to view the data that has been logged by the loggers to that point. This will enable viewing historical data without having to stop the study at the base station.

RF Map

Users can graphically view the RF Signal strength of the loggers and their connections to other loggers and base station for stronger RF networks. A background image can also be set for the RF map to position the loggers on a real floor plan. The users can use this as back up documentation for looking at the position of the loggers at a later time.

Real Time Graphing Calculations

Real time graphing provides min/max/avg calculations for the RH and Temp parameters of all the loggers being plotted in the real time graph.

Auto Calibration / Verification

RF ValProbe System enables auto calibration/ verification for the users when using the RF loggers, Kaye IRTD, Kaye Temperature baths. This enables the user to select the set points and let the software run the calibration/verification including loading of offsets into the loggers automatically.

The software will control the Kaye drywells and read the reference temperature data from a connected Kaye IRTD permitting full automatic calibration with the Kaye calibration products. Providing that the users configure the communications port , access to automatic calibration will be permitted. Calibration is still permitted if either drywells or IRTD is not present, in which case either semi- automatic or manual mode calibration is used.

Independent Report Wizard

Along with the RF ValProbe software, there is an additional software program called the "Kaye Report Wizard". This report wizard permits the user to launch the "Create Reports" section independently of the Kaye product installed on the user's PC. The user can decide install the Report Wizard in a separate folder and use it to report on following Kaye products.

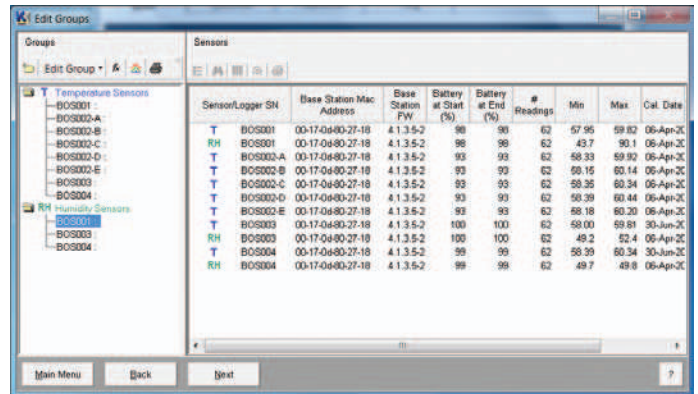### Validator 2000 | ValProbe | RF ValProbe

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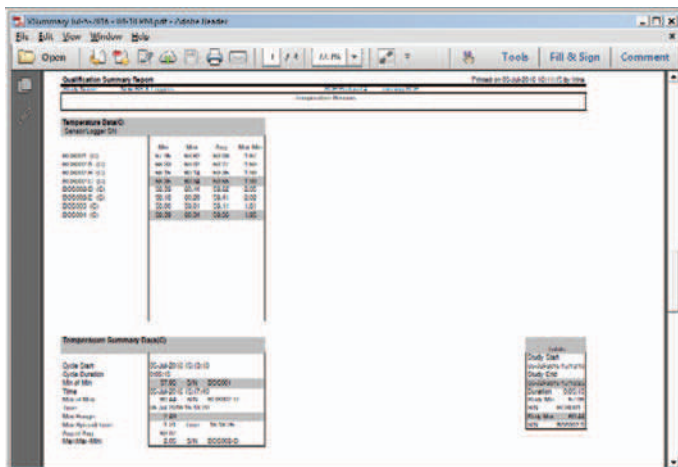
Summary reports present study set-up details and post study user comments, along with group interval and lethality calculations, as well as data for each group and cycle. Use of the Summary and Group Summary Reports can greatly reduce the need to export data for manipulation in Excel®.

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.

Data files can be merged from multiple RF ValProbe, ValProbe and Validator 2000 studies. Users can add up to 15 cycles, separating qualification data into specific process phases, and create up to 25 groups with their own calculations and graphs during reporting.

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.

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, tamper-proof electronic records in a format accessible only through the system software.

All user inputs which 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.
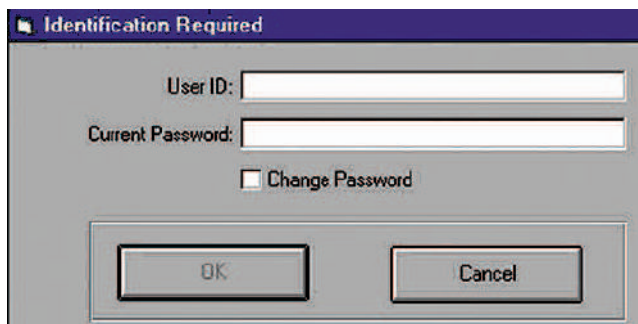

The reporting software has been enhanced to enable easy review and printing of the audit trail based on dates, times and/or events for example, the system administrator can select to review "all failed login attempts for the last 30 days." There is now also notification to the user and logged entries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

Mean Kinetic Temperature

The Reporting Software provides Mean Kinetic Temperature calculation to the user. Mean Kinetic Temperature (MKT) is single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

Saturated Steam Calculation

Easy integration between temperature and pressure enables EN554
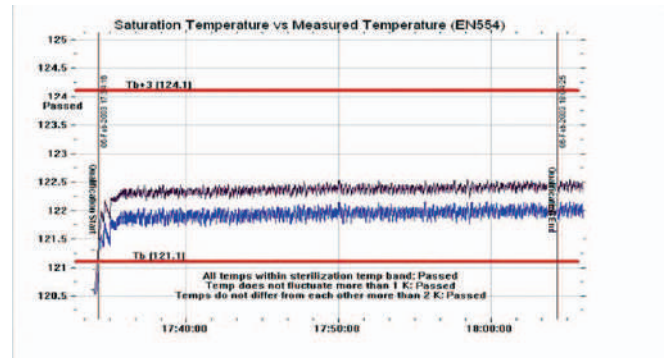
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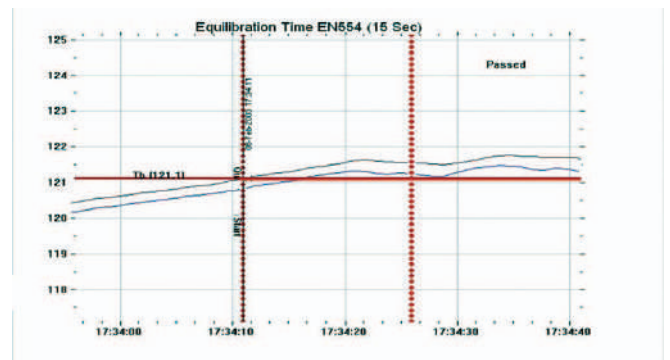
Steam In Place Application

The Kaye RF ValProbe® system permits up to 40 distributed loggers, measuring both temperature and pressure. The system allows large SIP systems to be validated or re-validated in single large sections without the need for repeated SIP studies.

The temperature sensor is a precision small diameter bendable type RTD designed to permit easy access to pipes and vessels through gaskets. The temperature probe remains in place and can be fed along pipe work or placed into stainless vessels or filter bodies.

The high accuracy pressure transducer is designed for 121C and 134C operation and is calibration compliant to ISO 17025 at these extended temperatures. It is powered externally, easy to connect and simple to configurate with the RF ValProbe software.

Specifications

Environmental

- Body (Logger Enclosure):
  -40°C to 60°C (Storage)
  0 to 90% RH non-condensing
  -25°C to 60°C (Operating)
  0 to 90% RH non-condensing

- Body (Base Station Enclosure):
  -40°C to 60°C (Storage)
  0 to 90% RH non-condensing
  0°C to 50°C (Operating)
  0 to 90% RH non-condensing

- External probe: -196°C to 200°C

- Logger Dimensions:
  110 mm x 65 mm x 30 mm
  (4.3 in x 2.6 in x 1.2 in)
- Base Station Dimensions:
  190 mm x 130 mm x 55 mm
  (7.6 in x 5.2 in x 2.2 in)

Temperature

Single/Multi Channel External Sensor

- ±0.1°C, range -50°C to +130°C
- ±0.2°C, range -80°C to -50°C
- -196°C to -80°C & +130°C to 200°C
  Contact factory for accuracy

RH

- ±2% from 25 to 85%RH
  @ 25°C to 40°C (Non-condensing environment)
- Certificate states ICH Points

Auxiliary Inputs

- Contact: Dry
- Voltage and current 0.5% FS

Battery Life (varies ±10%)

- 1 min sample rate: 1 Year

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

We provide a complete array of services for the RF ValProbe® product range:

- Onsite installation, commissioning and IQ/OQ for RF ValProbe system.
- Operator training and technical support.
- Maintenance agreements.
- Factory calibration.
- Rental services

Validation Reference

The Kaye RF ValProbe system is supported with Design Qualification documentation. The Validation Reference Binder provides a comprehensive overview of our 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.

RF Thermal Validation System Ordering Information

RF ValProbe Loggers									
Model#	RTD1	RTD2	RTD3	RTD4	RTD5	RH	Voltage	Current	Contact
X3001D-0-0	✔								
X3001D-H-0	✔					✔			
X3001D-H-V	✔					✔	✔		✔
X3001D-H-A	✔					✔		✔	✔
X3002D-2	✔	✔							
X3002D-5	✔	✔	✔	✔	✔				
X3001N-R									

RF ValProbe Sensors	
Model#	Description
237-076-N02	RF VP Validation Probe, 2ft Long Flexible Cable with PT100 Pt. Element
237-076-N03	RF VP Validation Probe, 3ft Long Flexible Cable with PT100 Pt. Element
237-076-N05	RF VP Validation Probe, 5ft Long Flexible Cable with PT100 Pt. Element
237-076-N10	RF VP Validation Probe, 10ft Long Flexible Cable with PT100 Pt. Element
237-076-N15	RF VP Validation Probe, 15ft Long Flexible Cable with PT100 Pt. Element
237-076-N30	RF VP Validation Probe, 30ft Long Flexible Cable with PT100 Pt. Element
237-077-B20	RF ValProbe Bendable Probe, 20" Long with PT100 Pt. Element

RF ValProbe Ordering Example (x3001D-0-0-XXX, XXX=Probe length suffix)	
Model#	Description
X3001D-0-0-N10	RF ValProbe Logger with Display, includes Single 10ft External Temperature Probe, no RH Sensor, no auxiliary inputs. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3001D-H-0-N10	RF ValProbe Logger with Display, includes Single 10ft External Temperature Probe, Internal RH Sensor, no auxiliary inputs. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3001D-H-V-N10	RF ValProbe Logger with Display, includes Single 10ft External Temperature Probe, Internal RH Sensor with contact switch and 0-10V Voltage auxiliary Input. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3001D-H-A-N10	RF ValProbe Logger with Display, includes with Single 10ft External Temperature Probe, Internal RH Sensor with contact switch and 4-20mA current loop auxiliary Input. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3002D-2-N10	RF ValProbe Logger with Display, includes Dual Channel Logger with external 10ft Temperature Probes. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3002D-5-N10	RF ValProbe Logger with Display, includes Five Channel Logger with external 10ft Temperature Probes. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3001N-R	RF ValProbe Repeater Logger without Display

RF ValProbe Base Station	
Model#	Description
X3000	RF ValProbe Base Station includes USB/Ethernet cross link Cable, PC Software and User Manual. Also include IRTD Cable, Bath Cable & Cal PC (USB A-A) cable for customer calibration.

RF Steam In Place Application

Model#	Description
**RF ValProbe SIP**	
X3001D-H-0-B20	RF ValProbe Logger with Display, includes External 20" Long Bendable and Flexible Temperature Probe and RH Sensor. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3001D-H-V-B20	RF ValProbe Logger with Display, includes External 20" Long Bendable and Flexible Temperature Probe, RH Sensor, 0-10v Voltage input and Contact Closure which accommodates Kaye Pressure Transducer. Rubber Boot for Mounting and Protection and Calibration Certificate.
X3001D-H-A-B20	RF ValProbe Logger with Display, includes with External 20" Long Bendable and Flexible Temperature Probe, RH Sensor, 4-20mA Current Input and contact closure. Rubber Boot for Mounting and Protection and Calibration Certificate.
X2576E	Kaye Pressure Transducer 110-220V
K0448	Feedthru Triclover clamp
M1989	Smart Gasket® Silicone, one port

KAYE - A Continuing History of Innovation, Quality and Compliance.

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