



# Kaye ValProbe®

Wireless process validation and monitoring system



**Amphenol**  
Advanced Sensors

# Table of Contents

Kaye ValProbe® Wireless Process Introduction .....	1
Temperature Logger.....	2
Cryo Temperature Logger .....	2
Combined Temperature/ .....	3
Pressure Logger .....	3
Combined Temperature/Humidity Logger .....	3
Dual Logger .....	4
ValProbe® Reader Station .....	5
Data Loggers Specifications .....	6
Dual Logger Specification .....	8
Dual Logger Configuration .....	8
Performance.....	8
Regulatory Compliance.....	9
Study Set-Up.....	10
Reports.....	11
Post Qualification Reporting .....	11
Merged Reporting .....	12
Temperature Calibration and Reference .....	13
ValProbe Series Specifications .....	14 - 16

# Kaye ValProbe® Wireless process validation and monitoring

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

Kaye ValProbe® 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 and regulatory compliance are priorities:

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

Built in data processing and reporting capabilities extend the ValProbe systems operating convenience far beyond mere data acquisition. The ValProbe system performs calculations and generates custom user-defined reports for up to 200 sensors at one time. Graph reports can include many sensors and limits for easy review of study data. User calibration and verification is a quick and easy process with the new CTR-40 Temperature Reference. 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.

- RTD technology delivers unrivaled measurement accuracy over a wide operating range
- System downloads up to 10 probes simultaneously
- 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 calibration
- Battery life indicator and field replaceable battery
- Available as a economical validation starter kit complete with software, single reader, two temperature and one pressure logger (P/N V2543).
- Reporting capability enhanced with up to 25 user programmable groups.

The ValProbe 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 including:

- Sterilizers
- Ovens
- Tunnels
- Lyophilizers
- Stability chambers
- Warehouses
- Temperature chambers
- Cryogenic Chambers
- Fridges; Freezers

# Temperature Logger

The ValProbe family of temperature loggers is designed for accurate, convenient and reliable process measurement for pharmaceutical and medical device applications. The wireless design greatly simplifies monitoring and validation of serve and hard-to-reach environments.

Probes are available in rigid, flexible and bendable version.

## Features

- RTD technology delivers unrivaled measurement accuracy over a wide operating range
- System downloads up to 10 probes simultaneously
- Easily defined cycle-based data collection, calculation, and reporting from up to 200 sensors
- Enables compliance with FDA Regulation 21 CFR Part 11
- Designed for easy on-site calibration
- Battery life indicator and field replaceable battery.
- Reporting capability to merge with a Validator study or a RF ValProbe study

## Applications

- Sterilizers
- Ovens
- Tunnels
- Lyophilizers
- Stability chambers
- Warehouses
- Temperature chambers



# Cryo Temperature Logger

## Temperature range to -85°C

The new Cryo Logger provides an extended temperature range from -85°C to + 140°C and provides a single solution for a variety ultra low temperature applications. RTD Technology delivers unrivalled measurement accuracy and the new logger design improves the battery life by three times. It is fully compatible with existing multi channel and single readers operating seamlessly with the ValProbe software. The Freeze dryer logger offers ultimate surface measurement and performance wirelessly.

## Features

- Temperature range for complete logger: -85°C to 140°C
- Battery Life Performance - 3 x better than current loggers in the market
- Optimized surface temperature design even during low vacuum

## Applications

- Cryogenic Vessels
- Freeze Dryer
- Freezers
- Sterilizers
- Incubators
- Warehouses



# Combined Temperature/ Pressure Logger

The combined Kaye ValProbe Pressure/  
Temperature Logger provides an integrated solution  
to small scale sterilizer validation, monitoring and  
routine control.

Combining with the Kaye Single Reader provides a  
very cost effective solution to smaller sterilization  
applications such as bench-top or lab sterilizers,  
hospital validation and routine control, and other  
sterilization validation needs in dental offices and  
other users of medical equipment.

## Features

- Combined Pressure and Temperature Logger
- High accuracy Temperature and Pressure measurement to meet regulatory requirements
- 10,000 data sample memory
- Cost Effective field-replaceable battery
- Operator programmable sample rates from 1 sec to 12 hours
- Configurable start, change and stop events
- Enables compliance with ISO-17665, EN 285 and HTM-2010

## Applications

- Steam Sterilizer Validation
- Hospital Validation and Routine Control
- Small scale sterilization in dental offices
- Parametric Release applications



# Combined Temperature/ Humidity Logger

The ValProbe humidity logger is designed for  
accurate, convenient and reliable process  
measurement for pharmaceutical, medical device  
and food processing applications. The wireless  
design greatly simplifies monitoring and validation of  
severe and hard-to-reach environments

## Features

- High accuracy humidity and temperature measurement in a single unit
- 10,000 data sample memory
- Economical field-replaceable battery
- Field-replaceable humidity sensor
- Operator programmable sample rate, start, delay and stop function

## Applications

- Stability chambers
- Warehouses
- Temperature chambers



# Dual Logger

The Dual Logger is equipped with two high-accuracy temperature sensors, each capable of capturing 10,000 data points. The dual sensor configuration is ideally suited for measuring penetration and distribution parameters from a single instrument. Precision platinum RTD sensors provide exceptional accuracy and durability. The Dual Logger is available with pairs of bendable or flexible probes, or with a single rigid probe paired with either flexible or bendable probe.

## Features

- Precision Platinum RTD Sensors
- Broad measurement range
- Economical field-replaceable battery
- Operator programmable sample rate, start, delay and stop function

## Applications

- Autoclaves
- Ovens
- Temperature Chambers
- Depyrogenation Tunnels

For the most extreme operating conditions, the Dual Logger is compatible with the low profile Insulating canister.



---

# Insulating Canister

Designed for use with the bendable probes, the Insulating Canister protects the internal electronics and battery for maximum “time at temperature”.

In combination with the 12” bendable Temperature Logger a perfect solution for Dry Heat applications.



# ValProbe® Reader Station

The ValProbe system is designed to provide easy access to process and validation study data. Loggers are programmed via a straightforward interface of the ValProbe system software.

The ValProbe USB System high speed Reader2 (10 reader station) accommodates 10 probes at one time for programming and downloading stored data

The Single Reader serves as the interface between individual loggers and the powerful ValProbe system software. Along with the system software the Single Reader facilitates pre-study programming and data download upon study completion. Its compact design makes it well suited for field use or desktop applications requiring a limited number of measurement points



## Features

- ValProbe system capacity up to 100 loggers/200 sensors
- Compact design for field or desktop operation 2.5 x 2.6 x 5 in ( 65 x 68 x 126 mm)
- Powered from computer connections – no external power required
- USB or RS232 network connection (Windows 2000 or Windows XP required for USB connectivity)
- LED indicator confirms data communication
- CE, UL certified
- ValProbe system software satisfies international regulatory requirements including FDA 21CFR part 11, EN285, DIN ISO 17665

Compatible with the entire line of high-accuracy temperature, humidity and pressure loggers, the Single Reader is ideal for a wide range of process validation applications including:

## Applications

- Hospital sterilizers
- Warehouses
- Stability chambers
- Depyrogenation tunnels





# Data Loggers

Sensing Element	Precision Platinum RTD
Measurement Range and Accuracy	0°C to 140°C, ±0.1°C -45°C to 0°C, ±0.25°C -85°C to 0°C, ±0.25°C (Cryo Valprobes) -45°C to 0°C, ±0.25°C (Standard Valprobes)
Environmental Temperature	-85°C to 140°C (-196°C to + 260°C Liquid Nitrogen)
Humidity	0% to 100% humidity, condensing
Pressure	0 to 10 bar absolute (0 to 130 psia)
Logger Material	316L stainless steel
Logger Base Dimensions	1 13/16 in x 1 3/8 in diameter (46 mm x 35 mm)

Sensing Element	Precision Platinum RTD
Battery	Field-replaceable 3.6 V lithium thionyl chloride
Sampling Rate	1 second to 12 hours
Data Storage	10,000 samples retained in non-volatile EEPROM memory
Calibration	Factory calibrated (NIST-traceable) with user calibration capability
Real Time Clock Accuracy	15 seconds per 24 hours (0.0174%) from -85°C to 140°C
Regulatory Compliance	UL, CE and Intrinsically safe for the -45°C to 140°C versions (Standard)

## Rigid Probe

Probe Construction	Configuration
<ul style="list-style-type: none"> <li>316L stainless steel</li> <li>.12 in (3 mm) diameter with M5 threaded base</li> </ul> <p>Consult factory for 1/16 in (1.6 mm) and 3/16 in (4.8 mm) diameter probes</p>	<ul style="list-style-type: none"> <li>Specify probe length (L) in inches <ul style="list-style-type: none"> <li>1 1/2 inch (38mm); 3 inch (76mm) rigid Cryo ValProbe</li> <li>6 inch (152,4mm); 9 inch (228,6mm) standard ValProbe</li> </ul> </li> <li>Specify tip configuration (T) as pointed (P) or round (R)</li> <li>Part number XVP-L-T (Standard Valprobes) XCVP-L-T (Cryogenic Valprobes)</li> </ul>

Probe Construction	Configuration
<b>Standard:</b> XSVP6R XSVP6P XSVP9R XSVP9P	Rigid Temperature Logger – 6" rounded tip Rigid Temperature Logger – 6" pointed tip Rigid Temperature Logger – 9" rounded tip Rigid Temperature Logger – 9" pointed tip
<b>Cryo:</b> XCVP1.5R XCVP1.5P XCVP3R XCVP3P	Rigid Temperature Logger – 1.5" rounded tip Rigid Temperature Logger – 1.5" pointed tip Rigid Temperature Logger – 3" rounded tip Rigid Temperature Logger – 3" pointed tip
xxxx	Surface Temperature Logger

## Flexible Probe

Probe Construction	Configuration
<ul style="list-style-type: none"> <li>316L stainless steel</li> <li>.12 in (3 mm) probe tip</li> </ul> <p>Consult factory for 1/16 in (1.6 mm) and 3/16 in (4.8 mm) diameter probes</p>	<ul style="list-style-type: none"> <li>Specify flexible PTFE cable length (C) <ul style="list-style-type: none"> <li>Standard lengths of 6 in (150 mm), 12 in (300 mm), 18 in (460 mm), 24 in (600 mm) to 120 in (3 m) in 12 in (300 mm) increments</li> <li>Custom lengths available from 6 in (150 mm) to 120 in (3 m)</li> </ul> </li> <li>Specify stainless tip length (L) in inches <ul style="list-style-type: none"> <li>Minimum 1.5 in (38 mm)</li> <li>Maximum 9 in (230 mm)</li> </ul> </li> <li>Specify tip (T) P or R</li> <li>Part number XFVP-C-L-T</li> </ul>

Flexible Probe	
XSFVP12-1.5R	Flexible Temperature Logger – 12" Flexible and 1.5" rounded tip
XSFVP24-1.5R	Flexible Temperature Logger – 24" Flexible and 1.5" rounded tip
XSFVP36-1.5R	Flexible Temperature Logger – 36" Flexible and 1.5" rounded tip
XSFVP12-2R	Flexible Temperature Logger – 12" Flexible and 2" rounded tip
XSFVP12-3R	Flexible Temperature Logger – 12" Flexible and 3" rounded tip
XSFVP36-2R	Flexible Temperature Logger – 36" Flexible and 2" rounded tip
<b>Liquid Nitrogen:</b>	
XDFLVP120-1.5-120-1.5	Flexible/Flexible Dual Temperature Logger - 2 flexible probes 120" and 1.5"tip
XFLVP60	Flexible Temperature Logger - 60" and 1.5" tip

## Bendable Probe

Probe Construction	Configuration
<ul style="list-style-type: none"> <li>316L stainless steel</li> <li>1 1/2 in (32 mm) pointed stainless steel tip of .12 in (3 mm) diameter</li> <li>Mineral insulated bendable stem with M5 threaded base</li> </ul>	<ul style="list-style-type: none"> <li>Specify stem length (L) in inches <ul style="list-style-type: none"> <li>Minimum 6 in (150 mm)</li> <li>Maximum 60 in (1.5 m)</li> </ul> </li> <li>Part number XBVP-L</li> </ul>

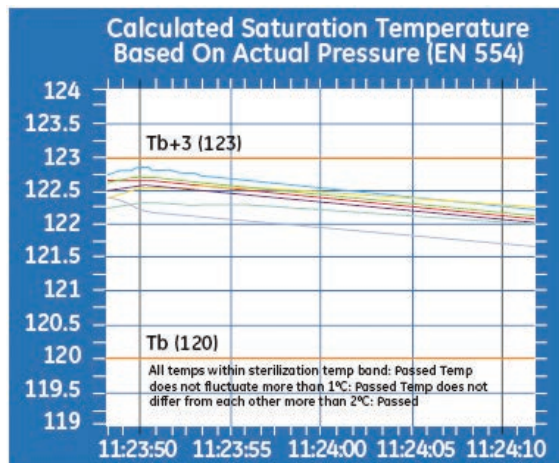
Bendable Probe	
XSBVP12R	Bendable Temperature Logger – 12" long with round tip
XSBVP12P	Bendable Temperature Logger – 12" long with pointed tip
XSBVP18P	Bendable Temperature Logger – 18" long with pointed tip
XSBVP24R	Bendable Temperature Logger – 18" long with round tip
XSBVP36R	Bendable Temperature Logger – 26" long with round tip
XSBVP26P	Bendable Temperature Logger – 36" long with pointed tip



# Data Logger Specifications

## Pressure Logger Specifications

Sensing Element Pressure	Absolute pressure sensor	
Operating Range	0 to 5 bar absolute (0 to 73 psia) from 0°C to 140°C	
Accuracy	Temperature Range	Accuracy
	>0°C to 120°C	±25 mb
	>120°C to 135°C	±10 mb
	>135°C to 140°C	±25 mb
Environmental Temperature	-60°C to 140°C	
Pressure	0 to 5 bar absolute (0 to 73 psia)	
Logger Dimensions	1 13/16 in x 1 3/8 in diameter (46 mm x 35 mm)	
Total Height	2 13/16 in (72 mm)	
Logger Material	316L stainless steel	
Battery	Field-replaceable 3.6 V lithium thionyl chloride	
Sampling Rate	1 second to 12 hours	
Data Storage	10,000 samples retained in EEPROM memory	
Calibration	Factory calibrated (NIST-traceable) with user calibration capability	
Real Time Clock Accuracy	20 seconds per 24 hours (0.0174%) from 0°C to 95°C (32°F to 203°F)	
Regulatory Compliance	UL, CE and Intrinsically Safe	
Part Number	X2530	



## Humidity Logger Specifications

Sensing Element Humidity	Absolute pressure sensor	
Operating Range	Operating Range	Accuracy
	25% to 85% RH (non condensing)	±2% RH at 25°C and 40°C (EMD4000)
	EMD4000	±2% at 25°C (EMD3000)
	0 to 55°C (with RH Sensor)	±0.1°C
Measurement Range and Accuracy Humidity	0 to 95°C (without RH Sensor)	
	Operating Range	Accuracy
	25% to 85% RH (non-condensing)	±2% RH at 25°C and 40°C
Temperature	0 to 55°C (with RH sensor)	±0.1°C
	0 to 95°C (without RH sensor)	
Environmental Temperature	5 to 40°C (with RH sensor)	
	0 to 95°C (without RH sensor)	
Humidity Pressure	0% to 100% humidity, condensing 0 to 10 bar absolute (0 to 145 psia)	
Logger Material	316L stainless steel	
Logger Dimensions	1 13/16 in x 1 3/8 in diameter (46 mm x 35 mm)	
Total Height	3 1/8 in (79 mm)	
Battery	Field-replaceable 3.6 V lithium thionyl chloride	
Sampling Rate	2 second to 12 hours	
Data Storage	10,000 samples retained in EEPROM memory for each sensor (humidity and temperature)	
Calibration	Factory calibrated (NIST-traceable) with user calibration capability	
Real Time Clock Accuracy	20 seconds per 24 hours (0.0174%) from 0°C to 95°C	
Regulatory Compliance	UL, CE and Intrinsically Safe	
Part Number	X2520	



## Dual Logger Specification

Sensing Element	Precision Platinum RTD	
Measurement Range and Accuracy	0°C to 140°C, -45°C to 0°C,	±0.1°C ±0.2°C
Environmental		
Temperature	-45°C to 140°C	
Humidity	0% to 100% humidity, condensing	
Pressure	6 Pa to 10 bar absolute	
Logger Material	316 stainless steel	
Battery	Field-replaceable 3.6 V lithium thionyl chloride	
Sampling Rate	1 second to 12 hours	
Data Storage	10,000 samples per sensor retained in EEPROM memory	
Calibration	Factory calibrated (NIST-traceable) with user calibration	
Real Time Clock Accuracy	20 seconds per 24 hours (0.0174%) from -45°C to 140°C	
Regulatory Compliance	UL, CE and Intrinsically Safe	

## Insulating Canister

Proprietary insulating materials provide for a compact, low profile design, making the insulating canister suitable for the most demanding thermal validation applications including depyrogeneration tunnels and dry heat ovens. For use with Kaye ValProbe bendable and dual readable temperature loggers.

### Features

- Proprietary insulating material greatly extends ValProbe operating range
- Low profile design for use in space-restrictive applications (45mm dia. X 149mm long)
- Robust 316 SS construction

## Dual Logger Configuration

1.5" rigid sensor w/ bendable probe (specify length)
Two bendable probes (specify length)
1.5" rigid sensor w/ flexible probe (specify length)
Two flexible probes (specify length)

## Performance

Temperature	Accuracy	Maximum Exposure
360°C	±0.5°C	45 min.
300°C	±0.5°C	60 min.
250°C	±0.2°C	80 min.
200°C	±0.2°C	115 min.
170°C	±0.2°C	165 min.



# Regulatory Compliance

## ValProbe<sup>sm</sup> Audit Trail

01-Sep-2010 to 24-Sep-201

Printed by Ralf Wottrich on 24-Sep-2010 at 13:40:18

000001	22-Sep-2010 14:11:22	Audit Trail Started		
000002	22-Sep-2010 14:11:22	Path: C:\Program Files\Kaye\Val Probe\ Machine ID: 285341		
000003	22-Sep-2010 14:14:04	Version Changed		
000004	22-Sep-2010 14:14:14	0 to Software Version: 1.50		
000005	22-Sep-2010 14:14:26	Program Launch	113005042	
000006	22-Sep-2010 14:14:26	Login Failure	No Such Operator: KAYe	
000007	22-Sep-2010 14:14:26	Login Failure	No Such Operator: 111	
000008	22-Sep-2010 14:14:26	Successful Login	Kaye Default Administrator	System Administrator
000009	22-Sep-2010 14:14:51	Create User	Ralf Wottrich	System Administrator
000010	22-Sep-2010 14:14:51	Delete User	Automatic Event	
000011	22-Sep-2010 14:15:07	Kaye Default Administrator	Success	
000012	22-Sep-2010 14:15:07	Site Options Modified	Ralf Wottrich	
000013	22-Sep-2010 14:15:07	Allow Operators to change D value in lethality calculation : Yes		
000014	22-Sep-2010 14:15:36	Site Options Modified	Ralf Wottrich	
000015	22-Sep-2010 14:15:36	Require User ID and password : No		
000016	22-Sep-2010 14:15:36	Site Options Modified	Ralf Wottrich	
000017	22-Sep-2010 14:15:36	Allow Operators to change Preferences : Yes		
000018	22-Sep-2010 14:15:36	Site Options Modified	Ralf Wottrich	
000019	22-Sep-2010 14:15:36	Expired days change from 90 to 0.		
000020	22-Sep-2010 14:15:53	Create User	Ralf Wottrich	Operator
000021	22-Sep-2010 14:16:15	Ralf Op	Success	
000022	22-Sep-2010 14:16:15	Preferences Modified	Unknown User	
000023	22-Sep-2010 14:20:30	Standard Reader to Reader 2		
000024	22-Sep-2010 14:26:11	Program Launch	113005042	
000025	22-Sep-2010 14:26:11	New Study Created	Unknown User	
000026	22-Sep-2010 14:26:11	Program Loggers	Unknown User	
000027	22-Sep-2010 14:26:11	Software Version: 1.50		
000028	22-Sep-2010 14:27:52	New Study Created	Unknown User	
000029	22-Sep-2010 14:27:52	Unknown User		
000030	22-Sep-2010 14:27:52	Study Programmed	Unknown User	
000031	22-Sep-2010 14:27:52	Validation Accelerated Stability Test chamber #2413		
000032	22-Sep-2010 14:43:42	Study Programmed	Unknown User	
000033	22-Sep-2010 14:43:42	Validation Accelerated Stability Test chamber #2413		
000034	22-Sep-2010 14:45:37	Low Battery Warning	Unknown User	SN: W225
000035	22-Sep-2010 14:50:53	Program Launch	113005042	
000036	22-Sep-2010 14:51:40	Study Canceled	Unknown User	
000037	22-Sep-2010 14:51:26	Program Launch	113005042	
000038	22-Sep-2010 16:10:55	Preferences Modified	Unknown User	
000039	22-Sep-2010 16:11:17	USB to COM Port0		
000040	22-Sep-2010 16:36:54	Study Read	Unknown User	
000041	22-Sep-2010 16:36:54	Validation Accelerated Stability Test chamber #2413		
000042	22-Sep-2010 16:37:40	Unknown User		
000043	22-Sep-2010 16:37:40	Low Battery Warning	Unknown User	SN: W225
000044	22-Sep-2010 16:39:11	Low Battery Warning	Unknown User	SN: S012
000045	22-Sep-2010 16:39:26	Low Battery Warning	Unknown User	SN: Y006
000046	22-Sep-2010 16:39:39	Low Battery Warning	Unknown User	SN: Y007
000047	22-Sep-2010 16:39:58	Low Battery Warning	Unknown User	SN: P215
000048	22-Sep-2010 16:40:04	Study Canceled	Unknown User	
000049	22-Sep-2010 16:40:04	Validation Accelerated Stability Test chamber #2413		
000050	22-Sep-2010 16:40:04	Unknown User		
000051	22-Sep-2010 16:41:26	Study Read	Unknown User	
000052	22-Sep-2010 16:41:26	Validation Accelerated Stability Test chamber #2413		
000053	22-Sep-2010 16:41:26	Unknown User		
000054	22-Sep-2010 16:41:26	Unknown User		

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

The Kaye ValProbe is specifically designed to enable compliance with FDA 21 CFR Part 11. 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 have been improved 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 with or deleted from within Windows Explorer<sup>TM</sup>.

Password Maintenance

Add New User

Name:

User ID:

Password:

Reenter Password:

☒ Operator ☐ System Administrator

☐ Disable User Account

User Account Creation

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

Identification Required

User ID:

Current Password:

☐ Change Password

OK Cancel

Login Window

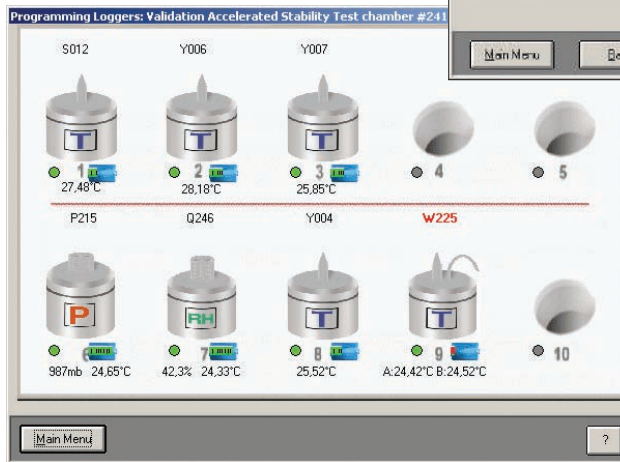
Each person has a unique signature, as defined by a user ID and password. This signature is required for any action that can affect data—at the ValProbe or PC—whether you are in Set-up, calibration or qualification mode.

# Study Set-Up

## Intuitive and Versatile

The software, provided with all Kaye products, permits set-up, running of a qualification, calibration, generating validation reports and enables compliance with regulations including Part 11 and EN norms.

The Kaye ValProbe was designed to help you get the data you want from a validation study quickly and easily. It starts with the ValProbe software that allows you to set up and customize sensor calibration, qualification, and report generation.



You can customize reports right down to 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 other ways. You can define sensors individually—creating your own labels and detailed descriptions, or applying an individual sensor definition 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 average for each sensor during cycles.

Users can add unlimited cycles, separating qualification data into separate process phases, and up to 25 groups, with their own calculations and graphs during reporting, often eliminating the need for post-processing in Excel®.

Lethality Calculations screen

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

# Reports

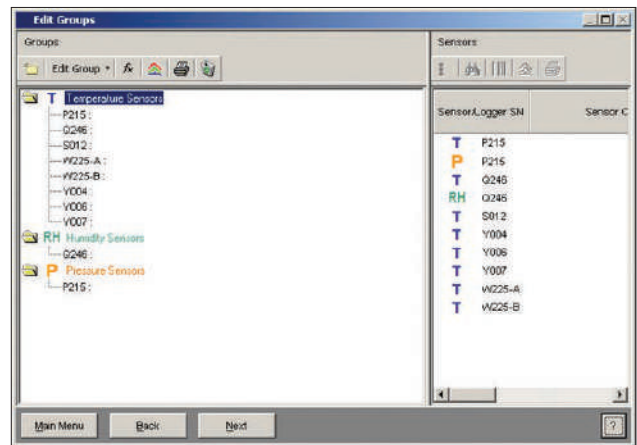
The Kaye reporting Software includes an intuitive, yet powerful reporting utility for generating Set-Up, Calibration, Qualification and Calibration Verification reports to document validation study results. Reports are generated from secure data files that can only be read by the system software. Upon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

## Features

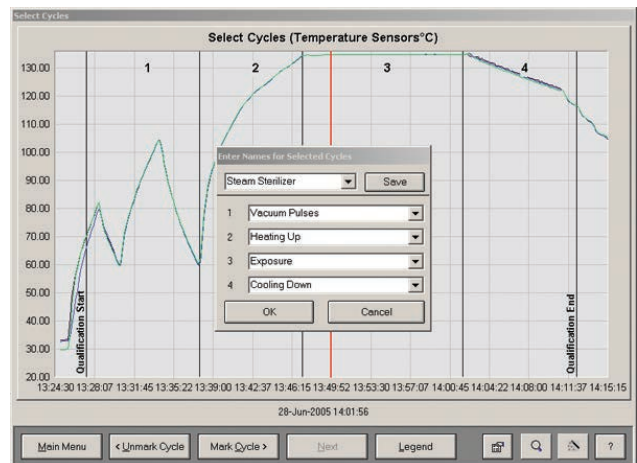
- Common reporting software for Validator®, ValProbe® and RF ValProbe® gives added flexibility and convenience in merging data files from multiple Kaye devices.
- Powerful graphing tool during reporting with report wizard shows all sensors and samples through a complete study.
- Report wizard allows to select lethality calculation during reporting. Lethality parameters can be changed.

# Post Qualification Reporting

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



Cycles are like events—the qualification data is separated into distinct phases and summary reports can be generated for each cycle.



## Cycle Headers

The user 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 better access to graph properties such as colors and data limit lines.

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.

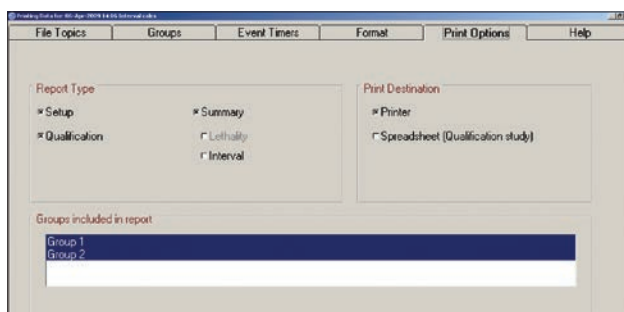


# Merged Reporting

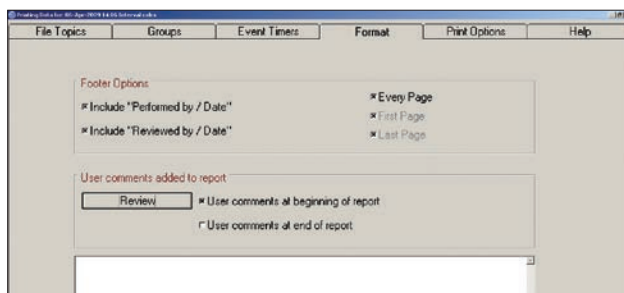
Users have the ability to combine or merge reports from several Validators or ValProbes, providing the validations were run concurrently. A typical example would be during a freeze dryer validation where two ValProbes are needed, or if a ValProbe pressure logger is used alongside ValProbe temperatures.

For qualification reporting, the software provides more capability to analyze your study. Using various selections—calculations, intervals, events, conditions, elapsed time, specific groups—you can answer questions about your study that could only be done previously in an exported spreadsheet application.

If you need to perform additional analysis, simply open our validation file in another application. The original data is not modified.



Print Options

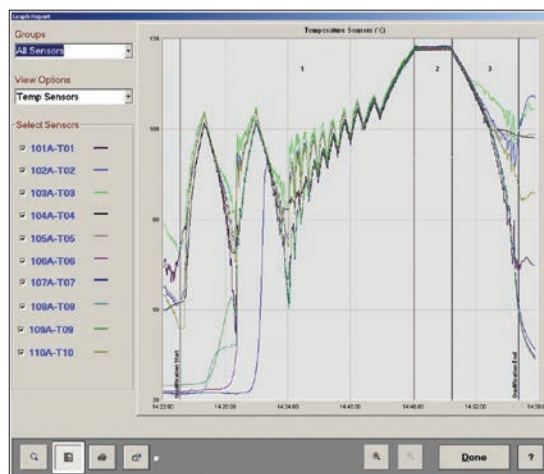


Footer Options and User Comments

SOPs require a sign off on validation reports. But SOPs vary on the number of signatures and the pages. The Kaye ValProbe lets you make these selections, as well as where you want user-entered notes. With the report generator you can print the information and data from an entire study, or a smaller report from one of your defined groups.

## Graphing

A powerful graphing utility within the system software greatly simplifies process analysis and reporting. Sliding vertical axes enable the operator to flag and define process transition points, eliminating unnecessary reporting and streamlining the review process. The graph utility features increased flexibility for graph customization, including specifying X and Y axis ranges, background colors, line styles and labeled limit lines.



Kaye ValProbe powerful graphing utility



Validator - Qualification Summary Report													
Study Name: LSC-1000-Mini-200-C-2000-Storage						Location: LA							
Temperature Data(C)													
Logan: S/N	Heating Up				Exposure				Cooling Down				Totals
	Min	Max	Avg	Cycle	Min	Max	Avg	Cycle	Min	Max	Avg	Cycle	
101A-T01 (C)	51.13	118.95	91.76	0.03	120.11	123.44	122.91	8.91	68.27	120.03	96.02	0.06	8.90
102A-T02 (C)	51.06	120.03	91.78	0.05	120.18	123.41	122.89	8.86	67.79	120.75	96.56	0.06	8.87
103A-T03 (C)	51.70	120.35	92.43	0.11	120.10	123.47	122.97	8.00	68.85	120.38	95.70	0.03	9.09
104A-T04 (C)	51.28	120.01	91.91	0.05	120.16	123.39	122.78	8.63	67.60	120.48	96.27	0.03	8.71
105A-T05 (C)	50.95	118.99	91.54	0.03	120.15	123.50	122.98	8.04	68.52	120.98	97.13	0.09	8.16
106A-T06 (C)	51.46	120.40	92.40	0.11	120.35	123.53	123.03	9.14	68.97	120.51	95.76	0.03	9.28
107A-T07 (C)	51.28	120.10	91.94	0.05	120.25	123.42	122.91	8.90	67.72	120.63	96.41	0.06	9.01
108A-T08 (C)	50.97	118.96	91.54	0.04	120.05	123.56	122.96	9.26	68.77	120.34	95.52	0.06	9.41
109A-T09 (C)	51.10	120.09	91.76	0.05	120.25	123.52	123.00	9.10	68.15	120.87	96.82	0.08	9.23
110A-T10 (C)	51.76	120.53	92.63	0.14	120.65	123.58	123.08	8.23	68.65	120.35	95.51	0.03	9.40
111A-T11 (C)	51.66	120.37	92.35	0.11	120.51	123.49	122.98	8.03	67.25	120.33	95.88	0.03	9.17
112A-T12 (C)	52.04	120.70	92.96	0.17	120.26	123.54	123.03	8.11	68.00	119.99	94.85	0.00	9.28
201A-T13 (C)	51.16	118.95	91.72	0.03	120.10	123.51	122.80	8.67	67.99	120.55	95.53	0.03	9.73
202A-T14 (C)	51.87	120.62	93.05	0.17	120.46	123.48	122.97	8.00	65.60	120.15	94.72	0.00	9.17
203A-T15 (C)	51.94	120.41	92.71	0.11	120.32	123.38	122.88	8.83	66.34	120.01	95.09	0.00	9.17
204A-T16 (C)	50.93	120.13	92.06	0.05	120.28	123.54	122.84	8.75	67.26	120.48	96.00	0.03	8.93
Totals													
8.90													
8.97													
9.14													
8.71													
9.16													
9.28													
9.01													
9.41													
9.23													
9.40													
9.17													
9.28													
9.73													
9.17													
8.94													
8.93													
Temperature Summary Data(C)													
Cycle Start	Heating Up				Exposure				Cooling Down				Totals
	Min	Max	Avg	Cycle	Min	Max	Avg	Cycle	Min	Max	Avg	Cycle	
10 Jul 2008 15:36:22	10 Jul 2008 15:43:48	10 Jul 2008 15:49:36	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	10 Jul 2008 15:53:00	
Cycle Duration	0:07:26	0:05:48	0:03:24	0:03:24	0:05:48	0:03:24	0:03:24	0:03:24	0:03:24	0:03:24	0:03:24	0:03:24	
Min of Min	50.95	51.16	51.10	51.10	51.10	51.10	51.10	51.10	51.10	51.10	51.10	51.10	
Max of Max	120.70	120.70	120.70	120.70	120.70	120.70	120.70	120.70	120.70	120.70	120.70	120.70	
Time	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	10 Jul 2008 15:43:46	
Max Range	68.75	68.75	68.75	68.75	68.75	68.75	68.75	68.75	68.75	68.75	68.75	68.75	
Max Spread/Time	2.40	Time 15:37:38	0.98	Time 15:49:34	3.11	Time 15:52:08	3.11	Time 15:52:08	3.11	Time 15:52:08	3.11	Time 15:52:08	
Min Alch	0.03	S/N 101A-T01	8.63	S/N 104A-T04	0.00	S/N 112A-T12	0.00	S/N 105A-T05	0.00	S/N 105A-T05	0.00	S/N 105A-T05	
Max Alch	0.17	S/N 112A-T12	9.25	S/N 108A-T08	0.09	S/N 105A-T05	0.09	S/N 105A-T05	0.09	S/N 105A-T05	0.09	S/N 105A-T05	
Avg of Avg	22.22	22.22	22.22	22.22	22.22	22.22	22.22	22.22	22.22	22.22	22.22	22.22	
Performed by:	Date:												
Reviewed by:	Date:												

Summary report

# Kaye ValProbe® Series

## Temperature Calibration and Reference

### Features

- Operates on standard line voltage
- Positions for two IRTD standards

### Fluid Baths

- Wide operating range covers most common application requirements
- CTR-40 stability to  $\pm 0.005^{\circ}\text{C}$  or CTR-80 stability to  $\pm 0.01^{\circ}\text{C}$
- Rapid cool down from ambient to  $-40^{\circ}\text{C}$
- Very low noise
- Modest footprint with floor cart available for portability
- Quick drain spout simplifies fluid change
- 120 minute cool-down from ambient to  $-80^{\circ}\text{C}$
- Mounted on casters for portability

### Dry Wells

- HTR and LTR Series dry wells
- Rapid response time with no oils or fluids
- Stability of  $\pm 0.02^{\circ}\text{C}$  to  $\pm 0.05^{\circ}\text{C}$  for temperatures exceeding  $300^{\circ}\text{C}$
- Lightweight yet rugged design for portability

## Temperature Calibration

### CTR-40

The CTR-40 is a portable temperature bath designed to meet the calibration and validation needs of the ValProbe system. Combined with the Intelligent RTD (IRTD) and ValProbe software, the CTR-40 provides pre-study and post-study verifications, as well as ValProbe temperature sensor calibration.

The advanced design combines excellent temperature stability and uniformity with a broad temperature range  $-40^{\circ}\text{C}$  to  $150^{\circ}\text{C}$  to address most ValProbe applications. The generous nine liter tank and specially designed ValProbe immersion basket accommodate up to eight ValProbe loggers, making calibration or verification a quick and easy process.

The portable tabletop design easily fits onto a benchtop without consuming precious space. An optional floor cart, with locking casters, raises the unit to a convenient operating height and allows easy transport within your facility.

### Intelligent RTD Standard

The IRTD Temperature Standard (IRTD 400) is a National Industry of Standards and Technology (NIST) traceable instrument calibrated from  $-195^{\circ}\text{C}$  to  $420^{\circ}\text{C}$  with  $0.025^{\circ}\text{C}$  accuracy over the entire range. This completely self-contained measurement system serves as the secondary standard providing traceability for ValProbe calibration or verification. By interfacing with the ValProbe software, the IRTD 400 eliminates the potential for human error, ensuring accurate and traceable measurements.

### Stable Uniform Heat Sources

Kaye temperature references are designed for easy operation while delivering the highest level of temperature stability possible. These stable uniform heat sources combine rapid heat-up and cool-down with large sensor capacity to minimize overall calibration time. Multiple calibration set points are programmed via the easy-to-use operator panel and displayed (set point or well temperature) to 0.01 degree accuracy. These references provide fully automated sensor calibration when used with Kaye's Validator® 2000 and traceable IRTD temperature standard.

### HTR and LTR Series Dry Wells

The HTR and LTR Series dry wells are specifically designed for calibrating sensors used for process validation. These are the most advanced reference units on the market, featuring fast heat-up and cool-down, large well capacity to accommodate 18 to 24 thermocouples, and they use no messy oils or fluids.

The HTR 400 is ideal for high-temperature applications such as autoclaves, dry heat ovens and sterilizer tunnels. The LTR models offer low-temperature performance for applications including freezers, cold rooms, incubators and autoclaves. The LTR model selection should be based on the application's low-temperature point.

### CTR-80 Cryo Temperature Bath

Operating from  $-80^{\circ}\text{C}$  to  $30^{\circ}\text{C}$ , the CTR delivers fast response, high stability, and automated sensor calibration for the most severe cold-temperature applications. A generous 3.7 liter tank is heated and cooled quickly and quietly by a two-stage refrigeration system (R507 and R508B). The CTR-80 is the ideal unit for calibrating temperature sensors used in freeze dryer, freezer, and cryo unit validation.



# ValProbe Specifications: CTR-40

## Temperature Range

-40°C to 150°C

## Ambient Operating Range

15°C to 25°C

## Set-Point Accuracy

0.5°C

## Temperature Stability

- $\pm 0.005^{\circ}\text{C}$  at  $-40^{\circ}\text{C}$
- $\pm 0.005^{\circ}\text{C}$  at  $-25^{\circ}\text{C}$
- $\pm 0.005^{\circ}\text{C}$  at  $-150^{\circ}\text{C}$

## Temperature Uniformity

$\pm 0.01^{\circ}\text{C}$

## Typical Cool-Down Time

25°C to  $-40^{\circ}\text{C}$ , 110 minutes

## Access Opening

94 mm x 172 mm with positions for IRTD and up to eight ValProbe data loggers with immersion basket

## Display

LED with  $0.01^{\circ}\text{C}$  resolution

## Computer Interface

RS232

## Off Cart Dimensions (h x w x d)

584 mm x 305 mm x 622 mm

## On Cart Dimensions (h x w x d)

819 mm x 305 mm x 622 mm

## Volume

9 liters

## Recommended Bath Fluids

- $-40^{\circ}\text{C}$  to  $130^{\circ}\text{C}$ , Silicone oil type 200 (five centistoke viscosity)
- $-30^{\circ}\text{C}$  to  $150^{\circ}\text{C}$ , Silicone oil type 200 (10 centistoke viscosity)

## Weight

32 kg

## Power

115 VAC 60 Hz, 16 A or 230 VAC 50 Hz, 8 A 1700 W

## Fault Protection

- Oven temperature limits (user can set)
- Low voltage cutout
- Automatic refrigeration turn off
- Electrical fuse



# ValProbe Specifications: CTR-80

## Temperature Range

-80°C to 100°C

## Ambient Operating Range

15°C to 25°

## Set-Point Accuracy

0.5°C

## Temperature Stability

±0.01°C

## Temperature Uniformity

±0.012°C

## Typical Cool-Down Time

25°C to -80°C, 20 minutes

## Access Opening

86 mm x 114 mm with positions for (two) IRTDs and (three) 11 mm diameter x 203 mm deep calibration wells

## Display

LED with 0.01°C resolution

## Computer Interface

RS232

## Dimensions (h x w x d)

762 mm x 305 mm x 610 mm

## Weight

57 kg

## Power

115 VAC 60 Hz, 16 A or 230 VAC 50 Hz, 8 A 1700 W

## Fault Protection

- Oven temperature limits (user can set)
- Low voltage cutout
- Automatic refrigeration turn off
- Electrical fuse



ValProbe immersion basket shown with IRTD Standard (not included).



LTR Series

# ValProbe Specifications: IRTD-400

## Temperature Range

-195°C to 420°C

## Accuracy Over Range

0.025°C

*Accurate for one year, 0°C to 60°C ambient.  
Includes calibration certificate with traceability to NIST.*

## Resolution

0.001°C

## Sensor Element

200  $\Omega$  platinum RTD sensor

## Sheath Material

Inconel 600

## Immersion Depth (Minimum)

101.6 mm

## Calibration

$\pm 0.01^\circ\text{C}$

*Amphenol Advanced Sensors provides a re-certification service for calibrating the temperature standard.*

## Power Probe

- Unregulated DC, 10 to 25 V
- 850 mW at 15 V for first probe
- 550 mW for each additional probe

## Power Supply

115 VAC US-style adaptor or 230 VAC VDE-approved adaptor *Power supply is not required for use with the ValProbe system.*

## Measurement Rate

One reading per second

## Environmental

- Ambient temperature range 0°C to 60°C
- Humidity 0 to 95% non-condensing

## Overall Dimension Length

603 mm

## Grip

89 mm x 32 mm

## Sensor Sheath

457 mm x 6.35 mm

	HTR 400	LTR -25/140	LTR -40/140
Temperature Range	25°C above ambient to 400°C	-25°C to 140°C	-40°C to 140°C
Ambient Operating Range	5°C to 50°C	5°C to 50°C	5°C to 50°C
Set-Point Accuracy	0.2°C to 300°C	0.2°C	0.2°C
	0.3°C to 400°C		
Temperature Stability	0.02°C to 300°C	0.02°C	0.02°C
	0.05°C to 400°C		
Transfer Calibration Accuracy*	50°C to 150°C: $\pm 0.1^\circ\text{C}$	-25°C to 80°C: $\pm 0.1^\circ\text{C}$	-40°C to -25°C: $\pm 0.15^\circ\text{C}$
IRTD Standard to Thermocouples	50°C to 250°C: $\pm 0.2^\circ\text{C}$	80°C to 130°C: $\pm 0.15^\circ\text{C}$	-25°C to 80°C: $\pm 0.1^\circ\text{C}$
	250°C to 350°C: $\pm 0.3^\circ\text{C}$	130°C to 140°C: $\pm 0.18^\circ\text{C}$	80°C to 130°C: $\pm 0.15^\circ\text{C}$
	350°C to 400°C: $\pm 0.4^\circ\text{C}$		130°C to 140°C: $\pm 0.18^\circ\text{C}$
Typical Heat-Up Time	Ambient to 90°C: 5 minutes	Ambient to 80°C: 6 minutes	Ambient to 80°C: 6 minutes
	90°C to 125°C: 3 minutes	Ambient to 140°C: 14 minutes	Ambient to 140°C: 14 minutes
	350°C: 25 minutes		
Well Configuration	Reference wells (2): 6.7 mm diameter x 127 mm deep	Reference wells (2): 6.7 mm diameter x 155 mm deep	Reference wells (2): 6.7 mm diameter x 155 mm deep
	Calibration wells (8): 9 mm diameter x 155 mm deep	Calibration wells (6): 9 mm diameter x 155 mm deep	Calibration wells (6): 9 mm diameter x 155 mm deep
Display	LED w/0.01°C resolution	LED w/0.01°C resolution	LED w/0.01°C resolution
Computer Interface	RS232	RS232	RS232
Dimensions	343 mm x 198 mm x 317.5 mm	343 mm x 198 mm x 317.5 mm	343 mm x 198 mm x 317.5 mm
Weight	8.2 kg	13.6 kg	13.6 kg
Power	115 VAC 60 Hz, 6 A or 230 VAC 50 Hz, 3 A 700 watts	115 VAC 60 Hz, 3 A or 230 VAC 50 Hz, 1.5 A 350 watts	115 VAC 60 Hz, 3 A or 230 VAC 50 Hz, 1.5 A 350 watts
Fault Protection	Sensor burnout protection, over temperature thermal cutout, electrical fuse	Sensor burnout protection, over temperature thermal cutout, electrical fuse	Sensor burnout protection, over temperature thermal cutout, electrical fuse

\* Transfer calibration accuracy is the difference between the thermocouple tip and the sensor of the IRTD temperature standard. This accuracy includes well to well uniformity.

