

BAX[®] System Q7 Version 5.0.0.18610 Features and Instructions

BAX System Q7 software release v 5.0 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 <u>diagnostics.support@hygiena.com</u> or your local Hygiena[®] representative for Windows 10 upgrade support.

This release is NOT applicable for Windows 7 or Windows 11 systems.

Software Assay Updates for Release v5.0.0.18610

- There are no changes to the analysis for BAX assays (vs. versions 4.21 and 4.22)
- Two foodproof[®] assays now with verified result interpretation (displayed as 'Certified' within the software):

| Product Name | Product Number |
|--|----------------|
| foodproof [®] Aspergillus Detection LyoKit (Real-time only) | KIT230145 |
| foodproof [®] Salmonella plus Cronobacter Detection LyoKit | KIT230131 |

foodproof assays with verified result interpretation do not require visual verification of the graphs. However, as a best practice, Hygiena recommends customers review all results.

Seven additional foodproof assays with *experimental* analysis files for assistance with result interpretation:

| Product Name | Product Number |
|--|----------------|
| foodproof [®] <i>Listeria</i> 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 [®] Staphylococcus Detection LyoKit | KIT230103 |
| foodproof [®] STEC Screening LyoKit | KIT230077 |

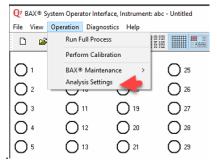
foodproof/microproof[®] assays with <u>improved</u> experimental analysis files for assistance with result interpretation:

| Product Name | Product Number |
|---|----------------|
| foodproof [®] Enterobacteriaceae plus Salmonella Detection LyoKit | KIT230137 |
| microproof [®] Legionella Quantification LyoKit | KIT230119 |
| foodproof [®] Salmonella Genus plus Enteritidis & Typhimurium Detection LyoKit | KIT230134 |
| 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 in 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 analysis files set to "None". The user can go 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 displayed as "Certified."
- □ If you are using 4.22 to run foodproof assays, your selected setting will remain the same. Only the new foodproof assays in 5.0 will need to be adjusted to your preference.

Software Feature Updates for Release v5.0.0.18610

- Users are now able to 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 <u>https://suretrend.hygiena.com/Register</u>
- Users can now export comma-delimited text files (.CSV)
- There is a one-step compressed log file export
- Software will now check that the correct calibration file is imported for the instrument in the case of equipment replacement by loaners or service units. Each Q7 has a unique calibration file and should only be used with that Q7.
 - □ Every calibration file generated with software version 4.0 and higher collects the serial number of the camera of the Q7 and the serial number of the thermal block. This information is stored in the calibration file. When a calibration file is imported, the application will compare the serial numbers in the calibration file to the serial numbers of the instrument on which you are importing. If the serial numbers don't match, the following pop-up message will appear. If this message appears, locate the correct calibration file (if it's a recent replacement unit, it can be found in the sleeve on the back of the unit or contact Hygiena to request the correct file). If the correct file cannot be located, calibrate the instrument as instructed in the BAX Q7 User Guide.

| BAX® Sy | stem | Message #19 | | |
|---------|---|------------------|-----------|-------------|
| | The Q7 instrument of the export calibration | | | sed to make |
| | Are you absolutely s | sure you want to | continue? | |
| | | | Yes | No |

If "Yes" is clicked in the pop-up message above, a secondary message will appear

| 1 | III WARN | ING !!! |
|--------------------|---------------------|---|
| | ct calibration file | ment shows indications the for this instrument. |
| If you choose to c | continue your d | lata may be affected. |

If 'Continue' is selected, the calibration will import, and no additional warnings or notifications will appear.

Software Upgrade Instructions:

- 1. Required Prerequisites:
 - Regional Settings are in English
 - Core Isolation setting should be turned off in windows security settings
 - Read/Write Permissions for the below 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.
 - Obtain 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.

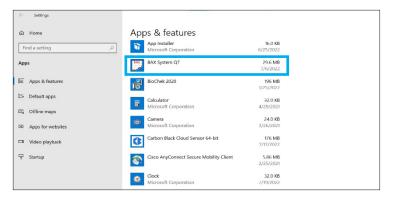
- □ Select Operations > BAX Maintenance > Export Calibration from the menu bar.
- \Box Navigate to a new folder in which to store the backup file and click Save.
- \Box Name the calibration file (example: Q7Cal_date.bqc).

Uninstall the previous version of the BAX Q7 application.

□ Navigate to Windows Settings and select Apps.

| Settings | | | | - 1 | Ċ1 | × |
|--|--|---|---|-----|----|---|
| | Window | vs Settings | | | | |
| | Find a setting | ٩ | | | | |
| System Display, sound, notification power | Bluetooth, printers, mouse | Link your Android, iPhone | Network & Internet Wi-Fi, sirplane mode, VPN | | | |
| Personalization Beckground, lock screen, co | Hors Apps Uninstall, defaults, optional features | Accounts Your accounts, email, sync, work, other people | Time & Language Speech, region, date | | | |
| Gaming Xhox Game Bar, captures, G Mode | ame Generation Access Nerrator, magnifier, high contrast | Search Find my files, permissions | Privacy Location, camera, microphone | | | |
| Update & Security Windows Update, recovery, backup | | | | | | |

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

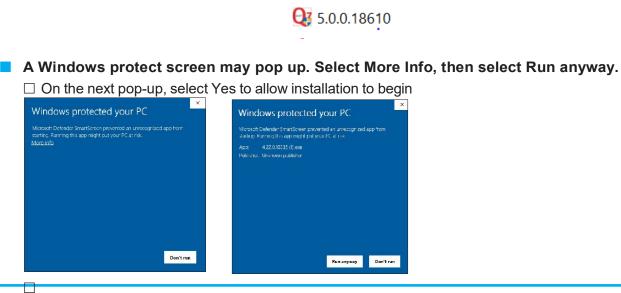


If updating from 4.21 or 4.22, removal of MATLAB is not required. If updating from any previous versions, click on the MATLAB application, select Uninstall, and click Agree on the next window (this may take several minutes).

| 6 Home | Apps & features | |
|--------------------|---|----------------------------|
| Find a setting | Intel® Optane [™] Memory and Storage Manag INTEL CORP | gement 16.0 KB 4/1/2022 |
| Apps | Intel® Serial IO | 2/12/2021 |
| t⊇ Apps & reatures | Mail and Calendar Microsoft Corporation | 6.99 MB 5/19/2022 |
| 四, Offline maps | Maps Microsoft Corporation | 16.0 KB 5/28/2021 |
| Apps for websites | MATLAB Runtime 9.9 | 6/9/2022 |
| □ Video playback | Microsoft .NET Runtime - 5.0.17 (x64) | 91.1 MB 5/25/2022 |
| ☐ Startup | Microsoft 365 Apps for enterprise - en-us | 6/25/2022 |
| | Microsoft Edge | //24/2022 |

Restart computer BEFORE continuing to step 3.

- 3. Download 5.0.0.18610 software by clicking this link or the button from the BAX Q7 Page.
 - Transfer download to a memory/USB stick if computer doesn't have internet access.
 Click on the Q7 5.0.0.18610 icon and the program will automatically start execution of install.



4. There may be some prerequisites that need to install to prepare your computer 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

BAX System Q7 - InstallShield Wizard

| BAX System Q7 requires the following items to be installed on your computer. Click Install | BAX System Q7 - InstallShield Wizard |
|---|---|
| to begin installing these requirements. | BAX System Q7 requires the following items to be installed on your computer. Click Install to begin installing these requirements. |
| Status Requirement Pending CheckMemoryIntegrity Pending Microsoft Visual C++ 2005 SP1 Redistributable Package (x86) Pending Microsoft Visual C++ 2013 Redistributable Package (x86) Pending Microsoft Visual C++ 2015 Redistributable Package (x64) Pending Microsoft Visual C++ 2015 Redistributable Package (x64) Pending MatlabRuntime_2020b | Status Requirement Pending Microsoft Visual C++ 2005 SP1 Redistributable Package (x86) Pending Microsoft Visual C++ 2013 Redistributable Package (x86) Pending Microsoft Visual C++ 2015 Redistributable Package (x64) Pending MatabRuntime_2020b |
| Install Cancel | Install Cancel |

Checking memory integrity and Correct regional settings (not shown) are the first two prerequisites that need to be addressed or the Application will not install successfully.

In case this install error occurs: VCRUNTIME140.dll was not found (shown below).

Please download and install the patch: vc_redist.x64.exe from <u>https://www.microsoft.com/en-us/download/details.aspx?id=52685.</u> The installation will end when you click OK.

| unzip.exe | e - System Error | × |
|-----------|---|-----|
| 8 | The code execution cannot proceed because VCRUNTIME140.dll was not found. Reinstalling the prog may fix this problem. | ram |
| | 0 | к |

5. MATLAB updates will be installed (after prerequisites). Follow prompts below and select the default responses:

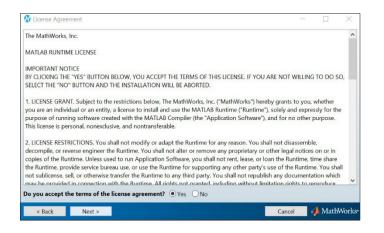
After installing this patch, MATLAB Installation is continued.

| | | | > |
|---|------------------------|-------|-----|
| | Connection Settings | hygi | en |
| Hygiena Matlab Runtime Installer 1.0 | | | |
| Installs a Matlab runtime needed by Hygiena BaxSystem application. Hygiena | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| < Back Next > | Cancel | | |
| | | | |
| | | | |
| Installation Options | | | > |
| hoose installation folder: | | hygi | ene |
| :\Program Files\HygienaMatlabRuntimeInstaller | Browse | 1 | |
| | Restore Default Folder | 1 | |
| Add a shortcut to the desktop | | | |
| | | | |
| < Back Next > | Cancel | | |
| < Back Next > | Cancel | | |
| | Cancel | | × |
| Required Software | Cancel | | × |
| Required Software ATLAB Runtime is required. | - | | |
| Required Software ATLAB Runtime is required. noose installation folder: | - | | × |
| < Back Next > Required Software IATLAB Runtime is required. noose installation folder: Afrogram Files/MATLAB/MATLAB Runtime | Browse | [ATLA | |
| Required Software ATLAB Runtime is required. noose installation folder: | M | | |
| Required Software ATLAB Runtime is required. noose installation folder: | Browse | | |

 With our distribution of the state of the international trademarks of the international trademarks or registered trademarks of their respective holders.

 WARNING: This program is protected by copyright law and international treaties. Copyright 1984-2020, The MathWorks, Inc. Protected by U.S. and other patents. See MathWorks.com/patents

 < Back</td>
 Next >



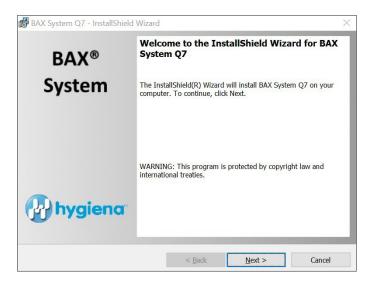
| Onfirmation - | - 🗆 X |
|--|----------|
| Hygiena Matlab Runtime Installer will be installed in: | hygiena' |
| C:\Program Files\HygienaMatlabRuntimeInstaller | |
| Hygiena Matlab Runtime Installer requires MATLAB Runtime R2020b. | |
| MATLAB Runtime R2020b will be installed in: | |
| C:\Program Files\MATLAB\MATLAB Runtime\v99 | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| < Back Install > Cancel | |



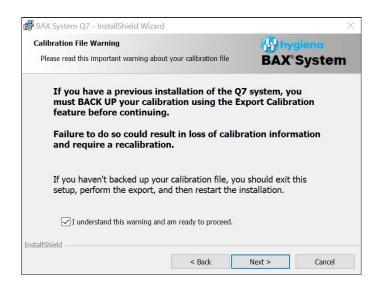
| 🚱 Installation Complete | - 🗆 X |
|--------------------------------------|--------|
| Installation completed successfully. | — 🗆 🗙 |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | Finish |

6. Following MATLAB installation, the BAX Q7 application installation will be initiated. Read the prompts carefully. Choose the default responses.

□ Welcome Window – click Next.

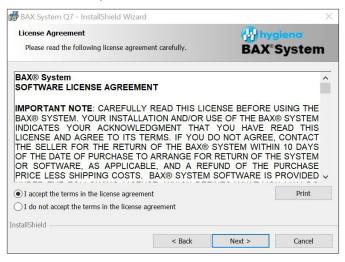


Calibration File Warning – ENSURE YOU HAVE BACKED UP THE CALIBRATION FILE.
 Check the box and click Next.



License Agreement.

□ Check Accept Terms box and click Next.



Custom Setup.

□ Click Next.

| 💕 BAX System Q7 - InstallShield Wizard | × | |
|---|--|--|
| Custom Setup | (hygiena | |
| Select the program features you want installed. | BAX [®] System | |
| Click on an icon in the list below to change how a feature is | s installed. | |
| BAX® System Program Files | Feature Description | |
| Documentation Q7InstrumentSettings | Files required for creating, editing and analyzing .bax files. | |
| | This feature requires 18MB on your hard drive. It has 1 of 1 subfeatures selected. The subfeatures sequire 8KB on your hard drive. | |
| Install to: | | |
| C:\Program Files (x86)\BAX\ | Change | |
| InstallShield | | |
| Help Space < Back | Next > Cancel | |

Password Protection.

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

| 🛃 BAX System Q7 - InstallShield Wiz | ard | | |
|--|-------------------------|--------------------|-----------------|
| BAX Security Enable Password Option | | | system |
| By default, password protection is disa application cannot be launched without during amplification/detection, which p entered. | a password. This option | automatically lock | the workstation |
| O Enable Password Protection | | | |
| Do Not Use Password Protection | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| nstallShield | | | |
| | < Back | Next > | Cancel |

Ready to Install Program.

| BAX System Q7 - InstallShield Wizard | | |) |
|--|--------|-------------------------|--------|
| Ready to Install the Program The wizard is ready to begin installation. | | BAX [®] System | |
| Click Install to begin the installation. Click Cancel to exit the wizard. | | | |
| stallShield | < Back | Install | Cancel |

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 Diagnostics Support in troubleshooting. However, please review and decide what is appropriate for your lab.
- \Box Select Next to complete the installation.

| 💕 BAX Syste | em Q7 - InstallShield Wizard | - 🗆 X | BAX System Q7 - InstallShield Wizard | × |
|-----------------|---|------------------------|---|------|
| | BAX System Q7 gram features you selected are being installed. | Hygiena BAX*System | Error Log Reporting | |
| tip- | Please wait while the InstallShield Wizard installs BAX Sy several minutes. | stem Q7. This may take | Check the option below if you DO NOT AGREE to upload log information to Hygiena serv No PII will be uploaded and data will only be used for product improvement. | ers. |
| | Status: | | No, I do not want to upload log information | |
| | | | | |
| | | | | |
| | | | | |
| InstallShield - | | | InstallShield | |
| | < Back | Next > Cancel | < Back Next > Can | cel |

InstallShield Wizard Complete.

□ Select Finish.

| 🕞 BAX System Q7 - InstallShield | Wizard × |
|---------------------------------|--|
| BAX® | InstallShield Wizard Completed |
| System | The InstallShield Wizard has successfully installed BAX System Q7. Click Finish to exit the wizard. |
| hygiena ⁻ | ☐ Show the Windows Installer log |
| | < Back: Finish Cancel |

 \Box Click on the desktop icon to initiate the program. The new open screen will have software version 5.0.0.18610.

| Package 5.0.0.18610 | | | | |
|---------------------|----------------|--|--|--|
| , donago o | .0.0.10010 | | | |
| Bax System | n: 5.0.0.18604 | | | |
| Bridge: | 5.0.0.18607 | | | |
| SDS: | 1.3.1036.1 | | | |
| Analysis: | 5.0.318.18151 | | | |
| | | | | |

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

| Instrum | ent Name | |
|---------|--|--|
| This | Please enter a unique name for this instrument. will be used to identify it in documents, printouts and files. | |
| | Instrument Name | |
| Instrum | ent Number | |
| | | |
| | e enter the instrument number from the Q7 instrument. This e used to identitfy calibration files used with this instrument. | |
| | | |

7. Check 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.

| Q7 Calibration Diagnostics | \times | Q7 Calibration Diagnostics | \times |
|--|----------|---|----------|
| Check Calibration | OK | Check Calibration | ОК |
| Calibration directory: C:\ProgramData\BAX Q7 System\Q7 | | Calibration directory: C:\ProgramData\BAX Q7 System\Q7 | |
| Run "Check Calibration" to get results. | ~ | Cal files from 'C:\ProgramData\BAX Q7 System\Q7': ROI: Invalid, Header: Valid, Background: Valid, Uniformity: Valid, Corrected: No Dye cals Present: SYBR **** You MUST perform or restore an ROI calibration ROI last modified 16:00 12/31/1969 Cal last modified 16:21 03/07/2021 You DO NOT have dye coefficients for these assays: foodproof - RT Aspergillus foodproof - RT Aspergillus foodproof - RT E4 - Salmonella microproof - RT Sal spp + 5 Cronobacter foodproof - RT Sal spp + 5 E + ST foodproof - RT Sal spp + 5 E + ST foodproof - RT Vibrio foodproof - RT Vibrio foodproof - RT Vibrio foodproof - RT Vast and Mold Quant Real Time E. coli 0157:H7 Real Time E. coli 0157:H7 Real Time E. coli 0157:H7 Real Time Salmonella Real Time Shaphylococcus aureus Real Time Staphylococcus aureus Real Time STEC Panel 1 026,011,0121 Real Time STEC Panel 2 045,0103,0145 Real Time STEC Screen stx,eae | ~ |
| Create New Cal File Generate Cal Report | | Create New Cal File Generate Cal Report | |

Appendix A: Algorithm Analysis across Software Versions

The table below provides information to identify algorithm consistency more easily 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 v5.0 |
|-------------------|---|---|
| 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 <i>L. monocytogenes</i> | 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 <i>L. monocytogenes</i> | 4.0 |
| KIT2018 | BAX System Real-Time PCR Assay for Campylobacter | 4.0 |
| KIT2019 | BAX System Real-Time PCR Assay for Genus Listeria | 4.0 |
| KIT2020 | BAX System Real-Time PCR Assay for <i>Staphylococcus aureus</i> | 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 | 5.0 |
| KIT230145 | foodproof Aspergillus Detection LyoKit (Real-time only) | 5.0 |