From: RMED Rint ISD [mailto:isd@radiometer.dk]
Sent: Friday, August 24, 2012 1:48 PM
Subject: Field Action Note 915-304
Importance: High

Dear Distributor,

We have still neither received the confirmation fax (action #1), an explanation for the delay, nor an action plan. Please submit immediately.

Please note that shipments of Radiometer products and services to your facility will be stopped until this case has been solved.

Kind regards,
Jens Sørensen
Service Coordinator

Radiometer Medical ApS
International Sales Division

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For the latest trends in acute care testing, go to Radiometer's knowledge site www.acutecaretesting.org

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Management Cover RADIOMETER

for Field Action Notes

915-304 **Product: AQT90 FLEX** **July 26, 2012**

Subject: Potential risk of patient result mixup

Background: We have recently become aware that there is a potential risk of mix-up of patient results

Affected product:
AQT90 FLEX with software versions below V8.3.40 and using the HL7 2.5 communication protocol for transmitting results to a HIS/LIS system.

The mix-up occurs if:

- The communication line is interrupted or disconnected
- Two or more patient results are queued for transmission
- The communication is re-established and the analyzer transmits the results in the queue.

In this situation the first result will be transmitted with the correct patient ID, whereas succeeding results in the queue will be appended to the first patient ID.

Action: The corrective actions are as follows:

Action 1:

1. Translate the customer letter into your local language, as necessary, and print on your official company paper.
2. Visit each AQT90 FLEX customer using the HL7 V2.5 communication protocol for transmitting results to a HIS/LIS system to:
    a. Upgrade the software in the analyzer to V8.3.40, and
    b. Hand over a copy of the customer letter to the customer

. **Action 2:**
Upgrade the software in remaining AQT90 FLEX to V8.3.40.

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Tools: ***Customer letter (action 1 only)***.

Software: Please refer to the link for downloading the software: *Available until:* ***02 August 2012***

933-264 (AQT90 V8.3.40).iso

Additionally, the software will become available on CD under part number 933-264.

Documentation: The actions listed under "Action 1" must be completed and confirmed to RMED (Confirmation Fax #1) by **August 24, 2012.**

The actions listed under "Action 2" must be completed and confirmed to RMED (Confirmation Fax #2) by **July 1, 2013.**

Inquiries: Please refer all inquiries related to this Technical Update to ISD Technical Support:

Email: ISD@radiometer.dk or

Telephone: +45 3827 2262

Regulatory: For regulatory reasons the following additional actions apply for the different countries. All subsidiaries and distributors must email complete customer lists for each country to RMED.

USA/Canada: The product has not been distributed to these markets.

Europe: The field action is a "Field Safety Corrective Action". This means that RMED have reported the action to all European Health Authorities.

All distributors in EEA member states receiving this FAN must mail the translated copy of the customer information letter (for distributors serving different regions with different languages we will need a copy in each language) to RMED.

Note that any distributor within the EEA may receive requests for additional information from their Competent Authority. Please forward such requests (translated into English) to RMED before answering so that we can coordinate the answer.

Prepared by: Mogens Thomasen
Senior Specialist
Technical Product Support

FAN 915-304 AQT90 Flex. Potential risk of

FAN 915-304 Confirmation 1.docx

FAN 915-304 Confirmation 2.docx

FAN 915-304 Customer Letter HL7