

Field Safety Notice

Product code and description: IE700 - Optilite Analyser
Software Version: 7.0 & 7.0.1
Reference: GLB132169
Date: 09 April 2020
Action: **Optilite Software Version 7.0 / 7.0.1 – Recalibrate all Optilite assays and ensure single reagent lot use.**

Dear Valued Customer,

We understand that your laboratory is running the Optilite Analyser Software Version 7.0 or 7.0.1 and need to inform you of a rare but potentially occurring software issue.

Summary of issue: The Binding Site has determined the potential occurrence of the issue to be very rare and the clinical risk to be unlikely. The software bug is not assay specific and if it occurs, it may cause a result to be calculated against a previously validated, although historical calibration curve for the affected assay. Therefore, there is the potential to affect result accuracy. However, a number of pre-conditions are required to occur for the issue to present, which makes the potential of its occurrence to be very rare and it may not occur at all.

Actions to be taken by the user:

The Binding Site are taking action to correct the software bug in Software Version 7.0.2 and request that the following instructions are followed to ensure the issue cannot occur:

1. Upon the receipt of this notice perform a full re-calibration of all assays. Only one kit lot of each assay should be calibrated.
2. Ensure only one kit lot for each assay is in use for testing.
3. To re-calibrate assays, even if not prompted by the software, when any parameter changes are made including minor parameter changes in the test definitions screen, or the QC triggers (see list of relevant parameter changes at the end of this document).

These actions must be followed until Software Version 7.0.2 is provided. In the meantime, should you have any additional questions on this, please contact your local Binding Site technical support.

Details of affected devices:

This Field Safety notice (FSN) affect Optilite analyser (IE700) running Software Version 7.0 and 7.0.1.

Please complete, sign and date the attached form (*TSWS18 E-Back Form*) as acknowledgement of this notice and associated advice.

The Binding Site apologises for the inconvenience caused.

Kind regards,



Colin Booth
Quality and Regulatory Director

Associated Document:

- *TSWS18 E-Back Form*

Transmission of this Important information:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action until Software Version 7.0.2 is provided to ensure effectiveness of the corrective action.

Should you require any further information please contact

Your local Binding Site Representative

or

Technical Support Group

UK: +44(0) 1214569696

Technical.support@bindingsite.com

List of minor parameter changes which should be followed by calibration:
1. Switching a test out of use and back into use
2. Changing sample acceptance between automatic and manual mode
3. Changing the measuring units
4. Changing the number of decimal places
5. Adding a reference range
6. Adding or changing the TVR limit (for selected assay)
7. Adding critical limits
8. Adding a QC procedure
9. Changing QC acceptance between manual and automatic
10. Changing the QC triggers, including selecting and deselecting