EKF-diagnostic GmbH • Ebendorfer Chaussee 3 • 39179 Barleben

Document Reference: SI-260010FSCA

Original date (as submitted): Barleben, 13 May 2026
Amended date (corrected): Barleben, 18 May 2026

URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

Dear Valued Customer,

At EKF-diagnostic GmbH (EKF), patient safety and product quality are our highest priorities. We are issuing this Field Safety Corrective Action (FSCA) to notify you of an important matter concerning the product listed below:

Details of affected products:

Impacted Product:	Chip Sensor Lactate, Type II / REF 5206-3029
Impacted Product Lot:	CL2615

Based on our records, we have verified that your organization received the identified product and affected lot of the Chip Sensor Lactate, Type II.

Description of the problem:
An internal investigation has revealed that some sensors in batch CL2615 may have been mislabeled. Based on current information, a small number of lactate sensors may bear the following product label on their primary packaging:

Correct product labelling	Mislabeled product
- Chip Sensor Lactate, Type II - REF: 5206-3029 - LOT: CL2615	- **Chip Sensor Glucose**, Type II - REF: 5206-3011 - LOT: CL2615
	

The lot number and expiration date are correct; however, there is a risk of confusion when using the sensors with the Biosen glucose/lactate device.

EKF-diagnostic GmbH
An EKF Diagnostics Holdings plc Company
Ebendorfer Chaussee 3
39179 Barleben – Germany
CEO Dr. Olga Suckau, Dirk Schulz

Phone |+49| 39203 – 5110
Fax |+49| 39203 – 511171
E-Mail info@ekf-diagnostic.de
Internet www.ekfdiagnostics.de
Company registry Stendal HRB 101939

Deutsche Bank Magdeburg
IBAN DE80 8107 0000 0118 6253 00
BIC DEUTDE8MXXX
Commerzbank Magdeburg
IBAN DE42 8104 0000 0209 6006 00
BIC COBADEFFXXX

Patient Impact:
The Biosen measuring system is used for the quantitative determination of glucose and lactate in blood, plasma or serum.

When the chip sensors are inserted into the Biosen device, the device automatically detects whether a glucose chip sensor or a lactate chip sensor has been used. The measured values are displayed on the Biosen device's screen along with a corresponding abbreviation, which ensures clear identification.
Furthermore, using the wrong chip sensor during the daily check of the Biosen measurement system with the EasyCon test solution results in the target values specified for the test solution not being achieved.
If, however, a lactate chip sensor is used instead of a glucose chip sensor, extreme deviations in the measured value will occur, which are completely implausible in a clinical context, so that a defect or measurement error must be assumed.

Taken together, these device safeguards are intended to allow the user to recognise the use of an incorrect chip sensor before a clinical decision is made, so that the residual risk to patients is considered low. To date, EKF has received no reports of patient harm associated with this issue.

Action Taken by EKF:

- EKF has identified all affected customers and product lots placed on the market.

If you have further questions, please contact Technical Support at:
+49 39203 511 414 or support@ekf-diagnostic.de.

CUSTOMER REQUIRED ACTION

1. Please immediately discontinue use of the affected product only and quarantine, and dispose of those specific items identified in this FSCA.
2. Please ensure this information is shared with your laboratory staff and other pertinent personnel.
3. If you are a distributor, please complete and return the 'Customer Response Form' enclosed herein. Please also forward this FSCA to your end user(s) without delay for completion and return.
4. If you are the end user in receipt of this FSCA from the distributor, please complete the 'Customer Response Form' and return it to the distributor.
5. If you are an end user in receipt of this FSCA directly from EKF, please complete the 'Customer Response Form' and return it to EKF.
6. The enclosed 'Customer Response Form' must be returned via fax or email within 10 business days.
7. Please ensure a copy of this notification is retained as part of your Quality System records.
8. Upon receipt of the fully completed and signed 'Customer Response Form', we will contact you to process the product replacement or refund.

EKF-diagnostic GmbH
An EKF Diagnostics Holdings plc Company
Ebendorfer Chaussee 3
39179 Barleben – Germany
CEO Dr. Olga Suctau, Dirk Schulz

Phone |+49| 39203 – 511 0
Fax |+49| 39203 – 511 171
E-Mail info@ekf-diagnostic.de
Internet www.ekfdiagnostics.de
Company registry Stendal HRB 101939

Deutsche Bank Magdeburg
IBAN DE80 8107 0000 0118 6253 00
BIC DEUTDE8MXXX
Commerzbank Magdeburg
IBAN DE42 8104 0000 0209 6006 00
BIC COBADEFFXXX

We sincerely apologize for any inconvenience this issue may cause and appreciate your cooperation. EKF remains committed to supporting you in upholding the highest standards of patient safety, quality and regulatory compliance

Sincerely,

Digital unterschrieben von
Alexandra Selinger
Datum: 2026.05.18 12:19:07
+02'00'

i.A. Alexandra Selinger
Regulatory Affairs Associate / Deputy PRRC
EKF-diagnostic GmbH

EKF-diagnostic GmbH
An EKF Diagnostics Holdings plc Company
Ebendorfer Chaussee 3
39179 Barleben – Germany
CEO Dr. Olga Suctau, Dirk Schulz

Phone |+49| 39203 – 511 0
Fax |+49| 39203 – 511 171
E-Mail info@ekf-diagnostic.de
Internet www.ekfdiagnostics.de
Company registry Stendal HRB 101939

Deutsche Bank Magdeburg
IBAN DE80 8107 0000 0118 6253 00
BIC DEUTDE8MXXX
Commerzbank Magdeburg
IBAN DE42 8104 0000 0209 6006 00
BIC COBADEFFXXX

FSCA RESPONSE FORM

Document Reference: SI-260010FSCA

To satisfy regulatory requirements for reporting, please complete this 'Customer Response Form' and return it to EKF using one of the methods below.
Please enter the following in the subject: RESPONSE TO SI-260010FSCA - <COMPANY NAME >

FAX +49 (0) 39203 511 171
E-Mail support@ekf-diagnostic.de

Return Response:

We acknowledge receipt of the URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION and confirm we have read and understand the instructions provided therein.

☐ Yes / ☐ No

Are you aware of any adverse events or quality issues associated with affected product?
☐ Yes / ☐ No

If yes, please provide further information:

The following has been verified (SELECT ALL THAT APPLY):
For clarity, only the mis-labeled units are considered affected product. No other units within the lot are considered impacted. We attest that;

☐ We confirm that all areas where the product could be located have been identified and checked.
☐ We do not have any affected product.
☐ We do have affected product and have quarantined the product. **Indicate lots and quantities below**.
☐ We have appropriately disposed of the affected product. **Indicate lots and quantities below**.
☐ Product was redistributed to another facility; and the notice was forwarded.

Please provide any additional information below, (if applicable).

Signature	
Date	
Name	
Company name	
Address	