



Hygiena CalCheck LED Calibration Verification Device

For the EnSURE® Touch and SystemSURE Plus® Luminometers

1. Description and Intended Use

CalCheck is a reusable device recommended for verifying that EnSURE® Touch and SystemSURE Plus® luminometers continue to operate correctly and are within specifications. Calibration verification with CalCheck is performed at regular intervals (e.g., weekly, monthly) as specified by user-defined quality procedures.

When powered on, the CalCheck power button emits a 3-second green LED light, and the device remains powered on for 60 seconds, which is enough time to run a positive test. The negative test (i.e., empty chamber for EnSURE Touch or a powered-off CalCheck for SystemSURE Plus) can alert users to background instrument light leakage or rare sensor calibration errors.



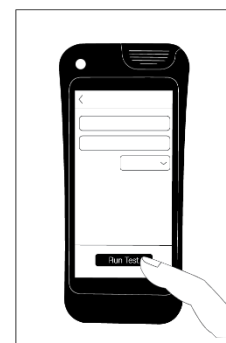
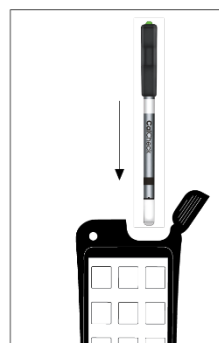
2. For EnSURE Touch Luminometers

2.1. Instructions

Note: Do not twist or bend any part of the device, especially the black battery housing where the power button light is displayed.

1. Turn on the EnSURE Touch.
2. Tap the Calibration App icon: 
3. Follow the steps on the screen to initiate the calibration checks:
 - a. Internal LED test (empty chamber)
 - b. Negative test (empty chamber)
 - c. Positive test (CalCheck on)

Note: The power button will glow green to confirm activity. If the button glows red or remains dark, the battery may need to be replaced. See [Battery Replacement](#).



2.2 Interpretation of Results

Upon completion of the calibration tests, the results are automatically recorded in the instrument and will be synced to your SureTrend® account when connected to WiFi.

If CalCheck results are not within the ranges in Table 1, see [Troubleshooting](#).

Table 1. In-Calibration RLU Ranges for the EnSURE Touch.

Test	Passing RLU Range
Internal LED	> 500
Negative	0–4
Positive	255–345



3. For SystemSURE *Plus* Luminometers

3.1 Instructions

Note: Do not twist or bend any part of the device, especially the black battery housing where the power button light is displayed.

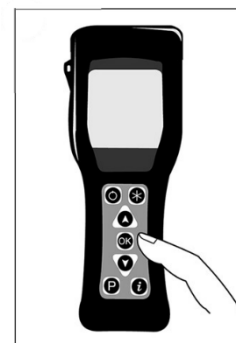
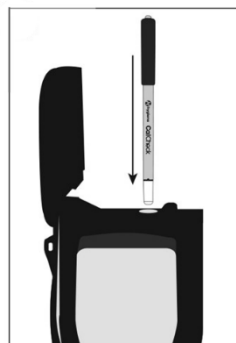
For optimal recordkeeping, we recommend that a specific location be programmed in the SureTrend data analysis platform for measuring CalCheck on a SystemSURE *Plus* luminometer.

Upon first use, CalCheck positive and negative measurements must be recorded in Table 2 to serve as a reference for future calibration verifications.

Negative test

1. Carefully insert CalCheck into the luminometer without pressing the power button on the top. Then, close the lid.
Note: If the CalCheck is accidentally turned on, wait for at least 1 minute for it to turn off before proceeding to the next step.

2. Press 'OK' to initiate the measurement.
3. Record the initial negative CalCheck RLU in Table 2. For ongoing testing, refer to [3.2 Interpretation of Results](#).



Positive test

1. Open the luminometer lid and press the power button on the end of the CalCheck to turn on the device.
Note: The power button will glow green for 3 seconds to confirm activity. If the button glows red or remains dark, the battery may need to be replaced. See [Battery Replacement](#).
2. Close the lid and press 'OK' to initiate the measurement.
Note: The test should be initiated within 20 seconds after turning on the CalCheck device.
3. Record the initial positive CalCheck RLU in Table 2. For ongoing testing, refer to [3.2 Interpretation of Results](#).

Table 2. Initial CalCheck Measurements.

Information	User Records
Date	
Instrument Serial No.	
Negative CalCheck RLU	
Positive CalCheck RLU	

3.2 Interpretation of Results

If CalCheck results are not within the ranges in Table 3 or vary by more than $\pm 20\%$ from the initial CalCheck RLU as recorded in Table 2, see [Troubleshooting](#).

Table 3. In-Calibration RLU Ranges for the SystemSURE *Plus*.

Test	Passing RLU Range
Negative	0–4
Positive	40–80 Or $\pm 20\%$ of the initial positive RLU from Table 2



4. Troubleshooting

If you obtain results outside of the expected range, clean the CalCheck device and the luminometer reading chamber as described below and repeat the tests. If the issue is not resolved, contact Hygiena for technical support at www.hygiena.com/support.

1. **CalCheck:** Clean outside of the rod with a lint-free cloth containing isopropyl or ethyl alcohol. Allow the device to air dry.
2. **Luminometer:** Clean the read chamber as follows:
 - **EnSURE Touch** (see the *Maintenance* section of the EnSURE Touch Instructions for additional details, available at www.hygiena.com/documents):
 - a. Turn off the instrument.
 - b. Remove the plug at the bottom of the instrument with the supplied tool (or Allen wrench, flat-head screwdriver or large coin).
 - c. Moisten a cotton swab or pipe cleaner with water or isopropanol and use it to clean the inside of the read chamber.
 - d. Allow the water or isopropanol to dry and replace the plug into the instrument. Do not overtighten the plug.
 - **SystemSURE Plus** (see the *Cleaning and Replacing the Protective Pocket* section of the SystemSURE Plus instructions for additional details, available at www.hygiena.com/documents):
 - a. Turn off the instrument.
 - b. Remove the protective pocket containing the read chamber by opening the instrument lid and gently pulling the protective pocket out of the instrument using the tab.
 - c. Carefully clean the interior of the pocket using water or a very mild detergent.
 - d. Allow the pocket to dry completely before carefully inserting it back into the instrument.
3. Repeat the tests.

5. Storage

- Store CalCheck at 10 to 25 °C (50 to 77 °F) in the original packaging when not in use.
- If CalCheck is exposed to extreme temperatures (e.g., direct sunlight, heat, refrigeration or frozen), allow the device to acclimate to ambient temperature (10 to 25 °C/50 to 77 °F) for 30 minutes before use.
- Take care not to press the power button during storage, as this will shorten battery life.

6. Battery Replacement

CalCheck is powered by a single CR1025 lithium coin battery (3V), available from any common battery supplier. Repeatedly powering on the CalCheck device may prematurely drain the battery.

When to change the CalCheck battery

When the power button glows red, CalCheck is not ready to perform a positive check, and its battery may be nearing the end of its life.

To determine if the battery should be replaced after seeing a red light on the CalCheck power button, wait 2 minutes and press the power button again:

1. If there is no light, replace the battery.
2. If the red light appears again, replace the battery.
3. If the green light appears, CalCheck is ready to use.

Note: luminometer readings should be initiated within 20 seconds of the appearance of the green light.



How to change the CalCheck battery

Note: Do not twist or bend any part of the device, especially the black battery housing where the power button light is displayed.

1. Remove the battery door (located on the side of the black end of the device) by inserting your fingernail along the edge of the door and gently removing the cover.



2. Insert the new battery and replace the door.

Note: Ensure that the battery's positive and negative sides match the battery connector and that the battery fits securely between the connectors.

7. Disposal

CalCheck contains RoHS-compliant materials and a small battery. With the battery in place, CalCheck should be discarded as electronic waste. With the battery removed, CalCheck may be disposed of as trash.

CAUTION – RISK OF EXPLOSION IF BATTERY IS REPLACED BY AN INCORRECT TYPE. DISPOSE OF USED BATTERIES ACCORDING TO YOUR LOCAL REGULATIONS.

8. Warranty

Hygiena warrants CalCheck, when purchased new, to be free from defects in materials and workmanship, and will repair or replace, at its discretion, any CalCheck device which, used under proper conditions, exhibits such defects. Under the terms of this warranty, the product must be returned in the original packaging, transportation prepaid, with a copy of the Proof of Purchase, to your local distributor. Contact your local distributor to receive authorization to return the instrument, and enclose a detailed description of the problem. This warranty is provided to the original purchaser for one year from the date of purchase. In no event will Hygiena be liable for indirect, incidental or consequential damages; the original user's remedies being limited to repair or replacement of CalCheck at the manufacturer's option. Unauthorized modification of any part of CalCheck, including removal of labeling will void this Warranty.

9. Contact Information

For more information, visit www.hygiena.com/contact. For technical support, visit www.hygiena.com/support.