



18 October 2022

IMPORTANT: LM10/12/14 Laser Re-Classification

Dear customer,

Why are you receiving this letter?

You purchased a NanoSight LM10 microscope with a LM12 and/or LM14 laser module ("Instrument"). We recently discovered that when analyzing samples containing bubbles, the Instrument may release low levels of Class 3B light radiation near the Instrument, which is harmful to the eye under direct exposure.

Although we designed the Instrument to meet Class 1 laser safety requirements, this recently discovered information means we need to reclassify the Instrument as a Class 3B laser product.

What does this mean for you?

A laser is classified as Class 3B if it has a power output between 5mW and 500mW. Since the Instrument's output is about 10mW, it is just inside the low end of the range. Additionally, the risks that the Instrument may release any Class 3B light radiation is extremely low if you use it according to our user manuals.

Our user manuals (that you received with your instrument and are available at <https://www.malvernpanalytical.com/en/learn/knowledge-center/user-manuals/MAN0510EN>) explain that users must remove any bubbles in the samples before operating the Instrument. However, if you use the instrument without first removing bubbles from the samples, there is a small risk that people near the Instrument may be exposed to Class 3B levels of light radiation. Please note that we are updating the manuals, so older versions may refer to the Instrument as a Class 1 device.

In some territories, we may need to modify your instrument slightly to meet local requirements, but rest assured the modifications will not affect the instrument's performance.

What should you do?

First, you should ensure that you are using the Instrument as specified in your manual by removing any bubbles from your sample. If you still have questions about whether the bubbles have been sufficiently removed, we're happy to provide additional instructions on this procedure.

Second, please email us at LM10.support@malvernpanalytical.com with your contact information and the serial number(s) for the Instrument, including each laser module. Once we verify your information, we will notify you of the next steps in the re-classification process.

Finally, we understand that your company and local regulatory institutions or agencies may have different procedures and requirements for working with Class 3B laser products than Class 1, so we encourage you to verify that you are using the Instrument consistent with their requirements and recommendations.

We apologize for any inconvenience this may cause. Please don't hesitate to contact us at LM10.support@malvernpanalytical.com with any questions you may have.

Sincerely,

Pauline Carnell-Morris
Group Product Manager – Nano-Materials