SD BIOSENSOR
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(Tel) +82-31-300-0400, (Fax) +82-31-300-0499
www.sdbiosensor.com

Urgent FIELD SAFETY NOTICE about STANDARD F2400 Analyzer

- Product: STANDARD™ F2400 Analyzer
- SDB FSN Ref: BA200-20240508-QA5
- Issue date: 2024.05.08.
- SDB REF: V2404-002

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

*** For attention of:**

Users using both software version V001.046 of STANDARD™ F2400 Analyzer and STANDARD™ F *C.difficile* Toxin A/B FIA manufactured by SD Biosensor

[Details on affected devices]

FSN Type	New (A follow-up FSN with additional advice and information is not planned yet.)
Type of device	In-vitro diagnostic medical device
Product name	STANDARD™ F2400 Analyzer (Cat No.: 10FA24)
Legal manufacture	SD BIOSENSOR, Inc.
Primary clinical purpose	STANDARD F2400 Analyzer is an in vitro diagnostic medical device that measures quantitative or qualitative biomarkers of body fluids in a laboratory or POCT environment. The analyzer is indicated for monitoring and diagnosing from the body fluid parameter in clinical settings by healthcare professionals. In all cases, the Analyzer should be used with designated test devices produced by SD Biosensor, Inc.
Software Version	V001.046 * This only applies to customers using V001.046. There is no problem in version prior to V001.046, including V001.045 etc.

[Description of the problem]

■ **Factual statement:**

We updated F2400's software V001.046 in February 2024.
However, this version produced abnormal results in the STANDARD™ F *C.difficile* Toxin A/B FIA. The abnormal result was derived from a positive control as a negative result in the QC mode of F2400 Analyzer. This was due to an algorithm error that lowered the COI value of the positive control and required retesting. This is not a performance issue with STANDARD™ F *C.difficile* Toxin A/B FIA. Therefore we urgently release the software version about V001.047 and recommend that you update to V001.047 version on F2400

[Risk assessment]

■ **Probability:**

As a result of reviewing the sales history for 5 years, there were no claims/incidents caused by the same cause.

■ **Severity:**

On the IFU, it is specified to retest in case of fail in QC mode. Additionally, the algorithm error only applies to QC mode, and there was no problem in STANDARD mode, which uses actual specimens. Therefore, there is no possibility of determining a positive specimen as negative, and it is difficult to believe that a retest result for a positive control has had a serious impact on patients, users, or third parties.

[Action to be taken by the user]

■ Please update the F2400 Software version to V001.047
(Software download link: https://support.sdbiosensor.com/user)

■ Please write and reply by May 24, 2024 to 'Attachment 1.' that you have confirmed this FSN and performed the required action.

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[Action being taken by the Manufacturer]

■ Software update (V001.047)

[Transmission of this Field Safety Notice]

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)
Please transfer this notice to other organizations on which this action has an impact. (As appropriate)
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

■ Contact reference person

Contact point name	Phone number	E-mail address
Bestbion dx GmbH	+49 2234 98795-18	sandra.schramm@bestbion.com

We, SD Biosensor, Inc., sincerely apologizes for the difficulty that this action may cause to you and your facility. We greatly value our relationship with you. We appreciate your attention and timely cooperation in this matter. Please don't hesitate to contact us if you need any help related with the issue.

Sincerely,

[redacted]
QMR
SD BIOSENSOR, Inc.

SD BIOSENSOR

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Attachment 1. Customer/Distributor Verification Form

PLEASE CONFIRM THESE STATEMENTS, AND CHECK THE BOX.

1. We acknowledge receipt of the SD Biosensor Inc. product notice. (□ Y / □ N)
2. We have forwarded this information to our distributors and users. (□ Y / □ N)
3. We have confirmed that users have updated their F2400's software to V001.047 (□ Y / □ N)
4. Please indicate the number of confirmed customers compared to the total number of customers. (of)

NAME*: _____

TITLE: _____ DEPARTMENT: _____

INSTITUTION*: _____

PHONE NUMBER*: _____ E-MAIL*: _____

ADDRESS*: _____

Other comments

* Mandatory field

Please fill out and sign the form of this Field Safety Notice and reply to us by May 24, 2024 to be sure that you have verified this important information.

_____
SIGNATURE* / DATE*