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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, upgrade the AVS Firmware, and set up automatic time-based file synchronization. The Kaye AVS software installs with default system preferences. The System Administrator has the option of changing the default system preferences in the Kaye AVS 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  • Calibration tile In the Calibration tile, available calibration studies 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 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 text box 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 thermocouples 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 Validator 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 Validator 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. If you connect a contact to the output of your controller, you can synchronize the start and end of the exposure cycle at both the controller and Kaye Validator. At the Qualification screen, define the start of exposure to be when the contact closes and the end of exposure to be when the contact opens. • 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 thermocouples and you select 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 Interval Calculations Screen to define Calculation or modify if interval calculations have already 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 ta 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 Validator 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 Validator 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. If you connect a contact to the output of your controller, you can synchronize the start and end of the exposure cycle at both the controller and Kaye Validator. At the Qualification screen, define the start of exposure to be when the contact closes and the end of exposure to be when the contact opens.  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. |  |
| 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 | Use the Kaye Validator AVS software to create or modify a setup. A setup defines everything required to calibrate sensors and 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 calibration and verification setpoints • Specify temperature stability and deviation criteria for sensor calibration • Specify start and stop conditions for the qualification cycle and the exposure cycle • Specify how often to scan sensors (Sampling rate for data storage) • Define the output relays  After you have created and saved your setup the setup is displayed in the list of available setups, and can be used to calibrate sensors and run a qualification study. You load the setup to the Kaye Validator AVS 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. When naming a setup the following rules apply:   • You cannot save an existing setup using the same file name.  • Duplicate 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 Assets screen. | Define Setup Screen |
| EditReportParameters | Edit Report Parameters |  |
| EditReportParametersHelpParagraph1 | This Screen gives the 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 spare sensors instead.   2. Edit Calculations: Calculations can be customized and edited. The editing of Lethality calculations is dependent if editing is allowed or not. |  |
| 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 click on 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 the existing equipment can be searched by clicking on 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 1 digit for RH,2 digits for temperature, 3 digits for pressure and contact).  • You can define limit lines for the Y axis in temperature, humidity and pressure, by pressing the check box for limit line selection. Text boxes 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 1 digit for RH,2 digits for temperature, 3 digits for pressure and contact).  • When you have completed 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 now 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 the data cycles: Press the Add Cycle button. A window opens that lists   1. various cycle names such as Exposure, Ramp up, etc.  2. Press a cycle name. A window allows 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 |