

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: AQUIRE unit conversion

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of three potential clinical significant issues with unit conversion in AQUIRE:

1. Conversion of Ketone from mmol/l to mg/dl or vice versa.
2. Conversion of glucose and lactate from g/l to mmol/l or vice versa
3. Conversion of mg/dl to mg/l and g/dl to g/l or vice versa.

The issues may occur if the device is transmitting in a different unit than AQUIRE is displaying and/or AQUIRE transmitting to the HIS/LIS.

The problem can occur in the following situations:

1. The parameter ketone is measured on either the Siemens Clinitek or the DocuReader, which is supported by AQUIRE from v1.8.0 or 1.8.1, and the unit is converted from mmol/l to mg/dl or vice versa. An incorrect conversion factor of 18 is used instead of the correct conversion factor which is 10. This means results converted from mmol/l to mg/dl will be 80% too high, and results converted from mg/dl to mmol/l will be 45% too low.
2. Conversion of glucose and lactate from g/l to mmol/l or vice versa. In both cases a wrong conversion factor is used, which causes the reported result to be incorrect by a factor 10,000. This problem is present in all versions of AQUIRE.
3. Converting from mg/dl to mg/l and g/dl to g/l or vice versa. Conversion factor used is 1/10. The correct factor is 10. Reported results will be incorrect by a factor 100. This problem is not parameter specific and present in all versions of AQUIRE.

Please note that the AQUIRE database internally uses RADIOMETER standard units, which means that even though the issue is not visible when looking at results, it is possible that results in the database are incorrect because they are stored with a wrong conversion. To evaluate if your installation is affected, a test program designed to detect this problem must be run on all AQUIRE installations by a Radiometer IT Specialist.

Affected product:

For issue 1 only AQUIRE v1.8.0 and v1.8.1.

For issue 2 and 3 all versions below AQUIRE v1.8.2.

Solution:

Your local RADIOMETER IT specialist will contact you in order to run the test program on your AQURE database in order to determine if any of the above mentioned problems are present on your installation.

- If units are currently converted incorrectly, your RADIOMETER IT specialist will in collaboration with you discuss the upgrade to version 1.8.2 which should be performed as soon as possible.
- If units are converted correctly, you will be informed about this and you will be contacted at a later stage about upgrade to version 1.8.2 or higher.

If incorrect converted parameter values are found, RADIOMETER recommends that you review previous patient results in AQURE and HIS/LIS.

Until your installation has been tested and upgraded to version 1.8.2 or higher, please do not install any new analysers on AQURE or change units without contacting RADIOMETER first.

If you have any questions, please do not hesitate to contact us.

Radiometer sincerely apologizes for the inconvenience this situation may cause you.

Best regards,
<Radiometer distributor>

Response Fax Form 1

Fax No.:

Concerning:

AQURE unit conversion

- I acknowledge receipt of the customer letter and confirm that RADIOMETER has run the test program on my AQURE installation.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	

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Response Fax Form 2

Fax No.:

Concerning:

AQURE unit conversion

- I confirm my AQURE installation has been upgraded to version 1.8.2 or higher.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	

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