

DESCRIPTION

The P4300 Thermo Scientific Evolution Spectrophotometer is a device used to measure the optical absorbance or transmission of samples in the spectrums of visible or ultraviolet light (UV/VIS). Within the DoseControl dosimetry system, the instrument integrates with the DoseControl software that controls the instrument parameters and user workflow for the dosimetry for radiation processing applications.

The Thermo Evolution spectrophotometer is available in two models:

- Thermo Evolution OnePlus: Available beginning Nov 1, 2021, the Evo OnePlus model is functionally the same as the Evolution 220, with some improvements to align with current USP and EP requirements. The Evo OnePlus comes with a newly designed outer shell and the new Thermo Insight Pro software. The Thermo Insight Pro software with an improved user interface that is intuitive and easy to use.
- Thermo Evolution 220: Sold prior to Nov 1, 2021 the Evo 220 model included Thermo INSIGHT 2 software but now may use either that software or the user may purchase the new Thermo Insight Pro software.

APPLICATION

The Evolution spectrophotometer is part of the GEX DoseControl-Evolution Dosimetry System. The Evolution is used for the measurement of optical absorbance of dosimeters using a single wavelength in the UV/VIS spectrum.

Specialized hardware designed for dosimetry (sold separately from GEX) is installed inside the sample compartment of the Evolution ensures easy, accurate and repeatable measurements. GEX offers specialized dosimeter holders for GEX B3 radiochromic film dosimeters, FWT-60 radiochromic film dosimeters, Fuji CTA film dosimeters, and Harwell 4034 Red and 3042 Amber Perspex dosimeters. Other specialized hardware that can be installed inside the sample compartment of the Evolution include a barcode scanner for scanning B3 dosimeter IDs, or a laser micrometer for measuring the thickness of perspex dosimeters. The Evolution can also be used for measurement of any dosimeter that is analyzed in the UV/VIS spectrums if appropriate dosimeter holders are designed and implemented, such as various GAFCHROMIC® films.

PRODUCT PHOTO





ACCESSORIES

GEX Part No.	Description	Purpose	
<u>P4220</u>	Thermo Spectronic Standards Set	Photometric and wavelength accuracy verification	
<u>P4310</u>	Thermo Mercury Lamp Accessory	Wavelength accuracy verification and calibration	
<u>P4330</u>	Evo Dosimeter Holder Baseplate	The GEX baseplate for dosimeter holders and accessories	
<u>P4332</u>	Evo DoseStix Dosimeter Holder	Dosimeter positioning for GEX DoseStix style dosimeters	
<u>P4334</u>	Evo WINdose Dosimeter Holder	Dosimeter positioning for 1cm ² radiochromic film dosimeters	
<u>P4336</u>	Evo PMMA Dosimeter Holder	Dosimeter positioning for Red and Amber Perspex PMMA dosimeters	

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<u>P4350</u>	Laser Micrometer	Integrate thickness measurement of PMMA dosimeter inside the sample compartment
<u>P4360</u>	MS-2 Barcode Scanner	Integrated barcode reading inside the sample compartment (discontinued)
<u>P4355</u>	Custom Gage blocks	Calibrating the P4350 Laser Micrometer
<u>P4380</u>	Matrix 120 Barcode Scanner	Integrated barcode reading inside the sample compartment

SPECIFICATIONS

Evolution One Plus Specifications:

Product Dimensions		Packaging Dimensions		Product Weight	
59.3 cm (L) x 47.5cm (W) x 26.6 cm (H)			80 cm x 60 cm x 42 cm		
Manufacturer	Thermo Scientific				
Product Model Name	Evolution™ One Plus				
Material	Molded plas	Molded plastic			
Color	Grey or Whi	Grey or White			
Printing	Thermo Scie	entific logo and	product name printed on front		
Electrical Supply	100–240 VA	.C ±10%, 50–60	Hz, selected automatically; 150 W maximum		
Optical Design		Double-beam with sample and reference cuvette positions; Application Focused Beam Geometry (AFBG); Czerny-Turner Monochromator			
Spectral Bandwidth(s)	Variable: 1.0	nm; 2.0 nm; 2	2nm – "Micro"; 7nm – "Fiber"; 15nm – "Materials"	v	
Light Source	Xenon flash	Xenon flash lamp; 3-year source replacement warranty (Typical lifetime >5 years)			
Wavelength	Range:	Range: 190 –1100 nm			
	Accuracy:	Accuracy: ±0.8 nm (full range 190 to 1100 nm)			
		±0.5 nm (541.9, 546.1 nm mercury lines)			
	Repeatabilit	y: ≤0.0	5 nm (546.1 nm mercury line, SD of 10 measurem	ents)	
Photometric	Range:		>3.5 A		
	Display Rang	ge:	-0.3 to 4.0 A		
	Accuracy – I	nstrument:	1A: ±0.004 A		
			2A: ±0.008 A		
			Measured at 440nm using neutral density f	filters traceable to NIST	
	Repeatabilit	y:	1A: ±0.0002 A		
	Noise:		0A: ≤0.00015 A		
			1A: ≤0.00025 A		
			2A: ≤0.00050 A		
			260 nm, 1.0 nm SBW, RMS		
	Drift (Stabili	ty):	<0.0005 A/hour		
			500 nm, 1.0 nm SBW, 1 hour warm up		
Pharmacopoeia	Photometric Accuracy (60mg/L K2Cr2O7): ±0.010A				
Compliance Testing*	Stray Light: ≤1%T at 198 nm: KCl; ≤0.05%AT at 220 nm: Nal, Kl				
	Wavelength Accuracy: ±.5 nm 541.9, 546.1nm Hg emission lines, ±0.8 nm full range Wavelength Repeatability: ≤0.05 nm, repetitive scanning of 546.1 nm Hg emission line				
Baseline Flatness	±0.001 A, 200–800 nm, 1.0 nm SBW, smoothed				
Software	Thermo Insight Pro software only				

^{*}The Evolution One Plus model spectrophotometer meets all current USP and EP requirements. See the *Pharmacopeia Compliance Specifications* section of this document and published Thermo Evolution One/One Plus product information for complete details.

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Evolution 220 Product Specifications:

Product Dimensions		Packaging Dimensions Product Weight			
62.2 cm (L) x 48.6 cm (W) x 27.9 cm (H)		80.0	cm x 59.7 cm x 41.9 cm / 31.5" x 23.5" x 16.5"	20.0 kg / 44 lbs.	
Manufacturer	Thermo Scientific				
Product Model Name	Evolution™ 22	Evolution™ 220			
Material	Molded plastic	;			
Color	Grey or White	Grey or White			
Printing	Thermo Scient	ific logo plate	e on front		
Electrical Supply	100–240 V, 50	–60 Hz, selec	ted automatically; 150 W maximum		
Optical Design	Double-beam	with sample a	and reference cuvette positions; Czerny-Turner Mono	ochromator	
Spectral Bandwidth(s)	Variable: 1 nm	; 2 nm; 2nm	- "Micro"; 7nm – "Fiber"; 15nm – "Materials"		
Light Source	Xenon flash la	Xenon flash lamp; 3-year source replacement warranty (Typical lifetime >5 years)			
Wavelength	Range:	190 -	190 –1100 nm		
	Accuracy:	±0.8	nm (full range 190 to 1100 nm)		
		±0.5	nm (541.9, 546.1 nm mercury lines)		
	Repeatability:	≤0.1	nm (546.1 nm mercury line, SD of 10 measurements)		
Photometric	Range:		>3.5 A		
	Display Range		-0.3 to 4.0 A		
	Accuracy – Ins	trument:	0.5 A: ±0.004 A		
			1A: ±0.006 A		
			2A: ±0.010 A		
	Repeatability:		1A: ±0.0002 A		
	Noise:		0A: ≤0.00015 A		
			1A: ≤0.00050 A		
			2A: ≤0.00080 A		
			260 nm, 1.0 nm SBW, RMS		
	Drift (Stability):	<0.0005 A/hr		
			500 nm, 1.0 nm SBW, 1 hour on prior		
Baseline Flatness	±0.0010 A 20	0–800 nm, 1.	0 nm SBW, smoothing		
Software	Thermo INSIG	Thermo INSIGHT 2 or Insight Pro			

Note - For a complete list of specifications see the published specification information from Thermo Scientific. https://www.thermofisher.com/order/catalog/product/840-341400?icid=MSD_SPEC_MP_evolution-uv-vis-spectrophtometers_0921_

OTHER INFORMATION

Included Components:

- Thermo aluminum baseplate with cuvette holder
- USB thumb drive with INSIGHT 2/ Insight Pro software and driver
- Power cord
- USB interface cord

Packaging:

Unit is shipped in a cardboard box with a form-fitting protective foam clamshell.

Storage:

Store the unit in a cool and dry location. See *Operating Environment*.

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Operating Environment:

Temperature Range*	5°C to 35°C noncondensing (41°F to 95°F)
Relative Humidity	<20% to 80% noncondensing
Altitude	Up to 2,000m

^{*}Operating the instrument outside of this temperature range may cause permanent damage. Instrument performance should be verified when operating outside of these ranges.

Additional operating environment requirements:

- If the Evolution is moved or relocated, always protect the instrument from extreme changes in temperature and humidity. These changes may cause moisture condensation, which can permanently affect the optical components.
- The instrument should be positioned on a surface that is level and free of vibration. Excessive vibration may compromise spectral quality and measurements.
- The instrument is sensitive to excessive movement or bumping. Excessive bumps or movement may compromise spectral quality and measurements. See Care & Maintenance for more information.
- Intense magnetic fields can affect system performance. Minimize or eliminate exposure to magnetic fields.
- Consider all GLP's (Good Laboratory Practices) concerning cleanliness of the area. Install the spectrophotometer is a location that will not be exposed to excessive dust or airborne particulate matter that can damage the system.
- Ensure the power supply to the instrument meets the requirements. See *Power*.

Power:

Use conditioned power whenever possible by connecting via a surge suppression and/or battery backup intermediary.

- Line disturbances: Must not exceed 10% of input voltage (even for a half cycle).
- Noise: less then 2 V (common mode); less than 20 V (normal mode)
- Branch circuit protection: 15 A, 10,000 AIC circuit breaker
- Installation (overvoltage): Category II

CARE & MAINTENANCE

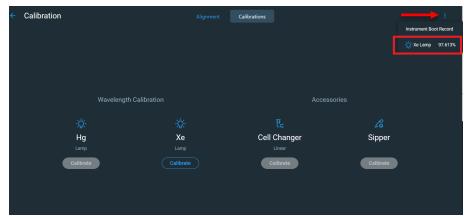
Lamp Life Status:

Users must monitor the lamp life status in the Thermo Insight software. The Xenon Flash Lamp has a 3-year source replacement warranty, and the typical lifetime >5 years.

How to view the Lamp Life status in the software:

Insight Pro software:

On the home screen, select the "Calibration" button on the bottom of the screen. In the Calibration screen, click the ellipses icon to display the remaining life of the Xenon Lamp.

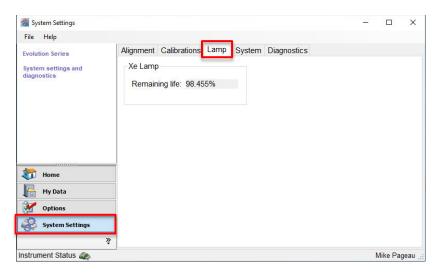


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INSIGHT 2 software:

Select the "System Settings" button in the lower-left of the home screen. Select the "Lamp" tab to view the remaining life of the Xenon lamp.



Lamp Replacement:

The lamp must be replaced by an authorized Thermo Service Technician at the customer site, or the user may send the instrument back to Thermo for lamp replacement using their Depot Services. To minimize risks related to shipping instruments, lamp replacement on-site is recommended whenever possible. Contact GEX Customer Service or Thermo for more information.

Manufacturer Service:

If the device requires service for any reason, there are two options:

1. Depot Service:

For customers in the USA and Canada, the instrument needs to be sent to Thermo Scientific in Madison, WI, U.S.A. for repair or other services. Contact GEX Customer Service at cs@gexcorp.com or your local Thermo Scientific representative for details.

2. On-site Service:

On-site service is available in many countries. Contact GEX Customer Service at cs@gexcorp.com or your local Thermo Scientific representative for details.

Cleaning:

The Evolution's exterior and the sample compartment and the dosimeter holder system should be periodically cleaned as part of a Preventative Maintenance program. An instrument that is maintained and cared for will perform better and have a longer life. Wipe off spilled chemicals immediately.

To clean the instrument exterior and the sample compartment:

- Use a lint-free cloth dampened with a weak solution of detergent and water to wipe the surface as necessary.
- Repeat using a cloth dampened with plain water.
- Dry the surface with another cloth.

Complete cleaning instructions which include the proper materials can be found in the Thermo Scientific Evolution User Guide(s). Instructions for cleaning the dosimeter holder system, see *GEX Doc #100-159*, Evolution Dosimeter Holder System.

Physical Movement, Bumps or Other Incidents that may Impact the Evolution

The instrument is sensitive to movement, vibrations, and bumps, and this may affect the instrument's performance. In these events, the user should perform a Xenon lamp or Mercury Lamp calibration in the Thermo INSIGHT 2 / Insight Pro software, followed by a complete performance verification test. See the Calibration section of this document for details and instructions.

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INSTALLATION

Step 1: Before installation

- A. Always keep shipping cartons upright. Damages due to improper moving techniques are not covered by the warranty.
- B. Move the shipping box with the Evolution to the installation location at least 24 hours before installation.

<u>CAUTION!</u> Whenever the spectrophotometer has been stored or shipped, immediate exposure to room air can cause condensation damage. <u>Move the shipping cartons to the installation location at least 24 hours before installation.</u> This allows the instrument to equilibrate at room temperature before the shipping cartons are opened and protective packaging is removed.

C. Verify that the Evolution spectrophotometer appears to be in good condition when the unit is removed from the shipping box, and no visible damage is apparent. Contact GEX support or your local supplier if the unit has been damaged during shipping.

Step 2: Install Evolution Spectrophotometer

- A. Locate the Thermo Evolution Site and Safety Information document.
 - a. Position the spectrophotometer in a suitable environment, in accordance with the environmental requirements that are listed in the Site and Safety Information manual and the *Operating Environment* conditions listed above in the Product Specifications section.
- **B.** Connect the power cord. Ensure the power connection meets the requirements listed in the Specifications section above. Use conditioned power whenever possible by connecting via a surge suppression and/or battery backup intermediary.
 - a. Do not power on the spectrophotometer until after Step 4.
- **C.** Connect the Evolution to the computer using the supplied USB cable. Insert the cable into the port on the back panel of the Evo, and connect the other end to a USB port on the computer.



Figure 1: Connect supplied USB cable to the back panel of the Evolution.

Step 3: Install Dosimetry Hardware

- **A.** Locate the specialized dosimetry hardware (purchased separately from GEX) and install inside the Evolution sample compartment. Specialized hardware includes the GEX dosimeter holder baseplate, dosimeter holders, internal barcode reader (optional), and laser micrometer (optional).
- **B.** Follow the instructions provided in the product sheet to install:

Evolution Baseplate and Dosimeter Holder System	GEX Doc #100-159
Matrix 120 Barcode Scanner	GEX Doc #100-132
Laser Micrometer	GEX Doc #100-164

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Step 4: Install Thermo Insight Pro Software (or Thermo INSIGHT 2 software)

IMPORTANT: You must install Thermo *INSIGHT 2 / Insight Pro* driver on the computer to allow GEX DoseControl to connect to the Evolution instrument. In addition, all instrument calibration and complete performance verification testing is done in Thermo Insight software.

- A. Install the Thermo Insight Pro software and driver (or Thermo INSIGHT 2 software and driver). The Evolution spectrophotometer is a computer-controlled instrument and requires Thermo Insight software and driver to be installed on the PC.
 - a. Insert the Thermo Evolution Insight Software installation USB drive into a USB port on the PC computer.
 - To install Thermo Insight Pro, go to Insight Pro 1.1.0.7\Insight Pro\ThermoScientific\InstallPC
 and double-click the setup.exe file to run the installer. Follow the prompts to install the
 application and the USB driver.
 - To install Thermo INSIGHT, go to INSIGHT 2 v2.5 Base\INSIGHT BASE
 2.5\ThermoScientific\InstallPC and double-click the setup.exe file to run the installer. Follow the prompts to install the application and the USB driver.
- **B.** <u>IMPORTANT!</u> Next, disable 'Insight Launcher' under Startup Apps. This will prevents the software from running automatically in the background when the PC is booted which blocks the USB port used by the GEX DoseControl software.

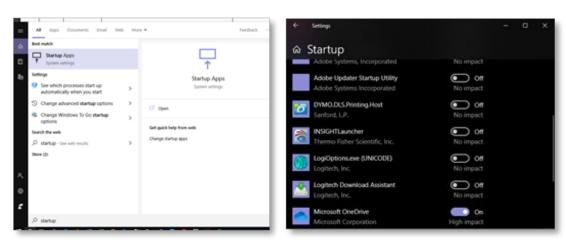


Figure 2: Go to Startup Apps; disable 'Insight Launcher' under Startup Apps.

Step 5: Power on the Evolution spectrophotometer

- **A.** Before powering on the Evolution, remove any dosimeter holders from the baseplate in the sample compartment. Close the lid of the Evo. See *Usage: Startup Procedure* section of this document for more information.
- B. Turn on the spectrophotometer using the main power switch on the back panel of the instrument.



Figure 3: Main power switch on the back panel of the Evolution.

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C. Evolution 220 model only: If the main power switch is already on, press the Power button on the keypad on the front panel. Hold the Power button down for 5 seconds to turn on/off.



Figure 4: Power on/off button on front panel of Evolution 220.

Solid blue indicator light means the Evolution has completed initialization and ready for use.

D. Wait for the Evo to initialize. This will take several minutes. The power indicator on the front panel keypad stops blinking and will remain a steady blue light when the initialization process is complete. See *Figure 4*.

NOTE: If the instrument fails to initialize properly, the power indicator light will blink rapidly. Contact GEX support.

Step 6: Connect Evolution to the computer

- **A.** Turn on the connected computer.
- **B.** Double-click the INSIGHT 2 / Insight Pro desktop icon to start the software.
- C. The Evolution spectrophotometer is successfully connected to the computer if a green check ✓ is visible for instrument status. If a red X is shown for the instrument status, check that the Evolution USB cable is connected to the computer port (see Step 2).



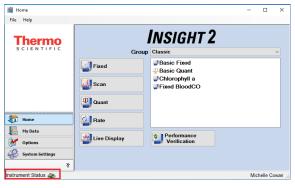


Figure 5 (above): Insight Pro software displays the Evo status in the upper right corner of the screen. Green checkmark indicates the Evo is connected and ready.

Figure 6 (above): INSIGHT 2 software displays the Evo status in the lower left corner of the screen. Green checkmark indicates the Evo is connected and ready.

Step 7: Computer Port Number and Baud Rate Settings for Evolution

Before using the Evolution as part of the GEX DoseControl dosimetry system, you will need to make a note of the Evo's computer Port Number and ensure the Port Settings are set to the 115200 baud rate. Follow this procedure to change the port setting properties on the computer:

- **A.** Open the computer's Control Panel -> Device Manager on the PC.
- B. Go to Ports (COM & LPT), and expand Ports to display connected devices, and find "Evolution Series".
- **C.** Right-click on "Evolution Series" and select "Properties".
- D. Click the "Port Settings" tab on the Properties window. Change the Bits per second to "115200".
- E. Click OK to save the setting.

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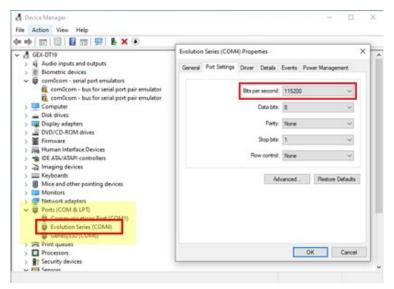


Figure 8: Make a note of the COM port of the Evolution; if needed, change the Evo's COM Port Settings to 115200 baud rate (bits per second).

Step 8: Perform Xenon Lamp or Mercury Lamp Calibration

Due to the bumping and normal handling that occurs during shipment of the instrument from the factory to the user, GEX recommends all users perform a calibration of the Evolution after installation the instrument. Do this calibration prior to any performance verification testing, qualification activities or usage. There are two options for the calibration of the Evolution spectrophotometer, which are easily performed in the Thermo INSIGHT 2 / Insight Pro software and take 10-15 minutes to perform. See the Calibration section of this document for details and instructions.

QUALIFICATION

See <u>GEX Doc# 100-267</u> - Implementation Guide for DoseControl Dosimetry System for detailed information on IQ, OQ, and PQ for the Evolution spectrophotometer as part of a complete dosimetry system.

For a IQOQ protocol for the GEX DoseControl Dosimetry System, see GEX Doc# 100-280 IQ/OQ Protocol for the DoseControl Dosimetry System

<u>NOTE</u>: GEX on-site installation, IQ/OQ service, and hands-on training on the Thermo Evolution-DoseControl dosimetry system are also available. For more information on qualification services, please email a request to support@gexcorp.com or visit the company website to submit a request online at http://www.gexcorp.com/support.html.

CALIBRATION

Calibration:

A Calibration Certificate for the Evolution spectrophotometer is <u>not</u> provided by Thermo Fisher Scientific. The Evolution is tested at the factory but ultimately is the user's responsibility to verify the instrument performance after installation at the user's site.

- Xenon Lamp Calibration: This instrument wavelength calibration is performed in Thermo Insight software using Evolution's internal Xenon lamp. The Xenon Lamp is not a recognized primary standard by these organizations, but by the same principles the xenon lamp can also be used to for calibration and performance verification of the Evolution spectrophotometer. The Xenon lamp has strong, fundamental lines throughout the UV-Vis range. These are an intrinsic property of the lamp and can serve as a fundamental wavelength standard that does not require calibration.
 - To calibrate the Evolution using its internal xenon lamp, follow the instructions in the Xenon Lamp Calibration and Performance Verification section of this document.
 - o The process takes about 10 minutes.

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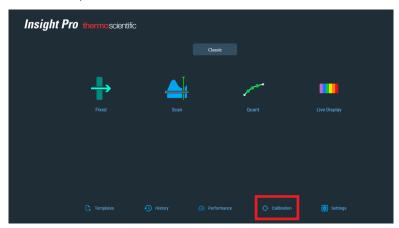


- Mercury Lamp Calibration (optional Thermo Mercury Lamp Accessory, GEX Product #P4310): The Mercury Lamp Accessory is recognized by the USP, EP and ASTM as a primary standard for the verification of wavelength accuracy of a UV-Visual Spectrophotometer instrument and can be used for calibration and performance verification of the Evolution spectrophotometer. The emission spectrum of a mercury lamp has a number of intense lines covering the UV and visible range. The frequencies of these lines are inherent, fundamental physical properties of mercury and do not change. Therefore, mercury lamps are primary standards and do not require recalibration, making them a dependable, economical solution for ensuring the performance of the Thermo Scientific UV-Visible spectrophotometer.
 - To calibrate the Evolution using the Mercury Lamp, follow the instructions provided in <u>GEX Doc# 100-257</u>, Thermo Scientific Mercury Lamp Accessory Product Specifications and Usage.
 - o The process takes about 15 minutes and is done in the Thermo INSIGHT 2 / Insight Pro software.

Based on guidance available in ASTM Standard E275 regarding Performance Verification of UV-Vis spectrophotometers, the calibration and performance verification wavelengths are obtained from the mercury or xenon emission spectrum. USP 857 explains that the accuracy of the atomic lines at a specific wavelength are characteristic of the source element (in this case, Mercury Lamp or Xenon Lamp), meaning that the emission lines are a physical standard and, therefore is a primary standard that does not require calibration.

Xenon Lamp Calibration Procedure – Thermo Insight Pro software:

- Step 1: Remove any dosimeter holders from the Evolution sample compartment. The baseplate can remain in place.
- **Step 2:** Disconnect the Matrix 120 scanner from the computer. Close the front panel and lid of the Evolution during the entire calibration process.
- Step 3: On the Insight Pro home screen, click the "Calibration" button on the lower section of the screen:



Step 4: On the Calibration screen, click the Xe Lamp "Calibrate" button:



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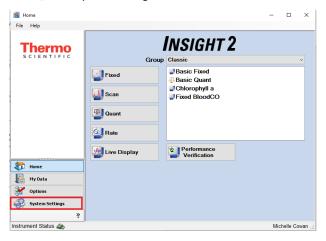


Step 5: The Xenon lamp calibration will begin. A status bar will appear on the screen. <u>NOTE</u>: No message will appear after the calibration completes.

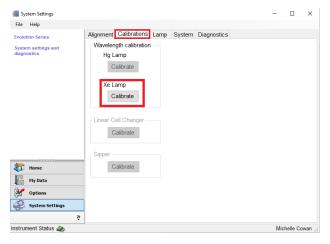


Xenon Lamp Calibration Procedure – in Thermo INSIGHT 2 software:

- Step 1: Remove any dosimeter holders from the Evolution sample compartment. The baseplate can remain in place.
- **Step 2:** Disconnect the Matrix 120 scanner from the computer. Close the front panel and lid of the Evolution during the entire calibration process.
- **Step 3:** On the *INSIGHT 2* home screen, click "System Settings" button in the lower left corner.



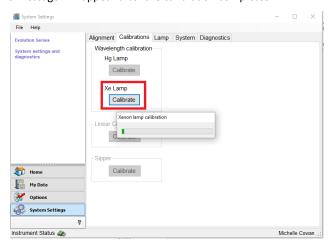
Step 4: Click the Calibrations tab on the top of the screen.



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Step 5: Click the Xe Lamp "Calibrate" button to begin the calibration. This process takes about 10 minutes. The status bar will appear on the screen. <u>NOTE</u>: No message will appear after the calibration completes.



PERFORMANCE VERIFICATION

IMPORTANT: See GEX Doc# 100-271 – Evolution Performance Verification Procedure. This procedure provides detailed instructions for how to perform the GEX recommended complete performance verification of the Evolution spectrophotometer. This procedure uses the Thermo Spectronic Standards Set 2 with an option to use the Thermo Mercury Lamp Accessory for wavelength accuracy testing.

The term 'Performance Verification' replaces the older term 'Calibration Verification' but the purpose of Performance Verification (P.V) is to determine if the instrument is performing within the manufacturer specifications for both wavelength and photometric accuracy. The user may conduct Performance Verification of the Evolution spectrophotometer using a variety of available options, including:

- Performance Verification of photometric and wavelength accuracy using the Thermo Spectronic Standards Set 2
 - Uses Thermo Spectronic Standards Kit 2 (GEX Part# P4220).
 - For instructions about how to perform a Performance Verification using the Spectronic Standards Kit, see GEX Doc #100-271, Evolution Performance Verification Procedure.
- Performance Verification of wavelength accuracy using the Thermo Mercury Lamp Accessory
 - Uses the Mercury Lamp Accessory, GEX Product #4310.
 - For instructions about how to perform a Mercury Lamp Performance Verification, see GEX Doc #100-157,
 P4310 Mercury Lamp Accessory.
- Performance Verification of wavelength accuracy using the Evolution's Xenon Lamp.
 - o To use the Xenon lamp in Performance Verification of the Evo, follow the procedure in this section (below).
 - For general information about the use of the Evolution's internal Xenon lamp in Calibration and Performance Verification - see the Calibration section of this document.
- The user may determine a Performance Verification process that complies with GLP or equivalent using standards and methods not dictated by Thermo Scientific or GEX.

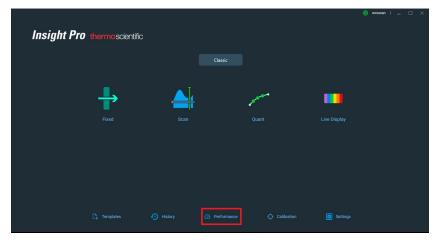
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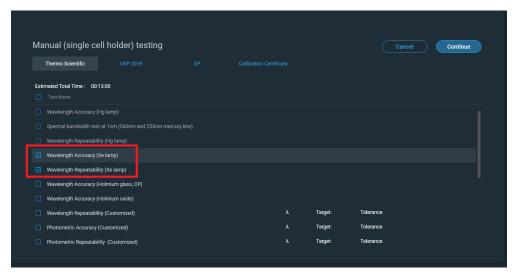
Procedure for Performance Verification Using the Xenon Lamp in Thermo Insight Pro software:

Performance Verification of the Evolution's Wavelength Accuracy and Repeatability may be performed using the internal Xenon lamp in the Evolution.

- Step 1: Remove any dosimeter holders from the Evolution sample compartment. The baseplate can remain in place.
- **Step 2:** Disconnect the Matrix 120 scanner from the computer. Close the front panel and lid of the Evolution during the entire performance verification process.
- Step 3: On the Insight Pro home screen, click the "Performance" button on the lower part of the screen.



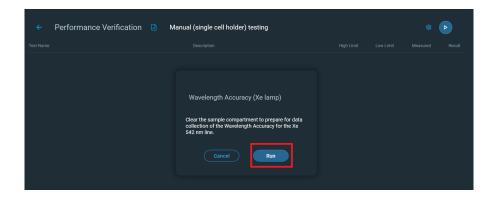
Step 4: On the Performance screen, use the default Thermo Scientific test list, and select only the Wavelength Accuracy (Xe Lamp) and Wavelength Repeatability (Xe Lamp) test items (<u>un-check all other test options</u>). Click "Continue" button in upper right corner.



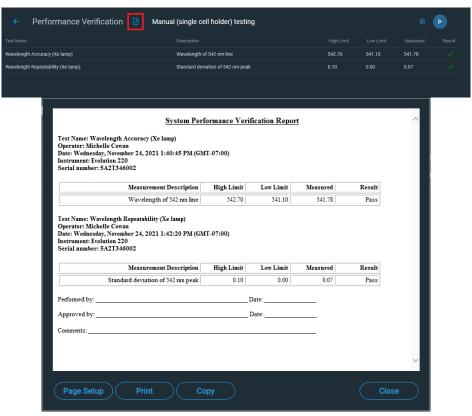
Step 5: Follow the prompts. Click the "Run" button to begin the Performance Verification.

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Step 6: After the Performance Verification completes, a Report of the results is available to print or copy. Click the 'Report' icon in the upper part of the screen to view the P.V. Report.



Step 7: If all tests pass, no further actions are required. If any tests fail, the Evolution will need to be calibrated using the Xenon lamp or Mercury Lamp. See *Calibration – Xenon Lamp* instructions section of this document, or to perform a Mercury Lamp Performance Verification, see *GEX Doc #100-157*, *P4310 Mercury Lamp Accessory*.

Procedure for Performance Verification Using the Xenon Lamp in Thermo INSIGHT 2 software:

Performance Verification of the Evolution's Wavelength Accuracy and Repeatability may be performed using the internal Xenon lamp in the Evo 220.

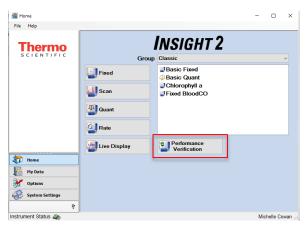
Step 1: Remove any dosimeter holders from the Evolution sample compartment. The baseplate can remain in place.

Step 2: Disconnect the Matrix 120 scanner from the computer. Close the front panel and lid of the Evolution during the entire performance verification process.

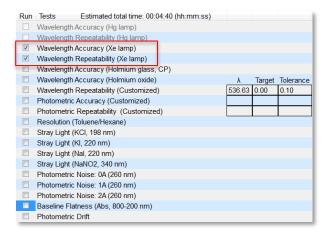
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Step 3: Select 'Performance Verification' button from the INSIGHT 2 Software's home screen.



Step 4: From the list of available tests, unselect all but 'Xe lamp' accuracy and repeatability.



Step 5: Select 'Run' in the upper left of the screen to begin the tests. Select 'OK' when prompted to clear the sample compartment. *NOTE:* A few prompts appear indicating to clear the sample compartment before proceeding. Select 'OK' at each prompt to continue the tests.

Step 6: After the Performance Verification completes, a Test Report is generated and displayed on the screen. Print a paper copy of the test, if desired.

Step 7: If all tests pass, no further actions are required. If any tests fail, the Evo220 will need to be calibrated using the Xenon lamp or Mercury Lamp. See *Calibration – Xenon Lamp* instructions section of this document, or to perform a Mercury Lamp Performance Verification, see *GEX Doc #100-157*, *P4310 Mercury Lamp Accessory*.

USAGE

Sample Compartment Lid:

- Routine use: The user may keep the sample compartment lid open, and the front panel removed and open during routine dosimeter measurements. The specialized baseplate and dosimeter holders blocks stray light.
- **Performance Verification testing and Calibration activities:** Per Thermo requirements, the lid should be closed during any Performance Verification (P.V) testing or Calibration activities.
- **Not in use:** Keep the lid closed when the Evo is not in use to reduce dust and particulate matter in the sample compartment.

Startup Procedure:

Ensure the Evolution's sample compartment is empty. (Remove any dosimeter holders from the baseplate).

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Figure 6: Remove the dosimeter holder from the baseplate. Close lid of Evolution before powering on the instrument.

- 2. Power 'ON' the spectrophotometer (refer to the Installation: Step 5 Power On the Spectrophotometer section above).
- The instrument will initialize and perform a series of self-checks. Initialization takes about three (3) minutes.
- 4. The blue light on next to the power button on the onboard keypad will flash until the unit is ready, and then it will be solid blue. See *Figure 3* in the *Installation* section.
- 5. There is no waiting period or "warm up" of the instrument after startup. You can begin measurements when initialization is complete, and the light is solid blue. (The Xenon lamp is a cold technology that does not require a traditional "warm-up" period.)
- 6. NOTE: The Evolution should be rebooted at least once per week. The instrument needs to initialize and perform the self-checks at least once per week.

USING THE EVOLUTION WITH GEX DOSECONTROL SOFTWARE:

For dosimeter measurements the instrument is controlled solely by the GEX DoseControl software which manages the instrument settings and workflows based on user-administrated configuration of DoseControl. Refer to <u>GEX Doc# 100-266</u> DoseControl Software User Guide for details.

PRECAUTIONS

Please refer to the Thermo Scientific Site and Safety User Guide for additional information and the full listing of precautions.

CAUTION!: Immediate exposure to room (ambient) air can cause condensation damage whenever the spectrophotometer has been stored or shipped. Move the shipping cartons to the installation location at least 24 hours before installation. This allows the instrument to equilibrate with the room temperature before the shipping cartons are opened and protective packaging is removed.

- Keep the top cover closed and front panel attached when not in use.
- The user should not attempt to repair or otherwise service the Evolution 220; doing so may void the warranty. Only the manufacturer and its authorized agents and subsidiaries can perform service.
- Minimize exposure of the spectrophotometer to airborne contaminants like smoke, dust, oil vapor, or chemical fumes.

WARRANTY/GUARANTEE

Warranty:

Please refer to the Thermo Scientific Evolution 220 Warranty Information.

Guarantee

1-year GEX satisfaction guarantee. Product may be returned within one year from the date of delivery for any customer dissatisfaction.

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RELATED DOCUMENTS

Go to the Thermo Fisher Scientific <u>website</u> to download product documents:

- o Thermo Scientific Evolution User Guide
- o Thermo Insight Pro Software User Guide
- o Thermo Scientific Site and Safety User Guide

Go to the GEX website's document library to download product documents and procedures:

- GEX Doc #100-113, P4220 Thermo Spectronic Standards Kit 2 Product Specification and Usage (PSU)
- GEX Doc #100-132, P4390 Matrix 120 Barcode Scanner Product Specification and Usage (PSU)
- GEX Doc #100-133, P4355 Custom Gage Blocks Product Specification and Usage (PSU)
- GEX Doc #100-157, P4310 Mercury Lamp Accessory Product Specification and Usage (PSU)
- GEX Doc #100-159, Evolution Dosimeter Holder System Product Specification and Usage (PSU)
- GEX Doc #100-164, P4350/P4355 MX2 Laser Micrometer Product Specification and Usage (PSU)
- GEX Doc #100-166, P4360 MS-2 Integrated Barcode Scanner Product Specification and Usage (PSU)
- GEX Doc #100-266, DoseControl Software User Guide
- GEX Doc #100-267, Implementation Guide for the DoseControl Dosimetry System
- GEX Doc #100-269, Spectrophotometer Performance Verification Form
- GEX Doc #100-271, Evolution Performance Verification Procedure
- GEX Doc #100-272, Spectrophotometer Measurement Repeatability Form
- GEX Doc #100-273, Spectrophotometer Measurement Repeatability Test Procedure
- GEX Doc #100-280, DoseControl IQOQ Protocol

PHARMACOPEIA COMPLIANCE SPECIFICATIONS:

Parameters	Standard(s) used	Pharmacopeia specification (tightest)	
	Mercury lamp	USP - ≤ ± 1 nm in UV range ≤ ± 2 nm in visible range	
Wavelength accuracy	Holmium perchlorate solution	USP - ≤ ± 1 nm in UV range ≤ ± 2 nm in visible range	
	Didymium solution or glass	USP - ≤ ± 1 nm in UV range ≤ ± 3 nm in visible range	
Wavelength repeatability	Mercury lamp	USP - \leq ± 0.5 nm over full λ range	
wavelength repeatability	Holmium perchlorate solution	EP/USP - \leq ± 0.5 nm over full λ range	
	Certified potassium dichromate (K2Cr2O7)	EP - \pm 0.010A USP - \leq \pm 0.010A in UV range \leq \pm 0.008A in visible range	
Photometric accuracy	Certified filters	EP - EP - ≥1.0A, ±0.8%A; <1.0A, ±0.008ª	
	Neutral density filters (Vis only)	TGA	
Stray light	Certified potassium chloride (KCI, 12g/L)	EP - > 2.0A @ 198 nm (< 1%T)	

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	Potassium iodide or sodium iodide (KI/NaI, 10g/L)	USP/EP - > 3.0A @ 220 nm
	Acetone	USP - > 0.7A @ 300 nm
	Sodium nitrite (NaNO2, 50g/L)	EP- > 3.0A @ 340 nm
Photometric linearity	Certified filters	EP - Verify linearity of transmission rate, R2 > 0.999
Resolution	Toluene in hexane (0.02%)	Ratio @ 0.5 SBW ≥ 2.3 at 25 °C

REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
03/29/2021	Operating Environment section: Altitude changed from 200m to 2000m. Removed the second sentence of the bullet underneath the table stating, 'GEX has verified instrument performance at an altitude of approx. 1610m.' ECO 70562.	E
06/15/2021	Added new bullet point to Connectivity section. Describes how to set the port settings for the DoseControl PC, so that DoseControl software connects successfully to the instrument. Related Documents section: updated titles to match current for 100-267 and 100-280. ECO 70576.	F
11/30/2021	 Revised title from "P4300 Evo220 Spectrophotometer" to "P4300 Thermo Evolution Spectrophotometer". Application section: elaborated language for the specialized hardware. Product photo section includes images of both Evo OnePlus and Evo220. Accessories section: removed P4320 CVC accessory and P4370 MS3 Barcode Scanner (no longer sold by GEX). Specifications section: Added Evolution One Plus specs, removed unnecessary items – the keypad and local control options. Added 'Other Information' section to include the components, packaging, storage, operating environment, and power information. Improved 'Care & Maintenance' section. Improved installation instructions and power requirement sections. Instructions and screenshots for the new Thermo Insight Pro software usage are included, in an addition to the instructions for older versions of Thermo INSIGHT. Installation section: improved description of Xenon lamp and Mercury Lamp calibration and performance verification testing. Added 'Using the Evolution with GEX DoseControl Software" section. Related Documents section: added reference to 'Thermo Insight Pro Software User Guide and Thermo Scientific Site and Safety User Guide. Added #100-133 P4355 Custom Gage Blocks PSU, #100-272 and #100-273 Spectrophotometer Measurement Repeatability Testing. Added Pharmacopoeia Compliance Testing specifications. 	G

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