



# Wireless Process Validation Data-Logger System -85°C to 360°C

## Kaye ValProbe®



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

# Kaye ValProbe<sup>®</sup> Wireless Process Validation

Kaye ValProbe is a wire-free process validation logger system designed around the measurement and reporting requirements of the most intensely regulated industries.

It simplifies access to hostile, remote, and hard-to reach environments by eliminating hard-wired sensors, greatly reducing study setup time and associated costs.

The ValProbe system is ideally suited for applications where high measurement accuracy, extreme environmental conditions and regulatory compliance are priorities, e.g.:

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

The ValProbe family of data loggers provide accurate, convenient, and reliable process measurements for a wide range of pharmaceutical and medical device applications. A 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 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	●		●	●					●
Humidity/Temp Logger					●	●			

Built in data processing and reporting capabilities extend the ValProbe system's operating convenience far beyond data acquisition alone. The ValProbe system performs calculations and generates custom user-defined reports for up to 200 sensors at once. Graph reports can include many sensors and limits for easy review of study data.

Along with the new CTR-25 Temperature Reference, user verification is a quick and easy process.

Of course, ValProbe satisfies FDA Regulation 21 CFR Part 11 requirements for electronic signatures and records, and complies with EN 554 for saturated steam sterilization.



# Applications - Challenges - Solutions

## Applications

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



## Markets

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

## Challenges

Pharmaceutical industries are faced with increasing operational challenges:

- A need for reliable data even in harsh conditions, extreme cold or hot temperatures.
- More complex and time consuming data organization.
- Increasing costs and times of validation and re-validation.
- Data Integrity – being compliant with the newest norms and standards.
- Increased IT security and lockdowns on portable data.
- Continuous changes in operating systems:
  - Hardware compatibility
  - Complex software operation



## Solutions

- RTD technology delivers unrivaled measurement accuracy over a wide operating range
- Simultaneous system downloads of up to 10 probes
- Easily defined cycle-based data collection, calculation, and reporting from up to 200 sensors
- Enables compliance with FDA Regulation 21 CFR Part 11
- Operates from -85°C to 360°C and up to 10 BAR absolute
- Designed for easy on-site verification
- Battery life indicator and field replaceable battery
- Reporting capability with user programmable groups



# Kaye ValProbe System

The ValProbe system is designed to provide easy access to process and validation study data. Using the ValProbe Reader Station it is easy to program all your loggers.

The ValProbe Reader2 programs and collects data from up to 10 ValProbe loggers simultaneously. The system is specially designed to be extremely reliable under harsh conditions e.g. 0-10 bar and -85°C to 360°C.

Included automated logger user verification simplifies regular logger verification.

## Features

- Capacity of up to 100 loggers / 200 sensors.
- Automated user verification of multiple loggers.
- An operator programmable sample rate, start, delay, and stop functions.
- ValProbe system software satisfies international regulatory requirements including FDA 21CFR part 11, EN285, DIN ISO 17665.
- A temperature range of -85 to 360°C.
- Up to 10.000 samples per sensor.
- Scan Rate down to 1 second.
- Customer interchangeable batteries.
- Accuracy up to 0.1°C.

# Kaye ValProbe Reader 2

The Reader 2 serves as the interface between individual loggers and the ValProbe System software. It is used for qualification and verification studies.

Loggers are programmed via the straight forward ValProbe system interface. The ValProbe USB high speed Reader 2 can accommodate 10 probes at once for programming and downloading stored data.

## Features

- Reader 2 can program/read 10 loggers simultaneously
- Compact design for field or desktop operation
- USB or RS232 connection
- LED indicator to confirm data communication
- CE, UL certified
- Compatibility for Kaye IRTD connection
- Operation between 100 – 240 V



# ValProbe Temperature Loggers

## Temperature range from -85°C to 360°C

The ValProbe logger family of temperature loggers are designed for accurate, convenient, and reliable process measurement for pharmaceutical and biotechnical applications. The wireless design greatly simplifies monitoring and validation of severe and hard-to-reach environments.

RTD technology delivers unrivalled measurement accuracy. The logger's electronic design permits usage of cost effective field replaceable batteries and guarantees long battery life.

Probes are available in rigid, flexible, and bendable versions.

## Temperature Logger - Rigid

### Features

- Temperature range for complete logger: -85°/-45°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°/-45°C to 360°C
- Single and dual bendable sensors available
- Sensor length 12, 24, 36"
- Sensor diameter 2.4mm (0.095")



## Freeze Dryer Logger – Temperature Range to -85°C

The freeze dryer logger offers the ultimate wireless surface measurement and performance.

### Features

- Temperature range for complete logger: -85°C to 140°C
- Ultra-flat surface sensor
- Surface sensor diameter 32mm
- Optimized surface temperature design, with the ability to work at low vacuum.



# ValProbe Temperature Loggers (cont.)

## Temperature Logger - Flexible

### Features

- Temperature range for complete logger: -85°C to 140°C
- Sensor length 40"
- Sensor tip diameter 2.4mm (0.095"), length 25mm (1")



## Pressure and Temperature Logger

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

RTD Technology delivers high measurement accuracy and the logger's electronic design allows usage of cost effective field replaceable batteries and guaranties long battery life.

### Features

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



## Humidity and Temperature Logger

The ValProbe humidity logger is designed for accurate, convenient, and reliable humidity measurements in pharmaceutical, medical device, and food processing applications.

### Features

- High accuracy humidity and temperature measurement in a single unit
- 10,000 data sample memory
- Economical field-replaceable battery



# Kaye ValProbe Specifications

Kaye ValProbe Generic Specifications	
Reader2 Dimensions	320mm x 155mm x 60mm (12,60" x 6,10" x 2,36")
Logger Dimensions	Height: 48mm / Diameter: 36mm (Height: 1,9" / Diameter: 1,4")
Logger Material	Stainless Steel 316L and Peek
Battery	Field replaceable - 3.6V Lithium
Sampling Rate	1 sec to 12 hours
Data Storage	10.000 Samples retained in non-volatile memory
Real-Time Clock Accuracy	< 15sec/day

Kaye ValProbe Generic Specifications	
Calibration	NVLAP/DAkKS Calibration
Verification	Automated User Verification capability
Sensing Element	Precision Platinum RTD
Environmental Temperature	-85°C/-45°C to 140°C
Environmental Pressure	0-10 bar absolute
Environmental Humidity	0-100% condensing
Regulatory Compliance	UL and CE

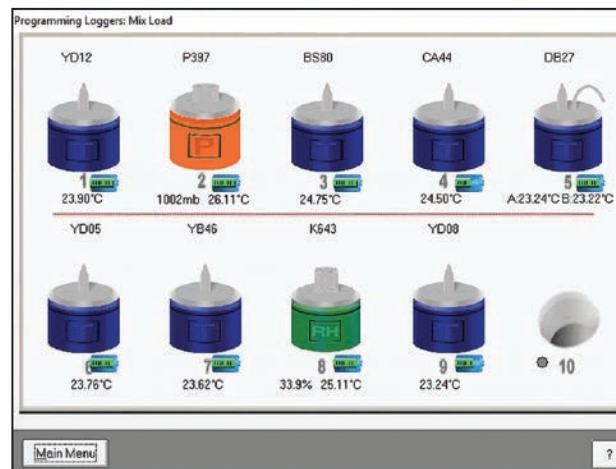
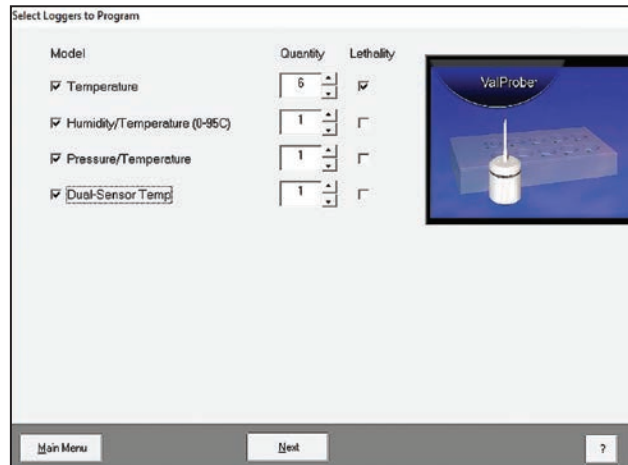
Kaye ValProbe Temperature Loggers Specifications				
Specifications	Rigid	Flexible	Bendable	Surface
Sensor Type	Single Sensor	Single Sensor	Single and Dual Sensor	Ultra Flat Surface Sensor
Sensor Length	1.5, 3, 6, 9" inches (38, 76, 152, 229mm)	40" inches (1000mm)	12, 24, 36" inches (305, 610, 915mm)	-
Tip Diameter	0.118" (3mm)	0.095" (2.4mm)	0.095" (2.4mm)	1.26" (32mm)
Measurement Range	-85°C /-45°C to 140°C	-85°C /-45°C to 140°C	-85°C /-45°C to 400°C	-85°C to 140°C
Accuracy	-85°C to 0°C, ±0.25°C / Cryo VP -45°C to 0°C, ±0.25°C / Standard VP 0°C to 140°C, ±0.1°C		±0.25°C from -85°C to 0°C / Cryo VP ±0.25°C from -45°C to 0°C / Standard VP ±0.1°C from 0°C to 140°C ±0.2°C from 140°C to 250°C ±0.5°C from 250°C to 360°C	-85°C to 0°C, ±0.25°C 0°C to 140°C, ±0.1°C

Kaye ValProbe Pressure, Temperature and Humidity Logger Specifications		
Specifications	Pressure & Temp.	Humidity
Environmental Temperature	0°C to 140°C	0°C to 90°C
Sensor Type	Single P/T Sensor	RH: EMD4000
Tip Diameter	1/4" NPT Connection Fitting	Diameter 18mm (0,71") Length 35mm (1,38")
Measurement Range	0°C to 140°C / 0-5bar abs.	25% to 85% RH
Accuracy	0°C to 120°C ±25mb 120°C to 135°C ±10mb 135°C to 140°C ±25mb 0°C to 140°C ±0.1°C	25% to 85% RH, ± 2% RH (at 25°C to 40°C) 0°C to 90°C, ±0.1°C

# Kaye ValProbe Software - Study Set-Up

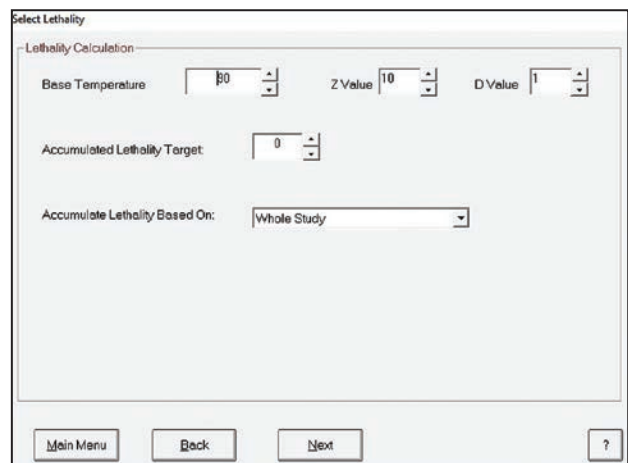
## Intuitive and Versatile

The software, provided with all Kaye products, permits set-up, qualification and calibration runs, generating validation reports, and enables compliance with regulations including CFR21 Part 11 and EN norms. The Kaye ValProbe software is designed to provide data from your validation study quickly and easily. The ValProbe software enables you to set up and customize sensor calibration, qualification, and report generation.



You can customize reports right down to the header information and user comments for each group. In addition, you can enter summary comments that relate to the entire study. The Kaye ValProbe software provides flexibility in many ways, e.g. define sensors individually— create your own labels and detailed descriptions, or apply individual sensor definitions to a range of sensors.

Featuring interval calculations and monitored events, the Kaye ValProbe provides more information about your study. You can calculate maximum, minimum, and averages for each sensor during cycles. Users can add unlimited cycles, separate qualification data into different process phases, and create up to 25 groups each with their own calculations and graphs during reporting; thus often eliminating the need for post-processing in Excel®.



*Set up or modify lethality calculations by defining base temperature, Z, and D values. Select conditions when you want to calculate lethality.*



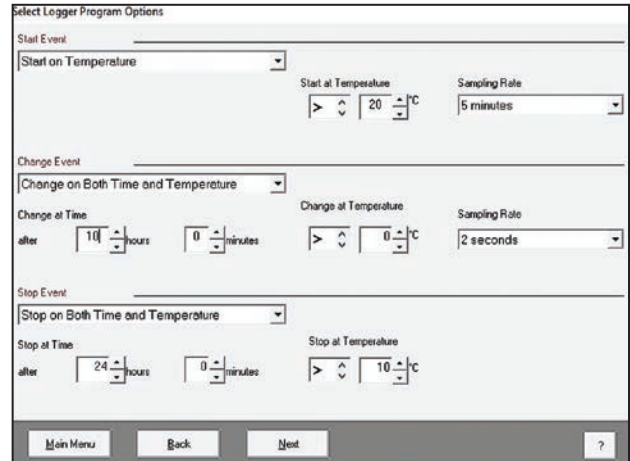
# Kaye ValProbe Software - Qualification/Study

## Qualification

The Kaye ValProbe software interface provides access to the Kaye ValProbe loggers, via the Kaye ValProbe reader where you can program multiple loggers with start/stop events and sample rates.

During a qualification study each logger collects and stores study data in internal memory. When the qualification study is complete, the data stored in each logger's internal memory must be read into the ValProbe program in order to generate reports.

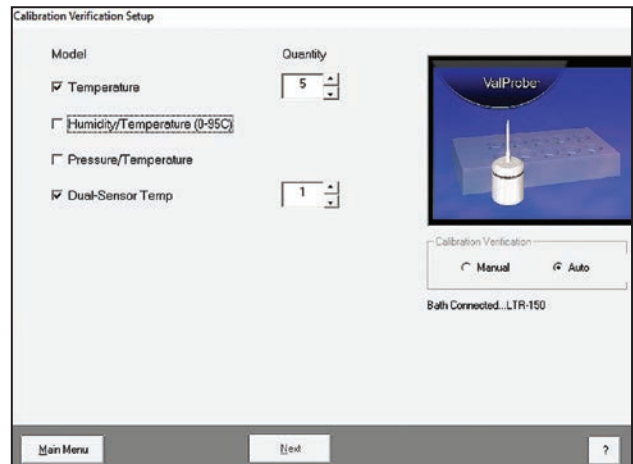
The Kaye ValProbe software verifies and transfers collected data to a secured data file. The data file, which meets the requirements of 21CFRpart11, is then used to create reports that documents the study results.



## Logger Verification

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

Kaye ValProbe is compatible with existing Kaye IRTD and calibration baths. The Automatic Calibration/Verification feature minimizes training and ensures accurate and repeatable verifications, all while being well documented.



# Kaye ValProbe Reporting Tool

The Kaye reporting software includes an intuitive, yet powerful reporting utility for generating Set Up, Calibration, Qualification, and Calibration Verification reports to document validation study results. Reports are generated from secure data files that can only be read by the system software. Upon study completion, process cycles to be analyzed are defined using the intuitive system graphic feature.

The flexible and user-friendly Kaye ValProbe reporting system allows users to add unlimited cycles and up to 25 groups during the reporting phase.

You can generate regulatory-accepted reports including Detailed and Summary reports by group and cycle (interval data). Graph reports have been improved, allowing more inputs and access to graph properties.

Report templates are automatically created, allowing the user to reprint an exact copy of the report at a later date, or save to a template for use in subsequent validation studies—a significant time savings for system operators.

Users have the ability to combine or merge reports from several Validators or ValProbes, providing the validations were run concurrently.

## 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.

## Setup Report

Setup Report				Printed on 25-Mar-2019 at 10:54:55 by Admin																																																							
Study Name:	CG Test 5	Company:	Amphenol	SOP/Protocol #:	VP-170-00	ValProbe Version:	1.70																																																				
Vessel ID:	13579	Test Operator 1:	Test Operator 1	Date:	25-Mar-2019 10:40:00	Comment:	CG Test 5 (Start On Temp, Stop On Temp)																																																				
Programmed By:	Test Operator 1	Test Operator 2:	Test Operator 1	Date:	22-Mar-2019 11:17:36	Comment:																																																					
<table border="1"> <thead> <tr> <th>Start Data Collection</th> <th>Sampling Rate</th> <th>Change to 2nd Sampling Rate</th> <th>2nd Sampling Rate</th> <th>Stop Data Collection</th> </tr> </thead> <tbody> <tr> <td>Temperature &gt; 80°C</td> <td>10 seconds</td> <td>Undefined</td> <td></td> <td>Temperature &lt; 70°C</td> </tr> </tbody> </table>								Start Data Collection	Sampling Rate	Change to 2nd Sampling Rate	2nd Sampling Rate	Stop Data Collection	Temperature > 80°C	10 seconds	Undefined		Temperature < 70°C																																										
Start Data Collection	Sampling Rate	Change to 2nd Sampling Rate	2nd Sampling Rate	Stop Data Collection																																																							
Temperature > 80°C	10 seconds	Undefined		Temperature < 70°C																																																							
<table border="1"> <thead> <tr> <th colspan="2">Lethality Calculation</th> <th colspan="2">---Temperature Loggers</th> </tr> </thead> <tbody> <tr> <td>Base Temperature:</td> <td>121.1°C</td> <td>Accumulate lethality during whole study</td> <td></td> </tr> <tr> <td>Z Value:</td> <td>10.00</td> <td></td> <td></td> </tr> <tr> <td>D Value:</td> <td>1.00</td> <td></td> <td></td> </tr> </tbody> </table>								Lethality Calculation		---Temperature Loggers		Base Temperature:	121.1°C	Accumulate lethality during whole study		Z Value:	10.00			D Value:	1.00																																						
Lethality Calculation		---Temperature Loggers																																																									
Base Temperature:	121.1°C	Accumulate lethality during whole study																																																									
Z Value:	10.00																																																										
D Value:	1.00																																																										
<table border="1"> <thead> <tr> <th colspan="4">Sensors Included in the Study</th> <th>MFG Cal Date</th> <th>User Verify Date</th> <th>Battery Life</th> </tr> </thead> <tbody> <tr> <th>Type</th> <th>Sensor S/N</th> <th>Probe ID</th> <th>PW Version</th> <th>Sensor Comments</th> <th></th> <th></th> </tr> <tr> <td>Temperature</td> <td>BAT5</td> <td></td> <td>1.43</td> <td></td> <td>18-Oct-2018</td> <td>50%</td> </tr> <tr> <td></td> <td>BAT9</td> <td></td> <td>1.43</td> <td></td> <td>26-Nov-2018</td> <td>50%</td> </tr> <tr> <td></td> <td>DC09</td> <td></td> <td>1.43</td> <td></td> <td>23-Apr-2018</td> <td>64-Aug-2018</td> <td>50%</td> </tr> <tr> <td></td> <td>XZ03</td> <td></td> <td>1.43</td> <td></td> <td>05-Apr-2018</td> <td>40%</td> </tr> <tr> <td colspan="4">Total Loggers Read In:</td> <td>Temperature</td> <td>4</td> <td>Total Loggers Expected:</td> <td>Temperature</td> <td>4</td> </tr> </tbody> </table>								Sensors Included in the Study				MFG Cal Date	User Verify Date	Battery Life	Type	Sensor S/N	Probe ID	PW Version	Sensor Comments			Temperature	BAT5		1.43		18-Oct-2018	50%		BAT9		1.43		26-Nov-2018	50%		DC09		1.43		23-Apr-2018	64-Aug-2018	50%		XZ03		1.43		05-Apr-2018	40%	Total Loggers Read In:				Temperature	4	Total Loggers Expected:	Temperature	4
Sensors Included in the Study				MFG Cal Date	User Verify Date	Battery Life																																																					
Type	Sensor S/N	Probe ID	PW Version	Sensor Comments																																																							
Temperature	BAT5		1.43		18-Oct-2018	50%																																																					
	BAT9		1.43		26-Nov-2018	50%																																																					
	DC09		1.43		23-Apr-2018	64-Aug-2018	50%																																																				
	XZ03		1.43		05-Apr-2018	40%																																																					
Total Loggers Read In:				Temperature	4	Total Loggers Expected:	Temperature	4																																																			

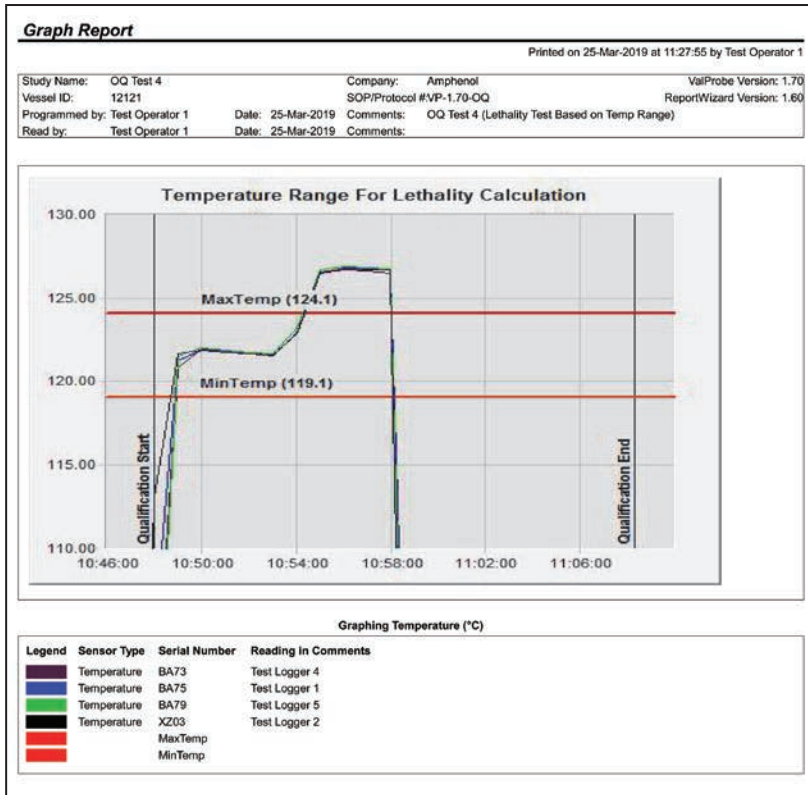
## Qualification Detailed Report

Qualification Detailed Report											Printed on 25-Mar-2019 13:23:01 by Test Operator 2		
Temperature Sensors													
Temperature Data(C) - Statistical Calculations													
	Min	S/N	Max	S/N	Max	Max-Min	Avg	Std Dev	Max Avg	Avg/Min	Cycle Time		
25-Mar-2019	47.81	CB66	67.72	PS28	19.91	57.92	14.01	9.91	9.91	0.5537			
14:41:27	47.97	CB66	67.58	PS28	19.61	57.61	14.00	9.96	9.96	0.5538			
14:41:30	48.07	CB66	67.39	PS28	19.32	58.03	14.09	9.96	9.96	0.5539			
14:41:43	48.21	CB66	68.08	PS28	19.88	58.15	14.06	9.94	9.94	0.5543			
14:41:41	48.34	CB66	68.20	PS28	19.86	58.27	14.04	9.93	9.93	0.5541			
14:41:42	48.43	CB66	68.34	PS28	19.91	58.30	14.08	9.96	9.96	0.5542			
14:41:43	48.58	CB66	68.43	PS28	19.85	58.51	14.04	9.93	9.93	0.5543			
14:41:44	48.70	CB66	68.50	PS28	19.80	58.60	14.00	9.90	9.90	0.5544			
14:41:45	48.82	CB66	68.57	PS28	19.75	58.70	13.97	9.88	9.87	0.5545			
14:41:45	48.93	CB66	68.66	PS28	19.73	58.80	13.95	9.88	9.87	0.5546			
14:41:47	48.96	CB66	68.79	PS28	19.74	58.83	13.98	9.87	9.87	0.5547			
14:41:48	48.98	CB66	68.78	PS28	19.67	58.87	14.01	9.91	9.91	0.5548			
14:41:49	48.93	CB66	68.86	PS28	19.93	58.90	14.09	9.97	9.97	0.5549			
14:41:50	49.01	CB66	68.98	PS28	19.97	59.00	14.12	9.99	9.99	0.5550			
14:41:51	49.04	CB66	69.16	PS28	20.12	59.10	14.23	10.08	10.08	0.5551			
14:41:52	49.07	CB66	69.30	PS28	20.23	59.19	14.33	10.12	10.12	0.5552			
14:41:53	49.09	CB66	69.47	PS28	20.36	59.25	14.41	10.19	10.19	0.5553			
14:41:54	49.15	CB66	69.51	PS28	20.46	59.30	14.47	10.23	10.23	0.5554			
14:41:55	49.19	CB66	69.73	PS28	20.54	59.45	14.52	10.27	10.27	0.5555			
14:41:55	49.27	CB66	69.90	PS28	20.53	59.54	14.52	10.27	10.27	0.5550			
14:41:57	49.35	CB66	69.92	PS28	20.57	59.64	14.55	10.29	10.29	0.5557			
14:41:58	49.34	CB66	69.98	PS28	20.04	59.60	14.59	10.32	10.32	0.5558			
14:41:59	49.33	CB66	69.99	PS28	20.06	59.60	14.61	10.30	10.30	0.5559			
14:42:00	49.11	CB66	69.55	PS28	20.44	59.33	14.45	10.22	10.22	0.5570			
14:42:01	47.79	CB66	69.33	PS28	21.54	58.58	15.23	10.77	10.77	0.5571			
14:42:02	48.89	CB66	69.22	PS28	22.42	58.91	15.85	11.26	11.21	0.5572			
14:42:03	48.32	CB66	69.14	PS28	22.82	57.73	16.14	11.41	11.41	0.5573			
14:42:04	48.21	CB66	69.13	PS28	22.92	57.67	16.21	11.48	11.48	0.5574			
14:42:05	48.35	CB66	69.17	PS28	22.92	57.78	16.14	11.41	11.41	0.5575			
14:42:06	48.48	CB66	69.07	PS28	22.59	57.79	15.97	11.30	11.30	0.5576			
14:42:07	48.47	CB66	68.93	PS28	22.26	57.80	15.74	11.13	11.13	0.5577			
14:42:08	48.86	CB66	68.80	PS28	21.94	57.83	15.51	10.97	10.97	0.5578			
14:42:09	47.10	CB66	68.65	PS28	21.55	57.88	15.24	10.78	10.78	0.5579			

## Qualification Summary Report

Qualification Summary Report											Printed on 25-Mar-2019 16:23:41 by Test Operator 2	
Temperature Sensors												
Temperature Data(C)											Totals	
	Min	Max	Avg	Cycle	Max/Min						Total	
CB66 (C)	47.81	121.81	102.42	19.50	78.03						10.50	
PS28 (C)	47.96	121.75	103.44	19.58	73.79						19.58	
Temperature Summary Data(C)											Totals	
Cycle Start	25-Mar-2019 13:45:00										Study Start	25-Mar-2019 13:45:00
Cycle Duration	1:00:00										Study End	25-Mar-2019 14:45:00
Min of Min	47.81	S/N	CB66								Study Min	47.81
Time	25-Mar-2019 14:41:18										Duration	1:00:00
Max of Max	121.75	S/N	PS28								Min/Max	47.81 / 121.75
Time	25-Mar-2019 14:17:59										S/N	CB66
Max Range	78.17										Min/Max	19.58 / 78.03
Max Spread/Time	22.92	Time	14:42:04								S/N	PS28
Min/Max	19.50	S/N	CB66								Study Min	47.81
Min/Max	19.58	S/N	PS28								S/N	CB66
Avg of Avg	102.93										Study Max	121.75
Max/Min	78.03	S/N	CB66								S/N	PS28

## Graph Report



## Reporting

- Setup Report
- Calibration Report
- Verification Report
- Graph Report
- Detailed Report:
  - Statistical
  - Lethality
  - Saturation
  - MKT
- Summary Report
- Merged Reports
- Audit Trail Report

## Verification Report

**Temperature Calibration Verification Report** Printed on 25-Mar-2019 at 10:15:45 by Admin

**Temperature Logger DD20**      Calibration Verified on 22-Mar-2019 by Test Operator 1

Company: Amphenol      Firmware Version: 1.43      ValProbe Version: 1.70  
 SOP/Protocol #: VP-1.70-OQ      Battery life: 50%      ReportWizard Version: 1.60  
 Temperature Standard: Kaye IRTD      KL25/60-H0112 KGER30-Jul-18      ITS-90 (°C)  
 Temperature Bath Info      Low Setpoint      High Setpoint

**Stability Criteria:**    Logger Stability: 1.00°C for 3 minutes      IRTD Stability: 0.012°C for 2 minutes  
**Deviation Criteria:**    Calibrated: 0.10°C for 3 minutes

**Start:** 11:52:50

**Setpoint 1:** 90.00°C --Passed--

**Stability and Deviation Evaluation**

Time of Stability: 12:19:10      Logger Temperature: 90.07°C      IRTD Temperature: 90.005°C  
 Logger Stability: 0.02°C      IRTD Stability: 0.004°C  
 Logger Deviation From IRTD: 0.06°C

**Temperatures Logged for 3 minutes Maximum Deviation 0.06°C**

Time	IRTD	Logger	Dev	Time	IRTD	Logger	Dev	Time	IRTD	Logger	Dev
12:19:30	90.006°C	90.07°C	0.06°C	12:20:00	90.006°C	90.07°C	0.06°C	12:20:30	90.007°C	90.07°C	0.06°C
12:21:00	90.008°C	90.07°C	0.06°C	12:21:30	90.009°C	90.07°C	0.06°C	12:22:00	90.010°C	90.07°C	0.06°C
12:22:30	90.010°C	90.06°C	0.05°C								

**Setpoint 2:** 121.10°C --Passed--

**Stability and Deviation Evaluation**

Time of Stability: 12:59:00      Logger Temperature: 121.21°C      IRTD Temperature: 121.144°C  
 Logger Stability: 0.02°C      IRTD Stability: 0.004°C  
 Logger Deviation From IRTD: 0.07°C

**Temperatures Logged for 3 minutes Maximum Deviation 0.07°C**

Time	IRTD	Logger	Dev	Time	IRTD	Logger	Dev	Time	IRTD	Logger	Dev
12:59:30	121.144°C	121.21°C	0.07°C	12:59:30	121.144°C	121.21°C	0.07°C	13:00:00	121.144°C	121.19°C	0.05°C
13:00:30	121.143°C	121.21°C	0.07°C	13:01:00	121.144°C	121.21°C	0.07°C	13:01:30	121.144°C	121.21°C	0.07°C
13:02:00	121.143°C	121.20°C	0.06°C								



# Flexible and Compliant

## Electronic Records, Secure Audit Trail, and Electronic Signature

The Kaye ValProbe is specifically designed to enable compliance with FDA 21 CFR Part 11 and to meet data integrity requirements.

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 passwords now being centrally managed in a network-installed version, users can explicitly set permissions for each user.

With the network capability, audit trails are designed to allow centralized management, searching and printing of department-wide audit trails from any connected PC. The sort and find utilities allow system administrators to perform thorough audits of their ValProbe users; for example, a list of all failed login attempts within a specified time period across all networked computers.

There is notification to the user and logged entries in the audit trail if files are tampered or deleted within Windows Explorer™.

### Audit Trail Report

ValProbe <sub>sm</sub> Audit Trail		10-Feb-2019 to 16-Apr-2019	
Printed by Test Administrator 1 on 16-Apr-2019 at 10:46:33			
000001	18-Mar-2019 11:54:30	Audit Trail Started	
Path: C:\Program Files (x86)\Kaye\Val Probe\ Machine ID: 016232			
000002	18-Mar-2019 11:54:30	Version Changed	
Software Version: 1.70.8 to Software Version: 1.70			
000003	18-Mar-2019 11:54:35	Program Launch	Heiko Hochwald
000004	18-Mar-2019 11:54:44	Successful Login	Kaye Default Administrator System Administrator
000005	18-Mar-2019 11:54:59	Create User	Kaye Default Administrator System Administrator
000006	18-Mar-2019 11:54:59	Delete User	Automatic Event Success
000007	18-Mar-2019 11:55:52	Successful Login	Steffen System Administrator
000008	18-Mar-2019 11:56:08	Successful Login	Steffen System Administrator
000009	18-Mar-2019 11:56:23	Preferences Modified	Steffen
Standard Reader to Reader 2			
000010	18-Mar-2019 11:58:18	Preferences Modified	Steffen
COM Port0 to COM Port2			
000011	18-Mar-2019 11:58:22	Preferences Modified	Steffen
Millibar to Kilopascal			
000012	18-Mar-2019 11:58:24	Program Launch	Heiko Hochwald
000013	18-Mar-2019 13:32:34	Successful Login	Steffen System Administrator
000014	19-Mar-2019 08:50:54	Successful Login	Steffen System Administrator
000015	19-Mar-2019 08:51:28	Site Options Modified	Steffen
Disable user account after 3 consecutive login failures : Yes			
000016	19-Mar-2019 08:51:28	Site Options Modified	Steffen
Minimum password length changed from 1 to 6.			
000017	19-Mar-2019 08:53:24	Create User	Steffen Success System Administrator
Test Administrator 1			
000018	19-Mar-2019 08:54:01	Create User	Steffen Success System Administrator
Test Administrator 2			
000019	19-Mar-2019 08:54:54	Create User	Steffen Success
Test Supervisor			
000020	19-Mar-2019 12:18:15	Create User	Steffen Success
Test Operator 1			
000021	19-Mar-2019 12:18:42	Create User	Steffen Success
Test Operator 2			
000022	19-Mar-2019 13:39:23	Create User	Steffen Failure Operator
Failure			
000023	19-Mar-2019 13:39:34	Create User	Steffen Failure
Failure			
000024	19-Mar-2019 13:39:47	Create User	Steffen Failure
Failure			
000025	19-Mar-2019 13:39:57	Create User	Steffen Failure
Failure			
000026	19-Mar-2019 13:40:11	Create User	Steffen Failure
Failure			
000027	19-Mar-2019 13:41:55	Audit trail Access	Steffen
000028	19-Mar-2019 13:43:04	Login Failure	No Such Operator: Kaye
000029	19-Mar-2019 13:43:21	Successful Login	Test Administrator 2 System Administrator
000030	19-Mar-2019 13:43:33	User Password Changed	Test Administrator 2 Success System Administrator
Test Administrator 2			
000031	19-Mar-2019 13:43:35	Successful Login	Test Administrator 2 System Administrator
000032	19-Mar-2019 13:56:27	Audit trail Access	Test Administrator 2
000033	19-Mar-2019 14:01:54	Program Launch	Heiko Hochwald
000034	19-Mar-2019 14:04:55	Successful Login	Test Administrator 2 System Administrator
000035	19-Mar-2019 14:06:19	Audit trail Access	Test Administrator 2
000036	19-Mar-2019 14:14:09	Program Terminated	
000037	19-Mar-2019 14:17:14	Program Launch	Heiko Hochwald

### User Management

Operator  Supervisor  System Administrator

Disable User Account  Print Audit Trail

Three levels of authorization protect access to the system – assigning users, making changes to tests, or running tests.

# System Documentation

## IQ/OQ Protocol

The Installation Qualification/Operational Qualification Protocol defines a set of procedures to ensure that the Kaye ValProbe 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 in digital format, 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 In-House or On-Site execution.

## Validation Reference

The Kaye ValProbe 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 an Amphenol's facility—complete, well organized, neatly packaged, and immediately accessible.



# Kaye ValProbe 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 ValProbe software, the IRTD-400 eliminates the potential for human error, assuring accurate and traceable measurements.

## Fast / Accurate References

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.

Good calibration practices using precise, traceable references are critical for achieving the highest level of measurement accuracy and complete understanding of process parameters.

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  $140^\circ\text{C}$

Verification of up to 10 rigid ValProbe 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 rigid loggers



# Accessories

To compliment your Validation systems, Kaye offers a complete line of accessories including a storage tray, shipping cases, 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 loggers during use. The ValProbe 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:

Temperature	Exposure Time
360°C	45 min.
300°C	60 min.
250°C	80 min.
200°C	115 min.
170°C	165 min.

## Europe/Asia

Amphenol Advanced Sensors Germany  
GmbH  
Sinsheimerstr 6  
75179 Pforzheim  
Germany

T: +49 (0) 7231 14335 0  
F: +49 (0) 7231-14335 29  
Email: Kaye-CCPF@amphenol-sensors.com

## USA

Amphenol Thermometrics Inc.  
967 Windfall Rd  
St. Marys, PA 15857

T: +1 814-834-9140  
F: +1 814-781-7969  
Email: StMarysCC@amphenol-sensors.com



[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

© 2019 Amphenol Corporation. All Rights Reserved. Specifications are subject to change without notice.

Other company names and product names used in this document are the registered trademarks of their respective owners.