ValProbe® RT

NEWEST STATE-OF-THE-ART TECHNOLOGY WIRELESS REAL-TIME TEMPERATURE AND PRESSURE DATA COLLECTION

Do You Need To Know In Real-Time What's Going On Inside Your Autoclave?

Kaye ValProbe® RT (Real-Time) is a wire-free real-time process validation and monitoring system designed around the measurement and reporting requirements of the most intensely regulated industries.

It is a state-of-the-art validation system design that meets industry and regulatory (FDA / GAMP) requirements for thermal validation. The ValProbe RT system combines high accuracy measurements, automated sensor calibration, an intuitive metro style user interface, and extensive reporting to simplify the complete validation process.

Kaye ValProbe RT is the successor of the widely recognized Kaye ValProbe, the accepted standard in wireless validations systems for over 15 years.

The ValProbe RT family of data loggers provide accurate, convenient, and reliable process measurement for a wide range of pharmaceutical and medical device applications. The wireless design greatly simplifies monitoring and validation of severe and hard-to-reach environments. See the table below for logger types and recommended applications.

Kaye ValProbe RT Datalogger	Temperature Rigid Logger	Temperature Flexible Logger	Temperature Bendable Logger	Temperature Freeze Dryer Logger	Pressure / Temp Logger
Steam Sterilizers	✓	✓	✓	✓	✓
Dry Heat Sterilizers			✓		
Steam in Place (SIP)	✓	✓	✓		✓
Water Cascade / Fall Sterilizer	✓	✓	✓	✓	✓
Incubators	✓	✓	✓		
Stability Chambers	✓	✓	✓		
Freezers	✓	✓	✓	✓	
Freeze Dryer / Lyophilization	✓	✓	✓	✓	
Vessels	✓	✓	✓		✓

Lifting Real Time Validation to the Next Level

The Kaye ValProbe RT System is a unique design and concept combining a ValProbe RT system with a Validation Console. The console is a rugged, hardened tablet to interface with your Kaye ValProbe RT and legacy hardware. It is pre-loaded with Kaye software and specifically engineered for validation tasks only. This concept greatly simplifies software validation and dependency on continuously changing PCs, operating systems, and core loads. The Kaye ValProbe RT offers easy, dedicated and reliable validation. The Kaye ValProbe RT is intuitive, efficient, and easy to operate – allowing you to focus on the validation, not the technology. Kaye ValProbe RT Logger simplifies access to hostile, remote, and hard-to-reach environments by eliminating hard-wired sensors, greatly reducing study setup time and associated costs.

- Hardened, dedicated validation console
- Asset centric data management concept
- Intuitive metro-style user onterface
- Portable validation console pre-loaded software
- Dedicated to validation tasks
- Simplified compliance and easy validation
- 21 CFR Part 11 Compliant

- Flexible data connection
- Console can interface with multiple units
- Quick pin connection attaches console to dock
- Three USB 3.0 inputs
- Two VGA male and one VGA female inputs
- Ethernet port

- Stand-alone operation
- Reliable data safety a smart redundancy concept
- 60 minute battery backup

Applications – Challenges – Solutions

APPLICATIONS

- Steam Sterilizer (Autoclaves)
- Dry Heat Sterilizers
- Washer Desinfectors
- Steam in Place (SIP)
- Water Cascade / Fall Sterilizers
- Incubators
- Stability Chambers
- Freezers
- Freeze Dryer / Lyophilization
- Vessels

CHALLENGES

- Pharmaceutical industries are faced with increasing operational challenges
- Need for live data during study even in harsh, extreme cold, or hot temperature
- Complex and time consuming data organization
  - Cost and time of validation and re-validation
- Data Integrity – compliance with newest norms and standards
- Increased IT security and lock down of portable data
- Continually changing operation systems
  - Hardware compatibility
  - Complex software operation

MARKETS

- Pharmaceutical Processing
- Medical Device Sterilization
- Food Processing
- Environmental Monitoring

SOLUTIONS

- Kaye ValProbe RT delivers reliable life data under harsh conditions at high or low temperatures
- Pre-loaded with Kaye software, the Kaye Validation Console is only dedicated for validation
- The system guarantees ease of use and dedicated reliable validation; allowing focus on validation tasks, not the technology
- 21 CFR part 11 compliant (data integrity)
- OS and hardware controlled and validated by Kaye
- Common software tools for Kaye hardware
- Backward compatible to existing Kaye products
- Elimination of IT control
- Intuitive metro-style touch screen interface
- Simplified validation
- Asset centric data management concept

ValProbe RT System

The ValProbe system is designed to provide easy access to process and validation study data. Loggers are programmed via the ValProbe RT base station in combination with the Kaye console.

The ValProbe RT base station communicates and collects data from 25 ValProbe RT Loggers. The system is specially designed to be extremely reliable under harsh conditions ex. 0-5 bar and -85°C to 140°C.

FEATURES

- Live data under harsh conditions via RF during validation study
- RF-range up to 150 meters
- Temperature range -85 to 400°C
- Up to 100,000 samples per sensor
- Scan rate down to 1 second
- Data transmission rate 3 seconds to 30 seconds
- ValProbe system capacity 25 loggers / 50 sensors
- Customer interchangeable batteries
- Accuracy up to 0.1°C
- Unmatched battery life

VALPROBE RT BASE STATION

The base station serves as the interface between individual loggers and the powerful ValProbe RT system software. It is used for qualification, calibration, and verification studies. Its compact design, including a battery backup, makes it well-suited for field use or desktop applications.

The ValProbe RT Base Station is compatible with the entire product range of Kaye baths and dry wells.

Base Station Features

- Dual antenna technology / allows installation of autoclave antenna
- Compact design for field or desktop operation
- Can operate as standalone system / internal 32 GB memory
- Power supply 100 – 240 V
- Battery backup for up to 60 minutes
- Ethernet network connection
- LED indicator confirming battery and study condition
- Logger wake-up sound indicator
- Wake-up magnet
- CE, UL certified

ValProbe RT Temperature Loggers

TEMPERATURE RANGE
-85°C TO 400°C

ValProbe RT Loggers provide a vast temperature range from -85°C to 400°C. They also provide a single solution for extreme low and high temperature applications, proven for pressure up to 5 bar. RTD technology delivers unrivalled measurement accuracy and the new logger electronic design guarantees long battery life. Operator programmable sample rates starting at 1 second, allow collection of up to 100,000 data points per sensor. The antenna diversity concept secures an unmatched RF communication reliability.

TEMPERATURE LOGGER – RIGID

Features

- Temperature range for complete logger:
  -85°C to 140°C
- Single sensor only
- Sensor length 1.5, 3, 6, 9"
- Sensor diameter 3mm; 0.118"

TEMPERATURE LOGGER – BENDABLE SINGLE AND DUAL SENSOR LOGGER

Features

- Temperature range for logger sensor:
  -85°C to 400°C
- Single and dual bendable sensor available
- Sensor length 12, 24, 36"
- Sensor diameter 2.4mm; 0.095"

FLEXIBLE TEMPERATURE SENSOR LOGGER AVAILABLE AS A SINGLE, DUAL, OR 5-SENSOR LOGGER

Features

- Temperature range for complete logger: -85°C to 140°C
- Single, dual, and 5-channel flexible sensor available
- Sensor length 40"
- Sensor tip diameter 2.4mm, length 25mm; 0,98"

FREEZE DRYER LOGGER

Features

- Temperature range for complete logger: -85°C to 140°C
- Ultra-flat surface sensor
- Surface sensor diameter 32mm; 1.26"
- Optimized surface design also for low vacuum applications

HUMIDITY AND TEMPERATURE LOGGER

Features

- Temperature range from 0°C to 70°C
- Humidity range from 15% to 95%
- Sensor tip diameter 7.5 mm, 0.295"
- Outer filter diameter 12 mm, 0.472"
- 1 meter sensor extension cable
- Field-replaceable humidity sensor

PRESSURE AND TEMPERATURE LOGGER

Features

- Temperature range for complete logger: 0°C to 140°C
- Pressure range 0 to 5 bar, 1mbar resolution
- ¼ NPT connection fitting

ValProbe RT Specifications

KAYE VALPROBE RT GENERIC SPECIFICATIONS

Base Station Dimensions	7.6 in x 5.2 in x 2.2 in 190 mm x 130 mm x 55 mm	**Real-Time Clock Accuracy**	< 15sec / day
		Calibration	NVLAP/DAkkS Calibration
Logger Dimensions	Height: 1,9" / Diameter 1,4" 48 mm / 36 mm	**Verification**	Automated User Verification capability
Logger Material	Stainless Steel 316L and Peek	**Sensing Element**	Precision Platinum RTD
Battery	Field replaceable – 3.6V Lithium	**Environmental Temperature**	-85°C to 140°C
Sampling Rate	Starting at 2 sec	**Environmental Pressure**	0-5bar absolute
Data Storage	100.000 Samples retained in non-volatile memory	**Environmental Humidity**	0-100% condensing
		Regulatory Compliance	UL and CE

TEMPERATURE LOGGERS

PRESSURE & TEMP LOGGER

Specifications	Rigid	Bendable	Flexible	Surface	Pressure
Sensor Type	Single Sensor	Single and Dual Sensor	Single, Dual and 5-Channel	Ultra Flat Surface Sensor	Single P/T Sensor
Sensor Length	1.5, 3, 6, 9" inches 38, 76, 152, 229 mm	12, 24, 36" inches 305, 610, 915 mm	40" inches 1000 mm	-	-
Tip Diameter	0.118"; 3mm	0.095"; 2.4mm	0.095"; 2.4mm	32mm diameter	1/4 NPT Connection fitting
Measurement Range	-85°C to 140°C	-85°C to 400°C	-85°C to 140°C	-85°C to 140°C	0°C to 140°C / 0-5bar abs
Accuracy	-85°C to 140°C, ±0.1°C	-85°C to 140°C, ±0.1°C 140°C to 400°C ±0.25°C	-85°C to 140°C, ±0.1°C	-85°C to 140°C, ±0.1°C	0°C to 120°C ±25mb 120°C to 135°C ±10mb 0°C to 140°C ±0.1°C

Validation Console

A NEW FLEXIBLE APPROACH TO VALIDATION

The Kaye Validation Console is a state-of-the-art portable and rugged console, dedicated to programming, displaying, reporting, and storing Validation data. The console is pre-loaded and configured with the suite of Kaye and legacy software. It is customized to specific validations tasks. The console offers direct docking and Wi-Fi connectivity with Kaye equipment. The Kaye Validation Console brings about a new approach to tackling your software validation.

VALIDATION CONSOLE SPECIFICATIONS

Operating System / Processor / Memory
- Microsoft Windows 10 Enterprise LTSC (64 bit)
- 8th Generation Intel® Core™-i5 Processor
- 8 GB RAM

Durability IP65 Rated
- Military grade durability with improved thermal management
- Maximum protection against dust, dirt, and water ingress
- Drop-tested from 4 feet
- Temperature-tested from -20°F to 145°F (-29°C to 62°C)

Display
- 11.6-inch, FHD 1920 x 1080
- 1000 Nit outdoor-readable
- Anti-glare, anti-smudge, polarizer
- Glove-capable touchscreen

System Storage
- 256GB M.2 Solid State Drive (SSD)

Integrated Communications
- Intel® Wireless-AC 9560
- 802.11ac with Bluetooth 5.0

Separate Docking Station Available

I/O Ports
- Docking Connector
- 1 - USB 3.1 Type-A with power delivery
- 1 - USB 3.0 Type-C port with DisplayPort Alt Mode / PowerShare
- 1 - Combo mic / headphone jack
- 256GB M.2 Solid State Drive (SSD)

Embedded I/O
- On-board camera capability of taking pictures with console
- 5 MP RGB + IR FHD webcam with privacy shutter / 8 MP rear camera with flash and dual microphone

Dimensions / Weight[1]
- 7.99in x 12.29in x .96in (256mm x 256mm x 24.3mm)
- 2.93 lbs (1.33 kg)(1)

Battery
- Battery life up to 6 hours[2]

Backwards Compatibility
- Can run with Kaye Validator and Kaye ValProbe software

1. Weight represents approximate system weight measured with a 34WHr battery. Actual system weight may vary depending on component and manufacturing variability.
2. Battery life varies by configuration, applications in use, utilized features, and operating conditions. Maximum battery capacity decreases with time and use.

Two ways to connect the Validation Console to ValProbe RT

1. DOCKING MODE (STAND-ALONE)

The console sits in the docking station and connects directly. The ValProbe RT offers a fully functional docking station with direct access to the ports located on the rear of the unit. The console battery charges while docked.

2. NETWORK MODE

The Validation Console can connect to a local network by using ethernet or Wi-Fi connection.
One validation console can handle multiple Kaye validation systems simultaneously.

The Kaye Validation Console can establish wireless connections* by utilizing any kind of available Wi-Fi infrastructure.

This feature simplifies your daily routine work. You can access live data wirelessly on the console screen. You can start or stop studies and read live data from a Kaye ValProbe RT system in a cleanroom without entering the room.

* This feature is not available in some countries. Please contact your local Kaye support for details.

ValProbe RT Software

ASSET CENTRIC DATA MANAGEMENT

The Kaye ValProbe RT includes an intuitive Asset Centric Data Management concept which allows you to store and access your data faster and more efficiently. Each individual process that you validate, whether an autoclave or freezer etc., can be setup and defined as an asset. All files and data related to an asset, such as setups, verifications, or study files, are organized and accessed in one single screen around the basic asset data. It is also possible to upload additional documents such as standard operation procedures or certificates and associate them with the asset. Assets can be sorted and searched by type, location, manufacturer etc. for easy access.
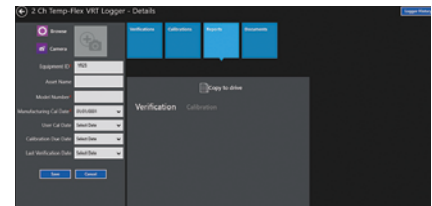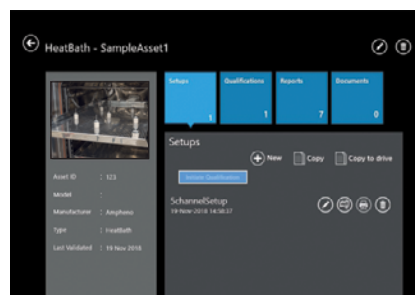
EQUIPMENT ASSETS

With the Kaye ValProbe RT you can define assets for each piece of Kaye Validation equipment. Data such as serial numbers and calibration due dates can be defined. The software automatically notifies the user when calibrations are due. The equipment search function uses the Kaye serial number, that is automatically retrieved as part of the study file, to find related files. Using just one fingertip you can have a list of qualification studies where the equipment asset was used.
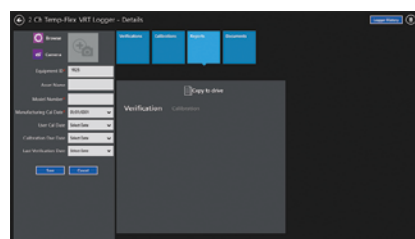
QUALIFICATION / STUDY

The Kaye Validation Console can connect to a ValProbe RT system directly through the docking station of the console or via WiFi to the network connected base station. It enables the user to transfer setups, start studies, and monitor live data or read finished studies. After starting a study, the ValProbe RT base station runs the tasks independently.

One Kaye Validation Console can control several validation systems in parallel and one validation system can handle several consoles. While connected to ValProbe RT the user can see the live data in list or graphical view, group based calculation, and event messages. Any connected hardware is displayed with a serial number.
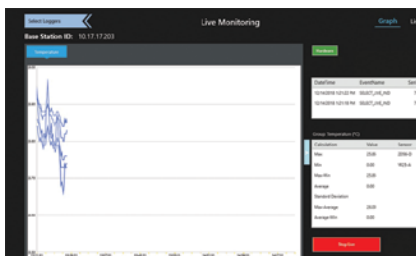
SENSOR VERIFICATION

Kaye, the original creator of the Automatic Logger Verification feature has included enhancements eliminating manual methods of logger verification resulting in better accuracy.

Kaye ValProbe RT is backward compatible with existing Kaye IRTD and calibration baths. The automatic verification feature minimizes training and ensures accurate and repeatable verifications, all while being well documented.

Select only loggers you want to verify. Defining a verification setup lets you verify a large number of loggers among all those displayed in equipment assets.

Set the criteria for a logger verification – the ValProbe RT system allows you up to six independent temperature verification points.
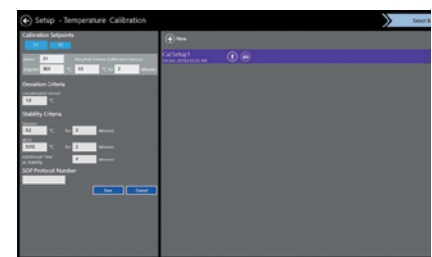
The console displays the entire verification process on one screen. Data fields change color to show the progress of stability and deviation for each logger. A status window lists each step and indicates where the system is in the process.
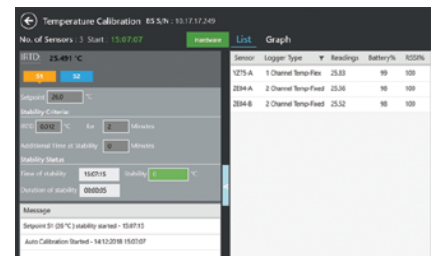
ValProbe RT Reporting Tool

The Kaye Validation Console includes an extensive and flexible Reporting Tool used to analyze and document your critical Validation studies. The Reporting Tool is a separate application which is seamlessly integrated into the Kaye software. It can be used to analyze and document not only ValProbe RT files, but Validator AVS files also. While offering several new features and enhancements, the Reporting Tool is designed to ensure that the proven and accepted formats of the ValProbe summary, detailed, and calibration formats are maintained. Enhancements to graphing reports, setup reports, as well as new reports such as ValProbe RT wiring layout and pass / fail reports provide faster and more detailed ways of analyzing your data. Reports can be previewed, printed, saved as a PDF, or exported in CSV format.

REPORTING

- ValProbe RT Wiring Layout
- Setup Report
- Calibration Report
- Verification Report
- Graph Report

- Detailed Report:
  - Statistical
  - Lethality
  - Saturation
  - MKT
- Summary Report
- Audit Trail Report
- Pass / Fail Report

CONFIGURATION CHOICES

Prior to generating reports the Reporting Tool provides a host of configuration choices:

- Sensors included in report
- Sensors separated by groups
- Sensor placement and description
- Define cycles (qualification, exposure, etc.)
- Calculations (statistical, lethality, saturation, MKT etc.)
- Header / footers
- Graphing
- Templates
- Pass / fail criteria

These features provide you with maximum flexibility to get the data and calculations you require in the correct formats to meet your Validation reporting needs.

Calibration Report

ValProbe RT Wiring Layout

Graph Report

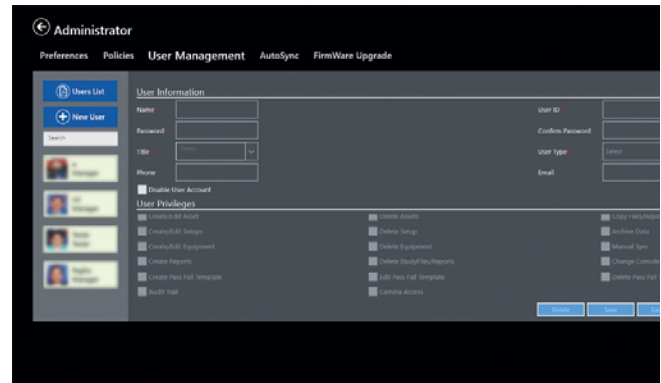Qualification Report

Graph Lethality Report

Detailed Lethality Report
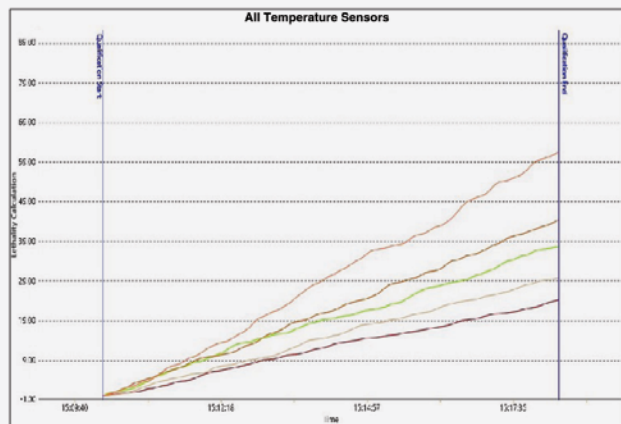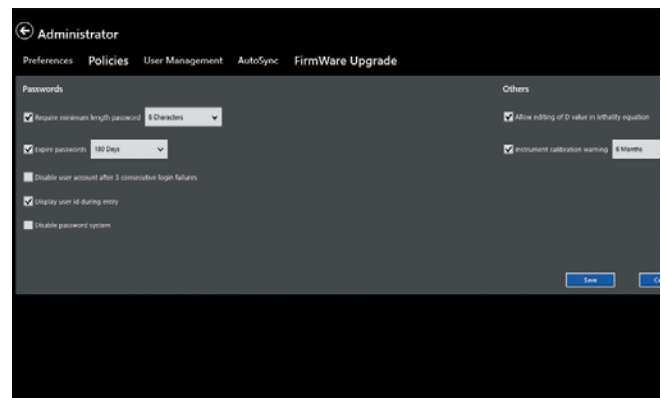
Flexible and Compliant

ELECTRONIC SIGNATURE

Kaye ValProbe RT is a state-of-the-art validation system designed to meet worldwide regulations and guidelines on Thermal Validation and Data Integrity. 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. In addition to pre-configured privilege levels, it is possible to explicitly set permissions for each user.

With data synchronization to a shared folder it is possible to exchange configuration and data files like your assets, setups, and study files with other Kaye validation consoles. The Kaye ValProbe RT can synchronize a user database and also merge audit trails of several consoles enabling sorting, searching, and printing of department-wide audit trails, for example, a list of all failed login attempts within a specified time period across all synchronized Kaye validation consoles. Every console has a unique but customizable machine ID for identification.

User Management

Policies

Audit Trail Report

System Documentation

QUALITY CONTROL DOCUMENTS

Kaye's quality policy, the ISO 9001 implementation and certificate, and document control standard operating procedures (SOPs)

DEVELOPMENT PROCEDURES

Design control and project management SOPs, and functional specifications

QUALITY ASSURANCE PROCEDURES

Test plan and test case procedures

RELEASE DOCUMENTS

Quality assurance certification and product release notices

QUALITY ASSURANCE TEST DOCUMENTATION

Quality assurance test plan and test cases

IQ/OQ PROTOCOL

The Installation Qualification / Operational Qualification Protocol defines a set of procedures to ensure that the Kaye ValProbe RT system is properly installed and operated according to Kaye's recommendations, 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.

The IQ/OQ Protocol includes the following:
• Installation Qualification document
• Operational Qualification document
• Operational Qualification document – Report
• Standard Operating Procedures document

If you prefer to have IQ/OQ executed by qualified Kaye technicians we also provide Validation IQ/OQ on-site execution.

VALIDATION REFERENCE

The Kaye ValProbe RT system is supported with documentation that verifies a fully validated system, including software, hardware, and firmware. The Validation Reference Binder provides a comprehensive overview of the Amphenol 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.

The Validation Reference is a serialized document, ensuring that registered users automatically receive notification and updates to keep documentation current. The result is a summary of information you would obtain by conducting an audit at Amphenol's facility – complete, well organized, neatly packaged, and immediately accessible.

ValProbe RT Onsite Verification

HIGH ACCURACY REFERENCING

Kaye's temperature calibration equipment is designed specifically to maximize overall system accuracy. Calibration equipment includes temperature references with superior uniformity, traceable intelligent RTD standards, and validation software to communicate with the hardware.

FAST / ACCURATE REFERENCING

System performance data is only as good as the accuracy of the baseline measurement and inaccurate measurements have no place in pharmaceutical and biotech processing.

Kaye baths, dry wells, and IRTD temp standards offer unparalleled accuracy over a wide temperature range and reliability to meet your validation and verification needs.

INTELLIGENT RTD STANDARD

The IRTD Temperature Standard (IRTD-400) is a NIST / DAkkS-traceable instrument that is calibrated over the range of - 196°C to 420°C. It is accurate to ±0.025°C over the entire operating range. Communicating directly with the console software, the IRTD-400 eliminates the potential for human error, assuring accurate and traceable measurements.
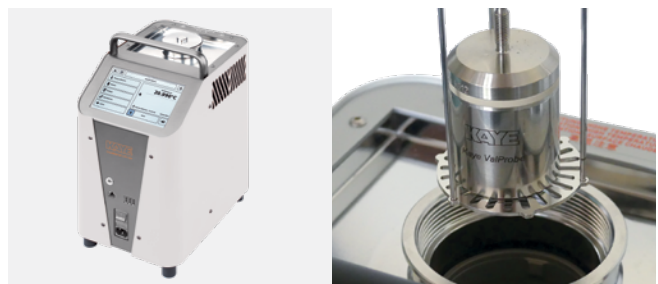

KAYE CTR-25

- Temp Range: -25°C to 140°C
  (closed cover)
- Verification of up to 10 rigid
 ValProbe RT loggers

KAYE LTR-150

- Temp Range: -30°C to 150°C
- Liquid micro bath tub with sensor cage
  and magnetic stirrer can hold ValProbe RT
  rigid loggers

Accessories

KAYE TRANSPORT AND STORAGE

The ValProbe transport/storage tray is an accessory designed to simplify the carrying, storage, and management of Kaye ValProbe RT loggers during use. The ValProbe RT transport/storage tray can accommodate up to 20 Kaye ValProbe loggers of any type.
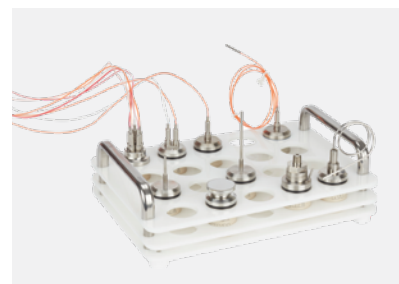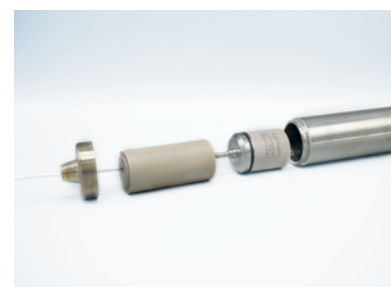

KAYE INSULATING CANISTER

Use the Insulating Canister in combination with minimum the 12" bendable temperature loggers for a perfect solution for dry heat applications.

Performance

Temp.	Exposure Time
350°C	40 min.
300°C	60 min.
250°C	80 min.
200°C	115 min.
170°C	165 min.

KAYE SHIPPING CASE

Protect your validation equipment and store it safely when not being used.

KAYE AUTOCLAVE ANTENNA

The Kaye Autoclave Antenna provides improved signal strength for challenging applications like large autoclaves or vessel in vessel setups. It is steam proven and can be installed via the standard Kaye Feedthru.

Visit our website:

Kaye representative contact:

Request a demo:

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