Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: AQURE unit conversion revision 2

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of four potential clinical significant issues in AQURE:

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.
4. Transmission of data to AQURE or LIS/HIS after modification on device.

Issues 1-3 may occur if the device is transmitting in a different unit than AQURE is displaying and/or AQURE transmitting to the HIS/LIS.

The problem with unit conversion can occur in the following situations:

1. The parameter ketone is measured on either the Siemens Clinitek or the DocuReader, which is supported by AQURE 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 AQURE.
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 AQURE.

Please note that the AQURE 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 AQURE installations by a Radiometer IT Specialist.

4. Another issue may occur when results, which already have been received by AQURE and forwarded to HIS/LIS, are modified on the device by the user. When the modified data is sent to AQURE, it is not always updated in AQURE or forwarded to LIS/HIS.

This issue only affects large AQURE installations with:

- more than 20 devices connected
- 1000+ users and
- 250.000+ patient observations per year etc.

The error may occur on devices where the patient result can be manually modified on the device and resend, including Radiometer devices.

Examples of data that can be modified are:

- Patient data, e.g. patient id, first name, last name, sex, sample type
- Temperature, which also updates temperature dependent parameters, like: pH(T), pCO2(T) and pO2(T)
- Other input parameters, e.g. FO2(I), RQ

Affected product:
For issue 1 only AQURE v1.8.0 and v1.8.1.
For issue 2 and 3 AQURE v1.8.1 and all versions below.
For issue 4 AQURE v1.8.2 build 263 and all versions below.

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

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 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 a version higher than 1.8.2 build 263, 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:	

Response Fax Form 2

Fax No.:

Concerning:

AQURE unit conversion

□ I confirm my AQURE installation has been upgraded to a version higher than 1.8.2 Build 263.

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