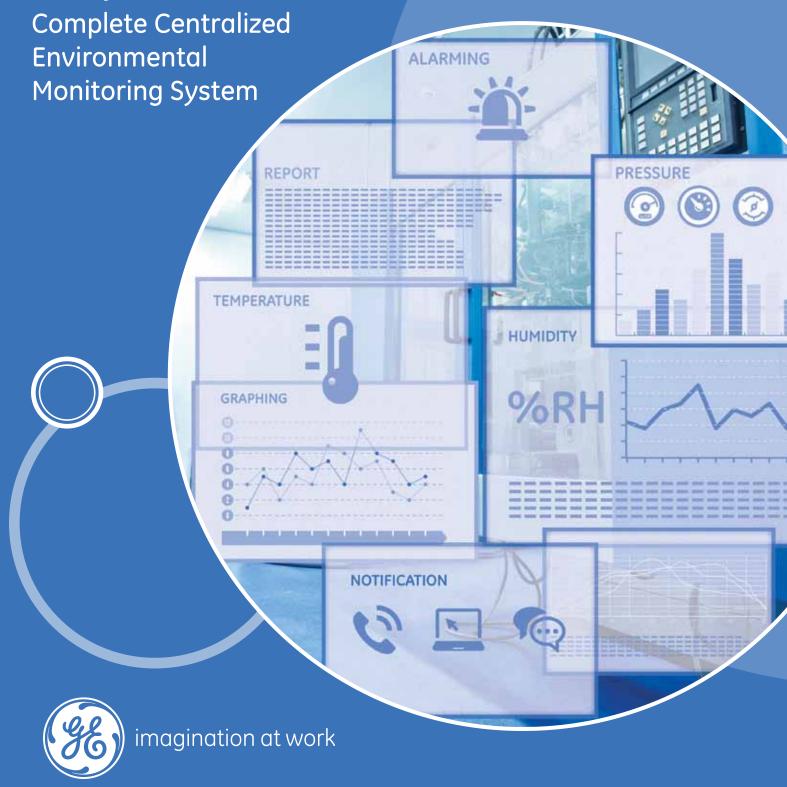
Kaye LabWatchTM LT



GE's 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, GE 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* 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.

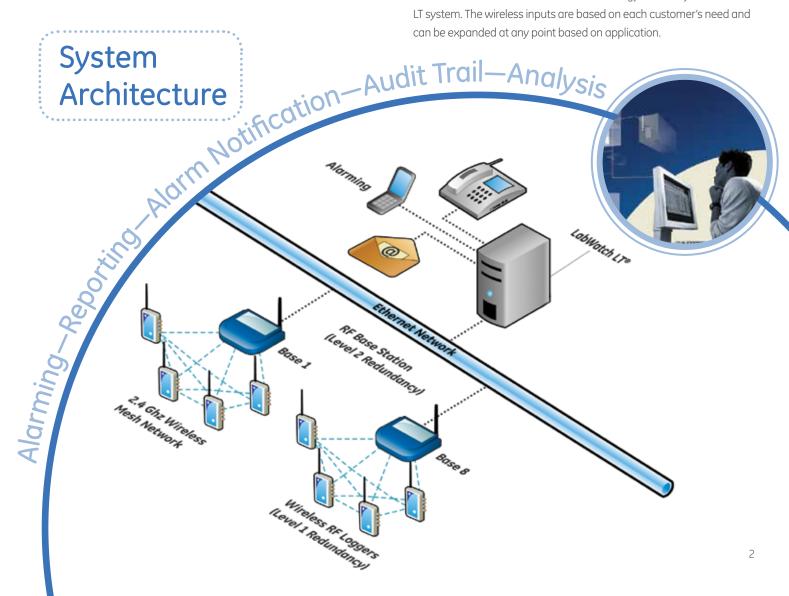
Wireless Flexibility

- 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* 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 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

Monitoring What Matters Most

WHERE WE MONITOR	WHAT WE MONITOR	SENSORS
 Warehouses Repositories Clean Rooms Blood Banks Tissue Banks Pharmacies Cold Storage Animal Rooms Laboratories 	 Stability Chambers Freezers Refrigerators Incubators Cryogenic Freezers LN2 Tanks Ovens Baths 	 Temperature Humidity CO₂ Pressure – Absolute and Differential Contacts – Door Switch, Relays Voltage/Current Inputs Light – Visible, Ultraviolet

RF Valprobe Wireless System

The Kaye RF ValProbe* 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 5-channel RF temperature loggers.

Kaye RF ValProbe* Wireless Loggers

- Environmental body: -40 to 60°C, 0% to 95% RH non-condensing
- 1 x temperature + 1 x RH + 0-10 VDC/4-20 mA + contact
- 5 x temperature
- External sensor range: -196 to +200°C (accuracy of 0.1°C from -80 to 130°C)
- Maximum cable length of external temperature sensor is 30 feet/9 meters
- Relative humidity internal sensor range: 0 to 100% RH (accuracy of 2% from 10 to 90% at 25°C)
- Auxiliary inputs contact dry (50 V maximum)
- Voltage 0-10 VDC (accuracy of 0.5% full scale)
- Current 4-20 mA (accuracy of 0.5% full scale)
- Logger dimensions: 2.5 in x 5 in x 1.25 in (64 mm x 127 mm x 32 mm)
- Base station dimensions: 7.5 in \times 5 in \times 1.75 in (190 mm \times 127 mm \times 45 mm)
- Standard AA battery: Energizer Ultimate Lithium with optimum long lasting performance
- 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

GE 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* for reliable communications.

SmartMesh* technology enables the wireless loggers to be spaced approximately 300 feet/100 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* 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*.



REGISTRATION

Easy Steps to Be Compliant

CONFIGURE **BASE STATIONS**

ASSIGN TAGS

CONFIGURE **TAGS**

CREATE TAGS GROUPS

ASSIGN GROUP

USERS

DEFINE **SCHEDULE**

DEFINE ALARM NOTIFICATIONS

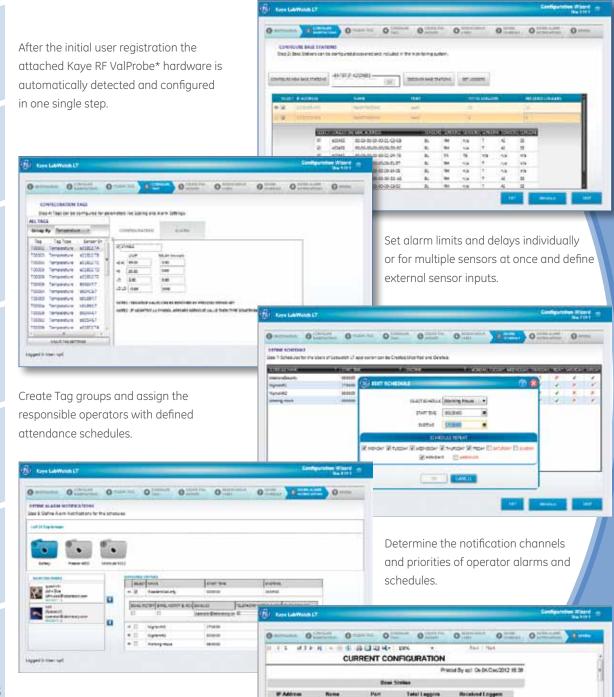
REVIEW

At the end of the setup receive a

comprehensive Configuration report for

simple GMP compliant documentation

and easy-to-change control records.



3 228 206 209

PAGESTATIONS

BARRETY TOWN

BACKSTATION: APPENDING

A01986.TA

ADTES 18 A01906.TC

A01996.TD

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.

Configurable Call List with Scheduler

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



	LT			Printed By Ralf Op on 01/04/2013 14:10					
01/04/2013 00:00 to 01/04/2013									
ag	Unit Tag Description		Sensor	Group	Group Description				
T00016	С	CH1 - Heating System Temperature		Stability Chamber 1					
Tag Details T00	<u>0016</u>								
Alarm Limits		LoLo : -10.00	Lo : 02.0	0 Hi : 29.	00 HiHi : 59.00				
Date		01/04/2013							
Total Alarms		5							
Acknowledged	Count	3							
Alarm History									
Alarm Ti	me	Alarm Type	e Alarm Value	Status	Comments				
		Alarm Typ		Status Not Acknowledged	Comments				
Alarm Ti	12:23		Value	Not					
Alarm Ti 01/04/2013	12:23	Hi	Value 32.20	Not Acknowledged Acknowledged by Responsible	* Alarm condition removed,				
Alarm Ti 01/04/2013 01/04/2013	12:23 12:24 13:44	Hi	32.20 31.54	Not Acknowledged Acknowledged by Responsible Person Not	* Alarm condition removed, normal operation.				

Single Tag Alarm Report.

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 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.

Kaye LabV	valuii L I						inted by	naii Op c		2013 08:3
	150									01/06/201
reezer 1450 01/06/2013 T00042 (C) T00043 (C) T00044 (C)										
			,	•		,	•		,	•
Start 00:00	End 00:59	Min. -24.94	Max. -20.52	Avg. -22.90	Min. -24.71	Max. -20.27	Avg. -22.08	Min. -25.65	Max. -21.09	Avg. -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	02:59	-27.52	-23.29	-26.02	-25.96	-22.93	-24.79	-27.73	-23.81	-26.34
04:00	03:59	-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.

Kaye L	abWatch l	_T				Pi	rinted By F	Ralf Op on 01/1	0/2013 11:1	
								01/10/2013 to	01/10/2013	
Calibration Date			01/04/2013			Due Date		01/10/2013		
Custo	mer			ing & Inspec gies GmbH			Issued By		Ralf Wottrich, GE Application Engineer	
Specif	ications	(General	Electric QEE	MS Spec	s				
Refere	nces Use	d l	Kaye IRT	D ITS-90, si	n I1007					
	ences Use	Tag Descripti	Kaye IRT	Standard Low	Actual Low	Standard High	Actual High	User Calibration	Expiry Date	
		Tag	.,.	Standard	Actual				Date	
Sr.No	Tag	Tag Descripti	Туре	Standard Low	Actual Low	High	High	Calibration Date	Date 01/04/201	
Sr.No	Tag	Tag Descripti	Type T	Standard Low	Actual Low	High 59.98	High 59.93	Calibration Date 01/04/2013		
Sr.No 1 2	Tag T00034 T00035	Tag Descripti	Type T	Standard Low 0.01 0.01	Actual Low 0 0.01	High 59.98 59.98	High 59.93 59.83	Calibration Date 01/04/2013 01/04/2013	Date 01/04/201 01/04/201	
Sr.No 1 2 3	Tag T00034 T00035 T00048	Tag Descripti	Type T T	Standard Low 0.01 0.01 0.01	0 0.01 0.01	High 59.98 59.98 59.98	High 59.93 59.83 59.94	Calibration Date 01/04/2013 01/04/2013 01/04/2013	01/04/201 01/04/201 01/04/201	

Calibration 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 timeframe, 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.

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Service and Support

Services offered include:

- System specification GE's 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 onsite 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 GE 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 32-bit and 64-bit, Microsoft® Windows® XP SP3
	32-bit, Microsoft® Windows® Server 2008R2-Standard

RF ValProbe Wireless Loggers

Temperature	External sensor range: -196 to +200°C (accuracy of 0.1°C from -80 to 130°C) Maximum cable length of external sensor is 30 feet/9 meters
Relative Humidity	Internal sensor range: 0 to 100% RH (accuracy of 2% from 10 to 90% at 25°C)
Auxiliary Inputs	Contact dry (50 V maximum) Voltage 0-10 VDC (accuracy of 0.5% full scale) Current 4-20 mA (accuracy of 0.5% full scale)
Input Capacity	$1 \times$ Temperature + $1 \times$ RH $1 \times$ Temperature + $1 \times$ RH + 0-10 VDC/4-20 mA + Contact Dry $5 \times$ Temperature
Environmental	Body: -40 to 60°C, 0% to 95% RH non-condensing Logger dimensions: 2.5 in \times 5 in \times 1.25 in (64 mm \times 127 mm \times 32 mm) Base station dimensions: 7.5 in \times 5 in \times 1.75 in (190 mm \times 127 mm \times 45 mm)
Battery Life	Standard AA battery: Energizer Ultimate Lithium with optimum long lasting performance
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 300 feet/90 meters from one node to the next Each node acts as a repeater
Logger Storage	Up to 72 hours of redundant data for each sensor





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