

Customer  
Hospital  
City  
Postal code  
Country  
*Attn.: XXX*

## **Field Safety Notice: AQUIRE Version 1.4.0 to 1.5.3**

### **Priority Level: Urgent**

Dear Customer

RADIOMETER has recently become aware that patient results are displayed incorrectly in AQUIRE when both:

- AQUIRE is setup to use non International System of Units (SI units)
- The result is outside reference and critical ranges.

An example:

- Customer is using mmHg (Non-SI unit) instead of kPa (SI unit)
- Lower reference limit set by customer is 35 mmHg (Non-SI unit)
- Actual measured ABL value is 34 mmHg (Non-SI unit)
- On the ABL analyzer the measured  $pO_2$  result is displayed as 34 mmHg (Non-SI unit), which is below the lower reference limit.
- The ABL always transmit the results in SI units to AQUIRE. In this case the 34 mmHg is transmitted as 4.5 kPa.
- AQUIRE does not convert the result to mmHg (Non-SI unit) and does therefore by mistake display the result as 4.5 mmHg. This is a mix of the value in kPa and mmHg as the unit.

Please note that the above example goes for all parameters where the selected unit is a Non-SI unit, and the result is outside the reference and critical ranges.

All results transmitted via AQUIRE to HIS/LIS systems are correctly transmitted.

Default setting for AQUIRE is to use SI units for all parameters.

#### **Affected products:**

AQUIRE Version 1.4.0 to 1.5.3

#### **Corrected product:**

The error is corrected in AQUIRE version 1.5.4 which will be available for update from Friday 8 March 2013.

A Radiometer representative will contact you regarding the update.

**Please take the following actions:**

**ACTION 1:**

Until you are contacted about the update to ACURE version 1.5.4 you have the following options:

Either

A. Make sure that you are not using results directly from AQURE, including FLEXLINK. Use only result from the analyzer or the HIS/LIS system.

or

B. Change all Non-SI units to SI units on AQURE

Please confirm this by completing Recall Response Fax Form 1 (page 3 of this letter) and return to your Radiometer representative before Friday 15 March 2013

**ACTION 2:**

When you are contacted regarding the update to AQURE version 1.5.4 please make sure you are ready to receive the update.

Please confirm upgrade to AQURE version 1.5.4 by completing Recall Response Fax Form 2 (page 4 of this letter) and return to your Radiometer representative before Monday 19 April 2013.

If you have any questions, please contact your Radiometer representative.

Best regards,  
<Radiometer distributor>

# Recall Response Fax Form 1

Fax No.:

Concerning:

## **AQURE Version 1.4.0 to 1.5.3**

- I have received the customer letter, and carried out Action 1.

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

# Recall Response Fax Form 2

Fax No.:

Concerning:

## **AQURE Version 1.4.0 to 1.5.3**

- I have carried out Action 2 and AQURE version 1.5.4 has been installed.

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