# URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

## All Phadia Prime software versions up to and including version 2.1.4 when connected to Phadia 250, Phadia 2500E/EE and Phadia 5000E/E+E instruments

[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 Phadia Prime software for the Phadia 250, Phadia 2500E/EE and Phadia 5000E/E+E Instruments when running EliA tests. This issue will be corrected through a mandatory update of the Phadia Prime software.

**REASON FOR THIS FIELD CORRECTION:**
Erroneous results may occur as a result of a software issue when specific conditions occur with the Phadia 250, Phadia 2500E/EE and Phadia 5000E/E+E instruments. This issue can occur with all versions of the Phadia Prime software up to and including version 2.1.4 connected to the Phadia 250, Phadia 2500E/EE and Phadia 5000E/E+E instruments when running EliA tests under specific scenarios as described below.

The issue will cause the software to disregard default dilution factors for rejected samples, when using the “OK to All” function for retesting of samples if the following criteria are met:

- More than one assay result are rejected within the same method -AND-
- The rejected results are run with tests which have different default dilution factors

If the two above scenarios occur at the same time, all samples will be retested with the dilution factor based upon the first rejected sample and assay dilution factor. A dilution factor that is set too low for a particular assay will be detected by the Phadia Prime software and will not be accepted by the instrument. However, a dilution factor that is set too high will not be detected, and hence will not be flagged by the system and potential erroneous test results may be displayed.

The QC samples for EliA are prediluted and will not indicate any problems if this issue occur.

**RISK TO HEALTH:**
The issue described above can lead to erroneous results for EliA tests. An erroneous result means that the reported value may be higher or lower than the real value, and hence false negative or positive results may be reported. The issue may cause a delay in a proper diagnosis and treatment, neither diagnosis of any of the relevant diseases nor a change of medication for an already diagnosed patient would be based on a single test result but will always be judged in relation to the clinical symptoms of the individual patient. In case of a false test result, all available clinical and laboratory information would be evaluated to establish a definitive diagnosis and appropriate treatment.

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 | Manufacturer's Product No. / Catalog No. | Lot/Serial Number/Version |
|---|---|---|
| Phadia Prime software | 12-4101-00 | All versions up to and including version 2.1.4 |
| Phadia 250 | 12-3900-01 | All instruments connected to any Phadia Prime software version up to and including version 2.1.4. |
| Phadia 2500E | 12-4100-01 | |
| Phadia 2500EE | 12-4100-02 | |
| Phadia 5000E | 12-4000-01 | |
| Phadia 5000E/E+E | 12-4000-02 | |

**ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:**

A mandatory Phadia Prime software update will be provided to correct the problem. Until your instrument receives the revised software, the following mandatory actions are required to be taken:

- **All Phadia system operators are to be instructed not to use the function "OK to All" in all versions of Phadia Prime up to and including 2.1.4 when rejecting and retesting samples with any EliA assay assay** (the "OK" function may be used for rejecting single tests and dilution of samples in accordance with product DfU).

- Review test results to determine if any results may be affected:
  - The dilution factor used for each test and sample stated in the Phadia Prime Laboratory Report (i.e. column "Dil", third column) can be compared with the dilution factor stated in Direction for Use for the test.

We recommend that you review your internal operating procedures to help you determine whether your laboratory may have been affected. If you need support in evaluating whether your laboratory may have been affected by this issue, we recommend that you contact Technical Support, who can further assist in assessing possible impact on the test results in the affected assay run.

- Please fill in the Field Safety Notice Acknowledgement and return by e-mail or fax provided.

**ACTIONS TO BE TAKEN BY THE MANUFACTURER:**

- Phadia AB will have a revision of the current Phadia Prime software version available shortly. This will be a mandatory Phadia Prime software update.
- 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 safety correction. By returning the attached Acknowledgment Form you will facilitate our reporting of this matter to the local authorities. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure accurate test results.

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

Sincerely,

Name

**URGENT MEDICAL DEVICE FIELD SAFETY NOTICE**
**Acknowledgment & Receipt Form**
**Response Required**

**CUSTOMER INFORMATION:**
[Customer name
Attn:
Address]

**All Phadia Prime software versions up to and including version 2.1.4 connected to Phadia 250, Phadia 2500E/EE and Phadia 5000E/E+E instruments**

I have read and understand the attached Customer Letter and the Field Safety Notice Instructions: _____ (initials)

Responsible members of the laboratory staff and instrument operators have been informed of the short term correction to mitigate the risk of any incorrect EliA Assay results being reported: _____ (initials)

Our laboratory is ***not*** aware of any adverse events (incorrect patient results) associated with the affected Phadia Prime Software when used with the Phadia 250, Phadia 2500E/EE or Phadia 5000E/E+E instruments related to this specific error: _____ (initials)

If any incorrect patient results were reported due to this error, please explain below:

_____

_____

_____

**FFECTED PRODUCT INFORMATION:**

| Product Names, UDI (if applicable) | Manufacturer's Product No. / Catalog No. | Lot/Serial Number |
|---|---|---|
| Phadia Prime software | 12-4101-00 | All versions up to version 2.1.4 |
| Phadia 250 | 12-3900-01 | All instruments connected to any Phadia Prime software version up to and including version 2.1.4. |
| Phadia 2500E | 12-4100-01 | |
| Phadia 2500EE | 12-4100-02 | |
| Phadia 5000E | 12-4000-01 | |
| Phadia 5000E/E+E | 12-4000-02 | |

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: | |