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Kaye Advanced Validation System (AVS) version 1.5 is a new Advanced Validation System software release version dedicated to the Windows 10 LTSC 2019 Platform for the Kaye Validation Console, including the enhancements described below. Kaye Validator AVS 1.5 is released with software version 1.5.0.6 and is compatible with firmware version 1.5.0.5 only.

To obtain AVS Software 1.5, it is required to upgrade the Kaye Validation console with a new system image. Please contact your Kaye support for assistance. The software can be used to upgrade AVS firmware to version 1.5.0.5.

Kaye recommends revalidating the AVS Software 1.5 with IQ/OQ procedure.

Advanced Validation System Console SW 1.5 Enhancements

- Defect fixes and performance improvements.
- Support for new hardware (DAQ2) with support for faster sampling rate (1 sec for 48 channels).
- Time Zone Added to report headers.

Known issues in AVS 1.5

- Message "No Response for GetStatus Command From AVS" is displayed on the Select AVS screen while trying to connect to AVS after long studies. AVS should be restarted in this case.
 - If Study is running and message is displayed, then the study file can be retrieved after reboot of the AVS.
- In Detailed and CSV reports, pressure values under statistical calculations are rounded to 2 digits instead of 3 digits.
- If Asset Name is with maximum characters possible, then Graph is getting aligned to middle of the page in View Complete Study screen.



Kaye Advanced Validation System (AVS) version 1.4.2 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.4.2 is a new Advanced Validation System software release version dedicated to the Windows 10 LTSC 2019 Platform for the Kaye Validation Console, including the enhancements described below. Kaye Validator AVS 1.4.2 is released with software version 1.4.2.2 and is compatible with firmware version 1.4.0.5 only.

To obtain AVS Software 1.4.2, it is required to upgrade the Kaye Validation console with a new system image. Please contact your Kaye support for assistance. The software can be used to upgrade AVS firmware to version 1.4.0.5.

Kaye recommends revalidating the AVS Software 1.4.2 with IQ/OQ procedure.

Advanced Validation System Console SW 1.4.2 Enhancements

- Support for Windows 10 operating system in tablet mode.
- Defect fixes and performance improvements.

Known issues in AVS 1.4.2

- Without Kaye IRTD connected, calibration failing at checkpoint. Please make sure to use Kaye IRTD during manual calibration.
- In Detailed and CSV reports, pressure values under statistical calculations are rounded to 2 digits instead of 3 digits.
- In Summary Report->Graph page, time is displayed in 12-hour format instead of 24-hour format.
- In Graph report, "Program Start Date" time format in report header is in 12-hour instead of 24-hour format.
- If Asset Name is with maximum characters possible, then Graph is getting aligned to middle of the page in View Complete Study screen.
- When marking cycle by selection line, there may be slight error in position of the line but the timestamp displayed below the X-axis is correct.

In the Setup if Exposure Stop and Qualification Stop are programmed to stop automatically and User presses "Quit Qual" or Qualification stops without exposure stop, then the Audit Trail will not document Qualification stop message.



Kaye Advanced Validation System (AVS) version 1.4.1 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.4.1 is a new Advanced Validation System software release version dedicated to the Windows 10 LTSC 2019 Platform for the Kaye Validation Console, including the enhancements described below. Kaye Validator AVS 1.4.1 is released with software version 1.4.1.3 and is compatible with firmware version 1.4.0.5 only.

To obtain AVS Software 1.4.1, it is required to upgrade the Kaye Validation console with a new system image. Please contact your Kaye support for assistance. The software can be used to upgrade AVS firmware to version 1.4.0.5.

Kaye recommends revalidating the AVS Software 1.4.1 with IQ/OQ procedure.

Advanced Validation System Console SW 1.4.1 Enhancements

- Support for Windows 10 operating system.
- Defect fixes and performance improvements.

Known issues in AVS 1.4.1

- Without Kaye IRTD connected, calibration failing at checkpoint. Please make sure to use Kaye IRTD during manual calibration.
- In Detailed and CSV reports, pressure values under statistical calculations are rounded to 2 digits instead of 3 digits.
- In Summary Report->Graph page, time is displayed in 12-hour format instead of 24-hour format.
- While entering user comments, it is recommended not to use "/" as Pass-Fail pdf report cannot be viewed. As a workaround user can navigate to data files folder to view Pass-Fail reports.
- If Asset Name is with maximum characters possible, then Graph is getting aligned to middle of the page in View Complete Study screen.



Kaye Advanced Validation System (AVS) version 1.4 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.4 is an upgrade for any previously released Advanced Validation System version, including the enhancements described below. Kaye Validator AVS 1.4 is released with software version 1.4.0.14 and is compatible with firmware version 1.4.0.5 only.

Upgrade AVS Software 1.4 first, then using the software, upgrade AVS firmware to version 1.4.0.5. AVS Software 1.4 needs to be revalidated with IQ/OQ procedure.

Advanced Validation System Console SW 1.4 Enhancements

- New report for Pass/Fail Criteria is added.
- Interval based calculations for Live screen and new report are added.
- New custom report (CEI600068) is added.
- EN 285 requirement is incorporated in Detailed and Pass/Fail reports.
- Support for common report headers in all the reports.
- Historical events are added in UI and reports.
- Group based headers in Setup creation screen.
- Group based headers printing in Summary, Detailed and Pass/Fail reports.
- Lethality Line and Bar graphs in Live and Graph report screens.
- Defect fixes and performance improvements.

Known issues in AVS 1.4

In Pass/Fail report, if "Accumulated lethality for (....) cycle" criteria, the cycle name value is correctly displayed in the header but in the criteria table the cycle name is named "Exp Start".

For example, if the user modifies the Exposure Cycle name to "Exposure", it shall be printed as "Exp Start" in the criteria table of the Pass/Fail report.

Note:

In User Privileges, "Copy files/reports" privilege is now selected by default for Supervisor role. In case of SW upgrade scenario, it is recommended to check the privileges for compliance with company requirements.

Software Upgrade Installation

Important: It is strongly recommended to take backup of data files using "Sync Out" feature. Please refer AVS user manual on how to use "Sync Out" feature.

The version 1.4 software is designed to upgrade the previous versions of AVS software on consoles running under Windows 8.1. Before installing the version 1.4 software you should close any programs that may be running.

Notes: The upgrade program keeps the existing data files intact during installation. Same data files are used by the upgraded software.

Installing the Version 1.4 Software from USB



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Complete the following steps to install the version 1.4 software:

- 1. Reboot console.
- 2. Sign out the Kaye Operator user and Login as Kaye Administrator.
- 3. Insert the USB drive containing Kaye Validator Upgrade installer into the Console.
- 4. Refer the Console SW Upgrade installer guide to complete the installation.



Kaye Advanced Validation System (AVS) version 1.3.1 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.3.1 is an upgrade for the Advanced Validation System version 1.3, including the enhancements described below. Kaye Validator AVS 1.3.1 is released with software version 1.3.1.6 compatible with firmware version 1.3.0.11 only.

Upgrade AVS Software 1.3.1 first, then using the software, upgrade AVS firmware to version 1.3.0.11. AVS Software 1.3.1 needs to be revalidated with IQ/OQ procedure.

Advanced Validation System Console SW 1.3.1 Enhancements

- Support for French language.
- Defect fixes and performance improvements.

Software Upgrade Installation

Important: It is strongly recommended to take backup of data files using "Sync Out" feature. Please refer AVS user manual on how to use "Sync Out" feature.

The version 1.3.1 software is designed to upgrade the previous versions of AVS software on consoles running under Windows 8.1. Before installing the version 1.3.1 software you should close any programs that may be running.

Notes: The upgrade program keeps the existing data files intact during installation. Same data files are used by the upgraded software.

Installing the Version 1.3.1 Software from USB

Complete the following steps to install the version 1.3.1 software:

- Reboot console.
- 6. Sign out the Kaye Operator user and Login as Kaye Administrator.
- 7. Insert the USB containing Kaye Validator Upgrade installer into the Console.
- 8. Refer the Console SW Upgrade installer guide to complete the installation.



Kaye Advanced Validation System (AVS) version 1.3 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.3 is an upgrade for the Advanced Validation System version 1.2, including the enhancements and fixes described below. Kaye Validator AVS 1.3 is released with software version 1.3.0.15 compatible with firmware version 1.3.0.11 only.

Upgrade AVS Software 1.3 first, then using the software, upgrade AVS firmware to version 1.3.0.11. AVS Software 1.3 needs to be revalidated with IQ/OQ procedure.

Advanced Validation System Console SW 1.3 Enhancements

- User can view Historical data for qualification, calibration and verification.
- Allows all the 10 files on AVS to upload directly to Console.
- Wiring Diagram support in Live Data.
- In Setup->Sensors Description screen, "Select all" option is provided to apply the same description for all the sensors.
- Allows to print USER LIST as PDF printout.
- Wiring Diagram support in Setup report.
- Deleted users in user management screen is not displayed now.
- Wiring Diagram in Setup related modification.
- Audit -Trail related changes.
- MAC Id of AVS along with IP address is now displayed in the about window.
- Asset related modifications.
- Manual Sync Options related modifications.
- Automatic Sync In, Sync Out and Archive operations to folder on network path (mapped drive) with Windows domain security at designated day and time.
- User Privileges related modifications.
- Login screen related modifications.
- Provision to View and Set bath temperature from Hardware screen.
- User is now warned if running Qualification, Calibration and Verification with incorrect hardware.
- Reporting tool flow is made more user friendly.

Software fixes:

Defect fixes and performance improvements.



Software Upgrade Installation

Important: It is strongly recommended to take backup of data files using "Sync Out" feature. Please refer AVS user manual on how to use "Sync Out" feature.

The version 1.3 software is designed to upgrade the previous versions of AVS software on consoles running under Windows 8.1. Before installing the version 1.3 software you should close any programs that may be running.

Notes: The upgrade program keeps the existing data files intact during installation. Same data files are used by the upgraded software.

Installing the Version 1.3 Software from USB

Complete the following steps to install the version 1.3 software:

- 9. Reboot console.
- 10. Sign out the Kaye Operator user and Login as Kaye Administrator.
- 11. Insert the USB containing Kaye Validator Upgrade installer into the Console.
- 12. Refer the Console SW Upgrade installer guide to complete the installation.



Kaye Advanced Validation System (AVS) version 1.2.3 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.2.3 is an upgrade for the Advanced Validation System version 1.2.1, including the enhancements and fixes described below. Kaye Validator AVS 1.2.3 is released with software version 1.2.3.0 software compatible with firmware version 1.2.1.61 only.

Upgrade AVS Software 1.2.3 first, then using the software, upgrade AVS firmware to version 1.2.1.61. No Upgrade of firmware is required if your Advanced Validation System firmware is already at version 1.2.1.61. AVS Software 1.2.3 needs to be revalidated with IQ/OQ procedure.

Advanced Validation System Console SW 1.2.3 Enhancements

Defect fixes and performance improvements.

Software Upgrade Installation

Important: It is strongly recommended to take backup of data files using "Sync Out" feature. Please refer AVS user manual on how to use "Sync Out" feature.

The version 1.2.3 software is designed to upgrade the previous versions of AVS software on consoles running under Windows 8.1. Before installing the version 1.2.3 software you should close any programs that may be running.

Notes: The upgrade program keeps the existing data files intact during installation. Same data files are used by the upgraded software.

Installing the Version 1.2.3 Software from USB

Complete the following steps to install the version 1.2.3 software:

- 13. Sign out the Kaye Operator user and Login as Kaye Administrator
- 14. Insert the USB containing Kaye Validator Upgrade installer into the Console.
- 15. Refer the Console SW Upgrade installer guide to complete the installation.



Kaye Advanced Validation System (AVS) version 1.2.1 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.2.1 is an upgrade for the Advanced Validation System version 1.2.0.21, including the enhancements and fixes described below. Kaye Validator AVS 1.2.1 is released with software version 1.2.1.0 software compatible with firmware version 1.2.1.61 only.

Upgrade AVS Software 1.2.1 first, then using the software, upgrade AVS firmware to version 1.2.1.61. No Upgrade of firmware is required if your Advanced Validation System firmware is already at version 1.2.1.61. AVS Software 1.2.1 needs to be revalidated with IQ/OQ procedure.

Advanced Validation System Console SW 1.2.1 Enhancements

 Improved support for Sync In, Sync Out and Archive operations to folder on network path (mapped drive) with Windows domain security.

Software fixes:

Defect fixes and performance improvements.

Software Upgrade Installation

Important: It is strongly recommended to take backup of data files using "Sync Out" feature. Please refer AVS user manual on how to use "Sync Out" feature.

The version 1.2.1 software is designed to upgrade the previous versions of AVS software on consoles running under Windows 8.1. Before installing the version 1.2.1 software you should close any programs that may be running.

Notes: The upgrade program keeps the existing data files intact during installation. Same data files are used by the upgraded software.

Installing the Version 1.2.1 Software from USB

Complete the following steps to install the version 1.2.1 software:

- 16. Sign out the Kaye Operator user and Login as Kaye Administrator
- 17. Insert the USB containing Kaye Validator Upgrade installer into the Console.
- 18. Refer the Console SW Upgrade installer guide to complete the installation.



Kaye Advanced Validation System (AVS) version 1.2 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.2 is an upgrade for the Advanced Validation System version 1.1, including the enhancements and fixes described below. Kaye Validator AVS 1.2 is released with software version 1.2.0.21 software and firmware version 1.2.1.61.

AVS Software 1.2 is compatible with firmware version 1.2.1.61 only.

Upgrade AVS Software 1.2 first, then using the software, upgrade AVS firmware to version 1.2.1.61. No Upgrade of firmware is needed if your Advanced Validation System firmware is already at version 1.2.1.61. AVS Software 1.2 needs to be revalidated with IQ/OQ procedure.

Advanced Validation System Console SW 1.2 Enhancements

- Optimization of AVS Wi-Fi configuration and functionality.
- Setup review to display complete information of Setup in Qualification screen.
- User can add Limit Lines for Real Time Qualification graph.
- User can have graph zoom ability to define fixed Y and X axis range.
- Support for manual scaling of graph.
- User can to synchronize time at start of qualification.
- User can add Cycle time and Exposure time to real-time screen (statistical box).
- User can set privilege for Stop Qualification.
- Display of Event messages during Qualification and effect in Audit Trail.
- User can start Qualification with at least some valid data for Manual operation.
- Improved cycle selection screen in Reports.
- Display of AVS LED connection and study status.
- User can have Customer logo in all reports.
- Allow user to define report footer parameters in Preferences and apply to Setup/Calibration/Verification reports.
- Update firmware versions format in Reports and Main App.
- Determine if AVS firmware and AVS console software are compatible or not.
- Improved software upgrade installation.
- AVS OS image and firmware auto installation from Console SW.

Software fixes:

Defect fixes and performance improvements.



Advanced Validation System FW 1.2.1.61 Enhancements

- Auto reconnect Wi-Fi (on network availability & AVS restart).
- Allow user to have up-to 63 characters for Wi-Fi password.
- Improved report file generation.
- Support of qualification cycle time feature.
- Improved LED indication function.

Firmware Upgrade Installation

AVS console SW 1.2 provides functionality to upgrade AVS FW to user with Admin privileges. The "AVS Firmware Upgrade" tool is accessible from the Admin tile. 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 supposed to get upgraded Note: FW upgrade using Ethernet or Wi-Fi is not supported!

Press the "Get AVS SN" number to establish a connection to the Kaye Validator AVS. This assures the connectivity and retrieves the serial number for the audit trail entry.

- 2. Insert a USB thumb drive with the firmware as provided by Kaye into the console USB port located on back of the Kaye Validator AVS unit. You can easily identify the correct USB port by referring to the displayed picture.
- 3. Now everything is ready to upgrade the firmware. Please make sure the Validator AVS is properly powered and not switched off during the upgrade process. Otherwise the system can be damaged and need to get restored in a Kaye Service Center. Press "Upgrade Firmware" and wait until a message tell you to restart the Kaye Validator AVS.

Software Upgrade Installation

Important: It is strongly recommended to take backup of data files using "Sync Out" feature. Please refer AVS user manual on how to use "Sync Out" feature.

The version 1.2 software is designed to upgrade the previous versions of AVS software on consoles running under Windows 8.1. Before installing the version 1.2 software you should close any programs that may be running.

Notes: The upgrade program keeps the existing data files intact during installation. Same data files are used by the upgraded software.

Installing the Version 1.2 Software from USB

Complete the following steps to install the version 1.2 software:

- 19. Insert the USB containing Kaye Validator Upgrade installer into the Console.
- 20. Refer the Console SW Upgrade installer guide to complete the installation.



Kaye Advanced Validation System (AVS) version 1.1 Enhancements and defect fixes

Kaye Advanced Validation System (AVS) version 1.1 is an upgrade for the Advanced Validation System version 1.0, including the enhancements and fixes described below. Kaye Validator AVS 1.1 is released with software version 1.1.0.9 software and firmware version 0.0.1.45.

AVS Software 1.1.0.9 is compatible with FW version 0.0.1.45 only.

Upgrade AVS Software 1.1.0.9 first, then using the software, upgrade AVS firmware to version 0.0.1.45. No Upgrade of firmware is needed if your Advanced Validation System firmware is already at version 0.0.1.45. AVS Software 1.1.0.9 needs to be revalidated with IQ/OQ procedure.

Advanced Validation System Console SW 1.1.0.9 Enhancements

- The Kaye AVS SW is changed to separate calibration and verification parameters in setup.
- The Kaye AVS SW is changed so that user define number of set points for calibration and verification in setup.
- The Kaye AVS SW is changed to so that user can modify verification parameters before starting verification process.
- The Kaye AVS SW is changed to so that user can run a manual calibration. Manual Calibration and Verification can be run in scenarios like without both IRTD and Bath connected, with IRTD and without Bath connected and without IRTD and with bath connected.
- The Kaye AVS SW is changed to provide archive functionality for exporting and removing old data files to and from the console.
- The Kaye AVS SW is changed so that CSV export may show details of Setup.
- The Kaye AVS SW is changed to allow AVS firmware upgrade via the Console.
- The Kaye AVS SW is changed to provide sync feature to allow data file synchronization across several consoles. The functionality is also used to backup, restore and archive files.

Software fixes:

- Issues related to incorrect set point information in calibration screen is solved.
- Issues related to incorrect checklist in calibration screen is solved.

Advanced Validation System FW 0.0.1.45 Enhancements

- The Kaye AVS FW is changed to separate calibration and verification parameters in setup.
- The Kaye AVS FW is changed to so that user can choose verification parameters (Low Set Point, High Set Point and Check Point) different than calibration parameters.
- The Kaye AVS FW is changed to so that user can run a manual calibration.

The Kaye AVS FW is changed to so that user can choose lethality calculation option "While Max Temp >=" and "While Min Temp >=".

