URGENT FIELD SAFETY NOTICE
Phadia 1000, all Instrument Software (ISW) versions

[Insert date]

[Insert Customer or Distributor name
Attn:
Customer / Distributor address]

Dear <insert Customer name or> Thermo Fisher Scientific Dealer Partner:

The purpose of this letter is to advise you of an issue with the instrument software (ISW) for the Phadia 1000 Instrument, article number 12-3800-01. This issue will be corrected through a mandatory update to the ISW version on your Phadia Instrument.

REASON FOR THIS FIELD CORRECTION:
This issue can occur with all Phadia 1000 instruments (article number 12-3800-01) and ISW versions since the introduction of the Phadia 1000 (originally introduced as the UniCAP 1000 or ImmunoCAP 1000), under certain specific scenarios as described below.

An error handling issue for code 7-101, Liquid Sensor Error, has been reported on the Phadia 1000 instrument. When error 7-101 occurs, ImmunoCAP dispensing will stop, whereas already dispensed samples will continue to be processed. Due to an ISW issue, the “Retry” command, used to clear this error, does not function properly and there will be no further pumping of Wash and Rinse Solution during the processing of the dispensed samples. Thus, if the error code 7-101occurs during the assay run, there may be a shortage of Wash and Rinse Solution that will affect assay performance and test results if the operator chooses to respond to the error with the “Retry” command.

Current instructions in response to the 7-101 Liquid Sensor Error allow the operator to respond with either the “Stop” or “Retry” command with the following outcomes:

- The “Stop” command will stop ImmunoCAP dispensing and all processing tests will be flagged as erroneous. All samples will have to be rerun and no erroneous test results will be reported out.

- The “Retry” will stop ImmunoCAP dispensing, while already dispensed samples will continue to be processed, and test results will not be flagged as erroneous. There may however, be a shortage of Wash and Rinse Solution and erroneous test results may be reported out.

The frequency of this error to occur is estimated to be remote. During the 10 plus years that the system has been available on the market, we are not aware of any previous complaints or adverse events as a result of Wash Solution buffer bottle level sensor error 7-101.

RISK TO HEALTH:
If the response to error code 7-101 is "Retry", erroneous results for ImmunoCAP specific IgE, Total IgE, Tryptase, Specific IgG, Specific IgG4 and Eosinophilic Cationic Protein (ECP) could occur. An erroneous result means that the reported value may be higher or lower than the real value. This may cause a delay in a proper diagnosis, however, the probability of a serious adverse health consequence or serious deterioration in state of health due to a delayed diagnosis is estimated to be remote.

PRODUCT AND DISTRIBUTION INFORMATION:

Product Names, UDI (if applicable)	**Manufacturer's Product No. / Catalog No.**	**Lot/Serial Number**	**Manufacturing/ Distribution Dates**	**Expiration Date (mm/dd/yyyy)**	**Quantity**
Phadia 1000, including all ISW versions	12-3800-01	All	All	N/A	All instruments

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:
A mandatory ISW update will be provided to correct the problem. In the meantime, we advise you to take the following actions:

- **All instrument operators are to be instructed that if the 7-101 error occurs, the "Stop" command must be selected. This will abort the run and results flagged as erroneous. Results from the assay run should not be approved.**

- Review records to determine if error 7-101 has occurred. If the instrument error message "*7-101 LIQIUD SENSOR ERROR (Wash upper ON lower OFF*)" has been reported, we recommend to contact Customer Support who can further assist in collecting log files and assess possible impact on the test results in scope.

- Please fill in the Field Safety Notice return response on page 4 and return to ImmunoDiagnostics by e-mail or fax provided in the response form attached.

ACTIONS TO BE TAKEN BY THE MANUFACTURER:
- Phadia AB will have a revision of the current ISW version available soon
- This revision will be a mandatory ISW update for all Phadia 1000 instruments
- A member of our Technical Support staff will be contacting you in regards to the scheduling of this mandatory software installation

We appreciate your immediate attention to this field correction. By returning the attached Acknowledgment Form you will facilitate our reporting of this matter to the authorities. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure accurate assay results.

If you have any questions, please contact <name, department, etc.> at <email address, phone number, fax number, etc.>.

Sincerely,

Name

URGENT FIELD SAFETY NOTICE
Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:
[Customer name
Attn:
Address]

Phadia 1000, all Instrument Software (ISW) versions

I have read and understand the attached Customer Letter and recall instructions: _____ (initials)

Any adverse events associated with the recalled product? _____ Yes _____ No

If yes, please explain:

_____

_____

AFFECTED PRODUCT INFORMATION:

Product/Brand Name (UDI, if applicable)	Manufacturer's Product No.	Affected Model or Lot/Serial No.		
Phadia 1000, including all ISW versions	12-3800-01	All		

Use additional sheet(s) if necessary.

RETURN RESPONSE (please provide additional information, if applicable):

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING EMAIL < > OR FAX NUMBER < >, ATTN: < >

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Email Address:	

Document name Field Safety Notice QA2017-05 - EU Number 638500 Version 1.0

Issued by Anna Lundh 2017-Jun-22 07:25 CET

Reviewed by Lena Kirsel 2017-Jun-22 09:01 CET

Approved by Fredrik Mirenborn 2017-Jun-22 10:07 CET
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