

### BAX<sup>®</sup> System Q7 Version 5.0.1.16813 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<sup>®</sup> representative for Windows 10 upgrade support.

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

### Software Assay Updates for Release v5.0.1.16813

- There are no changes to the analysis for BAX assays (vs. versions 4.21 and 4.22)
- Seven additional foodproof assays with *experimental* analysis files for assistance with result interpretation:

Product Name	Product Number
foodproof <sup>®</sup> <i>Listeria</i> Genus Detection LyoKit	KIT230088
foodproof <sup>®</sup> Listeria monocytogenes Detection LyoKit	KIT230092
foodproof <sup>®</sup> Listeria plus L. monocytogenes Detection LyoKit	KIT230129
foodproof <sup>®</sup> Salmonella Detection LyoKit	KIT230099
foodproof <sup>®</sup> Salmonella Enteritidis & Typhimurium Detection LyoKit	KIT230106
foodproof <sup>®</sup> Staphylococcus Detection LyoKit	KIT230103
foodproof <sup>®</sup> STEC Screening LyoKit	KIT230077

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

Product Name	Product Number
foodproof <sup>®</sup> Aspergillus Detection LyoKit (Real-time only)	KIT230145
foodproof <sup>®</sup> Enterobacteriaceae plus Salmonella Detection LyoKit	KIT230137
microproof <sup>®</sup> Legionella Quantification LyoKit	KIT230119
foodproof <sup>®</sup> Salmonella Genus plus Enteritidis & Typhimurium Detection LyoKit	KIT230134
foodproof <sup>®</sup> Salmonella plus Cronobacter Detection LyoKit	KIT230131
foodproof <sup>®</sup> Vibrio Detection LyoKit (Real-time only)	KIT230117
foodproof <sup>®</sup> 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</u> <u>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 v5.0.1.16813**

- Users are now able to register the Q7 to the SureTrend<sup>®</sup> 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 in trum make the export Are you absolut	ent detected is diff t calibration file on ely sure you want f	erent than the o December 17, 2 to continue?	one used to 1018.
			Yes	No

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

III WAR	NING !!!
The Calibration file for this inst it is not the correct calibration	rument shows indications that file for this instrument.
for a strange to continue or any	data 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.
      - Notify before restarting after a Windows upgrade is enabled
  - 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.

- $\Box$  Select Operations > BAX Maintenance > Export Calibration from the menu bar.
- $\hfill\square$  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								-	đ	×
			Window	ws Settir	gs					
			Find a setting		<i>Q</i>					
旦	System Display, sound, notifications, power		Devices Bluetooth, printers, mouse		Phone Link your Android, iPhone		Network & Internet Wi-Fi, sirplane mode, VPN			
Ę.	Personalization Background, lock screen, colors		Apps Uninstall, defaults, optional features	8	Accounts Your accounts, email, sync, work, other people	CA字	Time & Language Speech, region, date			
8	<b>Gaming</b> Xbox Game Bar, captures, Game Mode	G	Ease of Access Narrator, magnifier, high contrast	Q	Search Find my files, permissions	A	Privacy Location, camera, microphone			
C	Update & Security Windows Update, recovery, backup									

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



I 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).



**Restart the computer BEFORE continuing to step 3.** 

- 3. Download 5.0.1.16813 software by clicking this link or the button from the BAX Q7 Page.
  - Transfer the download to a memory/USB stick if the computer doesn't have internet access.
    Click on the Q7 5.0.1.16813 icon and the program will automatically start execution of installation.

A Windows protect screen may pop up. Select More Info, then select Run anyway.

□ On the next pop-up, select Yes to allow installation to begin

Windows protected your PC	Windows protected your PC
Monsott Debnder SmartSereen prevented an unecooprized apo from partire, Burning this app might put your PC at risk. <u>More info</u>	Morosoft Defender SmartSover, prevented an unecogn zed app from Idualing: Kunning Deviajn might prolytou. IC at like App: 422,01035 (Devia Potoning: Unecover publisher
Don'trun	Ren anyway Dan't run

## 4. There may be some prerequisites that 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

BAX System Q7 - InstallShield Wizard

BAX System Q7 requires the following items to be installed on your computer. Click Install to begin installing these requirements.	BAX System Q7 - InstallShield Wizard Q7 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  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.



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

After installing this patch, MATLAB Installation is continued.

🔮 Hygiena Matlab Runtime Installer Installer	-	
	Connection Settings	() hygiena
Hygiena Matlab Runtime Installer 1.0		
Installs a Matlab runtime needed by Hygiena BaxSystem application. Hygiena		
the second se		

oose installation folder:		hygiene
\Program Files\HygienaMatlabRuntimeInstaller	Brows	e
	Restore Default Fold	ler
Add a shortcut to the desktop		









- 🗆 🗙
🚱 hygiena'
Finish

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

 $\Box$  Welcome Window – click Next.



■ Calibration File Warning – ENSURE YOU HAVE BACKED UP THE CALIBRATION FILE.



#### License Agreement.

□ Check Accept Terms box and click Next.



#### Custom Setup.

□ Click Next.

🕼 BAX System Q7 - InstallShield Wizard	X
Custom Setup	whygiena'
Select the program features you want installed.	<b>BAX</b> <sup>®</sup> System
Click on an icon in the list below to change how a feature is installed.	
Fe	ature Description
Occumentation  InstrumentSettings	les required for creating, editing nd analyzing .bax files.
Ti hr su su hr	his feature requires 18MB on your ard drive. It has 1 of 1 lbfeatures selected. The lbfeatures require 8KB on your ard drive.
Install to:	
C:\Program Files (x86)\BAX\	Change
InstallShield	

### Password Protection.

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

🛃 BAX System Q7 - InstallShield Wa	tard		3
BAX Security Enable Password Option		BAX	giena System
By default, password protection is disa application cannot be launched withou during amplification/detection, which p entered.	bled. If you enable pass t a password. This optio prevents interaction with t	word protection, the n automatically lock the system unless th	BAX(8) System s the workstation e password is
O Enable Password Protection			
Do Not Use Password Protection			
nstallShield			
	< Back	Next >	Cancel

### Ready to Install Program.

BAX System Q7 - InstallShield Wizard			1
teady to Install the Program The wizard is ready to begin installation.		BA	hygiena <sup>.</sup> X°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
Installing The prog	BAX System Q7 gram features you selected are being installed.	BAX <sup>®</sup> System	Error Log Reporting
12	Please wait while the InstallShield Wizard installs BAX $S_{N}$ several minutes.	ystem Q7. This may take	Check the option below if you DO NOT AGREE to upload log information to Hygiena servers. No PII will be uploaded and data will only be used for product improvement.
	Status:		No, I do not want to upload log information
InstallShield -			InstallShield
	< Back	Next > Cancel	< Back Next > Cancel

### InstallShield Wizard Complete.

□ Select Finish.

🔀 BAX System Q7 - InstallShield	Wizard X
BAX®	InstallShield Wizard Completed
System	The InstallShield Wizard has successfully installed BAX System Q7. Click Finish to exit the wizard.
hygiena <sup>*</sup>	☐ Show the Windows Installer log
	< Back Finish Cancel

□ Click on the desktop icon to initiate the program. The new open screen will display software version 5.0.1.16813.

Package 5	.0.1.16813	
Bax System	n: 5.0.0.24047	
Bridge:	5.0.0.18607	
SDS:	1.3.1036.1	
Analysis:	5.0.318.18151	

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

Instrum	nent Name		
This	Please enter a unique n s will be used to identify it i	ame for this instrur n documents, printe	ment. outs and files.
	Instrument Name		
Instrum	nent Number		
Instrum Pleas will b	nent Number e enter the instrument num be used to identitfy calibration	ber from the Q7 ins on files used with th	strument. This his instrument.
Instrum Pleas will t	nent Number e enter the instrument num ne used to identitfy calibration Number	ber from the Q7 ins on files used with th	strument. This nis instrument.
Instrum Pleas will t	eent Number e enter the instrument num ee used to identitfy calibratio Number	ber from the Q7 ins on files used with th	strument. Th nis 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	×
Check Calibration	ОК	Check Calibration	OK
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 18:00 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 EJ Esalmonella microproof - RT EJ Esalmonella foodproof - RT Sal spp + 5E + ST foodproof - RT Sal spp + SE + ST foodproof - RT Vibrio foodproof - RT Sal spp + SE + ST foodproof - RT Sal spp + SE + ST Real Time SIE Call 1057:H7 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. The assay-specific algorithm has not changed 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 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 <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 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	5.0
KIT230145	foodproof Aspergillus Detection LyoKit (Real-time only)	5.0