Why Hygiena® Luminometers Do Not Require Periodic Calibration

EnSURE® Touch, SystemSURE *Plus*® and EnSURE luminometers

Calibration Requirements

Hygiene monitoring using handheld luminometers to detect ATP, indicator organisms or phosphatases are an integral part of reducing risks of contamination events. Using a well-designed, reliable instrument is one of the foundations of environmental and process monitoring. To ensure stable instrument performance, periodic verifications, or checks, of instrument calibration should be performed as defined in quality management systems like those associated with ISO standards. Maintaining calibration requirements is essential to support accurate and consistent measurements, ultimately affecting decisions about product safety and quality.

Today's luminometers use one of two main detection technologies with different calibration requirements that have varying impacts on performance when calibration standards are not met. Photomultiplier tube (PMT) detectors require manufacturer calibration every 6 to 12 months, depending on usage. Photodiode (PD) solid-state detectors, which are used in all Hygiena® luminometers (Table 1), do not require periodic recalibration.

Table 1. Representative Instruments with Different Light Detection Systems.

Hygiena Instruments with Photodiodes	Other Instruments with Photomultiplier Tubes
EnSURE® Touch luminometer	Clean-Trace® Luminometer (3M)
SystemSURE *Plus*® luminometer	novaLUM® II-X luminometer (Charm Sciences)
EnSURE® luminometer	

Detection Technology Overview: Photodiode vs. Photomultiplier Tube

We based our handheld luminometers (Figure 1) on PD detection because this technology has the sensitivity required for robust bioluminescent measurements and advantages related to durability, repeatability and variability (Table 2). Our design means that traditional periodic calibration of instruments used for monitoring manufacturing and production processes is no longer necessary, so there is no need to send them back to us for annual inspections.

In contrast, the level of sensitivity that PMTs offer exceeds what is needed for ATP bioluminescence applications, but sensitivity can often be decreased by other limitations of the instrument and devices, such as the optical geometry, electronics, testing chemistry and collection device. For example, Charm Science's novaLUM instrument uses a PMT, but has a high background (emitted light) in the chemistry which limits the system's level of sensitivity (see comparison).

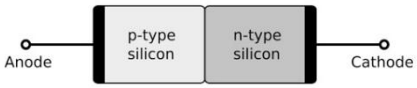
Figure 1. Hygiena Luminometers. From left to right, the EnSURE Touch, SystemSURE *Plus* and EnSURE instruments.

Table 2. Comparison of Photodiode and Photomultiplier Technology.

Photodiode Technology	Photomultiplier Tube Technology
 Representative size: 10 x 9 x 2 mm	 Representative size: 26 x 50 x 56 mm
Does NOT need recalibration	Needs manufacturer calibration every 6 to 12 months
Other factors affecting durability, repeatability and variability	
Shock and vibration resistant Solid-state technology can be mass-produced for consistency and has no fragile parts that need alignment	Susceptible to breakage from shock and vibrations Custom-made glass vacuum tubes can break and metal plates can become misaligned if the device is dropped
• Wide operating temperature range (–20 to 60 °C) • Not sensitive to pressure • Not susceptible to magnetic fields Can be used in a wide range of manufacturing or environmental conditions	• Narrower operating temperature range (5 to 40 °C) • Impacted by pressure changes • Susceptible to magnetic fields
Low susceptibility to damage from ambient light	Susceptible to damage from ambient light Must protect photocathode from ambient light, complicating instrument design and maintenance

Why Don't Hygiena Luminometers Need Annual Recalibrations?

All Hygiena luminometers use a solid-state PD detector (Figure 2) within a proprietary light detection architecture. Like the PDs used in solar panels, luminometer PDs can degrade over time as they are exposed to light. However, the deterioration of light detection in a luminometer is lower and slower because bioluminescence light levels are much lower and less damaging compared to the higher light levels of direct sunlight on a solar panel. Also, the degradation of a PD by ambient light is considerably less than that of a PMT. Taken together, the components and design of Hygiena luminometers mean that periodic calibration is not needed to ensure consistent instrument function.



converted into electrical energy. (Raffamaiden, CC BY-SA 3.0, via Wikimedia Commons, cropped off electrical symbol)

Why Do PMT Instruments Need Periodic Recalibrations?

Degradation of the scintillator or photocathode in a PMT can occur in two ways. First, when photons from the bioluminescent reaction strike the photocathode, an electron is emitted (Figure 3). This photon-to-electron conversion degrades the photocathode material with each exposure. While this degradation is typically small given the amount of light emitted from bioluminescent reactions, the number of tests and length of exposure can create noticeable degradation.

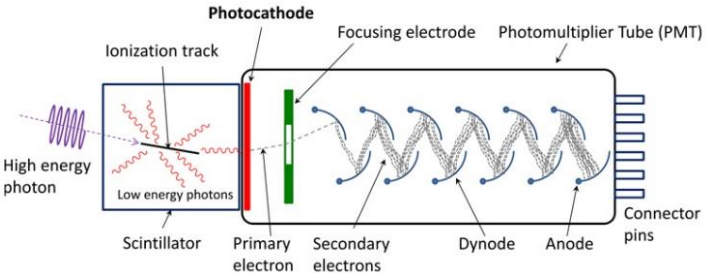


Figure 3. Schematic of a Photomultiplier Tube. Light energy is converted to electrons by the photocathode and amplified using a series of dynodes. (Qwerty123uiop, CC BY-SA 3.0, via Wikimedia Commons)

Second, bright or ambient light can significantly damage the PMT or degrade the photocathode. The extent of damage depends on the amount of light exposure, but even one exposure to ambient light could permanently damage a PMT. Therefore, it is important to check the PMT calibration regularly and adhere to the manufacturer's recalibration recommendations.

Recommendations for Monitoring Instrument Performance

Hygiena luminometers do not need to be shipped back to us for annual servicing, unless your Quality Management System requires periodic manufacturer calibration.

Our luminometers do not need regular calibrations because they use PD light detection technology made of stable, solid-state components. In addition, at each startup, they 'self-calibrate to zero' to verify that the system is working. During the self-calibration, the reading from an empty chamber is used to monitor the electronics so that the difference between no light and the visible light stays consistent over time.

To track calibration history for audit records, we offer the reusable Hygiena CalCheck LED Calibration Verification Device (Catalog No. CAL). This test for positive and negative calibration verification can be completed in less than one minute. The testing frequency can be customized to fit your application and should follow your standard operating procedures.

We understand that some Quality Management Systems specify manufacturer calibration for instruments. If you require this service, request a quote through Hygiena technical support for our calibration service.