May 03, 2023

FIELD SAFETY NOTICE
ACTION REQUIRED

Thermo Fisher Scientific Cascadion™ SM Clinical Analyzer
Incomplete attachment of the power cord

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 products listed below (Table 1). Our records indicate that you have purchased units of the affected products.

REASON FOR FIELD CORRECTION

It has been identified that incomplete attachment of the Cascadion™ SM Clinical Analyzer's power cord creates a risk of poor connection between the power cord and instrument and may result in a potential fire hazard or equipment breakdown.

Table 1. PRODUCT INFORMATION

Product Name	Product Code	Power Cord
Cascadion™ SM Clinical Analyzer	99990000	N15383 Cord Mains 2,5m CEE7/7- IEC320 C19 (EU); N15384 Cord Mains 2,5m BS 1363 - IEC320 C19 (UK)

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 ISSUE

Thermo Fisher Scientific Oy has received a customer complaint regarding the unplanned shutdown of a Cascadion™ SM Clinical Analyzer due to equipment failure. In addition to the instrument shutdown, it has been reported that the power cord mains connector had melted. Root cause investigation has identified that if the strain relief retaining clamp is not properly tightened against the power cord mains connector, it increases the risk that the connection between the power cord and instrument may become loose. A loose power cord connection creates the additional risk of heat generation within the power cord mains connector, creating the hazard of mains connector melting and analyzer shutdown.

IMPACT ON PATIENT RESULTS

There is no potential risk for wrong patient results. The risk associated with potential delay in results is low. To date no incidents or injuries to patients have been reported.

IMPACT ON USER

The use of an improperly attached power cord may lead to a potential thermal hazard. The likelihood of user injury is very low. To date no injuries to users have been reported.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

As an immediate correction the following instructions must be followed with Cascadion™ SM Clinical Analyzer:

1. You will be contacted by your local Thermo Fisher Scientific representative for further information and to agree the service visit. In case new power cord is required, it will be provided to you free of charge. You may continue using the analyzer until the service visit.
2. Retain a copy of this letter for your laboratory records.
3. As appropriate, contact your laboratory supervisor for evaluation of further action.
4. 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. Local Thermo Fisher Scientific representatives will contact the customer to schedule a service visit. During this service visit, the manufacturer representative will verify that the power cord mains connector is properly attached to the Cascadion™ SM Clinical Analyzer's appliance inlet, and that the strain relief retaining clamp is properly securing the power cord mains connector.
3. Thermo Fisher Scientific Oy is taking corrective actions to prevent recurrence of this issue.

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,

Electronically signed by: Rina Wahlroos
Reason: Approver of the GxP document
Date: May 3, 2023 13:01 GMT+3

Rina Wahlroos
Director, Quality Assurance and Regulatory Compliance
Thermo Fisher Scientific Oy
Clinical Diagnostics

MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

Thermo Fisher Scientific Cascadion™ SM Clinical Analyzer
Incomplete attachment of the power cord

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 and title:	
Date:	
Company/Institute:	
Telephone:	
E-mail:	

It is important that your organization acts as detailed in this letter and 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.