BAX® System Q7: Instructions for Use with foodproof® Assays*

Installation and Calibration Instructions for the Use of SDS v2.3 Software with the BAX® System Q7

Scope

If your laboratory already owns a BAX® System Q7, you may install the Applied Biosystems™ SDS v2.3 software with foodproof® and microproof® assays*, enabling amplification curve interpretation and extraction of Cq values for quantification purposes.

**Note: for the foodproof Salmonella plus Cronobacter LyoKit assay, use the BAX System Q7 Software version 5.1 or later.*

This requires the installation of the SDS v2.3 software on the workstation's PC. The programs do not interfere with each other, but must not be running simultaneously.

A power-down and restart of the BAX® System Q7 Instrument and PC is necessary when switching between the BAX System Q7 software and SDS v2.3 software.

For food and environmental use only. Not for diagnostic use.

Required Equipment & Materials

Component	Details	Contents/Function/Storage
BAX System Q7 PCR Cycler	Q7 Workstation ASY2013; Recommend start-up package with automated thermal block, ASY2016 (or, manual thermal block systems, ASY2018 or ASY2020)	Workstation includes: • BAX Q7 PCR cycler, monitor and software • A/B switch • USB cables • PCR tube racks • PCR tube holder trays Start-up Package includes the workstation, plus: • Thermal block with heating and cooling blocks, decapping tools, cluster tubes/ caps/racks, Pipettors (adjustable mechanical, repeating and multichannel), pipettor tips, gloves
SDS version 2.3 software	• Software file	• Downloadable version 2.3 (no other versions)
BAX System Q7 Calibration Kit (KIT2026) (or Spectral Calibration Kit I, 4360788, and Kit II, 4362201, from Applied Biosystems)	• Store at -15 to -25 °C in the original foil envelope to protect from light • Warm to room temperature before opening • Can be used multiple times when stored as above	• 96-well plate ready for use

Component	Details	Contents/Function/Storage
Hex Dye Calibration Kit (KIT230340), if needed	• Black cap • Designed for one (1) calibration • Store at -15 to -25 °C	• 2 x 1000 µL HEX Calibration Reagent Black cap HEX Calibration Reagent • 1 x MicroAmp™ Fast Optical 96-Well Reaction Plate • 1 x MicroAmp™ Clear Adhesive Film
Standard swing bucket centrifuge with rotor for multi-well plates	• Multiple vendor options	• Must hold 96-well plate upright
ClearFoam® Swab, or similar	• Durable cotton or nylon • Lint-free	• Store at ambient temperature in packaging
Deionized water	• Multiple vendor options	• PCR-grade, nuclease-free water
Powder-free gloves	• Provided with BAX Q7 start-up package • Available in multiple sizes from many vendors	• Minimizes contamination from hands
TaqMan® RNase P Instrument Verification Plate, Fast 96-well	• Available from multiple vendors	• Verifies the performance of the BAX System Q7 PCR cycler

- *Optional: Safety goggles*

Related documentation: For detailed information on instrument setup and the calibration process, please refer to the product instructions for use for each product number listed above.

System Requirements:

The computer hardware and operating system requirements for the SDS v2.3 software are:

- Windows® 7 with Service Pack 1, 32/64-bit or Windows® 10 (64-bit) Operating System
- Pentium 4 or compatible, with a minimum of 1 GB of RAM and 20 GB of hard drive capacity
- Minimum monitor resolution of 1280 x 1024
- One v1.1 USB port for connecting to the instrument directly (co-located configuration)
- Internet Explorer® 6.0 or higher (for online assay browsing and ordering)
- Microsoft® PowerPoint® software (for direct export of PowerPoint slides)
- Microsoft® Excel® software (for direct export of data to a spreadsheet)
- Software installation requires a minimum of 1 GB of random access memory (RAM).

Prepare your BAX® System Q7

To ensure that calibration is performed successfully, it is recommended that you clean the sample block and wells and back up your existing BAX® System Q7 calibration before installing the SDS v2.3 software (see the BAX System Q7 User Guide for additional details):

1. Open the instrument's access door and move the heated cover door to the back of the instrument
2. Pipette a small volume of deionized water into each well. Let sit for 5 minutes.

3. Scrub the inside of each well with a cotton or nylon swab (e.g., CleanFoam® swab), then absorb the excess water with a lint-free cloth or a dry swab. Repeat until the swab comes out clean after wiping the well.
4. After cleaning the sample block, back up your calibration files to external media by selecting **Operation > BAX® Maintenance > Export Calibration > Browse > Save** from the menu bar.

Procedures for Software Installation and Calibration

Important: To prevent data loss, it is strongly advised that all user data is backed up before upgrading the software.

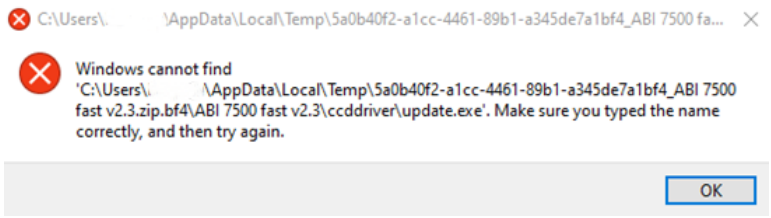
1. Software installation

1.1. Close all applications, open the SDS v2.3 file, and double-click on setup.exe

1.2. Follow the Install Wizard onscreen installation instructions.

1.3. When prompted, select **7500fast** for the Instrument and enter the Serial Number.

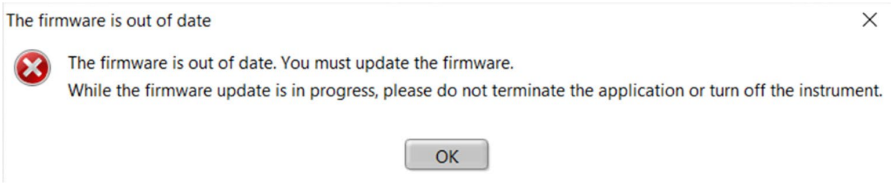
1.4. If you get the error message below, you can ignore it. Click “OK”.



2. Check the software and instrument for updates

2.1. Start the BAX Q7 instrument and the SDS v2.3 software.

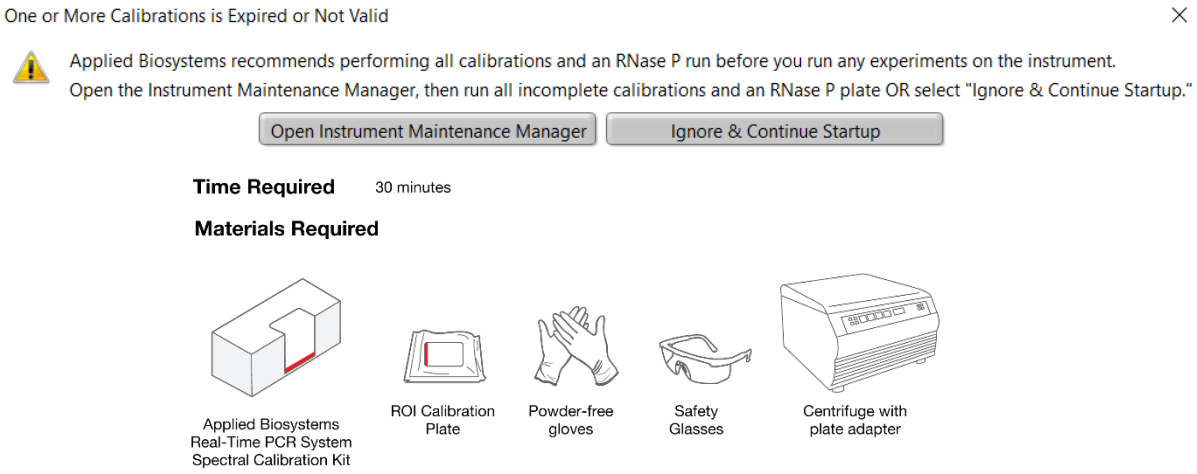
2.2. If the following window appears, click “OK”. (Release notes/instructions for firmware updates can be found on www.hygiena.com under the BAX System Q7 instrument product page).



3. Perform calibration

IMPORTANT: When installing the SDS software, you must perform the Regions of Interest (ROI), background, optical, and dye calibrations in sequence.

3.1. To calibrate, go to Instrument>Instrument Maintenance Manager. If the window below appears on startup, you can navigate there directly by clicking “Open Instrument Maintenance Manager”.



When to Perform an ROI Calibration:

- When installing the 7500/7500 Fast system; you must perform in sequence the ROI, background, optical and dye calibrations and the instrument verification run.
- Every 6 months, or as often as necessary, depending on instrument use.
- After replacing the lamp.

3.2. Regions of Interest (ROI) Calibration:

*3.2.1.**Prepare the ROI Calibration Plate***

3.2.1.1. Obtain the ROI calibration plate from the spectral calibration kit in the freezer.

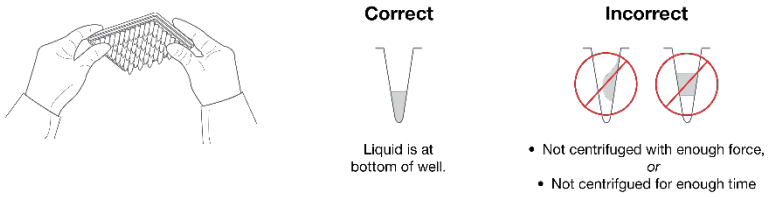
3.2.1.2. Allow the ROI calibration plate to warm to room temperature (approximately 5 min).

3.2.1.3. Remove the ROI calibration plate from its packaging. Leave the optical film on the plate.

IMPORTANT: Do not remove an ROI calibration plate from its packaging until you are ready to run it. The fluorescent dye in the plate wells is photosensitive. Prolonged exposure to light can diminish the plate’s fluorescence.

IMPORTANT: Do not discard the packaging for the ROI calibration plate. The plate can be used up to three times if it is stored in its original packaging sleeve.

3.2.1.4. Centrifuge the plate for 2 min at < 1500 rpm. Verify that the liquid in each well of the ROI calibration plate is at the bottom of the well. If not, centrifuge the plate again at a higher rpm and for a longer period of time.



IMPORTANT: The ROI calibration plate must be well mixed and centrifuged.

Note: If one or more wells have significantly less liquid, the calibration kit should be replaced.

3.2.1.5. Again, verify that the liquid in each well of the ROI calibration plate is at the bottom of the well. If not, repeat the previous step (3.2.1.4).

*3.2.2.**Load the Plate***

3.2.2.1. Push the tray door to open it.

3.2.2.2. Load the plate into the instrument's plate holder and ensure that it is properly aligned in the holder.

3.2.2.3. Close the tray door by applying pressure to the right side of the tray door at an angle.

*3.2.3.**Perform an Automated ROI Calibration***

3.2.3.1. In the SDS v2.3 software, select **Instrument ▶ Instrument Maintenance Manager**.

3.2.3.2. In the ROI screen of the Instrument Maintenance Manager, click **Start Calibration**.

3.2.3.3. Complete the calibration as instructed by the wizard. The ROI Calibration dialog box displays three tabs:

Setup – Displays instructions for setting up the ROI calibration. Clicking the **NEXT** prompt opens the Run tab.

Run – Clicking **START RUN** starts the calibration process and displays the processing messages. Clicking **NEXT** opens the Analysis tab.

Analysis – Indicates the calibration status (**Passed**/**Failed**).

*3.2.4.**Unload and Remove the Calibration Plate***

3.2.4.1. Push the tray door to open it.

3.2.4.2. Remove the calibration plate.

3.2.4.3. Push the tray door to move it into the instrument.

3.2.4.4. Place the calibration plate inside its packaging sleeve. If you plan to perform background and optical calibrations within the next 8 hours, keep the ROI calibration plate at room temperature because the optical calibration uses the ROI calibration plate. If you plan to perform background and optical calibrations on another day, return the packaged plate to the spectral calibration kit in the freezer.

3.3. Background Calibration

*3.3.1.**Prepare the Background Calibration Plate***

3.3.1.1. Obtain the prepared background plate from the BAX® System Q7 Calibration Kit in the freezer.

3.3.1.2. Allow the background plate to warm to room temperature (at least 5 min).

3.3.1.3. Remove the background plate from its packaging.

3.3.1.4. Check plates before use. If there are droplets on the top film, centrifuge the plate (2 min at < 1500 rpm) so drops return to the wells.

Note: If one or more wells have significantly less liquid, the calibration kit should be replaced.

3.3.1.5. Verify that the liquid in each well of the background plate is at the bottom of the well. If not, repeat the previous step.

*3.3.2.**Load the Plate***

3.3.2.1. Push the tray door to open it.

3.3.2.2. Load the plate into the instrument's plate holder and ensure that it is properly aligned in the holder.

3.3.2.3. Close the tray door by applying pressure to the right side of the tray door at an angle.

*3.3.3.**Perform the Background Calibration***

3.3.3.1. In the SDS v2.3 software, **select Instrument ▶ Instrument Maintenance Manager**.

3.3.3.2. In the Instrument Maintenance Manager, select the **Background** tab.

3.3.3.3. In the Background tab, click **Start Calibration**.

3.3.3.4. Complete the calibration as instructed by the wizard. The Background Calibration dialog box displays four tabs:

Overview – Displays information describing the calibration.

Setup – Displays instructions for setting up the background calibration. Clicking **NEXT** prompts the opening of the Run tab.

Run – Clicking **START RUN** starts the calibration process and displays the processing messages. Clicking **NEXT** opens the Analysis tab.

Analysis – Indicates the calibration status (**Passed**/**Failed**). If it fails, the software will state which wells have high fluorescence and recommend cleaning the sample block before redoing the background calibration.

3.3.4. ***Unload & Remove the Plate***

3.3.4.1. Push the tray door to open it.

3.3.4.2. Remove the calibration plate.

3.3.4.3. Push the tray door to move it into the instrument.

3.3.4.4. Place the calibration plate inside its packaging sleeve, then return the packaged plate to the BAX® System Q7 Calibration Kit in the freezer.

3.4. Optical Calibration

3.4.1. ***Prepare the ROI Calibration Plate***

IMPORTANT: Wear powder-free gloves when handling the plate.

3.4.1.1. Obtain the ROI calibration plate from the BAX® System Q7 Calibration Kit in the freezer. **Note**: If you stored the ROI plate at room temperature after the ROI calibration step, skip to step 3.4.1.4**.**

3.4.1.2. Allow the ROI calibration plate to warm to room temperature (at least 5 min).

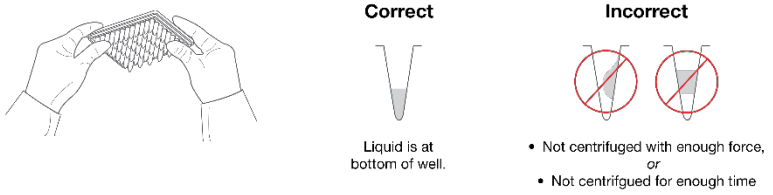
3.4.1.3. Remove the ROI calibration plate from its packaging.

3.4.1.4. Check plates before use. If there are droplets on the top film, centrifuge the plate for 2 min at < 1500 rpm so drops return to the wells.

Note: If one or more wells have significantly less liquid, the calibration kit should be replaced.

IMPORTANT: Do not vortex plates. Do not discard the packaging for the plate. The ROI calibration plate can be used up to 3 times if stored in its original packaging sleeve.

3.4.1.5. Verify that the liquid in each well of the ROI calibration plate is at the bottom of the well. If not, centrifuge the plate again at a higher rpm and for a longer period of time.



IMPORTANT: Do not allow the bottom of the background plate to become dirty. Fluids and other contaminants that adhere to the bottom of the plate can contaminate the sample block and cause an abnormally high background signal.

*3.4.2.**Load the Plate***

3.4.2.1. Push the tray door to open it.

3.4.2.2. Load the plate into the instrument's plate holder and ensure that it is properly aligned in the holder.

3.4.2.3. Close the tray door. Apply pressure to the right side of the tray door at an angle.

*3.4.3.**Perform the Optical Calibration***

3.4.3.1. In the SDS v2.3 software, select **Instrument ► Instrument Maintenance Manager**.

3.4.3.2. In the Instrument Maintenance Manager, select the **Optical** tab.

3.4.3.3. In the Optical screen, click **Start Calibration.**

3.4.3.4. Complete the calibration as instructed by the wizard. The Optical Calibration dialog box displays four tabs:

Overview – Displays information describing the calibration.

Setup – Displays instructions for setting up the optical calibration. Clicking **NEXT** prompts opens the Run tab.

Run – Clicking **START RUN** starts the calibration process and displays the processing messages. Clicking **NEXT** opens the Analysis tab.

Analysis – Indicates the calibration status (**Passed**/**Failed**).

*3.4.4.**Unload and Remove the Calibration Plate***

3.4.4.1. Push the tray door to open it.

3.4.4.2. Remove the calibration plate.

3.4.4.3. Push the tray door to move it into the instrument.

3.4.4.4. Place the calibration plate inside its packaging sleeve. Return the packaged plate to the BAX® System Q7 Calibration Kit in the freezer.

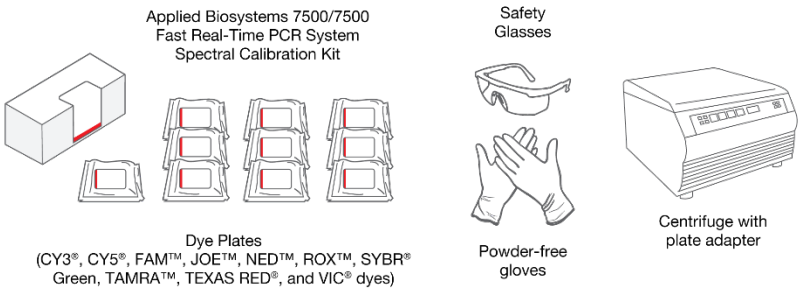
Note: The ROI Calibration Plate cam be used up to 3 times after opening.

3.5. Dye Calibration

Note: The dye calibration is a user-performed maintenance procedure.

Time Required 1 hour

Materials Required



*3.5.1.**Prepare the Plates***

IMPORTANT: Wear powder-free gloves when you handle the plate.

3.5.1.1. Obtain the BAX® System Q7 Calibration Kit from the freezer, then remove all dye plates.

3.5.1.2. Return the BAX® System Q7 Calibration Kit to the freezer.

3.5.1.3. Allow the dye plates to warm to room temperature (approximately 5 min).

*3.5.2.**Perform the Dye Calibration***

3.5.2.1. In the SDS v2.3 software, select **Instrument ►Instrument Maintenance Manager.**

3.5.2.2. In the Instrument Maintenance Manager, select the **Dye** tab.

3.5.2.3. In the Dye screen, select **System Dye Calibration**.

3.5.2.4. Click **Start Calibration**.

*3.5.3.**Complete the calibration for each plate as instructed by the wizard.***

IMPORTANT NOTE! The wizard guides you through the calibration of each dye separately. You must set up, run, and analyze each dye plate independently.

The Dye Calibration dialog box displays four tabs:

Overview – Displays information describing the calibration. When the software prompts you to obtain the required materials, select the dyes that you want to calibrate.

Setup – Displays instructions for setting up the dye calibration. Clicking **NEXT** prompts opens the Run tab. When the software prompts you to load each dye plate, prepare and load the plates as described in "**Load a Dye Plate**".

Run – Clicking **START RUN** starts the calibration process and displays the processing messages. Clicking **NEXT** opens the Analysis tab.

Analysis – Indicates the calibration status (**Passed**/**Failed**). When the software prompts you to analyze the spectra collected from each dye plate, verify the status of the calibration:

- **Passed** – The 7500/7500 Fast instrument passed the calibration. Go to "**Analyze the Calibration Data.**"
- **Failed** – The 7500/7500 Fast instrument failed the calibration.

*3.5.4.**Load a Dye Plate***

IMPORTANT: Before performing a dye calibration, you must first perform an ROI calibration (see Section 3.2), a background calibration (see Section 3.3) and an optical calibration (see Section 3.4).

IMPORTANT: Wear powder-free gloves when you handle the plate.

3.5.4.1. Remove the dye plate that is specified by the software from its packaging.

3.5.4.2. Allow the dye plates to warm to room temperature (approx. 5 min). If there are droplets on the top film, centrifuge the plate for 2 min at < 1500 rpm so the drops return to the wells.

IMPORTANT: Do not remove a dye plate from its packaging until you are ready to run it. The fluorescent dye in the wells of each dye plate is photosensitive. Prolonged exposure to light can diminish the plate's fluorescence signal strength.

Note: After centrifugation, if one or more wells have significantly less liquid, the calibration kit should be replaced.

3.5.4.3. Verify that the liquid in each well of the plate is at the bottom of the well. If not, repeat the previous step.

3.5.4.4. Verify that the dye plate that you are about to load matches the dye selected in the SDS v2.3 software.

3.5.4.5. Push the tray door to open it.

3.5.4.6. Load the plate into the instrument's plate holder and ensure that it is properly aligned in the holder.

3.5.4.7. Close the tray door. Apply pressure to the right side of the tray door at an angle.

*3.5.5.**Analyze the Calibration Data***

IMPORTANT NOTE: Because the wizard guides you through the calibration of each dye separately, perform the following procedure for each dye that you calibrate.

3.5.5.1. Verify the status of the calibration:

- **Passed** – The 7500/7500 Fast instrument passed the calibration. Continue to the next step.

- **Failed** – The 7500/7500 Fast instrument failed the calibration.

3.5.5.2. Verify the grouping of the dye spectra. In the plate layout, select the wells of the plate to inspect the raw data (2a). For each spectrum, verify that the peak is:

- Within the detectable range for the 7500/7500 Fast instrument (2b).

- Free of irregular spectral peaks (2b).

- Present in the correct channel for the dye (see Table 1).

Note: Among wells containing the same dye, variations in spectral position and peak position are caused by minor differences in the optical properties and excitation energy between the individual wells.

3.5.5.3. If all spectra are acceptable (1), then click **NEXT** (3).

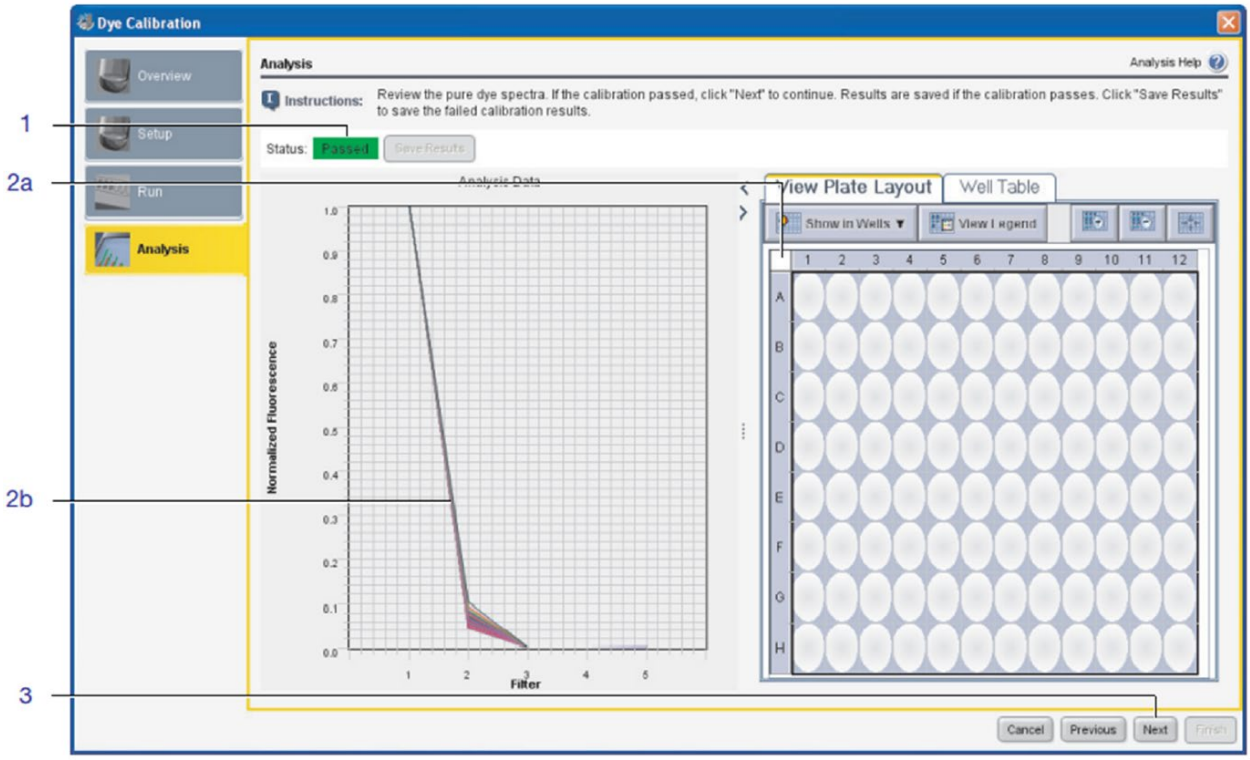
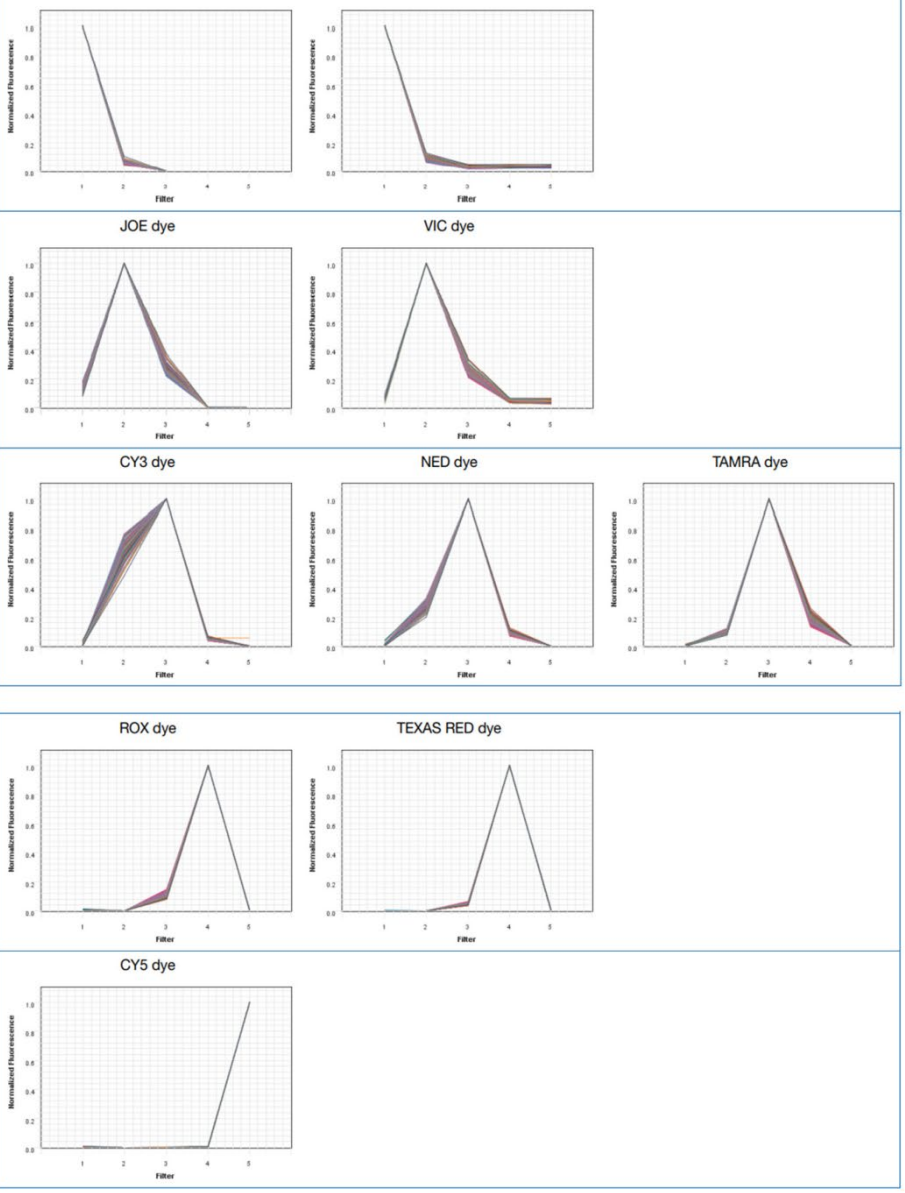


Table 1. Proper Channel Peaks and Spectra for Each Dye Used

Filter	Peak (nm)	Dye/Spectra
1	~520	FAM dye, SYBR Green dye
2	~550	JOE dye, VIC dye
3	~580	CY3 dye, NED dye, TAMRA dye
4	~610	ROX dye, TEXAS RED dye
5	~670	CY5 dye



*3.5.6.**Remove the calibration plate.***

3.5.6.1. Push the tray door to open it.

3.5.6.2. Remove the calibration plate.

3.5.6.3. Push the tray door to move it into the instrument.

3.5.6.4. Place the calibration plate inside its packaging sleeve. Return the packaged plate to the BAX® System Q7 Calibration Kit in the freezer.

3.5.6.5. After you remove the dye plate as instructed, click **FINISH**.

3.5.6.6. Prepare and run the next plate as explained in "**Prepare the Plates**".

3.5.7. Custom Dye Calibration (Optional)

The following Custom Dye Calibration is required if you run foodproof® assays that use HEX. This section may be skipped otherwise. Refer to specific assay instructions to determine if HEX dye is included/required.

3.5.7.1. In the **Instrument Maintenance Manager**, select the **Dye** tab.

3.5.7.2. In the Dye screen, select **Custom Dye Calibration.**

3.5.7.3. Click **Start Calibration**

3.5.8. Custom Dye Calibration Setup

3.5.8.1. Locate the required materials, including the HEX plate, powder-free gloves and centrifuge with plate adapter (safety goggles are optional). Refer to the HEX Calibration Kit Product Instructions for additional information on preparing HEX Calibration reagents.

3.5.8.2. Click on **New Dye** and then click **New** at the bottom of the pop-up window.

Field/Parameter	Action/Entry
Name	**HEX**
Wavelength	Leave Blank
Type	Select: **Reporter**

Click OK to Close then click the drop-down arrow next to Dye Name and select **HEX**

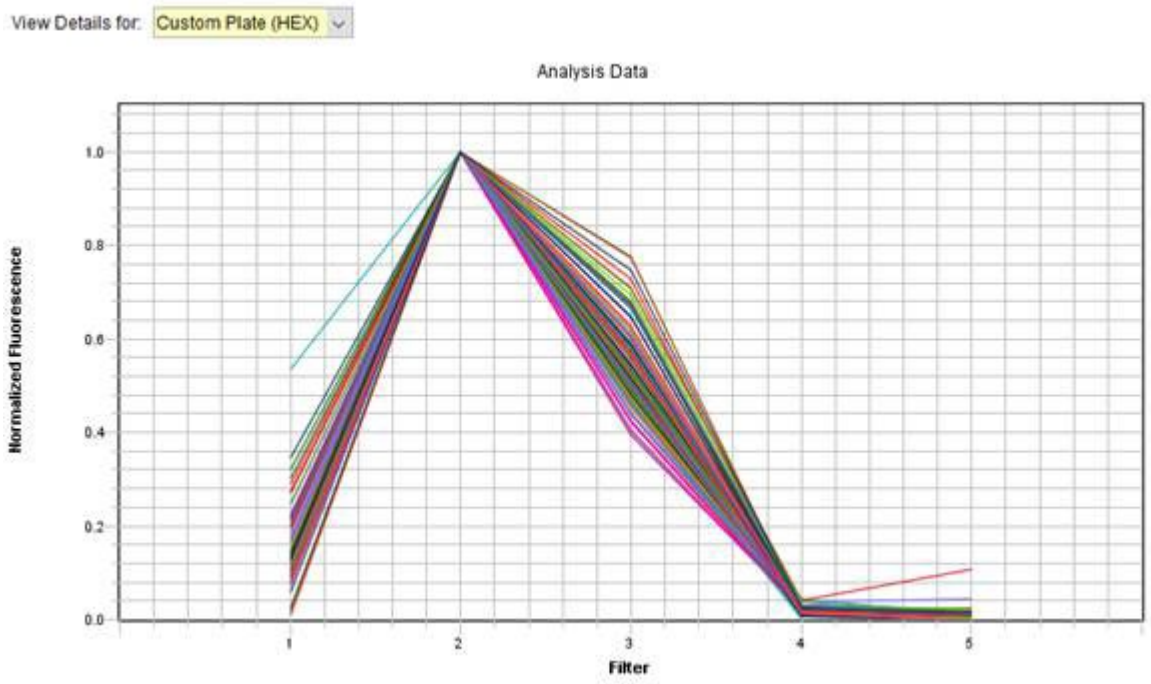
3.5.8.3. Keep the temperature at **60.0 °C**

3.5.8.4. Prepare the custom dye plate. Click **View Instructions** and follow the directions.

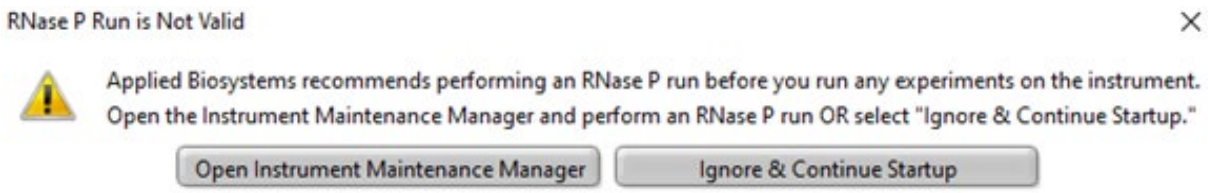
3.5.8.5. Load the Plate

3.5.8.6. Select the checkbox “The custom dye plate is loaded into the instrument” and then click **START RUN**

*3.5.9.**Analyze the Calibration Data***



IMPORTANT NOTE: The BAX Q7 does not need an RNase P Run. Every time the SDS v2.3 software is opened, the message below will appear. It can be ignored.



***Optional**: Perform an instrument verification with a TaqMan RNase P Instrument Verification Plate, Fast 96-Well, following the manufacturer´s instructions.*

Switching Software

The BAX® System Q7 Instrument can now operate BAX® System software and the SDS v2.3 software on a single computer, but both cannot run at the same time. You **MUST** shut down and restart **BOTH** the instrument and computer before switching from one software program to the other. Follow this procedure:

1. Exit from the system software.
2. Power down the instrument.
4. Power up the instrument.
5. Launch the desired software application.

Troubleshooting Calibration

Due to the particular nature of the calibration process, any minor deviation from the calibration protocol may result in a calibration failure. If the calibration process fails, you can perform one or more of the following adjustments and repeat the calibration process.

- Check the failed calibration plate for droplets on the top film. If you see any, centrifuge the plate (2 min at < 1500 rpm) so the droplets return to the wells.
- Allow the calibration plates to reach room temperature.
- Remove any smudges or dust particles from the halogen bulb. Wear gloves when handling the bulb to avoid leaving fingerprints.
- Remove the halogen bulb from the socket, rotate it 180° and re-insert it into the socket.
- Replace the calibration plates if one or more wells have significantly less liquid than the other wells.

If you continue to have issues, please contact technical support from our website at: www.hygiena.com/support

License Information

Before installing or using the software, you must agree to the terms of the Hygiena BAX Q7 System and Life Technologies End User License Agreement (EULA).