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ValProbe®

WIRELESS PROCESS VALIDATION DATA LOGGER SYSTEM



ValProbe 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, including:

- 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.

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.

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

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



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 Reader 2 programs and collects data from up to 10 ValProbe loggers simultaneously. The system is specially designed to be extremely reliable under harsh conditions ex. 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 21 CFR 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.

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 – 240V



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°C to 140°C
- Single sensor only
- Sensor length 1.5, 3, 6, 9"
- Sensor diameter 3mm (0.118")



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



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")



TEMPERATURE LOGGER – BENDABLE SINGLE AND DUAL SENSOR LOGGER

Features

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



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



ValProbe Specifications

KAYE VALPROBE GENERIC SPECIFICATIONS

Reader 2 Dimensions	320mm x 155mm x 60mm (12,60" x 6,10" x 2,36")	Real-Time Clock Accuracy	< 15sec/day
Logger Dimensions	Height: 48mm / Diameter: 36mm (Height: 1,9" / Diameter: 1,4")	Calibration	NVLAP/DAkkS Calibration
Logger Material	Stainless Steel 316L and Peek	Verification	Automated User Verification capability
Battery	Field replaceable – 3.6V Lithium	Sensing Element	Precision Platinum RTD
Sampling Rate	1 sec to 12 hours	Environmental Temperature	-85°C/-45°C to 140°C
Data Storage	10,000 Samples retained in non-volatile memory	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	-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 & Temp
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

ValProbe Software Study Set-Up

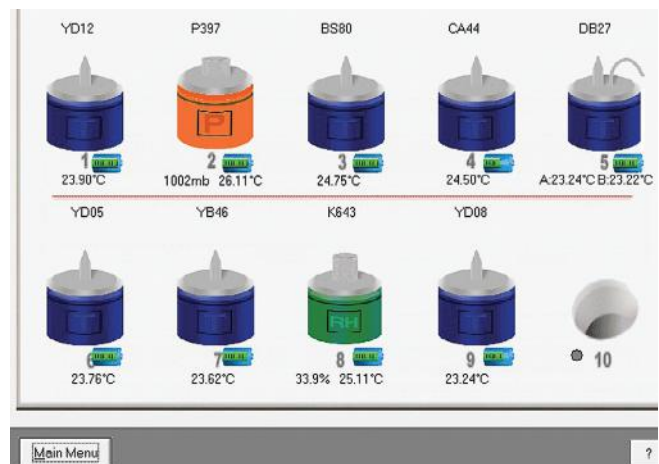
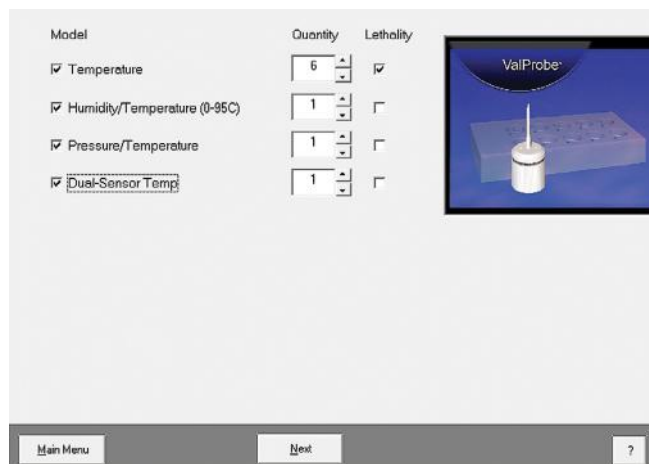
INTUITIVE AND VERSATILE

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.

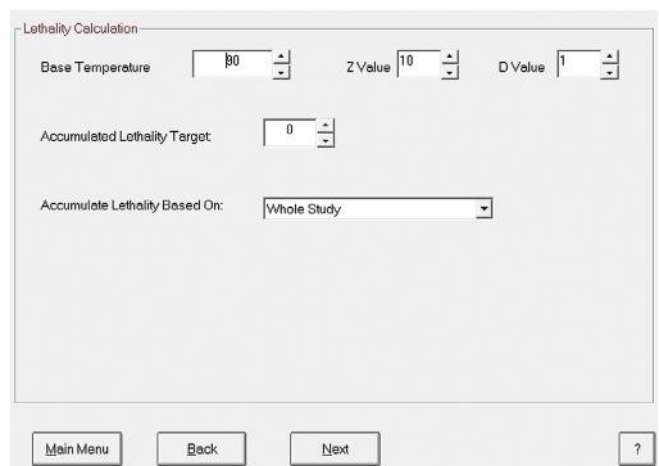
You can customize reports right down to the header information and user comments for each group. In addition, you can enter summary comments that relate to the entire study. The Kaye ValProbe software

provides flexibility in many ways, ex. 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.



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 21 CFR part 11, is then used to create reports that documents the study results.

The screenshot displays the 'Start Event' configuration screen. It features three main sections: 'Start Event', 'Change Event', and 'Stop Event'. Each section includes a dropdown menu for the event type, a 'Start at Temperature' field with a numeric input and a temperature unit (°C), and a 'Sampling Rate' dropdown menu. The 'Start Event' is set to 'Start on Temperature' with a start temperature of 20°C and a sampling rate of 5 minutes. The 'Change Event' is set to 'Change on Both Time and Temperature' with a change at time of 10 hours and 0 minutes, a change at temperature of 0°C, and a sampling rate of 2 seconds. The 'Stop Event' is set to 'Stop on Both Time and Temperature' with a stop at time of 24 hours and 0 minutes, and a stop at temperature of 10°C. At the bottom, there are buttons for 'Main Menu', 'Back', 'Next', and a help icon.

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.

The screenshot displays the 'Logger Verification' configuration screen. It includes a 'Model' section with checkboxes for 'Temperature' (checked), 'Humidity/Temperature (0-95°C)', 'Pressure/Temperature', and 'Dual-Sensor Temp' (checked). There are two 'Quantity' input fields with numeric values of 5 and 1. A small inset image shows a ValProbe logger in a calibration bath. Below the image, there are 'Manual' and 'Auto' buttons for 'Calibration Verification'. At the bottom, there are buttons for 'Main Menu', 'Next', and a help icon.

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
- 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						Printed on 25-Mar-2019 at 10:04:55 by Admin			
Study Name:	OO Test 3	Company:	Amphenol	ValProbe Version:	1.70	Reprinted Version: 1.00			
Vessel ID:	13819	Date:	23-Mar-2019 10:40:00	SCMProtocol #:	VP1-70-CO	Comment:			
Programmed By:	Test Operator 1	Date:	23-Mar-2019 11:17:26	Comment:	OO Test 5 (Start-On Temp, Step-On Temp)				
Head By:	Test Operator 1	Date:	23-Mar-2019 11:17:26	Comment:					
Data Collection		Sampling Rate	Change to 2nd Sampling Rate	2nd Sampling Rate	Step Data Collection				
Start Date/Collection		10 seconds	Undefined		Temperature + 70°C				
Temperature + 80°C									
Lethality Calculation						---Temperature Loggers			
Base Temperature:						121.1 °C			
Z Value:						10.00			
D Value:						1.00			
Accumulates lethality during whole study									
Sensors Included in the Study									
Type	Sensor	SN	Probe ID	FW	Version	Sensor Comments	MFG Cal Date	User Verify Date	Battery Life
Temperature	BA75			1.43			19-Oct-2018		80%
	BA76			1.43			26-Nov-2018		86%
	SD00			1.43			20-Apr-2018	04-Aug-2018	96%
	XD02			1.40			09-Apr-2018		40%
Total Loggers Read In:		4		Total Loggers Expired:		4			
Temperature		4		Temperature		4			

Setup Report

Qualification Summary Report						Printed on 25-Mar-2019 15:23:41 by Test Operator 2	
Study Name:	OO Test 5	SCMProtocol #:	VP1-70-CO	Temperature Sensor			
Temperature Data(C)						Totals	
Sensor/Logger SN							
	Min	Max	Avg	Min-Max	Max-Min	Total	Alerts
CB66 (C)	47.90	121.01	102.62	19.58	73.79	19.58	19.58
P528 (C)	47.90	121.75	103.64	19.58	73.79	19.58	19.58
Temperature Summary Data(C)						Totals	
Cycle Start	23-Mar-2019 13:45:00					Study Start	23-Mar-2019 13:45:00
Cycle Duration	1:00:00					Study End	23-Mar-2019 14:45:00
Min of Max	47.90 (SN CB66)					Duration	1:00:00
Time	23-Mar-2019 14:41:18					Min-Avg	19.58
Max of Max	121.75 (SN P528)					SN	CB66
Time	23-Mar-2019 14:17:58					Study Max	121.75
Max Range	73.79					SN	P528
Max Spread/Time	22.82 Time: 14:42:04					SN	P528
Min-Avg	19.58 (SN CB66)					Study Min	47.90
Max-Avg	102.62 (SN P528)					SN	CB66
Avg of Avg	102.62					Study Avg	102.62
Max(Min-Max)	73.79 (SN CB66)					SN	P528

Qualification Summary Report

Qualification Detailed Report					
Study Name: OO Test 5					
Temperature					
Temperature Data(C) - Statistical Calculations					
	Min	S/N Min	Max	S/N Max	Max-Min
25-Mar-2019					
14:41:37	47.91	CB66	67.72	P528	19.81
14:41:38	47.97	CB66	67.88	P528	19.91
14:41:39	48.07	CB66	67.99	P528	19.92
14:41:40	48.21	CB66	68.09	P528	19.88
14:41:41	48.34	CB66	68.20	P528	19.86
14:41:42	48.43	CB66	68.34	P528	19.91
14:41:43	48.58	CB66	68.43	P528	19.85
14:41:44	48.70	CB66	68.50	P528	19.80
14:41:45	48.82	CB66	68.57	P528	19.75
14:41:46	48.93	CB66	68.66	P528	19.73
14:41:47	48.96	CB66	68.70	P528	19.74
14:41:48	48.96	CB66	68.78	P528	19.82
14:41:49	48.93	CB66	68.86	P528	19.93
14:41:50	49.01	CB66	68.98	P528	19.97
14:41:51	49.04	CB66	69.16	P528	20.12
14:41:52	49.07	CB66	69.30	P528	20.23
14:41:53	49.09	CB66	69.47	P528	20.38
14:41:54	49.15	CB66	69.61	P528	20.46
14:41:55	49.19	CB66	69.73	P528	20.54
14:41:56	49.27	CB66	69.80	P528	20.53
14:41:57	49.35	CB66	69.92	P528	20.57
14:41:58	49.34	CB66	69.98	P528	20.64
14:41:59	49.33	CB66	69.99	P528	20.66

Qualification Detailed Report

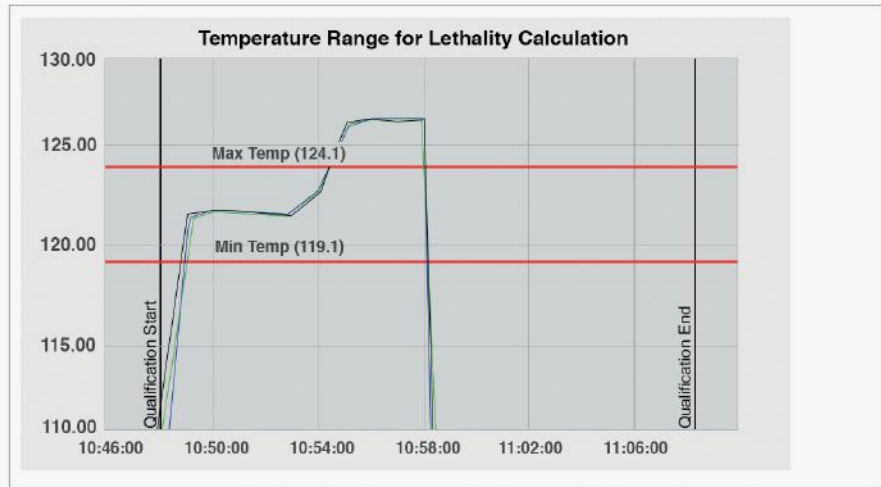
REPORTING

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

Graph Report

Printed on 25-Mar-2019 at 11:27:55 by Test Operator 1

Study Name: OQ Test 4	Company: Amphenol	ValProbe Version: 1.70
Vessel ID: 12121	SOP/Protocol #: VP-1.70-OQ	ReportWizard Version: 1.60
Programmed by: Test Operator 1	Date: 25-Mar-2019	Comments: OQ Test 4 (Lethality Test Based on Temp Range)
Read by: Test Operator 1	Date: 25-Mar-2019	Comments:



Graph 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	

Verification Report

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™.

ValProbe _{tm} Audit Trail			
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
000005	18-Mar-2019 11:54:59	Create User	Kaye Default Administrator
		Steffen	Success
000006	18-Mar-2019 11:54:59	Delete User	Automatic Event
		Kaye Default Administrator	Success
000007	18-Mar-2019 11:55:52	Successful Login	Steffen
000008	18-Mar-2019 11:56:08	Successful Login	Steffen
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
000014	19-Mar-2019 08:50:54	Successful Login	Steffen
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
		Test Administrator 1	Success
000018	19-Mar-2019 08:54:01	Create User	Steffen
		Test Administrator 2	Success
000019	19-Mar-2019 08:54:54	Create User	Steffen
		Test Supervisor	Success
000020	19-Mar-2019 12:18:15	Create User	Steffen
		Test Operator 1	Success
000021	19-Mar-2019 12:18:42	Create User	Steffen
		Test Operator 2	Success
000022	19-Mar-2019 13:39:23	Create User	Steffen
			Failure
000023	19-Mar-2019 13:39:34	Create User	Steffen
			Failure

Audit Trail Report

Password Maintenance

Add New User

Name:

User ID:

Password:

Reenter Password:

Operator
 Disable User Account

Supervisor
 Print Audit Trail

System Administrator

User Management

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.



ValProbe On-Site 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 $\pm 0.025^\circ\text{C}$ 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.



KAYE CTR-25

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



KAYE LTR-150

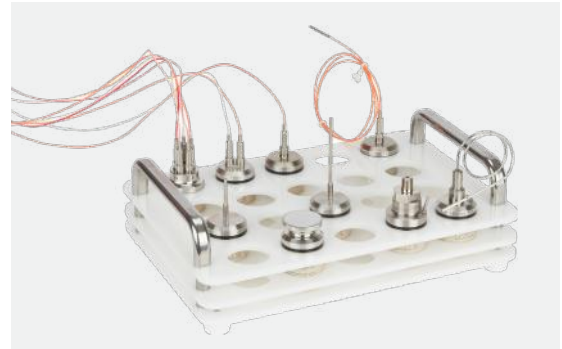
- Temp Range: -30°C to 150°C
- Liquid micro bath tub with sensor cage and magnetic stirrer can hold ValProbe RT rigid loggers



Accessories

KAYE TRANSPORT AND STORAGE

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



KAYE INSULATING CANISTER

Use the Insulating Canister in combination with any Kaye bendable temperature logger as a perfect solution for high-temp, dry heat applications.

Performance

Temp.	Exposure Time
360°C	45 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.



Visit our website:

Kaye representative contact:

Request a demo:

EUROPE, MIDDLE EAST, AFRICA AND ASIA

Amphenol Advanced Sensors Germany GmbH
Sinsheimer Strasse 6
D-75179 Pforzheim

T: +49 (0) 7231-14 335 0

F: +49 (0) 7231-14335 29

Email: kaye@amphenol-sensors.com
www.kayeinstruments.com

USA/AMERICAS

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

T: +1(814) 834-9140

F: +1(814) 781-7969

Email: kaye-us@amphenol-sensors.com
www.kayeinstruments.com

INDIA

Amphenol Interconnect India Pvt Ltd.
Plot no. 6, Survey No.64
Software Units layout

MAHAVEER TECHNO PARK

Hitech City, Madhapur

Hyderabad, Telangana – 500081

T: +91 40 33147100

Email: kaye-india@amphenol-sensors.com
www.kayeinstruments.com

CHINA

Amphenol (Changzhou) Connector Systems Co., Ltd
Building 10, Jintong Industrial Park,
No. 8 Xihu Road, Wujin High-Tech Development Zone,
Changzhou, Jiangsu 213164

T: 0086-519-83055197

www.kayeinstruments.com

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