

Field Safety Notice Letter
ID: FSN2019-04

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE – IMMEDIATE ACTION REQUIRED
Phadia™ 1000
Model No: 12-3800-01
Serial No: All

[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 that Phadia AB, part of Thermo Fisher Scientific, is issuing a Field Safety Notification for all Phadia™ 1000 Instruments.

REASON FOR FIELD SAFETY NOTICE:

An error handling issue for code 7-102, Liquid Sensor Error, has been reported on the Phadia™ 1000 instrument, caused by liquid flow restrictions or signal errors. When error 7-102 occurs, ImmunoCAP dispensing will stop, whereas already dispensed tests will continue to be processed. When this error occurs within an assay run, Rinse Solution will stop being supplied to the Rinse Buffer Bottles until the “Retry” command is initiated to clear this error.

The “Retry” command must be pressed within six minutes, otherwise there may be a shortage of Rinse Solution that will affect assay performance and test results. If the operator responds to the error with the “Retry” command after six minutes there may be a risk that the assay performance will not recover, thus, they should instead respond with the “Stop” command, terminating the assay.

Current instructions in response to the 7-102 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, including all tests completed after the error 7-102 occurred so no erroneous test results will be reported.
- The “Retry” command will continue ImmunoCAP dispensing and test results will not be flagged as erroneous. There may however be a shortage of Rinse Solution and erroneous test results may be reported if the “Retry” command is not selected in the specified time frame, six minutes.

The frequency of this error to occur is estimated to be remote. There have been no reports of adverse event as a result of error code 7-102, Liquid Sensor Error.

RISK TO HEALTH:

If the error 7-102 is present and the “Retry” command is selected beyond the six minute limit, there may be a shortage of Rinse Solution that will affect assay performance and test results. This could cause falsely increased test results or falsely decreased test results for the ImmunoCAP Specific IgE, Total IgE, Tryptase, Specific IgG, Specific IgG4 and Eosinophilic Cationic Protein (ECP) methods, which could in worst case cause a delay in a proper diagnosis and treatment of the patient, 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 unlikely.

PRODUCT AND DISTRIBUTION INFORMATION:

Product	Model number	Affected Serial Number
Phadia™ 1000	12-3800-01	All serial numbers



ACTIONS TO BE TAKEN BY THE CUSTOMER/USER <OR DISTRIBUTOR>:

1. Review instrument record logs to determine if error 7-102 has occurred.
 - If error message 7-102 has been reported contact Customer Support who can further assist in collecting log files and aid in assessing the possible impact on the test results within scope.
2. Use of the Phadia™ 1000 can continue as detailed in the owners manual with the following changes:

If the error 7-102 occurs, ensure that the error is handled as stated below:

- Select “Retry” if the error occurs outside of Assay run. *This selection has no effects on assay performance in this situation.*
- Select “Retry” if the error occurred within Assay run in the previous six minutes. *This selection has no effect on assay performance in this situation.*

Note: If you are unsure of the six minutes related to the error occurrence, select “Stop”

- Select “Stop” if the error occurred within Assay run after six minutes as indicated in the system software. *Note: Performing a “Retry” or “Stop” after six minutes presents a risk that assay performance and results are affected. Selecting “Stop” will stop ImmunoCAP dispensing and all processing tests will be flagged as erroneous. Corrective actions can then be performed.*

3. Whether you selected “Retry” or “Stop”, contact Customer Support after attending to error 7-102 according to the instructions above to provide notification to our technical department and to receive additional guidance.

Additionally;

- Ensure that the sound alarm is audible and that the visible alarm is visible within the laboratory.
- Ensure that the criteria according to the user manual for incoming water (rinse solution) is met. Further, it is recommended to ensure that regular Monthly Maintenance with 1% Sodium Hypochlorite (bleach) solution is performed according to the user manual.
- Ensure Rinse and Wash Bottle Stems are correctly installed in their respective bottles and are refilled in a timely manner when the instrument is operated.
- Ensure Stop Solution bottles are full at the start of Assay run, otherwise switch bottle connector to second bottle loaded prior to the first becoming empty. *Note: Stop Solution bottles contain 1200 doses.*

Phadia AB will have an update of the Phadia™ 1000 instrument.

- This update will be mandatory for all Phadia™ 1000 instruments
- A member of our Technical Support staff will be contacting you in regards to the scheduling of this mandatory update.

TYPE OF ACTION BY THE MANUFACTURER:

Corrective and preventive actions (CAPA) have been initiated to prevent this from recurring.

If this letter is being sent to a **Distributor**, use the following paragraph as well if the Distributor will be conducting the recall in regard to its customers:

Our records indicate that you may have purchased one or more of the above products for re-sale to your customers. You should complete the attached Acknowledgment Form in regard to inventory you have received and/or which is still in stock. In addition, please contact your affected customer base, advise them of the situation, and provide them with a copy of this letter. You should insert your contact information, email and fax numbers in the Acknowledgment Form and request that they return the Acknowledgment Form to you. In addition, qualified product support technicians will be available to address any questions about the affected product at **<insert phone number>**.

We appreciate your immediate attention to this field correction. Please keep this notification on file. By returning the attached Acknowledgment Form you will facilitate our reporting of this matter to the appropriate Regulatory Authorities. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

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

Sincerely,

Name
Title

MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE

**Acknowledgment & Receipt Form
Response Required**

CUSTOMER/DISTRIBUTOR INFORMATION:

[Customer name

Attn:

Address]

All Phadia™ 1000

I have read and understand the information in the attached Filed Safety Notification FSN2019-04

_____ (initials)

Any adverse events associated with this Notification? _____ Yes _____ No

If yes, please explain:

AFFECTED PRODUCT INFORMATION [revise as necessary]:

Product	Model number	Affected Serial Number	Quantity
Phadia™ 1000	12-3800-01	All serial numbers	

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:	