

Calibration Control Kit



Calibration verification of Hygiena SystemSURE Plus and EnSURE luminometers
Part No# PCD4000 (Kit Includes: 1 Positive Rod and 1 Negative Rod)

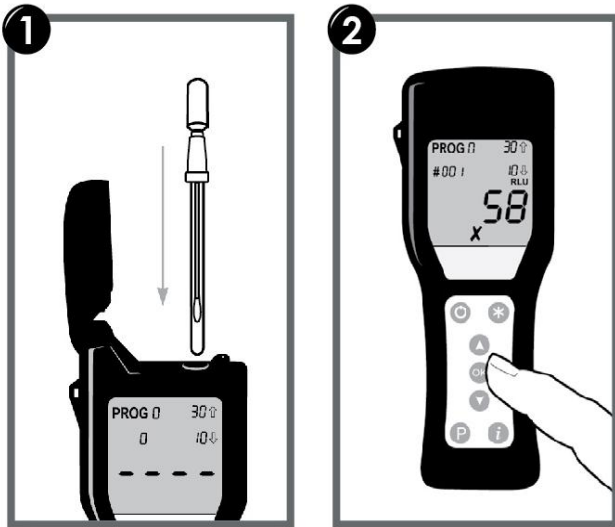
Description/ Intended Use:

Calibration control rods are used to verify calibration of Hygiena luminometers. Positive Rod consists of C¹⁴ radioactive source that emits very low level of low-energy β radiation in a plastic scintillation matrix. Matrix is configured to give constant light output at a high level for up to five years. Negative Rod is used to check for possible background light getting into instrument or light detector not calibrating correctly. Negative Rod produces low-light (0–4) RLU background. It is recommended to verify calibration with Calibration Control Kit each week or every other week depending on use and Quality Control Program requirements. Incorporating Calibration Control Kit into overall Quality Control program will validate luminometer is within specifications and operating correctly.

Directions:

Positive and Negative Rods are inserted and read in luminometer in same manner as ATP test devices. **Calibration rods do not need to be activated like ATP test devices. Do not activate Calibration rods.**

1. Open sample chamber and insert Positive Rod. Push rod in gently so it makes contact with bottom of chamber.
2. Close lid and press "OK" to initiate measurement.
3. Record result. Repeat steps 1 and 2 two more times and record results. Calculate average of three readings and enter in table provided below. Record Positive Rod Reference No. Refer to Interpretation of Results.
4. Repeat steps 1 through 3 using Negative Rod.
5. Repeat steps 1 through 4 for each luminometer. Record readings in table provided below. Additional tables are printed on back side of this sheet.



Instrument Serial No.:			
Positive Rod Reference No.:			
Test 1	Test 2	Test 3	Average
Negative Rod			
Test 1	Test 2	Test 3	Average

Interpretation of Results:

Refer to Table 1 below for acceptable RLU ranges. Results should not vary by more than ± 20% from Positive Rod Reference No. If results from Positive Rod are outside RLU range, or vary by > ±20% from Positive Rod Reference No., contact your Hygiena representative.

Table 1: In-Calibration RLU Ranges for Hygiena Luminometers

	EnSURE (RLU)	SystemSURE Plus (RLU)
Negative Rod	0-4	0-4
Positive Rod	80-160	40-80

Incorporating Calibration Control Kit into a Quality Control Program:

Calibration Control Kit is designed to be incorporated into a Quality Control Program that monitors and tracks performance of Hygiena luminometer and/or devices. It is recommended that a specific program point be assigned in luminometer for results. All results can be viewed directly from luminometer or in SureTrend data analysis software.

Troubleshooting:

Several factors can cause RLU readings to be outside acceptable range. Possible causes include:

- **Dirty calibration rods.** Clean outside of both rods with lint-free cloth that has been dipped in isopropyl or ethyl alcohol. Air dry and repeat reading.
- **Damaged calibration rods.** Return damaged calibration rods to Hygiena for replacement.
- **Luminometer contamination.** Results that have changed suddenly, especially immediately after a number of sampling devices have been run, can indicate contamination problems. Results from calibration rods can increase or decrease as a result of foreign materials disturbing optics chamber of luminometer. If contamination is suspected in luminometer, remove read chamber and clean. Scratches on bottom of read chamber do not affect readings. Refer to owner's manual for instructions on cleaning read chamber.
- **Position of rod.** It is important to make sure calibration rods are placed in read chamber so rod touches bottom of chamber. If rod does not reach bottom of chamber, rod will be too far from sensor, and will result in inaccurate results (low measurements).

Storage & Shelf Life:

- Five (5) year shelf life. Refer to expiration date printed on label.
- Store at 15 – 25 °C (59 – 77 °F) in box rods were received in, or dark container. Store away from light.

Precautions:

- **Limit exposure to light.** Store calibration rods in dark or weak ambient light. Kit box provided is recommended as appropriate dark storage. Do not expose to direct sunlight or intense artificial light for too long before use.
- **Handle with care.** Avoid crushing, cutting, or dropping calibration rods. Any damage that changes shape or light transmission properties of Positive Rod can affect assigned values. Do not use if scintillator tip of device is cracked or damaged.
- **Radioactive material.** Not for human use. Introduction into foods, beverages, cosmetics, drugs, or medicinal products, or into products manufactured for commercial distribution is prohibited. Exempt quantities should not be combined.
- For further safety instruction, refer to Calibration Control Kit Safety Data Sheet (SDS).

Disposal:

- **U.S. & Canada:** Level of radioactive material in Positive Rod does not require special hazardous waste treatment, per U.S. Federal regulations governing use and transfer of exempted radioactive materials. Contents of Positive Rod are exempt from NRC or Agreement State licensing requirements. Positive Rod contains extremely small amounts of radioactive Carbon-14, completely contained by outer housing of device. There are no radioactive emissions on surface of device, and no special precautions are needed in handling device to avoid exposure.
- **To dispose of Positive Rod, remove or deface "Caution Radioactive Materials" label on rod.** Positive Rod may then be disposed in trash.
- For disposal requirements in other countries, check with your national or local supplier.

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NOTE: Make copies of this page as needed if more luminometers are in use.

Instrument Serial No.:			
Positive Rod Reference No.:			
Test 1	Test 2	Test 3	Average
Negative Rod			
Test 1	Test 2	Test 3	Average

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Positive Rod Reference No.:			
Test 1	Test 2	Test 3	Average
Negative Rod			
Test 1	Test 2	Test 3	Average

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Positive Rod Reference No.:			
Test 1	Test 2	Test 3	Average
Negative Rod			
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Positive Rod Reference No.:			
Test 1	Test 2	Test 3	Average
Negative Rod			
Test 1	Test 2	Test 3	Average

Instrument Serial No.:			
Positive Rod Reference No.:			
Test 1	Test 2	Test 3	Average
Negative Rod			
Test 1	Test 2	Test 3	Average

Instrument Serial No.:			
Positive Rod Reference No.:			
Test 1	Test 2	Test 3	Average
Negative Rod			
Test 1	Test 2	Test 3	Average

Hygiena Liability:

Hygiena will not be liable to user or others for any loss or damage whether direct or indirect, incidental or consequential from use of this device. If this product is proven to be defective, Hygiena's sole obligation will be to replace product or at its discretion, refund the purchase price. Promptly notify Hygiena within 5 days of discovery of any suspected defect and return product to Hygiena. Please contact Customer Service for a Returned Goods authorization number.

Contact Information:

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