[redacted]

Cc: Chairman Medical Board

ABL90 FLEX and ABL90 FLEX PLUS

[08/11/2019]

Dear Radiometer Customer

Scope
This customer advisory letter is intended for customers **not** using the analyzer for measuring blood samples from newborn babies of up to four weeks of age.

> ***Important:*** In case you are out of the scope set above, hence, you **are** using the analyzer for measuring blood samples from newborn babies of up to four weeks of age; please contact your Radiometer representative for further instructions.

Background
Radiometer has become aware that some ABL90 FLEX and ABL90 FLEX PLUS analyzers may in rare cases be reporting biased results for tBil.

The bias increases with tHb concentration, but the increase is not linear.
The worst-case biases are as follows:

For a sample with tHb=15g/dL:

tBil: +20 µmol/L

For a sample with tHb=23g/dL:

tBil: +144 µmol/L

Risk for the patient

- ***For the overall population the following apply:***

In a reasonably foreseeable worst-case scenario for the overall population, the described error may lead to a repeated venous puncture to obtain a new blood sample for repeat testing for the erroneous parameter. This scenario is considered negligible, as the error only may result in temporary inconvenience for the patient.

- ***For newborn babies of up to four weeks of age the following apply:***

The described error has a remote risk of leading to moderate adverse health consequences for the patient. In a reasonably foreseeable worst-case scenario for a newborn patient, the patient will be subjected to unnecessary diagnostic investigation. Further, if the patient presents with jaundice, the patient may potentially receive unnecessary treatment, which may be in the form of unnecessary phototherapy and, ultimately, in the form of an unnecessary exchange blood transfusion. It is not considered likely that the described error is capable of causing permanent impairment of body function or permanent damage to a body structure or

necessitate medical or surgical intervention to preclude irreversible impairment or damage.

Affected product
ABL90 FLEX and ABL90 FLEX PLUS analyzers, which:

- Include hemolyzer units of certain production runs. The hemolyzer unit is a subcomponent of the Optical system, which measures *c*tHb and derivates.

Your actions
Radiometer kindly request you to perform the following actions upon receiving this letter:

( ) Complete the Recall Response Form (last page of this letter).
( ) Email a copy of the Recall Response Form to your Radiometer representative.

Solution provided by Radiometer
Your local Radiometer representative will, in conjunction with a future planned visit, check if your analyzer includes an affected hemolyzer unit, and if so, exchange the hemolyzer unit.

Your help is appreciated
If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end-user.

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

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

Best regards,
Radiometer S.E.A PTE LTD

[redacted]

Cc: Chairman Medical Board

ABL90 FLEX and ABL90 FLEX PLUS

[08/11/2019]

Dear Radiometer Customer

Scope
This customer advisory letter is intended for customers using the analyzer for measuring blood samples from newborn babies of up to four weeks of age, and tBil is actually reported.

> ***Important:*** In case you are out of the scope set above, hence, you are **not** using the analyzer for measuring blood samples from newborn babies of up to four weeks of age, please contact your Radiometer representative for further instructions.

Background
Radiometer has become aware that some ABL90 FLEX and ABL90 FLEX PLUS analyzers may be reporting biased results for tBil.

The bias increases with tHb concentration, but the increase is not linear.
The worst-case biases are as follows:

For a sample with tHb=15g/dL:

tBil: +20 µmol/L

For a sample with tHb=23g/dL:

tBil: +144 µmol/L

Risk for the patient

- ***For newborn babies of up to four weeks of age the following apply:***

The described error has a remote risk of leading to moderate adverse health consequences for the patient. In a reasonably foreseeable worst-case scenario for a newborn patient, the patient will be subjected to unnecessary diagnostic investigation. Further, if the patient presents with jaundice, the patient may potentially receive unnecessary treatment, which may be in the form of unnecessary phototherapy and, ultimately, in the form of an unnecessary exchange blood transfusion. It is not considered likely that the described error is capable of causing permanent impairment of body function or permanent damage to a body structure or necessitate medical or surgical intervention to preclude irreversible impairment or damage.

- ***For the overall population the following apply:***

In a reasonably foreseeable worst-case scenario for the overall population, the described error may lead to a repeated venous puncture to obtain a new blood sample for repeat testing for the erroneous parameter. This scenario is considered to be negligible, as the error only may result in temporary inconvenience for the patient.

Affected product

ABL90 FLEX and ABL90 FLEX PLUS analyzers, which:

- Are used for measuring blood samples from neonates and/or newborn babies, and tBil is actually reported, and
- Include hemolyzer units of certain production runs. The hemolyzer unit is a subcomponent of the Optical system, which measures *c*tHb and derivates.

Your actions

In the interim period until the solution provided by Radiometer described below is implemented Radiometer kindly request you to choose one of the options listed below:

Option 1: Turn off the tBil in the analyzer parameter panel such that tBil is no longer reported.

Option 2: For patient results where the tHb level is very high and at a level where further diagnostic investigation or treatment may be initiated, follow the steps below before initiating further diagnostic investigation or treatment.

( ) Re-test the sample on a different type of analyzer, e.g. in the Central Lab
( ) Assess the total clinical picture of the patient, e.g. presence of jaundice.

Further, we kindly request you to perform the following actions upon receiving this letter:

( ) Complete the Recall Response Form (last page of this letter).
( ) Email a copy of the Recall Response Form to your Radiometer representative.

Solution provided by Radiometer

Your local Radiometer representative will at the earliest convenience check if your analyzer includes an affected hemolyzer unit, and if so exchange the hemolyzer unit.

Your help is appreciated

If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end-user.

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

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

Best regards,
Radiometer S.E.A PTE LTD