Standard Operating Procedure For The Kaye Validator 2000 Thermal Mapping System

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1.0 INTRODUCTION
This standard operating procedure like all company controlled documents within PharmaTherm Limited will be managed in such way as to allow that only approved copies and the correct revision numbers are in circulation. The control of this document is the responsibility of Andrew Varley acting as the document co-ordinator on behalf of PharmaTherm Limited.

2.0 DOCUMENT CONTROL OBJECTIVE
The objective of document control is to ensure that all related documents are available to all members of staff, utilised, controlled, effectively updated and revised.

3.0 PURPOSE
To provide an operational procedure that describes the setup and use of the Kaye Validator 2000 system.

4.0 SCOPE
This procedure provides safety information, a list of required equipment, a description of the system, and instructions for connecting inputs to Sensor Input Modules (SIMs), starting the Validator 2000 software, creating/modifying a setup file, connecting the system, calibrating sensors, running a qualification study, verifying sensor calibration and generating reports. This procedure assumes that the Validator 2000 software has been installed and the System Administrator has created user accounts. See Chapter 3 in the Validator 2000 User’s Guide for more information.

5.0 SAFETY
The following safety precautions shall be observed when working around steam, high temperature ovens and autoclaves during qualification studies:
- Ensure all electrical plugs are plugged in completely.
- Ensure all extension cords are correctly routed from wall receptacles. Do not route cords across active hallways or walkways without taping to floor or routing overhead.
- Know location of emergency shut-off switches, if applicable.
- Remove any heat sensitive instruments from the system that could be damaged during steaming.
- Ensure all gaskets are in place before steaming.
- Ensure all doors, hatches and so forth are closed before starting qualification studies.
- Steaming temperatures may exceed 121°C. Do not touch any exposed surfaces while steaming.
- Ensure equipment being tested is cool before attempting to remove thermocouples.
6.0 EQUIPMENT

A complete Kaye® validation system includes:

- The Validator 2000 instrument with Version 2.30 firmware.
- The Validator 2000 Version 2.30 software for Windows® 95, 98, 2000, and NT, a notebook or desktop PC (minimum Pentium 166 with 32 MB RAM), and a printer that supports both portrait and landscape page orientation.
- Up to three Kaye Sensor Input Modules (SIMs).
- A Jofra high temperature reference (HTM-320).
- A Digitron Intelligent RTD probe (IRTD).
- Premium grade thermocouples.
- Ellison sensors pressure transducer.
- Additional temperature and non-temperature sensors for qualification studies (optional).
- A HP printer (optional) attached to the Validator 2000 for printing during sensor calibration and qualification studies. Attached to the PC with Validator 2000 software installed for printing sensor calibration and qualification studies following the reporting phase.

7.0 REFERENCE


8.0 SYSTEM DESCRIPTION

This section describes the Kaye Validator 2000 system and associated equipment.

8.1 Kaye Validator 2000

- Self-contained thermal validation device with high accuracy sensor measurement hardware and secure data recording capability.
- Standalone functionality when calibrating sensors, running qualification studies and verifying sensor calibration.
- Accepts up to 36 inputs in any combination of thermocouple, voltage and current inputs.
- System accuracy after calibration, taking into account all sources of error including the Validator 2000 and calibration and reference standards:
  - 0.25°C at 121°C
  - 0.38°C at 250°C
- Built in 3.5-inch floppy disk drive for loading setups, collecting data during sensor calibration/verification and qualification studies, and updating firmware.
- 12 line VGA display for viewing data during sensor calibration/verification and qualification studies.
- Over 2 MB of internal memory to maintain qualification data during a study. Qualification data resides in internal memory until system is powered down or a new setup is loaded.
- NiCad backup battery to provide short-term power in case of AC power loss. A fully charged battery will provide approximately 30 minutes to perform an orderly shutdown of the system.
8.2 Kaye Validator 2000 Version 2.10 Software
   - Create user accounts and assign user IDs, passwords and permission levels.
   - Create validation study setups that can be run standalone or PC-controlled. When calibrating sensors and running qualification studies from the PC, the Validator 2000 software features expanded tools for viewing and displaying data.
   - Generate reports from secure data files that contain original calibration and qualification data recorded during the study.

8.3 Kaye Sensor Input Modules (SIMs)
   - Sensor input module to which thermocouples or other measuring devices are connected.
   - Each SIM has 12 sensor connections.
   - Each SIM has a memory chip to store calibration offsets, SIM serial number, slot location and the serial number of the Validator 2000 measurement board on which calibration is performed.
   - SIMs can be wired at site or purchased pre-wired.

8.4 Kaye Temperature References

Kaye temperature references provide the stable temperature required for sensor calibration. Kaye has three models available:
   - **Jofra C320** (set point range 40°C above ambient to 320°C) Recommended for calibration of sensors used in steam autoclaves, dry heat ovens and tunnel sterilizers. The Jofra C320 accepts up to 24 thermocouples.
   - **Haven** (set point range -80°C to 30°C) Recommended for calibration of sensors used in freeze dryers, freezers, and cryogenic units. The Haven accepts up to 36 thermocouples.

8.5 Kaye IRTD & Digitron IRTD

The Digitron IRTD provides a traceable standard that is used to correct the temperature readings of the thermocouples.
   - **Digitron** standard system
     Measurement accuracy: ± 0.1°C; Range: -183°C to 200°C

9.0 SYSTEM ACCESS

The Validator 2000 software is designed for three levels of users. Each level has specific permissions that define system access.
   - **System Administrator** - Responsible for the security of the program. The System Administrator creates and maintains user accounts, sets site options, and backs up and restores user information.
   - **Supervisor** - Creates, modifies and deletes setups, calibrates sensors, runs qualification studies, generates reports, and deletes calibration and qualification files.
   - **Operator** - Uses prepared setups to calibrate sensors, run qualification studies and generate reports.
10.0 PROCEDURES

This section describes the steps necessary to wire Sims, start the Validator 2000 software, create/modify a setup, connect the system, calibrate sensors, run a qualification study, verify sensor calibration, and create reports.

10.1 Wiring SIMs
There are two methods for wiring SIMs. You can assign sensor locations in the setup file, and then wire the sensors according to the Setup Report, or you can buy pre-wired SIMs or wire the SIMs yourself and then create a setup that reflects the sensor locations. This section shows you how to wire SIMs yourself.

Procedure:
Loosen the two screws on the side of the SIM and open the cover.

Using appropriate thermocouple wire, cut through the outer insulation to separate the two wires. Strip back approximately one-half inch of insulation in order to make the connection with the SIM connectors. Connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector. The negative thermocouple lead is usually red.

Connect dry contacts inputs directly to the SIM connectors.

Connect voltage inputs (up to 10 volts) to the SIM connectors. Connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector.

For current applications, connect a 250Ω precision resistor to the SIM connector in parallel with the input leads. A 250Ω resistor will convert a 4-20 ma signal to 1-5 volts. Connect the positive (+) lead from the power supply to the positive (+) SIM connector, the positive (+) lead from the device to the negative (-) SIM connector, and the negative (-) lead from the device to the negative (-) power supply connector.

After all sensors have been connected, route the thermocouple wires around the terminal connectors and out the drain hole. Secure wires with tie wraps.

Close the SIM cover and tighten the screws.

For steam applications, slit the outer insulation at least 6 inches to 8 inches away from the SIM to provide a drip cut. Wrap a paper towel around the cuts to absorb the water.

10.2 Starting the Validator 2000 Software
- Click the Start button, point to Programs, point to Validator 2000, and then click Validator 2000.

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

10.3 Creating/Modifying a Setup
The setup defines everything required to calibrate sensors, run qualification studies and verify sensor calibration. The setup is created/modified using the Validator 2000 software. The PC does not have to be connected to the Validator 2000 to create/modify setups.

Procedure
1. From the Main Menu, click Define Setups.

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

2. Highlight a setup and click OK, or click New to create a new setup, enter up to 35 characters to describe the setup and click OK.

3. Add, modify or delete sensor definitions as necessary on the Sensors screen.
Select sensors by clicking a sensor location or clicking and dragging the cursor over multiple sensor locations in the same SIM.

To add or modify a sensor definition, enter/modify the sensor label and sensor description, and select a sensor type. Specify scale factors as required. To automatically number multiple sensor definitions, click the automatic numbering check boxes to append 2 digits in sequence to the sensor label and description label. Click OK.

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

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

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

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

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

4. Specify calibration parameters.
   - Click the Calibration tab.
   - Set the Temperature Set points as necessary.
   - Set the Stability Criteria as necessary.
   - Set the Deviation Criteria as necessary.

5. Specify qualification study conditions.
   - Click the Qualification tab.
   - Click the Modify button and set the Start/Stop Conditions as necessary.
   - Set the Data Storage file rate and Validator 2000 printer rate as necessary.
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- Set the Scan Rate to appropriate rate (8 inputs or 12 inputs per second).
- Set the Output Relay as necessary.

6. Save the setup file.
   - Click the File Topics tab.
   - Click Save.
   - Enter user ID and password and click OK
   - Enter a new setup file name or accept current file name and click OK.

7. Copy the setup file to floppy disk for standalone operation.
   - Insert a 3.5-inch disk into the PC’s disk drive.
   - Click Copy.
   - Set Data Directory to the floppy disk drive.
   - Click OK.
   - When complete, remove the disk and label with setup name.

8. Click Main to return to the Main Menu.

10.4 Connecting the System
    All system connections are on the back of the Validator 2000. Each connection port is labelled with an icon representing its function. Connection ports are as follows:
    - 2 IRTD ports (RJ11)
    - 1 temperature reference port (RJ11)
    - 1 PC serial communications port
    - 1 parallel printer port
    - 1 Relay NC/NO port

Procedure
1. Make sure the Validator 2000 and the temperature reference are powered off before connecting the system.
2. Insert the IRTD into the temperature reference.
3. Connect the IRTD to one of the RJ11 sockets, using the M2810 cable supplied with the IRTD.
4. Connect the temperature reference to one of the RJ11 sockets, using the W1885-1 cable supplied with the temperature reference.
   Insert the wired SIMs into the SIM slots. Label each SIM with the associated slot number.
5. Connect the PC to the 9-pin port, using the 9 to 9-pin W1890-1 cable. If necessary, use a 9 to 25-pin adapter at the PC.
6. Connect the temperature reference power cable to a grounded power source.
7. Connect the Validator 2000 power cable to a grounded power source.
8. Turn the temperature reference power switch to the on position.
9. Turn the Validator 2000 power switch to the on position.
10.5 Checking Hardware and Communications Connections
The Validator 2000 software graphically displays the validation system hardware and communications connections. It is good practice to check communications before starting the validation process.

Procedure
1. Click the Hardware tab.
   Each hardware item is shown with a communication link. A Device Not Found symbol indicates a communication problem.
2. Click any Device Not Found symbol to get help for that particular problem.

10.6 Calibrating Sensors
This section includes separate procedures for standalone and PC-controlled calibration.

10.6.1 Standalone Sensor Calibration
Standalone sensor calibration requires a Kaye temperature reference and IRTD.

Procedure
1. Power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.
2. Insert the thermocouple sensors into the temperature reference.

Load the setup from floppy disk into the Validator 2000.
- Insert the disk that contains the setup into the Validator 2000 disk drive.
- Press the Security key.
- Key in user ID and press Enter.
- Key in password and press Enter.
- Press Load Setup.
- Select the setup on the Setup List screen. If multiple setups are displayed, use the up and down arrow keys on the Validator 2000 keypad, or the Next and Previous options to select the setup.
- Press Load.
4. Select sensors to calibrate.
- Press the Security key.
- Key in user ID and press Enter.
- Key in password and press Enter.
- Press Calibrate Sensors.
- To select individual sensors, position the cursor on the sensor location and press Select.
- To select all sensors, position the cursor on All Sensors and press Select.
- Press Continue.
5. Calibrate sensors.
- Ensure a floppy disk is in the Validator 2000 disk drive to record calibration data.
- From the Sensor Confirmation screen, press Run Calibration.
- The Validator 2000 automatically performs sensor calibration at the specified set points.
• When calibration is complete, the system message “Floppy Disk Reporting Complete” displays.
• Press Continue.
• Remove the floppy disk from the Validator 2000 disk drive and label accordingly.

10.6.2 PC-Controlled Sensor Calibration

When performing PC-controlled sensor calibration, all major actions should be performed at the PC.

Procedure
1. Power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.
2. Insert the thermocouple sensors into the temperature reference.
3. At the PC, close all open applications and disable all power-conserve and screen saver features.
4. Start the Validator 2000 software if not already running.
5. Load the setup from the PC into the Validator 2000.
   • From the Main Menu, click Calibrate Sensors.
   • Select the setup on the File Selection screen and click OK.
   • Enter user ID and password and click OK.
6. Select sensors to calibrate on the Select Sensors screen.
   • To select individual sensors, click each sensor location.
   • To select all sensors in the same SIM, click Select All.
7. Calibrate sensors.
   • Ensure a floppy disk is in the Validator 2000 disk drive to record calibration data.
   • From the Select Sensors screen, click Calibrate Sensors.
   • Enter user ID and password and click OK.
   • The Validator 2000 automatically performs sensor calibration at the specified set points.
   • When calibration is complete, the message “Floppy Disk Reporting Complete” displays.
   • Click OK.
   • The message “The final data record has been received from the Validator” displays.
   • Click OK.
From the Data screen, click Return.
Click the File Topics tab.
Click Main to return to the Main Menu.
Remove the floppy disk from the Validator 2000 disk drive and label accordingly.

10.6.3 Running a Qualification Study
The Validator 2000 can perform standalone or PC-controlled qualification studies manually or automatically, depending on the start/stop conditions defined in the setup. This section includes separate procedures for standalone and PC-controlled qualification studies.

10.6.4 Standalone Qualification Study
When performing a standalone qualification study, all major actions should be performed at the Validator 2000.

**Procedure**

1. Power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.
2. Position sensors in vessel or chamber being tested.
3. Load the setup from floppy disk into the Validator 2000. If the setup is already loaded, go to step 4.
   - Insert the disk that contains the setup into the Validator 2000 disk drive.
   - Press the Security key.
   - Key in user ID and press Enter.
   - Key in password and press Enter.
   - Press Load Setup.
   - Select the setup on the Setup List screen. If multiple setups are displayed, use the up and down arrow keys on the Validator 2000 keypad, or the Next and Previous options to select the setup.
   - Press Load.
4. Insert a clean floppy disk into the Validator 2000 disk drive.
5. Start the qualification study (if start condition is defined as manual).
   - Press the Security key.
   - Key in user ID and press Enter.
   - Key in password and press Enter.
   - Press Start Qualification.
6. View qualification study data.
   - Press the right arrow key on the Validator 2000 keypad to scroll forward through the real-time data screens.
   - Press the left arrow key on the Validator 2000 keypad to scroll back through the real-time data screens.
7. Start exposure cycle (if manual exposure cycle defined in setup).
   - Press the Security key.
   - Key in user ID and press Enter.
8. Stop exposure cycle (if manual exposure cycle defined in setup).
   • Press the Security key.
   • Key in user ID and press Enter.
   • Key in password and press Enter.
   • Press Stop Exposure.

9. Stop qualification study (if stop condition defined as manual).
   • Press the Security key.
   • Key in user ID and press Enter.
   • Key in password and press Enter.
   • Press Stop Qualification.
   • The system message “Floppy Disk Reporting Complete” displays.
   • Press Continue.

10. Remove the floppy disk from the Validator 2000 disk drive and label accordingly.

10.6.5 PC-Controlled Qualification Study
When performing a PC-controlled qualification study, all major actions should be performed at the PC.

   Procedure
   1. Power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.
   2. Position sensors in vessel or chamber being tested.
   3. Insert a clean floppy disk into the Validator 2000 disk drive.
   4. At the PC, close all open applications and disable all power-conserve and screen saver features.
   5. Start the Validator 2000 software if not already running.
      • From the Main Menu, click Run Qualification.
      • Select the setup on the File Selection screen and click OK.
      • Enter user ID and password and click OK.
      • Enter/modify report header information for each group as necessary.
      • Click the Qualification tab.
      • Click Load Setup.
      • Enter user ID and password and click OK.
   7. Start the qualification study (if start condition is defined as manual).
      • Click Start Qualification Study on the Status screen, or click Start Qual on the Values screen.
      • Enter user ID and password and click OK.
8. View/graph qualification study data.
   - Click the Values, Messages, and Status tabs to view real-time qualification data.
   - Click the Graphs tab to graph qualification data. Select a group from the list box at the top of the screen, and then select items to graph from the list boxes at the right of the screen.

9. Start exposure cycle (if start condition is defined as manual).
   - Click Start Exposure Cycle on the Status screen, or click Start Exp on the Values, Messages or Graphs screens.
   - Enter user ID and password and click OK.

10. Stop exposure cycle (if stop condition is defined as manual).
    - Click Stop Exposure Cycle on the Status screen, or click Stop Exp on the Values, Messages or Graphs screens.
    - Enter user ID and password and click OK.

11. Stop qualification study (if stop condition defined as manual).
    - Click Stop Qualification Study on the Status screen, or click Stop Qual on the Values, Messages or Graphs screens.
    - Enter user ID and password and click OK.
    - The message “Floppy Disk Reporting Complete” displays.
    - Click OK.
    - The message “The final data record has been received from the Validator” displays.
    - Click OK.

12. Click Done from the Status, Values, Messages or Graphs screens.

13. Click the File Topics tab.

14. Click Main to return to the Main Menu.

15. Remove the floppy disk from the Validator 2000 disk drive and label accordingly.

10.7 Verifying Sensor Calibration
    This section includes separate procedures for standalone and PC-controlled calibration verification.

10.7.1 Standalone Calibration Verification
    Standalone calibration verification requires a Kaye temperature reference and IRTD.

Procedure
1. Power up the Validator 2000 and let it run for approximately 30 minutes in the operating environment in order to acclimate to the ambient temperature.
2. Insert the thermocouple sensors into the temperature reference.
3. Load the setup from floppy disk into the Validator 2000. If the setup is already loaded, go to step 4.
   - Insert the disk that contains the setup into the Validator 2000 disk drive.
   - Press the Security key.
   - Key in user ID and press Enter.
   - Key in password and press Enter.
Press Load Setup.

Select the setup on the Setup List screen. If multiple setups are displayed, use the up and down arrow keys on the Validator 2000 keypad, or the Next and Previous options to select the setup.

Press Load.

4. Select sensors.
   - Press the Security key.
   - Key in user ID and press Enter.
   - Key in password and press Enter.
   - Press Calibrate Sensors.
   - To select individual sensors, position the cursor on the sensor location and press Select.
   - To select all sensors, position the cursor on All Sensors and press Select.
   - Press Continue.

5. Verify sensor calibration.
   - Ensure a floppy disk is in the Validator 2000 disk drive to record calibration data.
   - From the Sensor Confirmation screen, press Run Verification.
   - The Validator 2000 automatically performs calibration verification at the specified set points.
   - When calibration verification is complete, the system message “Floppy Disk Reporting Complete” displays.
   - Press Continue.
   - Remove the floppy disk from the Validator 2000 disk drive and label accordingly.

10.7.2 PC-Controlled Calibration Verification

When performing PC-controlled calibration verification, all major actions should be performed at the PC.

Procedure

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

2. Insert the thermocouple sensors into the temperature reference.

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

4. Start the Validator 2000 software if not already running.

5. Load the setup from the PC into the Validator 2000.
   - From the Main Menu, click Calibrate Sensors.
   - Select the setup on the File Selection screen and click OK.
   - Enter user ID and password and click OK.

6. Select sensors to verify on the Select Sensors screen.
   - To select individual sensors, click each sensor location.
   - To select all sensors in the same SIM, click Select All.
7. Verify sensor calibration.
   - Ensure a floppy disk is in the Validator 2000 disk drive to record calibration verification data.
   - From the Select Sensors screen, click Verify Calibration.
   - Enter user ID and password and click OK.
   - The Validator 2000 automatically performs calibration verification at the specified set points.
   - When calibration verification is complete, the message “Floppy Disk Reporting Complete” displays.
     - Click OK.
   - The message “The final data record has been received from the Validator” displays.
     - Click OK.

8. From the Data screen, click Return.

9. Click the File Topics tab.

10. Click Main to return to the Main Menu.

11. Remove the floppy disk from the Validator 2000 disk drive and label accordingly.

10.8 Generating Reports
Reports are generated from secure data files that can only be read by the Validator 2000 software. You specify the reports to include in your study documentation and the groups to report on. For Qualification Reports, you can print qualification data exactly as it was recorded, or you can customize your report by adding statistical calculations, events, and time intervals to your report based on the stored data.

Note Reports are not saved; you create reports each time from the secure data files.

Procedure
   - From the Main Menu, click Create Reports.
   - A screen showing the four types of reports will appear. Chose the desired report.
   - The File Selection screen appears, listing all the files associated with the type of report selected in the previous step.
   - If you performed standalone sensor calibration, qualification, and/or calibration verification, you need to read this data into the default data path from floppy disk before you can select a file. Specify the floppy disk drive where your data resides in the File Location list box. All files that do not already reside in the default data path are automatically copied into the default data path.
   - Select a vessel ID from the Vessel ID list box to filter the list of qualification files to only those files that contain that specific vessel ID.
   - Select a file and click OK.

2. Specify the report types to be individually generated.
   - The Setup, Qualification, and Summary report types are enabled by default by selecting the qualification report. If you do not want to generate an individual report type, click the option name to disable it. You may also include or exclude Lethality and Interval Calculations from the Summary Report.
Click Calibration to include a Calibration Report. Select the calibration files to include in your study documentation from the list of files on the Cal Files screen and click OK.

Click Calibration Verification to include a Calibration Verification. Select the calibration verification files to include in your study documentation from the list of files on the Cal Files screen and click OK.

3. Specify the print destination on the Print Options screen.
   - The Printer option is enabled by default.
   - If the Qualification report type option is enabled, the Spreadsheet option is also available as a print destination. Enable this option if you want to export your qualification data to an Excel spreadsheet data file that can be imported into a spreadsheet application for further analysis.

4. Select the groups to include in your study documentation on the Print Options screen.
   - All groups are selected by default (group name is highlighted).
   - To exclude a group, click the group name. The excluded group name will no longer be highlighted.

5. Format report output.
   - Click the Format tab.
   - The “Performed by / Date” and “Reviewed by / Date” options are enabled by default. Click one or both options to exclude these signature lines from your report.
   - If you included one or both signature line options in your report format, but you do not want signature lines on every report page, click First Page, Last Page or Every Page to specify the signature line location.
   - If you selected the Qualification or Summary report options on the Print Options screen, you can add comments to the beginning and/or end of the reports. Click one of the User comments options and enter comments in the text box.

6. Delete sensors from post-qualification reporting.
   - Click the Groups tab.
   - Select a group from the list box.
   - Click individual sensor locations, or click Select All to exclude sensors from post-qualification reporting as necessary.
   - Repeat for all groups as necessary.

Add calculations and group events to Qualification Report.
   - Click the Calculations tab.
   - Select a group from the list box.
   - Add/modify group calculations as necessary.
   - Add group events as necessary.
   - Repeat for each group as necessary.

7. Add event timer intervals (maximum of 32) to qualification reports.
   - Click the Event Timers tab.
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- Select a message number and enter the message to print in the Qualification and Qualification Summary reports, up to 40 characters.
- Specify interval start and stop conditions.
- Repeat as necessary.

8. Print reports.

- Click the File Topics tab.
- Click Print.
- Select a printer and click OK.
- If the Spreadsheet option was selected, the Browse screen appears after the reports have been printed. Enter a filename for the spreadsheet-compatible file, select a drive and directory to store the file, and click OK. When complete, import the file into Microsoft Excel. The file generated is in Excel format.