Ängelholm January 4, 2017

To Users of:
HemoCue® Hb 201 DM Analyzer
HemoCue® Glucose 201 DM Analyzer
HemoCue® Glucose 201 DM RT Analyzer

Urgent Field Safety Notice

Identifier: FA-016
Affected products and article numbers:

For Sweden & Norway:	
HemoCue® Hb 201 DM Analyzer	121130, 121137
For Germany:	
HemoCue® Hb 201 DM Analyzer	121132, 121145
HemoCue® Glucose 201 DM Analyzer	121421
HemoCue® Glucose 201 DM RT Analyzer	124018

Dear Customer
Radiometer and HemoCue have recently become aware that a potential problem can occur when a specific version of the Radiometer software AQURE (v2.0.1) is used in combination with HemoCue devices (HemoCue® Glucose 201 DM Analyzer, HemoCue® Glucose 201 DM RT Analyzer and HemoCue® Hb 201 DM Analyzer).

AQURE may be used for creating and pushing a new configuration to the HemoCue device. Due to a design error in v2.0.1 of the AQURE it is only possible to configure the connected HemoCue device to use the unit mmol/L. However, the preconfigured unit (factory setting) for the HemoCue device might be mg/dL, g/L or g/dL and this unit must not be changed.

The Patient result will be shown correctly with regards to Value and Unit on the HemoCue device.

A patient risk associated with the problem may ONLY occur in the following sequence:

- The HemoCue device has been configured by AQURE.
- The operator is used to that the device uses the preconfigured unit of measurement and therefore expects that the value is displayed in the preconfigured unit.
- The operator reads the value only and reports the value to a physician with the preconfigured unit and does not notice that the value and unit is presented in mmol/L.

Risk for the patient
In a worst-case scenario for glucose determination, in a patient with affected consciousness or in coma, there is a remote probability that the described error could lead to an erroneous diagnosis of severe hypoglycemia in a patient with severe hyperglycemia, which may lead to wrongful treatment and cause immediate as well as long range health consequences for the patient.

HemoCue AB
Visit: Kuvettgatan 1
SE-262 71 Ängelholm
Sweden
hemocue.com

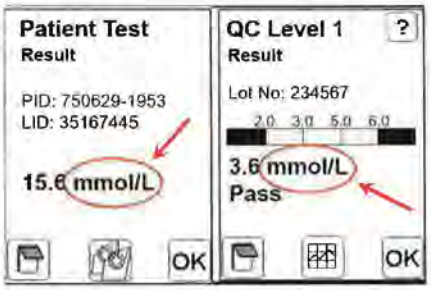
Post: HemoCue AB
P. O. Box 1204
SE-262 23 Ängelholm
Sweden

Phone: +46 431 48 12 00
Fax: +46 431 48 12 25
E-mail: info@hemocue.se
Org no: 556342-9272

During hemoglobin determination the patient may in worst case be subjected to unnecessary sampling of blood for verification of the unexpected, and erroneously diagnosed anemia, and may thus experience temporary inconvenience.

What you should do:
HemoCue recommends that you:

- Check the configuration of your HemoCue devices by running a patient test or QC test with the device. See figure below for where the unit is displayed.



- Fill in the attached Field Safety Notice Verification Form with the result of your check and send to cuvettes@hemocue.se. For the devices with incorrect unit setting, HemoCue will contact you with information on how to proceed with the re-configuration to correct unit.

Transmission of the Field Safety Notice
Radiometer records indicate that you have had AQURE v2.0.1 installed and according to HemoCue records you have received one or more of the affected HemoCue devices. Since there is a potential risk of incorrect unit of the HemoCue device this notice needs to be passed on to all that need to be aware within your organisation. HemoCue kindly requests your cooperation in verifying the unit of your devices and completing and returning the enclosed Field Safety Notice Verification Form in order to confirm you receipt of this letter.

Applicable Competent Health Authorities have been notified of this Field Safety Corrective Action.

Radiometer and HemoCue apologize for any inconvenience this may cause. If you have any questions regarding this Field Safety Notice, please send an e-mail to cuvettes@hemocue.se.

Yours sincerely,
HEMOCUE AB

[redacted]

Field Safety Notice Verification form

Identifier: FA-016

☐ I hereby confirm that I have read and understood the information in this Field Safety Notice concerning possible incorrect unit setting of HemoCue devices.

☐ I confirm that this notice has been passed on to all that need to be aware within my organisation.

☐ I have checked the configuration of all affected HemoCue devices and indicated below the identification (Serial number) of devices that needs reconfiguration.

Hospital name:	
Serial number of HemoCue devices that needs reconfiguration:	
Your Name:	
Date:	
Signature:	
Email Address:	

Please sign and return, no later than February 28, 2017, to e-mail address:
cuvettes@hemocue.se

Ängelholm January 4, 2017

To Users of:
HemoCue® Hb 201 DM Analyzer
HemoCue® Glucose 201 DM Analyzer
HemoCue® Glucose 201 DM RT Analyzer

Information regarding URGENT Field Safety Notice

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Dear Distributing partner
Radiometer and HemoCue have recently become aware that a potential problem can occur when a specific version of the Radiometer software AQURE (v2.0.1) is used in combination with HemoCue devices (HemoCue® Glucose 201 DM Analyzer, HemoCue® Glucose 201 DM RT Analyzer and HemoCue® Hb 201 DM Analyzer).

AQURE may be used for creating and pushing a new configuration to the HemoCue device. Due to a design error in v2.0.1 of the AQURE it is only possible to configure the connected HemoCue device to use the unit mmol/L. However, the preconfigured unit (factory setting) for the HemoCue device might be mg/dL, g/L or g/dL and this unit must not be changed.

The Patient result will be shown correctly with regards to Value and Unit on the HemoCue device.

A patient risk associated with the problem may ONLY occur in the following sequence:

- The HemoCue device has been configured by AQURE.
- The operator is used to that the device uses the preconfigured unit of measurement and therefore expects that the value is displayed in the preconfigured unit.
- The operator reads the value only and reports the value to a physician with the preconfigured unit and does not notice that the value and unit is presented in mmol/L.

Risk for the patient
In a worst-case scenario for glucose determination, in a patient with affected consciousness or in coma, there is a remote probability that the described error could lead to an erroneous diagnosis of severe hypoglycemia in a patient with severe hyperglycemia, which may lead to wrongful treatment and cause immediate as well as long range health consequences for the patient.

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During hemoglobin determination the patient may in worst case be subjected to unnecessary sampling of blood for verification of the unexpected, and erroneously diagnosed anemia, and may thus experience temporary inconvenience.

What you should do:
All customers that have had Radiometer software AQURE (v2.0.1) installed AND used in combination with any of the mentioned HemoCue devices HemoCue devices (HemoCue® Glucose 201 DM Analyzer, HemoCue® Glucose 201 DM RT Analyzer and HemoCue® Hb 201 DM Analyzer) need to receive the attached Urgent Field Safety Notice.

Radiometer and HemoCue sincerely apologize for the added workload this will cause.

Actions to take:

1. Verify the attached list of your affected end users and send the end user list to cuvettes@hemocue.se no later than January 13, 2017.
2. Translate the Field Safety Notice into local language (if applicable). Return the local language translation in PDF-format to cuvettes@hemocue.se no later than January 13, 2017.
3. Send the Field Safety Notice in English as well as local language version to the identified affected end users. All customers shall be informed by January 13, 2017.
4. When information to end users are completed, send a confirmatory e-mail to cuvettes@hemocue.se.
5. In parallel with verifying your affected end-users, ensure to verify the unit of your own HemoCue devices (if any) if you ever have used the combination of Radiometer software AQURE (v2.0.1) AND any HemoCue device for demonstration purpose or alike. Send an e-mail to cuvettes@hemocue.se to verify that you have checked your potentially affected HemoCue devices and indicate if any HemoCue device has incorrect unit and needs to be reconfigured.

Confirm by e-mail to cuvettes@hemocue.se that you have read and understood the information in this letter. Please use the same e-mail for additional questions.

Yours sincerely,
HEMOCUE AB