

PRODUCT RECALL MARKET WITHDRAWAL FIELD CORRECTIVE ACTION NOTIFICATION

TO: All users of the Thermo Scientific Indiko, Indiko Plus, Gallery, Gallery Plus and Gallery Plus Beermaster analyzers

FROM: Thermo Fisher Scientific Oy, Clinical Diagnostics Finland

DATE: September 11, 2013

SUBJECT: Continued ON-HOLD for Indiko models while new SW is tested

IMPORTANT NOTIFICATION

for all users of the Thermo Scientific Indiko, Indiko Plus, Gallery, Gallery Plus and Gallery Plus Beermaster analyzers

----- Continued ON-HOLD for Indiko models while new SW is being further tested -----

Description: During the internal test runs a bug in the new software with potential risk of mis-match of dispensed reagent was identified. This causes a potential risk of wrongly reported results for the Indiko and Gallery basic models. In the Plus models there is no risk for wrongly reported results.

Root cause: The software may handle the reagent barcode identification incorrectly. It will happen only, if the user over time has inserted 10 or more different lots of the same system reagent. In the Plus models, the instrument will not allow the 10th system reagent lot to be used. In the Basic models, there is a risk of reagent mismatch.

Immediate actions: To avoid mis-match of reagents, you MUST perform Clear Rack - command when a reagent rack is removed from the instrument. Otherwise the instrument will reject the new lot from the 10th lot onwards.

Please also note that the on-hold time frame is extended to Sept 20th, 2013.

Corrective actions:

- Bug fix and launch of sw 5.0.1.
- SW expected to be released after extensive testing on Sept 20th, 2013.
- Mandatory update of software once released.

We are extremely sorry for the inconvenience caused. We ask for your continued understanding while we take an additional 2 weeks to run the tests and validate the SW.

For any questions, please feel free to contact us at info.cdx.fi@thermofisher.com.

Sincerely,
Päivi Sormunen
Director of Quality, Regulatory and Compliance
CDD Finland
Thermo Fisher Scientific Oy

END-USER CONFIRMATION

ref. IMPORTANT NOTIFICATION dated Sept 11th, 2013
regarding software issue with Indiko and Indiko Plus instruments

Distributor/Sales office: _____

I hereby acknowledge the receipt of the Important Notification
letter from Thermo Fisher Scientific Oy, concerning software
issue in Indiko and Indiko Plus analyzers dated Sept. 11th, 2013

Signature: _____ Date: _____

Name: _____

Title: _____

Please sign and return this page to your local sales office:

CONFIRMATION OF INFORMING CUSTOMERS

ref. IMPORTANT NOTIFICATION dated Sept 11th, 2013
regarding software issues with Indiko and Indiko Plus
instruments

Distributor/Sales office: _____

I confirm that we have informed our affected customers about
issues mentioned in the above Important Notification.

Signature: _____ Date: _____

Name: _____

Title: _____

Please sign and return this page back to us, after you have
informed your affected customers, to:

Thermo Fisher Scientific Oy
CDD / Hanna Valo
P.O.Box 100
FI-01621 Vantaa
Finland

A scanned version can also be sent to:
hanna.valo@thermofisher.com