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Urgent Field Safety Notice

GLUCOSE liquicolor
Recall and Mandatory Settings update on HumaStar 100, 200 and 300SR

03.12.2024

Attention:
Distributors of HUMAN and end users of:

Details on affected devices:

Product name	Size	REF
GLUCOSE liquicolor	1000 ml	10121
GLUCOSE liquicolor	4 x 100 ml	10260
GLUCOSE liquicolor	2 x 150 tests	10260300
GLUCOSE liquicolor	6 x 210 tests	10260600
Independent of their LOT number		

When applied on:
HumaStar 100 (REF 16890)
HumaStar 200 (REF 16895)
HumaStar 300SR (REF 16930)

Description of the problem:
During internal evaluations following one single confirmed customer complaint, HUMAN has identified that, in rare cases, HumaStar 300SR in combination with the GLUCOSE liquicolor reagent may report falsely low glucose values for samples with concentrations above 450 mg/dL.
It was estimated that only for such samples a falsely low result 15-40% below the real concentration may be displayed. For samples with glucose concentrations above the upper limit of the measuring range (500 mg/dL), this can lead to samples being not correctly displayed as above measuring range. These discrepancies were only observed in a very few single instruments.
To fix these discrepancies, HUMAN has already developed an optimized setting, which should be installed immediately on all HumaStar 300SR instruments on which GLUCOSE liquicolor is measured.

During internal investigations, a similar behaviour was observed on one single HumaStar 100 instrument.
As an additional security measure, HUMAN has optimized the settings for HumaStar 100 and HumaStar 200 accordingly and recommends installing the new settings on all active systems.

Advice on action to be taken by:
Distributor:
Please inform your customers, who measure GLUCOSE liquicolor on HumaStar 100, HumaStar 200 and HumaStar 300SR based on this Urgent Field Safety Notice. Inform your customers that

an updated settings database is available via HSB 0055, which accompanies this FSN. Please install this updated database on all HumaStar 100, 200 and 300SR instruments as soon as possible. The performance of the GLUCOSE liquicolor assay will be improved in general.

Please fill in the attached Reply Form confirming receipt of this Urgent Field Safety Notice and send it to support@human.de.

User:
Please ensure that the instructions resulting from this Urgent Field Safety Notice are implemented in the laboratory accordingly.
Review your Glucose results. If you have no results displayed as above the upper limit of measuring range (> 500 mg/dL) and this is not in line with your expectation for your typical patient cohort, then this could be an indication, that your instrument might be affected by the described problem. If discrepancies are identified, take appropriate follow-up action.

Verification Support: If you would like assistance in verifying whether your specific instrument is affected, contact your local distributor for guidance.

End users should confirm receipt of this Urgent Field Safety Notice to the local distributor.

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

The Federal Institute for Drugs and Medical Devices (BfArM) and the National Competent Authorities of European countries which are affected by the recall have received a copy of this Urgent Field Safety Notice.

Contact reference person:
(For distributors only. Distributors should provide their own detailed contact information to their end users):

Petzold, Tony
e-mail: support@human.de
Telephone: +49-6122-9988-383

We regret the inconvenience.

With kind regards,

Petzold, Tony
Customer Support & Applications

David Solbach
Head of Product Management II

Attachment
Reply Form

Reply Form

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Please return by e-mail this filled in and signed Reply Form latest until December, 13, 2024 to:

support@human.de

I confirm receipt of this Urgent Field Safety Notice and have informed all end users, who have obtained the affected products, in writing about the problem and the HUMAN recommendations.

If requested by national regulations, I have informed the respective authorities about the problem. (Note: to comply with European regulatory requirements HUMAN will inform European competent authorities directly.)

For distributors in the European Economic Area (EEA) and Turkey:
Please also provide the Urgent Field Safety Notice in your national language, which you have sent out to your end customers, as HUMAN will be approached by your national competent authority to provide this.

Date: _____

Company: _____

Name: _____ Signature: _____