Abbott Diagnostics Technologies AS
Kjelsåsveien 161
P.O.Box 6863 Rodeløkka
NO-0504 Oslo, Norway

EN

Field Safety Notice

Immediate Action Required

Date Issued May 31 2023

Product

Product Description	Part Number(s)	Serial number(s)
Afinion 2 Alere Afinion 2	1116553, 1116556, 1116557 , 1116558, 1116597, 1116598, 1116679, 1116680, 1116681, 1116682, 1116684, 1116770 , 1116771, 1116772, 1116774 , 1116777, 1116778, 1117031, 1117132	All serial numbers with software versions ≤ 21.13

Note: All distributed Afinion 2 instruments had software versions ≤ 21.13 on 19 May 2023.

Explanation

Abbott has identified an issue related to overheating of Afinion 2 instruments with software version ≤ 21.13.

- The issue is related to occurrences where the lid motor remains in a high current mode for an extended time period due to a software defect.
- When the malfunction occurs, it is known to cause damage to the plastic material of the motor lid bracket, often in the form of softening or deformation of the plastic material. At this point, lid functionality may become impaired causing the instrument to become non-operative.
- The instrument may produce a smell of warm plastic, and the instrument/lid may feel hot to touch, but not at temperatures that will burn.

We are also informing you of an issue corrected in earlier Afinion 2 software versions:

Affected software versions	Issue	Software version with correction of issue
21.05 21.06 21.07 21.08	**Connectivity:** Afinion 2 may cause network problems for customer running a control sample when the connectivity setting is set to "patient results only". Depending on the communication protocol used, the Afinion instrument may stop sending control data or the instrument may continuously send "empty data" and thereby potentially causing network problems. This issue impacts ASTM-LL, ASTM-HL and HL7	21.09 (release date: 17 March 2020)

	communication protocols. The POCT1-A communication protocol is not impacted.	

Updating to the Afinion 2 software to version 21.14 will be correct for both issues described above.

Impact

Overheating: The overheating may impair the lid functionality of the Afinion 2 analyzer and cause the instrument to become non-operative. No user injuries associated with overheating (burns, blisters, or skin irritation etc.) have been reported relating to the malfunction.

Connectivity: The issue may only occur when running controls. No impact to patient test results.

Necessary Actions

- Complete and return the Customer Reply Form
- If you have forwarded the product listed above to other laboratories, please inform them of this field safety notice and provide them a copy of this letter.
- Please retain this letter for your records.
- Please upgrade the software on your Afinion 2 using the Afinion USB Flash Drive with software version ≥ 21.14 that Abbott will send you using the information provided on the Customer Reply Form. Afinion USB Flash Drive will be available upon regulatory authorization. You may continue using your instrument with current software until the Afinion USB Flash Drive is received to allow update to new software version.

Contact Information

If you have any questions, please contact your local Abbott representative.

It is important that your organization takes the actions detailed in the Field Safety Notice and confirms that you have received the Field Safety Notice.

Your organization's reply is the evidence Abbott needs to monitor the progress of the corrective actions.

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Customer Reply

Field safety notice – Acknowledgement form

Product Description	Part Number(s)	Serial number(s)
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1. Customer details

Account/Customer Number	
Healthcare Organization Name*	
Street*	
City*	
State*	
Zip code*	
Contact name*	
Department/Unit	
Title or function	
Telephone number*	
E-mail*	
Shipping address if different than above*	

2. Customer action taken on behalf of Healthcare Organization. Please check ALL appropriate boxes.

☐	I have read and understand the instructions provided in the letter dated 19 May 2023 **and will update the software of the Afinion instrument(s)**
☐	I confirm that my facility has affected product(s) at site. Current software version used: _____
☐	I do not have affected product. Please explain: _____

Print Name	Date/signature

3. Return acknowledgement to sender

Email	**[Replace by with email address receiving entity]**
Fax	**[Replace by with fax number for receiving entity, delete if not needed]**
Deadline for returning this form	Please complete and return this form within **10 business days** of receipt