Certified CalCheck for EnSURE™ Touch

LED Calibration Verification for Hygiena Luminometers

Part Number: **ATP4003-CT-ET**

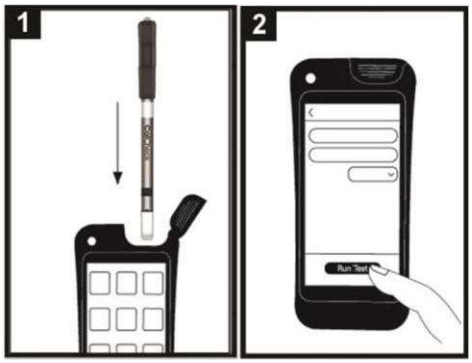
Description/ Intended Use:

CalCheck is a reusable device. Scigiene recommends incorporating CalCheck into a quality control program to verify that the luminometer continues to operate correctly and is within specifications. When powered on by pressing the button on CalCheck's cap, the device emits a 3-second green LED light output. In the off state, Calcheck can be used as a negative control to alert users to background instrument light leakage or rare sensor calibration errors. When certified yearly please refer to the certified value on your certificate and the reading on you meter should agree within 5% of this. Should this value not meet specification please follow direction below for cleaning and battery replacement and repeat test. If this fails then contact Scigiene immediately for help. Scigiene recommends verification of luminometer calibration with CalCheck at a regular interval (e.g., daily) as specified by user-defined quality procedures.

Instructions:

Do not twist or bend CalCheck.

1. Turn on EnSURE™ Touch
2. Press the Pink Check Calibration App
3. Follow steps on screen to initiate negative calibration check. It should read 0 RLU.
4. Follow steps on screen to initiate positive calibration check. This should match the certified value on your Certificate.
5. Upon completion, results are automatically recorded in the instrument and will be synced to your SureTrend™ Cloud account when connected to WiFi.



Troubleshooting:

Higher-than-expected CalCheck RLU readings indicate system calibration failure. Physical contamination can cause lower-than-expected CalCheck RLU readings.

- Clean outside of rod with lint-free cloth containing isopropyl or ethyl alcohol. Air dry and repeat reading.
- For instructions on how to clean EnSURE™ Touch please visit: https://help.hygiena.com/kb-doc/how-to-clean-the-instrument/
- If issue is not resolved, contact Scigiene for technical support.

Incorporating CalCheck into a Quality Control Program:

CalCheck is designed to be incorporated into a quality control program that monitors and tracks performance of Hygiena luminometer(s). For optimum recordkeeping, it is recommended that a specific location be programmed in SureTrend™ Cloud data analysis software for measuring CalCheck on luminometer.

Storage & Shelf Life:

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

Battery Replacement:

- When button cap glows red, CalCheck is not ready to perform a positive check and may be approaching end of battery life. Wait 2 minutes and try again. If red light continues to appear, battery should be replaced.
- If light remains dark upon pressing button, battery should be replaced.
- CalCheck is powered by 1-CR1025 coin lithium battery (3V) available from any common battery supplier. Battery door is located on CalCheck's black cap. Remove by inserting your fingernail along edge of door and gently removing cover. Insert new battery and replace door.

Caution:

Wait 2 minutes between each positive reading. Repeatedly activating CalCheck may drain battery prematurely.

Disposal:

CalCheck contains RoHS-compliant materials and a small battery. With battery in place, CalCheck should be discarded as electronic waste. With battery removed, CalCheck may be disposed as trash. CAUTION – RISK OF EXPLOSION IF BATTERY IS REPLACED BY AN INCORRECT TYPE. DISPOSE OF USED BATTERIES ACCORDING TO THE INSTRUCTIONS.

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.

Contact Information:

If more information is required, please visit www.scigiene.com or contact:

Scigiene

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www.scigiene.com

Certified CalCheck for EnSURE™ and SystemSURE Plus™

LED Calibration Verification for Hygiena Luminometers

Part Number: **ATP4003-CT-E / ATP4003-CT-S**

Description/ Intended Use:

CalCheck is a reusable device. Scigiene recommends incorporating CalCheck into a quality control program to verify that the luminometer continues to operate correctly and is within specifications. When powered on by pressing the button on CalCheck's cap, the device emits a 3-second green LED light output. In the off state, Calcheck can be used as a negative control to alert users to background instrument light leakage or rare sensor calibration errors. When certified yearly please refer to the certified value on your certificate and the reading on you meter should agree within 5% of this. Should this value not meet specification please follow direction below for cleaning and battery replacement and repeat test. If this fails then contact Scigiene immediately for help. Scigiene recommends verification of luminometer calibration with CalCheck at a regular interval (e.g., daily) as specified by user-defined quality procedures.

Instructions:

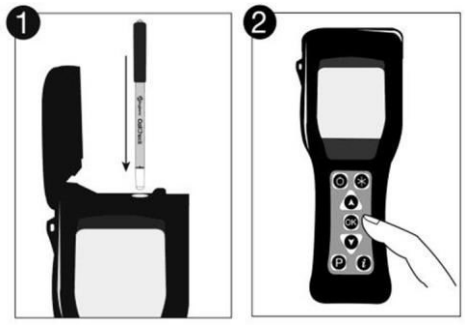
Do not twist or bend CalCheck., CalCheck positive and negative measurements must be recorded in your meter and verified against the stated certified value on your certificate to serve as reference for future calibration checks.

Negative Check:

1. Taking care not to press button on cap, insert CalCheck into luminometer and close lid.
2. Press “OK” to initiate measurement.
3. Follow steps on screen to initiate negative calibration check. It should read 0 RLU

Positive Check:

1. Insert CalCheck into luminometer. Press button on CalCheck cap to turn device on. Button will glow green to confirm activity. (If button glows red or remains dark, battery should be replaced. See Battery Replacement).
2. Close lid and press “OK” to initiate measurement.
3. Follow steps on screen to initiate positive calibration check. This should match the certified value on your Certificate.



Troubleshooting:

Higher-than-expected CalCheck RLU readings indicate system calibration failure. Physical contamination can cause lower-than-expected CalCheck RLU readings.

- CalCheck: Clean outside of rod with lint-free cloth containing isopropyl or ethyl alcohol. Air dry and repeat reading.
- EnSURE™: To remove the read chamber, open the lid of the system, and insert your finger into the read chamber, and pull it out. The read chamber can be washed with warm soapy water and allowed to air dry. Once completely dry, the read chamber may be replaced in the system. For instructions on further cleaning of EnSURE™, please visit: help.hygiena.com/kb-doc/how-to-clean-the-instrument.
- If issue is not resolved, contact Scigiene for technical support.

Incorporating Certified CalCheck into a Quality Control Program:

The Certified CalCheck is designed to be incorporated into a quality control program that monitors and tracks performance of Hygiena luminometer(s). For optimum recordkeeping, it is recommended that a specific location be programmed in SureTrend™ data analysis software for measuring CalCheck on luminometer.

Storage & Shelf Life:

- Store at 10 – 25 °C (50 – 77 °F) in original packaging.
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- Take care to not press power button during storage as this will shorten battery life.
- Replace CalCheck as needed. Please return to Scigiene yearly for recertification
- Keep CalCheck in box when not in use.

Battery Replacement:

- When button cap glows red, CalCheck is not ready to perform a positive check and may be approaching end of battery life. Wait 2 minutes and try again. If red light continues to appear, battery should be replaced.
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Disposal:

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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.

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