

Ängelholm July 29, 2013

**Product information letter**

To users of the HemoCue<sup>®</sup> Hb 201  
Microcuvettes single pack

**Affected products:**

HemoCue<sup>®</sup> Hb 201 Microcuvettes single pack  
Article number: 111715, 111717, 111722, 111723, 116101  
Within lot number: 1208655 to 1304738

**Identifier:** 2013-07-29\_Hb\_201

**Information regarding possible defect packaging material for single packed microcuvettes**

HemoCue has recently become aware of a production related problem which has affected some of the packaging material for single packed Hb 201 microcuvettes from lot numbers mentioned above.

The affected packaging material could potentially lead to Microcuvettes not performing as intended due to exposure to moisture. The root cause of the problem has been identified and the problem has been corrected in the manufacturing process.

The occurrence of affected microcuvettes within the specified lot numbers is low. Affected Hb 201 microcuvettes will either not fill or will only fill partly with air bubbles. According to the instructions for use (see operating manual and package insert) the microcuvette cavity is to be filled completely and microcuvettes with air bubbles in the optical eye must be discarded. As long as these instructions for use are followed, measurement performance is not affected and there is no safety risk for the patients.

**Instruction of actions to take**

1. If the microcuvette fills as intended, i.e. fills completely and without air-bubbles, the microcuvette will perform as intended and can be used as usual.
2. If the microcuvette does not fill completely or if air-bubbles are formed during filling, the microcuvette must be discarded as described in the instructions for use.
3. If affected microcuvettes are found, this must be reported through the normal complaint procedure.

**Transmission of the Product information letter**

This notice must be passed on to all that need to be aware within your organisation. Please sign the Product Information Verification form below and return to HemoCue AB.

We apologize for any inconvenience this may cause you. If you have any questions regarding this issue, please send an e-mail to local representative or [cuvettes@hemocue.se](mailto:cuvettes@hemocue.se)

Yours sincerely,  
HEMOCUE AB



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**Product information Verification form**

**Identifier:** 2013-07-29\_Hb\_201

I hereby confirm that I have read and understood the information in this Product Information Letter concerning defect packaging material.

I confirm that this notice has been passed on to all that need to be aware within my organisation.

Date:.....

Signature:.....

Name in block letters:.....

Institution:.....

Full address:

**Please sign and return to:**

e-mail: to local representative or [cuvettes@hemocue.se](mailto:cuvettes@hemocue.se)

or

fax: +46 77 570 02 12