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| --- | --- | --- |
| Key |  | Comments |
| AdminHelpHeader | System Administration | Admin Screen |
| AdminHelpParagraph1 | All system administration tasks are accomplished through the Admin module from the Main Menu. This menu allows a user with System Administrator permissions to create and maintain user accounts, set application preferences and policies, and set up automatic time-based file synchronization. The Kaye software installs with default system preferences. The System Administrator has the option of changing the default system preferences in the Kaye software, if necessary, or allowing users with assigned permission to change the default system preferences. | Admin Screen |
| AssetDetailsHelpHeader | Asset Details | Asset Details Screen |
| AssetDetailsHelpParagraph1 | This screen is the central place to manage all validation activities for a chosen asset. In the left upper corner, asset type and name are listed together with asset details in the pane below:  • Assets’ Images – Up to three images • Eq ID # • Manufacturer • Type  • Model • Last Validated • Validation Frequency  The two round action button in the right upper corner allows editing asset details or deleting the asset. By default, only Supervisors and System Administrators can edit and delete assets. To complete the operation, you need to verify your login. Please note that an asset can only be deleted if all associated content is deleted beforehand.  In the upper right from the Asset’s detailed pane, five tiles list the following categories associated with this asset. Each tile presents a pane with action buttons for the desired operation:  • Setups Tile – Sensor Setup Management  In this tile, the available sensor setups for an asset are displayed in a list. The number of available setups is displayed in the tile. If the list exceeds the space, a down arrow icon indicates more available setups and enables scrolling.   To start a study, select a setup. This activates the buttons for initiating a qualification, calibration, or verification study. After confirmation of SOP Protocol Number and Run Number you can select the Kaye Validator AVS to run the selected study.   The following action buttons for setups are available:  - Create Setup (New) Start the setup wizard for creating a new setup.  - Copy sensor setup from other assets (Copy) If a suitable setup was already created you can use this function to copy setups from other assets to this setup. The button opens a list of available setups. Checkmark the setups you want to copy and press “Copy” or use the back button to abort the operation.  - Copy to drive This will open a Windows path selection for copying the setup. This can be used to import the setup to other Kaye Validation consoles or send it as an Email attachment to Kaye support for analysis.  Setup Associated Action Buttons:  - Edit Setup (Pencil icon) Opens the sensor setup wizard with the existing setup where a user can apply changes in a setup and save it under a new or the same name.  - Wiring Diagram (Plan icon) Opens the wiring diagram as defined per group in the setup. Diagrams are selectable per group and the action button for printing allow pdf report generation per displayed group or all groups. Use the red cross button to close the screen.  - Print setup report (Printer icon) Generates the setup and wiring report as a pdf file.  - Delete setup (Trashcan icon) Deletes the setup after login verification  After selecting a study file, the "Generate Reports" button becomes active. The button opens the report tool for generation of a calibration report with the selected data file.   • Qualification tile In this tile, the available qualifications for the asset are displayed in a list. The number of available studies is displayed in the tile itself. If the list exceeds the allotted space, a down arrow icon appears indicating more setups are available. Pressing the arrow enables scrolling and selecting setups in a list view.  After selecting a study file the "Generate Reports" button is active. The button opens the report tool for generation of a qualification report with the selected data file.  • Reports tile – Generating Reports The Reports tile displays a list of the available setup, qualification, and verification/calibration reports generated for an asset. If a report was created previously the action button for displaying the pdf file is active.   •Documents tile – Upload documents This tile provide option to upload documents as pdf files related to the Asset like calibration certificates, wiring diagrams or procedures. Other formats than pdf are currently not supported. The list shows the file name and the upload date. The action button behind the document name will open the file in the pdf viewer.  Press the Back arrow to return to the Assets Hub screen. | Asset Details Screen |
| AssetsHelpHeader | Asset Hub | Asset Hub Screen |
| AssetsHelpParagraph1 | The Asset Hub screen lists the various assets validated by the AVS system. On the top text menu, you can click on each category to display the assets by:  • Type (sterilizer, dry heat bath, controlled temperature, etc.) up to 20 user-designated types  • Manufacturer  • Location  The Asset tile displays each asset with a type, model number, and name. If the number of assets exceeds the screen size, a scroll bar enables you to view the other assets.  To search for a particular asset, press the search icon (Magnifier icon), and a textbox enables entering search data.  For further details about a particular asset, press the tile for that asset to open its corresponding Asset Details window.  To add any assets to the list, press the Plus icon (+) to open the New Asset creation window.  Press the Back icon (the left arrow) to return to the main screen | Asset Hub Screen |
| CalibrationParametersHelpHeader | Calibration Parameters | Calibration Parameters Screen |
| CalibrationParametersHelp  Paragraph1 | The Kaye AVS Validator provides both sensor and calibration verification. You specify all calibration parameters on the Calibration Parameters screen.   Before you perform a qualification study, calibrate the temperature sensors from the correct raw temperature readings to a NIST-traceable temperature standard. During calibration the Kaye AVS Validator automatically corrects raw temperature sensor readings to a NIST-traceable temperature standard to compensate for any errors inherent in sensor materials and stores these offsets in the associated SIMs. You can specify a one-point calibration, a two-point calibration, or a two-point calibration with a point check. Sensors that do not meet the calibration test criteria are marked as failed and are not calibrated.   After the qualification study, the Kaye AVS Validator performs a calibration verification to verify that the sensor readings are still within the calibration criteria. You can specify a one-point, two-point or three-point calibration verification. If a sensor fails calibration verification, the sensor is noted as failed but the readings are still reported. Calibration offsets are not changed during calibration verification.   Set the calibration parameters by specifying:  • Temperature setpoints for calibration. You can specify a low setpoint, a high setpoint and a check setpoint. If you specify both a low setpoint and a high setpoint, the high setpoint must be at least 2°C higher than the low setpoint.  • Temperature setpoints for calibration verification to verify that each sensor is still within your calibration criteria. You must select at least one setpoint for calibration verification. • Sensor and IRTD stability in terms of temperature variation over a fixed time period. Stability is the amount of change that is acceptable over the fixed time period. • Deviation criteria for uncalibrated temperature sensors, and deviation criteria for calibrated temperature sensors over a fixed time period. Deviation is the difference in temperature between sensor values and the temperature standard.  Temperature Setpoints:   Temperature setpoints are the temperature reference temperatures at which calibration is performed and verified. You specify temperature setpoints on the Calibration Parameters screen.  Calibration may be performed at a low setpoint and a high setpoint. In addition, you can specify a calibration check setpoint, usually between the low and high setpoints. Calibration verification may be performed at low, high, and check setpoints.    To specify temperature setpoints:  • On the Calibration Parameters screen, select your calibration setpoints by clicking the Low, High, and Check checkboxes, as required. You must select either a low setpoint and a high setpoint. The high setpoint must be at least 2° higher than the low setpoint. • Enter the values for the selected setpoints directly into the text boxes.  • Select calibration verification setpoints by clicking the Low, High and Check checkboxes, as required. You must select at least one setpoint.  Stability Criteria:  Stability is the maximum allowable change in each sensor’s temperature readings, and the maximum allowable change in the temperature standard’s temperature readings over a fixed time period. You specify temperature stability parameters on the Calibration Parameters screen.  When you specify temperature stability, you specify the maximum allowable temperature variation for each sensor and the IRTD; and the time period to compute these variations. If you are using a Kaye IRTD, the temperature stability of the IRTD is fixed at 0.012°C (0.022°F) if all temperature setpoints are equal to or greater than 0.0°C (32.0°F). If any temperature setpoint is less than 0.0°C (32.0°F) you can enter the IRTD stability value manually. For example, you want to run a qualification study on a freezer that normally runs at -80°C. Using liquid nitrogen as your temperature reference, you need to calibrate your sensors at a low point of -196°C, which is out of the range of a Kaye temperature reference. The default value of 0.012°C may be too tight for your IRTD temperature stability. The Kaye AVS Validator software allows you to manually enter the stability requirement for the IRTD to give you more flexibility in your IRTD stability criteria. During calibration, temperature stability readings are computed once the temperature standard is within 5°C of setpoint. To achieve temperature stability during calibration, the temperature standard must meet its stability criteria, and all sensors that you have specified must meet the sensor stability criteria as a group. For example, if the maximum spread of readings for a sensor is 0.50°C over a 3-minute time interval, all sensors that you have specified must meet that criteria before the calibration process can continue.   To specify temperature stability:  • On the Calibration Parameters screen, enter the maximum allowable change in Sensor temperature readings directly into the textbox. You can enter values from 0.10° to 9.0°C.  • Enter the time to compute the maximum allowable change in the Minutes textbox. You can enter a time from a minimum of 2 minutes to a maximum of 9 minutes.  • If any calibration setpoint is outside the range of Kaye’s temperature reference, you can enter a new IRTD stability value directly into the IRTD text box.  • Enter the time to compute the maximum allowable change in the IRTD’s temperature reading directly into the IRTD’s Minutes textbox. You can enter a time from a minimum of 1 minutes to a maximum of 5 minutes.  Deviation Criteria:  Deviation is the difference between the reading reported by a sensor and the reading reported by the temperature standard during the calibration process. You specify deviation criteria parameters on the Calibration Parameters screen.  Deviation is used in two comparisons:  • Deviation of uncalibrated thermocouples – enter the maximum allowable deviation from the temperature standard before calibration. • Deviation of calibrated thermocouples – enter the maximum allowable deviation from the temperature standard after calibration.  To specify deviation criteria:  • On the Calibration Parameters screen, enter the maximum deviation allowed between an uncalibrated sensor and the temperature standard directly into the textbox. You can enter values from 0.50°C to 9.90°C. • Enter the maximum deviation allowed between a calibrated sensor and the temperature standard directly into the textbox. You can enter values from 0.10°C to 5.0°C. • Enter the number of minutes to compute and log calibrated deviation data directly into the Minutes textbox. Data is computed and logged at 30 second intervals. You can specify a time duration from 1 to 9 minutes. | Calibration Parameters Screen |
| CaliculationsHelpHeader | Calculations | Caliculations Screen |
| CaliculationsHelpParagraph1 | Once you have defined sensors and assigned them to one or more groups, the next step is to specify the calculations to be performed on the group of sensors during the qualification study.   The Calculations screen allows users to specify the calculations to be performed on each group.  Calculations include statistical, lethality, interval, saturation pressure of steam, and saturation temperature of steam calculations. You can also define one event per group to monitor during the study. You specify group calculations and also define one event condition per group to monitor during the study.  Statistical Calculations:  Statistical calculations are computed in each scan based on all sensors in the group. For example, if a group contains 10 sensors and you select the statistical maximum calculation, in each scan the program determines the highest temperature and displays that value. The program can also identify which sensor is registering the maximum temperature if you enable the Location of Max and Min selection.  Note: Statistical calculations cannot be performed on a group with only one sensor or on a group where all sensors in the group are contacts.  To see Statistical Calculation selections press the Statistical Calculation icon.  The following Statistical Calculations can be done on the below parameters:  • Max Value • Min Value • Average and Standard Deviation • Location of Max and Min • Difference between Max and Min • Difference between Max and Avg • Difference between Avg and Min   The Statistical Calculations are preselected by default and apply to all groups.  Lethality Calculations:  Specify the lethality calculation to be performed during the qualification study on the Lethality Calculation screen.   During a penetration test, the product must receive an adequate amount of heat for a long enough period of time to be properly sterilized. Lethality is defined as the equivalent sterilization time spent at the base temperature. The temperature sensors, instantaneous lethality, and accumulated lethality are processed every scan to provide maximum accuracy.  Lethality is computed for each temperature input for a specified interval.   The Lethality Calculation Parameters displayed on the screen:  • Base Temperature • D Value (default value is 1.00) • Z Value (default value is 10)  Base Temperature  Enter the base temperature (1 to 400°C).  The standard for steam sterilization is 121.1 °C with a Z value of 10.0. The standard for dry heat sterilization is 170.0°C with a Z value of 20.0. Z Value The Z value of a microorganism is a measure of how heat resistance changes with differences in temperature. Z is defined as the number of degrees required to change the D value by a factor of 10. Enter the Z value (1 to 99). D Value  The D value is the time (in minutes) at a given temperature required to reduce the number of microorganisms by 90% (one logarithmic reduction). The default value is one minute. When creating a setup, the D value field is displayed only if the System Administrator has enabled the site option allowing the Supervisor to change the D value. If the D value field is not displayed, the default value is 1. When modifying a setup, the D value field displays and is changeable if there is a D value other than 1 in the existing setup.  Calculate Lethality conditions:  Defines when the Lethality calculation starts and stops.  • While Min Temp  Lethality is calculated as long as the minimum temperature in the group is less than or greater than a specified value. For example, you can configure the Kaye Sensor System to calculate lethality for all sensors in the group as long as the minimum temperature in the group is greater than 110.0°C. If the minimum temperature falls below 110.0°C, the Kaye Sensor System stops calculating lethality. • While Max Temp  Lethality is calculated as long as the maximum temperature in the group is less than or greater than a specified value. • During Entire Cycle  Lethality is calculated during the complete qualification study. You specify when the study starts and ends on the Qualification screen. • During Exposure Cycle  Lethality is calculated during the exposure cycle. You specify when the exposure cycle starts and ends on the Qualification screen.  • Until Exposure End  Lethality is calculated from the start of the qualification study until the exposure cycle ends. You specify when the qualification study starts and when the exposure cycle ends on the Qualification screen. • After Exposure Start  Lethality is calculated from the start of the exposure cycle until the qualification study ends. You specify when the exposure cycle starts and when the qualification study ends on the Qualification screen.  Note: The Lethality Calculation option is disabled if there are no temperature sensors defined for the selected group.  When comparing the minimum or maximum temperature against a fixed value, lethality will be computed for each data sample that meets the criterion.  Interval Calculations:  Interval calculations to be performed on each sensor in the group on the Interval Calculations screen. For each sensor you can calculate the maximum, average, and minimum readings for the specified interval, and the time and date the maximum and minimum readings occurred for that individual sensor. For example, if a group contains 10 sensors and the user selects the interval maximum calculation, the program stores the highest temperature reached by each sensor during the interval and the time that the maximum value was reached. For the group as a whole, you can calculate group extremes (minimum sensor reading of the entire group and maximum sensor reading of the entire group) for the specified interval, and the time duration of the interval.   During the qualification study, interval calculations are computed and displayed on your console/tablet display screen at the display rate specified for the qualification study on the Preferences screen.   To specify group- specific interval calculations: 1. Select a group in the Interval Calculations Screen to define Calculation or modify if interval calculations have been specified 2. Click the checkbox(es) next to any calculation to select it. Click the checkbox again to deselect it. 3. Select an interval start condition from the Interval Start list box. Enter interval start parameters if required. Selectable conditions are:  • Any input compared against a fixed number • Minimum, maximum, or average value compared against a fixed number • The start qualification event • The start exposure event • The end exposure event • Cycle time, defined as elapsed time from the start of qualification • Exposure time, defined as elapsed time from the start of exposure  4. Select an interval end condition from the Interval End list box. Enter interval end parameters if required. Selectable conditions are:  • Any input compared against a fixed number • Minimum, maximum, or average value compared against a fixed number • The start exposure event • The end exposure event • The end qualification event • A period of time starting at the specified interval start condition and ending when either the time expires, or the end qualification event occurs.  Note: Interval calculations cannot be performed on a group if all sensors in the selected group are contacts.  Saturation P/T Calculation:  The saturation pressure of steam calculation uses a temperature input to calculate the equivalent saturation pressure of steam. The pressure units are specified on the Preferences screen.  Note: The saturation pressure of steam calculation cannot be performed on a group if there are no temperature sensors defined.  You can select a temperature sensor from Select Sensor drop-down list that is on Saturation Pressure of Steam page. The selected sensor is used in the calculation. The saturation temperature of steam calculation uses a pressure input to calculate the equivalent saturation temperature of steam. The pressure units are specified on the Preferences screen.  Note: The saturation temperature of steam calculation cannot be performed on a group if there are no pressure sensors (Pressure (mA) or Pressure (V)) defined.  The Calculations screen displays a pressure sensor from the list to use in the calculation.  Events:  User can define one event per group to monitor during the qualification study. Events are monitored every scan. If an event occurs it is written as soon as it is detected. The time stamp, event message, and a snapshot of all the qualification data (sensor readings, accumulated lethality, and interval calculations) are recorded. During the qualification study events can be used to control the output relay.  The Event Calculations screen displays:  1. In the **Message** field, enter the message text to display when the defined event occurs for the selected group. Your message can include any characters up a maximum of 35.  Note: The condition will print out as part of the message, along with a label indicating whether the event is true or false.  2. In the **When** field, select the condition from the list box and enter the “when” condition. 3. In the **Label** field, enter an ID for the condition. Your label can include any characters up to a maximum of eight. 4. In the **Event** condition field, select an event from the list box and enter event conditions. Event conditions choices are: a. Any sensor input compared against a fixed value. b. The minimum accumulated lethality value across all groups compared against a fixed value. c. The minimum value for the group compared against a fixed value. d. The maximum value for the group compared against a fixed value. e. The difference between the maximum and minimum values for the group compared against a fixed value. f. The difference between the maximum and average values for the group compared against a fixed value. g. The difference between the average and minimum values for the group compared against a fixed value. | Caliculations Screen |
| CreateCycleHelpHeader | Create Cycle | Create Cycle Screen |
| CreateCycleHelpParagraph1 | • Overview -Prior to generating graphs or text reports for your qualification file, the Cycle Selection screen allows the user to review, modify or create cycles from the qualification study data. Each cycle is defined with a Start and End time or events which defines the duration of the cycle. The Cycles defined are used in the Qualification Summary Report to provide detailed calculations and analysis during each cycle. For each cycle, the Summary report contains the Min. Max, Max-Min, and Lethality, if configured for each sensor. The Summary report also contains additional calculations such as Cycle duration, Min of Min, Max of Max, range, spread, Std Deviation, Min Lethality, etc. to provide detailed analysis of the Cycle.  • Qualification Start / End - Upon entering the Cycle selection screen the system displays a graph, based on the sensor type selected, with the Qual Start and End marked on the graph and listed above showing the Start and End of Qual defined during the Qualification study. A pop-up box appears where the user can "Accept" or" Modify" the existing Start and End of Qual. If Modify is selected the user can modify the Start and End of Qual by either "Time" or "Selection Line ". Selecting "Time" allows the users to manually enter the time for Start and End Qual. "Selection Line" allows the user to manually move the line on the graph to the Start of Qual and then press **OK**. The process can then be repeated for the End of Qual. Features such as "Zoom", "Limit Lines", and "Display Events" assist in defining cycle markings.   • Exposure Start / End - If your Setup included Lethality calculations, or Exposure Cycle parameters were defined, then the Exposure Start and End will be marked on the graph and the user will be prompted to "Accept" or "Modify" the Exposure Start and End times. If "Modify" is selected the user can chose to modify Exposure Start and/or End by "Time", "Selection Line ", or "Event. "Time" allows the users to manually enter the time for Exposure Start and/or End. (i.e. used to synchronize with Autoclave controller). "Selection Line" allows the user to manually move the line on the graph to Exposure Start and /or End then press **OK**. "Event" allows the user to utilize a previously defined Event in your setup as the Exposure Start and / or End or to create a "New Event". If creating a new event, the user can specify a "Message" which will appear in the Detailed Report. The user can also specify "When" which defines when the event occurs, as well as a Label and the condition for the event. (i.e. Min Temp > 121.0 C). At the completion of marking Exposure Start / End the cycles are numbered 1-3. By selecting Show Cycles the user can modify the Cycle names (i.e Heat-up, Exposure, Cool-down)   • Adding Cycles – The system allows up to 15 additional Cycles to be defined. For each Cycle a Start and End time can be marked by “Time”, “Selection Line”, or Event. The method and functionality for defining cycles is the same as defined in Exposure Start / End.   • Show Cycles – All cycles created are displayed with defined Start and End times. The Show Cycle screens also allows modifications of cycles names. UnMark Cycle button can be used to delete a cycle. This option deletes from the last cycle to first, end of study, and then Start of study. Unmark All will unmark all the cycles, including study start and end. Hide Cycles closes the cycles window.  • When all of the desired cycles have been defined, the user can press **Next** at the upper right portion of the screen to move to Report /Graph creation  A user can also define cycles by clicking the Mark Cycle by > Time Selection option. Enter the required time stamp(s) in the time selection window in DATE and HH:MM:SS format for defining Qualification Start and End.  Define the data cycles After the Start and End of study have been defined, enter HH:MM:SS on the Cycle Time dialog box. Click on Ok and two boxes will be displayed. Enter names for the two cycles. More cycles can be added, one at a time, on the Cycle Time box. Once all cycles are defined, click on Close on the Cycle Time dialog box and press **Next** to continue.   Show Cycles   Pressing the Show Cycles down arrow displays a list of cycles. The Unmark Cycle button can be used to delete a cycle. This option deletes from the last cycle to first, end of study, and then Start of study. UnMark All will unmark all the cycles, including study start and end. Pressing the title of the columns, causes the cycles to be sorted ascending or descending based on that column. Hide Cycles closes the cycles window.  Press **Next** and to go to the next screen and choose from either of the options; Graph Report, Customize Groups, or Customize Calculations & Text Report. | Create Cycle Screen |
| CreateorEditAssetHelpHeader | New Asset or Edit Asset | New Asset or Edit Asset Screen |
| CreateorEditAssetHelpParagraph1 | " To enter a new asset, go to the Asset Hub screen and press the plus (+) icon. The New Asset screen opens.  To enter details for a new asset use the text boxes and drop-down menus to enter:  • The asset name (required field)  • The Equipment ID number (required field)  • The type of asset (required field)  • The manufacturer (required field)  • Location (required field)  • The model name  • The size in cubic units  • The validation frequency  • Last validated  You can enter an optional description of the unit and upload a bmp or jpeg image of the equipment or use the camera to take a picture.  When you have finished, press **Save** to save the entry or **Cancel** to reset all entries. Use the back-arrow button to return to the Equipment Hub. " | New Asset or Edit Asset Screen |
| CreateOrEditEquipmentHelpHeader | New Equipment or Edit Equipment | New Equipment or Edit Equipment Screen |
| CreateOrEditEquipmentHelpParagraph1 | To add a new piece of equipment to your Validator system, press the plus (+) icon on Equipment Hub screen. The New Equipment screen opens You can enter details separately for each new piece of equipment. Use the textboxes and drop-down menus to enter the details:  • Kaye Serial Number • Last Calibrated Date • Model Number • Equipment Type • Calibration Due Date You can also upload a bmp or jpeg image of the Equipment or use the camera to take a picture. When you have finished, press Save to save the entry and return to the Equipment Hub, or Cancel to reset entries on the screen. | New Equipment or Edit Equipment Screen |
| CustomizeCalculationsHelpHeader | Calculations |  |
| CustomizeCalculationsHelpParagraph1 | Once the sensors have been assigned to one or more groups, the next step is to specify the calculations to be performed on the group of sensors.  On this screen calculations like Lethality, saturation pressure of steam, saturation temperature of steam, and MKT (Mean Kinetic Temperature) can be customized. MKT can only be selected if no lethality calculation is defined.  Lethality: select Lethality and press Customize if you want to edit the base temperature, D- and z-value of lethality equitation. Also define when to calculate Lethality. Lethality results can be calculated in minutes or seconds.  Lethality explanations  Specify the lethality calculation to be performed on each group during the qualification study on the Lethality Calculation screen. During a penetration test, the product must receive an adequate amount of heat for a long enough period of time to be properly sterilized. Lethality is defined as the equivalent sterilization time spent at the base temperature. The temperature sensors, instantaneous lethality, and accumulated lethality are processed every scan to provide maximum accuracy. The accumulated results are saved to disk at the data storage rate.  Base Temperature  Enter the base temperature (1 to 400°C). The standard for steam sterilization is 121.1°C with a Z value of 10.0°C. The standard for dry heat sterilization is 170.0°C with a Z value of 20.0°C.  Z Value  The Z value of a microorganism is a measure of how heat resistance changes with differences in temperature. Z is defined as the number of degrees required to change the D value by a factor of 10. Enter the Z value (1 to 99).  D Value  The D value is the time (in minutes) at a given temperature required to reduce the number of microorganisms by 90% (one logarithmic reduction). The default value is one minute. When creating a setup, the D value field is displayed only if the System Administrator has enabled the site option allowing the Supervisor to change the D value. If the D value field is not displayed, the default value is 1. When modifying a setup, the D value field displays and can be changed if there is a D value other than 1 in the existing setup.  Calculate Lethality  Defines when the Lethality calculation starts and stops. • While Min Temp Lethality is calculated as long as the minimum temperature in the group is less than or greater than a specified value. For example, you can configure the Kaye Sensor System to calculate lethality for all sensors in the group as long as the minimum temperature in the group is greater than 110.0°C. If the minimum temperature falls below 110.0°C, the Kaye Sensor System stops calculating lethality. • While Max Temp Lethality is calculated as long as the maximum temperature in the group is less than or greater than a specified value. • During Entire Cycle Lethality is calculated during the complete qualification study. You specify when the study starts and ends on the Qualification screen. • During Exposure Cycle Lethality is calculated during the exposure cycle. You specify when the exposure cycle starts and ends on the Qualification screen.  Sat P or Sat T: Press **Customize** and select a sensor to be used for saturation calculations. Press **Apply** to save changes. **Cancel** to undo the changes.   MKT:  Mean Kinetic Temperature. The default Heat Activation 83.144 kJ\*mol-1 is displayed and can be customized to a different value if necessary.  Press **Apply** to save changes. **Cancel** to undo the changes. To select MKT calculation go back to **Text Repor**t. Press **Customize Structure** at the bottom of the left pane. Select **MKT** and press **Done** for the available Groups.  NOTE: Lethality and MKT cannot be select for same Group. An error message will show up when clicking Done and either Lethality or MKT need to be unchecked for the Group.  Mean Kinetic Temperature (MKT) is a simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods. The objective of this test is to ensure the MKT (Mean Kinetic Temperature) report functionality is working properly. This is done by collecting temperature data with one Thermocouple and then using the reporting of the Software to get a result of the MKT. The result is verified by manual calculations using the temperature data from the thermocouple.  Time of Sterilization |  |
| CustomizeGroupsHelpHeader | Customize Groups |  |
| CustomizeGroupsHelpParagraph1 | The existing Groups, created during the setup creation, are listed at the top.  To Create a new group  Press the +New Group button. A Group Name text box appears where the Group Name can be entered. The Group name textbox allows inputs up to 35 characters that can be upper and lower case, numeric, special characters like a hyphen, underscore, slash (forward and backward), and blank.   Below the +New Group all available sensors are shown. Press individual sensors to select them for the group. Those sensors appear with an orange checkbox.   Note: Only sensors of same type can be assigned to a Group; e.g. a pressure and a temperature sensor cannot be in the same Group.  Press **Save** to save changes. **Cancel** to undo the changes.  To view which sensors are assigned to existing Groups, press the desired Group. To edit an existing Group press the **Pencil** button next to Group name. Sensors of that Group are shown with an orange checkbox. To deselect a Sensor, press the sensor so that the orange checkbox disappears. To add a Sensor, select a sensor of same sensor type so that the orange checkbox is displayed.  Press **Save** to save changes. **Cancel** to undo the changes.  To delete a group select the desired group name and press the **Recycle Bin** button. Press **Yes** to confirm or **No** to return to the screen.  To move sensors to another Group (with same type of sensors only) select the desired Group and press the arrow button next to the Recycle Bin. A drop-down menu with available Groups displays. To move a sensor(s) to a new Group, select a Group and confirm with **Yes** or go back with **No**. The sensor(s) is moved to the new group, but the existing group stays empty. To get remove the empty group, select it and press the **Recycle Bin**.  To rename the new group, select the group, and press the Pencil icon. The group name is in a textbox and is in an editable format.  If all changes are complete, press **Save** and then press the ß symbol on top left of the screen. Navigate to Graph or Text Report to create reports.   Understanding Groups  Grouping is a key concept of the reporting utility. Grouping sensors allows you to associate sensors with specific calculations. You can define the calculations you want to perform on a per group basis. You can select any combination of the following calculations to appear in your report. • Maximum value in the group • Minimum value in the group • Average and standard deviation of all values in the group • Location of maximum and minimum group values • Difference between maximum and minimum values for the group • Difference between maximum and average values for the group • Difference between average and minimum values for the group For other calculations such as Lethality, MKT, Steam Calculation, and Interval refer to Customize Calculations help.  Use the following guidelines when defining groups:  • Groups must be homogeneous (all sensors in a group must be the same type) since calculations are performed on all the sensors. • Each group is independent. You cannot define a calculation that has inputs from more than one group.  • You can assign a sensor to more than one group to relate the sensor’s output to different conditions. For example, you might have the same sensors in more than one group to look at data over different intervals. You could specify the maximum sensor reading during exposure for one group, and specify the maximum sensor reading during the entire qualification cycle for another group. • You must assign a sensor to a group to record data from that sensor. Any sensor not assigned to a group is considered unused and no data is recorded for that sensor.  Grouping Examples • You may want to do a distribution study to find the coldest/warmest area of a vessel. Since you are only testing one vessel, you could assign all your sensors to one group for all your calculations.  • You may want to do a distribution study and a penetration study at the same time in order to speed up the validation process. Since these studies require different calculations, you could assign your distribution sensors to one group and perform the associated calculations on that group; then assign your penetration sensors to a second group and perform the associated calculations on that group. • You may want to use the same sensors in different groups in order to look at data in different ways. You may, for example, want to compute lethality during the complete cycle and during the exposure cycle. • You may be testing four small incubators with two sensors each. You could define one group for each incubator, and each group could have its own set of calculations. • You may want to exclude a sensor from post-qualification calculations. For example, if a sensor was removed during the qualification study, and you used more sensors than your SOP required, you could exclude the sensor(s) from the Qualification Summary, and Qualification Detailed Reports. The serial number will still be listed in the Setup Report. |  |
| DefineSetupHelpHeader | Define Setup | Define Setup Screen |
| DefineSetupHelpParagraph1 | A setup defines everything required to run a qualification study. To create or modify a setup you must have sufficient privileges (by default User type: Supervisor) set up by your System Administrator.  When you create a setup, you:  • Define the sensors you are going to use in the study • Assign sensors to groups and specify group calculations • Define group events to be monitored during the qualification study • Enter group-specific information to be used in report headers • Specify start and stop conditions for the qualification cycle and the exposure cycle • Specify how often to scan sensors (sampling rate for data storage)  After you have created and saved your setup the setup is displayed in the list of available setups and can be used to run a qualification study. You load the setup to the Kaye Sensor System when you select Start Calibration or Start Qualification from the selected Assets setup tile.  Define Setups  To define a New Setup:  1. From Assets hub select the desired Asset The Asset screen displays with the “Setups” tile highlighted. The Asset’s name and type is displayed at the left top corner.  2. Press “(+) New”  The Define Setup screen displays.  3. Fill out the following fields:   • Setup Name – required field You can accept the default name (current date and time), or enter the name of your new setup in the text box. The name can be any combination of up to 35 characters. Note: Duplicate setup file names are not permitted.   • Number of sensors – required field, numeric only (1 to 48).  • Eq ID, pre-populated from the asset details, not an editable field.  • SOP Protocol Number – optional field, with up to 50 alpha numeric characters. Special characters are not allowed with an exception of the following characters, “-“, “\_”, and slash (forward and backward).  • Load Description – optional field, with up to 50 alpha numeric characters. Special characters are not allowed with an exception of the following characters “-“, “\_”, and slash (forward and backward).  • Comments – optional field, with up to 25 alpha numeric characters.  After all required fields are filled out, press the “Sensors Configuration” tab to continue.  Press (←) to go back to the Assets screen. | Define Setup Screen |
| EditReportParameters | Edit Report Parameters |  |
| EditReportParametersHelpParagraph1 | This screen has options to customize a report.  1. Edit Groups: Allows editing of defined groups and saving to generate a Graph and Text Report in the future. Sensors are only part of calculations or the summary if they are assigned to a group. E.g. if a sensor failed during a qualification it is possible to exclude it from the calculations or add a spare sensor instead.   2. Edit Calculations: Calculations can be customized and edited. The editing of Lethality calculations depends if editing is allowed in the preferences. |  |
| EquipmentDetailsHelpHeader | Equipment Details | Equipment Details Screen |
| EquipmentDetailsHelpParagraph1 | ▪ Equipment Details screen To learn the details for a particular piece of Kaye Validation equipment press the tile for that particular item on the Equipment screen. The Equipment Details screen opens. The upper left corner displays the equipment type. On the left pane, the following details are displayed, an uploaded photo (optional), the Kaye serial number, and the calibration status. The right pane displays the study files containing the Kaye serial number of the device with a filename, the study type, and date. It is possible to sort or filter the list for quicker retrieval of a required file. The action buttons of the equipment details screen allow a user to **Edit** (pencil) and **Delete** (trashcan) Kaye equipment.  ▪ Edit Equipment: Press the **Edit** button (pencil) at the top right corner of the Equipment Details screen to change or update equipment information. On this screen a user can edit existing information other than the Kaye serial number. By default only System Administrators have privileges to create, edit, and delete equipment; a login verification is required to complete the operation.  ▪ Delete Equipment The **Delete** Icon at the top right corner of the Equipment details window can be used to delete Equipment. Press the **Delete** icon to delete the selected equipment. Pressing **Yes** or **No** at the confirmation dialog either deletes the equipment or cancels the actions. By default only System Administrators have privileges to create, edit, and delete equipment; a login verification is required to complete the operation. | Equipment Details Screen |
| EquipmentHelpHeader | The Equipment Hub | Equipment Hub Screen |
| EquipmentHelpParagraph1 | Equipment administration supports the management of the calibration status of the Kaye validation equipment and links validation equipment to the validation studies it was used for.  The number in the equipment tile displays the number of equipment that is due for calibration according to the calibration warning interval set in the policies.  The Equipment graphically represents your Kaye validation system and displays the available Kaye devices as tiles, with the device’s serial number as identifier and sorted by type.   If the device is due for calibration according to the warning interval set in the policies the tile shows the calibration due date within the tile and changes color from a dark purple to light purple.  ▪ Add new equipment to the system. Use the (+) button in the right upper corner of the screen to create a new validation equipment. In the New Equipment Screen all required information and a picture of the equipment can be added. For identification of the equipment within the application the serial number is used. The Equipment type is used to sort the tiles in the equipment screen. Pictures can be added by selecting an already available example picture of a Kaye device or by accessing the camera of the console. By default, only system administrators have privileges to create, edit, delete equipment, and a login verification is required to complete the operation. The same screen can be opened from equipment details to edit the equipment details.  ▪ Filter existing equipment The Filter equipment option can be used to filter studies based on Equipment serial number. The serial number of Kaye equipment is automatically retrieved from the devices during the studies (except temperature bath). Using the serial number, the study files the Kaye validation equipment was used can be displayed. The equipment is not created automatically from the retrieved information and needs to be created manually with the correct serial number before searching or filtering is possible.  Click on the “<Filter Symbol>” (funnel) at the top right corner of the Equipment page. All the created equipment tiles are displayed. Existing studies can be filtered by selecting any of the Equipment and then click the **Search** button. Now a list of all the files (Qualification/Calibration) generated with the equipment is displayed in the table.  Files are to be listed in the grid with study name, study file type (Qualification or Calibration), study Date and Time. All the studies can be filtered using File Name, Study Type(Qualification/Calibration), Date.  ▪ Searching Equipment by Serial Number All existing equipment can be searched by clicking the “<Search Symbol>” (magnifier) at the top right corner. Click on the Search symbol and enter the “Equipment Serial number” and observe that Equipment matching with the Serial number is filtered and displayed. | Equipment Hub Screen |
| GraphReportCustomizeHelpHeader | Graph Report Customize | Graph Report Customize Screen |
| GraphReportCustomizeHelpParagraph1 | If you have selected Summary Analysis in the Reports Analysis screen, once you have saved the report cycles, the Summary Analysis screen opens, with all the cycles you have created in the previous screen. Three buttons appear at the bottom: **Save as Template**, **Edit Cycles**, and **Customize**. On the initial Summary Analysis screen, the **Save as Template** button allows you to save the file as a template. The template’s name can have up to 40 alphanumeric characters, including spaces and hyphens.  Note: Duplicate template names are not permitted. Press the **Edit Cycles** button to edit the existing cycle selections. Press the **Customize** button to select calculations for the generated graph page. The screen displays all groups created during Setup creation, selected and unselected sensors, the min and max Y axis, and a list of calculations. Two buttons, **All Sensors** and **Clear All**, allow you to display or clear all sensors.  Depending on the sensor group and graph type selected, you can apply the following calculations:  • Max Value  • Min Value  • Avg and Std Dev  • Max-Min  • Max-Avg  • Avg-Min  • Lethality  • Sat P  • Sat T  • MKT Calculations  Textboxes enable you to select the minimum and maximum values of the Y axis for the selected calculation graph. (These boxes accept only numbers, along with the following symbols, the minus sign, decimal point and comma.). Above the Groups/Sensors pane, three tabs allow you to select the Lethality, Saturation Pressure, and Saturation Temperature calculations.  • The Lethality calculation is only available if temperature sensors are present in the study. The left pane displays the lethality graph for the study, while the right pane enables you to change the D, Z, and base temperature values.  • The Saturation Pressure calculation is only available if the study includes at least one temperature sensor along with pressure sensors. Here, the left pane displays the Saturation Pressure graph for the selected group, while the right panel allows you to select the reference temperature sensor.  • The Saturation Temperature calculation is only available if the study includes at least one pressure sensor along with temperature sensors. The left pane displays the Saturation Temperature graph for the selected group, while the right panel allows you to select the reference pressure sensor.  • No calculations are available for a contact sensor group.  Based on the group selection, the following calculation graphs are generated:  • Temperature Sensors  • Temperature Sensors Calculations  • RH (Humidity) Sensors  • RH Sensors Calculations  • Pressure Sensors  • Pressure Sensors Calculations  • Current Sensors  • Current Sensors calculations  • Voltage Sensors  • Voltage Sensors calculations  • Contact Sensors  • Lethality by Sensor - A bar should represent one sensor  • Lethality Sensor trends  • Saturation Temperature  • Saturation Pressure  • Equilibration Time  Note: For all types of graphs, Open, Under Range, Over Range, or NO SIM sensor values are not displayed; for such failure values, a broken graph appears. Users can zoom in and out of any graph, or apply the print option to send graphs to a default printer. By default, the graph reports are saved with a unique name, along with a date and timestamp. Header and footer details remain the same as in all other reports.  When you have finished, press the **Forward** (right) button in the upper right to proceed to the Report Options screen. | Graph Report Customize Screen |
| GraphReportHelpHeader | Graph Report |  |
| GraphReportHelpParagraph1 | The Graph Report screen allows you to generate multiple Graph Reports of sensor data or calculations.    The following options are available on Graph Report screen:    • Generate Report  • Edit Sensors  • Edit Limit Labels  • Reset Zoom  • Zoom In  • Zoom Out  • Set a Manual Zoom Level  • Select Group Drop-Down List  • Select Cycle Drop-Down List  You can create Portable Document Format (PDF) files from the study data.  Study data is presented in a graph form:  • The x-axis spans from the defined start of qualification to the defined end of qualification.   • The y-axis displays temperature, humidity, or pressure.  You can choose the sensors or calculations to include in each Graph Report. Selections made on the Graph Report screen are unique to the Graph Report. They do not affect the contents of the Setup, Qualification Detailed, or Qualification Summary Reports. The exception is the pressure sensor selected for saturation temperature reporting (see below).    Important  • If you clear a sensor from any of the graph reports, its sensors will not be included in the calculations graphs. If you want to include sensors in any of the calculations graphs from a sensor you have cleared in another graph view, select it again before switching to one of the calculations graphs.  • If a group has only one sensor, Statistical calculations are not available and the check boxes are greyed out.    • To Generate a Graph Report:    • Use the Select Group drop-down list to change the selected group for graphing.   • The number of Graph Report options available depends on the selections made during the study setup, the type of sensors used in the study, and the number of sensors in each group.  • Use the Statistical pane to select a Graph Report. To view data in greater detail, use the zoom or manual scaling to zoom into on a particular time period or sensor measurement range. The **Zoom In** and **Zoom Out** buttons change the graph magnification by preset levels. What is displayed on the screen is also displayed in the generated Graph report  The Graph Report screen provides an option to generate a hardcopy of the sensor data or calculations selected on the Graph Report screen when generating Qualification Reports. The **Generate Report** button is located in the lower left corner of the screen.   The format of the Graph Report is described below.   The report header lists the following:  • Date and time the report was printed  • Name of the user who printed the report  • Study name  • Your company’s name  • Software version number  • Eq ID number  • SOP/Protocol number  • Name of the user who programmed the sensors  • Date the sensors were programmed  • Comments entered during programming.  • Graph label on the top of the Graph body  • The graph displays sensor data by time and sensor measurement or calculations for all the sensors selected on the Graph Report screen.  • The legend section lists the sensors being graphed by type, serial number, associated graph line color, and comments entered during the read process, or the calculations being graphed and the associated graph line color.  • The Graph Report lists the user-defined cycles by cycle number or the associated cycle name.  To create a PDF file:  • Press the **Generate Report** button.  • Enter a Graph label, up to 50 characters when prompted and press **Apply**.  A Graph Report printed version appears.  • Press the **Export** icon printer from the printer list and press **OK**.  • Select the Adobe PDF file and press the **Export** button   • When prompted select the location, enter a file name, and then press the **Save** button.  • Press the **Back** button to return to the Graph Report screen   To print a Graph Report:   Note: The printer driver needs to be loaded   o Edit Sensors  Allows you to select or unselect available sensors from a particular group selected from Select Group drop-down list to be displayed in the graph.  Manual selection, select all, and unselect all options are available for sensor selection..  o Edit Limit Labels   The Edit Limit Labels screen displays upper and lower limits on a graph. The sensor type available depends on the sensor type for the graph.  To add limit lines to the graph, enter an upper and/or lower limit value. These display as horizontal lines at the selected measurement points.  • You can enter a MAX value for a line in the MAX box with a max of six characters.  • You can enter a MAX label for the line in the Label textbox with a max of 50 characters.  • You can enter a MIN value for the line in the MIN box with a max of six characters.  • You can enter a MIN label for the line in the Label textbox with a max of 50 characters.  When you have finished, press **Apply** in the Edit Limit Labels screen.   o Reset Zoom   The **Zoom In** and **Zoom Out** buttons change the graph magnification by preset levels.  + Increase zoom level  - Decrease zoom level  > Expand graph page to the right  < Collapse graph page to the left    o Select Cycle    Select Cycles option is available for selection if cycles were created from the Create Cycles screen.   All cycles can be selected from the Select Cycle drop-down list if enabled.   o Select Group   A drop-down list of available Sensors defined in the setup to display in the graph report.  The following graphs are available on the Graph Report screen and can be selected in the Select Group drop-down list. Some options may not be available due to the type of sensors used in the study and the selections made during the study setup.   • All Temperature Sensors  The Temperature Sensors graph shows the readings for all temperature sensors in the study. You can remove individual temperature sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.  The Temperature Statistical calculations are available for selection from Statistical pane.  Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.  • All RH (Humidity) Sensors  The Humidity Sensors graph displays the readings for all humidity sensors in the study. You can remove individual humidity sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.  The Humidity Sensors Statistical calculations are available for selection from Statistical pane.  Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.  • All Pressure Sensors  The Pressure Sensors graph shows the readings for all pressure sensors in the study. You can remove individual pressure sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.  The Pressure Sensors Statistical calculations are available for selection from Statistical pane.  Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.  • All Current Sensors  The Current Sensors graph shows the readings for all current sensors in the study. You can remove individual current sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.  The Current Sensors Statistical calculations are available for selection from Statistical pane.  Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.  • All Voltage Sensors  The Voltage Sensors graph shows the readings for all voltage sensors in the study. You can remove individual voltage sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.  The Voltage Sensors Statistical calculations are available for selection from Statistical pane.  Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report  • All Contact Sensors  No calculations are available for a contact sensor group.  o Statistical   Based on the Sensor Group selection, the following Statistical calculation graphs are generated:   • Max Value  The maximum reading among all included sensors at the specific timestamp.  • Min Value  The minimum reading among all included sensors at the specific timestamp.  • Avg Value  The average reading among all included sensors at the specific timestamp.  • Avg and Std Dev  The average reading and the standard deviation of all included sensors at the specific timestamp.  • Max-Min  The maximum reading among all included sensors at the specific timestamp minus the minimum reading of all included sensors at the specific timestamp.  • Max-Avg  The maximum reading among all included sensors at the specific timestamp minus the average reading of all included sensors at the specific timestamp.  • Avg-Min  The average reading of all included sensors at the specific timestamp minus the minimum reading of all included sensors at the specific timestamp.  • Lethality  The Lethality calculation is available only if temperature sensors are present in the study.   The accumulated Lethality (Sensor Trends) graph shows the lethality trends for each included sensor at each timestamp programmed or defined to calculate lethality.   Remove individual sensors from the report by clearing them from the Edit Sensors screen.  • Sat P   The Saturation Pressure calculation is only available if the study includes at least one temperature sensor along with some pressure sensors.    The Saturation Pressure vs. Measured Pressure graph shows the measured pressure from the selected pressure sensor and the saturation pressure calculated from the temperature sensors selected in the Edit Sensors screen. You can remove temperature sensors from the Graph Report by clearing the sensor from the list. Change the pressure sensor by selecting a new sensor from the Edit Sensors screen.     To access the Saturation Pressure vs. Measured Pressure graph:    • Select Temp and Pressure Sensors group from Select Group drop-down list.  • From the Statistical pane of the Graph Report screen, check the Sat P box. If you defined cycles on the Create Cycles screen, select a cycle from the Select Cycle drop-down list.  • Select a temperature sensor from the Edit Sensors screen.  The Saturation Pressure calculation is available only if the study includes at least one temperature sensor along with pressure sensors.     • Sat T  The Saturation Temperature calculation is available only if the study includes at least one pressure sensor along with temperature sensors.     The Saturation Temperature vs. Measured Temperature graph shows the saturation temperature calculated from the selected pressure sensor and the measured temperature from the sensors selected in the Edit Sensors screen. Red horizontal lines on the graph display the base temperature (Tb) entered during the study setup, and the base temperature +3 K. The text at the bottom of the graph tells you if the data passed or failed three conditions:    • All measured temperatures and the calculated saturation temperature are within the specified sterilization temperature band.  • Each measured temperature and the calculated saturation temperature do not fluctuate more than 1 K.  • All measured temperatures and the calculated saturation temperature do not differ from each other by more than 2 K.  To access the Saturation Temperature vs. Measured Temperature graph:  • Select the Temp and Pressure Sensors group from the Select Group drop-down list.  • From the Statistical pane of the Graph Report screen, check the Sat T box. If you defined cycles on the Create Cycles screen, then select a cycle from the Select Cycle drop-down list.  • Select a pressure sensor from the Edit Sensors screen.    • Equilibrium    The Equilibration Time graph shows whether all temperature sensors in the Edit Sensors list reached the lethality base temperature within a 15 or 30 second time period, satisfying the equilibration conditions.    Regulations require that sterilization chambers less than 800 liters have an equilibration time no greater than 15 seconds; sterilization chambers greater than 800 liters should have an equilibration time of no more than 30 seconds.    This graph is only available if the sensors had a one second sampling rate during the equilibration period, and at least one sensor reached the lethality base temperature. If you did not define the lethality base temperature during the study setup, the default temperature of 121.1°C is used.    The first vertical red line indicates the time the first Temperature sensor reached the lethality base temperature (Tb). The lethality base temperature is marked by a horizontal red line.    The second vertical line is either 15 or 30 seconds after the first Temperature sensor reached the base temperature, depending on the time period you select. The text at the top right of the graph indicates if the sensors Passed (including the actual equilibration time) or Failed according to the equilibration criteria.  Note: For studies including Humidity/Temperature sensors, the minimum sampling rate is 2 seconds. You should not use humidity sensors in your study if you want to access the Equilibration Time graph.    To access the Equilibration Time graph:    • From Graph Report screen, check the Equilibrium box to display the Edit Sensors screen. From this screen you can:    o Select/unselect sensors  o Select the Reference Sensor from the drop-down list  o Enter a Reference Temperature  o Choose a time of 15 or 30 seconds from the drop-down list  o Select OK to display Equilibration Time graph   EN554 reporting  To get the EN554 reporting you need to have the following minimum definitions in a Setup:  • a group with thermocouples and lethality calculations.  • a group with a Pressure sensor.   The pressure values need to fit with the TC readings, means at 121°C the pressure value must be around 2bar to get the correct results or corresponding to the base temperature defined for lethality calculation.  The time for each reading is displayed at the bottom of the graph.   Note: For all types of graphs, Open, Under Range, Over Range, or NO SIM sensor values are not displayed; for such failure values, a broken graph appears. |  |
| GraphReportNewHelpHeader | Graph Report New | Graph Report New Screen |
| GraphReportNewHelpParagraph1 | Boundary lines (i.e., the study start and end lines). A preview pane at the bottom of the graph displays the graph selection in a white window, while the unselected portion in the graph remains grey. The data appears without any markers initially. When the window is expanded, the button toggles to Hide Cycle Information. If you select Show Markers, the 􀁸 samples appear as dots with connecting lines. If you select Add/Remove Sensors, a window opens listing all the available sensors in that particular run. All the sensors are selected by default. A checkbox enables you to select and deselect sensors for analysis.  • If you select Import Events, a window lists all the available events programmed in that particular run, along with a checkbox to select and deselect the events to import into the graph. All the events are selected by default.  • The Graph Properties offers a number of options: A button enables you to change the trend color. Select the sensor serial number(s) from the list in the Sensor Trends frame, and then select the paint icon. A palette of available colors is displayed. Choose the desired color and press **OK**.  • For the axis range, you can modify the Y axis by entering time in the From and To fields. These fields accept time in the hours: minutes: seconds & lt;hh:mm:ss&gt; format, and as negative or positive integers (including zero). The fields allow up to three digits (excluding decimal digits), and display values with decimal precision of one digit for RH, two digits for temperature, three digits for pressure and contact.  • You can define limit lines for the Y axis in temperature, humidity, and pressure, by pressing the checkbox for limit line selection. Textboxes allow you to select type, width, and color fields. The upper and lower limit fields allow negative or positive integers (including zero). The fields allow up to three digits (excluding decimal digits) and display values with decimal precision of one digit for RH, two digits for temperature, three digits for pressure and contact.  • When you have finished editing the graph, press **Save** to save and show the changes on the graph. Press **Save** and **Continue** to proceed to the Add Cycles screen.   Once you have formatted the graph, you can set up the study data cycles. You can calculate the maximum, minimum, and average readings of all samples in a cycle. If the study was programmed to calculate lethality, you can also calculate accumulated lethality for each cycle. Cycle information is contained in the Qualification Summary Report. To define data cycles:  Press the Add Cycle button. A window opens that lists the following:   1. Various cycle names such as Exposure, Ramp up, etc.  2. Press a cycle name and a window opens allowing the user to type in a user defined cycle name that accepts up to 25 characters (alphanumeric and special characters).  3. You can base the cycle on either Time or Condition by pressing the associated radio button.  If you select the Time option, you enable the 􀁸 Start and End boxes to enter times in hh:mm:ss format. If you select the Condition option, you can enter the condition via two drop-down menus.  4. Press the **Add Cycle** button to save the created cycle and open a new creation page, or press **Cancel** to reset the selections and open a new cycle creation page. You can create up to a maximum of 15 cycles, after which the **Add Cycle** button is disabled. For each cycle, an **Edit** and **Delete** button appears next to the cycle name. Press **Edit** to modify the cycle, or **Delete** to delete the cycle.  When you have finished adding cycles, press **Save Cycles** to proceed to the Performance Analysis or Summary Analysis screens, as determined in The Reports Analysis Screen .  Note: Open, under range, over range, or NO SIM sensor values are not displayed in the graph and, for such failure values, a broken graph is displayed. | Graph Report New Screen |
| GraphReportTemplateHelpHeader | Graph Report Template | Graph Report Template Screen |
| GraphReportTemplateHelpParagraph1 | If you select Template Analysis at the Reports Analysis screen, once you have saved the report cycles, the Template Analysis screen opens. If you have not yet created any report templates, the drop-down list on the Template Analysis screen is initially empty. Once you have created templates, this list displays all the templates in alphabetical order.  When you use a graph template created from a specific study file and apply it to that file, the cycles are created per the sensor type selected in the template. The number and name of cycles and groups remain the same. However, for a graph template created from a different study file, the template cycle names are carried over up to the number of cycles in the template. Any further cycle names remain empty for users to select the option.  When you use a report template created from a specific study file and apply it to that file, the cycles are created per the sensor type selected in the template.  The number and name of cycles and groups remain the same, as do graph calculations. However, for a report template created from a different study file, if the same sensors are used that were used to create the template, the same sensors will be assigned to the group. If they are different, the groups will be empty for the user to name.  Note: If all the groups listed are empty, you cannot launch the Next screen until you have assigned sensors to at least one group in the Group pane. If the same sensors are used in the template and the current study file, the same calculations are assigned to the group. But if different sensors are used, only the statistical calculations (default calculations) are available. When you have finished, press the **Forward** (right) button in the upper right to proceed to the Report Options screen. | Graph Report Template Screen |
| GroupSensorsHelpHeader | Group Sensors | Group Sensors Screen |
| GroupSensorsHelpParagraph1 | Once sensors are defined for the qualification study, these sensors need to be assigned to groups. Grouping sensors allows you to associate a set of sensors with specific calculations. Groups are key to using the software efficiently and effectively. New users should start with reading the section “Understanding Groups” below.  The Groups screen allows you to identify the maximum number of groups as specified in the preferences. When creating a setup, at least one group must be identified before accessing the Calculations screen.   Creating Groups  Press the **Default Groups** button to have the software automatically create groups for all available physical measurands like temperature, current, voltage, or contact closures. In the case that different sensor types for the same measurand are available, they are all combined into one group, e.g. thermocouples and RTDs into the temperature group.  Customized groups can be created by pressing the **New Grou**p button. Enter a name for the new group button and save the new group. The group name textbox allows input up to 35 characters that can be upper and lower case, numeric, special characters, like a hyphen, underscore, slash (forward and backward), and a blank.  If the group button is selected it displays the previously assigned sensors (empty for a newly created group). By pressing the **Edit** button (the small pencil inside the group name button) all available sensors are displayed for selection.  Deleting a Group  To delete a group select the group button and press the **Delete** action button (a trash bin in a circle). After a safety question if you are sure the group is deleted. Please note there is no trash bin or undo function available.  Assigning Sensors to a Group:  The Group Sensors screen allows you to assign sensors to groups. An individual sensor can be in more than one group.  Important: A sensor must be assigned to a group in order to monitor and record readings from that sensor! Any sensor not assigned to a group is considered unused and no data is recorded for that sensor.   To assign sensors: - Select Group, all sensors in that group are displayed - Select the **Edit** button of the group (small pencil in a circle) to see all available sensors. Select sensors as required. - Press **Save** to save changes or **Cancel** to abort the operation.  Moving Sensors  A quick way to move sensors from one group to another is using the move sensor functionality. Press the **Move Sensors** action button (an arrow within a circle) to open a new window with two panes representing the source and the target group for moving the sensors. Select the source and target group and mark the sensors to be moved. The **Move** button between the panes will trigger the operation. Press **Close** or the cross on the upper right side to close the window.  Wiring Overlay  Pressing the action button for the wiring overlay (an open plan in a circle) enables the wiring overlay graphic to display (to go back to the sensor tile view press the **Sensor Tile** action button).   Any asset can store up to five wiring diagram pictures. To add or change a picture, select the corresponding picture slot and press the pencil icon to load a stored picture or activate the camera to take a picture. You can choose one of the wiring diagram pictures per group and place the sensors by drag and drop. The setup stores the position of the stored sensors statically together with the chosen picture. Per group, you can select one picture and the sensor configuration. The Wiring Diagram Overlay can be exported to a wiring report pdf file printer by pressing the **Print** action button. In asset details, the wiring diagram action button displays the wiring diagrams and permits the opportunity to pdf export all or a selected report. The wiring diagrams are part of the setup report.  When the group setup is finished, press **Calculations** to proceed to the Group Calculations screen.  Understanding Groups  Grouping is a key concept of the Kaye Validator software. When defining a setup, grouping allows to identify a maximum number of groups as specified in the preferences and to associate sensors with specific calculations. You can identify sensors and define the calculations you want to perform on sensors per group basis. After your qualification study is complete, grouping is used to customize reports. Use the following guidelines when defining groups: - There must be at least one group defined in a setup. Each group must have a unique name. - Groups should be homogeneous (similar sensor types) since calculations are performed on all the sensors.  - Each group is independent. You cannot define a calculation that has inputs from more than one group. - Sensors do not have to be in consecutive locations. You can assign any sensor on any SIM to a group. - You can assign a sensor to more than one group to relate the sensor’s output to different conditions. For example, you might have the same sensors in more than one group to look at data over different intervals. You could specify the maximum sensor reading during exposure for one group, and specify the maximum sensor reading during the entire qualification cycle for another group. - You must assign a sensor to a group to record data from that sensor. Any sensor not assigned to a group is considered unused and no data is recorded for that sensor.  Grouping Examples - Setup  You may want to do a distribution study to find the coldest/warmest area of an asset. Since you are only testing one vessel, you could assign all your sensors to one group for all your calculations.  You may want to do a distribution study and a penetration study at the same time in order to speed up the validation process. Since these studies require different calculations, you could assign your distribution sensors to one group and perform the associated calculations on that group, and assign your penetration sensors to a second group and perform the associated calculations on that group.  You may want to use the same sensors in different groups in order to look at data in different ways. You may, for example, want to compute lethality during the complete cycle and during the exposure cycle.  You may be testing four small incubators with two thermocouples each. You could define one group for each incubator, and each group could have its own set of calculations. | Group Sensors Screen |
| LiveDataHelpHeader | Select an AVS | Select an I/O Box Screen |
| LiveDataHelpParagraph1 | Once you have transferred a setup into your AVS, you can monitor live data or calibration / qualification study progress on the HMI.  On the Main Screen select the Discover tile to go to Select Kaye AVS screen. On Select Kaye AVS screen press the **Discover** button to locate the Kaye AVS units. This screen displays the available Kaye AVS units on the network. Press the tile for the AVS you need to use, and then press the **Connect** button to establish the connection between the Console and the AVS.   Once you have selected the AVS and established the connection, the Kaye AVS navigates to the Live data screen. On Live screen you can switch between List and Graph views.   Once Kaye AVS is connected, the Main Menu displays the status of the connected Kaye AVS with its name in the upper right, along with a Disconnect option.  The Events tile appears on the Console once it is connected to Kaye AVS. To navigate to the Events list screen, select the Events tile. | Select an I/O Box Screen |
| LoginScreenHelpHeader | Starting the Validator for the First Time | Login Screen |
| LoginScreenHelpParagraph1 | • Starting the Validator for the First Time  The Kaye Validator AVS software allows a user with System Administrator permissions to create and maintain user accounts, set preferences, and policies. All system administration tasks are accomplished through the Admin tile on the Main page and logged in the audit trail.  The Kaye Validator AVS software includes a Kaye Default System Administrator account that allows you to log in to the Password Maintenance utility, following initial program installation, in order to create your own System Administrator account. The Kaye default System Administrator account is automatically deleted when you exit the Password Maintenance utility. You can, then, use your own account to perform all your system administration tasks.  For first time login as the Kaye Default System Administrator: 1. Enter Kaye in the User ID textbox.  "Kaye" is the default System Administrator user ID. The User ID textbox is case sensitive, ensure that you enter the default user ID exactly as it appears here.  2. Enter "411" in the Current Password textbox. 411 is the default System Administrator password.  3. Press Login.  The Main screen appears. You are now ready to create your own System Administrator and other accounts  • Password Change  After creating a new user or an Administrator a password change is automatically triggered to ensure that the password is only known to the corresponding user. In addition, the user can change the password anytime on the login screen by checking the "Change password" checkbox. | Login Screen |
| MainScreenHelpHeader | Main Hub Page | Main Screen |
| MainScreenHelpParagraph1 | The Main Hub page provides access to the major functions of the Kaye Validator AVS software.  The user’s name and title are displayed on the top of the page along with the connection status to a Validator AVS.   The element of the software is: • Tiles – You will see this tile design throughout the Kaye Validator AVS Software. Click on a tile label to enter a task-specific part of the program. The Main Hub page is subdivided into two major sections: • Activities  • Hardware  Each of these sections are built with tiles that have defined functionalities:  Activities : • Assets  • Admin  • Equipment  • Audit • File Management  Hardware  If not connected to hardware:  • Discover  If connected to hardware:  • Monitoring  • Events  If connected and a qualification study is running:  • Qualification Study  • Events  Click this tile… To…  Assets To add, edit and view details Assets that are validated with the Kaye Validator AVS. On Asset Details screen you can begin the process of creating a setup, initiate calibration, initiate qualification and report generation.  Admin To change policies, preferences and user account management.  Equipment To add and search the equipment used in a given study, i.e. AVS, IRTDs and calibration baths.  Audit To provide a complete listing of events that affects the integrity of the Kaye Validator AVS program. The Validator AVS software maintains the audit trail, which contains all events and identifies the type of actions performed, the date and time the action occurred, the name of the responsible operator, and any additional information required to understand the action taken. Audit trail data by default is available to authorized personal.  File Management To synchronize the data for Assets (setups, study data report & documents), Users, Equipment & Audit trail with a remote folder. This can be used to exchange data with other consoles or backup and restore data. Additionally, data can be archived (moved to a remote folder) and single data files can be imported into the Kaye validation console.  Discover/Monitoring To locate and select available Kaye hardware. On Select Qualification study AVS screen press **Discover AVS** to display available Kaye AVS units on the network. Press the tile for the AVS you want to use, and then press **Connect** on the screen to establish the connection between the Console and the AVS. Once Kaye AVS is connected the Main Hub page displays the status of the connected Kaye AVS with its name at the upper right, along with a Disconnect option. Once you have selected the AVS and established the connection, the Kaye AVS navigates to the Live data screen. On Live screen you can switch between List and Graph view. Events tile appears on Console once it is connected to Kaye AVS. Selecting the Events tile, navigates to the Events list screen. Once you have transferred a setup into your AVS, you can monitor live data, calibration, or qualification study progress.  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 to the system and set site options. For the next log in, you will need to enter your own System Administrator user ID and password. The system can identify you by name using your unique user ID and password combination. Note: A good practice is to establish more than one individual with Administrative functions. This way the Administrative functions can still be accessed even if one of the System Administrators is unavailable. | Main Screen |
| PerformanceDataSourceHelpHeader | Performance Analysis |  |
| PerformanceDataSourceHelpParagraph1 | This functionality allows you to synchronize and superimpose up to three qualification runs.   It displays a graphical analysis to compare similar runs. For example, from “Sterilizer 1” with data from “Sterilizer 2” or “Autoclave run 2014” with “Autoclave run 2015”.  The Advanced Analytics screen displays all available Qualification runs for the selected Asset.   Select a file by pressing the action button for that file to synchronize with up to 2 additional files on next screen. Choose the Sensor Type and press OK. The next screen will shop up all available runs done with selected type of sensor, so for example all runs with temperature data. They will show up with Setup Name and Date and Time run was done.   Press Data Sources to displays two panels on screen. The left panel, Add Source, displays up to 12 available study files, with a **More** button that displays all other study files.   Note: The study files can include Validator, ValProbe, and RF ValProbe study files.    Highlight a study file and press the **Forward** (right) arrow to move the file to the right panel, which displays the setup files selected for the report. (To remove the file from the report, touch the file, it will be highlighted, and then touch the **Backward** (left) arrow.) The selected files are highlighted in a mix of dark blue and orange on the left, while the unselected files appear in light blue. Up to three qualification study files can be added. (A warning appears when trying to add a fourth study.)  Select two or three studies before using the **Synchronize** button at the bottom of the right panel. Synchronize displays the data of the files in graph form in a sequence.   At the right of each graph, a Sync Point textbox is used to enter the starting point of synchronization time in hh:mm:ss format. Select each Graph to define a Sync Point using the Timeline of each diagram. Press **Super Impose** on the bottom right of the screen. Enter the Sync duration of first file/run. The time of first file/run (Sync Time) from Sync Start to End Point is taken and used for the other files starting from their selected Sync Start Point. For example, if you selected the Sync Start Point of the first file at 10:00:00 and the Sync End Point at 10:27:00 the 27 minutes are taken and used from the Sync Start point of the other selected files. After having done so, the Graph is displayed with the Temp Scale on the y-axis and the time interval (if we take example above 27 minutes) on the x-axis. This permits for example, a comparison of the Exposure cycle of two or three runs with the same Setup at same autoclave but at different times. Sync Start Point can be the Exposure Start of each selected file and the Sync End Point to be defined for first selected file can be the end of Exposure or any other Time as this time will then be taken for the other selected files.  In the Graph properties you manipulate colors for the graph and the superimposed graph can be printed as well.  Two buttons appear at the bottom right:   •**Synchronize** — Redraws the graphs with a user-defined starting point and the conclusion of the study as the end point.  •**Super Impose** — Superimposes one file on to another for comparative analysis. |  |
| pgAllEvents | Event List |  |
| pgArchive | Archive |  |
| pgArchiveHelpParagraph1 | The Archive function works in a similar fashion to the Sync out function, except it does not copy but moves files to a file location for archiving purpose, removing the files from the console. Therefore, in addition to the Sync out function there is an archive date. All files older than the specified date are moved. Like in Sync out the assets can be selected individually. |  |
| pgAutoSync | Auto Sync | Auto Sync Screen |
| pgAutoSyncHelpParagraph1 | Automatic Data Synchronization  You can set the Kaye Validator AVS software for automatic backup synchronization based on a time interval. Once set, the console syncs to a folder connected via a networked mapped drive path. Automatic sync out to a local folder (e.g. USB thumb drive) is not supported. Please use manual sync out to backup data to a local folder instead. Please see manual sync out function for details.  Note: A Sync in from the folder to update content on the console must be initiated via the manual sync in function.  The following requirements for automatic sync out are as follows:  - Console must be connected to a network.  - A network drive must be mapped inside Windows Explorer with rights to create, modify, and delete files. The network server needs to be entered with IP address (not with the machine’s name) and it is recommended to have at least two folder levels and no blank characters in the path.  To set up automatic sync out: 1. Activate Auto Sync with the checkbox. 2. Select a mapped network drive in N/W path using the **Browse** button. 3. Enter a valid user name and domain separated by @ e.g. user.name@domain-name.com. 4. Enter a valid password for the user. 5. Choose an interval and a timepoint for synchronization. Keep in mind the machine should be connected to the network and preferably idle at that time.  You can test the Connection using the **Test Connection** button. On success, the system informs you of the folder with the given credentials.  The settings are stored even after deactivation of auto sync. The routine success of the sync out can be reviewed in the audit trail. |  |
| pgAVSConvert | AVS Convert |  |
| pgAVSConvertHelpParagraph1 | The AVS Convert function imports single study files into the Asset system of the console. Single study files can be copied to disk out of the Asset details for importing them into another console or send them by email. The study files copied through the USB side port, copies the files in a single file format that needs to be imported into the AVS software. Simply select a single data file in the browser, it is possible to add a comment for easier identification. If the corresponding asset does not exist already in the system, the software creates a new asset and setup file from the information stored in the study file. |  |
| pgCurrentEventHelpParagraph1 | The Kaye Validator software maintains the List of Events, Event Name displaying the type of action performed, Time displaying the date and time the action occurred, and the message giving information pertaining to that Event.  • Event Name – list of events which shows the particular action performed at that time. • Time - displays the time at which an event occurred. • Message - displays information related to an Event. |  |
| pgFileManagement | File Management |  |
| pgFileManagementHelpParagraph1 | The Kaye Validation console software can be used to synchronize data across several consoles. The functionality can also be used to backup, restore, and archive files. Synchronization requires a location to place commonly used data. This can be any folder the Operating system can access for read/write operations, like a shared folder in the network, an external drive or USB thumb drive, or a folder on the Kaye console itself. Please contact your system administrator to set up a file location. The sync functions can be used for a simple backup but also to merge the data of several Validation console data sets following some rules for merging: - Preferences and policies are not synchronized. - If two items with the same name exist, the item is updated with the latest version (depending on the modified date) in case for users and assets. - In the case of two items having the same name but different dates (reports, study files) both are retained. |  |
| pgFirmwareUpgrade | Firmware Upgrade |  |
| pgFirmwareUpgradeHelpParagraph1 | A new firmware upgrade release for the Kaye Validator AVS can be applied using the AVS Firmware Upgrade in the Admin functions. For upgrading the Firmware, please follow the steps exactly as outlined in the software:  1. Dock the console to the Kaye Validator AVS that is going to be upgraded. Note: A remote upgrade using Ethernet or Wi-Fi is not supported!  2. Press the **Get AVS SN** to establish a connection to the Kaye Validator AVS. This ensures the connectivity and retrieves the serial number for the audit trail entry.   3. Insert a USB thumb drive with the firmware provided by Kaye into the USB port located on the back of the Validator AVS. You can easily identify the correct USB port by referring to the displayed picture.  4. Everything is ready to upgrade the firmware, please ensure that the Validator AVS is properly powered and not switched off during the upgrade process; if not, the system can be damaged and then sent to in a Kaye Service Center to be restored. Press **Upgrade Firmware** and wait until a message tells you to restart the Kaye Validator AVS.  Note: Upgrading the AVS Operating system can take up to 15 minutes depending on the amount of copied data. Please be patient and do not switch the Validator AVS off before the corresponding message is displayed. |  |
| pgGraphCustomize | Customize Graph | pgGraphCustomization |
| pgGraphCustomizeHelpParagraph1 | The **Custom** button allows display customization within groups by changing the Max and Min values of the Y-axis of the graph and which sensor to display from a sensor list | pgGraphCustomization |
| PgHardware | Hardware | Hardware Screen |
| PgHardwareHelpParagraph1 | The Hardware screen graphically represents the validation system and connections. It can be accessed from any of the live data screens.   Communication Links On the Hardware screen hardware items like the IRTD and temperature baths (Kaye equipment) are displayed as active (green) or inactive (grey) and are shown with a communication link. The colors on the communication link are as follows, a green link indicates active communication and a grey link indicates inactive communication (or Device not found), which means that the hardware is not communicating and may not be connected properly.  Note: If the link to the AVS unit is not connected, all links will be marked with a grey color.  This screen displays temperature and information from up to two Intelligent RTD (IRTD) probes, illustrates the AVS validation equipment connected, and indicates whether the Kaye Validator, the temperature reference, and which communication links are functioning properly.  In the case of a connected device not being listed, pressing the **Refresh** button forces an update of all communication links.  Hardware Information Each hardware item has equipment-specific information that is displayed on respective icons. • Select the AVS unit graphic to display physical information about the Validator. The information displayed includes the Validator serial number, the date the Validator was last calibrated, the setup that is currently loaded into the Validator, and the version number of the Validator firmware.  • For each SIM, the SIM serial number, SIM Type, and the SIM calibration date are displayed. • Click the temperature reference graphic to view the information for Model and Version. Note: The current temperature reading of the reference is displayed. By entering a value into the set field and pressing **Set Tempera**ture, it is possible set the bath to a new target temperature. • Click the IRTD1 or IRTD2 graphic to view the information on Address, Probe ID, Label (including the serial number), Calibration Date, User Label, and Temperature scale. Note: The current temperature reading of connected IRTDs is displayed.  Sensor Offsets The **Sensor Offsets** button displays a table with sensor offsets for each SIM and the different sensor inputs (InputMin, OutputMin, InputMax, OutpitMax). If the values are displayed it indicates that the SIM and the sensors are calibrated correctly for the current SIM slot. If there are no values, but INVALID entries it indicates that the SIM and sensors are not calibrated, or the SIM is not in the same slot as during the calibration. Reviewing the offsets to ensure that the system is calibrated correctly and ready for use in a study.  Access AVS Files In monitoring mode (not while a study is running), it is possible to access the Validator AVS and review the study files stored in the machines memory. | Hardware Screen |
| pgLiveData | Live Data | pgLiveData |
| pgLiveDataHelpParagraph1 | The Monitoring screen displays real-time sensor readings and calculations on a group basis. Available groups are listed on the left panel of the screen and displayed based on the last transferred setup. Along with real-time sensor readings, the setup name and AVS serial number is displayed. The hardware connection button permits access to detailed information about the connected hardware and the current time from the AVS. Time synchronization between Console and AVS occurs at the start of any study where the console time sets the AVS time. In case of a discrepancy of the timestamp of the AVS with the console, it resolves automatically when the next study is started.   Sensor Readings – List View  Every Group is represented by a table showing the physical location of the sensor input with a SIM channel (SIM-CH) in addition to the label (derived from the last transferred setup) and the sensor readings. Real-time readings for each sensor assigned to the selected group are displayed by a sensor label on the left side of the screen in tables. The software arranges the tables automatically. It is possible to zoom and scroll inside the tables. If there are no valid readings available the software shows the following error messages:  TC SIM Error Code Open: Sensor open or contact closure open. Under: The reading is below the expected range of the sensor. Over: The reading is above the expected range of the sensor. INVALID: The reading is in the exponential range.  RTD SIM Error Code Open: Sensor open. Under: The reading is below the expected range of the sensor. Over: The reading is above the expected range of the sensor. INVALID: The reading is in the exponential range.  4 to 20mA SIM Error Code Open: Sensor open. Under: The reading is below the expected range of the sensor. Over: The reading is above the expected range of the sensor. INVALID: The reading is in the exponential range.    Sensor Readings – Graph View Pressing **Graph View** switches to real-time graphing of senor readings, leaving the live data screen to the software main hub the graphing will restart (switching to list view will not restart the graphing). The sensors are organized in groups defined in the setup. The different groups can be selected by pressing the buttons above the graph.   The graph scales automatically to the sensor readings and time range. Inside the graph it is possible to zoom and scroll. For easier handling, it is possible to lock one axis by unchecking the corresponding checkbox, which enables zooming in only one direction. The **Reset Zoom** button resets the zoom level to default.  Additionally, the Y axis can be set to a manually entered scale and reset anytime to automatic scaling. For better visualization of the process specification, two limit lines may be set. The current max and min value is highlighted with red and blue line colors and the sensor label, timestamp, and value are displayed. The current max and min value are also listed in the calculations pane. Pressing List view switches back to the table view of the sensor readings.    Calculations  The calculations are displayed in List and Graph view. Select a group from the on the left panel of the screen to display calculations for that group in the right-side panel. A click on the arrow button will hide or unhide the calculations window. When viewing sensor readings and calculations, the following guidelines apply: • Calculations are computed, and events are monitored, every scan and displayed. • The resolution of sensor readings and calculation results are dependent on the lowest resolution in the group. • Uncalibrated sensors are allowed to participate in all calculations and events during the qualification study. • Sensors with error messages are not allowed to participate in calculations or events. • Statistical Calculations – computed each scan based on all sensors in the group.  In Monitoring Mode, the statistical calculations (Max, Min, Max-Min, Average, Standard Deviation, Max-Average and Average-Min) are displayed.  If Kaye AVS is in monitoring status, you can switch between List and Graph view to see live data from the Validator on the screen. The Hardware Connection button on the live screen brings you to the Hardware screen which displays the communication status between all the devices and apparatus. | pgLiveData |
| pgMappingSensors | Mapping Sensors | Mapping Sensors Screen |
| pgMappingSensorsHelpParagraph1 | Mapping Sensors | Mapping Sensors Screen |
| pgProgramLoggers | Program Loggers | Program Loggers Screen |
| pgProgramLoggersHelpParagraph1 | Program Loggers | Program Loggers Screen |
| pgQualification | Qualification Study |  |
| pgQualificationHelpParagraph1 | During a qualification study, the live data screen displays real-time sensor readings and calculations for each group defined in the setup. In addition, a user can review the qualification parameters and start or stop manual events that are logged in an extra window. The Graph View enables viewing data graphically in respect to corresponding group.  Monitoring Screen  The Monitoring screen displays real-time sensor readings and calculations on a group basis. Available groups are listed on the left panel of the screen. Select a group from the left panel of the screen to display real-time sensor readings and calculations for that group in the right side panel. When viewing sensor readings and calculations, the following guidelines apply: • Calculations are computed, events are monitored, and displayed. • The resolution of sensor readings and calculation results are dependent on the lowest resolution in the group. • Uncalibrated sensors are allowed to participate in all calculations and events during the qualification study. • Open, under-range, over-range, or failed sensors are prohibited to participate in calculations or events.  Sensor Readings Real-time readings for each sensor assigned to the selected group are displayed by sensor label on the left side of the screen. Open, failed, over range and Under range sensors are marked as OPEN, FAILED, and OVER or UNDER respectively. If lethality has been defined for the selected group, Accumulated Lethality values are displayed.  Graph View Pressing **Graph View** switches to real-time senor readings graphing. The sensors are organized in groups as defined in the setup. The different groups can be selected by pressing the buttons above the graph. The graph scales automatically to the sensor readings and time range. Inside the graph it is possible to zoom and scroll. The current max and min value are highlighted with red and blue line colors respectively, along with the sensor label, timestamp, and value. It is possible to lock the zoom to either the X- or Y-axis for more accurate zoom operations. The **Reset** button resets the view to the automatic view.  The **Manual Scale** button sets the max and min value for the Y-axis manually by entering values. The button changes to **Auto Scale** which can be used to return to automatic scaling.  Historical Data When connecting a Validator AVS with a running study, the study data is automatically downloaded (indicated by a progress cycle and message in the Graph view). Once the download is complete, the historical data is accessible via the Graph View. With the dropdown menu the X-axis can be set to timeframes from 1 to 24 hours. The timeframes are displayed below the graph with time information and can be displayed by pressing on it. Depending on the number of chunks a scroll bar might become available. The arrows on each side allow movement through the data, or the timeframe can be set via the Manual scale function. Pressing the right double arrow jumps to the latest values and enables real-time data. While historical data is displayed, a line is available to mark any point in time to display the corresponding calculations and a checkbox to display the sensor readings in a table for that timestamp. Note: If you can see the marker line and the checkbox you don't see live but historical data on the screen!   Layout View The Layout View displays data using wiring diagrams defined in the setup. For every group, a separate wiring diagram with sensor tag positions can be defined. Selecting the "Senor Value in Table" switch opens a complete legend with sensor descriptions for the active Layout View.    Calculations  The real-time calculations defined for the selected group are displayed on the right side of the screen. Calculations. The calculations are displayed in List and Graph view. Select a group from the left panel of the screen to display calculations for that group in the right-side panel. Pressing the arrow button hides or unhides the calculations window. Statistical Calculations are computed each scan based on all sensors in the group.  Start and Stop Events  The bottom right corner in the qualification screen displays the command buttons. Those buttons can be used to order start and stop events like Qualification and Exposure and act depending on what is defined in the setup. For example, if a user has specified a manual qualification start condition, the qualification study screen displays only one command button in an active state with a Start Qualification label. The qualification study starts only once this button has been pressed. If the user has specified an automatic start condition, the command button (Start Qualification) is not available to the user and the qualification study start condition is displayed in the Qualification parameter window which appears when pressing the **Criteria** button (available in the same Qualification screen adjacent to the **Hardware** button).  Once qualification has started, the next function displays. For example, if exposure is programmed to start manually, then the next command button appears to be active with a Start Exposure label in the qualification screen. If exposure is programmed to start automatically, the corresponding command button (Start Exposure) remains inactive with the start exposure condition displayed in the Qualification parameter window. This appears by pressing the **Criteria** button (available in the same Qualification screen adjacent to the **Hardware** button).  Message box  During the qualification study the occurrence of all real-time events are displayed on the Messages box present in the Qualification study screen’s right panel.  New Messages are always displayed at the top of the message window. The time stamp (date and time) of each event is displayed beside the event message.   The **Hardware Connection** button in the Qualification study screen takes you to the Hardware screen, which displays the communication status between all devices and apparatus.  The **Criteria** button only displays during initiating a qualification study displays a popup on clicking the button; where it presents the Qualification parameters details defined in the corresponding loaded setup. |  |
| pgReportContentScreen | Report Content Screen |  |
| pgReportContentScreenHelpParagraph1 | The Report Content Screen is used to include/exclude selected group items or complete groups from a report. The table list the group names and associated calculations that can be included/excluded with checkboxes.    • Include/exclude all contents using **SelectAll / ClearAll** buttons respectively.  • Include/exclude groups with all associated calculation by checking the group name. After creating new groups in the Edit Group screen, it may be necessary to activate the group in this screen.   • Saturation Calculations (Sat T/Sat P) appear in the Detailed Report only and are select for all groups together.   • Lethality and MKT are mutually exclusive; if the MKT box is checked while Lethality is selected for that group, a message appears that only Lethality or MKT can be selected.   • MKT option if selected against a group will get reflect only in the Summary report. The Summary Report will use the Aleth column to display the MKT values   Save modifications on this screen by pressing the **Save** button or leave the screen without changes using the back-arrow button. |  |
| pgReportSelection | Report Selection Screen |  |
| pgReportSelectionHelpParagraph1 | The Report Selection screen is used to select the type of generated report.    1. Standard Reports: The data is displayed as a text report with tables: - The Qualification Detailed Report organizes information for each group by sensor data and type of calculation (lethality, statistical, saturated steam). You can customize the Qualification Report by specifying the groups to be reported, add events based on the stored data, and add explanatory notes and comments to the beginning or end of the report. - The Qualification Summary Report summarizes your study. You can apply several calculations.    2. Graph Report:  Generation of a Graph report for defined groups and cycles, graphical reports for statistical lethality, saturation pressure, saturation temperature, and equilibrium calculations. |  |
| pgSelectLoggers | Select Loggers | Select Loggers Screen |
| pgSelectLoggersHelpParagraph1 | Select Loggers | Select Loggers Screen |
| pgSensorsInformation | Sensors Information | Sensors Information Screen |
| pgSensorsInformationHelpParagraph1 | Sensors Information | Sensors Information Screen |
| pgStandardReport | Standards Report Screen |  |
| pgStandardReportHelpParagraph1 | The final step to print a report is the selection of report options and types. At the top of the screen, the asset type, number, study type, and date appear.  • Report Content: include/exclude selected group and calculations from the reports. • Header/Footer : customize the header/footer, add comments, and include/exclude system messages . • Select Print Rate option from dropdown to adjust the print sampling rate of the Detailed Report  Note:  • For new groups added under Edit Groups to be part of the Detailed/Summary report, it is required to select the corresponding Groups and its calculations in Report Contents.  Qualification Report types: - Select either the Summary or Detailed option. - Then press the **Generate Report** button in the bottom right corner to generate the respective report types |  |
| pgSyncIn | Sync In |  |
| pgSyncInHelpParagraph1 | The sync in function copies data from a file location to the console. It can be used to restore data of a backup generated with the Sync out or Archive function. As in the sync out function, the user can select which data and which assets are copied to the console. In addition to the Data selection there’s a date filter to prevent old data copying to the console. The date filter specifies a timeframe with a simple dropdown selection. The copied data is merged with the existing console data. |  |
| pgSyncOut | Sync Out |  |
| pgSyncOutHelpParagraph1 | The Sync out function is used to copy data content from the console to another file location. If the content of one console is copied to a dedicated folder, it serves as a backup function. In the case that the data of two or more consoles synchronizes to the same folder, the data is merged together, to build up a pool of shared data for a work group. You can select which data is copied. If an asset is selected the asset with all the information (setups, study files, reports, documents) is copied. It is also possible to select only one or a few assets to transfer from one console to another; it is also possible to make a complete transfer with user, audit, equipment, and asset data, depending on the setup. |  |
| PoliciesHelpHeader | Policies | Policies Screen |
| PoliciesHelpParagraph1 | The Kaye AVS permits users to set policies that give more flexibility when running the software. These options are initially disabled when you install the software.  As a System Administrator you can enable policies that:   ▪ Require minimum length password: For all user accounts, from 6 (default) to 16 characters.  ▪ Expire Passwords: Set passwords to expire after a number of days, from 1 day 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 180 days. The software displays the password expiration date to the user at login when there are five days or less until their password expires. Expired passwords are not accepted.  ▪ Disable user accounts after three consecutive login failures: This option disables a user account if there are three consecutive login failures at the console for the same user ID. If a user account is disabled, the System Administrator must enable the account and assign a new temporary password. By default, it is unchecked.  ▪ Display User IDs during entry option allows the user to display User ID at Login credentials window Default Display User ID during entry Option is enabled  ▪ Disable Password System Setting: Disable the password system for the entire application. By default, this setting is disabled. The password system should not be disabled in GMP environments. As per the 21 CFR Part 11 requirement in which all user actions should be recorded with proper details.  ▪ Allow Editing of D value in Lethality Equation: Allows users to change the D value in the lethality calculation. When this option is enabled, the D value field on the Lethality Calculations screen is displayed and active. If this option is not enabled, the D value field is displayed but not editable when creating a new setup or when customizing lethality in the report tool. However, if there is a D value other than 1 in an existing setup, the D value field is displayed and active.  ▪ Instrument Calibration Warning: To display a warning to the user when the Kaye AVS calibration is set to expire. The duration can be set from one month to 24 month(s), the default setting is six months. | Policies Screen |
| PreferencesHelpHeader | System Preferences | System Preferences Screen |
| PreferencesHelpParagraph1 | The Kaye AVS software installs with default system settings. A user can change any or all the settings on the Preferences screen. The new settings become effective immediately.  Company Name: This field is used to enter a company name. Use the onscreen keyboard to enter your company’s name. The maximum character length is 100 with a combination of characters/alphanumeric.  Temperature: A dropdown selection list is available with options to set the temperature units to Celsius or Fahrenheit. All calculations are performed in the temperature units specified here. The IRTD and the temperature reference (LTR –90, LTR –25/140, LTR –40/140, HTR 400, CTR –40, or CTR –80) are also programmed to operate in these units.  Important: If a setup is created using one temperature unit and then changed in the Preferences screen, users are prompted to change to the new settings the next time the setup is saved. However, only the label is changed, not the temperature value. The user needs to ensure that all temperature values entered are still appropriate for the new temperature units. For example, if user created a setup using ˚C, they may have entered 100.0 ˚C as a calibration setpoint. If the temperature unit is changed to ˚F, the software changes the calibration setpoint to 100.0˚F, not 212.0˚F. If the setpoint should be 212.0˚F, go to the Calibration screen and change the temperature value.  Max Groups: - Maximum groups allowed in a setup can be customized with “Max Groups” preference setting. The default for the Max Groups selection is 20. A user can change the default preference setting by selecting any of the options (10, 20, 25) available in dropdown list.  Line Frequency: - Frequency matching the user environment can be selected from a dropdown list between 60 Hertz or 50 Hertz. If the line frequency setting does not match the used power line, the system cannot measure with maximum accuracy.  Pressure: - Select the units used for display and report tool. Absolute pressure units for saturated steam calculations can be selected from the Pressure Units dropdown list. If the “other” option is selected from dropdown list, enter a value of one atmosphere for the absolute pressure units.  Alternate Console ID: If necessary, user can enter an alternate machine identification number. Different console IDs are displayed in the audit trail for identification.  Data Directory: The default data file directory path is displayed as C:\Program Files (86)\Kaye\Kaye AVS\Data Files.  Allow User to Change Lethality: Enable users editing the Lethality calculation in the report tool. Press Yes or No to indicate if you want to enable a user to change lethality.  IRTD Stability Threshold Lower Limit: Setting the threshold directly, affects the IRTD stability located in Stability Criteria->Calibration Parameters, while defining a setup. With Temperature Units selected as Celsius/Fahrenheit IRTD stability is changed to default values of 250 ˚C/482 ˚F  Enter the lower limit for IRTD stability.  Logo: A user can upload a picture/image using “+” Change button. The graphic can be in the following formats .bmp/.png/.gif/.jpeg etc. The uploaded file size should be less than 5 mb. The ideal logo size is set to 90 x 30 pixels. Any other size is resized this format.   Report Footer: This setup specifies the footer for Setup, Calibration, and Verification reports. The footer for Detailed, Summary, and Graph reports are specified in the report tool directly. | System Preferences Screen |
| QualificationParametersHelpHeader | Qualification Parameters | Qualification Parameters Screen |
| QualificationParametersHelpParagraph1 | Specify the conditions that control qualification study on the Qualification Parameters screen. From this screen you specify:   Start Qualification: - Used to start the qualification cycle manually or automatically. There are multiple conditions to start a qualification automatically. Please define by selecting from list box.  Select the condition to start qualification from the Start Qualification list box. Valid conditions are manual, any input compared to a fixed number, a contact input, and time of day. Enter the event limit value, event switch state, or time of day in 24-hour format, as required.  Note: If a user selects to automatically start qualification, the trigger condition must go from FALSE to TRUE to be recognized. For example, a contact may be programmed to start qualification when CLOSED. If the contact is initially CLOSED when a setup is downloaded, it must cycle through OPEN and back to CLOSED to be recognized as a CLOSED event. All other events are recognized whenever a qualification cycle is active, and the condition is TRUE. For example, a contact may be programmed to start exposure when CLOSED. If the contact is initially CLOSED when the Start Qualification event occurs, Start Exposure occurs on the data set following Start Qualification.  Start Exposure: - Used to start an exposure cycle manually or automatically. Use one of the conditions from the dropdown list to start the cycle automatically. Select the condition to start the exposure from the Start Exposure list box. Valid conditions are, undefined, manual, any input compared to a fixed number, a contact input, cycle time defined from the Start Qualification event up to at least 9999 hours later, minimum temperature of any group compared to a fixed number, and maximum temperature of any group compared to a fixed number. Enter the event limit value, event switch state, or event elapsed time, as required.  Note: If user selects Undefined, this setup will not use an exposure cycle. End Exposure is automatically set to Undefined. For exposure or lethality calculation they are defined in the setup. The report tool requires the definition of an exposure cycle as mandatory.  Stop Exposure: - It is used to stop an exposure cycle manually or automatically. Please use one of the conditions from dropdown list to stop automatically.  Select the condition to stop exposure from the Stop Exposure list box. Valid conditions are, undefined, manual, any input compared to a fixed number, a contact input, cycle time defined from the Start Qualification event up to at least 9999 hours later , minimum temperature of any group compared to a fixed number, maximum temperature of any group compared to a fixed number, minimum accumulated lethality exceeds a fixed number, and exposure time defined from the Start Exposure event up to at least 9999 hours later . Enter the event limit value, event switch state, or event elapsed time, as required.  Note: If user selects Undefined, this setup will not use an exposure cycle. Start Exposure is automatically set to Undefined.  Stop Qualification: - Used to stop the qualification cycle manually or automatically. There are multiple conditions for stop qualification automatically. Define the condition by selecting it from the list box.  Select the condition to stop qualification from the Stop Qualification list box. Valid conditions are, manual, any input compared to a fixed number, a contact input, cycle time defined from the Start Qualification event up to at least 9999 hours later, minimum accumulated lethality compared to a fixed number. Enter the event limit value, event switch state, or event elapsed time, as required.  Note: If you want to set all conditions to manual operation, click the **Manual** button.  Data Storage: - Used for collecting Samples based on the sampling rate which is selected in dropdown list. This data is stored and available for analysis. Large data files require a longer time for analysis and handling. It's recommended to use reasonable sampling rates derived from the application requirement. If SIM slot number four is configured in the setup, the fastest sampling rate is reduced to two seconds.  Clock Adjustment: If set to qualification start, the operator can change the console clock within a +/- 15 minutes range at the start of the study. This can be useful when synchronizing the Kaye Validator AVS to time of a validated asset. The privilege to adjust the clock needs to be activated per user in User Management.  Relay: - You can set two output relay events in Qualification Parameters and set events such as, During Exposure Cycle, Qualification Study, User defined events (out of 20 events), or set Unused from dropdown list. | Qualification Parameters Screen |
| ReportAnalysisHelpHeader | Report Analysis | Report Analysis Screen |
| ReportAnalysisParagraph1 | To access the Reports Details screen (which has data for any particular report selected through the Reports Hub), press the button for a specific asset on the Reports Hub.  Note: You can access the Reports Details screen for a particular asset by pressing the **Report Details** button on the Asset Details screen.  The header lists the particular asset (by name) for which you are looking up reports. A row below includes information such as Equipment ID, Type, Size, and Manufacturer name.  You can sort the reports by pressing: • Type – if it’s a Setup report, Qualification, Calibration or Calibration Verification. • Filename – name of the report given during programming. • Date – date the report was created. • Run Number – If a run number for Qualification or Calibration is available • Actions – Generate a report or view a PDF version of the report.  Each category has a filter, where the search can be narrowed down to locate the report. To save a PDF of a report already generated, select the report and press the PDF icon.  (Only available for Setup, Calibration, and Calibration Verification reports; for Qualification reports you first need to go through reporting)  To generate a report, press the checkbox and then press the graph icon. Select Sensor type and press **OK**.  When selecting a qualification study, the **Export CSV** button becomes active. The **Export CSV** button exports the study to an Excel readable format (.csv). The csv format is an open table format that can be easily imported into spreadsheet programs. It is possible to select different datasets (Readings, Lethality, Statistical Calculations, Sat T & Sat P) for export. They are then saved as single csv files together with an index file into one ZIP Archive file. | Report Analysis Screen |
| ReportAnalysisScreen | Report Analysis Screen | The Report Analysis Screen |
| ReportAnalysisScreenHelpParagraph1 | The header of the Report Analysis screen displays the type of asset (e.g., sterilizers or autoclaves or heat chambers), and the name of the asset. You can choose from different types of analysis for a qualification study:  • Standard Reporting – Creates Setup, Summary, Detailed and Graph reports.  • Advanced Analytics – Provides an analysis option for study files.  (Note: This option is only available when using the Report Tool application directly.)  Press either Standard Reporting or Advanced Analytics to proceed to the Report Detail Screen. | The Report Analysis Screen |
| ReportContentHelpParagraph1 | In the Report Content screen, a user can select report options that to include/exclude selected group items from reports.  This screen is a part of the Report Content screen which has the functionality to customize the group options as mentioned below:  • Include/exclude all contents using **SelectAll / ClearAll** buttons respectively.  • Lethality and MKT are mutually exclusive; if a user checks the MKT box while Lethality is selected for that group, a message appears stating only Lethality or MKT can be selected when pressing the **Done** button of the Report structure window.   • MKT option, if selected, against a group will get reflect only in Summary report. The Summary Report will use the Aleth column to display the MKT values  • Save modifications by clicking the **Save** button. | Report Content Screen |
| ReportContentPageHelpHeader | Report Content Screen | Report Content Screen |
| ReportDashBoardHelpHeader | Report Files list screen |  |
| ReportDashBoardHelpParagraph1 | The Report Files List screen displays all available files for a selected Asset (e.g. Sterilizer or “Others”)  If entered during Asset creation, a line containing Equipment-ID located below the asset name, type, model, capacity, and manufacturer.  All available Setup, Calibration, Qualification or Calibration Verification files for the selected Asset are displayed with type, actions, filename, date, run number, and study file comment (if entered during file transfer).  The reports are shown in sections using the Setup name as section headers to separate them.  You can sort the reports per section lowest to highest and vice versa by pressing the small triangle next to the header:  Type, filename, date, run number, study file, and comment  There is an additional filter function at the end of each header section (except for Actions).  Type, filename, run number and study file comment can be also filtered using filters below:  Is equal to, is not equal to, starts with, ends with, contains, and does not contain.  The date can be filtered using filters below:  Is equal to, is not equal to, is greater than, is greater than or equal to, is less than, is less than, or equal to.  Enter text or date to filter per section. The filter can also be cleared.  Extend the filter function to combine two filters with “and” or “or” functionality.  You can generate a report by pressing the **Generate Reports** button directly out of the asset details. In the Report tool the action button displays the **Report Generation** button for a qualification run or pdf button for Setup, Calibration, or Calibration verification. The report generation action button will open the Select Sensor(s) Type window to select the sensor type you want to define cycles upon. |  |
| ReportDetailHelpHeader | Report Detail | Report Detail Screen |
| ReportDetailHelpParagraph1 | The Reports Details screen can by accessed via the Report Tool hub by selecting an asset or directly from the Asset details by selecting a qualification study and pressing **Generate Report**.  When navigating through the Asset Details screen the preselected qualification study is the only data file in the list. When navigating through the Report Tool hub all available data files for the asset are displayed.   The header lists the asset name for the study list. A row below includes information such as equipment ID, type, size, and manufacturer name.  You can sort the reports by selecting: • Type – if it’s a Setup report, Qualification, Calibration or Calibration Verification. • Filename – Name of the report given during programming • Date – Date the report was created • Run Number – if Run number for Qualification or Calibration is available • Actions – Generate a report or view a PDF version of the report.  Each category has a filter, where the search can be narrowed down to locate the report. To save a PDF of a report already generated, select the report and press the PDF icon. (Only available for Setup, Calibration and Calibration Verification reports; for Qualification reports you first need to go through reporting)  To generate a report, select the checkbox and then press the graph icon. Select Sensors type and press **OK** to proceed to the Mark Cycles screen.  If the report contains more than 1.2 million data points (the product of numbers of sensors and number of samples per sensor e.g. 12 sensors with 100000 data points per sensor or 24 sensors with 50000) the report tool skips the Mark Cycles screen and moves directly to the Standard reports screen.  When selecting a qualification study the **Export CSV** button is active. Use the **Export CSV** button to export the study to an Excel readable format (.csv). The csv format is an open table format that can be easily imported into spreadsheet programs. It is possible to select different datasets (Readings, Lethality, Statistical Calculations, Sat T & Sat P) for export. It is saved as a single csv file with an index file and ZIP archived. | Report Detail Screen |
| ReportHeaderFooter | Report Header / Footer |  |
| ReportHeaderFooterHelpParagraph1 | This screen includes the ability to customize comments, headers/footers, and system messages in a report.  Contents of the left panel and its preview need to be included in the report are mentioned below;  • Comments: Enter optional comments for the first and last page (up to 150 characters) to be included in the generate report.  • Header/ Footer Text: It is possible to change the SOP/Protocol # or performed by or reviewed by labels up to a maximum of 20 characters that appear in the report header/footer by editing the corresponding boxes. • Display Footer: To include the above header and footer information to either all pages or the first and last pages, select the respective checkboxes. If footer content is not required in the report, uncheck all the corresponding page checkboxes. • System Messages: Details of event information such as start/stop qualification and events (Exposure/User defined events/Interval events/Relay events) with timestamps. |  |
| ReportHelpHeader | Report Hub Screen | Report Hub Screen |
| ReportHelpParagraph1 | The Kaye AVS software includes a comprehensive reporting utility that allows you to generate Setup, Calibration, Qualification, and Calibration Verification reports to document the specifics of your validation study. All reports are generated from secure data files that can only be read by the Kaye AVS software.   Creating a report does not alter the raw data file. If a secure data file is tampered with, it is no longer readable by the software and it is unable to generate reports.  Since reports are created each time from a secure data file, you can specify which groups to include in your Qualification Report. For qualification reporting, in addition to reporting the data that was available during the study, the software allows you to perform post-qualification analysis. You can add statistical calculations, events, and time intervals to your report based on the stored data. You can also export your qualification data to a CSV file to perform additional analysis. The secure data file remains unchanged; you can always access the secure data file to recreate reports using the Kaye AVS software.  Note: You can create Portable Document Format (PDF) files from the study data and then use a third-party document management system to electronically sign the reports.  When any of the options below are selected, the font color of the selection changes to blue.  Each tile under the asset type has an asset type, asset name, asset ID, and the date it was last validated. Type - Sorts the reports based on the types of assets such as Sterilizer, Autoclaves, Heat Chambers, etc. Size – Sorts the reports based on the asset’s capacity; for example cubic feet, cubic meter, etc. Activity – Sorts the assets based on the date the assets were created.  If the number of tiles in any of the above options exceed the screen size, then a vertical swap on the screen will bring up the next set. Search icon (located in the top right corner) - locates the desired asset from the asset list based on asset name  Note: If no asset is defined, then all the reports can be accessed by navigating through the ‘Others’ option imported Kaye Validator 2000 files. | Report Hub Screen |
| ReportingOptionsHelpHeader | Report Screen |  |
| ReportingOptionsHelpParagraph1 | This screen displays   1. Edit Groups: Permits editing of defined groups and saving for generating a Graph and Text Report.  2. Edit Calculations: Calculations can be customized and edited. Lethality calculation depend on the policy if editing is allowed. |  |
| ReportOptionsHelpHeader | Report Options | Report Options Screen |
| ReportOptionsHelpParagraph1 | The final step in setting up the report for printing is the selection of the report options and types. At the top of the screen, the asset type and number, and study type and date appear.  In the Text Report screen you can choose report options that allow including/excluding selected groups from reports, customizing report headers and footers, adding study comments, changing the print sampling rate of the Qualification Detailed Report, and selecting the type of report to generate.  This screen consists of a left panel with contents that are needed to be included in the report (Summary or Detailed) and a right panel that includes a preview view to view the definition of left panel contents.  Contents of left panel and its preview that need to be included in a report are mentioned below:  • First Page: Sim and Groups included information with comments (up to 150 characters). • Calculation Contents: Description of default or customized calculation details including Lethality, MKT, and Saturation Pressure/Temperature • Group Information: Description of the default or customized groups information like Group Name, Sensor Inputs, and Interval Calculations.  • System Messages: Details of event information including, start/stop of Qualification and Events (Exposure/User defined events/Interval events/Relay events) with timestamps. • Last Page: Comments (up to 150 characters) to be included.  Header/Footer Customization:  Apart from the above contents, the Left panel also includes header footer customization, with an option to either include them in All pages or just the first and last page.  A user can change the SOP/Protocol #, performed by, or reviewed by labels (maximum 20 characters) that appear in the report header by editing the corresponding boxes in the left panel. To include the above changes, to either all pages or just the first and last page, select the respective checkboxes. If you do not want the above information in the report, uncheck all corresponding page checkboxes.  If you want either of the header/footer options to not display on any pages, then remove the data from the corresponding boxes, except the SOP/Protocol# data which is mandatory. Attempts to remove the SOP/Protocol# data causes an alert message that the SOP field cannot be empty.  Customize Structure (report structure):  Customize Structure located in the left panel, has the functionality to customize report options as mentioned below: • Include/exclude - All contents using **All/None** buttons respectively. • Include/exclude - First or last page info by selecting corresponding checkboxes. • Include/exclude - Select groups or select corresponding checkboxes. • Include/exclude - Respective group calculations like statistical, either of the Lethality or MKT, and Interval calculations selected from corresponding checkboxes. • Include/exclude - Saturation Pressure/Temperature by selecting corresponding checkbox. • Include/exclude - System messages by selecting corresponding checkbox. • Select Print Rate - Option from dropdown, depending on the qualification study duration based on the the corresponding sampling rate is displayed.  After performing the above selection operations in the Report Structure window either press the **Done** button to save the changes, or press the **Cancel** button to revert the changes by closing the window.  Note:  • For a new group added under Customize Groups section to be part of the Detailed/Summary report, a user must select the corresponding groups and their calculations in the Customize Structure window. Once selected, the user must apply the changes by pressing the **Done** button which then displays the changes in the left panel and the Summary/Details report after pressing the **Generate Repor**t button. • Lethality and MKT are mutually exclusive; if the MKT box is selected while Lethality is selected for that group, a message appears that only Lethality or MKT can be selected.  • The MKT option, if selected against a group, is reflected only in the Summary report. The Summary Report uses the Aleth column to display the MKT values  Qualification Report types: - Select either the Summary or Detailed option from the dropdown list in the top right corner. - Press the **Generate Report** button at the bottom right corner to generate the respective report types. | Report Options Screen |
| ReportSelectionPageHelpHeader | Report Selection Screen | Report Selection Screen |
| ReportSelectionPageHelpParagraph1 | This screen displays    Using the Report Selection screen you can choose report options.     1. Standard Report: Which describes the Report after selecting cycle displays. Report Options Screen and pdf file of qualification can be generated.    2. Graph Report: Generation of a Graph report for defined groups and cycles.    3. CSV Report: Generation of a CSV report for defined groups and cycles. | Report Selection Screen |
| ReportTemplateDataHelpHeader | Report Template | Report Template Screen |
| ReportTemplateDataHelpParagraph1 | If you have selected Template Analysis at the Reports Analysis screen and saved the report cycles, the Template Analysis screen opens.  If you have not yet created any report templates, the dropdown list in the Template Analysis screen is initially empty. Once you have created templates, this list displays all templates in alphabetical order.  When you use a graph template created from a specific study file and apply it to that file, the cycles are created per the sensor type selected in the template. The number and name of each cycle and group remain the same. However, for a graph template created from a different study file, the template cycle names are carried over up to the number of cycles in the template. Any further cycle names remain empty for users to select that option.  When you use a report template created from a specific study file and apply it to that file, the cycles are created per the sensor type selected in the template. The number and name of cycles and groups remain the same, as do graph calculations. However, for a report template created from a different study file, if the same sensors are used as were used to create the template, the same sensors are assigned to the group. If they are different, the groups will be empty for the user to name.  Note: If all groups listed are empty, you cannot launch the next screen until you have assigned sensors to at least one group in the Group pane.If the same sensors are used in the template and the current study file, the same calculations are assigned to the group. However, if different sensors are used, only the statistical calculations (default calculations) are available. | Report Template Screen |
| ReviewHelpHeader | Review | Review Screen |
| ReviewHelpParagraph1 | After finishing all tabs it shows summary of Setup. The Review screen opens, listing all the pertinent details about the setup just created.  Copy as New Setup -- Copying the current setup as a new setup and saving it under a different name.  Create Setup Report — Creates an initial setup report from the review page for saving and printing.  The center of the screen displays the following sections, each with an Edit icon (except Asset Details) to permit rapid changes:   • Asset Details • Sensor Details • Calculations • Groups • Report Header • Calibration Parameters • Qualification Parameters  Press the **Save** Button to save the setup, or go back to the Qualification Parameters screen without changes. | Review Screen |
| SensorsConfigurationHelpHeader | Sensors Configuration | Sensors Configuration Screen |
| SensorsConfigurationHelpParagraph1 | From the Define Setup screen, with all required field filled out, press **Sensors Configuration** to open the Sensors Configuration screen.   The study name is displayed in the top left corner of the screen. Below the current study name, the header row shows that you reached the Sensors Configuration screen, in the setup creation process. Two tabs ‘Define Setup’ and ‘Group Sensors’ are available for navigation on the Sensors Configuration screen.  The Sensors Configuration screen graphically represents four Sensor Input Modules labeled SIM 1, SIM 2, SIM 3, and SIM 4. The numbers on the icons correspond to the numbers on the input connectors (up to 12) mounted inside the SIM. From this screen you select sensors, specify the sensor type, and enter a label and description for each sensor.  Inside the Sensors Configuration screen a user can do the following:  - Select sensors to use in the study - Define the sensors type and parameters - Specify the minimum and maximum input and output scaling factors for current or voltage types and the engineering unit - Enter a sensor label, up to eight characters - Enter a sensor description, up to 25 characters  Select Sensors  For an initial setup, all the input connector tiles are blue, to indicate that they have not been selected. Press an individual connector tile to select it. You can also select a series of sensors in the Select Sensors series of dropdown boxes at the right. Select a range of sensors from one SIM to another SIM, press **Select**, and those sensors all appear as selected on the left pane. The multiple definition feature saves time when you are defining several sensors of the same type. Automatic numbering and description options help identify the sensors.To deselect a sensor, press on the individual sensor, or select a new range on the Select Sensors pane, and press **Select**.   Configure Sensors - Sensor Type  Open the Configure Sensors dropdown list and assign the sensors in each selected SIM to one of the following color-coded types. By default, the Sensor Type is displayed as ‘Undefined”.  ‘Sensor Label’, ‘Auto Numbering’, and ‘Assign’ fields are enabled until Sensor Type is selected. To assign the sensors you need to follow these steps:  1. Select the Sensor Type from Sensor Type dropdown list. As soon as the ‘Sensor Type’ is selected the ‘Sensor Label’ and ‘Auto Numbering’ fields become active with default number equal to ‘01’. 2. Enter the Sensor Label to activate the **Assign** button. 3. Select the Auto Numbering checkbox to activate auto numbering features. If Auto Numbering is not selected all sensors will have the same label. 4. For Current and Voltage sensor types the Scale Factors is available to scale current and voltage signal to the engineering unit. 5. Press the **Assign** button to see the selected sensors for a SIM. Sensor Type Parameters:  Thermocouple • Type T Premium • Type J • Type K • Type T • Type E • Type B • Type R • Type S • Type N  The resolution for Premium T Type thermocouples is 0.01; all other thermocouples are programmed with a 0.1 resolution.  Contact Select Contacts to define a contact closure (switch). Any conditions of the switch (Open/Close) are defined in the corresponding setup pages.  Voltage - Enter the input and output parameters to scale the voltage signal to engineering units. The default values are: Input Min = 0.00 V Input Max = 10.00 V Output Min = 0.00 Output Max = 10.00  For example, if you have a 1-5 volt humidity sensor with 0-100% output, you would enter: 1.00 for Input Min 5.00 for Input Max 0.00 (default value) for Output Min 100.00 for Output Max %H for units  For voltage, you can enter up to three decimal values in the input and output fields. The default values are: Input Min = 0.00 V, Input Max = 10.00 V, Output Min = 0.00 Output Max = 10.00.  For pressure, you can enter up to three decimal values in the voltage input and output fields. The default values are: Input Min = 0.00 V, Input Max = 10.00 V, Output Min = 0.00 Output Max = 10.00.   Connect a Voltage Input Connect a voltage input (up to 10 VDC) to the connectors. Always connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector. Note: The SIM contains a static sensitive component which stores calibration information. Use caution when connecting a sensor. Amphenol Advanced Sensors recommends that you wear an anti-static ground strap when connecting sensors and routing wires.  Note: The Input range to be from -1V to 12V on software.  Thermocouples, voltage and contact closures can connect to the Thermocouples SIM. You can mix there sensor types within one SIM.  Current Enter the input and output parameters to scale the current signal to engineering units.   Current Scaling Factors The default values are: Input Min = 4.00 mA Input Max = 20.00 mA Output Min = 0.00 Output Max = 10.00  For example, if you have a 4-20 mA pressure transducer with a 0-50 PSI output, you would enter: 4.00 for Input Min 20.00 for Input Max 0.00 for Output Min 50.00 for Output Max PSI should be set in the preferences for Units.  The default values are: Input Min = 4.00 mA, Input Max = 20.00 mA, Output Min = 0.00, Output Max =10.00.  Note: The range of Input current is from 1 to 25mA. 0 is reserved for connect and disconnect indication.   Current (4 to m20mA) can connect only to the Kaye 4 to 20mA SIM. You cannot mix 4 to 20mA sensors with other sensor types within one SIM.  Sensor Type Parameters Select one of the following pressure sensor types if you are going to calculate the saturation temperature of steam.  Pressure (V) Enter the input and output parameters to scale the voltage signal to absolute pressure units.  Pressure (mA) Enter the input and output parameters to scale the current signal to absolute pressure units.  The pressure units are defined in the preferences.  PT100- RTD sensor type For two, three, or four wire RTD sensors there is a special SIM available for connection. PT100-RTD sensors can connect to the special RTD SIM only. You can configure a maximum of six RTD sensors (the first six tiles) per SIM and cannot mix with other sensor types within one SIM.  Note: If you are going to use the saturated steam calculations, select the Pressure (V) and/or Pressure (mA) sensor types, as appropriate. If you selected a voltage or current sensor type, enter the input and output parameters to scale the voltage or current signal to engineering units. Sensor Label Enter a descriptive label using any characters up to a maximum of eight. If you are defining multiple sensors and automatically numbering them, the maximum number of characters you can enter for a label is six. Sensor labels display on all reports and screens. Sensors Description  Enter a description of the sensor using any characters up to a maximum of 25. If you are defining multiple Sensors and automatically numbering them, the maximum number of characters you can enter for a description is 23. Sensor descriptions display on the Setup Report.  Sensors Description You can enter the description sensor label number, and to enable/disable auto numbering.   When defining multiple sensors, you can automatically number sensor labels, descriptions, and set the starting number. If automatic numbering is not enabled, all the selected sensors have the same label and description. However, you can then edit each label individually. To enable automatic numbering: 1. Select the label checkbox, the description checkbox, or both checkboxes to enable automatic numbering. Note: When automatic numbering is enabled, the maximum number of characters in the label and description fields is reduced by two characters to provide room for numbers.  When you have finished, press the **Close** button on the Description screen to go back to the Sensor Configuration screen.  To save a newly created or modified setup you must have a Supervisor or System Administrator account set up by your System Administrator (however, it is always possible to review a setup). | Sensors Configuration Screen |
| SetupDashBoardHelpHeader | The Setup Hub Screen | Setup Hub Screen |
| SetupDashBoardHelpParagraph1 | Pressing the Setups tile on the Asset Details screen, the Validator software navigates to the Setup Hub screen. In the upper left corner, the asset type and ID number appear. The next row lists the equipment ID, capacity, manufacturer, and other details, along with the New Setup icon.  On the second row, four filter options appear: Status, Activity, Setup, and Date. Two other columns hold Comments and Actions. Near the filter options, up and down arrows permit you to sort the options in ascending or descending order (alphabetical order or date).  For actions, you can select one, two, or three options, depending on the type of activity.  • Pressing the Print icon sends the file to a default printer for printing.  • Pressing the PDF icon creates a PDF from the file.  • For qualification studies, pressing the Graph icon creates a graph of the qualification data.  Press any setup to proceed to the Sensor Configuration screen. Press the New Setup icon to proceed to the Study Details screen and begin a new study. | Setup Hub Screen |
| StandardReportHelpParagraph1 | The final step in setting up the report for printing is the selection of the report options and types. At the top of the screen, the asset type and number, and study type and date appear.  The Text Report screen allows to choose report options that allow you to include/exclude selected groups from a report, customize the report headers and footers, add study comments, change the print sampling rate of the Qualification Detailed Report, and select the type of report to generate.  Apart from the above contents, this screen follows the below mentioned details;  • Report Content: Choose report options that allow you to include/exclude selected group items from reports. • Header/Footer : Customize the header/footer. • Select Print Rate - Options from dropdown, depending on the qualification study duration, which corresponding sampling rate is displayed.  Note:  • For a new group added under Edit Groups section to be included in the Detailed/Summary report, select the corresponding Groups and calculations in the Edit Parameters window and apply changes. • MKT option if selected against a group, is only reflected in the Summary report. The Summary Report uses the Aleth column to display the MKT values  Qualification Report types: - Select either Summary or Detailed option. - Press the **Generate Report** button (located in the bottom right corner) to generate the respective report types. | Standard Report Screen |
| StandardReportPageHelpHeader | Standard Report Screen | Standard Report Screen |
| SuperImposeHelpHeader | Super Impose | Super Impose Screen |
| SuperImposeHelpParagraph1 | Super Impose — Superimposes one file on another for comparative analysis. | Super Impose Screen |
| SynchronizeHelpHeader | Synchronize | Synchronize Screen |
| SynchronizeHelpParagraph1 | Synchronize — Redraws the graphs with a user-defined starting point and the conclusion of the study as the end-point. | Synchronize Screen |
| UserManagementHelpHeader | User Management | User Management Screen |
| UserManagementHelpParagraph1 | The User Management screen of the AVS software allows the System Administrator to create users and to assigned user privileges for each user. Initially when the system is first powered on, there is a default User ID “Kaye” and with a default password “411”; these must be entered to access the software. Once signed in, the user automatically goes to the “User Management” screen. A new System Administrator must be assigned at this time. The privileges are automatically assigned. Once saved the default Kaye / 411 User ID and password are automatically deleted. The Administrator can then login and assign other users and privileges.   Note: It is good practice to always assign more than one System Administrator for protection purposes. The System Administrator is responsible for the security of the program. Only a System Administrator can access the User Management as well as Preferences, Policies, and Firmware Upgrades.   As part of the User definition the Administrator must select the User Type (Administrator, Supervisor, Operator) for each User. When selected, the defaults listed below are assigned. The defaults can be edited so that each new user can be assigned whatever privileges that are desired.    Operator Supervisor System Admin Admin X Delete Assets X Delete Setups X Delete Equipment X Archive Data X Create/Edit  Equipment X Delete Study Files  /Reports X Copy Study Files  /Reports X Create/Edit Setups X  Run Qualification X X  Run Calibration X X  Create/Edit Assets X X Manual Sync X X Create Reports X X X Audit Trial X X X Change Console Time     User Definition  NEW USER: - Select to create a new user. Active users are displayed below  USERS LIST: - Provides PDF listings of all active, deleted, and disabled users. List can be printed, and or saved.  NAME: - The Name Field/Textbox in the new user form is used to enter a name for newly created user. A user’s name is associated with the user ID that is created. The name textbox accepts a maximum of 35 characters in a combination of numbers and characters. The name you enter here appears in the active user list and on the Main Menu when logged in.   USER ID: - Enter a Unique User ID in the User ID textbox. 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. User ID must be unique and is not allowed to be reused with any other user.  PASSWORD: - Enter a temporary password for the user in the Password textbox. The temporary password can be any combination of numbers and characters, up to a maximum of 16 (default six characters from Preferences). The user is required to change this password when they first login to the software.  CONFIRM PASSWORD: - Enter the temporary password in the Confirm password textbox. At this point, you should record the new account’s user ID and password. The administrator provides the created user ID and temporary password to the new user.   TITLE: - The title textbox is used to enter a title for the newly created user. The default designation available is “Manager”, new titles can be assigned by entering the required title inside the textbox. Title selection is a mandatory field. Titles appear in the user list and Main Menu when logged in.  USER TYPE: - The user type dropdown list contains three user types (System Administrator, Supervisor, and Operator). The user type selection from the dropdown list assigns default privileges at the USER PRIVILEGES section of form. These privileges can be edited and customized for each user.  PHONE: - Add a contact number for the user in the textbox. The phone field accepts any combination of numeric digits from (0-9). The maximum input for the textbox is 20 digits. Phone is an optional field and is used for information purposes only.  EMAIL: - Enter a valid email address for the newly created user. The email address should be in this format, <Valid email>@domain.com with a combination of character/alphanumeric content. Email is an optional field and used for information purposes only.  DISABLE USER ACCOUNT: This checkbox is unchecked by default for newly created user. It can be used to disable or re-enable users   DELETE: The delete button is disabled at NEW USER creation for a newly created user.  SAVE: **SAVE** button is disabled at new user creation until all mandatory fields are entered for the newly created user. Press the **Save** button to save the newly created user.  CANCEL: Press **Cancel** to not save the created user. | User Management Screen |