

KAYE

Complete Monitoring Solution

LabWatch[®] LT



Complete Centralized Environmental Monitoring System

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

Kaye LabWatch® LT System Delivers a Complete Monitoring Solution to Protect Your Critical Assets



No matter how complex or simple your monitoring needs may be, Kaye understands these unique requirements and offers the Kaye LabWatch LT system, a cost effective self-configurable solution to automate the monitoring, alarming and data collection of critical assets.

Reliable Real-Time Monitoring

The Kaye LabWatch LT system provides continuous real-time monitoring of your critical environment conditions wirelessly and reliably. Core measurements of temperature, humidity, pressure, CO₂, Contact, Voltage, and 4-20 ma inputs can be monitored wirelessly.

The system provides built-in redundancies at multiple levels. At the primary input of the system lie the extremely accurate calibrated wireless Kaye RF ValProbe® and Kaye RF ValProbe II data loggers. The RF loggers store and forward the real-time data to the RF base stations.

The loggers communicate data in real time via a robust and reliable wireless network interconnected via the SmartMesh® technology to the Kaye LabWatch LT system. The Kaye LabWatch LT is a self-contained scalable system that includes up to 100 sensor inputs with remote access via VPN. The Kaye LabWatch LT system provides the ability to customize based on your specific monitoring needs today and in the future.

A Complete Software and Sensor Solution

The Kaye LabWatch LT system offers a user-friendly intuitive software platform integrated with high quality wireless sensing technologies for a complete real-time environmental monitoring system with alarm notification functionality, informative reporting, and secure data archiving.

Based on user-defined parameters, the Kaye LabWatch LT system will monitor and detect system excursions and can alert user-selected personnel wherever they are located. Fully configurable groups can document any number of chambers without generating stacks of paper. The data is protected with secure storage. The system creates an audit trail of alarms and actions taken by the system and system operators, and provides ready access to historical data.

Regulatory Compliance

The extensive reporting capabilities of the Kaye LabWatch LT system allow you to generate reports in compliance with 21 CFR Part 11 as well as other FDA, GMP/GLP, AABB, JCAHO, AAALAC and other regulatory requirements.

The system features secure access via password and user ID protection, data encryption records, and complete audit trail of events to meet 21 CFR Part 11 requirements. By maintaining a secure archive of monitored values from your sensors, the system can readily provide the information you need for internal analysis and regulatory required documentation.

Protecting Your Critical Assets

Highly self-configurable software delivers real-time data where and how you want it. The Kaye LabWatch LT system can be an effective turnkey solution for your laboratory, warehouse, blood banks, clean rooms, tissue banks and all your critical controlled environments.

The system provides the flexibility you need to monitor real-time data for regulatory compliance of critical environmental conditions. Information is provided to assure that your assets are being exposed to the environmental conditions you defined and provide a ready trail of compliance.

Wireless Flexibility

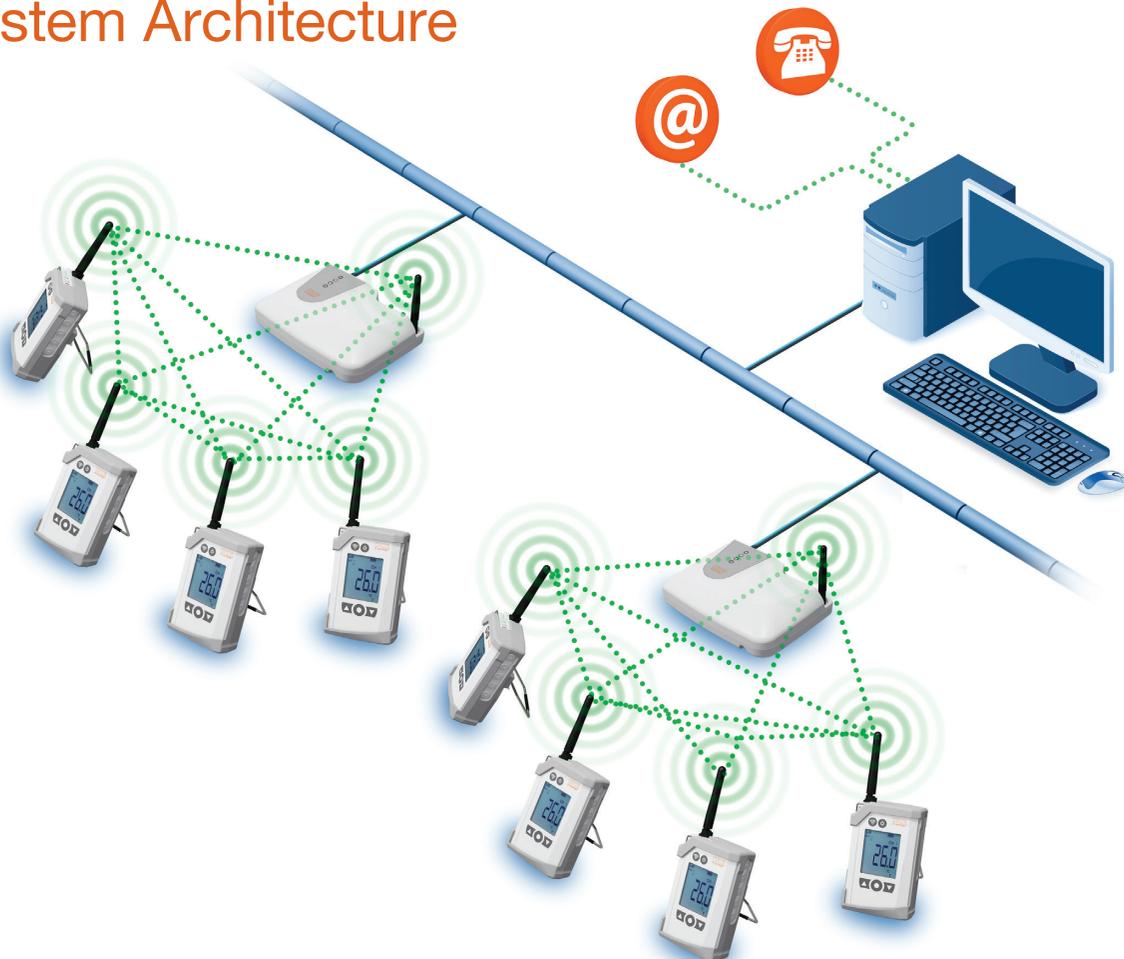
- Easy user-configurable setup
- Full suite of sensing technology for temperature, humidity, pressure, and CO₂ is *expandable* to accept any additional analog output sensor
- Reliable mesh network technology
- Redundant data storage – loggers and base stations
- Remote access via VPN
- Alarm notification – phone and email
- Complete reporting function
- Services – start-up installation support, training, calibration services, and continuous technical support

Robust and Reliable System Platform

The Kaye LabWatch LT system is built as an Enterprise Architecture Model encompassing intelligence and redundancy at multiple levels in the system. Each of the loggers in the architecture is a robust, complete and independent subsystem. At the primary input of the system lie the extremely accurate calibrated sensors (temperature/humidity/CO₂/Pressure/etc.). These sensor elements feed into the wireless Kaye RF Valprobe and Kaye RF ValProbe II data loggers. The battery operated RF loggers store and forward the real-time data from the sensor to the RF base stations. Up to 10,000 samples per sensor can be stored on these loggers and can be retrieved in case of a power failure on the base stations or RF transmission issues for up to 72 hours.

The loggers communicate data in real time at 1 minute intervals via a robust and reliable 2.4 GHz RF (Radio Frequency) wireless network interconnected via the SmartMesh® technology to the Kaye LabWatch LT system. The wireless inputs are based on each customer's need and can be expanded at any point based on application.

System Architecture





Monitoring What Matters Most

WHERE WE MONITOR	WHAT WE MONITOR	SENSORS
<ul style="list-style-type: none"> • Warehouses • Repositories • Clean Rooms • Blood Banks • Tissue Banks • Pharmacies • Cold Storage • Animal Rooms • Laboratories 	<ul style="list-style-type: none"> • Stability Chambers • Freezers • Refrigerators • Incubators • Cryogenic Freezers • LN2 Tanks • Ovens • Baths 	<ul style="list-style-type: none"> • Temperature • Humidity • CO₂ • Pressure – Absolute and Differential • Contacts – Door Switch, Relays • Voltage/Current Inputs • Light – Visible, Ultraviolet

System Benefits

- Operates in compliance with 21 CFR Part 11 Electronic Signatures and Records
- Automatically provides audit trail history of alarms and actions taken by the system and the people who log onto the system in one central location
- Protects your time by avoiding nuisance alarms and guards your product investment by providing reliable alarm detection
- Notifies an unlimited number of people to handle specific alarm conditions with a variety of notification methods via phone and email
- Lets you retrieve data easily for viewing, reporting, analysis, and regulatory inspection; provides tools to review historical data and create reports based on your requirements
- Provides secure data storage via encryption of database to prevent tampering
- Runs on reliable, up-to-date Windows® platform software



RF Valprobe® Wireless System

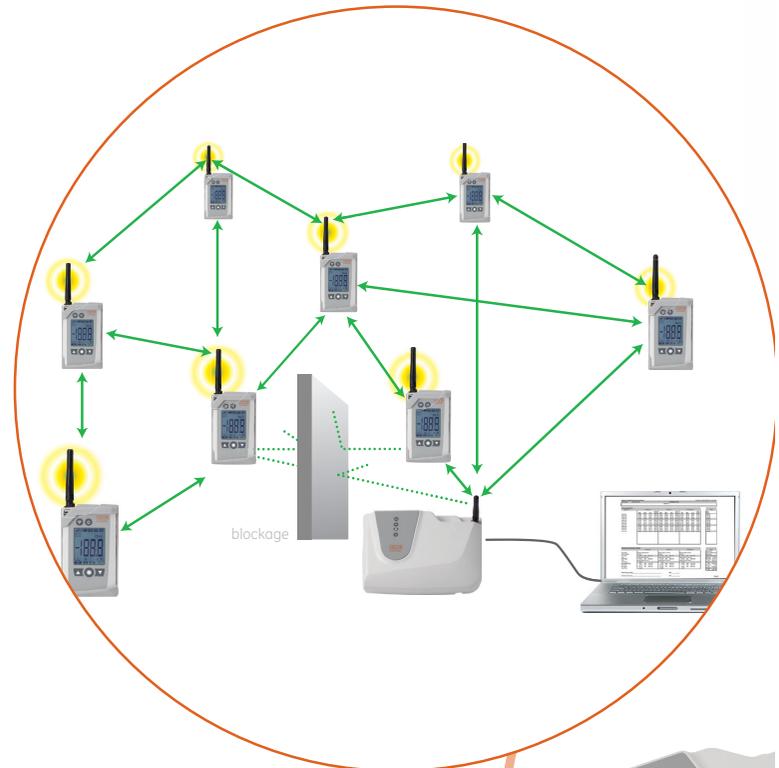
The Kaye RF ValProbe II system is comprised of RF wireless loggers, RF base stations and software. The loggers provide high accuracy measurement of temperature, humidity, contact or any 4-20 ma or 0-10 V input from other transducers. Kaye RF ValProbe software enables support for standard and multi-channel temperature loggers.

LabWatch LT system can use legacy RF ValProbe loggers as well as next generation of RF ValProbe II loggers with display.

Kaye RF ValProbe Wireless Loggers

- -40°C to 60°C, 0 to 90% RH non-condensing.... Storage Temperature
- -25°C to 60°C, 0 to 90% RH non-condensing.... Operating Temperature
- Logger on Battery mode only (Logger External Power adaptor rated for operating temperature 0°C to 60°C)
- 1 x temperature + 1 x RH + 0-10 VDC/4-20 mA + contact
- 1 x temperature, 2 x temperature, 5 x temperature
- Single / Multi channel External Sensor range
-196°C to 200°C
±0.1°C, range -50°C to +130°C
±0.2°C, range -80°C to -50°C
- Accuracy for -196°C to -80°C & +130°C to 200°C.... Contact factory.
- Maximum cable length of external temperature sensor is 30 feet/9 meters
- Relative humidity external sensor range and accuracy:
0 to 90% RH (accuracy ±2.0% from 25% to 85% RH at 25°C to 40°C)
- Certificate states ICH Points
- Auxiliary Inputs
- 3.8 to 22 mA Input, 16 bit A/D input, accuracy: 0.5% FS
- 0 to 10 V input, 16 bit A/D input, accuracy: 0.5% FS
- Contact Closure (dry)

- Logger dimension: 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)
- Logger battery: Kaye# 200-165, 2 AA Lithium primary (Non-rechargeable) Batteries- 2600mAH
- Power adapter: Input: 100 to 240 Volts AC 50-60 Hz input
- Base station battery: Up to 10 minutes of battery backup
- Max number of RF base stations: 4
- Max number of sensor inputs in total: 100 inputs
- Max number of loggers per RF base station: 40 loggers
- RF base station connection: Ethernet or USB2.0 (One RF base station via USB)



Data Redundancy

The RF SmartMesh® technology provides a secure, reliable transmission through several layers of redundancy. Should RF transmission be blocked the data is stored on the loggers and base stations. When RF communications are resumed the system detects the gap in data and automatically retrieves missing data.

SmartMesh® Technology

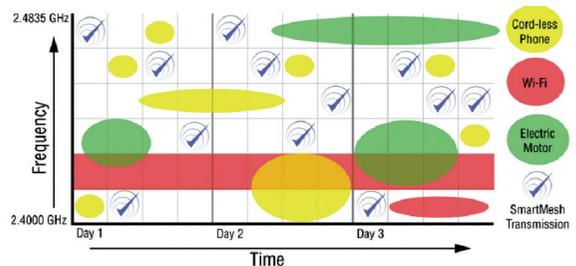
utilizes reliable mesh networking technology that has been proven in many harsh environment applications. Its integration in the Kaye product line allows up to 100 loggers to be connected in a seamless, reliable and self-forming mesh network. The mesh technology permits loggers to communicate with the base station and each other, correcting for weak RF links and automatically adjusting to dynamic RF environment. Interference from WiFi and other existing industrial RF networks is minimized due to the frequency hopping features. No special knowledge or expertise is required to install or operate the Kaye RF ValProbe II for reliable communications.

SmartMesh® technology enables the wireless loggers to be spaced approximately 150 feet/45 meters from one logger to another. Each logger can act as a repeater. RF Type Approval Certifications are available in the United States, Canada, EU, India, China, Korea, Japan, Brazil, Argentina, Israel and other countries. (Please contact the factory for an up-to-date country list).

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 adjusts 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 time stamped with this network time.

Coexistence with Other RF Systems

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



Easy Steps to Be Compliant

1
REGISTRATION

2
CONFIGURE
BASE STATIONS

3
ASSIGN TAGS

4
CONFIGURE
TAGS

5
CREATE TAGS
GROUPS

6
ASSIGN GROUP
USERS

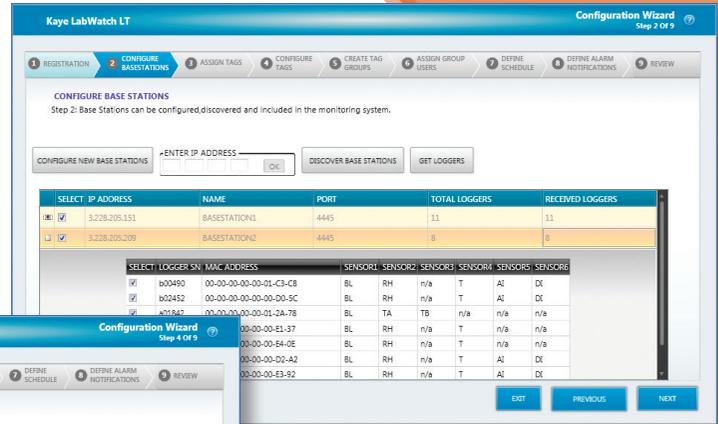
7
DEFINE
SCHEDULE

8
DEFINE ALARM
NOTIFICATIONS

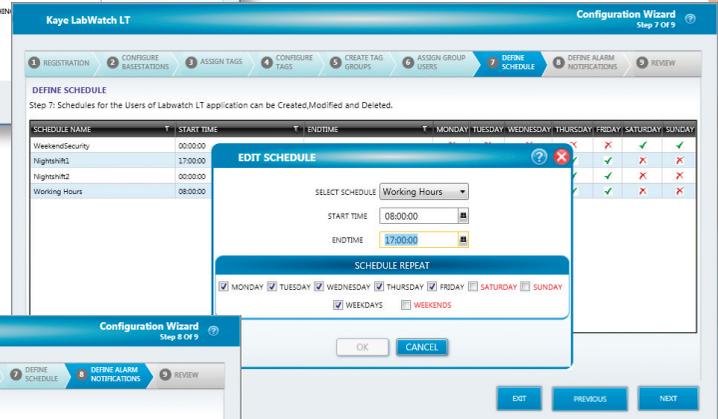
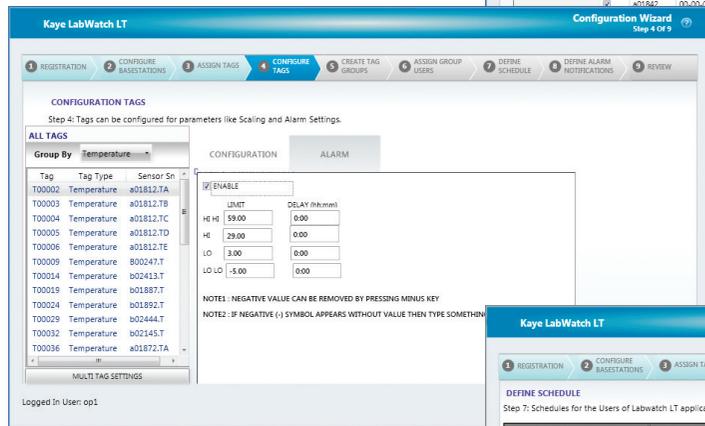
After the initial user registration the attached Kaye RF ValProbe® hardware is automatically detected and configured in one single step.

Create Tag groups and assign the responsible operators with defined attendance schedules.

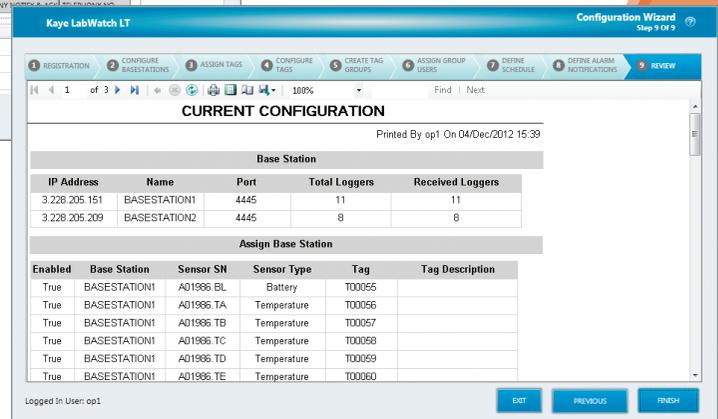
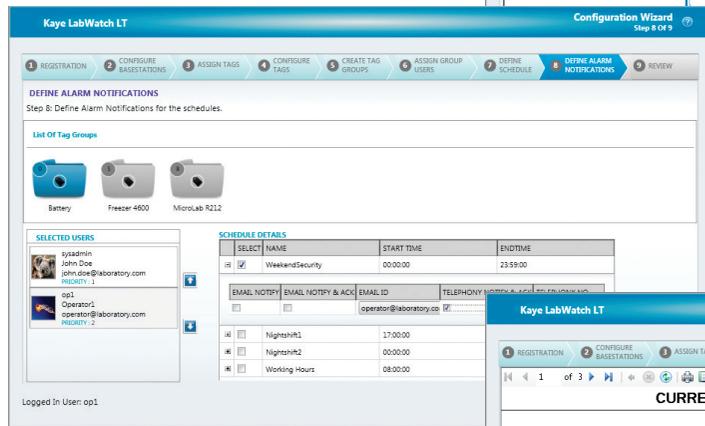
At the end of the setup receive a comprehensive Configuration report for simple GMP compliant documentation and easy-to-change control records.



Set alarm limits and delays individually or for multiple sensors at once and define external sensor inputs.



Determine the notification channels and priorities of operator alarms and schedules.



Access Real-Time and Historical Data When You Need it Most

Customizable Views

Kaye LabWatch LT software offers maximum flexibility in viewing and analyzing your data. Users can select up to four graphical or text view combinations, including floor plan image, data graphing and real-time text view. For each view the user can also select independent sensor groupings as customized by the user.

The customized floor plan view allows the user to import actual images of their installation as a visual backdrop so they can overlay the tag locations on the image to complete the visual representation. All can be saved and stored for future reference.

Expandable to Your Monitoring Needs

New Measurement Requirement

We understand monitoring requirements change. We have made the Kaye LabWatch LT system expandable to 100 loggers and up to four base stations. It's simple to add additional points to the system. The additional hardware is available and in a few simple steps your system will be expanded to meet your new requirements.

Data Collection and Management

Historical Data, Audit Trail Storage, and Reporting

Historical Graphing

The Kaye LabWatch LT system stores live data at 1 minute intervals that can be used to display graphical process trends. The user can view multiple parameters on a historical screen for any time period selected. Move the cursor to any point on a graph to display the instantaneous value or zoom in or out to get a historical overview of the min/max/avg of the entire process.



Historical graphing provides the user with the ability to pre-select a group of sensors and create a template for the group and trend. Users may view up to 24 hours of data of up to 1440 samples per single tag input. The user has the ability to export the data from the graph to a bitmap file or printer for further analysis.

Security

The Kaye LabWatch LT system is a complete stand alone system that enables the system administrator to grant access privileges and maintain an operator registry. Users are assigned individual ID and password combinations that permit system operation and provide access to system features dependent on the security level.

Audit Trail

The monitoring system creates an audit trail for every action executed. Examples of actions taken that are recorded include alarm acknowledgement, enable/disable alarms, limit/delay changes, etc. To generate an accurate audit trail, each system user is required to follow the login procedure with a proper login name and password. The software provides a commenting feature to add comments into the audit trail to record events as part of future audit trail reports.

The Kaye LabWatch LT system has a powerful filter and sort capability that allows the operator to quickly and easily sort the audit trail by date or any text string. This makes retrieving data for regulatory inspection easy and meets the 21CFR Part11 guideline.

Alarming and Notification

The goal of the Kaye LabWatch™ LT system is to detect environmental excursions the moment they occur and notify the appropriate personnel for corrective response. Using high-quality industrial sensors, high-accuracy measurement electronics, and two-point sensor calibration, the system provides reliable, accurate and repeatable results. The Kaye LabWatch LT system continuously scans all inputs and notifies the user only when genuine alarms occur.

Four Levels of Alarms with Programmable Delay Function to Prevent False Alarming

Different levels of alarming in the Kaye LabWatch LT system allow you to customize alarm detection to suit your operating requirements. Individual alarm delays for each limit setting help prevent unnecessary alarm notification.

Real-Time Alarm History Access

The Kaye LabWatch LT system provides easy access to view and acknowledge active alarms with the alarm category feature.



10

Stability chamber 1 Heating system					
Kaye LabWatch LT			Printed By Ralf Op on 01/04/2013 14:16		
01/04/2013 00:00 to 01/04/2013 14:14					
Tag	Unit	Tag Description	Sensor	Group	Group Description
T00016	C	CH1 - Heating system	Temperature	Stability Chamber 1	
Tag Details T00016					
Alarm Limits		LoLo : -10.00	Lo : 02.00	Hi : 29.00	HiHi : 59.00
Date		01/04/2013			
Total Alarms		5			
Acknowledged Count		3			
Alarm History					
Alarm Time	Alarm Type	Alarm Value	Status	Comments	
01/04/2013 12:23	Hi	32.20	Not Acknowledged	*	
01/04/2013 12:24	Hi	31.54	Acknowledged by Responsible Person	Alarm condition removed, normal operation.	
01/04/2013 13:44	Hi	57.95	Not Acknowledged	*	
01/04/2013 13:45	HiHi	59.31	Acknowledged by Responsible Person	Alarm condition removed.	
01/04/2013 13:46	Hi	29.20	Acknowledged by Responsible Person	fixed	
History for T00016					

Single Tag Alarm Report

Configurable Call List with Scheduler

The system provides flexibility in defining notification priority and method of contact via email or phone.

Reporting Features

The reporting features of the system provide complete traceability of alarm events and actions, including user comments.

Daily Reports – The daily report generation can be executed with one simple click, to provide a complete view of the previous day's data—or manually generated to select any previous date for data display.

Historical Alarm Reports provide historical alarm reports from a secure database. You can quickly report on high-or-low-alarm events or chamber-specific descriptions over a defined period of time.

- **Historical Data Reports** – Kaye LabWatch LT reports provide a variety of historical data reports to help retrieve historical data for any sensor input over a defined period of time. The types of Historical Data Reports available are Min/Max/Avg reports, Values Reports and Period Summary Reports.

- **Min/Max/Avg Reports** provide the minimum, maximum, and average values for selected sensors at specified intervals over a defined period of time. These can be used to produce daily or weekly reports.

- **Values Reports** include all values for selected sensors at specified intervals over a period of time. You can also filter sensor values by defining upper and lower limits. Included in the report are values that exceed the specified upper limit and those that fall below the specified lower limit.
- **Period Summary Reports** provide the minimum, maximum, and average for each sensor tag over a defined period of time.

Mean Kinetic Temperature Report – Mean Kinetic Temperature (MKT) is the isothermal temperature that corresponds to the kinetic effect of a time temperature distribution. The MKT calculation produces a single value that characterizes the effect of fluctuating temperature on long-term product storage by weighting higher temperatures more heavily than lower ones. This is appropriate because at higher temperatures, product degradation occurs at an accelerated rate. Generating MKT reports with the Kaye LabWatch LT system is very simple. The system extracts historical data from a secure database, as data is stored in the database, not in files.

Daily report Freezer 1450													
Kaye LabWatch LT Printed By Ralf Op on 01/07/2013 08:38													
01/06/2013													
Freezer 1450													
01/06/2013		T00042 (C)			T00043 (C)			T00044 (C)					
Start	End	Min.	Max.	Avg.	Min.	Max.	Avg.	Min.	Max.	Avg.	Min.	Max.	Avg.
00:00	00:59	-24.94	-20.52	-22.90	-24.71	-20.27	-22.08	-25.65	-21.09	-23.31			
01:00	01:59	-27.49	-24.11	-26.16	-25.90	-23.17	-24.78	-27.68	-24.73	-26.44			
02:00	02:59	-25.39	-20.41	-22.91	-23.73	-20.17	-21.93	-25.52	-21.00	-23.26			
03:00	03:59	-27.52	-23.29	-26.02	-25.96	-22.93	-24.79	-27.73	-23.81	-26.34			
04:00	04:59	-25.93	-20.44	-23.15	-24.19	-20.21	-22.02	-26.06	-21.05	-23.45			
05:00	05:59	-27.50	-22.21	-25.60	-25.88	-21.91	-24.55	-27.71	-22.75	-25.98			
06:00	06:59	-26.47	-20.40	-23.57	-24.76	-20.25	-22.28	-26.67	-21.08	-23.84			
07:00	07:59	-27.49	-20.78	-24.87	-25.90	-20.52	-24.03	-27.70	-21.35	-25.30			
08:00	08:59	-26.87	-20.36	-24.32	-25.22	-20.19	-22.83	-27.08	-21.01	-24.54			
09:00	09:59	-27.58	-20.40	-24.57	-25.99	-20.23	-23.82	-27.79	-21.05	-25.02			
10:00	10:59	-26.97	-20.90	-24.72	-25.32	-20.53	-23.12	-27.19	-21.48	-24.90			
11:00	11:59	-27.64	-20.51	-24.78	-26.09	-20.32	-24.01	-27.86	-21.14	-25.23			
12:00	12:59	-26.91	-20.64	-24.62	-25.25	-20.46	-23.06	-27.11	-21.29	-24.82			
13:00	13:59	-27.74	-21.47	-25.49	-26.21	-21.20	-24.58	-27.98	-22.04	-25.90			
14:00	14:59	-26.60	-20.59	-24.05	-24.94	-20.40	-22.63	-26.80	-21.21	-24.29			
15:00	15:59	-27.80	-22.92	-26.27	-26.27	-22.60	-25.17	-28.05	-23.46	-26.64			
16:00	16:59	-26.06	-20.64	-23.39	-24.35	-20.43	-22.18	-26.23	-21.29	-23.69			
17:00	17:59	-27.67	-23.30	-26.26	-26.12	-22.94	-25.07	-27.91	-23.82	-26.60			
18:00	18:59	-25.82	-20.45	-23.14	-24.08	-20.28	-22.01	-25.99	-21.09	-23.45			
19:00	19:59	-27.61	-23.55	-26.27	-26.09	-23.19	-25.04	-27.84	-24.07	-26.60			
20:00	20:59	-25.69	-20.48	-23.05	-23.95	-20.26	-21.96	-25.85	-21.11	-23.38			
21:00	21:59	-27.65	-24.05	-26.43	-26.09	-23.75	-25.13	-27.89	-24.62	-26.75			
22:00	22:59	-25.47	-20.48	-22.99	-23.71	-20.31	-21.98	-25.60	-21.12	-23.33			
23:00	23:59	-27.68	-24.52	-26.55	-26.13	-23.80	-25.15	-27.93	-25.14	-26.83			

Daily Report

Single Tag Alarm Report – The single tag alarm report provides a detailed history of all alarm events of one single tag within a user-defined time frame, including a graphical overview on the data.

Calibration Report – The calibration report enables a comprehensive documentation on the system sensor calibration status—including offsets, used reference standards, calibration and calibration expiration dates.

Calibration Report									
Kaye LabWatch LT Printed By Ralf Op on 01/10/2013 11:16									
01/10/2013 to 01/10/2013									
Calibration Date	01/04/2013			Due Date	01/10/2013				
Customer	Amphenol Advanced Sensors Technologies GmbH			Issued By	Ralf Wottrich, Application Engineer				
Specifications	Amphenol Advanced Sensors QEEMS Specs								
References Used	Kaye IRTD ITS-90, sn I1007								
Sr.No	Tag	Tag Description	Type	Standard Low	Actual Low	Standard High	Actual High	User Calibration Date	Expiry Date
1	T00034		T	0.01	0	59.98	59.93	01/04/2013	01/04/2014
2	T00035		T	0.01	0.01	59.98	59.83	01/04/2013	01/04/2014
3	T00048		T	0.01	0.01	59.98	59.94	01/04/2013	01/04/2014
4	T00049		T	0.01	0.01	59.98	59.95	01/04/2013	01/04/2014
5	T00067		T	0.01	0.01	59.98	59.9	01/04/2013	01/04/2014
6	T00068		T	0.01	0.03	59.98	59.98	01/04/2013	01/04/2014

Calibration Report

Service and Support

Services offered include:

- **System specification** – Kaye LabWatch LT team will meet with you, review your needs and suggest the optimum solution for reliable monitoring of your site a complete description of what's included in the system from start to finish.
- **Start-up Installation and training** – Our specialists are available to get you up and running with on site or virtual assistance that best suits your needs.
- **After-sales service and support** – As with any service offered, we provide full factory trained and authorized support for your system long after initial installation and startup.

The success of the Kaye LabWatch LT system extends far beyond hardware and software installation.

Installation (IQ) and Operational Qualification (OQ) Protocol

Validation Documents are available to meet cGMP requirements. The documents define a set of procedures so that the Kaye LabWatch LT system and its associated components are properly installed and operated according to recommendations and adequately documented and controlled according to cGMP requirements.

Kaye LabWatch™ LT Specifications

General Specifications

Operating Systems Microsoft® Windows® 7 and Microsoft® Windows 10 - 64-bit

RF ValProbe II Wireless Loggers

Temperature Single / Multi Channel External Sensor: $\pm 0.1^{\circ}\text{C}$, range -50°C to 130°C , $\pm 0.2^{\circ}\text{C}$, range -80°C to -50°C
 -196°C to -80°C & $+130^{\circ}\text{C}$ to 200°C (Contact factory for accuracy)
Maximum cable length of external sensor is 30 feet/9 meters

Relative Humidity 2% from 25 to 85%RH (Certificate states ICH Points)

Auxiliary Inputs Current 3.8 to 22 mA Input, 16 bit A/D input, accuracy: 0.5% FS
Voltage 0 to 10 V input, 16 bit A/D input, accuracy: 0.5% FS
Contact Closure (dry)

Input Capacity 1 x Temperature + 1 x RH
1 x Temperature + 1 x RH + 0-10 VDC/4-20 mA + Contact Dry
1 x Temperature, 2 x Temperature, 5 x Temperature

Environmental Body (Logger Enclosure): -40°C to 60°C , 0 to 90%RH
External probe: -196°C to 200°C
Logger Dimensions: 115 mm x 71 mm x 43 mm (4.5 in x 2.8 in x 1.7 in)
Base Station Dimensions: 194 mm x 133 mm x 55 mm (4.5 in x 2.8 in x 2.2 in)

Battery Life Logger: 1 Year (1 min sample rate, varies $\pm 10\%$)
Logger with display can also be powered by a power supply (Kaye #201-3002)
Base station: Up to 10 minutes battery backup

RF Base Station Max number of RF base stations: 4
Max number of sensor inputs in total: 100 inputs
Max number of loggers per RF base station: 40 loggers
Connection: Ethernet or USB2.0 (one RF base station via USB)

RF Specifications 2.4 GHz SmartMesh® Technology
Range is approximately 150 feet/45 meters from one logger to the next
Each logger acts as a repeater

Logger Storage Up to 72 hours of redundant data for each sensor

Amphenol
Advanced Sensors

www.kayeinstruments.com

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