

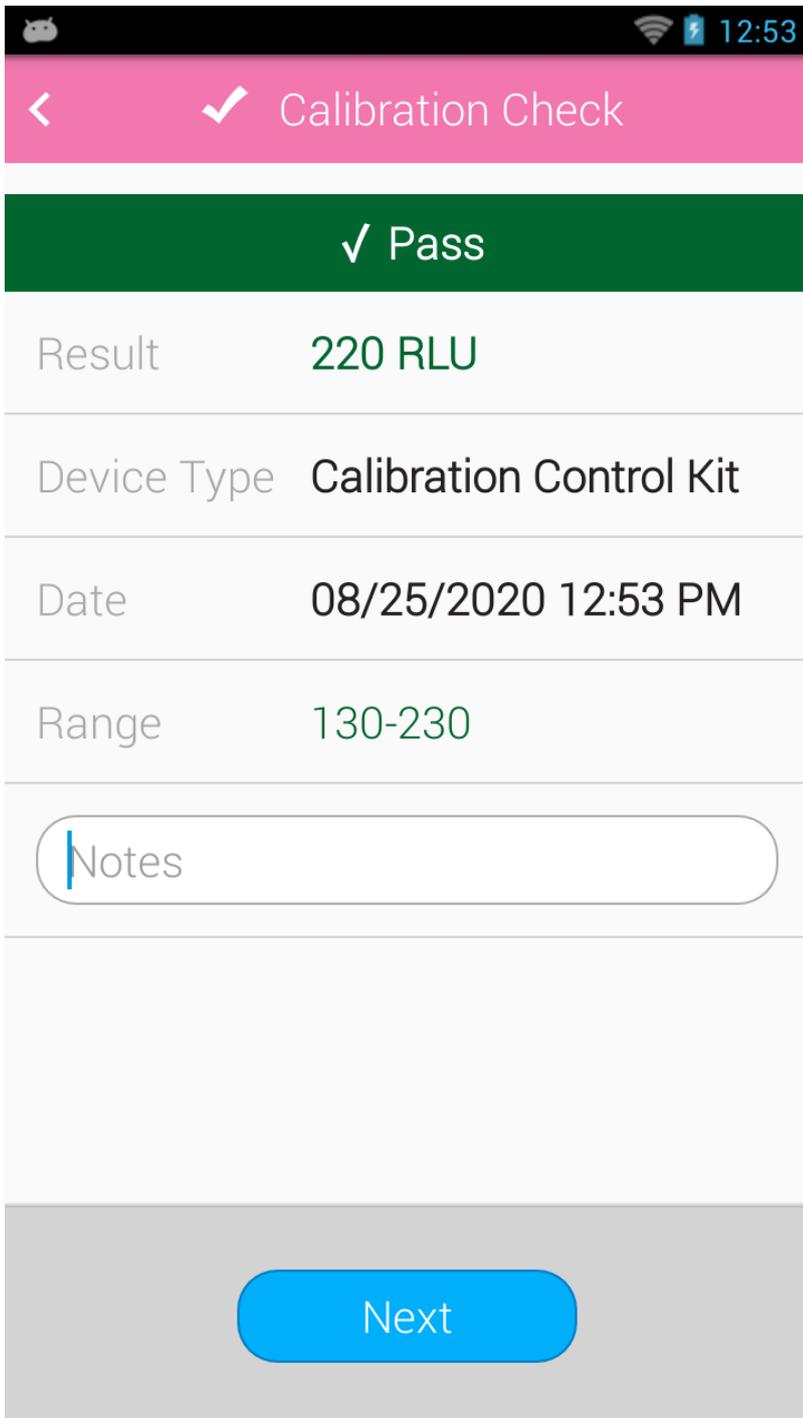
Calibration Checks in Simulation Mode

Introduction

EnSURE Touch offers a simulation mode that allows users to simulate equivalent RLU readings from another ATP luminometer. Calibration checks allow users to verify the accuracy of the instrument using calibration devices like the [CalCheck](#) or [Calibration Control Kit](#). This article will discuss how simulation mode affects calibration checks and what values users should expect for passing results.

Calibration Checks

Under non-simulated, or native settings, the positive test range for calibration checks are 130—230 RLU for Calibration Control kit and 255—345 RLU for CalCheck. The negative test range is 0—4 RLU for an empty chamber, inactive ATP test device, or negative control rod from the Calibration Control kit. Simulating another instrument does not change the RLU values to the simulated instruments values during calibration checks. Users should expect RLU values within the respective target ranges previously mentioned, even while simulating another instrument. For instructions on how to perform a calibration check, please see this [instructional video](#). For more information regarding calibration targets, please see the [Calibration Target Comparison](#) section of the EnSURE Touch manual.



If your instrument is failing calibration checks, please contact Hygiena Technical Support for further assistance by clicking [here](#).

EnSURE™ Touch In Field Calibration

Introduction

Each EnSURE Touch instrument undergoes an End Of Line (EOL) QC process during manufacturing. This EOL process is used to validate the instrument and configure the EnSURE Touch for consistency. Some of the key steps in the EOL process are to calibrate the device detection sensor, light detection sensor, and accelerometer. The calibration data is stored on each EnSURE Touch.

If the calibration data were to get damaged or reset to defaults the instrument would not work correctly. Today the only way to correct the instrument is to run it through the EOL process again. The following instructions show you how to recalibrate in the field

Prerequisites

You will need the following:

1. Windows TeamViewer client
2. Internet access for your windows computer and the EnSURE Touch to be updated.
3. EnSURE Touch unlocking tokens. Request a token from the Software Development Team. No more than 24 hr prior to the field calibration event as the token will expire
 1. You will need the customers' serial number that they can copy from the back of the unit and share it with a tech support person via email to create the token.

Customer will need the following:

1. EnSURE Touch instrument preferably connect to power.
2. WiFi/Internet access for the EnSURE Touch.
3. CalCheck or calibration control kit.

1. Optionally a SystemSURE Plus or EnSURE.
2. Optionally a second EnSURE Touch or a second CalCheck.

Steps for In-field Calibration

Step 1 (Customer)

Connect the EnSURE Touch to WiFi (internet).

Settings/WiFi

Wifi needs to be turned on for this process



Step 2 (Hygiene Rep)

Launch TeamViewer QuickSupport

Settings/Support

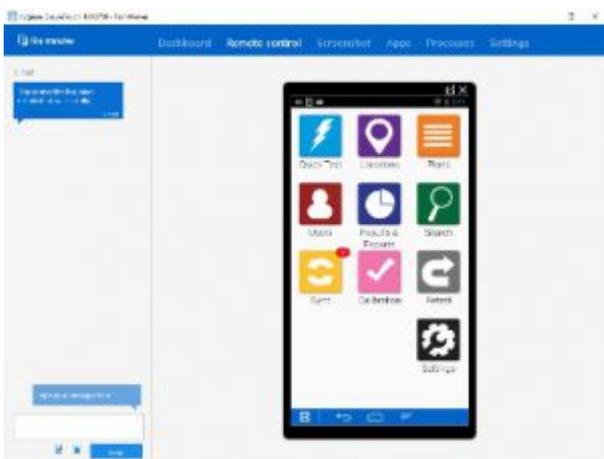
Follow the steps and launch TeamViewer QuickSupport

If the "Your ID" does not supply a number, the internet connection is not working, and a firewall or router is blocking your access, and support will not work. There is a rare case that TeamViewer service is down.



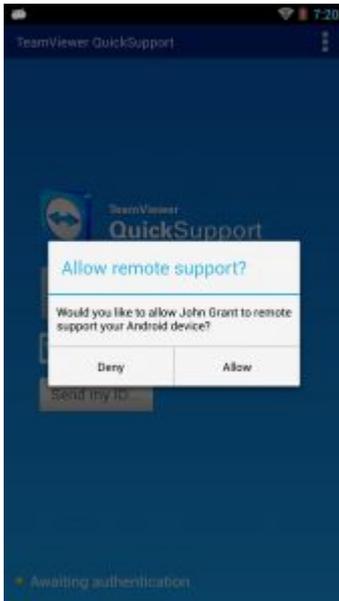
Step 3

Use Windows TeamViewer client to connect to the instrument.
You will need the user TeamViewer ID.



Step 4

Users must allow access by pressing the Allow button.



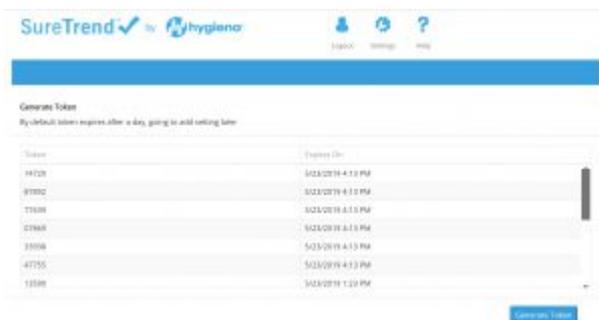
Step 5

Acquire unlocking tokens from <https://SureTrend.Hygienea.com>

You will need to have the Hygienea Support Role.

Please See Software Development to set up a role.

Press the Generate Token



Step 6

Unlock the instrument.

Settings/Diagnostics/Debugging



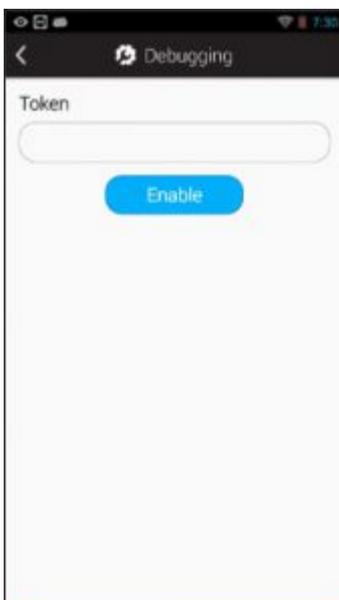
Step 7

Enter the unlocking token and press the Enable button.

This should only take a few seconds.

If it fails the internet is not working, the date and time on the instrument is incorrect, or the token is incorrect.

Tokens are acquired for the system than are connected to. Today we have 4 systems, Production, Stage, Test, and Dev. If the instrument is pointing to production, you need unlocking tokens from production.



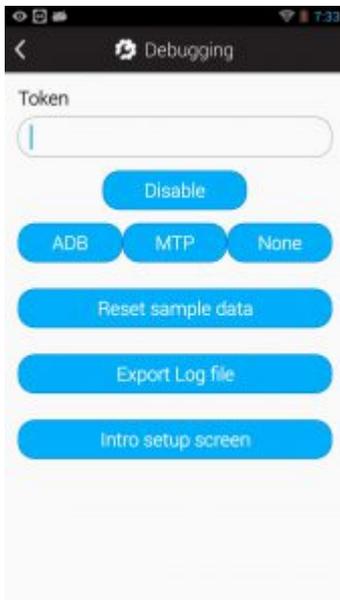
Step 8

If the unlock was successful you will see an addition buttons on your EnSURE TOUCH.

The instrument is unlocked.

*** Warning ***

Be very careful the instrument is unlocked, and you can perform many functions that could damage customer data or leave the instrument unusable. We should never leave an instrument unlocked. You can press the None button and then the Disable to lock the instrument. Locking the instrument is covered later in this document.



Step 9

Press the Home button.

Then press Settings/Diagnostics to get to the unlocked diagnostics screen.

You will see a lot more options available for you to use.



Step 10

Select the Light Test from the menu.



Step 11

Select the Setting tab on the top to get to the setting.



Step 12

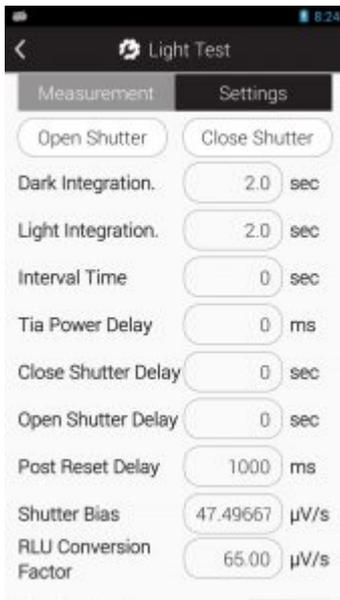
Just calibration troubleshooting - Good information and confirmation that the calibration is the only issue.

Note: the Shutter Bias and RLU Conversion Factor values.

The Shutter Bias should be set from the Light Detection Test in the EOL process.

If the Shutter Bias is 0 the entire EOL process needs to be executed.

The RLU Conversion Factor should not be 65.0, if it equals 65.0 then the unit has most likely lost its calibration values. Note the current RLU Conversion factor in the CRM Case. Generally, a number less than 65.



Step 13

1st step of calculating the calibration in the field.

Press the Measurement tab on the top.

Perform a screen capture and save for further reference if needed. Attach an image to the CRM case.

Place the CalCheck in the instrument, press the button at the top of the CalCheck. The CalCheck button should turn green. If it turns red or does not light at all it is not working.

And would need a new CalCheck battery.

Close the lid and press the Run Test Button within 10 seconds.

The CalCheck will only stay on for 60 seconds.

The Device does not need to be changed and no other values should be changed.

After reading the Run Test button will return and data will be populated in the table show here.

Use the **Diff $\mu\text{V/s}$ *** value to calculate the correct RLU conversion factor as follows:

*if value fluctuates by more than 5% then repeat the test with the same freshly activated CalCheck unit.

The light source is only on for 60 sec. If it continues to fluctuate by more than 5%

stop process and proceed with a new CalCheck or initiate the repair process.

RLU Conversion Factor(RLUCF) = Round-Up to one decimal point (13994.15/300) = 46.7 : 300 represent the median signal value that the CalCheck is adjusted to when the calibration LED are produced.

300 is the target RLU value expected when using CalCheck.

For Calibration Control Kit the median target is 180 RLUs. So the RLU Conversion Factor would be: RLU Conversion Factor = Round Up (8406.00/180,1) = 46.7

Repeat Calibration step 12. **Two** more times writing down the ***Diff uV/s*** value and calculated RLUCF

Average the three RLU Calibration Factors(RLUCF) as follows:
(RLUCF#1+RLUCF#2+RLUCF#3) / 3 (number of tests)

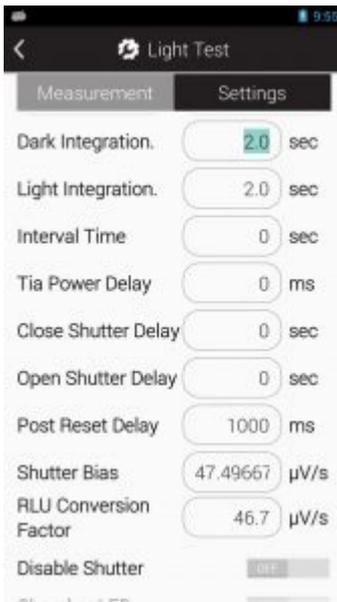
Record all calculations and the new Average RLU Correction factor in the Case in CRM.



Step 14

Press the Settings Tab at the top and enter the calculated average RLU Conversion Factor from the previous step. The customer must use the EnSURE touch key touch screen to edit the RLU Conversion Factor. Team viewer will not update the instrument settings you need to input on the unit itself.

Example, 46.7



Step 15

Test the new setting.

Press the Measurement tab at the top.

Place the CalCheck in the instrument, press the button at the top of the CalCheck. The CalCheck button should turn green. If it turns red or does not light at all it is not working.

Close the lid and press the Run Test Button.

The Device does not need to be changed and no other values should be changed. After reading the Run Test button will return and data will be populated in the table shown here.

The RLU values should be ~300 RLUs and between the acceptable range from 255 to 345 RLUs. In general, it should be much closer. If the number is off, you may want to repeat the process.

The instrument should be calibrated. Not it is important to lock the instrument.



Step 16

Press the back button from the Light Test screen.

This will show the Diagnostics menu.

Press the Debugging menu.



Step 17

From the Debugging Screen press the None button.

Then Press the Disable button.

Then Press Home

You can validate by navigating to Settings/Diagnostics.

It should be lock and require unlocking keys.

This should lock the instrument.

Reboot the instrument

Done!



Failing Calibration: Troubleshooting Tips

Overview

If you are seeing RLU reading that vary by more than +/- 10% on the CalCheck or Calibration Control Kit when read on the EnSURE Touch, this document will walk you through the potential reason, troubleshooting steps or allow you to get the product returned for repair.

Common Reasons for Issue

1. Reading chamber has gotten dirty and the lens protecting the reading sensor is cloudy/blocked
2. Instrument lid is loose and not sitting perfectly closed and light is leaking in
3. CalCheck is expired or damaged

4. Calibration Control Rod is expired or damaged
5. EnSURE Touch will only read 0 to 4 RLUs with either CalCheck or Calibration Control Kit

Troubleshooting and Solutions

The following are steps to determine what the issue is and how to resolve:

Reading chamber has gotten dirty and the lens protecting the reading sensor is cloudy/blocked

1. Erratic readings are sometimes caused because the liquid has gotten into the reading chamber and dried on the lens that the sensor reads through.
2. On the bottom of the instrument, unscrew the chamber cleaning hole with an allen wrench or flat head screwdriver.
3. Take a slightly damp swab (Q-tip) and clean the lower part of the read chamber. Do not press too hard on the clear plastic chamber. You should be able to see the sensor.
4. Let dry. The chamber is liquid-tight so you shouldn't have to worry about excess liquid getting into the chamber.
5. Screw back in chamber screw so that it is flush with the bottom of the instrument.
6. Take reading with CalCheck or Calibration Control Rod to see if readings are within specifications.

If readings are not within specifications, try the next troubleshooting step.

Note: If you are putting personal labels on Hygiene swabs, this can disrupt readings and also device detection. Do not put additional labels on Hygiene swabs. There is a space on the label to write information.

Instrument lid is loose and not sitting perfectly closed

1. Look at the instrument lid and see if it is sitting perfectly closed properly.
2. The top of the lid should be perfectly flush to the top of the instrument.
3. Seam line should be consistent around the entire lid and you should feel the magnet pulling the lid shut as it gets close to the opening. Dirt can get in the grooves and hinge that might prevent the lid from closing all the way. Clean out any debris that might prevent the lid from shutting

completely.

4. If the lid is fine and you are still getting erratic readings, look at the other troubleshooting issues.

CalCheck Rod is Expired or Broken

1. Check the expiration date of the [CalCheck](#). If it has expired, you should buy a new CalCheck.
2. If the CalCheck rod is still good, look for physical damage to the rod. Press the button on the top of the CalCheck to make sure the light turns "green". If the light turns "red" you will need to replace the battery in the CalCheck itself.
3. If there is no damage to the CalCheck and the button on the top is still turning green, then try running the CalCheck in another EnSURE Touch or Hygiena instrument if you have one. If the readings are within specifications that means the CalCheck is working properly and there is an issue with the EnSURE Touch.
4. If your CalCheck is reading the same number each time on the EnSURE Touch, but it's out of the acceptable calibration ranges established on the instrument, the system can be recalibrated to the CalCheck without having the instrument sent in for repairs.

If you still need help [click here to submit a ticket for technical support](#). Be prepared to share your RLU values from your CalCheck.

Calibration Control Rod is expired or damaged

1. Check the expiration date of the Calibration Control Kit rod. If expired, buy a new [CalCheck](#) kit.
2. If the Calibration Control Rod rod is still good, look for physical damage to the rod around the end of the rod where the sensor reads the light. Clean if there is any film or debris on the bottom.
3. If no damage to the Calibration Control Rod, then try running the Calibration Control Kit in another EnSURE Touch or Hygiena instrument if you have one. If the readings are within specification it means the Calibration Control Rod is still good and there is something wrong with the EnSURE Touch. Click [here](#) to submit a return ticket to have your instrument repaired or replaced.

4. If your Calibration Control Rod is reading the same number each time on the EnSURE Touch, but it's out of the acceptable calibration ranges established on the instrument, the system can be recalibrated to the Calibration Control Rod without having the instrument sent in for repairs.

If you still need help [click here to submit a ticket for technical support](#). Be prepared to share your RLU values from your Calibration Control Rod.

EnSURE Touch Will Only Read 0-RLUs with Either CalCheck or Calibration Control Kit

1. If you have confirmed either the CalCheck or Calibration Control Kit are still working correctly and the EnSURE Touch will only give you 0-RLUs, the shutter has likely been damaged from either being dropped or liquid has gotten onto it and dried it shut. The instrument will need to be repaired.



2. To verify the shutter is stuck, go to , put in a swab, CalCheck turned on or Calibration Control Kit. Take a reading.
3. Around the 4-3 second reading time, listen for the shutter to move back and forth. It will move back around 4-3 second mark and shut around the 2-1 second mark. If you do hear the shutter opening, it is working and there is likely something else going on. [Click here to submit Tier 3 issue ticket](#) and a technical representative will get back to you quickly.
4. If you do not hear the shutter moving the instrument needs to be repaired.

If you still need help [click here to submit a ticket for technical support](#).

EnSURE™ Touch Only Reads 0 RLU

Introduction

If EnSURE™ Touch only reads 0 RLUs with a [CalCheck](#), [Calibration Control Kit](#), or when you intentionally grossly contaminate a Hygiena™ ATP test device (ie. swab your hand) it is likely the shutter has become dislodged or stuck. This can happen if the instrument is dropped without the protective case on or if liquids are trapped in the read chamber, leaked into the shutter compartment and caused the shutter to become stuck. Most likely you need to send the instrument in for repair. However, we would like you to verify the shutter is stuck before sending in. Follow the instructions below to verify the shutter is stuck.

How To Troubleshoot a Stuck Shutter on EnSURE™ Touch



- Go to Quick Test
- Place a Calibration Device (CalCheck or Calibration Control Kit) or Hygiena ATP device (activated or unactivated) into EnSURE Touch and shut lid.
- Run Test
- During the 10 second count down around the 4-3 second mark and 2-1 second mark you should hear the shutter open and close. If you do not hear any mechanical click, it means the shutter is stuck.

If you still need help [click here to submit a ticket for technical support.](#)

CalCheck Negative Control Failing

Introduction

If when reading an unactivated ATP test, an activated ATP test that hasn't swabbed a surface or running the negative calibration check with the CalCheck results > 4 RLUs there could be some light leakage into the chamber or some phosphorescing material in the chamber around the sensor. Some good examples are:

1. EnSURE Touch lid is not closing completely and or the lid is damaged.



2. The read chamber plug at the bottom of the EnSURE Touch is not screwed all the way into the base of the unit.



3. Cracks in the case. While the EnSURE Touch has a light-tight inner chamber it is possible cracks or broken parts of the case could allow light into the chamber.

4. Phosphorescing or light-emitting material has gotten into the chamber by the sensor and dried to the surface. This can include:

a. Chemistry from the ATP devices if the device was not used correctly and chemistry from the device was able to get on reading chamber walls. Example: placing the EnSURE Touch on a flat surface while the device is still in the chamber.

b. If the user added their own white labels to the CalCheck control calibration device. (White labels will generate RLU signal)

5. To detect a light entering the chamber have everything ready to run the test and shut the lights off for complete darkness to verify that there is no light entering the chamber.



6. If your unit is still failing please see our How to Clean your instrument related article below and then repeat the test.

If you still need help [click here to submit a ticket for technical support.](#)