DiaSpect
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DiaSpect Medical GmbH • Ebendorfer Chaussee 3 • 39179 Barleben

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Field Safety Notice

Barleben, 27th February 2019

Product: DiaSpect Hemoglobin T-LOW analyzer
FSN reference: DIA022019

Dear valued customer,

This letter is to inform you that previously delivered DiaSpect Hemoglobin T-LOW analyzers might show an incorrect reading when measuring at the upper end of or outside the measuring range

Details of Affected Devices:
DiaSpect Hemoglobin T-LOW analyzer (REF 90C0005)
Serial numbers: [redacted]

Description of the Problem:
The affected DiaSpect Hemoglobin T-LOW analyzers might show an incorrect, fixed value instead of the actual value at the upper end of the measuring range above 2.70 g/dl or instead of the error message E033 outside the measuring range.

Possible Impact:
There is the possibility of misinterpretation of measured values above 2.70 g/dl as incorrect values or values exceeding the measuring range might not be recognized.

Actions to be taken by the Customer:
To identify if your device is affected by this issue please do a measurement of a whole blood sample (value above 4.00 g/dl) with your measuring system.
If the analyzer is showing the error message E033 your analyzer is not affected by this issue and you can continue using your analyzer without restrictions.
If the analyzer is showing a value instead of the error message E033, your device is affected by this issue. You can continue to use your DiaSpect Hemoglobin T-LOW with the restriction not to use the results above 2.70 g/dl generated with the affected device. Results up to 2.70 g/dl can be used without restrictions.

Please confirm receipt and acknowledgement of this information by sending back the attached response form.

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Product Correction:
DiaSpect Medical GmbH is investigating the issue and developing a solution that can be installed into affected devices to correct this issue. DiaSpect Medical GmbH estimates a timeline of 3 month for the development of a software update. Upon availability, DiaSpect Medical GmbH will notify customers about the correction. Until that time, please refer to the recommended customer actions as described above.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected products have been transferred.

Please complete actions by 31st March 2019.

Contact:

Technical Support for DiaSpect Medical GmbH
EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany
+49 (0) 39203 511 414
support@ekf-diagnostic.de

We apologize for the inconvenience this issue has caused and thank you for your assistance.

The undersigned confirms that this notice has been notified to the responsible regulatory authority.

[redacted]

Steffen Borlich
Managing Director
DiaSpect Medical GmbH

[redacted]

FSN RESPONSE FORM

Product: DiaSpect Hemoglobin T-LOW analyzer
FSN reference: DIA022019

This response form is to confirm receipt of the enclosed Field Safety Notice dated 8th February 2019 regarding the DiaSpect Hemoglobin T-LOW analyzer.

Please fax or email a scanned copy of this completed form to DiaSpect Medical GmbH until 31st March 2019.
Fax: +49 (0) 39203 511 171
Email: support@ekf-diagnostic.de

☐ I have read and understood the Field Safety Notice instructions provided in this letter.

Please mark as applicable

☐ Yes, we have received affected products as indicated in the Field Safety Notice.
If Yes, please answer the following questions to enable further investigation.

Serial number:	
Device affected?	☐ No ☐ Yes (mark serial number if multiple devices listed)
Supplier:	

☐ No, we have not received affected products as indicated in the Field Safety Notice.

Signature	
Date	
Name	
Company name	
Address	