

# KAYE

## Kaye ValProbe® RT



Newest State-of-The-Art Technology

Wireless real-time temperature and pressure data collection

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

# 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	Steam Sterilizers	Dry Heat Sterilizers	Steam in Place (SIP)	Water Cascade/Fall Sterilizer	Incubators	Stability Chambers	Freezers	Freeze Dryer / Lyophilisation	Vessels
Temperature Rigid Logger	●		●	●	●	●	●	●	●
Temperature Flexible Logger	●		●	●	●	●	●	●	●
Temperature Bendable Logger	●	●	●	●	●	●	●	●	●
Temperature Freeze Dryer Logger	●			●			●	●	
Pressure/Temp Logger	●		●	●					●

- Hardened, Dedicated Validation Console
- Asset Centric Data Management Concept
- Intuitive Metro-Style User Interface



# 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 to Validation tasks only. This concept greatly simplifies software validation and dependency on continuously changing PC's, 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.



- 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



- Stand-Alone Operation
- Reliable Data Safety a Smart Redundancy Concept
- 60 Minute Battery Backup



# Applications - Challenges

## Applications

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

## Markets

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

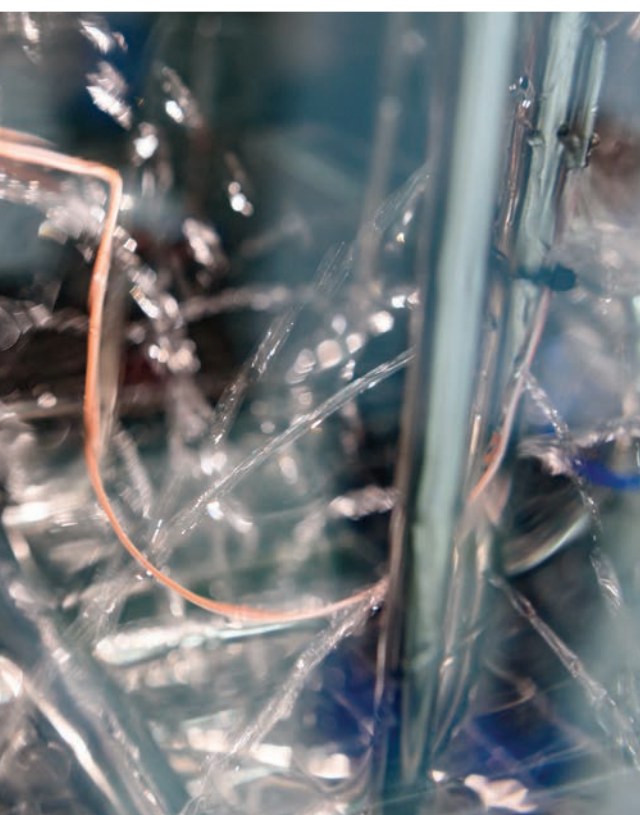
## Challenges

Pharmaceutical industries are faced with increasing operational challenges

- Need for life 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



# - Solutions



## 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

# Kaye 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 e.g. 0-5 bar and -85°C to 140°C.

## Features

- Life data under harsh conditions via RF during validation study
- RF-Range up to 150 meters
- Temperature Range -85 to 400°C
- Up to 100000 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.

## 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



The ValProbe RT Base Station is compatible with the entire product range of Kaye Baths and Dry Wells.

# 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 5bar.

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 100000 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”



## 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



# Temperature Logger – Flexible

## 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"



## Pressure and Temperature Logger

The ValProbe RT Pressure/Temp Logger provides a wide temperature range from 0°C to 140°C. The loggers are a single solution for pressure and temperature measurements for pressure up to 5bar.

RTD technology delivers high measurement accuracy and the new logger electronic design guarantees long battery life.

The antenna diversity concept delivers an unmatched RF communication reliability.

### Features

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



# Kaye 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	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 1 sec	Environmental Pressure	0-5bar absolute
Data Storage	100.000 Samples retained in non-volatile memory	Environmental Humidity	0-100% condensing
Real-Time Clock Accuracy	< 15sec/day	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

# Kaye 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

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.

### 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

### 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<sup>(1)</sup>

- 7.99in x 12.29in x .96in (256mm x 256mm x 24.3mm)
- 2.93 lbs (1.33 kg)<sup>(1)</sup>

### Battery

- Battery life up to 6 hours<sup>(2)</sup>

### Backwards Compatibility

- Can run with Kaye Validator and Kaye ValProbe Software

# Two ways to connect the Validation Console to Kaye 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 a 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.

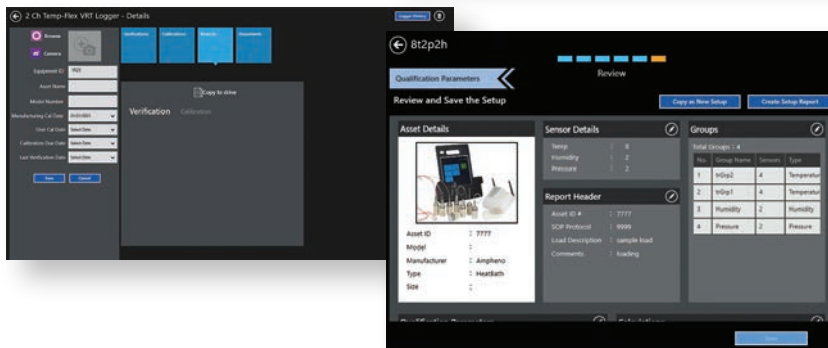
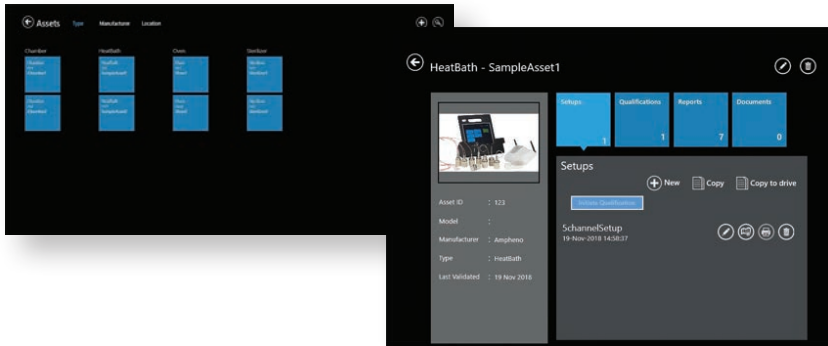
This feature simplifies your daily routine work. You can access live data wirelessly on the console screen. You can start or stop studies and read live data from a Kaye ValProbe RT system in a cleanroom without entering the room.

# Kaye 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

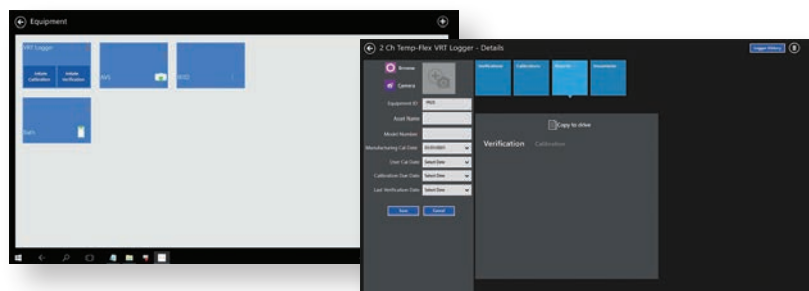
in one single screen around the basic asset data. It is also possible to upload additional documents such as standard operation procedures or certificates and associate them with the asset. Assets can be sorted and searched by type, location, manufacturer etc. for easy access.



- Organized Study Data
- Simplified Data Search

## 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.



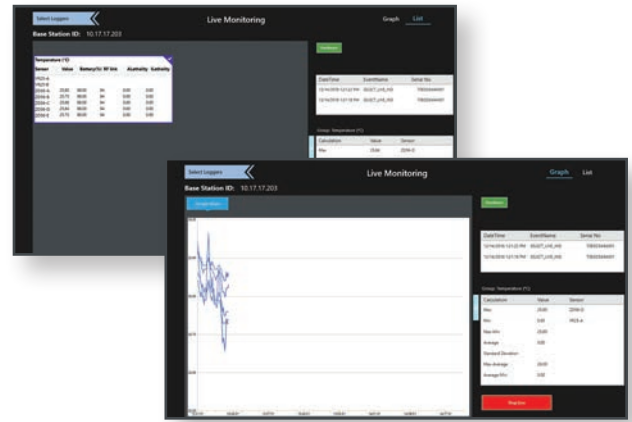
## Qualification / Study

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.

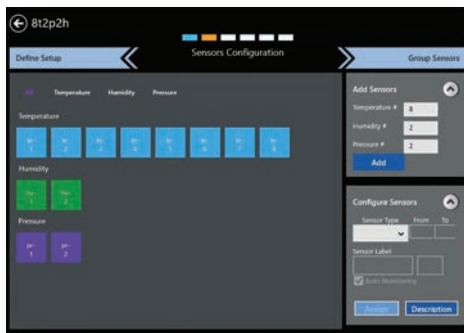
One Kaye Validation console can control several Validation Systems in parallel and one Validation system can handle several consoles.

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.



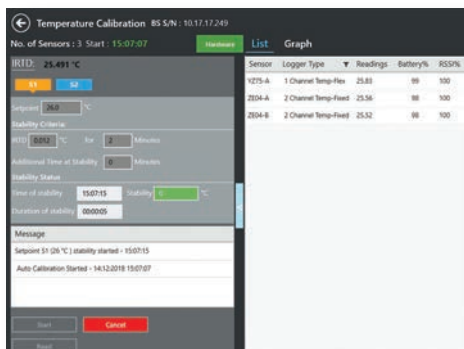
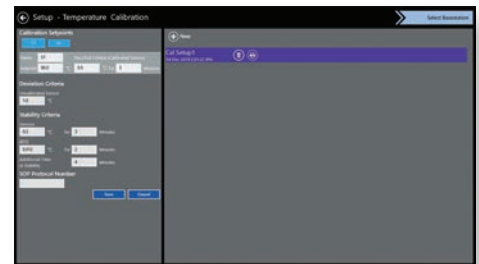
## Sensor Verification

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.

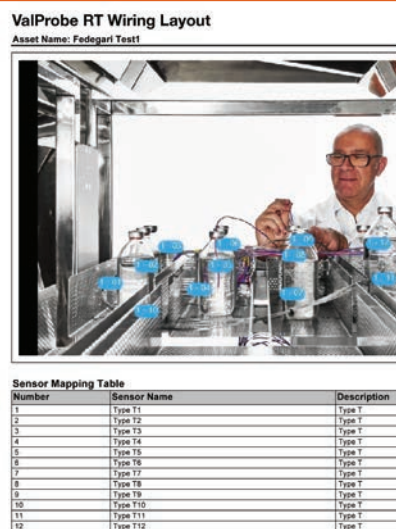
Set the criteria for a logger verification – the ValProbe RT System allows you up to six independent temperature verification points.



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 Wiring Layout

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.



**Sensor Mapping Table**

Sensor	Sensor Name	Description
1	Type T1	Type T
2	Type T2	Type T
3	Type T3	Type T
4	Type T4	Type T
5	Type T5	Type T
6	Type T6	Type T
7	Type T7	Type T
8	Type T8	Type T
9	Type T9	Type T
10	Type T10	Type T
11	Type T11	Type T
12	Type T12	Type T

## 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.

## Detailed Lethality Report

**VRT Qualification Detailed Report** Printed on: 10/24/2018

Study Name: 20 temp sensors SOP / Protocol #: 235

11grp Comments

11grp - Lethality Data

Time Name	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	1.10	1.11	1.12	Max	Min	StdDev
10:44:10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
10:44:15	0.71	1.62	04.32	20.88	42.47	209.82	219.72	82.49	475.92	100.22	1.82	410.96	1.02	1.02	1.02
10:44:20	78.21	6.39	188.27	128.44	431.78	265.62	418.82	246.18	1328.18	1078.27	1208.92	431.74	8.39	4.39	4.39
10:44:25	143.33	11.80	189.79	221.99	421.48	421.84	743.11	244.72	1489.89	1149.49	2104.89	442.84	11.80	11.80	11.80
10:44:30	248.30	15.29	189.82	218.77	405.42	601.49	1044.49	309.91	1893.29	1047.42	2068.82	400.39	15.29	15.29	15.29
10:44:35	812.59	13.00	210.48	218.87	481.78	673.86	1788.48	608.88	1883.88	2421.38	8119.00	6036.49	13.00	13.00	13.00
10:44:40	878.81	13.00	210.52	218.84	481.87	708.00	1888.88	617.81	1888.81	2424.88	8141.78	6036.32	13.00	13.00	13.00
10:44:45	886.25	65.00	211.87	219.88	482.82	817.81	1888.88	1043.83	1721.17	2427.75	8121.30	6036.81	65.00	65.00	65.00
10:44:50	894.50	126.89	212.31	482.87	475.74	1124.49	1874.23	1289.70	1708.14	2422.84	4402.80	6028.89	126.89	126.89	126.89
10:44:55	946.70	188.89	214.84	481.89	1028.88	1888.88	1877.88	1888.88	1888.88	1888.88	1888.88	1888.88	188.89	188.89	188.89
10:45:00	751.87	308.51	219.54	752.15	487.25	1182.88	1887.48	1468.81	1814.78	2887.82	4885.88	1488.48	308.51	308.51	308.51
10:45:05	888.88	371.18	248.32	721.29	483.82	1178.88	1810.88	1214.77	1887.88	3874.48	8227.18	1884.88	371.18	371.18	371.18
10:45:10	908.11	375.11	271.25	758.81	822.88	1238.38	2239.88	1888.88	3331.38	8288.88	1888.88	1716.43	375.11	375.11	375.11
10:45:15	1031.72	804.11	338.91	777.43	821.88	1333.51	2888.81	1708.43	1886.72	3882.11	8888.88	8844.88	804.11	804.11	804.11
10:45:20	1077.82	846.87	482.88	1188.87	812.89	1447.88	2879.88	1889.82	2881.48	3882.87	8824.88	8883.47	846.87	846.87	846.87
10:45:25	1203.84	878.71	482.88	1481.22	727.89	1481.91	2815.82	1871.27	3822.32	3482.84	8820.73	8888.88	878.71	878.71	878.71
10:45:30	1086.74	798.38	418.88	1423.11	893.78	1214.38	2038.18	1873.82	2204.42	2413.88	8888.88	8822.32	798.38	798.38	798.38
10:45:35	1188.81	798.82	430.79	1469.78	884.32	1847.27	2844.32	1238.84	2208.84	3418.71	8842.83	8872.77	798.82	798.82	798.82
10:45:40	1224.88	818.18	458.88	1577.72	878.84	1818.88	2888.88	2129.82	2848.81	3884.88	8882.82	8888.88	818.18	818.18	818.18
10:45:45	1228.08	1124.80	844.00	1594.80	1018.88	1832.88	3218.17	2084.10	3885.58	3244.11	14488.88	844.00	1124.80	1124.80	1124.80
10:45:50	1385.88	1120.22	1513.84	1591.85	1042.88	1888.88	3783.88	2448.48	2448.48	3841.18	8888.22	3778.75	1120.22	1120.22	1120.22
10:45:55	1469.78	1120.20	1177.88	1887.21	1031.48	1888.88	3818.88	2814.48	3827.87	3882.12	11888.22	1469.78	1120.20	1120.20	1120.20
10:46:00	1484.18	1158.88	1180.82	1488.88	1188.88	1888.88	3882.18	2818.78	3878.81	3882.84	8878.82	1487.43	1158.88	1158.88	1158.88
10:46:05	1882.88	1142.88	1181.88	1823.78	1258.82	1701.91	4284.88	2782.77	3184.82	3884.88	14883.81	1842.88	1142.88	1142.88	1142.88
10:46:10	1888.88	1188.88	1188.88	1888.88	1888.88	1888.88	4888.88	4888.88	3888.88	3888.88	1888.88	1888.88	1188.88	1188.88	1188.88
10:46:15	1888.88	1178.88	1828.18	1778.23	1274.83	1722.10	4878.23	3888.49	3818.74	3888.84	10888.88	1878.88	1178.88	1178.88	1178.88
10:46:20	1942.71	1184.72	1883.79	1883.21	1288.28	1882.10	4881.82	4188.10	4187.10	3888.46	10888.12	1888.88	1184.72	1184.72	1184.72

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

## Calibration Report

**KAYE VRT Temperature Calibration Report** Printed on: 10/24/2018

**Temperature Sensor - SN00012-A** Calibration: 10/24/2018

Company: \_\_\_\_\_ Firmware Version: 2.00

SOP Protocol #: \_\_\_\_\_ Battery life: \_\_\_\_\_

Temperature Standard: Kaye IRTD KLS1500-L0201 GISM 08MAR-17 ITS

Start Time: 10:57:05

**Setpoint 1: 20.20°C --Passed--**

**Stability Criteria:** Logger Stability: 0.20°C for 2 minutes VRTD Stability: 1.00°C

**Deviation Criteria:** Before User Cal: 1.00°C After User Cal: 1.00°C

**Stability and Deviation Evaluation (before user calibration)**

Time of Stability: 00:00:00 Logger Temperature: 20.20°C

Logger Stability: 0.00°C

Logger Deviation From IRTD: 0.00°C

**Temperature Logged for 1 minutes (after user calibration) Maximum Deviation**

Time	VRTD	Sensor	Dev	Time	VRTD	Sensor	Dev	Time
11:01:10	20.200°C	20.20°C	0.000°C	11:01:15	20.200°C	20.20°C	0.000°C	11:01:20
11:01:25	20.200°C	20.20°C	0.000°C	11:01:30	20.200°C	20.20°C	0.000°C	11:01:35
11:01:40	20.200°C	20.20°C	0.000°C	11:01:45	20.200°C	20.20°C	0.000°C	11:01:50
11:01:55	20.200°C	20.20°C	0.000°C	11:02:00	20.200°C	20.20°C	0.000°C	11:02:05

**Setpoint 2: 30.00°C --Passed--**

**Stability Criteria:** Logger Stability: 0.20°C for 2 minutes VRTD Stability: 1.00°C

**Deviation Criteria:** Before User Cal: 1.00°C After User Cal: 1.00°C

**Stability and Deviation Evaluation (before user calibration)**

Time of Stability: 00:00:00 Logger Temperature: 30.00°C

Logger Stability: 0.00°C

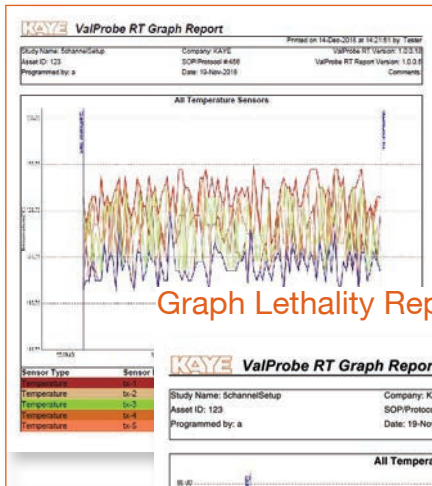
Logger Deviation From IRTD: 0.00°C

**Temperature Logged for 1 minutes (after user calibration) Maximum Deviation**

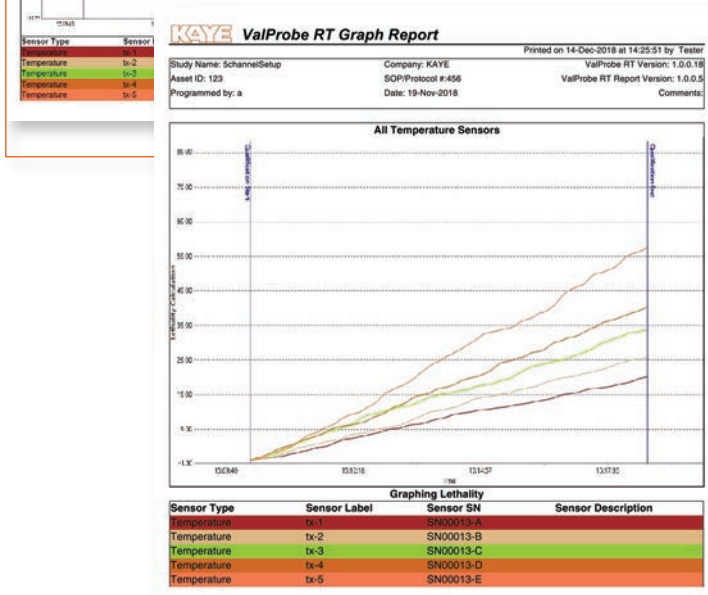
Time	VRTD	Sensor	Dev	Time	VRTD	Sensor	Dev	Time
11:07:15	30.000°C	30.00°C	0.000°C	11:07:20	30.000°C	30.00°C	0.000°C	11:07:25
11:07:30	30.000°C	30.00°C	0.000°C	11:07:35	30.000°C	30.00°C	0.000°C	11:07:40
11:07:45	30.000°C	30.00°C	0.000°C	11:07:50	30.000°C	30.00°C	0.000°C	11:07:55
11:08:00	30.000°C	30.00°C	0.000°C	11:08:05	30.000°C	30.00°C	0.000°C	11:08:10



## Graph Report



Graph Lethality Report



12-Apr-2018 at 17:28:26 by a

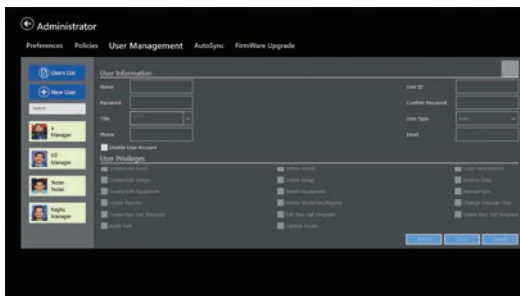
Max	Min	Cycle Time
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075.02	0.0	00:00:10
1328.16	0.0	00:00:10
2068.00	0.1	00:00:10
4006.00	0.1	00:00:10
8033.49	0.1	00:00:10
16063.02	0.1	00:00:10
32093.91	0.1	00:00:10
64187.82	0.1	00:00:10
128375.64	0.1	00:00:10
256751.28	0.1	00:00:10
513502.56	0.1	00:00:10
1027005.12	0.1	00:00:10
2054010.24	0.1	00:00:10
4108020.48	0.1	00:00:10
8216040.96	0.1	00:00:10
16432081.92	0.1	00:00:10
32864163.84	0.1	00:00:10
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26291331.08	0.1	00:00:10
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841322594.56	0.1	00:00:10
1682645889.12	0.1	00:00:10
3365291778.24	0.1	00:00:10
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# Flexible and Compliant

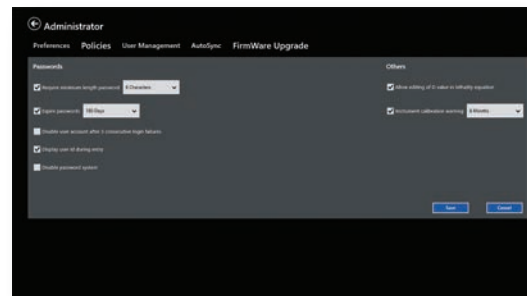
## Electronic Signature

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

Logged In User ID	User Name	Date / Time	Action	User Comment - Audit Trail	Device Identifier	MM ID
1	Tester	14/06/2018 at 09:34:19	User ID '1' created by User ID '1' - User Name 'Tester'			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:34:19	User ID '1' - User Name 'Tester' logged in to the 'UserManagement' application in 'UserManagement' screen			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:35:01	User ID '1' - User Name 'Tester' logged in to the 'UserManagement' application in 'UserManagement' screen			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:35:16	User ID '1' - User Name 'Tester' logged in to the 'UserManagement' application in 'UserManagement' screen			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:35:56	User ID '1' - User Name 'Tester' logged in to the 'UserManagement' application in 'UserManagement' screen			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:36:53	User ID '1' - User Name 'Tester' logged in to the 'UserManagement' application in 'UserManagement' screen			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:39:40	Application Crash			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:38:51	Login attempt failed for User ID '1', User Name 'Tester'			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:39:15	User ID '1' - User Name 'Tester' logged in to the 'Qualification' application in 'Qualification' screen			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:39:22	User ID '1' - User Name 'Tester' logged in to the 'Qualification' application in 'Qualification' screen			8F2CC8F19E538A42D2
1	Tester	14/06/2018 at 09:39:38	Qualification stopped for User ID '1', User Name 'Tester'			8F2CC8F19E538A42D2

# 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.

# Kaye 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.

## 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  $\pm 0.025^\circ\text{C}$  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.



## 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.



### Kaye CTR-25

Temp Range:  $-25^\circ\text{C}$  to  $140^\circ\text{C}$   
(closed cover)

Verification of up to 10 rigid ValProbe RT loggers



### Kaye LTR-150

Temp Range:  $-30^\circ\text{C}$  to  $150^\circ\text{C}$

Liquid micro bath tub with sensor cage and magnetic stirrer can hold ValProbe RT rigid loggers

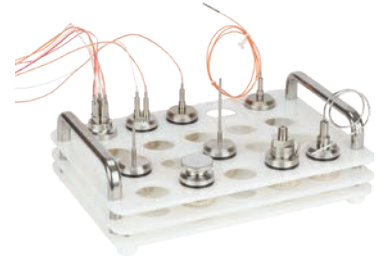


# Accessories

To compliment your Validation systems, Kaye offers a complete line of accessories including a storage tray, shipping cases, autoclave antennas, and validation documentation to assist you in meeting your validation requirements.

## 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 Shipping Case

Protect your Validation Equipment and store it safely when not being used.



## 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 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.



## Europe/Asia

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[www.kayeinstruments.com](http://www.kayeinstruments.com)

### Warranty and disclaimer:

The information in this document is based on our current tests, knowledge and experience. Because of the effect of possible influences in an application of the product, they do not exempt the user from their own tests, checks and trials. A guarantee of certain properties or a guarantee for the proper suitability of the product for a specific, especially permanent application cannot be derived from our data. Liability is therefore excluded to that extent permitted by law. Any proprietary rights of third parties as well as existing laws and regulations must be observed by the recipient of the product on his own responsibility.

**Amphenol**  
Advanced Sensors

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