

Maintenance, Calibration and Performance Verification of the BAX® System Q7 Instrument

Maintenance

The instrumentation, software and assays that make up the BAX® System have been designed to work together for ease of use and reliability. Careful design has created a system that does not require routine maintenance other than cleaning, as described in Section IV of the BAX® System User Guide.

Calibration

Calibration is important when running real-time PCR assays. BAX® System cycler/detectors sold after September 2006 have been calibrated prior to shipment, and re-calibration is only necessary when the halogen bulb is replaced. For systems purchased prior to September 2006, customers who wish to run real-time PCR assays should contact their Hygiena technical account manager for calibration. Calibration kits are available directly from Qualicon Diagnostics, New Castle, DE www.hygiena.com, product code KIT2026.

Note: The quality of replacement bulbs can vary widely. For warranted results, use only bulbs that have been tested and approved for use with the BAX® System. You can order approved replacement bulbs from Hygiena (Part No. MIS2001).

Performance Verification

Verification is a functional test to confirm the system is operating properly.

Verification is not a calibration.

Self-diagnostics

The BAX® System automatically performs self-diagnostics at power up and at the start of each process run to ensure the hardware is operating properly. If any of these tests fail, the system will prevent you from operating the cycler/detector until the problem is corrected.

Signal checks

For standard PCR assays the intercalating dye in each amplified sample emits a fluorescent signal in response to light. For these assays, the BAX® System uses end-point analysis of “melting curves,” which are generated by changes in signal intensity as temperature is varied. Melting curve analysis, which focuses only on these changes, does not require great stability or precise calibration as long as the signal is within the dynamic range of the measurement system.