

NIHON KOHDEN EUROPE GmbH, Raiffeisenstraße 10, 61191 Rosbach v.d.H.

To all end-users of
NIHON KOHDEN Hematology Analyzers MEK-9100 *Celltac G*

Rosbach v.d.H., April 12th, 2018

Subject: Important FIELD SAFETY NOTICE

**Information about a Field Safety Corrective Action for NIHON KOHDEN
Hematology Analyzer MEK-9100 *Celltac G*
FSCA Ref. "FSCA-9145"**

Dear Valued Customer,

With this Field Safety Notice (FSN) we want to inform you about a potential malfunction of NIHON KOHDEN Hematology Analyzers series MEK-9100 *Celltac G*. The related affected serial numbers in Europe are in the range between 00004 and 00241.

You get this FSN because you received at least one potential affected unit from your local NIHON KOHDEN Representative! You will find a detailed list of affected products attached to this Field Safety Notice!

The potential affected units can be identified by the serial number which is located on the product identification label at the backside of the Hematology Analyzer.



Hematology Analyzer MEK-9100 *Celltac G*

Please make sure that all potential users in your facility are informed about this Field Safety Notice! Please confirm by returning attached receipt of this Field Safety Notice!

Description of the potential malfunction:

There is a risk of approx. 0.003% that the Hematology Analyzer MEK-9100 *Celltac G* could indicate an incorrect patient data to the related blood sample. We did not receive any report about any health hazard so far.

Advise to users:

The potential affected Hematology Analyzer MEK-9100 *Celltac G* can still be used, but you should pay strong attention to check about the correct patient data related to the individual blood sample.

Corrective action:

The improved software version 01-15 eliminates the potential malfunction. Your local NIHON KOHDEN Representative will contact you for arranging a date for the free-of charge software upgrade directly as soon as possible.

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The European Competent Authorities are informed about this Field Safety Corrective Action and are monitoring progress and finalization.

If you have any question please do not hesitate to contact your local NIHON KOHDEN Representative or our European NIHON KOHDEN Headquarter in Germany:

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We apologize for the inconvenience this Field Safety Corrective Action may cause and thank you for your understanding and co-operation.

Best regards
NIHON KOHDEN EUROPE GmbH
Quality Assurance Department

Attachments: ② Receipt of the Field Safety Notice (end-users)
List of affected products