DESCRIPTION

The P4350 MX2 Laser Micrometer is an optional component of the DoseControl Dosimetry System that measure the thickness (*t*) of a PMMA (Perspex) dosimeter nearly simultaneously with the optical absorbance (*A*). The method of acquiring both values ensures that both are associated with the sample ID being measured which provides optimal integrity of measurement for this type of dosimeter.

The MX2 Laser Micrometer, dosimeter holder, and baseplate fits within the sample compartment of the Thermo Evolution spectrophotometer. The MX2 consists of two separate pieces, an 'emitter' and a 'receiver', that are each mounted on opposite ends of an aluminum baseplate (GEX Part# P4330). The receiver is connected to a PC via a mini-USB cable. The PMMA Dosimeter Holder (GEX Part# 4336) holds the dosimeter sample in place for measurement and is nested into the baseplate between the emitter and receiver. The laser is emitted between the emitter and receiver and the dosimeter sample is accurately measured.

The MX2 Laser Micrometer requires the P4336 PMMA Dosimeter Holder, which is designed to accommodate dosimeters that are 2mm to 4mm in thickness. Specially designed gage blocks manufactured to fit the P4336 PMMA Dosimeter Holder are used for validation and performance verification of the system (GEX Part# 4355 Gage Blocks). The DoseControl dosimetry software controls the spectrophotometer and MX2 Laser Micrometer. When the user selects the "Measure" button in the DoseControl software, the software captures the dosimeter's thickness measurement and optical absorbance nearly simultaneously, and the software determines the dosimeter's specific response (optical absorbance / thickness = response) value.

SPECIFICATIONS

GEX Part No.	Product Description	Product Dimensions	Packaging Dimensions	Weight
P4350	MX2 Laser Micrometer	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.)

Measurement Accuracy	±0.018mm
Measurement Range	2mm to 4mm
Method	Laser (670nm class I laser diode) through-beam with CCD Element
Operating Temperature	0°C to 50°C
Indicator Lights	Green LED = Sensor ON; Blue LED = Object Present
Connection to PC	USB
Material	Aluminum
Color	Silver
Printing	Serial number affixed to both emitter and receiver components.
Packaging	Hard, black plastic case with custom foam insert.
Operating Temp	OC to 50C
Storage Temp	-20C to 70C

Included Components:

- MX2 laser micrometer (2 components: emitter labeled with letter 'E' and receiver labeled with letter 'R')
- Baseplate with beam tubes for the Evolution (GEX Part# P4330)
- PMMA dosimeter holder for the Evolution (GEX Part# P4336)
- USB to Mini USB interface cord (to connect to PC)
- Interconnect cable (to connect the emitter to the receiver)
- Microfiber lens cleaning cloth

Storage:

Store the equipment in a cool and dry location when not in use.

Calibration:

The unit is tuned at the manufacturer while mounted on the baseplate and using the P4336 holder. Calibration by the user is not possible. See *Performance Verification* section.
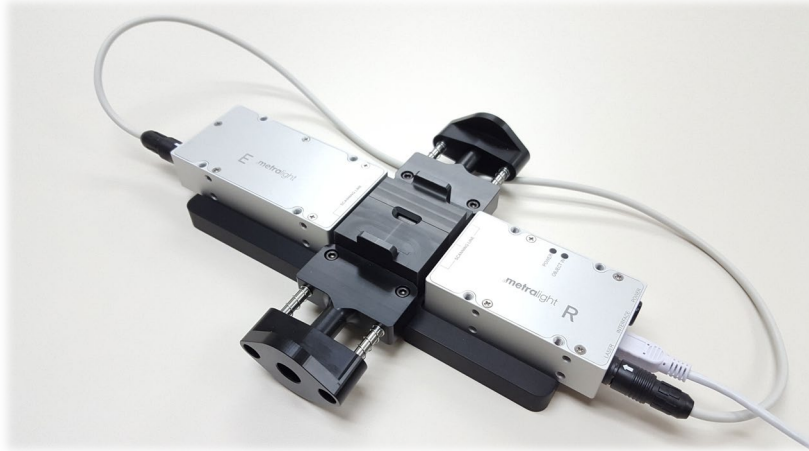
PRODUCT PHOTOS

Image above: MX2 Laser Micrometer assembly. GEX Part#4350 MX2 Laser Micrometer emitter ("E") and receiver ("R") mounted on the baseplate (GEX Part#4330) with the PMMA Dosimeter Holder (GEX Part# 4336) in place between the emitter and receiver.

ACCESSORIES

GEX Part No.	Description	Purpose
P4355	Gage Block Set	Validation and performance verification of the P4350 laser micrometer assembly.

INSTALLATION

Prior to Installation:

GEX performs a quality inspection and testing of the product in accordance with internal work instructions before the P4350 MX2 Laser Micrometer is shipped to the customer (Factory Acceptance Testing or FAT).

> **CAUTION:** *Do not remove the laser micrometer emitter or receiver from the P4330 Baseplate for any reason!*
>
> *Removal of the laser micrometer device from the P4330 Baseplate will void any warranty and will require shipment back to the manufacturer for alignment and calibration.*
>
> *The system should be maintained and cared for in-place.*

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Installation and Setup:

Setup the MX2 Laser Micrometer for use with the DoseControl Dosimetry System instructions:

A)   Install the MX2 Laser Micrometer hardware

B)   Install and configure the Metralight Software (software for the MX2 Laser Micrometer)

C)   Configure the MX2 Laser Micrometer in DoseControl software

Prior to installation and setup of the MX2 Laser Micrometer, confirm the following items are received:

MS2 Laser Micrometer and Baseplate Assembly: GEX Part#4350 MX2 Laser Micrometer installed on the baseplate (GEX Part#4330)	
Interconnector cable: This cable connects the laser micrometer emitter to the receiver.	
USB cable: This cable connects the laser micrometer receiver to the PC.	
PMMA dosimeter holder (GEX Part# P4336)	
Thermo spectrophotometer baseplate (provided separately with the Thermo Scientific Evolution spectrophotometer.	

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A)   Laser Micrometer Hardware Installation:

> **CAUTION**: *The P4350 MX2 Laser Micrometer 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.*

1.   Unbox the P4350 MX2 Laser Micrometer Assembly from the plastic storage box. Keep the storage box for future storage or shipping of the laser micrometer assembly.

2.   Confirm the P4350 MX2 Laser Micrometer Assembly consists of an *Emitter* and *Receiver* mounted to an anodized aluminum base plate with two beam tubes attached. See Figure 1.
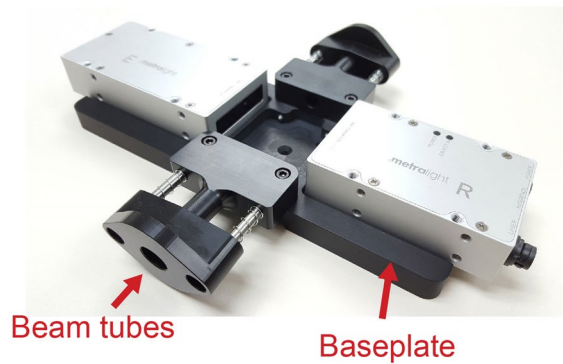

Beam tubes

Baseplate

FIGURE 1: P4350 MX2 Laser Micrometer Assembly

3.   Attach the P4350 MX2 Laser Micrometer Assembly to the Thermo Evolution or Thermo Evolution One Plus spectrophotometer baseplate. Follow the steps described below:

Step 1: Remove screw from the Thermo baseplate using a flathead screwdriver.

Step 2: Carefully place the MX2 Laser Micrometer Assembly onto the Thermo baseplate. Ensure the guide is in place (A) and screw the Assembly onto the Thermo baseplate using the screw (B).
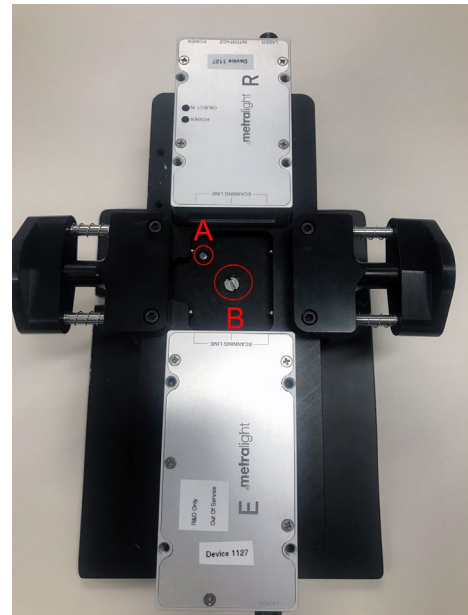
4. Connect the micrometer emitter (labeled with the letter "E") to the receiver (labeled with the letter "R") using the short Interconnect cable. See figure 2.

    a. Orient the interconnect cable with the arrows facing up. Simply press the interconnect cable connectors into the micrometers until the connectors positively snap in place. Retract the collars to disconnect the cable.
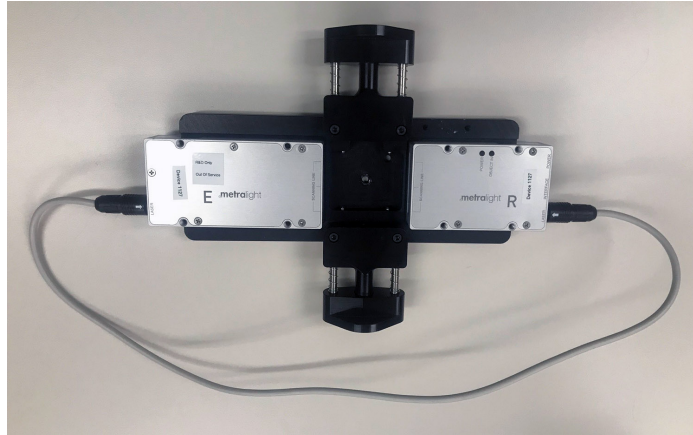

Figure 2: Emitter and Receiver connected with the Interconnect cable

5. Connect the assembly to the PC computer using the mini-USB interface cord that plugs into the micrometer receiver (labeled "R").
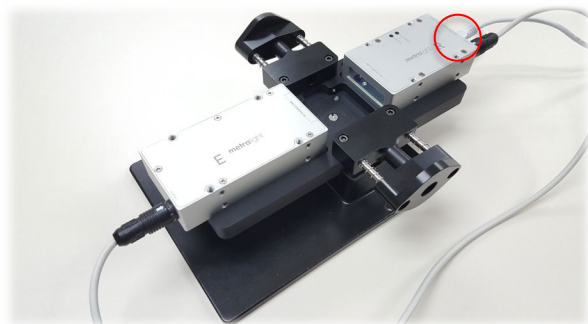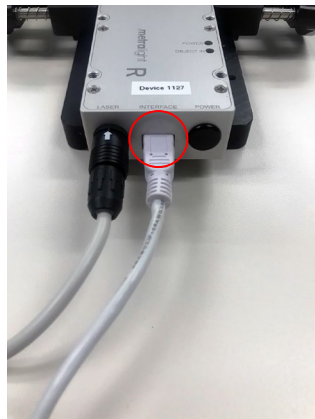

Figure 3: USB mini-interface cable attached to the "R" Receiver end of the laser micrometer

6. Carefully install the P4350 Laser Micrometer assembly into the sample compartment of the spectrophotometer. Follow the instructions in *GEX Doc# 100-159 Evolution Dosimeter Holder System*. Thread the interface cable and USB cable under the baseplate, and ensure the baseplate is snapped firmly into place inside the sample compartment. See *Figure 4* below. The USB cable can be threaded through the foam located at the front of the sample compartment, as shown in *Figure 5* below.

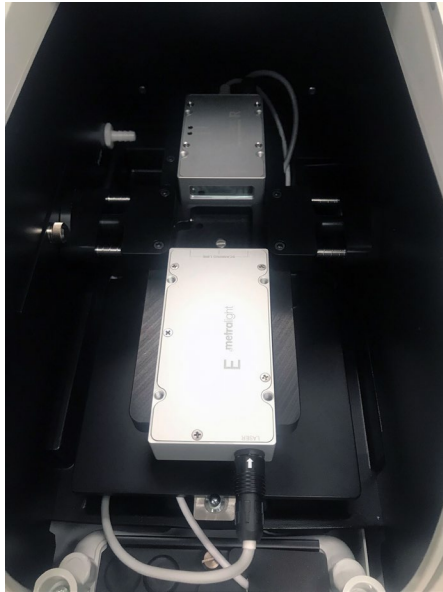   a. Next, plug the USB cable into the USB port on the PC computer.

Figure 4: The P4350 Laser Micrometer assembly installed in the spectrophotometer sample compartment

Figure 5: The USB cable threaded through the foam piece in the front of the sample compartment. The cable can now be plugged into the PC USB port

7. Insert the PMMA dosimeter holder (GEX Part# P4336) into the baseplate. See *Figure 6* below. Ensure the holder should snap in and out of the holder without forcing and should fit securely. Follow the instructions in *GEX Doc# 100-159 Evolution Dosimeter Holder System*.

Figure 6: PMMA holder inserted into the baseplate

B)   Metralight Software Installation and Usage:

1. Ensure the Laser Micrometer is plugged into a USB port on the PC. A green LED light indicates the instrument is active and ready.
2. Download the MicroStudio Software .zip from this location: http://metralight.com/index.php/software/microstudio/
3. Open the folder and run the MicroStudio.exe application. See *Figure 7* below.
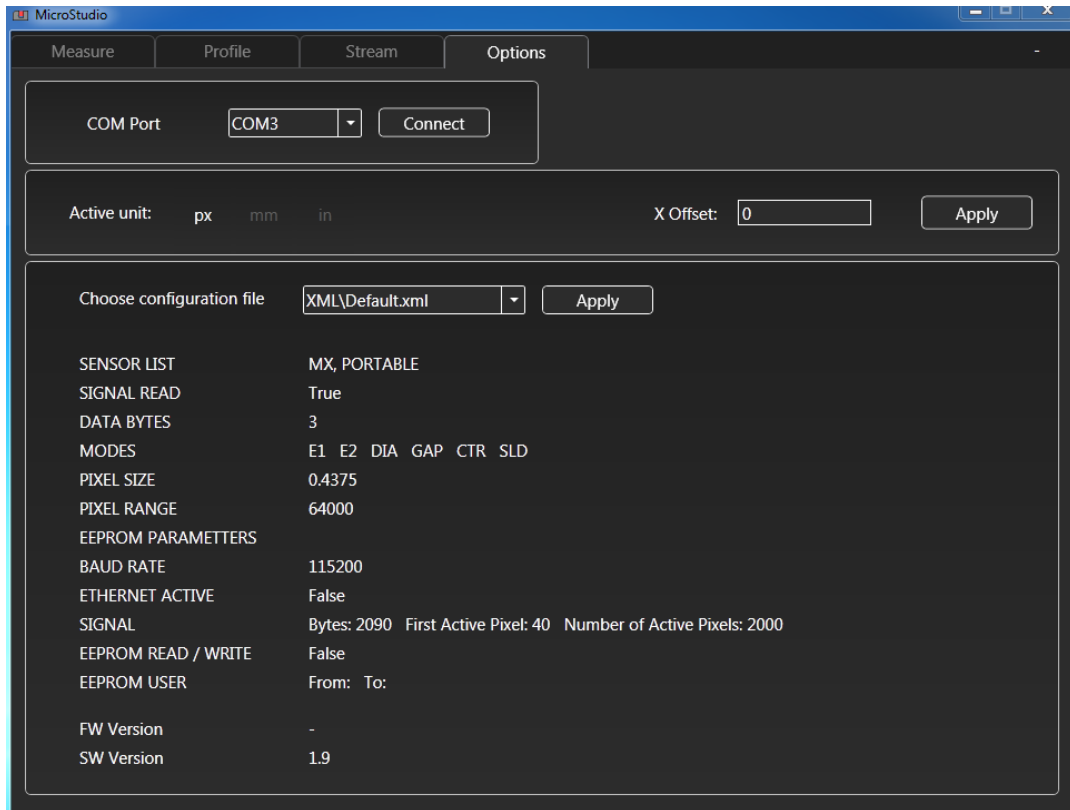
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FIGURE 7: Screenshot of the MicroStudio Software

4. 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.
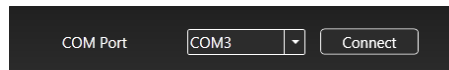
5. The button text will change to display 'Disconnected' when the micrometer is successfully connected.

6. Select your preferred unit of measurement, mm.
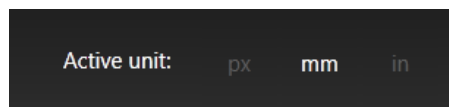
7. Select the 'Measure' tab at the top of the screen. Change the capture mode to measure diameter by selecting the 'Dia' option.

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C) **Configure the MX2 Laser Micrometer in DoseControl software:**

1. Ensure the Laser Micrometer is plugged into the PC and the green LED light is on.

2. Reference the instructions in *GEX Doc#100-266 DoseControl User Guide, Section 6, Readers Configuration.* Open the DoseControl software and open the Setup Menu and click the "Readers" button. Enter the spectrophotometer information as instructed in the *100-266 User Guide*.

    a. In the Reader configuration, tick the box for the Laser Micrometer.

        i. Enter the correct COM port for the Laser Micrometer into the Reader configuration. The COM port number can be found in the PC device manager. See *Figure 7*.

        ii. Enter 115200 for the baud rate. In the PC device manager, right-click the COM port for the laser micrometer and select ". See Figure 8.
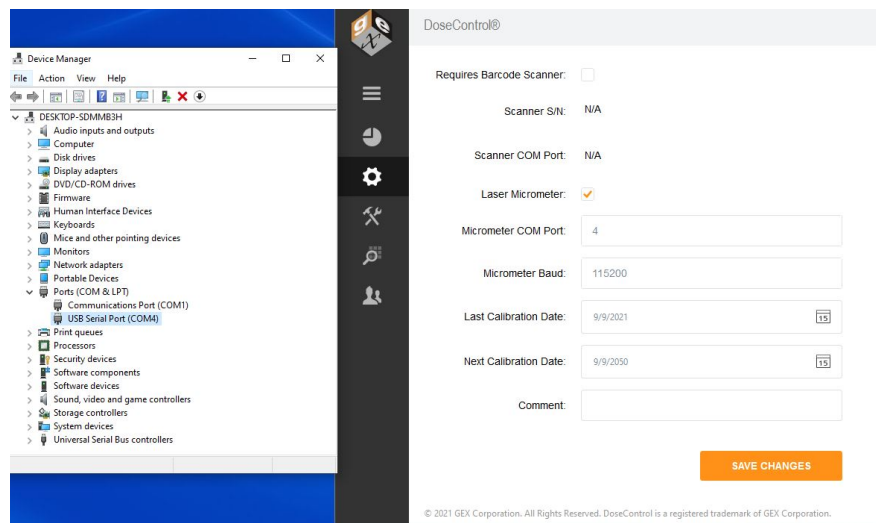

Figure 7: Enter the laser micrometer COM port into the Reader configuration in DoseControl
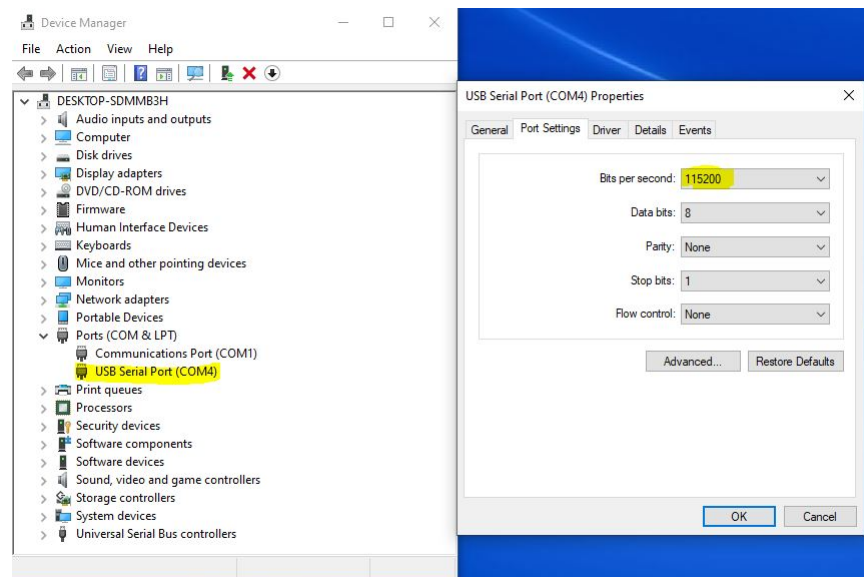

Figure 8: Enter the baud rate of 115200 in DoseControl. Check to make sure this matches the value in Device Manager

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ROUTINE OPERATION

The MX2 Laser Micrometer assembly functions as part of the GEX DoseControl system and is controlled by the DoseControl software.

On the DoseControl measurement screen, the user places the PMMA dosimeter into the holder inside the spectrophotometer sample compartment. Next, the user will click the "Measure" button on the screen. The software captures the thickness measurement value using the integrated MX2 Laser Micrometer and the absorbance measurement value. These values appear on the measurement screen and can be output in an Excel or PDF formatted dosimetry report.

See *GEX Doc #100-266, DoseControl User Manual* for complete instructions of routine usage of the device as part of the DoseControl Evolution 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

CARE & MAINTENANCE

Ensure both lenses are clean and free of fingerprints or debris. Remove with a lint-free wipe as necessary.

PERFORMANCE VERIFICATION

Upon receipt of the MX2 Laser Micrometer, the user must ensure the device is working properly by performing Installation Qualification (IQ), Operational Qualification (OQ). See *Installation Qualification (IQ) and Operational Qualification (OQ)* section below for details.

INSTALLATION QUALIFICATION (IQ) / OPERATIONAL QUALIFICATION (OQ)

Purpose:
IQ/OQ 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 user must ensure the device is working properly by performing Installation Qualification (IQ), Operational Qualification (OQ).

<u>**PROCEDURE**</u>
IQ/OQ consists of the following:

- Installation of the laser micrometer assembly into an Evolution Spectrophotometer per GEX instructions.
- Thickness measurements of the GEX P4355 Gage 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 gage block as at or within ±3 CV (six sigma). Use this information to establish ongoing performance verification criteria.
- Determine performance of the device using PMMA dosimeters.

<u>**Installation Qualification (IQ)**</u>

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. IQ Instructions:

1. Insert a P4336 PMMA Dosimeter Holder into the baseplate. Ensure the holder firmly snaps into place. Refer to *GEX Doc# 100-159, Evolution Dosimeter Holder System* for dosimeter holder mounting instructions.
2. Open the Metralight software.

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

Measured Value

0.000 mm

Edge 1   Edge 2   **Dia**   Gap

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

Successful completion of step 4 provides evidence 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 Instructions Part 1

Part 1 consists of performing a series of thickness measurements using the gage blocks 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 ±0.010mm.

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 and verify the PMMA dosimeter holder is in place in the baseplate inside the spectrophotometer.

2.   Perform thirty (30) measurements for each of the P4355 gage blocks and record the measurement values. The gage 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 gage block. This is where the laser from the micrometer intercepts the dosimeter sample. The recorded values will be used as the average thickness for the determination of the acceptance criteria.

   a.   Insert one of the gage blocks into the dosimeter holder until it bottoms out in the holder. Observe the measurement within the MicroStudio software.

   b.   Record the thickness measurement.

   c.   Remove the gage 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.

   d.   Determine an average and standard deviation for the 30 replicated measurement set for each gage block.

3.   Verification of Precision: The 3-sigma value of the measured standard deviation should be equal to or less than the measurement reproducibility specification of ±0.0066mm at k=2 (we have derived ±0.010mm as the acceptance criteria from the value at k=3).

4.   Calibration Verification: The average value of each gage block from the data set should be within ±0.018mm of the certified thickness value of the gage block which is the combination of the accuracy and precision specifications.

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<u>OQ Part 2</u>

Part 2 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, and verify the PMMA dosimeter holder is in place in the baseplate inside the spectrophotometer.

2. Acquire a representative dosimeter sample.

3. Insert the sample into the dosimeter holder until it bottoms out in the holder. Observe the measurement within the MicroStudio Software.

4. Record the thickness measurement.

5. 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.

6. 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 ±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 OQ 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 Evo base plate) to the manufacturer for service. Contact GEX customer support at support@gexcorp.com.

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.

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REFERENCES

Download GEX documents here: https://library.gexcorp.com

GEX Documents:
- *GEX PSU #100-133, Custom Gage Blocks*
- *GEX PSU #100-159, Evolution Dosimeter Holder System*
- *GEX Doc #100-266, DoseControl Software User Manual*

Metralight documents:
- "Metralight MX2 User Guide" download here: http://www.metralight.com/products/doc/mx/mx_user_d.pdf

REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
12/03/2021	- Included components section: updated reference of Evo220 to Evolution. - Changed reference of 100-159 title from Evo220 Dosimeter Holder System to Evolution Dosimeter Holder System. - Added 'Revision History'. ECO 70593	E

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