

Advisory Notice

Date Released: 2016-August-29

Posted By: Quality Control

Effective Date: 2016-August-29

Product Affected: Lumax

Brief Description of Advisory: E1 Range Change, Critical for TSH CLIA

To whom it may concern,

Recent product improvements to Monobind TSH Tracer *increase assay sensitivity* resulting in a greater light output for calibrators and samples which necessitates a change to the current settings (factors) in the Lumax instrument. These factors are related to light-tolerance range and embedded in the program by Monobind to assure assay performance. When violated an E1 (too much light) or E2 (too little light) message will display in the results. It is not necessary that the end-user understand these meanings, but it is an important diagnostic tool for technical support when reviewing any invalid assay.

It is now necessary that the **E1 value** be updated in the instruments and this can be accomplished with a few steps in Version K EPROM or with a replacement EPROM for earlier versions. Additionally, users can request upgraded EPROMs to receive the new setting and new test information from Monobind.

Identify EPROM version

Upon power-up of machine, the EPROM version is printed.

Version I (or earlier) EPROM

Request replacement, new version EPROM from Monobind at techsupport@monobind.com please include your SN #s and how many you require

Version K EPROM

The range can be modified with the following

- 1) Turn on Lumax
- 2) Press "Menu" button
- 3) Press "No" button to override warmup
- 4) Type "240" and press Enter. This test will show the current Luminescence Factor (LFac) range. The default is Lo = 0.3 and Hi = 8. Please write these values down.
- 5) Press "Menu" button. Type "241" and press Enter. This test will allow editing of the LFac ranges. Please enter **0.1 for "Lo" and 8 for "Hi"** and press enter.
 - a. If passwords have been set and the system is CLOSED, only the Administrator can run Test 2411
 - b. If passwords have been set and the system is OPEN, both Administrator and User with passcode can run TEST 241.
- 6) Press "Menu" button and type "240" and press Enter to verify your LFac ranges are Lo = 0.1 and Hi = 8.

7) Confirm by running a TSH CLIA assay

Please note:

IMPORTANT! Both factors must be entered in TEST 241 - if the HI factor is not entered the firmware will set it to 0.0. Please edit the factors to:

E1 < 0.1

E2 > 8

The firmware will NOT return to the default value of 0.3. Once the factor is changed to 0.1, it will remain 0.1. Should you require any additional assistance, please do not hesitate to contact us.

As an official of the company, I verify this information to be true and correct.

Sincerely,



Anthony Shatola
Quality Control Director