

Reflect your health

Hölker Feld 5
D-42279 Wuppertal
Tel. 0202 / 6474-550
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mbr@mbr-os.com

URGENT FIELD SAFETY NOTICE

Advice on **haemospect®**

2015-12-05

Field Safety Notice identifier: FSCA15-01

Attention

Users and distributors

Identification of the product

haemospect®

Description of the problem:

We wanted to inform you that we have been notified of an anomaly regarding the accuracy of the haemospect blood screening unit.

It appears that during screening for haemoglobin values, some readings in the very low range of the spectrum are incorrectly displayed as being in the higher range. The affected donor clientele seems to consist of people with anaemia and low ferritin value (primarily female donors).

If these prospective donors will be admitted by the blood transfusion services, there might be a health risk in the aftermath of a blood donation.

MBR Optical Systems GmbH & Co. KG (MBR) is working alongside the customer in question and their local authorities to understand the anomalies and initiate an update in the technology and/or handling as appropriate.

Until the matter is resolved, we would like to issue the following precautionary recommendation:

Action to be taken

Action by the user:

Apply extra vigilance when selecting your donors in particular with those donors showing clinical symptoms as well as repeat donors, especially female.

All possible indications for a case of anaemia should be regarded with extra vigilance.

In addition, we ask you to consider the matter described as part of your routine quality checks.

In case of doubt as a precautionary measure, we would recommend declining the donor.

Action by the distributor:

Please forward this notice to your customers using the device mentioned.

Geschäftsführer:
Dipl.-Ing. Heinz Schmiersal
Komplementär: MBR Optical Systems Verwaltungs GmbH, Wuppertal
Registergericht Wuppertal
HRA 22414

Stadtparkasse Wuppertal
Kto.-Nr. 278911
BLZ 330 500 00
IBAN : DE08 3305 0000 0000 2789 11
SWIFT-BIC. : WUPSDE33XXX

Transmission of this Field Safety Note

Please forward this Urgent Field Safety Notice to relevant persons in your organization. This notification should be carried out to the user level. Your assistance is appreciated and necessary.

In addition, if you have further distributed these products, please notify the consignees at once of this notification.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please confirm that you have read this information by signing the attached document and send it back to: distributor@mbr-os.com or fax 0049 202 64 74 560

A copy of this notice was forwarded to the National Competent Authority.

We sincerely apologise for the matter and hoping to re-earn your trust in the future.

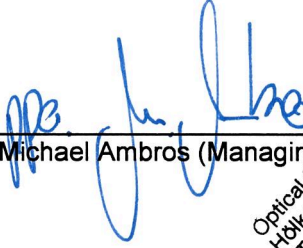

We are working on a contemporary solution to the problem, e.g. a potential software update.

As soon as we have more details, we will as a matter of course inform you immediately. Should you have any additional questions, please contact your distributor or the MBR directly.

Contact for further inquiry

MBR Optical Systems GmbH & Co. KG
Hölker Feld 5
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GERMANY

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Fax.: 0049 (0) 202 6474 560
Mail: distributor@mbr-os.com


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Please complete this form to acknowledge receipt of this Field Safety Notice.

Please return signed and stamped to:

distributor@mbr-os.com

or

Fax 0049 (0) 202 64 74 560

Confirming of attention

Hereby we confirm the notice of this **Field Safety Notice** related to haemospect dated 2015-12-05.

Name

Organisation

Stamp

Place, date

Signature