

Kaye ValProbe®

User's Guide



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M5000E Rev. E
April 2011

GE
Measurement & Control Solutions

Kaye ValProbe®

Process Monitoring and Validation System

User's Guide

M5000E Rev. E
April 2011



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Chapter 1. Features

1.1 Introduction

1.1.1 Unpacking

Unpack the Kaye ValProbe® Loggers and Reader carefully and inspect them for any damage that may have occurred during shipment. If there is shipping damage, notify the carrier immediately. Verify that the following are present:

- Kaye ValProbe Reader and power cord (a power cord is not required for the Single Reader)
- Communications cable (W1890-1) (the Reader 2 and Single Reader also include a USB cable)
- Kaye ValProbe Loggers and calibration certificates
- Kaye ValProbe English Software Package (X2060E)
- Kaye ValProbe Battery Replacement Kit (V2549)

1.1.2 Safety Information

Use this instrument only as specified in this User's Guide.

- The protection provided by the equipment may be impaired if the equipment is used in a manner not specified by GE.
- Do not use this equipment in environments other than those listed in the User's Guide.

1.1.3 Overview

The Kaye ValProbe is a wireless process monitoring and validation system that collects temperature, humidity, and pressure data in environments that are hostile to traditional sensor wires or that are difficult to access. The Kaye ValProbe system is designed for accurate, convenient, and reliable process measurements for pharmaceutical, medical device, and food processing applications. These applications include steam, dry heat and EtO sterilizers, ovens, incubators, stability and temperature chambers, and warehouses.

1.1.3 Overview (cont.)

The system consists of Kaye ValProbe Loggers, a Kaye ValProbe Reader, and Windows-based software for programming and reading the Loggers, calibrating Loggers, verifying their calibration, and generating reports (see Figure 1 below).

Data from multiple wireless Loggers is combined in a single encrypted file from which reports are generated. These reports are designed for implementation of 21 CFR Part 11 requirements for electronic records. Users can customize the reports by defining process cycles and specifying cycle-based calculations.



Figure 1: Kaye ValProbe System Components

1.1.4 Kaye ValProbe Loggers

There are five types of Kaye ValProbe Loggers:

- Temperature - Measures temperature from -45°C to 140°C . The bendable Temperature Logger may be used in conjunction with an Insulating Canister to measure temperature up to 360°C .
- Relative Humidity and Temperature - Measures relative humidity from 20% to 85%, and temperature from 0°C to 95°C .
- Pressure - Measures pressure from 0 to 5 bar (certified to 10 bar over pressure).(Obsolete – Please use X2532 to order new units.)
- Pressure and Temperature - Measures pressure from 0 to 5 bar (certified to 10 bar over pressure) and temperature from 0°C to 95°C .
- Cryo Logger - a single-channel temperature logger that measures from -85°C to $+140^{\circ}\text{C}$, with accuracy of $\pm 0.1^{\circ}\text{C}$ from 0°C to 140°C , and of $\pm 0.25^{\circ}\text{C}$ from -85°C to 0°C .



Figure 2: Kaye ValProbe Loggers

1.1 Kaye ValProbe Loggers (cont.)

The intrinsically safe Kaye ValProbe Loggers are made from pharmaceutical grade 316 stainless steel and designed for in-situ use. For example, they can be immersed in cleaning fluid or detergents, or used in harsh environments.

WARNING! Substitution of components may impair intrinsic safety.

AVERTISSEMENT: LA SUBSTITUTION DE COMPOSANTS PEUT COMPROMETTRE LA SECURITE INTRINSEQUE.

Do not heat the Temperature Logger above 140°C.

Do not heat the Pressure/Temperature Logger above 140°C.

Do not heat the Humidity/Temperature Logger with RH sensor above 50°C and without RH sensor above 95°C.

Do not submerge the Logger in oil, cleansing liquid or detergents for more than two hours at temperatures below -20°C. After two hours the

O-ring seal may degrade and should be replaced.

Note: *See instructions for O-ring replacement on page 25.*

IMPORTANT: *To maintain the seal, the Logger contains a cup O-ring made of EPDM material. The cup O-ring should be replaced whenever the Logger is opened.*

1.1.1 Temperature Loggers

The Kaye ValProbe Temperature Logger accurately measures temperature from -45°C to 140°C using a precision Platinum RTD element. The RTD element is housed in the probe tip and ensures the following accuracy:

Table 1: Temperature Logger Accuracy

Temperature	Accuracy
0°C to 140°C	$\pm 0.1^{\circ}\text{C}$
0°C to -45°C	$\pm 0.25^{\circ}\text{C}$

The Temperature Loggers are available in different probe configurations (see Figures 3 and 4 below):

- **rigid** (model #XVP-L-T)
- **flexible** (model #XFVP-C-L-T)
- **bendable** (model #XBVP-L-T)
- **dual flexible** (model #XDFVP-(Ca)-(La)-(Cb)-(Lb))
- **dual rigid/flexible** (model #XDVP1.5R-F(Cb)-(Lb))



Figure 3: Rigid..... Flexible Bendable



Figure 4: Dual Loggers

1.1.1 Temperature Loggers (cont.)

The Cryo Logger is a single-channel temperature logger that provides a single solution for a variety of applications, such as cryogenic chambers, lyophilizers, ultralow freezers and other ultra low temperature applications. The external temperature sensor covers an extended temperature range from -85°C to $+140^{\circ}\text{C}$, with accuracy of $\pm 0.1^{\circ}\text{C}$ from 0°C to 140°C , and of $\pm 0.25^{\circ}\text{C}$ from -85°C to 0°C . Users can perform verification between studies with the IRTD and low temp CTR-80 bath.



**Figure 5: Cryo Logger
Temperature Logger**

1.1.2 Bendable Temperature Loggers

To prevent breaking and/or stress on the inner conductors of the bendable Temperature Logger probe, the following guidelines should be followed:

- The minimum bending radius is 2x the diameter of the probe. For example, a probe with a 1/8 inch (3.18 mm) diameter would require a minimum bending radius of 1/4 inch (6.35 mm). To ensure that the limit is not exceeded, GE recommends bending the probe around a cylinder with a diameter of 1/2 inch (13 mm).
- Avoid repeated bending of the probe at the same point.
- The probe should not be bent within 1 inch of the Logger body or 1 inch from where the tip is welded to the probe.

1.1.3 Insulating Canister

The Kaye ValProbe Insulating Canister (Part Number X2540) enables you to operate bendable Temperature Loggers from -80°C to 360°C by ensuring that the Logger base does not exceed 140°C or go below -45°C . The canister consists of an insulated base, a PTFE cylinder that attaches to the top of the Logger, and a cap that is secured by locking on to the four tabs at the top of the base (see Figure 6 below).



Figure 6: Insulating Canister

1.1.3 Insulating Canister (cont.)

IMPORTANT: *The Insulating Canister is for air applications only; do not submerge the canister in liquid.*

Sensor readings are collected with the following accuracy at these additional temperature ranges (see Table 2 below):

Table 2: Insulating Canister Sensor Accuracy

Temperature	Accuracy
250°C to 360°C	±0.5°C
140°C to 250°C	±0.2°C
-80°C to -45°C	±0.35°C

Note: *The bendable Temperature Logger can collect data in temperatures from -80°C to -45°C and from 140°C to 360°C without the Insulating Canister if only the probe (not the Logger base) is exposed to the operating environment.*

CAUTION! The Insulating Canister is for use in non-hazardous locations only.

To insert a Logger into the Insulating Canister:

1. Remove the cap by pressing down on the cap and turning it clockwise until the clips are free from the tabs.
2. Place the PTFE cylinder over the bendable Temperature Logger probe and slide it to the base of the Logger.
3. Screw the cylinder onto the threads at the base of the probe until it is secure. Place the Logger and PTFE cylinder into the canister.

1.1.3 Insulating Canister (cont.)

4. Insert the probe through the center hole on the Insulating Canister cap and slide the cap to the cylinder base. Line up the clips with the tabs on the cylinder base. Press down on the cap and turn counter-clockwise so that the clips are secured onto the tabs.

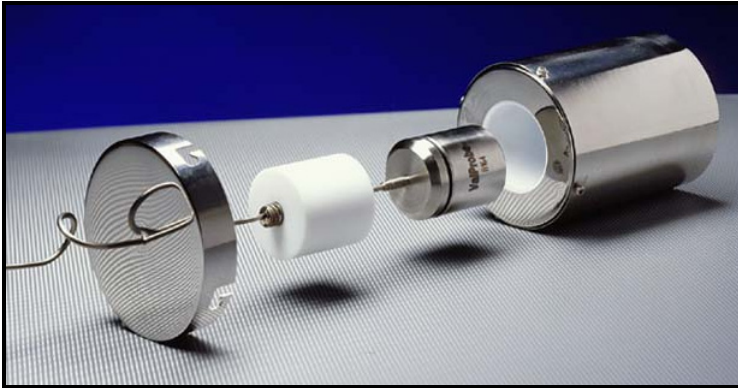


Figure 7: Inserting a Logger into an Insulating Canister

Table 3 below shows the length of time the Logger can remain in the chamber with the internal Insulating Canister temperature remaining below 140°C. The table assumes that the Logger and Insulating Canister (including the PTFE cylinder) were initially at room temperature before being placed in the chamber, and that the oven is stable.

Table 3: Logger Time Inside Canister

Temperature	Maximum Time
360°C	48 minutes
300°C	63 minutes
275°C	72 minutes
250°C	85 minutes
225°C	105 minutes
200°C	127 minutes

1.1.3 Insulating Canister (cont.)

CAUTION! If the Logger and Insulating Canister remain at a high temperature longer than the maximum time indicated in the table, the Logger base might be subjected to temperatures greater than 140°C, which can damage the Lithium Thionyl Chloride battery. This may result in a leakage of electrolyte.

WARNING! In the event the Logger base has been subjected to temperatures above 140°C, safety glasses and protective gloves should be worn before attempting to service the Logger to avoid electrolyte contact with eyes and skin.

If skin contact occurs, flush with cold water for at least 15 minutes. If symptoms persist, seek medical attention.

If eye contact occurs, flush with cold water for at least 15 minutes and seek medical attention.

Once a high-temperature study is complete, allow the canister to cool at room temperature. Remove the cap and the PTFE cylinder and place the Logger into the Reader to read the study data.

1.1.4 Humidity/Temperature Loggers

The Kaye ValProbe Humidity/Temperature Logger (models #X2520 and X2520-EtO) accurately measures relative humidity from 25% to 85% using a reactive polymer humidity sensor, and temperatures from 0°C to 95°C using a precision Platinum RTD element (see Table 4 below.) It comes in two versions — EMD3000 and EMD4000. The EMD4000 sensor (N1193) is the standard and suitable for stability chambers, storage mapping and other applications. The EMD3000 sensor (N1193-EtO) is suitable for ETO applications.

Table 4: Humidity/Temperature Logger Accuracy

Operating Range	Accuracy
25% to 85% RH (non-condensing)	±2% RH at 25°C and 40°C (EMD4000)
	±2% RH at 25°C (EMD3000)
EMD4000	±0.1°C
0 to 55°C (with RH Sensor), 0 to 95°C (without RH Sensor)	
EMD3000	
20 to 30°C (with RH Sensor), 0 to 95°C (without RH Sensor)	

If a Humidity Logger is subjected to temperatures above 95°C, the system issues a warning message until you replace the sensor and note the change in the software. See *Humidity Sensor Replacement* on page 13.

Note: *When performing user calibration or calibration verification, first complete the temperature calibration/verification and then the humidity calibration/verification. Make sure the Logger is allowed to dry following the temperature calibration/verification. The user calibration and calibration verification procedures are described in the online Help that comes with the Kaye ValProbe software.*

1.1.4 Humidity/Temperature Loggers (cont.)



Figure 8: Humidity/Temperature Loggers

1.1.5 Humidity Sensor Replacement

Replacing the humidity sensor is a two-step process, which involves:

- Replacing the existing humidity sensor
- Reprogramming the Logger with the new sensor's batch code

Note: *In an EtO environment, the sensors deteriorate and need to be replaced on a regular basis.*

Replacing the Existing Humidity Sensor

Humidity sensors are accurate to better than 2% over the operating temperature and humidity range, thereby permitting the field replacement of humidity sensors, provided the correct batch code is programmed into the Logger. The batch code specifies the manufacturing calibration offsets to be applied to the replacement humidity sensor. Use only the humidity sensor supplied by GE (Part Number N1193 or N1193-EtO) to maintain accuracy specifications.

Note: *If you are installing an EMD4000 sensor, be sure to run the “ValProbe EMD4000 Humidity Sensor Installation”(setup.exe) from the M4377 CD. Otherwise, the ValProbe installation will not permit you to use humidity loggers with EMD4000 sensors installed.*

Note: *Do not interchange sensors among Loggers. Each replacement humidity sensor is labeled with a batch code that specifies the manufacturing calibration offsets to be applied. After replacing the humidity sensor in a Logger, the Logger must be reprogrammed with the manufacturing calibration offsets.*

To replace the humidity sensor:

1. Unscrew the humidity cap and remove the existing humidity sensor.
2. Replace the humidity sensor with one supplied by GE to maintain accuracy specifications. Make sure the sensor is fully inserted and then remove the white protective cover. The humidity sensor should only be handled by its edges and care should be taken not to contaminate the sensing surface.

CAUTION! **Be careful to touch the sensor as little as possible as oils from fingers can contaminate the sensor.**

Replacing the Existing Humidity Sensor (cont.)

3. Record the two-character batch code located on the humidity sensor.
4. Replace the humidity cap.

Reprogramming the Logger with the New Sensor's Batch Code

After replacing the humidity sensor in a Humidity/Temperature Logger, the Logger must be reprogrammed with the new sensor's batch code in order for the humidity readings to be accurate. The batch code, located on the humidity sensor, specifies the manufacturing calibration offsets to be applied to the humidity sensor. The sensor change is recorded in the Logger and in the audit trail (see Chapter 2 for instructions on installing the software).

Note: *Reprogramming a Logger with the new humidity sensor batch code nullifies user calibration and user calibration verification for that humidity sensor.*

To reprogram the Logger with the new batch code:

1. Insert the Humidity/Temperature Logger into the Reader.
2. From the Hardware screen, click the Logger icon. The Logger information screen appears.
3. Click **Change RH Sensor**.
4. If user identification is required, enter your user ID and password when prompted and click **OK**.

A message appears stating you will need the two-character batch code in order to change the humidity sensor.

5. Click **OK**.
6. Enter the two-character batch code located on the new humidity sensor (e.g., M4, P2, etc.) and click **OK**. If the batch code is not recognized by the Kaye ValProbe software, you are prompted to insert the Humidity Sensor Calibration Disk that came with the new sensor into the floppy disk drive. This disk specifies the manufacturing calibration offsets to be applied to the humidity sensor for that batch code. Insert the disk into the floppy disk drive and click **OK**.
7. Click **OK** when prompted that the sensor change has been noted in the Logger.
8. Click **OK** to return to the Hardware screen.

1.1.6 Pressure Loggers

The Kaye ValProbe Pressure Logger (Obsolete – Please use X2532 to order new units) accurately measures pressure from 0 to 5 bar using a piezo resistive mems pressure sensor. The Pressure Logger can operate in temperatures from 0°C to 140°C.

The Pressure Logger is EN554 compliant for saturated steam sterilization. The Kaye ValProbe software provides tools for reporting on saturation of steam calculations (see the Kaye ValProbe online Help for information on creating reports).



Figure 9: Pressure Logger

1.1.6 Pressure Loggers (cont.)

Pressure sensor readings are collected with the accuracy shown in Table 5 below:

Table 5: Pressure Logger Accuracy

Operating Range	Note: <i>Certified to 10 bar over pressure.</i>
0–5 bar absolute from 0°C to 140°C	
Measurement Range	Accuracy
0°C to 120°C	±25 mb
120°C to 135°C	±10 mb
135°C to 140°C	±25 mb

CAUTION! Do not insert objects into the top of the Pressure Logger. This can damage the diaphragm in the Logger, invalidating the pressure readings.

Note: *Clean the Pressure Logger with an alcohol rinse and air dry.*

1.1.7 Pressure/Temperature Loggers

The ValProbe Pressure/Temperature Logger (X2532) can measure pressure from 0 to 5 Bar (certified to 10 Bar over pressure) using a strain gage pressure sensor, and temperature from 0°C to 140°C using a precision Platinum RTD element. The Loggers are made from 316 stainless steel, are intrinsically safe, and are intended for in-situ use. They can store the study setup and up to 5,000 pressure samples and 5,000 temperature samples with variable stop/start conditions in non-volatile memory.



Figure 10: Pressure/Temperature Logger

1.1.8 Data Collection

Each Kaye ValProbe Logger collects and stores up to 10,000 data samples in EEPROM memory at a user-specified sample rate. The Humidity/Temperature Logger stores 10,000 samples for each sensor. The Pressure/Temperature Logger stores 5,000 samples for each sensor.

The Loggers can be programmed to start data collection immediately, at a specified time or temperature, or at a specified time *and* temperature.

Table 6 below provides the time ranges available for programming Logger sample rates, start times, and stop times:

Table 6: Available Time Ranges

Logger Function	Minimum	Maximum
Sample Rate	1 second	12 hours
Start Delay	0 seconds	3 days
Stop Delay	1 minute	10 days

Note: *If the study includes Humidity/Temperature Loggers, the minimum sample rate is 2 seconds.*

You can also specify a change event that will switch the Loggers to a different sample rate. The change event can be at a specified time or temperature, or at a specified time *and* temperature.

When an event triggers, such as reaching temperature, the event value will be logged with the time it occurred, but thereafter the timestamps are synchronous with the sample rate. For example, if the event triggered at 8:05:03 and there was a 5 second sample rate specified, the Logger stores data at 8:05:03, and then synchronizes thereafter to the five second timestamps, i.e., 8:05:05, 8:05:10, 8:05:15, etc. This ensures that all Loggers in the study are synchronized to the same timestamp.

1.1.9 The Logger Battery

The Kaye ValProbe Logger contains a field-replaceable 3.6 VDC, Lithium Thionyl Chloride battery.

WARNING! To prevent ignition of a hazardous atmosphere, the battery must be changed only in an area known to be non-hazardous.

AVERTISSEMENT: AFIN DE PREVENIR L'INFLAMMATION D'ATMOSPHERES DANGEREUSES, NE CHANGER LES BATERIES QUE DANS DES EMPLACEMENT DESIGNES NON DANGEREUX.

Do not recharge or heat the battery above 140°C. For measuring temperatures above 140°C, a special probe and insulating canister are required to keep the temperature of the Logger below 140°C for the duration of the study. (See *Insulating Canister* on page 7.)

Use only the factory-specified battery (part number M3205) in the Kaye ValProbe Logger. The use of non-specified batteries will void the warranty and may damage the Logger and/or cause burns to the operator. Replacement battery kits are available from GE.

The battery should be replaced by a qualified technician in an anti-static environment.

Batteries must be disposed of in accordance with local, state, and federal regulations.

Battery life is affected by a number of factors, including sample rate, temperature, and hours of use. In addition, individual battery characteristics and capacity vary inherently from one battery to another by up to 10%. Refer to the battery life tables in the Kaye ValProbe online Help for the best approximation of the number of runtime hours you can expect from the battery at different sample rates and temperatures.

The Kaye ValProbe software tracks each Logger's battery life to within 10% of a potential low-voltage occurrence to help prevent interrupted or incomplete studies. When determining the battery life remaining, the software bases its calculations on the assumption that the battery can supply a predictable amount of energy (mAh) over the temperature range.

1.1.9 The Logger Battery (cont.)

When the batteries are used in environments at room temperature or above, and the battery life runs down to a fixed percentage, that remaining percentage is generally not available in environments below room temperature due to battery chemistry. The battery life calculation is accurate when a Logger is used exclusively for studies at or above room temperature, or exclusively for studies below room temperature. GE Measurement & Control Solutions therefore recommends that you change the battery when switching between the temperature ranges.

A low battery warning is issued when the remaining battery life is below the warning percentage specified in the Kaye ValProbe software. The low battery warning is issued until you replace the Logger battery and reset its battery life to 100%. If you do not specify a percentage, the low battery warning is set to 10%. GE recommends that you replace the battery when there is 10% battery life remaining. If the battery life falls below 10%, the Logger accuracy specifications may be affected.

- If the battery is used up or is removed, the study setup and data, as well as the calibration information, are maintained in non-volatile memory inside the Logger.
- If the battery is used up during a study, the study is terminated at the point the battery failed. Study data to the point of termination is stored in the Logger and can be read once a new battery is installed.

1.1.9 The Logger Battery (cont.)

- If a battery is used up after a study is complete, all study data can be read once a new battery is installed.
- If you change the battery before the study is started, you need to re-program the Logger. Although the setup is maintained in non-volatile memory, the Logger needs to be programmed in order to reset its clock.

1.1.10 Installing the Logger Battery

Kaye ValProbe Loggers are shipped with the battery outside the Logger. The batteries must be installed prior to using the Kaye ValProbe system by completing the following steps:

1. ***Pre-condition the Logger battery:*** If the battery is unused for a prolonged period of time, there may be an internal buildup of oxide. Before installing the battery, this oxide buildup needs to be removed by placing the battery in the *Battery Conditioner* for three minutes.

IMPORTANT:*Do not leave the battery in the Battery Conditioner for more than three minutes, as it will begin to discharge and thereby shorten the expected battery life.*

2. ***Open the Logger:***

- a. Slide the Logger opener over the probe tip and onto the top of the Logger. The Logger opener (included in the Battery Replacement Kit) is provided to make it easier to unscrew the bottom cup. You may also unscrew the Logger by hand.
- b. Unscrew the bottom cup while holding the opener firmly against the probe base.

1.1.10 Installing the Logger Battery (cont.)



Figure 11: Canister-Style . . . and . . . Clip-Style Holders

3. **Install the Logger battery:** Instructions for installing the battery differ depending on your Logger model (Figure 11 above shows the two types of battery holders). To install the new battery, follow the instructions for your model.

- **Canister-Style Holder**

- Insert the new pre-conditioned battery into the battery canister, with the negative (-) terminal on top (facing the battery cap).
- Place the cap on the canister by lining up the tabs on the cap with the clips on the top of the canister.
- Push down and turn the cap clockwise to secure the cap to the canister. A small red LED on the top edge of the board should blink three times to reset the Logger.

Note: *The Cryo Logger LED will blink after ~25 sec after battery insertion. See Figure 12 on the next page for the LED location.*

- Replace the Logger cover and finger-tighten until the cup O-ring is no longer visible.

1.1.10 Installing the Logger Battery (cont.)

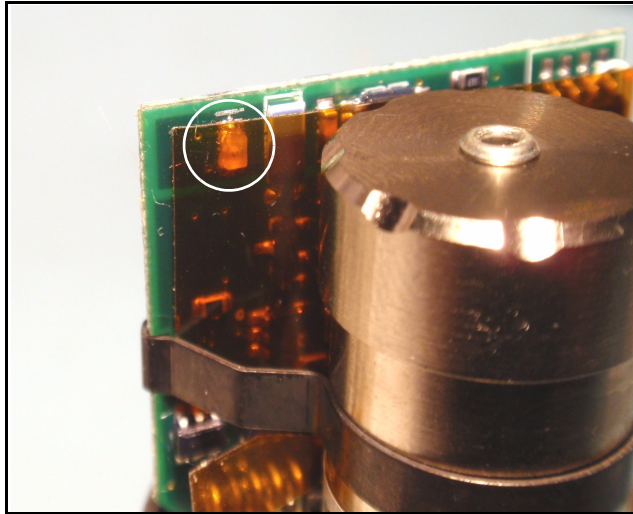


Figure 12: Location of Cryo Logger LED

- **Clip-Style Holder**
 - a. Insert the new pre-conditioned battery into the battery holder. The board is marked to show the + terminal.
 - b. Once the battery is installed, lift and release the top clip of the battery holder. A small red LED on the top edge of the board should blink three times to reset the Logger.
 - c. Replace the Logger cover and finger-tighten until the cup O-ring is no longer visible.
- 4. **Set the battery life indicator:** The Kaye ValProbe software calculates the percentage of battery life left in a Logger and issues a low battery warning when a Logger's battery life is below a user-defined percentage. After installing the Logger battery, you must set the battery indicator to 100% in order for the software to calculate the life of the battery (see Chapter 2 for instructions on installing the software). If you do not specify a percentage, the low battery warning is set to 10%. You can change this setting on the Preferences screen.

1.1.10 Installing the Logger Battery (cont.)

- a. Start the Kaye ValProbe software.
- b. From the Hardware screen, click a Logger icon.
- c. When the Logger Information screen displays, click Change Battery.
- d. If user identification is required, enter your user ID and password when prompted and click OK. A System Administrator user ID and password are required to set the battery life indicator, unless the System Administrator has enabled the Allow Operators to Change Preferences site option.
- e. Click OK when prompted to use only a factory-specified battery.

Note: *The factory-specified battery has been tested for temperatures greater than 85°C and is certified for intrinsic safety applications. The use of non factory-specified batteries will void the warranty and may damage the Logger and/or cause burns to the operator.*

- f. Click OK when prompted that the battery change has been noted in the Logger.
- g. Click OK to return to the Hardware screen.

1.1.11 Replacing the Logger Battery

To replace a fully-discharged or defective battery, complete the following steps:

Note: *Replacement batteries, a Logger opener, O-rings, EtO compatible O-ring grease, and a Battery Conditioner are included in the Battery Replacement Kit (Part Number V2549).*

1. **Pre-condition the Replacement battery:** If the battery is unused for a prolonged period of time, there may be an internal buildup of oxide. Before installing the battery, this oxide buildup needs to be removed by placing the battery in the *Battery Conditioner* for three minutes.

IMPORTANT: *Do not leave the battery in the Battery Conditioner for more than three minutes, as it will begin to discharge and thereby shorten the expected battery life.*

1.1.11 Replacing the Logger Battery (cont.)

2. *Remove the existing O-ring and battery:*

CAUTION! To ensure that the Logger maintains its waterproof and pressure-tight seal, a thin coat of grease was applied to the O-ring during assembly. The grease material is KRYTOX® GL-203, and safe handling and storage practices should be followed. KRYTOX is a registered trademark of DuPont Chemicals. The Material Safety Data information is available from DuPont Chemicals.

- a. Slide the Logger opener over the probe tip and onto the top of the Logger. The Logger opener (included in the Battery Replacement Kit) is provided to make it easier to unscrew the bottom cup. You may also unscrew the Logger by hand.
 - b. To remove the O-ring, lift it from the groove and slide off in the direction of the probe tip.
3. To remove the battery, use one of the following options depending on your style of battery holder (see Figure 11 on page 22 to identify your holder style):
- a. **For Canister-Style Battery Holders:** Push down on the top cap of the battery canister and turn it counter-clockwise to release it. Then remove the cap and remove the battery from the canister.
 - b. **For Clip-Style Battery Holders:** Expand and release the battery retention clips to break the adhesion, and then remove the battery from its holder.

WARNING! When disposing of the old battery, you must comply with all local, state, and federal environmental regulations for the proper disposal of lithium batteries.

4. ***Install the Replacement O-ring:*** Whenever you open a Logger, you need to replace the cup O-ring to ensure that the Logger maintains its seal. There are two types of O-rings included in the battery replacement kit:
- Use O-ring # **K0376** for Humidity Loggers, Pressure Loggers, Temperature Loggers with the clip-style battery holder, and Temperature Loggers that have been retrofit with the battery canister. Retrofit Temperature Loggers will **not** have the ATEX certificate number **ITS03ATEX21490** stamped on the bottom of the Logger.

1.1.11 Replacing the Logger Battery (cont.)

- Use O-ring # **K0385** for Temperature Loggers with the canister-style battery holder as original equipment. These Loggers will have the ATEX certificate number **ITS03ATEX21490** stamped on the bottom of the Logger.
 - a. Before you install a new O-ring, carefully apply a thin coat of grease to all surfaces of the O-ring, making sure not to cut or scratch the O-ring. Do not apply too much grease; the O-ring should have a shiny appearance with no excess grease visible.
 - b. Next, slide the O-ring over the tip end of the probe and into the O-ring groove. Do not stretch or deform the O-ring, and avoid contact with the threads to prevent nicking and/or cutting the O-ring.
 - 5. ***Install the new battery:*** Instructions for installing the new battery differ depending on your Logger model (Figure 1-8 on page 1-19 shows the two types of battery holders). To install the new battery, follow the instructions for your model.
 - ***Canister-Style Holder***
 - a. Insert the new pre-conditioned battery into the battery canister, with the negative (-) terminal on top (facing the battery cap).
 - b. Place the cap on the canister by lining up the tabs on the cap with the clips on the top of the canister.
 - c. Push down and turn the cap clockwise to secure the cap to the canister. A small red LED on the top edge of the board should blink three times to reset the Logger.
- Note:** *The Cryo Logger LED (in the upper left corner of the PCB) will blink after ~25 sec after battery insertion. See Figure 12 on page 23.*
- d. Replace the Logger cover and finger-tighten until the cup O-ring is no longer visible. Clean the exterior of the Logger with a soft cloth to remove any excess lubricant.

1.1.11 Replacing the Logger Battery (cont.)

- *Clip-Style Holder*

- a. Insert the new pre-conditioned battery into the battery holder. The board is marked to show the + terminal.
- b. Once the battery is installed, lift and release the top clip of the battery holder. A small red LED on the top edge of the board should blink three times to reset the Logger.
- c. Replace the Logger cover and finger-tighten until the cup O-ring is no longer visible. Clean the exterior of the Logger with a soft cloth to remove any excess lubricant.

1.1.11 Replacing the Logger Battery (cont.)

6. ***Set the battery life indicator:*** The Kaye ValProbe software calculates the percentage of battery life left in a Logger and issues a low battery warning when a Logger's battery life is below a user-defined percentage. After installing the Logger battery, you must set the battery indicator to 100% in order for the software to calculate the life of the battery (see Chapter 2 for instructions on installing the software). If you do not specify a percentage, the low battery warning is set to 10%. You can change this setting on the Preferences screen.
 - a. Start the Kaye ValProbe software.
 - b. From the Hardware screen, click a Logger icon.
 - c. When the Logger Information screen displays, click Change Battery.
 - d. If user identification is required, enter your user ID and password when prompted and click OK. A System Administrator user ID and password are required to set the battery life indicator, unless the System Administrator has enabled the Allow Operators to Change Preferences site option.
 - e. Click OK when prompted to use only a factory-specified battery.
- Note:** *The factory-specified battery has been tested for temperatures greater than 85°C and is certified for intrinsic safety applications. The use of non factory-specified batteries will void the warranty and may damage the Logger and/or cause burns to the operator.*
- f. Click OK when prompted that the battery change has been noted in the Logger.
 - g. Click OK to return to the Hardware screen.

1.1.12 Calibration

1.1.12a Calibration Data Storage

Calibration data, including calibration constants, offsets, and when the calibration was performed and by whom, are stored in the Logger in non-volatile memory. The data remains intact even if the battery is exchanged.

1.1.12b Verifying Calibration

The Kaye ValProbe software allows you to verify Logger calibration at one or two setpoints. For Humidity/Temperature and Pressure/Temperature Loggers, each sensor type must be verified independently. You will want to verify that the Loggers are within their calibration criteria before running a study, however, you do not need to recalibrate them. Since Kaye ValProbe is a self-contained instrument, the sensor and instrument errors are accounted for during factory calibration.

The following section provides an overview of verifying Logger calibration. The online Help that comes with the Kaye ValProbe software provides step-by-step instructions on calibration procedures.

1.1.12c Measurement Range and Accuracy Specifications

The Kaye ValProbe Loggers are calibrated to the following accuracy specifications for one year:

Table 7: Logger Calibration Accuracy Specifications

Measurement Range	Accuracy
<i>Temperature Loggers</i>	
0°C to 140°C	±0.1°C
0°C to -45°C	±0.25°C
<i>Cryo Loggers</i>	
0°C to 140°C, -85°C to 0°C	±0.1°C ±0.25°C
<i>Bendable Temperature Loggers with Insulating Canister</i>	
-80°C to -45°C	±0.35°C
140°C to 250°C	±0.2°C
250°C to 360°C	±0.5°C
<i>Humidity/Temperature Loggers</i>	
25% to 85% RH (non-condensing)	±2% RH at 25°C and 40°C (EMD4000) ±2% RH at 25°C (EMD3000)
EMD4000 0 to 55°C (with RH Sensor) 0 to 95°C (without RH Sensor) EMD3000 20 to 30°C (with RH Sensor) 0 to 95°C (without RH Sensor)	±0.1°C
<i>Pressure Loggers</i>	
0°C to 120°C	±25 mb
120°C to 135°C	±10 mb
135°C to 140°C	±25 mb

1.1.12d Required Equipment

When verifying sensor calibration, you must consider the measurement uncertainty of the equipment you are using in combination with the uncertainty of the equipment used by GE Measurement & Control Solutions to calibrate the Loggers at the factory.

For example, if you verify calibration for a Logger's humidity sensor using a calibration chamber with a measurement uncertainty of $\pm 1.5\%$ RH, and the GE chamber has a measurement uncertainty of $\pm 1.0\%$ RH, you may obtain a deviation greater than the 2.0% RH specified by the factory as the accuracy of the sensor.

The Certificate of Calibration that was shipped with each Logger provides detailed information about the equipment used by the factory to calibrate the Loggers, including the measurement uncertainty. The Humidity/Temperature Loggers are shipped with two certificates, one for each sensor.

The equipment required to accurately verify calibration for each sensor type is listed below.

Temperature Sensors

In order to verify that the temperature sensors in the Loggers are within the 0.1°C calibration accuracy, the total system measurement uncertainty for the calibration equipment must be better than 33mK (0.033°C) in order to achieve a 3:1 measurement uncertainty ratio. The following equipment is required to perform calibration verification:

- IRTD model 400 (25mK)
- Temperature bath with the following stability and uniformity specifications:

Table 8: Temperature Bath Specifications

Bath Stability	Bath Uniformity
7mK	7mK

High Temperature Calibration Verification

Bendable Temperature Loggers used with the Insulating Canister for high temperature studies can be verified at setpoints above 140°C. The Logger should be removed from the Insulating Canister for the calibration verification process.

Safety measures should be taken to ensure that the Logger base does not exceed 140°C. The Logger probe should be submerged in a temperature bath to a depth of at least 3.5 inches. Place a heat shield between the bath and the Logger base, and position the Logger base at least 3 inches above the shield.

A temperature bath with the stability and uniformity specifications shown in Table 1-9 below is required for verifying calibration at temperatures from 140°C to 360°C:

Table 9: Temperature Bath Specifications

Bath Stability	Bath Uniformity
0.05°C	0.125°C

Humidity Sensors

In order to verify the RH sensors meet the calibration accuracy specification, the RH Humidity Calibrator must have an error equal to or better than $\pm 1\%$. The following equipment is recommended to perform calibration verification:

- Humidity Calibrator, $\pm 1\%$ accuracy or better
- Salt Solutions, traceable to $\pm 1\%$ accuracy or better

Pressure Sensors

In order to verify the pressure sensors meet the calibration accuracy specification, the pressure calibration equipment must have an accuracy of 0.15% full scale (of 5 bar) or better.

1.2 The Kaye ValProbe Readers

The Kaye ValProbe **Standard Reader** serves as the interface between multiple Loggers and the Kaye ValProbe system software. The Standard Reader, connected to your computer using a standard RS-232 serial port, programs and collects data from up to 10 Loggers at a time, to a maximum of 100 Loggers or 200 sensors. Its rugged, durable design ensures reliable transfer of critical data (see Figure 13 below).

Note: *Allow enough time for the Loggers to return to room temperature before inserting them into the Reader.*

Loggers should be wiped clean before inserting them into the Reader. Do not insert damp Loggers into the Reader.

The Reader is powered from a direct line connection rated to the nominal 90–260VAC, 50–60Hz. Connect the Reader to a grounded AC power source, using the supplied polarized power cord. Standard Reader operation is unaffected by a line outage of < 30ms.

An updated version of the Reader, the **ValProbe Reader 2** (x2551), connects to a PC via either a standard RS232 serial port or a USB port (but not via both at once). It also programs and collects data from up to 100 Loggers per study. Up to 10 Loggers can be programmed or read at a time by placing them in the Reader 2 sockets.

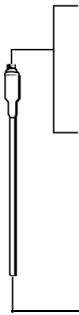


Figure 13: Kaye ValProbe Standard Reader

1.2.1 Connection Ports

The backs of the Readers have connection ports for electrical and communication connections. Each connection port is labeled with an icon representing its function.

CAUTION! Make sure the Reader is powered off before making any connections.



RJ11 Connector

There are three 6-pin RJ11 connectors, labeled with an IRTD icon, on the Standard Reader for connecting the IRTD. (On the Reader 2, there are two RJ11 connectors.) The IRTD temperature measurement standard is a self-contained measurement system providing temperature data directly to the Kaye ValProbe software during calibration and calibration verification.

Connect the IRTD to one of the RJ11 sockets, using the M2810 cable supplied with the IRTD.



PC Connector

There is one 9-pin D shell subminiature serial communications cable connector, labeled with a PC icon, for connecting a PC or notebook.

Connect your PC to the 9-pin port, using the 9 to 9-pin W1890-1 cable. If necessary, use a 9 to 25-pin adapter at the PC. See Chapter 2 for PC requirements.

USB PC Connector



One USB PC connector, labeled with a USB icon, is available on the Reader 2 for connecting a PC or other device.

1.2.2 The Kaye ValProbe Single Reader

The Kaye ValProbe Single Reader serves as the interface between individual Loggers and the Kaye ValProbe system software. Intended for studies using a small number of Loggers, the Single Reader can perform many of the same functions as the Standard Reader and Reader 2. Its portable design requires no dedicated AC power source, and it communicates with a PC or laptop by serial or USB connection.

Note: *To communicate with the Single Reader using the USB connection, Windows Vista or Windows XP is required.*

The Kaye ValProbe software CD includes the USB driver for the Single Reader. Install the software before connecting the Single Reader to your PC or laptop.

To ensure proper communication with the Single Reader, the maximum recommended length for the USB cable is 16 feet.



Figure 14: Kaye ValProbe Single Reader

1.2.2 The Kaye ValProbe Single Reader (cont.)

The Reader model is selected on the Preferences screen of the Kaye ValProbe software. The Standard Reader is selected by default.

Because the Single Reader does not have a connection port for the IRTD, user calibration or calibration verification for temperature sensors can only be performed using the Standard Reader or Reader 2.

1.3 Additional Items

1.3.1 Setting the Kaye ValProbe Time and Date

When the Kaye ValProbe software programs the Loggers, the current time and date are automatically transferred from your computer to the Logger. No action on your part is required.

1.3.2 Cleaning the Kaye ValProbe Reader

To clean the Kaye ValProbe Standard Reader, Reader 2 and/or the Kaye ValProbe Single Reader, the factory recommends that you use only a soft, dry cloth.

1.3.3 Transporting and Shipping the Kaye ValProbe Reader

To ship the Kaye ValProbe Standard Reader and Reader 2, use a safe and durable container padded on all sides with four inches of cushioning filler.

To ship the Kaye ValProbe Single Reader, use a safe and durable container padded on all sides with two inches of cushioning filler.

If you need to return the Kaye ValProbe Single Reader to the factory for service, contact Customer Service for a Return Materials Authorization (RMA) Number before you ship. Include the RMA number with the instrument.

1.3.4 The IRTD 400

The IRTD 400 (M2801) temperature measurement standard is a self-contained measurement system providing temperature data directly to the Kaye ValProbe software during temperature sensor calibration and calibration verification. The measurement accuracy is NIST-traceable to 0.025°C, with a range of –196°C to 420°C.

The IRTD provides a traceable standard that is used to calibrate Kaye ValProbe Loggers and to verify Logger calibration. During the calibration and calibration verification process, the Kaye ValProbe software automatically reads and monitors the value of the IRTD probe.

The IRTD probe is shipped from the factory with its baud rate set to 9600 and its address set to 01. The Kaye ValProbe software communicates with IRTD probes with addresses 01 or 02. However, if two or more IRTD probes are set to 01, the software displays a communications error. The software also reports a communications error if an IRTD is disconnected from the unit during the calibration or the verify calibration process.

Chapter 2. Installing and Using the Software

2.1 Introduction

Before using the Kaye ValProbe system, you will need to install the Kaye ValProbe software on your PC and perform some basic system administration tasks.

The Kaye ValProbe software provides the interface to the Kaye ValProbe Loggers, via the Kaye ValProbe Reader, and enables you to program multiple Loggers with their start/stop events and sample rate, and then collect the data after a qualification study for calculation, processing and reporting. The Kaye ValProbe software verifies and transfers the collected data to a secure data file. The data file, which meets the requirements of 21 CFR Part 11, is then used to create reports that document the study results. The software is also used to verify Logger calibration, and to perform periodic calibrations.

2.1.1 Overview

In this chapter you will:

- Install the Kaye ValProbe software on your PC.
- Start the software and log in to the Password Maintenance utility using the default System Administrator account.
- Create System Administrator and Operator accounts.
- Set site options.
- Select the Communications Port.
- Access the online Help.

2.1.2 PC Requirements

To run the Kaye ValProbe Windows-based software, your PC should meet the following minimum requirements:

- Pentium 800 MHz processor speed and 256 MB RAM.
- Microsoft Windows 7, Windows 2000, Windows Vista, or Windows XP.
- Microsoft Office 2000 (Word 9.0, Excel 9.0, SR-1/a), or Office XP, Office 2003, Office 2007 or Office 2010
- One unused serial port for communicating with the ValProbe Reader (do not configure any other programs, e.g., electronic pocket organizers, to use the same serial communications port you have selected to communicate with the ValProbe Reader). A USB serial port may be used for the Reader 2, and a USB serial port adapter may be used for the Standard Reader if your PC does not have an available serial port.
- One PC serial port or USB port if connecting to a ValProbe Single Reader or Reader 2.
- 100 MB free disk space.
- Internet Explorer 4.0 or later (5.0 or later recommended).

In addition, the following equipment is recommended for optimal use of the ValProbe system:

- Windows printer with graphical printer capability.
- Adobe Acrobat 5.0, with Acrobat PDFWriter installed, to convert report files to Portable Document Format (PDF) files.

2.2 Installing the Kaye ValProbe Software

Before you install the software, close any applications that may be running.

1. Insert the Kaye ValProbe CD into your CD-ROM drive.
2. If your system is not configured to automatically start the CD, complete the following steps:
 - a. Click **Start** on the Windows task bar, click **Run**, and then click **Browse**.
 - b. From the Browse dialog box, select your CD-ROM drive, click **setup.exe**, and then click **Open**. Click **OK**.
3. The Setup program prompts you through the installation process. Follow the on-screen instructions to complete the installation.

Note: *If you are installing the software into a directory other than the default path, double-click on the destination folder and then click **OK**.*

2.3 Starting the Kaye ValProbe Software

The Kaye ValProbe software includes a Password Maintenance utility that allows a user with System Administrator permission to create and maintain user accounts, set site options, backup and restore user information, view, print, and maintain the audit trail, and change the machine ID assigned to the PC. All Kaye ValProbe system administration tasks are accomplished through the Password Maintenance utility and logged in the audit trail.

A default System Administrator account is included with the software. You use this account to initially log in to the Password Maintenance utility and create a System Administrator account. The default account is deleted once you create your own System Administrator account. You can then use your own account to perform all your system administration tasks.

2.3 Starting the Kaye ValProbe Software (cont.)

When you start the Kaye ValProbe software for the first time, you will be prompted to enter your company name and log in to the Password Maintenance utility.

1. On the taskbar, click the **Start** button, point to **Programs**, point to **ValProbe** and then click **ValProbe**.

The Registered Company Name screen (shown in Figure 15 below) appears.

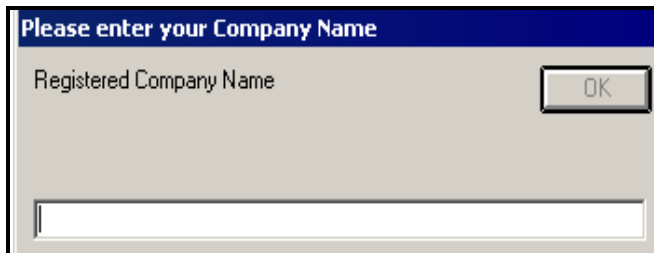


Figure 15: Registered Company Name Screen

2. Enter your company name and click **OK**. The name you enter here displays on all reports.

The System Administrator Log In dialog box appears, as shown in Figure 16 below.

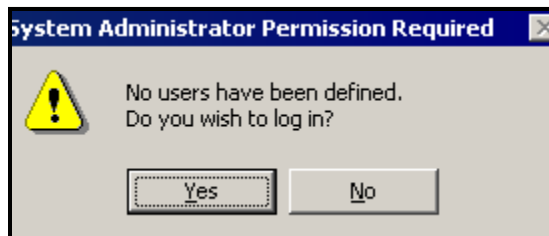


Figure 16: System Administrator Log In Dialog Box

2.3 Starting the Kaye ValProbe Software (cont.)

3. Click **Yes** to log in to the Password Maintenance utility.

Note: *Once you have created your System Administrator account you will no longer see this message when you start up the software. To access the Password Maintenance utility **after** your initial login, press **ALT+S** when the ValProbe splash screen appears, and enter your System Administrator user ID and password in the System Administrator Log In dialog box.*

The Identification Required dialog box appears, as shown in Figure 17 below.

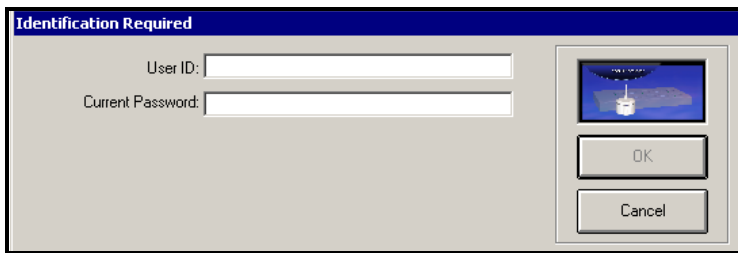


Figure 17: Identification Required Dialog Box

4. Enter **Kaye** in the **User ID** field.

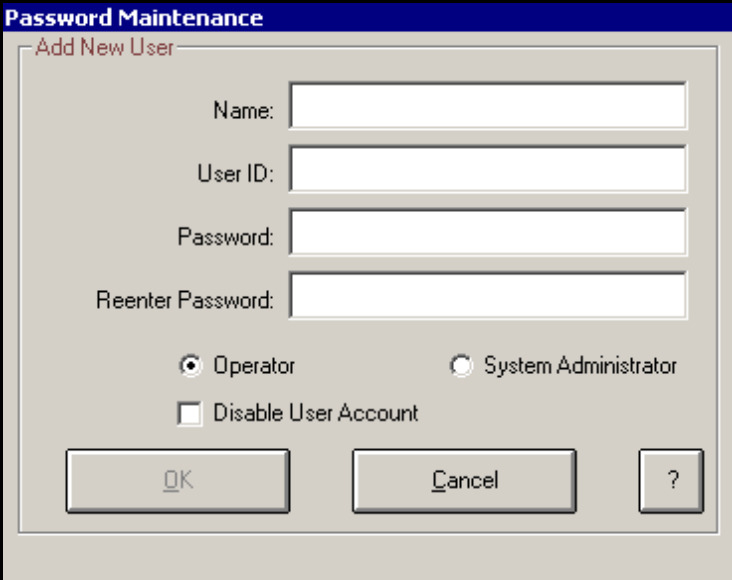
Kaye is the default System Administrator user ID. The user ID field is case sensitive so be sure to enter the default user ID exactly as it appears here.

5. Enter **411** in the **Current Password** field. 411 is the default System Administrator password.

2.3 Starting the Kaye ValProbe Software (cont.)

6. Click OK.

The Password Maintenance Add New User screen appears, as shown in Figure 18 below.



The screenshot shows a dialog box titled "Password Maintenance" with a sub-tab "Add New User". It contains the following elements:

- Four text input fields labeled "Name:", "User ID:", "Password:", and "Reenter Password:".
- Two radio buttons: "Operator" (selected) and "System Administrator".
- A checkbox labeled "Disable User Account".
- Three buttons at the bottom: "OK", "Cancel", and a help button with a question mark.

Figure 18: Password Maintenance Add New User Screen

You are now ready to create your own System Administrator account and add users to the system. The next section provides instruction on creating your new System Administrator account from this screen and adding additional users.

2.4 Creating User Accounts

The Kaye ValProbe software is designed for two levels of users:

System Administrator - Creates and maintains user accounts, sets site options and system preferences, backs up and restores user information, and views, prints, and maintains the audit trail. The System Administrator also performs Logger calibration.

Operator - Programs Loggers, reads Loggers, creates reports, and performs calibration verification. Operators can also change system preferences if the System Administrator has enabled the **Allow Operators to change Preferences** site option.

In this section you:

- Create a new System Administrator account.
- Create Operator accounts.

2.4.1 Creating a New System Administrator Account

The first task you must perform when you log in for the first time is creating a System Administrator account. Once this is accomplished, you can add users (Operators or other System Administrators) to the system and set site options.

The next time you log in to the Password Maintenance utility you will need to enter your own System Administrator user ID and password. The Password Maintenance utility is able to identify you by name using your unique user ID and password combination.

Note: *It is good practice to establish more than one individual as a System Administrator. This way, the Password Maintenance utility functions can still be accessed, even if one of the System Administrators is unavailable.*

Note: *If you want to use the Kaye ValProbe software to program Loggers, read Loggers and generate reports, create an Operator account for yourself using a different name and user ID than your System Administrator account.*

2.4.1 Creating a New System Administrator Account (cont.)

To create a new System Administrator account:

1. The Password Maintenance Add New User screen should be displayed after you logged in to the system for the first time using the default System Administrator account. Enter your name (up to 32 characters) in the **Name** field.

The name you enter here displays in the active user list. User names must be unique. Once you have added your name to the active user list, you can never enter the same name again. Your name is associated with the unique user ID/password combination that you enter in steps 2 and 3. You use this user ID/password combination to log in to the Password Maintenance utility. The user ID and password are case sensitive.

2. Enter your new System Administrator identification in the **User ID** field. Your user ID can be any combination of numbers and characters, up to a maximum of 16. A user ID may not be used by more than one active account.
3. Enter your new System Administrator password in the **Password** field. Your password can be any combination of numbers and characters, up to a maximum of 16. For security reasons, it is preferable to use more than six characters or numbers.
4. Enter your password again in the **Reenter Password** field.

At this point you should record your user ID and password for future reference. You will need them to log in to the Password Maintenance utility. Because this is the first System Administrator account created, the system assumes that this is your account, and you will not need to change the password. However, for any additional System Administrator accounts created, the user will need to change the password when logging in for the first time.

5. The permission level is set to **System Administrator** by default. Click **OK**.

The Password Maintenance (shown in Figure 2-5 on the next page) screen appears. Your new System Administrator account name appears in the active user list.

2.4.1 Creating a New System Administrator Account (cont.)

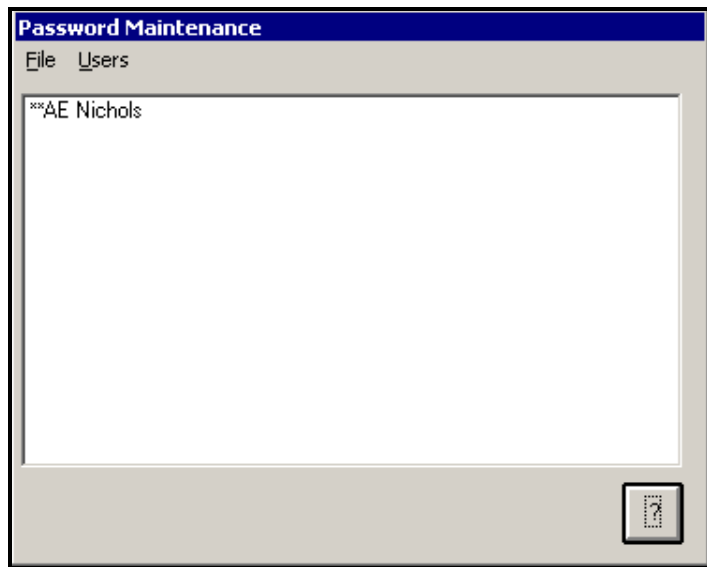


Figure 19: Password Maintenance Screen

Now that you have created your own System Administrator account, you are ready to add user accounts. All Password Maintenance activity you now perform will be recorded in the audit trail under your user name.

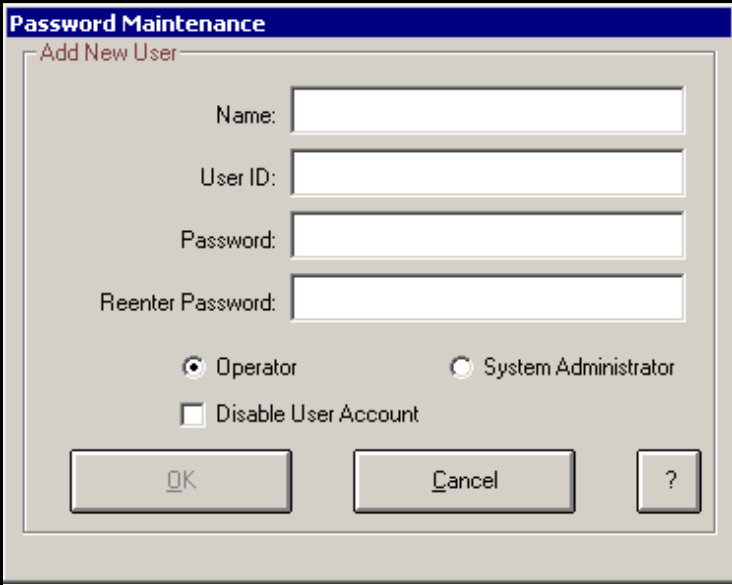
2.4.2 Creating Operator Accounts

When you create user accounts, each user's name is added to the active user list. You assign a unique user ID for each user and a temporary password. The user will change the password when they first login.

To create Operator accounts:

1. On the Password Maintenance screen, click the **Users** menu, and then click **Create User**.

The Password Maintenance Add New User screen (shown in Figure 20 below) appears.



The screenshot shows a dialog box titled "Password Maintenance" with a subtitle "Add New User". It features four text input fields labeled "Name:", "User ID:", "Password:", and "Reenter Password:". Below these fields are three radio buttons: "Operator" (which is selected), "System Administrator", and "Disable User Account" (which is a checkbox). At the bottom of the dialog are three buttons: "OK", "Cancel", and "?".

Figure 20: Password Maintenance Add New User Screen

2. Enter the new user name (up to 32 characters) in the **Name** field.
The user name is associated with the user ID/password combination that you enter in steps 3 and 4. The user ID/password combination is used to identify the user to the Kaye ValProbe software. The name you enter here appears in the active user list.

2.4.2 Creating Operator Accounts (cont.)

Note: *User names must be unique. Once a name has been used, it cannot be used again. You should keep a separate record of all user names that you assign to avoid future problems.*

3. Enter the new user identification in the **User ID** field. The user ID can be any combination of numbers and characters, up to a maximum of 16. The user ID and password are case sensitive. A user ID may not be used by more than one active account.
4. Enter the new user password in the **Password** field. The password can be any combination of numbers and characters, up to a maximum of 16. The user will change this password when they first log in to the Kaye ValProbe software.
5. Enter the password again in the **Reenter Password** field.

At this point you should record the new user ID and password. You will need to supply this information to each new user. A user ID/password combination is required any time a user:

- Programs and/or reads Loggers
 - Verifies sensor calibration
 - Creates reports
 - Moves or copies data files
 - Changes preferences (if the System Administrator has enabled the **Allow Operators to change Preferences** site option)
6. Click **Operator** to set the account's permission level.

2.4.2 Creating Operator Accounts (cont.)

7. The **Disable User Account** option allows you to deny access to the system for this user. For example, if you are creating an account for a user who will not need access to the system for several months, you may want to select this option to deny access to the user. You can de-select this feature once the user is ready to use the system (see the Kaye ValProbe online Help for instructions on editing user accounts).

Select this option if you want to disable the user account.

8. Click **OK**.

The Password Maintenance screen (Figure 21 below) appears with the newly added user name in the active user list.

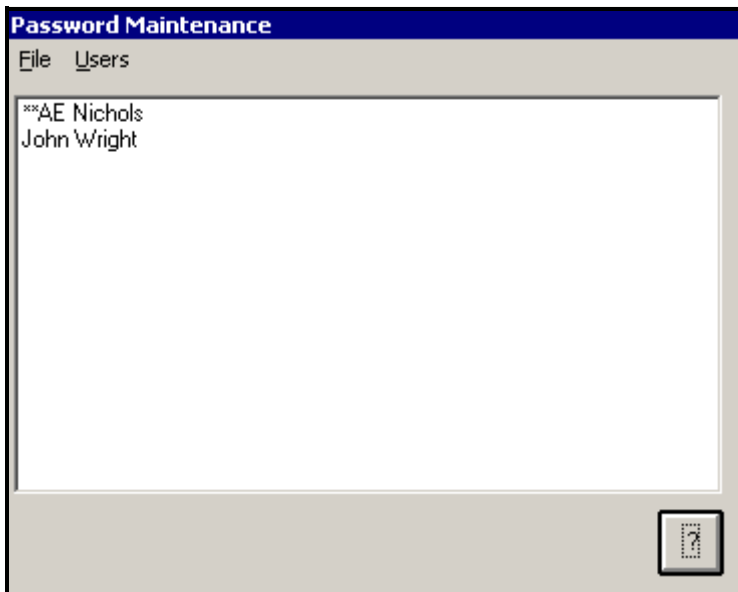


Figure 21: Password Maintenance Screen

9. Repeat steps 1 through 8 to add more users to the system.

2.4.3 Printing the User List

All active and deleted user accounts are included in the printed list.

To print the user list:

1. On the Password Maintenance screen, click the **File** menu, and then click **Print Users**. The Windows Print dialog box appears.
2. Select a printer and click **Print**.
3. Click **OK** when prompted that the user list has been printed.

2.5 Setting Site Options

The Password Maintenance utility provides site options that give users more flexibility while running the Kaye ValProbe software. As the System Administrator, you can select options that will:

- Disable the user identification requirement.

IMPORTANT: *If you disable the user identification requirement, the Kaye ValProbe system does not meet FDA regulations for electronic signatures (21 CFR Part 11). GE Measurement & Control Solutions recommends that you always require user identification.*

- Set passwords to expire after a number of days, up to 366. The user will be prompted to change their password once their current password has expired. By default, passwords are set to expire after 90 days.
- Require minimum-length passwords for all user accounts, from 1 to 16 characters.
- Disable user accounts after three unsuccessful login attempts. This option will disable a user account if there are three consecutive login failures for the same user ID. If a user's account is disabled, the System Administrator must enable the account and assign a new temporary password.

2.5 Setting Site Options (cont.)

- Allow Operators to change Preferences. Preferences are system defaults that specify the temperature units, the pressure units, the communications port, the Reader model, and when to issue low battery warnings. Any changes made to the system preferences are effective immediately, and all setups created after the preferences have been changed will reflect these new settings. If this option is not enabled, the System Administrator is responsible for changing preferences.
- Allow Operators to change the D value in the lethality calculation. This option should be enabled only if your SOP requires a D value other than 1. If this option is not enabled, the D value defaults to 1.

To set site options:

1. On the Password Maintenance screen, click the **File** menu, and then click **Options**. The System Administrator Site Options screen (Figure 22 below) appears.

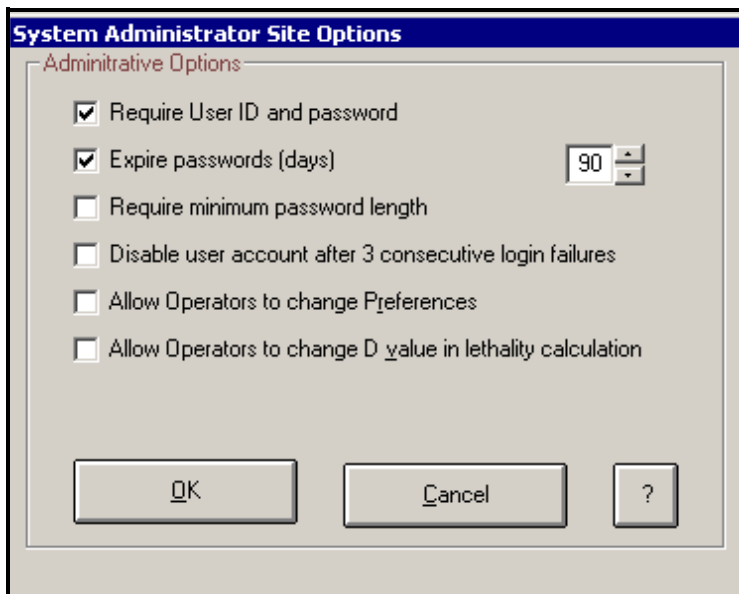


Figure 22: System Administrator Site Options Screen

2.5 Setting Site Options (cont.)

Note: *The System Administrator Site Options screen lists the options that you can set for your site. These options are not mutually exclusive. You can select any combination that your site supports.*

2. Select the check box next to any option to enable that option. To set the number of days until passwords expire, use the spin buttons to set the number of days in 30-day increments, or enter a number from 1 to 366 in the box. To specify a minimum password length, select the *Require minimum password length* option and use the spin buttons to set the password requirement from 1 to 16 characters, or enter the number directly into the box.

To disable an option, clear the associated check box.

3. Click **OK**. The Password Maintenance screen appears.
4. On the **File** menu, click **Exit** to log out of the Password Maintenance utility. The ValProbe Main Menu appears.

2.6 Selecting a Communications Port

The Kaye ValProbe Reader is the communications link between the Kaye ValProbe Loggers and your computer. After installing the Kaye ValProbe software and connecting the Reader to your PC, you must select a communications port in order for the Reader to communicate with your PC.

To select a communications port:

1. On the Kaye ValProbe Main Menu, click the **Preferences** tab. The Change Preferences (Figure 23 below) dialog box appears.

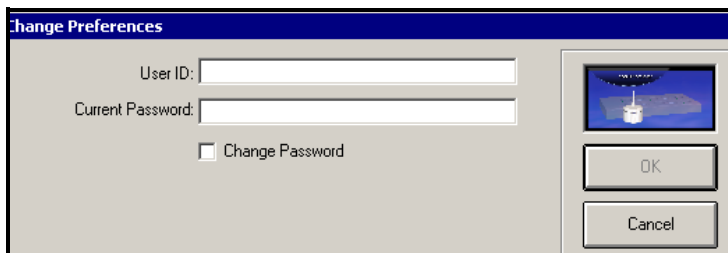


Figure 23: Change Preferences Dialog Box

2.6 Selecting a Communications Port (cont.)

2. Enter your System Administrator user ID and password and click **OK** (you can use an Operator user ID and password if the **Allow Operators to change Preferences** site option is enabled).

The Preferences screen (Figure 24 below) appears.

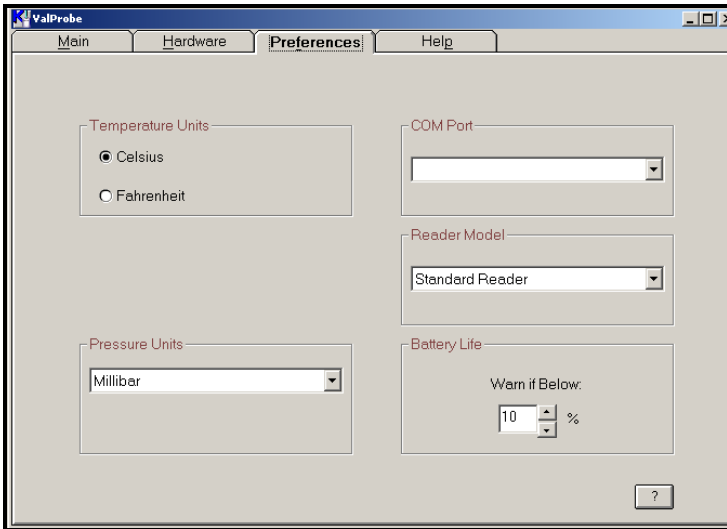


Figure 24: Preferences Screen

3. If the Standard Reader or Reader 2 is connected to the PC, first select the reader model, and then select a communications port from the **COM Port** list. The Standard Reader is the default Reader Model selection. (The USB port appears on the list if it is connected to the Reader 2.)
4. If the Single Reader is connected to the PC, first select the Single Reader as the Reader Model, and then select a communications port from the **COM Port** list. Click the **Main** tab to accept the changes and automatically reboot the system.

2.6 Selecting a Communications Port (cont.)

Note: *When using the Single Reader with Windows 2000 or Windows XP, you can connect to your computer using a standard RS-232 serial port or USB. If connected using USB, the available USB ports are added to the COM port list.*

Note: *Do not configure any other devices, e.g., electronic pocket organizers, to use the same communications port you have selected to communicate with the Kaye ValProbe Reader.*

2.7 Accessing the Kaye ValProbe Online Help

The Kaye ValProbe online Help provides step-by-step instructions for using the software, including: programming Loggers, reading Loggers, creating reports, and performing calibration verification.

Note: *The Kaye ValProbe online Help requires Internet Explorer 4.0 or later (5.0 or later is recommended).*

To access online Help:

- With the Kaye ValProbe program running, click the **Help** tab and then click the **Contents and Index** button.

The Kaye ValProbe Help window (shown in Figure 25 below) appears.

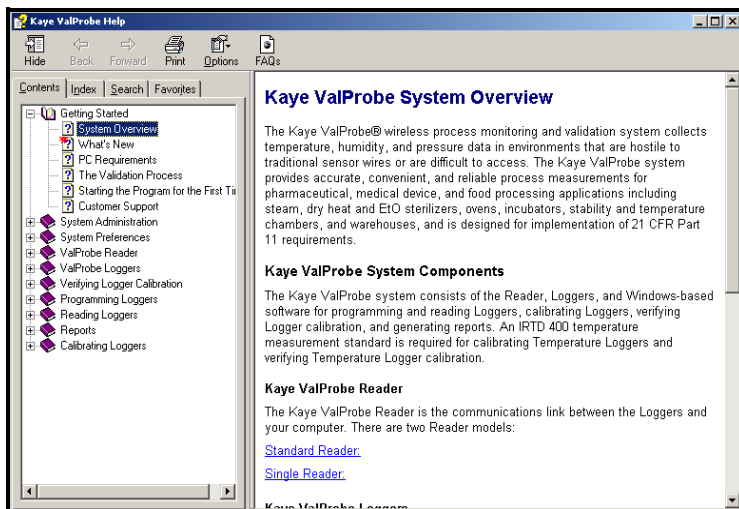


Figure 25: Kaye ValProbe Help Window

2.7.1 Tabs


The following tabs and buttons are available to assist you in navigating Help:

- The **Contents** tab displays the Table of Contents. Click a book to display the pages in that book. Click a page to view the corresponding help topic in the right-hand window.
- The **Index** tab displays the Index. Enter the keyword to search for, select it from the list, and click **Display** to view the associated topic.
- The **Search** tab provides full-text search capabilities. This feature enables you to search the entire Help system for a word or phrase. Enter the word or phrase and click **List Topics**. Select a topic from the list and click **Display**. The word or phrase you searched for will be highlighted in the topic text.
- The **Favorites** tab enables you to store a list of your favorite or most frequently used Help topics. Whenever you open Help, you can quickly go to the topics you view most often by selecting them from this tab. When a topic you would like to store in the favorites list is displayed in the right-hand pane, click **Add**. You can update the list at any time by removing topics you no longer want to mark as favorites.

2.7.2 Buttons

- The **Show/Hide** buttons show or hide the left pane of the Help window. When you access Help for individual screens within the Kaye ValProbe software, you can use the **Show** button to access the **Contents**, **Index**, **Search**, and **Favorites** tabs. Use the **Hide** button to view a topic only and provide more room on your screen.
- The **Back** button returns you to the previously viewed Help topic.
- The **Forward** button opens the next topic in a previously viewed sequence.
- The **Print** button prints the current Help topic to your default printer.
- The **Options** button opens a menu that provides access to the **Show/Hide**, **Back**, **Forward**, and **Print** features, in addition to:
 - **Home** - Links to the website.
 - **Stop** - Stops loading a new topic or stops downloading information (click this option to stop a Web page from opening).
 - **Refresh** - Updates the topic content displayed in the topic pane.
 - **Search Highlight On/Off** - When this option is enabled (default setting), words entered using the **Search** feature are highlighted in the topic text
- The **FAQ's** button provides a link to the Kaye ValProbe Frequently Asked Questions page. Use this link if you have a question about your Kaye ValProbe system and are unable to find the answer in the online Help. The FAQ's are continuously updated with answers to common questions.

2.7.3 Screen-Level Help

You can also access online Help for individual screens in the Kaye ValProbe software by clicking the  button in the lower right corner of the screen, or by pressing **F1**.

Appendix A. Specifications

A.1 Kaye ValProbe System

A.1.1 Pollution Degree:

Pollution Degree 2

A.1.2 Installation Category:

overvoltage Category II, indoor use, maximum altitude up to 2,000 m

A.2 Kaye ValProbe Standard Reader

A.2.1 Power:

90 to 260 VAC $\pm 10\%$, 50/60 Hz, 0.5 A rms maximum

A.2.2 Environmental:

Temperature: 0 to 50°C

Relative Humidity: 0-95%, non-condensing

A.2.3 Fuse Type and Rating:

250 VAC, T500 mA

A.2.4 Regulatory Compliance:

CE, UL

A.3 Kaye ValProbe Reader 2

A.3.1 Power:

90 to 260 VAC \pm 10%, 50/60 Hz, 0.5 A rms maximum

A.3.2 Environmental:

Temperature: 0 to 50°C

Relative Humidity: 0-95%, non-condensing

A.3.3 Fuse Type and Rating:

250 VAC, T500 mA

A.3.4 Regulatory Compliance:

CE, UL

A.4 Kaye ValProbe Single Reader

A.4.1 Power:

RS232: -25 to +25 V, 7 mA

USB: 5 V, 6 mA

A.4.2 Environmental:

Temperature: 10 to 45°C

Relative Humidity: 5 to 85%, non-condensing

A.4.3 Regulatory Compliance:

CE, UL

A.4 Kaye ValProbe Temperature Logger

A.4.1 Measurement Accuracy:

±0.25°C from -45 to 0°C
±0.1°C from 0 to 140°C
±0.2°C from 140 to 250°C
±0.5°C from 250 to 360°C

A.4.2 Environmental:

Temperature: -45 to 140°C
Humidity: 0 to 100%, condensing
Pressure: 0 to 10 bar absolute

A.4.3 Regulatory Compliance:

CE, UL

A.4.4 EEx ia IIC T3 X:

Intrinsically Safe (SECURITE INTRINSEQUE) – level of protection “ia”, for use in Group IIC atmospheres and is assigned a T3 temperature code based on an ambient temperature range of -45 to 140°C

A.4.5 II 1G - Certificate Number ITS03ATEX21490:

Meets the requirements of ATEX directive 94/9/EC for Category I equipment for use in Group II gaseous atmospheres

A.4.6 Sensing Element:

precision platinum RTD

A.4.7 Sampling Rate:

1 sec to 12 hrs

A.4.8 Data Storage:

10,000 samples

A.4.9 Real Time Clock Accuracy:

15 sec per 24 hr (0.0174%) from -45 to 140°C

A.5 Kaye ValProbe Dual Temperature Logger

A.5.1 Measurement Accuracy:

±0.25°C from -45 to 0°C

±0.1°C from 0 to 140°C

A.5.2 Environmental:

Temperature: -60 to 140°C

Humidity: 0 to 100%, condensing

Pressure: 6 Pa to 10 bar absolute

A.5.3 Regulatory Compliance:

CE, UL

A.5.4 EEx ia IIC T3 X:

Intrinsically Safe (SECURITE INTRINSEQUE) – level of protection “ia”, for use in Group IIC atmospheres and is assigned a T3 temperature code based on an ambient temperature range of -45 to 140°C

A.5.5 II 1G - Certificate Number ITS03ATEX21490:

Meets the requirements of ATEX directive 94/9/EC for Category I equipment for use in Group II gaseous atmospheres

A.5.6 Sensing Element:

precision platinum RTD

A.5.7 Sampling Rate:

1 sec to 12 hrs

A.5.8 Data Storage:

10,000 samples per sensor retained in EEPROM memory

A.5.9 Real Time Clock Accuracy:

15 sec per 24 hr (0.0174%) from -60 to 140°C

A.6 Kaye ValProbe Humidity/Temperature Logger

A.6.1 Measurement Accuracy:

Operating Range

25% to 85% RH (non-condensing)

EMD4000

0 to 55°C (with RH Sensor),

0 to 95°C (without RH Sensor)

EMD3000

20 to 30°C (with RH Sensor),

0 to 95°C (without RH Sensor)

Accuracy

±2% RH at 25°C and 40°C (EMD4000)

±2% RH at 25°C (EMD3000)

±0.1°C

A.6.2 Environmental:

Temperature: 0 to 95°C

Humidity: 0 to 100%, condensing

Pressure: 0 to 10 bar absolute

A.6.3 Regulatory Compliance:

CE, UL

A.6.4 EEx ia IIC T3 X:

Intrinsically Safe (SECURITE INTRINSEQUE) - level of protection “ia”, for use in Group IIC atmospheres and is assigned a T3 temperature code based on an ambient temperature range of -60 to 140°C

A.6.5 II 1G - Certificate Number ITS03ATEX21490:

Meets the requirements of ATEX directive 94/9/EC for Category I equipment for use in Group II gaseous atmospheres

A.6 Kaye ValProbe Humidity/Temperature Logger (cont.)

A.6.1 Sensing Element:

Temperature: precision platinum RTD

Humidity: reactive polymer

A.6.2 Sampling Rate:

2 sec to 12 hr

A.6.3 Data Storage:

10,000 samples for each sensor type (humidity and temperature)

A.6.4 Real Time Clock Accuracy:

15 sec per 24 hr (0.0174%) from 0 to 95°C

A.7 Kaye ValProbe CryoLogger

A.7.1 Sensing Element:

Precision Platinum RTD

A.7.2 Measurement Range and Accuracy:

0°C to 140°C, $\pm 0.1^\circ\text{C}$

-85°C to 0°C, $\pm 0.25^\circ\text{C}$

A.7.3 Environmental:

Temperature -85°C to 140°C

Humidity 0% to 100% humidity, condensing

Pressure 0 to 10 bar absolute (0 to 130 psia)

A.7.4 Logger Material:

316L stainless steel

A.7.5 Logger Base Dimensions:

1 13/16 in x 1 3/8 in diameter (46 mm x 35 mm)

A.7.6 Battery:

Field-replaceable 3.6 V lithium thionyl chloride

5500 hours at 10 sec at 20°C / 550 hours at 10 sec at -85°C

A.7.7 Sampling Rate:

1 second to 12 hours

A.7.8 Data Storage:

10,000 samples retained in non-volatile EEPROM memory

A.7.9 Calibration:

Factory calibrated (NVLAP accredited) with user calibration capability

A.7.10 Real Time Clock Accuracy:

20 seconds per 24 hours (0.0174%)

A.7.11 Regulatory Compliance:

UL and CE

A.7.12 Specific Probe Length:

1 1/2 inch (38 mm); 3 inch (76 mm) rigid

A.8 Kaye ValProbe Pressure Logger

A.8.1 Pressure Measurement Range:

0 to 5 bar absolute from 0 to 140°C, certified to 10 bar over pressure

A.8.2 Measurement Range Accuracy:

±25 mbar from 0 to 120°C

±10 mbar from 120 to 135°C

±25 mbar from 135 to 140°C

A.8.3 Environmental:

Temperature: 0 to 140°C

Humidity: 0 to 100%, condensing

Pressure: 0 to 10 bar absolute

A.8.4 Regulatory Compliance:

CE, UL

A.8.5 EEx ia IIC T3 X:

Intrinsically Safe (SECURITE INTRINSEQUE) - level of protection “ia”, for use in Group IIC atmospheres and is assigned a T3 temperature code based on an ambient temperature range of -60 to 140°C

A.8.6 II 1G - Certificate Number ITS03ATEX21490:

Meets the requirements of ATEX directive (94/9/EC) for Category I equipment for use in Group II gaseous atmospheres

A.8.7 Sensing Element:

Pressure: piezo resistive mems

Temperature: precision platinum RTD (for pressure measurement compensation)

A.8.8 Sampling Rate:

1 sec to 12 hr

A.8.9 Data Storage:

10,000 samples

A.8.10 Real Time Clock Accuracy:

15 sec per 24 hr (0.0174%) from 0 to 140°C

A.9 Kaye ValProbe Pressure/Temperature Logger

A.9.1 Measurement Accuracy:

Temperature: $\pm 0.1^{\circ}\text{C}$ from 0 to 140°C

Pressure: ± 25 mbar from 0 to 120°C

± 10 mbar from 120 to 135°C

± 25 mbar from 135 to 140°C

A.9.2 Environmental:

Temperature: 0 to 95°C

Pressure: 0 to 10 bar absolute

A.9.3 Regulatory Compliance:

CE, UL

A.9.4 EEx ia IIC T3 X:

Intrinsically Safe (SECURITE INTRINSEQUE) - level of protection “ia”, for use in Group IIC atmospheres and is assigned a T3 temperature code based on an ambient temperature range of -60 to 140°C

A.9.5 II 1G - Certificate Number ITS03ATEX21490:

Meets the requirements of ATEX directive 94/9/EC for Category I equipment for use in Group II gaseous atmospheres

A.9.6 Sensing Element:

Temperature: precision platinum RTD

Pressure: piezo resistive mems

A.9.7 Sampling Rate:

2 sec to 12 hr

A.9 Kaye ValProbe Pressure/Temperature Logger (cont.)

A.9.1 Data Storage:

5,000 samples for each sensor type (pressure and temperature)

A.9.2 Real Time Clock Accuracy:

15 sec per 24 hr (0.0174%) from 0 to 95°C

A.10 Battery

A.10.1 Type:

Field-replaceable 3.6 VDC Lithium Thionyl Chloride

A.10.2 Battery Life:

Battery life is affected by a number of factors, including sample rate, temperature, and hours of use. Individual battery capacity can vary from one battery to another by up to 10%. Refer to the online Help for an approximation of the number of runtime hours you can expect from the battery at different sample rates and temperatures.

A.10.3 Shelf Life:

10 years

A.10.4 Transportation Regulations:

Classified as non-restricted (can be shipped by common carrier without special requirements). Batteries should be separated from each other during shipment to prevent shorting.

A.11 Insulating Canister

A.11.1 Size (h x d):

110 mm x 79 mm (4.3 in. x 3.1 in.)

A.11.2 Weight:

0.59 kg (1.3 lb)

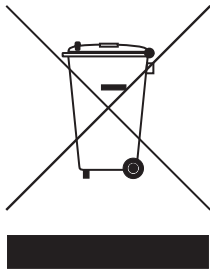
Appendix B. Environmental Compliance

This appendix contains information on the following topics:

- WEEE Directive (see *Section B.1 on page 73*)
- Battery disposal (see *Section B.2 on page 74*)

B.1 Waste Electrical and Electronic Equipment (WEEE) Directive

GE Measurement & Control Solutions is an active participant in Europe's Waste Electrical and Electronic Equipment (WEEE) take-back initiative, directive 2002/96/EC.



The equipment that you bought has required the extraction and use of natural resources for its production. It may contain hazardous substances that could impact health and the environment.

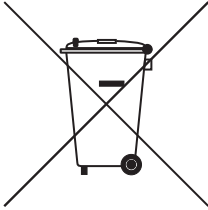
In order to avoid the dissemination of those substances in our environment and to diminish the pressure on the natural resources, we encourage you to use the appropriate take-back systems. Those systems will reuse or recycle most of the materials of your end life equipment in a sound way.

The crossed-out wheeled bin symbol invites you to use those systems.

If you need more information on the collection, reuse and recycling systems, please contact your local or regional waste administration.

Visit www.ge.com/inspectiontechnologies for take-back instructions and more information about this initiative.

B.2 Battery Disposal



This product contains a battery that cannot be disposed of as unsorted municipal waste in the European Union. See the product documentation for specific battery information. The battery is marked with this symbol, which may include lettering to indicate cadmium (Cd), lead (Pb), or mercury (Hg). For proper recycling return the battery to your supplier or to a designated collection point.

B.2.1 What do the Markings Mean?

Batteries and accumulators must be marked (either on the battery or accumulator or on its packaging, depending on size) with the [separate collection symbol](#). In addition, the marking must include the chemical symbols of specific levels of toxic metals as follows:

- Cadmium (Cd) over 0.002%
- Lead (Pb) over 0.004%
- Mercury (Hg) over 0.0005%

B.2.2 The Risks and Your Role in Reducing Them

Your participation is an important part of the effort to minimize the impact of batteries and accumulators on the environment and on human health. For proper recycling you can return this product or the batteries or accumulators it contains to your supplier or to a designated collection point.

Some batteries or accumulators contain toxic metals that pose serious risks to human health and to the environment. When required, the product marking includes chemical symbols that indicate the presence toxic metals: Pb for lead, Hg for mercury, and Cd for cadmium.

- **Cadmium** poisoning can result in cancer of the lungs and prostate gland. Chronic effects include kidney damage, pulmonary emphysema, and bone diseases such as osteomalacia and osteoporosis. Cadmium may also cause anemia, discoloration of the teeth, and loss of smell (anosmia).
- **Lead** is poisonous in all forms. It accumulates in the body, so each exposure is significant. Ingestion and inhalation of lead can cause severe damage to human health. Risks include brain damage, convulsions, malnutrition, and sterility.
- **Mercury** creates hazardous vapors at room temperature. Exposure to high concentrations of mercury vapor can cause a variety of severe symptoms. Risks include chronic inflammation of mouth and gums, personality change, nervousness, fever, and rashes.

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Warranty

Each instrument manufactured by GE Sensing is warranted to be free from defects in material and workmanship. Liability under this warranty is limited to restoring the instrument to normal operation or replacing the instrument, at the sole discretion of GE Sensing. Fuses and batteries are specifically excluded from any liability. This warranty is effective from the date of delivery to the original purchaser. If GE Sensing determines that the equipment was defective, the warranty period is:

- one year for general electronic failures of the instrument
- one year for mechanical failures of the sensor

If GE Sensing determines that the equipment was damaged by misuse, improper installation, the use of unauthorized replacement parts, or operating conditions outside the guidelines specified by GE Sensing, the repairs are not covered under this warranty.

The warranties set forth herein are exclusive and are in lieu of all other warranties whether statutory, express or implied (including warranties or merchantability and fitness for a particular purpose, and warranties arising from course of dealing or usage or trade).

Return Policy

If a GE Sensing instrument malfunctions within the warranty period, the following procedure must be completed:

1. Notify GE Sensing, giving full details of the problem, and provide the model number and serial number of the instrument. If the nature of the problem indicates the need for factory service, GE Sensing will issue a RETURN AUTHORIZATION number (RA), and shipping instructions for the return of the instrument to a service center will be provided.
2. If GE Sensing instructs you to send your instrument to a service center, it must be shipped prepaid to the authorized repair station indicated in the shipping instructions.
3. Upon receipt, GE Sensing will evaluate the instrument to determine the cause of the malfunction.

Then, one of the following courses of action will then be taken:

- If the damage is covered under the terms of the warranty, the instrument will be repaired at no cost to the owner and returned.
- If GE Sensing determines that the damage is not covered under the terms of the warranty, or if the warranty has expired, an estimate for the cost of the repairs at standard rates will be provided. Upon receipt of the owner's approval to proceed, the instrument will be repaired and returned.

We,

**GE Sensing
1100 Technology Park Drive
Billerica, MA 01821
USA**

declare under our sole responsibility that the

Kaye ValProbe™

to which this declaration relates, is in conformity with the following standards:

- EN 60079-0: 2007
- EN 60079-11: 2007
- EN 50281-1-1: 1998
- II 1 G EEx ia IIC T3 (Tamb = -60°C to +140°C); ITS03ATEX21490
(Intertek Testing & Certification Ltd, Leatherhead, Surrey, KT227SB, UK - NoBo 0359)
- EN 61326-1: 2006, Class A, Table 2, Industrial Locations
- EN 61326-2-3: 2006

Other standards used:

- EN 50014: 1997 +A1, A2: 1997
- EN 50020: 2002
- EN 50284: 1999

following the provisions of the 2004/108/EC EMC and 94/9/EC ATEX Directives.

Where products were initially assessed for compliance with the Essential Health and Safety Requirements of the ATEX Directive 94/9/EC using earlier harmonized standards, a subsequent review has determined that "technical knowledge" is unaffected by the current harmonized standards listed above.

Billerica - October 2010

Issued



Mr. Gary Kozinski
Certification & Standards, Lead Engineer



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M5000E Rev. E

