

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

PRETERM RECALIBRATION OF oneHbA1c IS FOR INNOVASTAR

Falsely low results in patient samples for HbA1c determinations on InnovaStar

Date	April 07, 2016
Product and Lots	oneHbA1c IS, Cat. No. 1 3329..., Lots 83, 84 and 85
Explanation	<p>Internal measurements for quality assurance have shown that a preterm recalibration of oneHbA1c IS lots 83, 84 and 85 is mandatory to ensure the high quality of analysis.</p> <p>Initial calibrations for lots 83, 84 and 85 stored on "ParamCard" included into the oneHbA1c IS reagent kits show falsely low results for patient samples but an acceptable recovery of controls.</p>
Impact on patient results	Falsely low results (up to -15%) for patient samples are observed whereas recovery of dedicated controls is found within acceptance range.
Measures	<p>Please inform all users about the preterm recalibration of oneHbA1c IS lots 83, 84 and 85 immediately.</p> <p>DiaSys recommends reviewing the previously obtained results with these lots together with the laboratory management.</p> <p><i>For customer <u>already using</u> oneHbA1c IS lots 83, 84 and 85 on InnovaStar:</i></p> <p>Immediately recalibrate your InnovaStar by typing in the recalibration codes (see next page) into the InnovaStar. Do not use the previously stored calibration anymore.</p> <p><i>For customers going to use oneHbA1c IS lots 83, 84 and 85 <u>in future</u> on InnovaStar:</i></p> <p>Read in the ParamCard provided together with the reagent kit and immediately type in the recalibration codes from the next page.</p> <p>Instructions for entering the recalibration codes can be found in the manual or in the attached document "Instruction for entering the recalibration codes for oneHbA1c IS".</p>

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DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back by fax or as scan until **end of April 2016**.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Recalibration codes oneHbA1c IS lot 83, 84 and 85

Parameter	Lot	Expiry Reagent	Recalibration-codes	Security-code	Expiry recalibration
HbA1c	83	2017-01	10379691	025	2017-01
			20547663		
			30691610		
			41085684		
			51640661		
HbA1c	84	2017-01	10373509	017	2017-01
			20544522		
			30695530		
			41103579		
			51542542		
HbA1c	85	2017-01	10378468	237	2017-01
			20540480		
			30670414		
			41076408		
			51526442		

Kind regards



Confirmation of receipt

Please confirm that the customer information below is received by your facility:

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Herewith I confirm that above named customer information reached me and is forwarded to the users of these DiaSys products.

Customer name: _____

Contact person: _____
(same as signature)

Date / Signature: _____

Please send this fax to DiaSys Diagnostic Systems GmbH (Holzheim / Germany)

Fax-Number: +49-6432-9146-167

Thank you for your efforts!

Empfangsbestätigung

Bitte bestätigen Sie, dass Sie die folgende Kundeninformation erhalten haben.

DRINGENDE SICHERHEITSINFORMATION

VORZEITIGE REKALIBRATION DES oneHbA1c IS TESTES FÜR INNOVASTAR

Hiermit bestätigen wir, dass wir die oben genannte Kundeninformation erhalten und an unsere Kunden weitergeleitet haben.

Name des Distributors: _____

Kontaktperson: _____
(Name des Unterzeichners)

Datum / Unterschrift: _____

Bitte senden Sie das ausgefüllte und unterzeichnete Dokument per Fax an: DiaSys Diagnostic Systems GmbH (Holzheim / Deutschland)

Fax-Nummer: +49-6432-9146-167
Vielen Dank für Ihre Bemühungen!

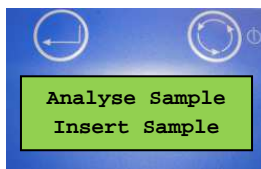
Instruction for entering the recalibration codes for oneHbA1c IS

Recalibration codes oneHbA1 IS:

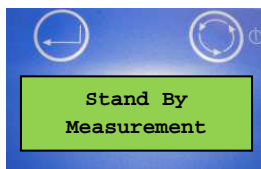
First Recalibration code: xxxxxxxx
Second Recalibration code: xxxxxxxx
Third Recalibration code: xxxxxxxx
Fourth Recalibration code: xxxxxxxx
Fifth Recalibration Code: xxxxxxxx
Security code: xxx

All given recalibration codes and the security code have to be entered into the device as described below.

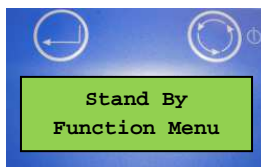
1. Switch on the device. After the start up procedure the following screen will appear.



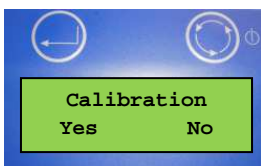
2. Press the right button two times until the "Stand by Measurement Menu" screen appears.



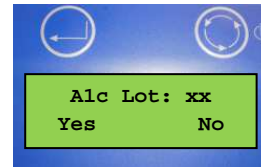
3. By pushing the left button you enter the "Stand by Function Menu"



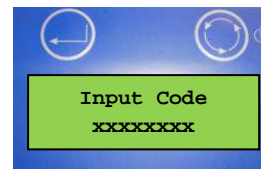
4. Push the right button 6 times to get to the menu "Calibration".



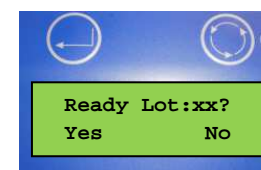
5. Push "Yes" (left button) to enter the calibration menu. If different HbA1c Lots are stored, you have to select the desired Lot by pushing "No" (right button) when other Lots appear.



6. Push "Yes" (left button) to enter the recalibration code for the desired Lot. To enter each digit use the right button to scroll to the desired number and the left button to confirm it.



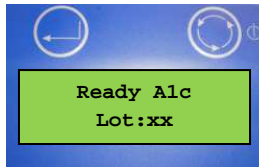
7. After entering all numbers of the first recalibration code and confirming each number with the left button, the following screen will appear. Select "No" by pushing the left button if more than one recalibration code has to be entered.



9. After pushing "No" the following screen will appear. Please enter the second recalibration code as described in step 6.



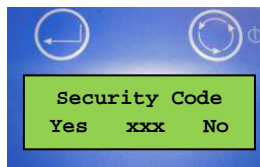
10. Please enter all given recalibration codes as described in steps 6-8. After entering all given recalibration codes you have to confirm the following screen with "Yes".



11. Enter the security code xxx by pushing the right button to scroll and the left button to confirm.



12. The correct manual input of the security code is questioned by the following screen. Choose "Yes" (left button), if the security code is displayed correctly.



12. A screen with "OK" will appear and the device returns to the "Calibration" menu. This means that the recalibration was done successfully.

13. Return to the "Analyse Sample" menu to run further HbA1c tests with the recalibrated Lot.