

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Urgent Field Safety Notice (US: URGENT Medical Device Recall) **All versions of the ABL80 analyzer, Risk of patient mix-up**

Dear Customer

Background

Radiometer has become aware that the internal barcode reader, included in all versions of the ABL80 analyzer, may potentially misinterpret the contents of a locally printed barcode label used for entering patient ID or accession number into the analyzer in connection with a sample measurement.

The issue identified only relates to barcode types not using a check digit. A check digit enables the barcode reader to validate the data read, and hence, to capture if the barcode has been misinterpreted and consequently to reject such data.

For barcodes without a check digit, the following factors may add to the risk of misinterpretation:

- Poor paper quality
- Poor printer quality
- Improper handling of the barcode (e.g. the barcode is folded or exposed to liquid)

Radiometer uses only barcode types with a check digit when producing barcode labels used for e.g. sampler identification.

Risk for the patient

Misinterpretation of a barcode, including e.g. patient ID or accession number, may result in the following hazardous situations:

1. Patient mix-up
2. Loss of sample resulting in delayed medical treatment

Affected product

All versions of the ABL80 analyzer.

Your actions

Radiometer kindly requests you to:

- Check if your institution is using barcode types without a check digit, including e.g. patient ID or accession number, to be read on the ABL80.
 1. If you use barcode types **without** a check digit, Radiometer recommends either to:
 - Enable the check digit on the barcode type currently used, or
 - Change the type of barcode to one that includes a check digit, as this enables the barcode reader to validate the data read, and hence, to recognize if the barcode has been misinterpreted and consequently to reject such data.

2. If you use barcode types **with** a check digit, the barcode reader already validates the data read and is able to identify if the barcode has been misinterpreted and consequently rejects such data. Hence, no short-term action is required.
 3. If you do not use locally generated barcodes to be read by the ABL80, no short-term action is required.
- Complete the Recall Response Form (last page of this letter) and submit to your Radiometer distributor within two weeks from receipt of this letter.

Solution provided by Radiometer

Radiometer will provide the following solution to your analyzer irrespective of which barcode type is used, or if no barcodes are used at all:

The solution planned is for the analyzer software to perform multiple scans when reading every barcode (as opposed to scanning only once). Further, the data read during the multiple scans must be identical.

For barcode types without a check digit, this change may potentially reduce the risk of misinterpretation as described above.

Implementation of the above change requires an update of the analyzer software. Radiometer is currently planning a software update to address this issue and will contact you when a new software version is released.

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 distributor.

Best regards,
<Radiometer distributor>

Recall Response Form

Concerning:

ABL80 analyzer, Risk of patient mix-up

- I have received the customer advisory letter, and can confirm that:
 - We use a barcode type **without** a check digit. Further:
 - We acknowledge that Radiometer recommends either to enable the check digit on the barcode type currently used, or to change the type of barcode to one that includes a check digit, but we cannot currently do this.
 - We will either enable the check digit on the barcode type currently used, or change the type of barcode to one that includes a check digit.
 - We use barcode types **with** a check digit. Hence, no short-term actions performed.
 - We do not use barcodes to be read by the ABL80. Hence, no short-term actions performed.

Please note, that Radiometer will provide the solution described to your analyzer irrespectively of the answers above.

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