

DESCRIPTION

The P4350 MX2 Laser Micrometer is a component of the DoseControl Dosimetry System used to measure the thickness of Harwell PMMA (Perspex) Dosimeters. The MX2 is designed to be mounted, connected, and used within the Thermo Evolution 220 Spectrophotometer, and utilized by the DoseControl software to simultaneously capture the thickness measurement and optical absorbance of PMMA (red and amber color) as well as Gammachrome YR dosimeters in order to determine the dosimeter's specific response value.

The MX2 Laser Micrometer requires the P4336 PMMA Dosimeter Holder, which is designed to accommodate dosimeters that conform to the stated thickness range of Harwell PMMA dosimeters (3mm (± 0.55 mm)). The P4355 Gauge Blocks are designed to fit the P4336 PMMA Dosimeter Holder and is used for system validation and performance verification.

SPECIFICATIONS

Physical Specifications:

GEX Part No.	Product Description	Product Dimensions	Packaging Dimensions	Weight
P4350	MX2 Laser Micrometer Assembly (2 components)	23.0cm (L) x 17.3cm (W) x 3.8cm (H) (9.1"L x 6.8"W x 1.5"H)	33.0cm (L) x 25.4cm (W) x 5.1cm (H) (13.0" x 10.0" x 2.0")	1.1 kg (2.5 lbs.)
P4355	Gauge Block Set (3 pieces)	3 pieces: one 2.5mm, one 3.0mm, and one 3.5 mm (± 0.1 mm) nominal thickness block. 3.81cm (L) x 1.09cm (W) (1.5"L x 0.43"W)	N/A (packaged in poly-zip bag)	0.03 kg (0.061 lb.)
Material	Aluminum			
Color	Silver			
Packaging	Unit is shipped in a cardboard box with bulk packaging			

Calibration:

- P4355 Gauge Block Set - Recalibrate at minimum two (2) year frequency.

Included Components:

- MX2 laser micrometer (comprised of 2 components: emitter labeled with letter 'E' and receiver labeled with letter 'R')
- Mini USB interface cord
- Interconnecting patch cable
- P4330 Evolution 220 Hot-Swappable Baseplate with beam tubes

Storage:

Store the instrument in a cool and dry location.

PRODUCT PHOTOS



USAGE

Gauge Blocks:

The GEX P4355 Gauge Block Set consists of three individual gauge blocks with nominal thicknesses of 2.5, 3.0 and 3.5 mm (± 0.1 mm). GEX performs incoming acceptance testing that involves visual inspection for quality and measurement of a central area thickness using a calibrated micrometer source traceable to a national standard. Users are encouraged to determine and establish a certified thickness value associated with the center of these gauge blocks independently by using a practice that involves use of traceable national standard references, and incorporates a periodic calibration.

The gauge blocks are provided with a calibration certificate. Suggestion is to calibrate the gauge at 2 year minimum frequency.

Laser Micrometer:

See *GEX Doc #100-266, DoseControl User Manual* for complete instructions of routine usage of the device as part of the DoseControl Evolution 220 Dosimetry System. For basic instructions and information, please refer to the "Metralight MX2 User Guide" here: http://www.metralight.com/products/doc/mx/mx_user_d.pdf

Installation Qualification (IQ) / Operational Qualification (OQ) / Performance Qualification (PQ)

Purpose:

IQ, OQ, PQ provides an outline for verification and validation of the laser micrometer's thickness component of the GEX DoseControl Dosimetry System. This laser micrometer system is specifically intended for measuring Harwell PMMA Perspex dosimeters over a thickness range of 2.0mm to 4.0mm.

General Information:

The MX2 Laser Micrometer (referred to as laser mic) is an off-the-shelf product that has been incorporated and is integrated into the GEX DoseControl Software. The laser mic is ordered, received, and inspected under the GEX Quality Management System prior to being delivered to the customer. Upon receipt, the customer must ensure the device is working properly by performing Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

PROCEDURE

IQ/OQ/PQ consists of the following:

- Installation of the laser mic. assembly into an Evolution 220 Spectrophotometer per GEX instructions.
- Thickness measurements of the GEX P4355 Gauge Block Thickness Set using the Metralight MicroStudio Software program in accordance with the Metralight User Guide instructions.
- Establish the characterized thickness values as acceptance limits for each individual gauge blocks as at or within ± 3 CV (six sigma).
- Determine performance of the device using PMMA dosimeters.

Installation Qualification (IQ)

IQ of this thickness measurement system should involve establishing confidence that equipment and ancillary systems or components are compliant with appropriate codes and approved design intentions, and that manufacturer recommendations are suitably considered. This involves verification that the equipment components as supplied and installed are able to be operated in accordance with these instructions and determine an observable thickness measurement value displayed in mm.

Laser Mic Installation:

1. Unbox the P4350 MX2 Laser Micrometer Assembly. Confirm it consists of an *emitter* and *receiver* mounted to an anodized aluminum base plate with two beam tubes attached. See Figure 1.



FIGURE 1: P4350 MX2 Laser Micrometer Assembly

2. Connect the micrometer emitter (labeled with the letter “E”) to the receiver (labeled with the letter “R”) using the short patch cable.

NOTE: Orient the cable with the arrows facing up. The spring loaded collars do not need to be depressed for connection. Simply press the cable connectors into the micrometers until they positively snap in place. Retract the collars to disconnect the cable.

3. Connect the assembly to the computer using the mini USB interface cord that plugs into the micrometer receiver (labeled “R”).
4. Install a P4336 PMMA Dosimeter Holder into the baseplate. Ensure the holder firmly snaps into place. Refer to *GEX Doc# 100-159 Evolution 220 Dosimeter Holder System* for dosimeter holder mounting instructions.
5. See Figures 2 and 3 for the finished assembly (pictures do not show the dosimeter holder installed).

NOTE: The assembly is sensitive and should be installed with extreme care to ensure it is not damaged. The assembly is not designed to be installed and removed on a routine basis.

NOTE: Do not remove the laser micrometer emitter or receiver from the P4330 Hot-swappable Baseplate for any reason! Doing so will require shipment back to the manufacturer for alignment and calibration. The system should be maintained and cared for in place.



FIGURE 2: P4350 Laser Micrometer (before mounting)



FIGURE 3: P4350 Laser Micrometer (mounted inside the Evo 220)

Metralight Software Installation and Usage:

1. Download the MicroStudio Software .zip from this location: <http://metralight.com/index.php/software/microstudio/>

- Open the folder and run the MicroStudio.exe application. See Figure 4 below.

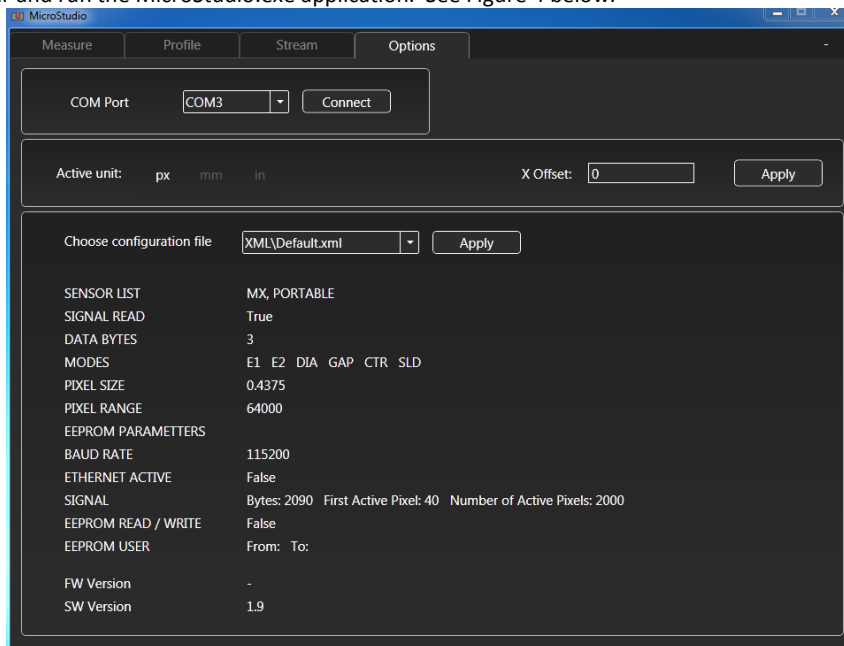


FIGURE 4: MicroStudio Software

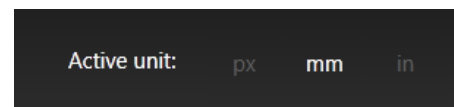
- From the COM Port dropdown menu, select the port that the micrometer is connected to. Press 'Connect'.
NOTE: The micrometer may appear in Microsoft Windows Device Manager as "USB Serial Port" or similar.



- The button text will change to display 'Disconnected' when the micrometer is successfully connected.



- Select your preferred unit of measurement, mm.



- Select the 'Measure' tab at the top of the screen. Change the capture mode to measure diameter by selecting the 'Dia' option.



- Insert a dosimeter sample or P4355 Gauge Block into the holder. Observe whether a thickness measurement value in mm is displayed in real time.

Successful completion of step 7 provides indication that the P4350 MX2 Laser Micrometer Assembly and its ancillary equipment and sub systems are operating in accordance with GEX design requirements. Compile documentation of this IQ process. This completes the IQ testing activities. Note and report any discrepancies to GEX in order to determine an appropriate corrective action before attempting to commence the OQ activities.

Operational Qualification (OQ)

Operational Qualification involves establishing confidence that the thickness measurement system and sub-systems are capable of consistently operating within known and demonstrated limits and tolerances that can effectively satisfy the user's requirements. This involves performance of the series of measurements and analysis actions as described in this document intended to characterize the thickness measurement system's operational performance. OQ assumes IQ is satisfactorily completed and the thickness measurement system is demonstrated to be fully operational.

OQ consists of performing a series of thickness measurements with the P4350 MX2 Laser Micrometer System to characterize its operational performance and verify that the results are within the 3 sigma acceptance limits of $\pm 0.01\text{mm}$.

1. Open the MicroStudio Software. Verify that the laser micrometer is properly connected to the computer per the instructions described in the IQ section above.
2. Insert a P4336 PMMA Dosimeter Holder into the baseplate. Ensure the holder firmly snaps into place. Refer to *GEX Doc# 100-159, Evolution 220 Dosimeter Holder System* for dosimeter holder mounting instructions.
3. Acquire and perform thirty (30) measurements for each of the P4355 gauge blocks. The gauge blocks include a certificate of calibration that specifies the uncertainty of measurement. The "Ref Position" value is the certified traceable thickness values at the center of each gauge block. This is where the laser from the micrometer intercepts the dosimeter sample. The obtained values will be used as the average thickness for the determination of the acceptance criteria.
4. Insert one of the gauge blocks into the dosimeter holder until it bottoms out in the holder. Observe the measurement within the MicroStudio software.
5. Record the thickness measurement.
6. Remove the gauge block from the holder and reinsert it into the holder as before. Record the measurement and continue this process for a total of 30 consecutive measurements.
7. Determine an average and standard deviation for the 30 replicated measurement set for each gauge block.
8. Verification of Precision: the 3 sigma value of the measured standard deviation should be equal to or less than the measurement reproducibility specification of $\pm 0.0066\text{mm}$ at $k=2$ (we have derived 0.01mm as the acceptance criteria from the value at $k=3$).
9. Calibration Verification: the average value of each gauge block from the data set should be within $\pm 0.01\text{mm}$ of the certified thickness value of the gauge block.

Performance Qualification (PQ)

Performance Qualification (PQ) of the P4350 MX2 Laser Micrometer System is performed to characterize its operational performance and determine normally expected thickness variability limits of actual dosimeters.

PQ consists of performing a series of 30 thickness measurements of a single, representative dosimeter sample.

1. Open the MicroStudio Software. Verify that the laser micrometer is properly connected to the computer per the instructions described in the IQ section above.
2. Insert a P4336 PMMA Dosimeter Holder into the baseplate. Ensure the holder firmly snaps into place. Refer to *GEX Doc# 100-159, Evolution 220 Dosimeter Holder System* for dosimeter holder mounting instructions.

3. Acquire a representative dosimeter sample.
4. Insert the sample into the dosimeter holder until it bottoms out in the holder. Observe the measurement within the MicroStudio software.
5. Record the thickness measurement.
6. Remove the dosimeter from the holder and reinsert it into the holder as before. Record the measurement and continue this process for a total of 30 consecutive measurements.
7. Determine an average, standard deviation, and CV for the measurement set. GEX has determined the normally expected variability for the measurement of PMMA dosimeters in the P4350 PMMA Dosimeter Holder is approximately $\pm 0.6\%$ at $k=3$. The measured C.V. should be less than or equal to this value. Contact GEX to discuss results outside of this range.

This concludes the PQ testing actions associated with validation of the P4350 MX2 Laser Micrometer System and provides evidence that it satisfactorily operates within specified requirements. However, it should be noted that additional functional performance testing of the P4350 MX2 Laser Micrometer as a sub-system of the P4300 DoseControl Dosimetry System is required as part of the overall dosimetry system validation.

NOTE: These limits can be used to establish normally expected performance limits for the laser mic that can be used as acceptance criteria for future verification and validation analysis or as “daily checks” pass/fail criteria or for use in investigation of non-conforming thickness measurements, etc. Analysis of the distribution of measurement results may also be used for SPC purposes to demonstrate an in-control state. The CV value may also be useful in establishing an aggregate Type A component value for use in an uncertainties budget.

PRECAUTIONS

Avoid contact with the glass lenses to prevent smearing or damage to the lenses that may affect the measurement output. Clean the lenses with a soft, lint-free wipe and use an optics lens cleaner if smeared with fingerprints or other oils.

Avoid sharp bends in the cables and prevent the cable connectors from being bent or forced in any one direction.

The laser mic assembly must be returned (laser mics mounted to the Evo220 base plate) to the manufacturer for service.

WARRANTY/GUARANTEE

Warranty:

One year manufacturer’s limited warranty against defective materials and workmanship.

Guarantee:

1 year GEX satisfaction guarantee. Undamaged product may be returned with or without reason within one year from the date of delivery.

REFERENCES

GEX Documents:

- *GEX PSU#100-159, Evolution 220 Dosimeter Holder System*
- *GEX Doc #100-266, DoseControl User Manual*

To learn more about GEX products and services, visit www.gexcorp.com or contact a GEX representative at +1 303 400-9640.