



Ängelholm September 10<sup>th</sup>, 2019

To users of HemoCue® 201 DM – DMS  
Software CD and HemoCue® Glucose  
201 DM RT System

## Urgent Field Safety Notice

**Affected product:** HemoCue® 201 DM – DMS Software CD

**Article number:** 131050, 131071

**Affected lot numbers:** From version 3.0 of the software

**Identifier:** FA-0031

### Dear Customer

HemoCue has become aware that the HemoCue 201 DM – DMS Software includes old revisions of Analyzer Instructions for Use and Reference Manuals.

The changes to the manual for HemoCue Glucose 201 DM RT System include updates to the operating temperature and adding the following limitation to the intended use “The system should not be used on critically ill neonates in neonatal intensive care settings”.

If the Glucose 201 DM RT system is used in wrong operating temperature or on critically ill neonatal patients, it might lead to erroneous measuring results.

The manual accompanying the HemoCue Glucose 201 DM RT Systems in the box is correct and should be used instead of the outdated revisions located on the CD and installed together with the software.



**Transmission of the Urgent Field Safety Notice**

Our records indicate you have received one or more of the affected CD's. This notice needs to be passed on to all that need to be aware within your organisation. HemoCue kindly requests your cooperation in completing and returning the enclosed Field Safety Notice Verification Form in order to confirm you receipt of this letter.

HemoCue apologizes for any inconvenience this may cause. If you have any questions regarding this Field Safety Notice, please send an e-mail to [cuvettes@hemocue.com](mailto:cuvettes@hemocue.com)

Yours sincerely,  
HEMOCUE AB

Andreas Moe  
Technical Manager  
Data Management & Connectivity

Maria Fagerberg  
Senior Director, RAQA



## Field Safety Notice Verification Form

**Identifier:** FA-0031

I hereby confirm that I have read and understood the information in this Field Safety Notice concerning FA-0031.

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

<b>Customer name:</b>	
<b>Your Name:</b>	
<b>Date:</b>	
<b>Signature:</b>	
<b>Email Address:</b>	

**Please sign and return, no later than October 4, 2019, to your local distributor.**