Urgent Field Safety Notice
Phadia 1000
Corrective action

Date: November 18, 2014

Dear Phadia 1000 Customer,

We are writing to you concerning an issue regarding all instrument software (ISW) versions of the Phadia 1000 instrument (Part Number 12-3800-01). During an investigation of instrument log files we discovered that erroneous results could potentially occur if samples with a barcode reading problem are handled in a certain fashion. This problem can occur when responding to the error: 0-1502 BAR CODE ERROR (Sample Rack), in combination with other events more fully described below. This problem can result in wrong results being reported, as the instrument will be sampling from the incorrect sample rack.

Product affected:

This product correction applies to all Phadia 1000 instruments (Part Number 12-3800-01) and ISW versions since the introduction of the Phadia 1000 (originally introduced as the UniCAP 1000).

Description of the problem:

In specific circumstances involving multiple steps, a rack sequencing error may occur. This will result in a mismatch between the sample ID and the test result reported for all subsequent sample racks in that run. If this sequence of events occurs, an additional error message ("1-034") will be generated whenever samples in the last rack are due to be aspirated.

The initial rack sequence error will occur when the following chain of events takes place:

1. A barcode reading error 0-1502 occurs (Error #1)
2. The operator then selects "Enter ID" in order to manually assign the sample tube a sample ID number
3. Another error message of any kind occurs (Error #2) before the sample ID is entered (the "Enter ID" screen remains open on the instrument)
4. When more than 5 minutes elapse after "Error #2" occurs, but before the "Enter ID" screen is closed by the operator, a third error (Error #3) occurs which requires a response from the operator
5. The operator then closes the "Enter ID" screen by touching either the "Rack Pass" or "Back" buttons on the touch screen

After the fifth step, the instrument ejects two racks after sampling instead of the designated, single rack. From that point onward in the assay run, the instrument aspirates from the rack after the one intended. This sequence of errors then results in a mismatch between the sample ID and the sample actually tested.

Risk to health:

For this rack sequencing error to happen, a series of manual (operator responses) and instrument generated error events needs to occur in the specific sequence described above. Accordingly, the frequency of this error to occur is estimated to be remote, but will vary depending upon the laboratories' routines. During the over ten years that the system has been on the market, no known instances of patient harm have been reported that can be associated with the rack sequencing error described above.

Analytes affected by this Product Correction:

- ImmunoCAP Specific IgE
- ImmunoCAP Total IgE
- ImmunoCAP Tryptase

Actions to be taken by the customer/user:

We recommend that you review your internal operating procedures to help you determine whether your laboratory may have been affected. For example, if your lab does not routinely utilize the "Enter ID" feature when there is difficulty reading the barcode, then your laboratory may not have been subject to this error. Since the problem described in this letter will generate multiple QC failures, as well as other errors when trying to aspirate sample from a missing rack, QC and/or instrument error investigation procedures should prompt the user to investigate the error situation, resulting in the compromised patient/QC samples being identified. This would further reduce the likelihood of incorrect patient results leaving your laboratory.

We will be providing a software update to correct the above described scenario. In the meantime, we strongly recommend that all instrument operators are instructed to take the following actions.

If a user is presented with **a 0-1502 error, BAR CODE ERROR (Sample Rack):**

- **select "Pass" (i.e., do not select "Enter ID"), or**
- **do nothing (since the error will be automatically released after more than five minutes).**

Any sample with a barcode reading error will then not be processed. It may be processed later in the run after the sample rack has been ejected from the sampling area.

Actions to be taken by the manufacturer:

Phadia AB will have a revision to the current ISW 2.30 (2.30-2) available before year end. This is a mandatory upgrade for all Phadia 1000 instruments. A Phadia local representative will be contacting you in regards to the installation of this mandatory software upgrade at a later date.

Phadia will have a revision to the current ISW 2.30 (2.30-2) available soon. This will be a mandatory upgrade for all Phadia 1000 instruments. A member from our Technical Support staff will be contacting you in regards to the installation of this mandatory software upgrade at a later date.

Transmission of this Notification:

Please ensure that this notice is shared with anyone who needs to be made aware within your organization, or to any organization on which this notification potentially has an impact.

Phadia needs your assistance with our efforts to process this Product Correction. We are requesting that a responsible member of your laboratory sign and return a copy of the attached Acknowledgement Form to verify receipt of this letter. Please complete the last page of this letter and either scan/email or FAX it to:

TBD, commercial Organizations contact person:
Name
Address
Telephone
E-mail

We apologize for any inconvenience this may cause.

If you have any questions, please contact us.

Sincerely,

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Phadia 1000 ISW Product Correction Notice

The information in the Phadia 1000 ISW Product Correction Notice has been read and understood by our laboratory. We acknowledge that this information applies to the Phadia 1000 instrument (all ISW versions) and will be communicated to all Phadia 1000 operators until such time as the ISW upgrade has been performed (version ISW 2.3-02) on your Phadia 1000 Instrument(s).

I hereby acknowledge receipt of this notification: FSN 2014-04 Phadia 1000

Date::_____

Signature:_____

(Please print name):_____

Name of
laboratory:_____

E-mail a signed, scanned copy or fax to (*to be defined by Commercial Organizations*):

Name
ImmunoDiagnostics
Thermo Fisher Scientific

Address

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Document name FSN 2014-04 Phadia 1000 Europa, ROW Number 584789 Version 1.0

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