



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

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1.0. OBJECTIVE:

To lay down the procedure for safe and smooth Operation and Calibration of Kaye Validator-2000 system.

2.0 SCOPE:

This SOP is applicable to Kaye Validator 2000.

3.0 RESPONSIBILITY

3.1 Trained Personnel shall be responsible for operation of Kaye Validator.

3.2 Trained Personnel shall be responsible for the calibration of Temperature sensors.

3.3 Assistant Manager and above of QA department shall be responsible for the verification of the equipment operation as per the written procedure.

4.0. ACCOUNTABILITY:

Head QA

5.0 PROCEDURE:

This section describes the steps necessary to:

- Start the Validator 2000 software
- Create/ modify a setup
- Connect the system
- Calibrate sensors
- Run the qualification study
- Verify sensor calibration
- Create reports from study data
- Access the audit trail



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5.1 Starting The Validator 2000 Software

5.1.1 On the taskbar, click the **Start** button, point to **Programs**, point to **Validator 2000**, and then click **Validator 2000**. In case of any major changes in the system, equipment or process.

5.1.2 The Validator 2000 screen appears, followed by the Main Menu. The Main Menu provides access to the major functions of the Validator 2000 software.

5.2 Creating/Modifying a Setup

5.2.1 The setup defines everything required to calibrate sensors, run qualification studies, and verify sensor calibration. The setup is created/modified using the Validator 2000 software. The PC does not have to be connected to the Validator 2000 to create/modify setups. In case of failure in requalification study the non-compliance shall be handled as per the "Handling of Deviation".

5.2.2 Procedure

5.2.2.1 On the Main Menu, click **Define Setups**

5.2.2.2 The File Selection screen appears. Existing setups are listed by the date and time the files were saved.

- To create a new setup, click **New**, enter up to 35 characters to describe the setup, and click **OK**.
- To modify an existing setup, select the setup from the file list and click **OK**.
- The Sensors screen appears.

5.2.2.3 Add, modify or delete sensor definitions as necessary

- Select sensors by clicking a sensor location or clicking and dragging the pointer over multiple sensor locations in the same SIM.
- The Sensor Definition screen appears.
- To add or modify a sensor definition, enter/modify the sensor label and sensor description, and select a sensor type. Specify scale factors as required. To



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automatically number multiple sensor definitions, select both **Automatic Numbering** check boxes to append 2 digits in sequence to the sensor label and description label. Click **OK**.

- To delete sensor location(s), click **Delete**. Click **Yes** when prompted to delete sensors.

5.2.2.4 Identify/modify groups

- Click the **Groups** tab.
- Change group titles or add groups as necessary (up to 4 groups, 35 characters) in the group list box.

5.2.2.5 Assign sensors to groups

- Click the **Sensor Selection** tab (if not already displayed).
- Select a group from the list box.
- Assign sensor locations as necessary.
- Repeat for all groups as necessary.

5.2.2.6 Specify group calculations and events.

- Click the **Calculations** tab.
- Select a group from the list box.
- Specify group calculations as necessary.
- Define the group event (one per group) as necessary.
- Repeat for all groups as necessary.

5.2.2.7 Specify report header information.

- Click the **Report Header** tab
- Select a group from the list box.
- Enter/modify report header information as necessary.
- Repeat for all groups as necessary



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5.2.2.8 Specify calibration parameters.

- Click the **Calibration** tab
- Set the Temperature Set points as necessary.
- Set the Stability Criteria as necessary.
- Set the Deviation Criteria as necessary

5.2.2.9 Specify qualification study conditions.

- Click the **Qualification** tab.
- Click the **Modify** button.
- The Start/Stop Conditions screen appears.
- Set the Start/Stop Conditions as necessary and click **OK**.
- Set the Data Storage File Rate and Validator 2000 Printer Rate as necessary.
- Set the Scan Rate to appropriate rate (8 inputs or 12 inputs per second).
- Set the Output Relay as necessary.

5.2.2.10 Save the setup file.

- Click the **File Topics** tab
- The Setup Files screen appears.
- Click **Save**.
- The Identification Required dialog box appears.
- Enter user ID and password and click **OK**.
- The Save Setup File screen appears.
- For a new setup, enter a new setup file name, or accept current file name.
- For a modified setup, enter a new setup name.
- Click **OK**.
- The Setup Files screen appears



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5.3 Connecting the System

5.3.1 All system connections are on the back of the Validator 2000. Each connection port is labeled with an icon representing its function. Connection ports are as follows:

- 2 IRTD ports (RJ11)
- 1 temperature reference port (RJ11)
- 1 PC serial communications port
- 1 parallel printer port
- 1 Relay NC/NO port

5.3.2 Procedure

5.3.2.1 Make sure the Validator 2000 and the temperature reference are powered off before connecting the system.

5.3.2.2 Insert the IRTD into the temperature reference.

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

5.3.2.4 Connect the temperature reference to one of the RJ11 sockets, using the W1885-1 cable supplied with the temperature reference.

5.3.2.5 Connect the 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.

5.3.2.6 Connect the temperature reference power cable to a grounded power source.

5.3.2.7 Connect the Validator 2000 power cable to a grounded power source.

5.3.2.8 Insert the wired SIMs into the SIM slots. Label each SIM with the associated slot number.

5.3.2.9 Turn the temperature reference power switch to the ON position.

5.3.2.10 Turn the Validator 2000 power switch to the ON position.

5.4 Checking Hardware and Communications Connections





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5.4.1 The Validator 2000 software graphically displays the validation system hardware and communications connections. It is good practice to check communications before starting the validation process.

5.4.2 Procedure

5.4.2.1 Click the **Hardware** tab. Each hardware item is shown with a communication link. A Device Not Found symbol  indicates a communication problem.

5.4.2.2 Click any Device Not Found symbol  to get help for that particular problem.

5.5 PC-Controlled Operation

This section includes procedures for operating the Validator 2000 from the PC. Procedures include sensor calibration, running a qualification study, and verifying sensor calibration.

5.6 PC-Controlled Sensor Calibration

Calibrate sensors before running the qualification study. When performing PC-controlled sensor calibration, all major actions should be performed at the PC.

5.6.1 Procedure

5.6.1.1 Place the Validator 2000 in a location with stable and even temperature, not exposed to any local heat sources (i.e., close to a sterilizer, an open door causing a draft, etc.).

5.6.1.2 Power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.

5.6.1.3 Insert the thermocouple sensors into the temperature reference.

5.6.1.4 At the PC, close all open applications and disable all power-conserve and screen saver features.

5.6.1.5 Start the Validator 2000 software if not already running.

5.6.1.6 Load the setup from the PC into the Validator 2000.

- On the Main Menu, click **Calibrate Sensors**.



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- The File Selection screen appears, listing all setup files in the default data path.
- Select the setup to be used for the qualification study and click **OK**.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.
- The Select Sensors screen appears.

5.6.1.7 Select sensors to calibrate.

- To select individual sensors, click each sensor location.
- To select multiple sensors in the same SIM, click and drag the pointer over the sensor locations.
- To select all sensors in the same SIM, click **Select All**.

5.6.1.8 Calibrate sensors.

- Click **Calibrate Sensors**.
- Click **Yes** when prompted to initiate calibration.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.
- The Validator 2000 automatically performs sensor calibration at the specified set points.
- Click the **Data** tab to display sensor readings and stability and deviation values.
- Click the **Status** tab to view the status of the calibration process.
- When calibration is complete, the program prompts you to add a comment to the calibration file. Click **Yes** to enter a comment, **No** to continue.
- The message "The final data record has been received from the Validator" appears.
- Click **OK**.
- On the Data screen, click **Return**.



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- The Select Sensors screen appears. Calibrated sensors are displayed with a pound sign (#).

5.6.1.9 Return to Main Menu.

- Click the **File Topics** tab.
- The Calibrate Sensors screen appears.
- Click **Main** to return to the Main Menu.

5.7 PC-Controlled Qualification Study

The Validator 2000 can perform PC-controlled qualification studies manually, automatically, or in combination, depending on the start/stop conditions defined in the setup. When performing a PC-controlled qualification study, all major actions should be performed at the PC.

5.7.1 Procedure

5.7.1.1 If not already on, power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.

5.7.1.2 Position sensors in vessel or chamber being tested.

5.7.1.3 At the PC, close all open applications and disable all power-conserve and screen saver features.

5.7.1.4 Start the Validator 2000 software if not already running.

5.7.1.5 Load the setup from the PC into the Validator 2000.

- On the Main Menu, click **Run Qualification**.
- The File Selection screen appears.
- Select the setup and click **OK**.
- The Report Header screen appears.
- Enter/modify report header information for each group as necessary.
- Click the **Qualification** tab.
- Click **Load Setup**.



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- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.
- The Status screen appears.

5.7.1.6 Start the qualification study. If the start condition is defined as Manual:

- Click **Start Qualification Study**.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.

5.7.1.7 View/graph qualification study data. This step can be performed at any time during the qualification study.

- Click the **Status** tab to view group event status.
- Click the **Values** tab to view real-time sensor readings and calculations by group.
- Click the **Messages** tab to view real-time events.
- Click the **Graphs** tab to graph real-time sensor readings and calculations by group.
- Click the **Sensor Offsets** tab to view sensor offsets from the most recent calibration.

5.7.1.8 Start the exposure cycle. If the start condition is defined as Manual:

- Click **Start Exposure Cycle** on the Status screen, or click **Start Exp** on the Values, Messages or Graphs screens.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.

5.7.1.9 Stop the exposure cycle. If the stop condition is defined as Manual:

- Click **Stop Exposure Cycle** on the Status screen, or click **Stop Exp** on the Values, Messages or Graphs screens.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.

5.7.1.10 Stop the qualification study. If the stop condition is defined as Manual:



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- Click **Stop Qualification Study** on the Status screen, or click **Stop Qual** on the Values, Messages or Graphs screens.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.
- When the qualification study has ended, the program prompts you to add a comment to the qualification file. Click **Yes** to enter a comment, **No** to continue.
- The message "The final data record has been received from the Validator" appears. Click **OK**.
- Click **Done** on the Status, Values, Messages or Graphs screens.
- The Qualification screen appears.

5.7.1.11 Return to the Main Menu.

- Click the **File Topics** tab.
- The Run Qualification screen appears.
- Click **Main** to return to the Main Menu.

5.8 PC-Controlled Calibration Verification

Verify sensor calibration after running the qualification study. When performing PC-controlled calibration verification, all major actions should be performed at the PC.

5.8.1 Procedure

- 5.8.1.1 If not already on, power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.
- 5.8.1.2 Insert the thermocouple sensors into the temperature reference.
- 5.8.1.3 At the PC, close all open applications and disable all power-conserve and screen saver features.
- 5.8.1.4 Start the Validator 2000 software if not already running.
- 5.8.1.5 Load the setup from the PC into the Validator 2000.
 - On the Main Menu, click **Calibrate Sensors**.



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- The File Selection screen appears.
- Select the setup used to perform the qualification study and click **OK**.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.
- The Select Sensors screen appears.

5.8.1.6 Select sensors to verify.

- To select individual sensors, click each sensor location.
- To select multiple sensors in the same SIM, click and drag the pointer over the sensor locations.
- To select all sensors in the same SIM, click **Select All**.

5.8.1.7 Verify sensor calibration.

- Click **Verify Calibration**.
- The Identification required dialog box appears.
- Enter user ID and password and click **OK**.
- The Validator 2000 automatically performs calibration verification at the specified set points.
- Click the **Data** tab to display sensor readings and stability and deviation values.
- Click the **Status** tab to view the status of the calibration verification process.
- When calibration verification is complete, the program prompts you to add a comment to the calibration verification file. Click **Yes** to enter a comment, **No** to continue.
- The message "The final data record has been received from the Validator" appears.
- Click **OK**.
- On the Data screen, click **Return**.
- The Select Sensors screen appears.

5.8.1.8 Return to the Main Menu.



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- Click the **File Topics** tab.
- The Calibrate Sensors screen appears.
- Click **Main** to return to the Main Menu.

5.9 Generating Reports

Reports are generated from secure data files that can only be read by the Validator 2000 software. Reports are not saved; you create reports each time from the secure data files. You can generate Setup, Calibration, Qualification, and Calibration Verification Reports to document the specifics of your validation study. If Adobe Acrobat Version 5.0 with Acrobat PDF Writer is installed on your PC, you can create Portable Document Format (PDF) files from the study data.

5.10 Generating Setup Reports

Setup Reports can be generated individually or as part of the Qualification Report set if the setup file was used for a qualification study. This section documents the procedure for generating an individual Setup Report.

5.10.1 Procedure:

5.10.1.1 Select the report file.

- On the Main Menu, click **Create Reports**.
- The Report Files dialog box appears.
- Select **Setup** and click **OK**.
- The File Selection screen appears, listing the setup files available in the default data path.
- Select the file to document and click **OK**.
- The Format screen appears.

5.10.1.2 Format report output.

- The "Performed by / Date" and "Reviewed by / Date" options are enabled by default. Click one or both options to exclude these signature lines from your report.



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- If you included one or both signature line options in your report format, but do not want signature lines on every report page, clear the **Every Page** option. The **First Page** and **Last Page** options are then selected by default. Select one or both options as required.

- Click the **File Topics** tab.

- The Report Files screen appears.

5.10.1.3 Preview the report and/or create a PDF file.

- Click **Preview**.

- The first page of the Setup Report appears in the Print Preview window.

- To preview the report, use the scroll bars, or click and drag the mouse, to navigate through the displayed report page. Use the spin buttons to page through the report, or enter a page number directly and press **Enter** to go to that page.

- To create a PDF file from the report, click **PDF**. On the Output PDF File screen, specify the folder to save the file in, enter a file name, and click **OK**.

- Click **Done** to return to the Report Files screen.

5.10.1.4 Print the report.

- On the Report Files screen, click **Print**.

- Select a printer on the Print dialog box and click **Print**.

- Click **Main** to return to the Main Menu.

5.11 Generating Calibration Reports

This section documents the procedure for generating Calibration Reports from data stored during a sensor calibration.

5.11.1 Procedure:

5.11.1.1 Select the report file(s).

- On the Main Menu, click **Create Reports**.

- The Report Files dialog box appears.



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- Select **Calibration** and click **OK**.
- The File Selection screen appears, listing the calibration files available in the default data path.
- Select one or more files to document and click **OK**.
- The Format screen appears.

5.11.1.2 Format report output.

- The "Performed by / Date" and "Reviewed by / Date" options are enabled by default. Click one or both options to exclude these signature lines from your report.
- If you included one or both signature line options in your report format, but do not want signature lines on every report page, clear the **Every Page** option. The **First Page** and **Last Page** options are then selected by default. Select one or both options as required.
- Click the **File Topics** tab.

5.11.1.3 Preview the report and/or create a PDF file.

- Click **Preview**.
- The first page of the first Calibration Report appears in the Print Preview window.
- To preview the report, use the scroll bars, or click and drag the mouse, to navigate through the displayed report page.
- To create a PDF file from the report, click **PDF**. On the Output PDF File screen, specify the folder to save the file in, enter a file name, and click **OK**.
- Click **Done** to display the next report and repeat step 3. If there are no more reports in this series, the Report Files screen appears.

5.11.1.4 Print the report.

- On the Report Files screen, click **Print**.
- Select a printer on the Print dialog box and click **Print**.



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- Click **Main** to return to the Main Menu.

5.12 **Generating Qualification Reports**

The complete Qualification Report set includes the Setup, Qualification, and Qualification Summary Reports.

5.12.1 **Procedure**

5.12.1.1 Select the report file.

- On the Main Menu, click **Create Reports**.
- The Report Files dialog box appears.
- Select **Qualification** and click **OK**.
- The File Selection screen appears, listing all qualification files stored in the default data path.
- Select a **Vessel ID** from the list box to filter the list to only those files containing that Vessel ID.
- Select the file to document and click **OK**.
- The Print Options screen appears.

5.12.1.2 Specify the report types to be individually generated.

- The **Setup**, **Qualification**, and **Summary** report types are enabled by default. If you do not want to generate an individual report type, click the option name to disable it.
- The Summary Report has two additional options if the setup specified these calculations for any group. Select **Lethality** to include the total accumulated lethality for each sensor in the Summary Report. Select **Interval** to include the final interval calculation for each sensor in the Summary Report.

5.12.1.3 Specify the groups to include in your study documentation.

- All groups are selected by default (group name is highlighted).
- To exclude a group, click the group name. The excluded group name will no longer be highlighted.



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5.12.1.4 Specify the print sampling rate.

- The print sampling option allows you to print the report data at a rate different from the data collection rate. When the report is printed, time stamps in the qualification data file that match the selected print sampling rate will be included, while all others (except event times) will be suppressed.
- To specify the print sampling rate, select a rate from the **Print Sampling** list box.

5.12.1.5 Specify the print destination.

- The **Printer** option is enabled by default.
- Select the **Spreadsheet** option to export qualification data to an Excel spreadsheet file. If you selected a print sampling rate, and only want to export events that occurred at the new print sampling rate, select **Exclude off-sample-rate events** to suppress events that do not occur in sync with the new print sampling rate. When you print the report you will be prompted to name and store the spreadsheet file.

5.12.1.6 Format report output.

- Click the **Format** tab.
- The "Performed by / Date" and "Reviewed by / Date" options are enabled by default. Click one or both options to exclude these signature lines from your report.
- If you included one or both signature line options in your report format, but do not want signature lines on every report page, clear the **Every Page** option. The **First Page** and **Last Page** options are then selected by default. Select one or both options as required.
- To add comments to the beginning and/or end of the Qualification and Qualification Summary Reports, click the associated **User comments** option and enter comments in the text box.

5.12.1.7 Add event timers.

- Click the **Event Timers** tab.



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- Select a message number from the **Event Message** list and enter the message to print in the Qualification and Qualification Summary Reports.

- Specify start and stop conditions for the event timer.

- Repeat as necessary.

5.12.1.8 Exclude sensors from post-qualification calculations as necessary.

- Click the **Groups** tab.

- Select a group from the list box.

- Under the Sensor Selection tab, click individual sensor locations or click **Deselect All** to exclude sensors from post-qualification calculations as necessary.

- Repeat for each group as necessary.

5.12.1.9 Add calculations and group events.

- Click the **Calculations** tab.

- Select a group from the list box.

- Add/modify group calculations as necessary.

- Add group events as necessary.

- Repeat for each group as necessary.

5.12.1.10 Preview individual reports and/or create a PDF file.

- Click the **File Topics** tab.

- The Report Files screen appears.

- Click **Preview**.

- The first page of the first report appears in the Print Preview window.

- To preview the report, use the scroll bars, or click and drag the mouse, to navigate through the displayed report page. Use the spin buttons to page through the report, or enter a page number directly and press **Enter** to go to that page.



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- To print that individual report, click **Print**. Select a printer on the Print dialog box and click **Print**.
- To create a PDF file from that report, click **PDF**. On the Output PDF File screen, specify the folder to save the file in, enter a file name, and click **OK**.
- Click **Done** to display the next report and repeat step 10. If there are no more reports in this series, the Report Files screen appears.

5.12.1.11 Print the entire report set.

- On the Report Files screen, click **Print**.
- Select a printer on the Print dialog box and click **Print**. All reports in the series are printed.
- If the Spreadsheet option was selected, the Export File screen appears after the reports have been printed. Enter a filename for the Excel file, select a drive and folder to store the file, and click **OK**.
- Click **Main** to return to the Main Menu.

5.13 Generating Calibration Verification Reports

This section documents the procedure for generating Calibration Verification Reports from data stored during sensor calibration verification.

5.13.1 Procedure:

5.13.1.1 Select the report file(s).

- On the Main Menu, click **Create Reports**.
- The Report Files dialog box appears.
- Select **Calibration Verification** and click **OK**.
- The File Selection screen appears, listing the calibration verification files available in the default data path.



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- To filter the list of files to display only those calibration verifications performed on or after a specific date, click **Date**. Select the date of your calibration verification on the calendar and click **OK**.
- To filter the list of files by serial number, select a Validator 2000 serial number from the list box.
- Select one or more files to document and click **OK**.
- The Format screen appears.

5.13.1.2 Format report output.

- The "Performed by / Date" and "Reviewed by / Date" options are enabled by default. Click one or both options to exclude these signature lines from your report.
- If you included one or both signature line options in your report format, but do not want signature lines on every report page, clear the **Every Page** option. The **First Page** and **Last Page** options are then selected by default. Select one or both options as required.
- Click the **File Topics** tab.
- The Report Files screen appears.

5.13.1.3 Preview the report and/or create a PDF file.

- Click **Preview**.
- The first page of the first Calibration Verification Report appears in the Print Preview window.
- To preview the report, use the scroll bars, or click and drag the mouse, to navigate through the displayed report page. Use the spin buttons, or enter a page number and press Enter to page through the report, or enter a page number and press **Enter** to go to that page.
- To create a PDF file from the report, click **PDF**. On the Output PDF File screen, specify the folder to save the file in, enter a file name, and click **OK**.



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- Click **Done** to display the next report and repeat step 3. If there are no more reports in this series, the Report Files screen appears.

5.13.1.4 Print the report.

- On the Report Files screen, click **Print**.
- Select a printer on the Print dialog box and click **Print**.
- Click **Main** to return to the Main Menu.

5.14 Using the Validator 2000 Audit Trail

The Validator 2000 software maintains the audit trail, which contains all events and identifies the type of action performed, the date and time the action occurred, the name of the responsible operator, and any additional information required to understand the action taken. A new audit trail file is automatically created each month and placed in the Validator 2000 application folder.

5.15 Accessing the Audit Trail

Audit trail data is only available to the System Administrator through the Password Maintenance utility program.

5.15.1 Procedure

5.15.1.1 Log in to the Password Maintenance utility program.

- Start the Validator 2000 PC program. Press **ALT** and **S** simultaneously when the Validator 2000 splash screen appears.
- The Identification required dialog box appears.
- Enter System Administrator user ID and password and click **OK**.
- The Password Maintenance screen appears.

5.15.1.2 Access the audit trail.

- Click **File**, and then click **Audit Trail**.
- The Audit Trail screen appears.



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5.16 Filtering and Printing the Audit Trail

All events for the current month are displayed on the Audit Trail screen.

5.16.1 Procedure

5.16.1.1 Select the starting and ending dates of the audit trail.

- Click **Options**, and then click **Dates**.
- The Begin Audit Trail Display screen appears.
- Select the start date and click **OK**.
- The End Audit Trail Display screen appears.
- Select the end date and click **OK**.

5.16.1.2 Filter the audit trail by event type.

- Click **Filter**.
- Select a filtering option as necessary.

5.16.1.3 Filter the audit trail by Validator 2000 serial number.

- Click **Options**, select **Source**, and then click **Validator: All**.
- Click **OK** to view events for multiple Validator 2000s, or enter the **Validator 2000 serial number** and click **OK** to view events for a specific Validator 2000.

5.16.1.4 Print the audit trail.

- Click the **printer** icon.
- Select a printer on the Print dialog box and click **Print**.

5.16.1.5 Create a PDF file of the audit trail. You will need to have Adobe Acrobat Version 5.0 with PDF Writer installed on your PC.

- Click the **printer** icon.
- Select **Acrobat PDF Writer** on the Print dialog box and click **Print**.
- The Save PDF File As screen appears.
- Enter the PDF file name, specify the folder to save the file in, and click **Save**.



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5.17 Backing up the Audit Trail

Audit trail files can be backed up to a local or network drive. To maintain data integrity, audit trail files cannot be backed up to a removable drive.

5.17.1 Procedure

5.17.1.1 Backup the audit trail.

- On the Audit Trail screen, click **File**, and then click **Backup**.
- The Audit Trail Backup Directory screen appears.
- Specify the path where the audit trail files are to be copied and click **OK**.
- On the Audit Trail screen, click **File**, and then click **Done**.
- The Password Maintenance screen appears.

5.17.1.2 Click **File**, and then click **Exit** to exit the Password Maintenance utility.

5.17.1.3 Enter the entry into the log book after every operation

5.18 Calibration of Kaye Validator 2000 unit, LTR-25/ 140, HTR 400 and IRTD

Perform the Calibration of Kaye Validator 2000 unit, LTR-25/140, HTR 400 and IRTD from the outside calibration agency (approved) at every one year.

6.0 REFERENCE:

SOP No.	Title
	Handling of Deviation

7.0 ANNEXURE:

Not Applicable

8.0 ABBREVIATIONS:

SOP : Standard Operating Procedure
No. : Number
Dept. : Department
Ltd. : Limited