

BAX® System Q7 Version 5.1.0.28942 Features and Instructions

BAX® System Q7 software release v5.1 contains several user interface features, new target options, and error logging improvements.

We strongly recommend that you install the latest version as soon as possible for optimal performance.

Please read all instructions thoroughly and ensure all required prerequisites are confirmed prior to beginning the installation of the software update.

If you currently have a Windows 7 computer system, please contact us at www.hygiena.com/support or your local Hygiena® representative for Windows 10 upgrade support.

This release is ONLY applicable for Windows 10 and Windows 11 Operating systems.

Software Assay Updates for Release v5.1.0.28942

- There are no changes to the analysis for BAX assays (vs. versions 4.21, 4.22 or 5.0)
- The addition of the 'SalQuant' option in the target dropdown menu. Select this option when analyzing samples using BAX SalQuant[®] protocols. Refer to 'BAX SalQuant v5.1 Instructions with SureTrend^{®'} for additional details.
- One foodproof® assay with verified result interpretation (displayed as 'Certified' within the software):

Product Name	Product Number
foodproof® Salmonella plus Cronobacter Detection LyoKit	KIT230131

Note: foodproof assays with 'Certified' results interpretation do <u>not</u> require visual verification of the graphs. However, as a best practice, Hygiena recommends customers review all results.

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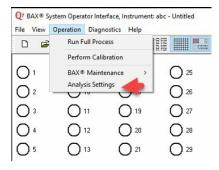
foodproof/microproof® assays with <u>improved</u> **experimental** analysis files for assistance with results interpretation:

Product Name	Product Number
foodproof® Aspergillus Detection LyoKit (Real-time only)	KIT230145
foodproof® Enterobacteriaceae plus Salmonella Detection LyoKit	KIT230137
microproof® Legionella Quantification LyoKit	KIT230119
foodproof® Listeria Genus Detection LyoKit	KIT230088
foodproof® Listeria monocytogenes Detection LyoKit	KIT230092
foodproof® Listeria plus L. monocytogenes Detection LyoKit	KIT230129
foodproof® Salmonella Detection LyoKit	KIT230099
foodproof® Salmonella Enteritidis & Typhimurium Detection LyoKit	KIT230106
foodproof® Salmonella Genus plus Enteritidis & Typhimurium Detection LyoKit	KIT230134
foodproof® Staphylococcus Detection LyoKit	KIT230103
foodproof® STEC Screening LyoKit	KIT230077
foodproof® Vibrio Detection LyoKit (Real-time only)	KIT230117
foodproof® Yeast and Mold Quantification LyoKit	KIT230112

Important Note: All foodproof and microproof assays with **experimental** kit analysis files are designed to assist with result interpretation but require <u>visual verification</u> of the graphs.

Additional information for viewing data from **experimental** analysis files:

□ Analysis files are now available for all assays (i.e., BAX, foodproof, microproof). By default, all assays with experimental analysis files will have the analysis file set to "None". The user can navigate to Operation → Analysis Settings to set the analysis file (Algorithm) to "Experimental" for targets that do not have verified analysis files. This setting enables improved assistance with results interpretation.



☐ All verified assays will have only one setting, which is displayed as "Certified."

☐ If you are using 4.22 or 5.0 to run foodproof assays, your selected analysis setting will remain the same. (Refer to the <u>video tutorial</u> for instructions on registering the instrument on SureTrend)



Software Feature Updates for Release v5.1.0.28942

Instrument Lamp / Bulb:		
$\ \square$ Bulb replacement warning message is displayed once lamp hours reach 1,800 hours.		
☐ Lamp hours are included in the calibration report.		
Analysis settings from previous versions are preserved during installation.		
Target selection settings:		
☐ Target selection from previous versions is preserved during upgrades.		
☐ If a .bax file that contains results for an unselected assay is loaded, the software automatically selects the appropriate target and enables the selection in settings.		
Users can register the Q7 to the SureTrend application available on the cloud:		
☐ Ability to review data online both graphically and by result status with the SureTrend software.		
☐ To use this feature, you must register a SureTrend account https://suretrend.hygiena.com/Register		

For BAX Q7 Users with SureTrend Premium Accounts:

- Ability to view amplification curves during the run.
- Detection of empty wells, wrong target selection, and non-empty wells the software identifies common human errors, saving time and avoiding re-runs.
- Indication of Premium Account status in the 'About' box.
- Validation of Premium SureTrend package.

Additional integration with SureTrend:

- Status of connection to SureTrend displayed as 'Connected' in bottom right corner of program window.
- Display 'Registration Ready' and 'Registered' checkmarks on the status bar.
- Display registered Account ID, Site ID and Site Name for registered instruments in the About BAX[®] System window.



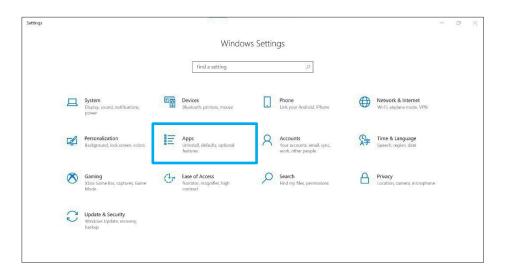
Software Upgrade Instructions:

1. Required Prerequisites:

- Regional Settings are in English.
- The Core Isolation setting should be turned off in Windows security settings.
- Check Read/Write Permissions for the following file locations for all users.
 - ☐ C:\Program Files\MATLAB
 - ☐ C:\Program Files (x86)\BAX
 - ☐ C:\ProgramData\BAX Q7 System
 - All Power and Sleep Settings are set to Never.
 - Disable this setting in the 'Local Group Policy' Editor:
 Local Computer Policy>Computer Configuration>Administrative Templates>Windows
 Components>Windows Update. Then select Enable>Apply the 'No auto-restart with logged on users for scheduled automatic updates installations'. Click OK.
- Obtain the HEX Calibration Kit (Product No.: KIT230340) from Hygiena if you plan to run foodproof/microproof assays that utilize the HEX dye (see kit instructions).
 - This additional calibration plate is a stand-alone product and is not included with other calibration kits.
 - Please visit the <u>Contact Us</u> page for ordering and technical support.

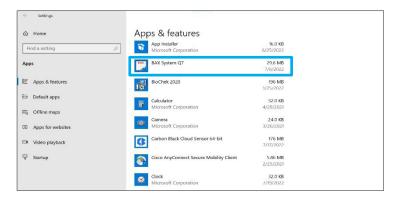
2. Calibration, Storage and Removal of Current Software:

- Back up the system's calibration file.
 - ☐ Select Operations > BAX Maintenance > Export Calibration from the menu bar.
 - ☐ Navigate to a new folder in which to store the backup file and click Save.
 - ☐ Name the calibration file (example: Q7Cal_date.bqc).
- Uninstall the previous version of the BAX Q7 application.
 - ☐ Navigate to Windows Settings and select Apps.

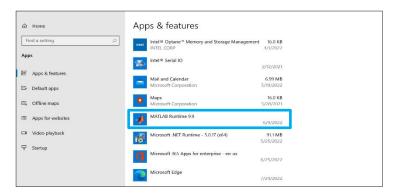




Click on BAX System Q7, select Uninstall, and agree (click Yes) on the next window to initiate removal.



If updating from 4.21, 4.22, or 5.0, then removal of MATLAB is not required. If updating from any other previous version of the BAX Q7 software, click on the MATLAB application, select Uninstall, and click Agree on the next window (this may take several minutes).



Restart the Computer BEFORE Continuing to Step 3.

- 3. Download v5.1.0.28942 software by clicking this <u>link</u> or the button from the BAX Q7 Page on <u>www.hygiena.com</u> (the Hygiena website).
 - Transfer the download to a memory/USB stick if the computer doesn't have internet access.
 - $\ \square$ Click on the Q7 5.1.0.28942 icon and the program will automatically start executing the installation.
 - A 'Windows protected' screen may pop up. Select More Info, then select Run anyway.
 - $\hfill\square$ On the next pop-up, select Yes to allow installation to begin.

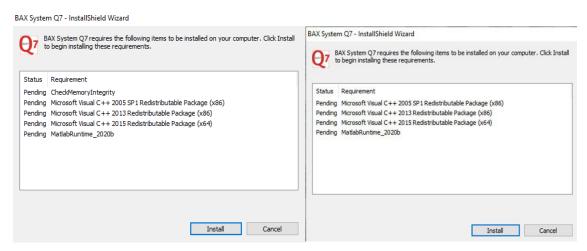






4. Some Prerequisites May Need to Be Installed First to Prepare Your Computer for the BAX Application Installation.

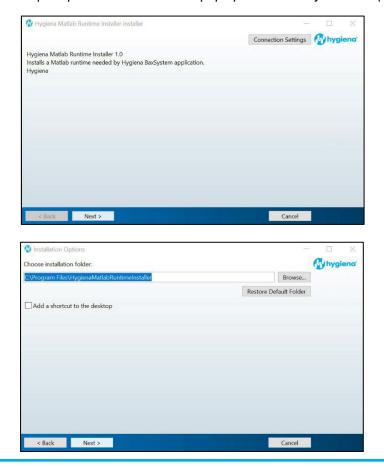
If you see these, you may have to restart multiple times to get the prerequisites installed before MATLAB Runtime can install:



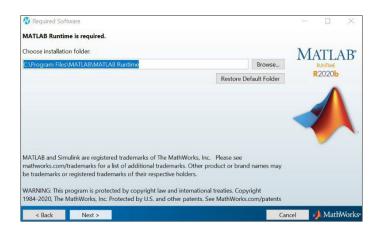
The first two prerequisites, 1. Checking memory integrity, and 2. Correct regional settings (not shown), need to be addressed, or the application will not install successfully.

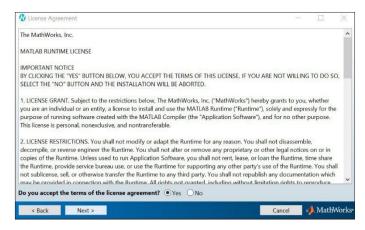
5. MATLAB Updates Will be Installed (After Prerequisites). Follow the Prompts Below and Select the Default Responses:

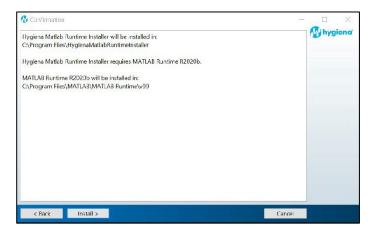
Note: a prompt to install Matlab will pop up if not already installed (such as on a new installation).





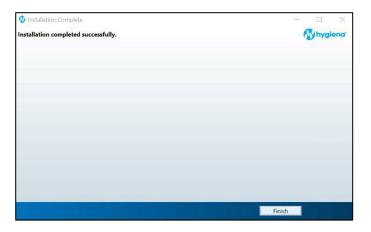




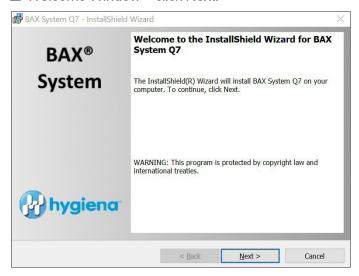




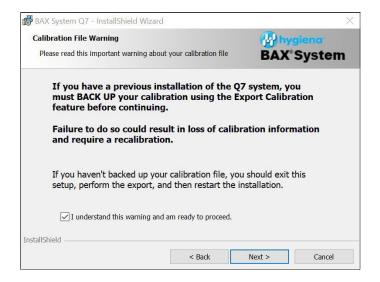




- 6. Following MATLAB Installation, the BAX Q7 Application Installation Will Be Initiated. Read the Prompts Carefully. Choose the Default Responses.
 - ☐ Welcome Window click Next.



- Calibration File Warning
 - ☐ Check the box and click Next.





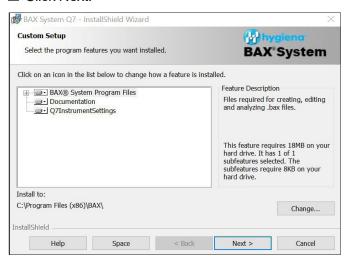
License Agreement.

☐ Check the Accept Terms box and click Next.



Custom Setup.

☐ Click Next.



Password Protection.

☐ BAX default is disabled password protection. Choose an option for your lab, then click Next.

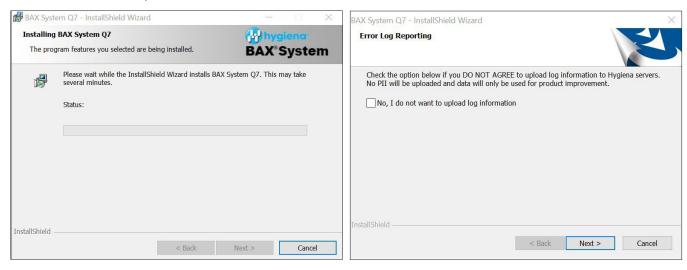




Ready to Install Program.

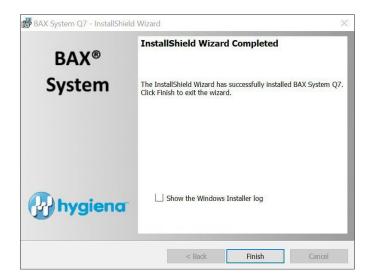
Installing BAX System Q7 Software.

- □ During installation, an Error Log Reporting window will pop up. We recommend NOT checking the box so the system can collect software and/or hardware errors in the Log Files to assist Technical Support in troubleshooting. However, please review and decide what is appropriate for your lab.
 - Note: 'Error reporting' only uploads errors and not the entire log file. Technical Support may ask you for logs even if you have error reporting enabled.
- \square Select Next to complete the installation.

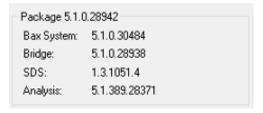




- InstallShield Wizard Complete.
 - ☐ Select Finish.



☐ Click on the desktop icon to initiate the program. The new open screen will display software version 5.1.0.28942.



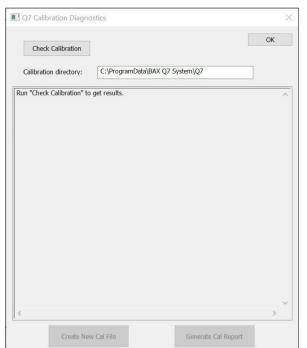
- ☐ Enter the Instrument Name and Serial Number.
 - This will appear on reports and should be utilized.

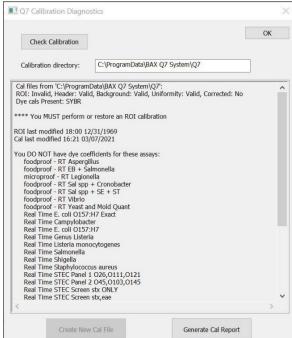




7. Check the System's Calibration

- From the menu bar, select Diagnostics > Calibration to open the Q7 Calibration Diagnostics window
 - ☐ Click the Check Calibration button to determine the status:
 - If calibration is available, no further actions are needed.
 - If calibration is NOT optimal or NOT found:
 Import the backed-up calibration file by selecting Operations > BAX Maintenance > Import Calibration from the menu bar and selecting the backed-up calibration file from step 2.
 - To utilize many foodproof assays, additional calibration using the HEX calibration kit must be performed. Please follow the onboard instructions in the BAX Software to perform calibration.







Appendix A: Algorithm Analysis Across Software Versions

The table below provides information to easily identify algorithm consistency across software versions and validations. There have been no changes to the assay-specific algorithm since the analysis version listed.

Product Number	Assay	BAX Q7 Software Version with Same Algorithm as v5.1
KIT2000	BAX System Real-Time PCR Assay for <i>E. coli</i> O157:H7	4.0
KIT2001	BAX System PCR Assay for Cronobacter (E. sakazakii)	4.0
KIT2002	BAX System PCR Assay for <i>L. monocytogenes</i> 24E	4.0
KIT2003	BAX System PCR Assay for Genus <i>Listeria</i> 24E	4.0
KIT2004	BAX System PCR Assay for <i>E. coli</i> O157:H7 MP	4.0
KIT2005	BAX System Real-Time PCR Assay for L. monocytogenes	4.0
KIT2006	BAX System Real-Time PCR Assay for Salmonella	4.0
KIT2007	BAX System Real-Time PCR Assay for Shigella	4.0
KIT2008	BAX System Real-Time PCR Assay for STEC Panel 1	4.0
KIT2009	BAX System Real-Time PCR Assay for STEC Panel 2	4.0
KIT2010	BAX System Real-Time PCR Assay for Vibrio	4.0
KIT2011	BAX System PCR Assay for Salmonella 2	4.0
KIT2016	BAX System PCR Assay for Genus Listeria	4.0
KIT2017	BAX System PCR Assay for L. monocytogenes	4.0
KIT2018	BAX System Real-Time PCR Assay for Campylobacter	4.0
KIT2019	BAX System Real-Time PCR Assay for Genus <i>Listeria</i>	4.0
KIT2020	BAX System Real-Time PCR Assay for Staphylococcus aureus	4.0
KIT2021	BAX System Real-Time PCR Assay for STEC Screening	4.0
KIT2039	BAX System Real-Time PCR Assay for <i>E. coli</i> O157:H7 Exact	4.0
KIT230131	foodproof Salmonella plus Cronobacter Detection LyoKit	5.1