Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: AQURE V1.5.4

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of a potential issue with AQURE V1.5.4.

The issue may occur when an analyzer is connected to AQURE and the analyzer has been set up to use parameter repression on one or more parameters.
Parameter repression on the analyzer is a setup of the analyzer whereby parameter values will not be displayed / printed, if the parameter is flagged with a question mark. An example could be that the previous calibration has failed for the parameter in question.

Repressed results are transmitted to AQURE and HIS/LIS with a "?" and a comment indicating the cause of the flagging.

The issue is that repressed parameter values are shown in AQURE and transmitted to HIS/LIS systems, despite the repression.

- In AQURE the repressed parameter value is shown in red, with a "?" next to the value, as well as an icon which may be clicked to open the comments for the parameter.
- AQURE transmits the repressed parameter value(s) to a HIS/LIS system together with the parameter comments including the "?". As a consequence of this, the HIS/LIS system may show the repressed parameter value, which the analyzer did not show.

Affected product:
AQURE V1.5.4.

Solution:
Your local RADIOMETER IT specialist will reconfigure the database of the AQURE system to ensure that all "?" marked results are blanked in AQURE and also blanked prior to transmission to the HIS/LIS.

RADIOMETER recommends that you review previous patient results with repressed parameter values in AQURE and HIS/LIS.

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

Fax No.:

Concerning:

AQURE V1.5.4

☐   I acknowledge receipt of the customer letter and confirm that RADIOMETER has reconfigured the database of the AQURE to prevent all "?" marked results from being shown.

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