FIELD SAFETY NOTICE
ACTION REQUIRED

Thermo Fisher Scientific Cascadion SM Clinical Analyzer
Software anomaly on Data Processing

January 25, 2021

Dear Valued Customer:

The purpose of this letter is to advise you that Thermo Fisher Scientific Oy, part of Thermo Fisher Scientific Inc., is conducting a Field Safety Corrective Action (FSCA) for the *in vitro diagnostic* product as listed below (Table 1). Our records indicate that you have purchased units of the affected product.

REASON FOR FIELD CORRECTION

It has been identified that there is a software anomaly in the Cascadion SM Analyzer Software subcomponent called Suhaili Service (version 2.0.3 and earlier) that is affecting the Cascadion SM Analyzer. Suhaili Service controls raw data processing based on assay configuration data from Sample Prep software. Processed results are sent to Sample Prep software for patient result reporting. This anomaly, as a result of this interface, has a potential risk of reporting wrong patient results for Vitamin D.
To date no incidents or injuries to patients have been reported.

The information related to Cascadion SM Analyzer Software provided in this letter serves as an immediate correction by adhering to the supplemental instructions until the current Cascadion SM Analyzer Software is updated. The software release is currently expected at the end of January 2021.

Table 1. PRODUCT INFORMATION

Product Name	Product Code	Analyzer Software version
Cascadion SM clinical Analyzer	99990000	Software 2.0.2 and earlier

The Thermo Scientific™ Cascadion™ SM Clinical Analyzers are fully automated liquid-chromatography mass spectrometric random access analyzers that are intended for the in vitro determination of a variety of analytes that may be adaptable to the analyzer depending on the assays used.

DESCRIPTION OF THE SOFTWARE ANOMALY

Thermo Fisher Scientific Oy has become aware that under certain infrequent circumstances, the software may falsely accept an Internal Standard chromatographic peak integration even though the peak's signal-to-noise (S/N) ratio does not meet quality

criteria set for the data and should normally reject the result without the software anomaly. Even though falsely results may occur, the data quality calculations and algorithms for the assays and the analysis tools for the data quality assurance are working according to specification. As an outcome of the software anomaly a peak in the chromatogram close to the analyte peak retention time can be mistakenly identified and integrated, resulting in false results.

IMPACT ON PATIENT RESULTS

A low risk of falsely reported Vitamin D patient results exists due to the software anomaly. Reported test results are assessed and interpreted by clinicians in conjunction with information known about the patient's medical history, clinical examination findings, and results of other diagnostic tests. An unexpected abnormal test result(s) that does not correlate with the patient's clinical findings may be recognized and repeated by the treating provider before any targeted treatment measures are initiated.

This Software anomaly affect to the Cascadion Immunosuppressants Panel Assay (ISD Assay) is considered very low and unlikely due to the different parameter used in the ISD Assay.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

As an immediate correction the following instructions must be followed with Cascadion SM Clinical Analyzer Software versions 2.0.2 and earlier until the installation of the new software version 2.1.

1. Please change the Quick Connect Cartridge Cs on the instrument to new ones.
2. After the cartridge change, if a sample is reported to have concentration of total 25-hydroxy Vitamin D below assay measuring range, follow these instructions to prevent the error from being reported:
    a. Repeat the sample analysis with a Cascadion SM Clinical Analyzer
    b. In case the repeated result is below assay measuring range, the sample should be rerun on another assay and platform.
3. Retain a copy of this letter for your laboratory records.
4. As appropriate, contact your Medical Professional for evaluation of further action.
5. Please, fill out the MEDICAL DEVICE FIELD SAFETY NOTICE - Response Form and return it within 5 days of the date of this letter to your manufacturer as instructed in the form and as listed below:
   Email: vigilance.clinical.fi@thermofisher.com

TYPE OF ACTIONS TO BE TAKEN BY THE MANUFACTURER

1. Thermo Fisher Scientific Oy has informed the appropriate Regulatory Agencies, as appropriate, of this field safety corrective action.
2. When, available, the final corrective action will be to update Cascadion SM Clinical Analyzer software v2.1. Installation of the new software v2.1 is mandatory to all installations . You will be notified when the software update is available and this update will be provided to you free of charge.

We appreciate your immediate attention to this Field Safety Corrective Action. Please distribute this information immediately to any staff that may be impacted by this issue. 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 further questions, please contact your local Thermo Fisher Scientific representative.

Sincerely,

Rina Wahlroos
Director, Quality Systems and Compliance Affairs
Thermo Fisher Scientific Oy
Analyzers & Automation
Clinical Diagnostics

MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

Thermo Fisher Scientific Cascadion analyzer
Software anomaly on Data Processing

I have read and understand the attached Field Safety Notice and field action instructions: _____ (initials)

I understand that this applies to the medical device listed in Table 1 that I have received: _____ (initials)

Do you have any knowledge of adverse medical events associated with the products listed in this Field Safety Notice?
_____ Yes _____ No

If yes, please explain:

_____

_____

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

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL:
vigilance.clinical.fi@thermofisher.com

Signature of Acknowledgement and Receipt by Customer:

_____

Customer Name/Title:	
Date:	
Company/Institute:	
Telephone:	
Email Address:	

It is important that your organisation takes action as detailed in this letter and also replies without delay by using this response form. Your reply is evidence, which Thermo Fisher Scientific and Regulatory Agencies need to monitor the progress of FSCAs. Without your reply Thermo Fisher Scientific Oy cannot verify the effectiveness or completeness of this Field Safety Corrective Action.